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CLINICAL AND RADIOGRAPHIC EVALUATION OF 70% ETHANOL ALCOHOL VERSUS NORMAL SALINE AS ROOT CANAL IRRIGATING SOLUTIONS IN PARTIAL PULPECTOMY OF PRIMARY MOLARS A RANDOMIZED CONTROLLED (PILOT TRIAL)

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ABSTRACT

Objective: Calcium Hydroxide-Iodoform paste is very common as an obturating material in pulp treatment in primary teeth. Although the high clinical success rates of the material it has a low radiographic success rate due to its fast dissolution inside the canals of primary teeth specially in vital teeth causing rapid resorption and leaving a hollow-tube effect. Irrigating the canals with Ethanol Alcohol is believed to increase the success rate of Calcium Hydroxide-Iodoform paste compared to normal saline. **Subjects and methods:** In this randomized controlled (pilot trial) 20 Children (4-7 years) diagnosed with decayed second primary mandibular molars experiencing irreversible pulpitis were selected randomly and were divided into two equal groups (n=10): The intervention group was (70% ethanol alcohol irrigation) and the control group was (normal saline irrigation). Post-operative pain was measured using the Visual Analog Scale (VAS). Clinical evaluations occurred at 3, 6, 9, and 12 months, while radiographic assessments were conducted at 6 and 12 months. **Results**: Both groups showed no significant difference in Visual Analog Scale (VAS). Clinically, ethanol alcohol had 100% success, while normal saline had a 90% success rate with one failure. Radiographically, both groups had a 90% failure rate at the 12-month follow-up, lacking statistical difference. **Conclusion:** There is no significant difference between 70% ethanol alcohol and normal saline as an intracanal irrigation solution in primary teeth with Calcium Hydroxide-Iodoform paste.

KEYWORDS: Irrigation, Ethanol Alcohol, Metapex, Pulp Therapy, Primary Molars

INTRODUCTION

Pulp therapy in deciduous teeth aims to save the tooth by resolving the infection and providing radiographic evidence of successful obturation. It includes both pulpotomy which is the ablation of inflamed pulpal tissues, leaving the residual vital pulp tissues intact. While on the other side, pulpectomy means the complete removal of pulpal tissues [(1)]. Even after the pulpal tissues have been debrided, the filling material will come into contact with the remaining pulpal tissue that is still present in the root canal due to the accessory canals presence in primary molars root [(2)].

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Additionally, since the pulp tissues were not entirely removed during the pulpectomy procedure, a partial pulpectomy might have been unintentionally carried out. The direct contact between Metapex (Calcium Hydroxide-Iodoform Paste) and the remaining pulpal tissues will result in root resorption and dissolution of the material [3].

Irrigating the canals of primary teeth with Ethanol Alcohol before filling the canals with Metapex increases the success of Metapex in primary teeth pulp therapy[4]. Ethanol alcohol irrigation is considered a promising alternative to formocresol for tissue fixation, particularly because of concerns about formocresol's potential carcinogenic and toxic effects[5]. Moreover, ethanol alcohol is highly effective at killing bacteria, viruses, and fungi. It is also notably one of the most volatile liquids available[6]. However, one of the most common irrigating solutions used in root canal treatments is saline. However, this solution does not have any antibacterial properties and is just used to rinse out the root canal[7].

Therefore, the aim of the study was to perform a clinical and radiographic evaluation of 70% ethanol alcohol versus normal saline as root canal irrigating solution in partial pulpectomy of primary molars.

Protocol Registration and Blinding tests

The protocol was referee registered on www.clinicaltrials.gov with ID NCT04669392. Approval of the board of the Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University was granted on 7-12-2021. Approval of the Ethics Committee, Cairo University was granted on 28-12-2021 with acceptance number 9-12-21. Participants and their legal guardians together with the statistician were blinded from this study.

SUBJECTS AND METHODS

A total number of 20 children, meeting specific inclusion criteria, were randomly chosen from the dental and pediatric public health clinic at the Faculty of Dentistry, Cairo University. They were then divided into two groups, each with 10 children. One group received the intervention with 70% ethanol alcohol irrigation, while the other group was the control, receiving normal saline irrigation.

In this randomized clinical trial, utilizing computer-generated randomization, a 1:1 ratio was used to assign mandibular second primary molars to either the intervention or control groups. The allocation process involved generating two codes (A&B) representing intervention and control, concealed in opaque sealed envelopes, and opened just before the intervention to determine the assigned group for each primary molar based on randomized numbers.

Sample Size Calculation

Twenty patients were recruited since it was a pilot study (equally allocated to two groups; 10 teeth per group with a total of 20 teeth). The sample size was reviewed and approved by the Evidence-based Committee at the Faculty of Dentistry, Cairo University.

Informed consent and assent

The child's legal guardian received a detailed explanation of the trial, including its protocol, benefits, and possible drawbacks. The guardian signed a translated written consent in Arabic.

Inclusion criteria

The study involved patients aged 4 to 7 years who were medically within normal limits, with their parents providing written informed consent. The selected teeth were restorable mandibular second primary molars with a history of irreversible pulpitis. Preoperative radiographs showed no evidence of root resorption, whether internal or external, no widening of the periodontal ligament (PDL) gap, and no periapical or inter-radicular radiolucencies.

Children were excluded from the study if they had systemic disorders, physical or mental disabilities,

were incapable of attending follow-up visits, or if they or their parents refused to participate. Teeth were excluded if they had been previously accessed, if they were mobile or if there was swelling in the vestibule, on palpation, or if there was pain on percussion.

Study procedures

In a controlled, randomized trial, ten teeth from each group of molars that were going to undergo vital pulp treatment were randomly allocated after a digital x-ray and clinical evaluation. The removal of deterioration occurred after the administration of local anesthesia, each tooth was anesthetized by buccal infiltration or nerve block according to the rule of 10 using 4% articaine with 1:100,000 epinephrine (Artinibsa ; Inibsa Dental, Lica de Vall, Spain) and the use of a rubber barrier (Sanctuary Dental Dam system, Malaysia) to isolate the affected region with KSK posterior clamp number W8A (Dentech Tokyo, Japan).

A sharp spoon excavator was used to remove coronal pulp tissue after a high-speed diamond bur (Meisinger Co., Germany) was used to establish an access hole. A partial pulpectomy was performed because to the presence of irreversible pulpitis. Size #10 K-files (Sphinx medical, Egypt) were used to assess the canal's patency, then mechanical preparation was started with sizes 15, 20, and 25K-files, employing saline irrigation between files until hemostasis was achieved. According to the type of final irrigant used after partial pulpectomy, the included molars were divided into one of the following groups:

The Intervention Group

The canals of the molars included in this group were finally flushed with 2mL of 70% Ethanol Alcohol (Upper-Egypt Pharmaceutical Industries) utilizing a 30 gauge side-vented irrigating needle[8]. The needle was gently inserted into the canals without applying pressure followed by a back-and-forth motion throughout the delivery of the solution. The 70% Ethanol Alcohol was placed in the canals for 10 seconds, after which any excess was removed using a single size #25 paper point. After that, we let the roots air dry for two minutes to be sure they were totally dry.

The Control Group

One last irrigation was done with 5 mL of normal saline using a 30-gauge blunt-tip needle for the canals. By utilizing paper points, the canals were blot dried until the last point visually confirmed that they were completely dry.

Before obturating the canals with Metapex (Meta Biomed Co. Ltd, Cheongwongun, Chungbuk, Korea), a modification to the disposable plastic intra-canal tip was done by cutting 4 mm from the tip using a surgical scissor to facilitate the flow of the obturation material. Metapex was used to fill the canals, and any excess material that moved into the pulp chamber was managed. A small, moist cotton pellet was then employed to gently compress the material within the canals.

For the restorations, we used resin-modified glass-ionomer (SDI Riva, Melbourne, Australia). Then, we used glass-ionomer cement (Meron Voco, Cuxhaven, Germany) to secure the stainless-steel crowns (KidsCrowns, Maharashtra, India) over the recovered teeth. Excess cement was removed and cleaned with a small wet cotton palate and interproximal excess cement was then removed using dental floss.

Postoperative periapical radiographs were taken to establish a baseline record. The primary outcome measured was postoperative pain level, it was then documented using a Visual Analog Scale (VAS) by the operator [9,10]. starting from the same day of the treatment then every 24 hours until the fourth day after treatment. All patients underwent clinical evaluations at three, six, nine, and twelve months for evaluating the swelling presence fistula, pain on percussion and sinus. While radiographic assessments which was the secondary outcome

were conducted at 6 and 12 months to evaluate the presence of periodontal ligaments widening, periapical radiolucency, interradicular radiolucency/ internal/ external resorption through the use of binary outcome [11]. Clinical evaluation was done by the operator throughout the follow up visits and the radiographs that were taken after the treatment visit and at each subsequent visit were evaluated independently by the two evaluators (the supervisors of this study). Cohen's Kappa agreement index was above 90, the level of agreement was almost perfect between both evaluators (the supervisors of this study) [12].

Value of Kappa	Level of Agreement	% of Data that are Reliable
0-20	None	0-4 %
21-39	Minimal	4-15%
40-59	Weak	15-35%
60-79	Moderate	35-63%
80-90	Strong	64-81%
Above 90	Almost perfect	82-100%

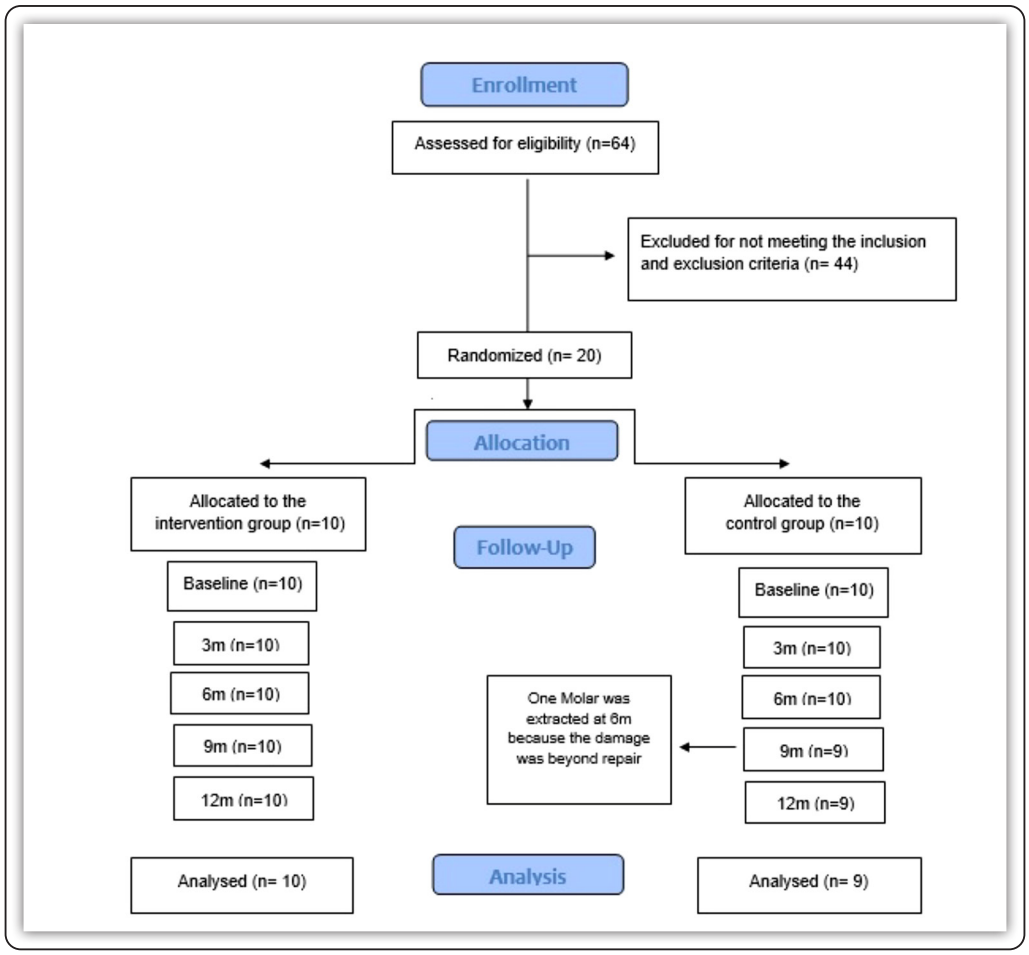

FIG (1) Consort flow chart for the trial

Data management

Each patient's data was entered into a unique diagnostic chart, which was then saved as a soft copy alongside the digital periapical radiographs. Additionally, an online drive and an external hard drive were used to back up the data. Data entry was restricted to the primary researcher, and both the senior and co-supervisor later reviewed it. Patient's files were stored in a numerical sequence and stored in an accessible and secured place.

Statistical Analysis

The study used chi-square and Cochran's Q tests for categorical data, for age data that was normally distributed, the t-test was utilized, however for non-parametric pain data, the Mann-Whitney U test and Friedman's test were used. Means and standard deviations were used to display numerical data, while percentages and frequencies were used for categorical data. The Shapiro-Wilk test was used to ensure normality. No statistical test was conducted without using a significance level of $p < 0.05$. The study was carried out using R, a statistical program for Windows (v4.1.3).

RESULTS

In this clinical trial, 20 patients with 20 decayed second primary molars participated in the study. They were divided into two groups of 10 each at random. Normal saline was given to the control group, whereas 70% ethanol alcohol was administered to the intervention group. There were 4 men and 6 women in every group. There were no statistically significant differences in gender or age among the two groups ($p<0.05$), with the intervention group having a mean of 5.70±0.95 years and the control group 5.90±0.88 years.

Post-operative pain was assessed with Scale of Visual Analog (VAS), In the intervention group (70% ethanol alcohol) VAS dropped from a mean± standard deviation of 1.20±2.53 on the day0 to 0.20±0.63 on day1and 0.00±0.00 on day2, day3, and day4. Which was close to the control group (normal saline) VAS that also dropped from mean ± standard deviation 1.00±1.05 on day0 to 0.20±0.63 on day1 and 0.00±0.00 on day2, day3, and day4. At all intervals, no substantial difference was found between both groups ($p>0.05$). **(Figure 2)**

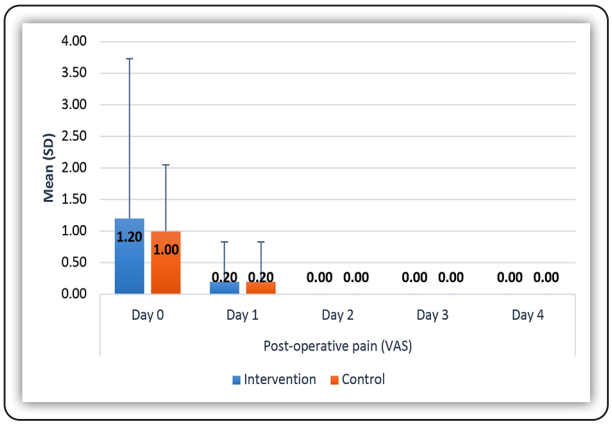

FIG (2) Bar Chart Showing Mean and Standard Deviation Values for Post-operative Pain (VAS).

Regarding the clinical evaluation of the presence of swelling, sinus and tenderness incidence, after 6 months, swelling and tenderness on percussion were seen in one lower mandibular second molar in the control group (normal saline). For other intervals, both groups were free, and no statistically substantial difference was found either in the intergroup comparison or intragroup comparison ($p>0.05$). Moreover, there was no incidence of sinus in the intervention (70% ethanol alcohol) and control groups (normal saline). For both groups, there was no substantial difference among incidence in different intervals ($p>0.05$) **(Figure 3,4).**

The intergroup comparisons to the clinical outcomes were presented in **table (1)**. There was a single failed molar in the control group (normal saline) with 90% success rate and 100% success rate in the intervention group (70% ethanol alcohol) and there was no statistically substantial difference ($p=1$).

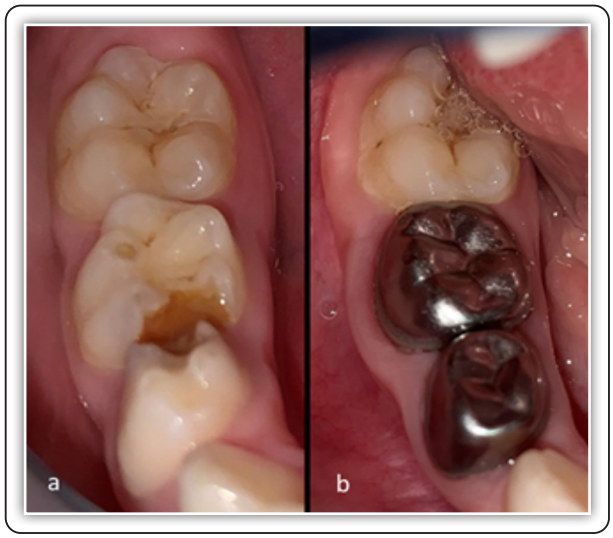

FIG (3) a) Preoperative Photograph of badly decayed lower right second primary molar, b) Postoperative Photograph of lower right second primary molar covered with stainless-steel crown after using normal saline irrigation and partial pulpectomy.

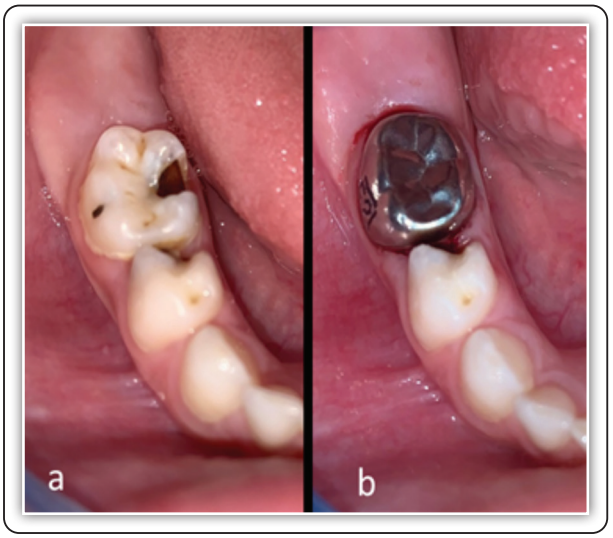

FIG (4) a) Preoperative Photograph of badly decayed lower right second primary molar. b) Postoperative Photograph of stainless-steel crown covering the lower right second primary molar after 70% ethanol alcohol irrigation followed by partial pulpectomy.

TABLE (1) Intergroup Comparison, Frequency, and Percentage Values for Clinical Outcome.

Clinical outcome		Group		p-value	Odds ratio (95% CI)
		Intervention	Control		
Success	**N**	10	9	**1ns**	**0.30 (0.01:8.33)**
	%	100.0%	90.0%		
Failure	**N**	0	1		
	%	0.0%	10%		

Regarding the radiographic evaluation, both groups had no periodontal ligament widening at the baseline. At 6 months, 4 molars in each group were affected. By 12 months, 7 molars in the group of intervention and 6 molars in the group of control were affected, with no substantial difference among them (p>0.05). However, the group of intervention indicated a substantial increase from baseline to 12 months (p=0.005), while the group of control did not (p=0.063).

Regarding periapical radiolucency, after 12 months, 2 molars were affected in both groups, with no occurrences at other intervals (p>0.05). Initially, no instances of interradicular radiolucency or internal/external resorption were found in either group. By the end of the 6 month, 4 molars had been affected in each group. As the 12 months ended, there was no statistically significant difference between the two groups (p>0.05). The intervention group had 8 lower mandibular second molar impacted, while the control group had 6 lower mandibular second molar impacted. The intervention group, on the other hand, had a significantly higher incidence from baseline to twelve months (p=0.002), but the control group did not (p=0.063).

After 6 months, calcium hydroxide-iodoform paste dissolution inside the canals of 4 molars in the intervention group (treated with 70% ethanol alcohol) and 4 molars in the group of control (treated with normal saline). The calcium hydroxide-iodoform paste was dissolved from the canals in 6 molars in the intervention group (using 70% ethanol alcohol) and 6 molars were also affected in the control group (using normal saline) after 12 months. **(Figure 5,6)** Yet the difference among both groups was not statistically substantial (p=1) and there was no substantial difference among incidence in different intervals (p>0.05). **(Table 2)**

The radiographic outcomes in this clinical study had 9 failed molars in the intervention group (70% ethanol alcohol) and 9 failed molars in the group of control (normal saline), no statistically substantial difference between both groups was found (p=1). **(Table 3)**

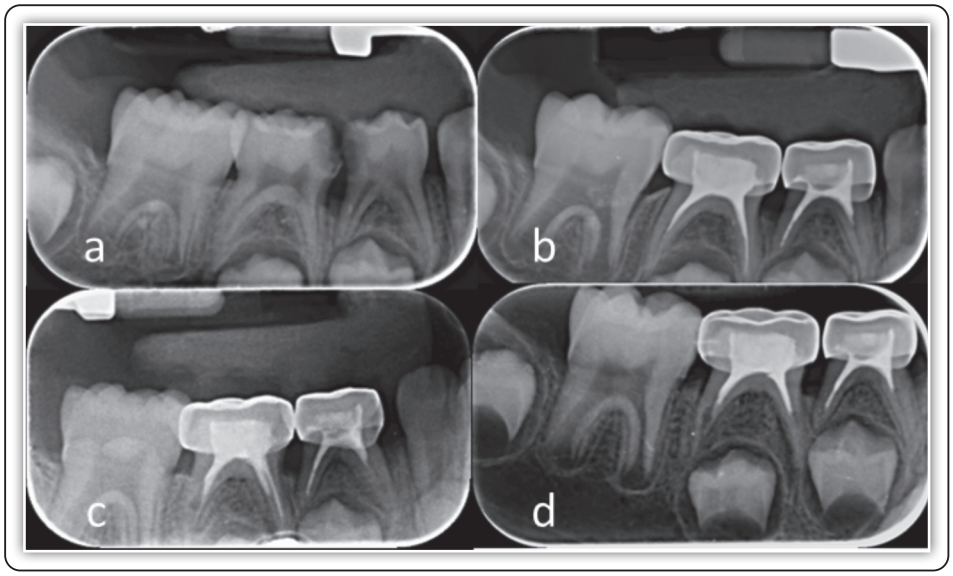

FIG (5) a) Preoperative X-Ray of badly decayed lower right second primary molar. b) Immediate Postoperative X-Ray after partial pulpectomy with Calcium Hydroxide-Iodoform paste using normal saline as an intracanal irrigant followed by stainless steel crown as a final coverage. C) 6 Months Follow-up X-Ray showing widening of the periodontal ligaments and internal resorption. d) 12 Months Follow-up X-Ray showing widening of the periodontal ligaments, internal root resorption, interradicular radiolucency.

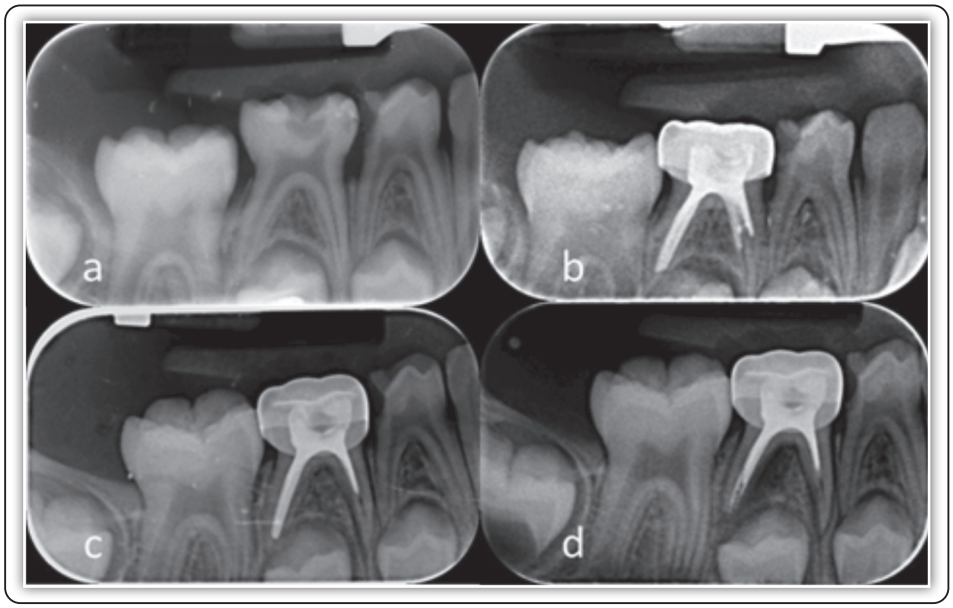

FIG (6) a) Preoperative X-Ray of badly decayed lower right second primary molar. b) Immediate Postoperative X-Ray after partial pulpectomy with Calcium Hydroxide-Iodoform paste using 70% Ethanol Alcohol as an intracanal irrigant. C) 6 Months Follow-up X-Ray showing widening of the periodontal ligaments. d) 12 Months Follow-up X-Ray showing widening of the periodontal ligaments, internal root resorption, interradicular radiolucency, and dissolution of Calcium Hydroxide-Iodoform paste.

TABLE (2) Inter and Intragroup, Frequency and Percentage Values for Incidence of Dissolution of Calcium Hydroxide and Iodoform paste.

Group	Incidence of dissolution of Calcium Hydroxide Iodoform paste		Interval		p-value
			6 months	12 months	
Intervention	**No**	**N**	6	4	**0.157ns**
		%	60.0%	40.0%	
	Yes	**N**	4	6	
		%	40.0%	60.0%	
Control	**No**	**N**	6	3	**0.083ns**
		%	60.0%	33.3%	
	Yes	**N**	4	6	
		%	40.0%	66.7%	
	p-value		**1ns**	**1ns**	

TABLE (3) Intergroup Comparison, Frequency, and Percentage Values for Radiographic Outcome

Radiographic outcome		Group		p-value	Odds ratio (95% CI)
		Intervention	Control		
Success	**N**	1	1	**1 ns**	**1.00 (0.05:18.57)**
	%	10.0%	10.0%		
Failure	**N**	9	9		
	%	90.0%	90.0%		

DISCUSSION

Intracanal irrigation using 70 % Ethanol Alcohol was never used clinically in primary teeth nor in vital pulp therapy. In this randomized controlled pilot trial, a clinical and radiographic evaluation of 70% ethanol alcohol versus normal saline as an intracanal irrigants in partial pulpectomy was done for the first time with no previous evidence to support or contradict the results.

Although Thiruvenkadam et al., 2016's in-vitro study showed an increase in the success rate of metapex after drying and irrigating the canals with 95% ethanol alcohol compared to normal saline irrigation with paperpoints for drying, when 70% ethanol alcohol was compared to normal saline in this clinical study the results showed no significant difference between both groups [8].

The results of postoperative pain after obturating the canals with Calcium Hydroxide-Iodoform paste were in agreement with Ali et al., 2022 who stated that immediate mild post-operative pain after obturating the primary canals with Calcium Hydroxide-Iodoform paste might be due to extruding the material beyond the apex and the clinical success gradually increased within one week to 33% and 100% after 3 month [13]. Paranna et al., 2022 also stated that 65% of patients experienced mild post-operative pain after pulpectomy with Calcium Hydroxide-Iodoform paste during the first 24 hours [14].

The clinical results were consistent with those of a previous study by Bommareddy et al. (2022), which reported clinical success rate of 100% with Metapex at the 6-month mark [15]. Goinka et al., 2020, Subramaniam and Gilhotra, 2011also had a clinical success rate of 100% with Metapex at 12 months in their research [16,17]. However, Metapex showed 90.48% clinical success at 6 months according to Gupta and Das, 2011and 87.5% clinical success at 12-month follow-up period according to Al-Ostwani et al., 2016 [18,19].

Calcium hydroxide and iodoform pastes high clinical success rate (Metapex and Vitapex) is due to the composition and the ingredients of the paste; calcium hydroxide keeps periapical tissue healthy, promotes healing, and has antimicrobial properties. Calcium hydroxide and iodoform are the two primary components of Vitapex and Metapex. Iodoform has antimicrobial effects, healing capabilities, and a higher rate of resorption than root resorption when added in excess [3,16].

Calcium Hydroxide-Iodoform paste showed very high clinical success and a very low success rate radiographically. Root resorption and dissolution in the canals during the first 6 months of follow-up and continued to increase further during the 12 months follow-up period with no clinical signs and symptoms. This study's findings were in line with those of Al-Ostwani et al. (2016), which found that after 9 months, 17 out of 30 treated teeth (56.6% of the total) showed material resorption prior reaching the roots [19].

Moreover, the clinical study results by Nakornchai et al., 2010 revealed that vitapex showed low radiographic success with 80% success at twelve months and 56% success at twelve months. Moreover, in another clinical study, vitapex was resorbed more quickly than roots, radiographic evaluation of teeth failed in 55% of cases, and clinical signs and symptoms were present in 61% of the radiographic failure cases [11].

Generalizability

The results of this randomized controlled pilot trial can be generalized on a larger population. Although there was a very high clinical success, the radiographic failure was significantly high.

Limitation

- During the clinical trial, the global COVID-19 pandemic had an impact affecting the recruited participants due to the repeated illness among the participants which affected the follow-up in the trial.
- There was no scientific evidence on the use of 70% ethanol alcohol clinically as a root canal irrigating solution in primary teeth and was never used clinically before obturating the canals with Calcium Hydroxide-Iodoform paste in primary teeth.
- Due to devaluation and the global economic crisis, the majority of imported materials and instruments were hard to find in the market.
- Although 70% ethanol is available in each house due to COVID-19, it was very hard to convince the parents of the nature of the study before starting.
- The use of an acrylic stent in pediatric patients was difficult due to the small size of their jaws and the small mouth opening which was difficult to insertion during the study.

CONCLUSION

Within the limitation of this in-vivo study, the following conclusions can be made:

- There is no radiographic and clinical difference among normal saline as root canal irrigating solutions and 70% ethanol alcohol.
- Normal saline and 70% ethanol alcohol have no effect on the dissolution of Calcium Hydroxide-Iodoform paste.

- The nature of Calcium Hydroxide-Iodoform paste is behind the hollow-tube effect.
- Despite the Calcium Hydroxide-Iodoform paste high clinical success rate, radiographs showed failure in most cases due to interradicular, internal, and external resorption, as well as the dissolution of the paste during the 12-month period.
- Calcium Hydroxide-Iodoform paste can be used in primary teeth that are near exfoliation.

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