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Clinical And Radiographic Evaluation Of Aloe Vera Gel Versus Formocresol Pulpotomy Of Vital Primary Molars: A Randomized Clinical Trial

Research Article

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Abstract

Aim: The study aimed to evaluate the clinical and radiographic performance of Aloe vera gel versus formocresol pulpotomy of vital primary molars.
Materials & Methods: Pulpotomy procedure was performed in (42) primary molars randomly allocated to two equal groups (21 molars per group). Aloe vera gel was used as a pulpotomy agent in Group A, while formocresol was used as a pulpotomy agent in Group B. All the pulpotomized teeth were evaluated clinically and radiographically at 3, 6, 9, and 12 months of time interval using predetermined criteria.
Results: The overall clinical success rate of Groups A and B at the end of the 12 months follow-up period was 36.8% and 81.3% respectively. The overall radiographic success rate of Groups A and B after 12 months follow-up period was 21.1% and 62.5% respectively. The overall success rate in Group A and Group B at the end of the 12 months follow-up period was 21.1% and 62.5% respectively showing a statistically significant difference between the two groups.
Conclusions: Formocresol was found to be superior when compared to Aloe vera gel as a pulpotomy agent in primary molars.

Keywords: Formocresol; Aloe Vera Gel; Pulpotomy; Vital Pulp Therapy; Primary Molars.

Introduction

Pulpotomy is one of the common treatments of cariously exposed pulps in symptom-free vital primary teeth; the procedure helps to maintain the integrity of primary teeth that have inflammation limited to the coronal pulp. The main goal is to preserve the radicular pulp, maintain vitality, and ultimately retain the tooth [1].

Formocresol, for many years, has been considered the conventionally used material for pulpotomy. Several areas of concern have been reported regarding formocresol including cytotoxicity, mutagenicity, systemic distribution, and a significant acceleration of the exfoliation of pulpotomized primary molars. Therefore, the substitutes of formocresol have now been tried to find more bio and tissue-compatible alternatives [2].

Interest in medicinal plants has burgeoned due to the increased efficacy of new plant-derived drugs. Aloe vera(Aloe barbadensis Miller), is one of the oldest medicinal plants on record. The name Aloe veraderives from the Arabic word "alloeh" meaning "shining bitter substance", while "vera" in Latin means "true"[3].

Aloe vera gel has been used for various therapeutic purposes owing to its anti-inflammatory, antibacterial, antifungal, antiviral, moisturizing, and pain-relieving properties. Consequently, several

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uses of Aloe verain dental practice have been reported [4].

A few studies used Aloe vera gel as a pulpotomy agent in vital primary molars. Controversies in the results regarding its efficacy as a pulpotomy agent have been noticed showing the need for more researches to be done to clarify whether Aloe vera gel is effective as a pulpotomy agent or not [5, 6].

The purpose of this study was to compare the clinical and radiographic success of Aloe vera gel and formocresol, used as a pulpotomy agent in carious vital primary second molars.

Materials and Methods

Ethical Approval

The research protocol was reviewed and approved by the Ethics Committee, (ID:16 10 31) to assess their ethical acceptability. The committee checked that the potential benefits of the new treatment, the patient's information was clear and satisfactory, the patient's recruitment for the trial was done properly, privacy and confidentiality of patient's data are protected. The study was registered in the Pan African Clinical Trials Registry (PACTR) (www.pactr.org).

Setting, design, and sample size calculation

This study has been carried out on patients from the outpatient clinic in the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry. It was a parallel randomized clinical trial with a 1:1 allocation ratio.

Sample size calculation was done with the help of a computer software Sealed Envelope Ltd. 2012. Calculation based on the formula: $n = 2 \times f(\alpha, \beta/2) \times \pi \times (100 - \pi) / d2$, $f(\alpha, \beta) = [\Phi\text{-}1(\alpha) + \Phi\text{-}1(\beta)]2$. where π is the true percent success in both the control and experimental treatment groups, and Φ-1 is the cumulative distribution function of a standardized normal deviation.

Based on the previous research published by Mettlach et al.,[7] the success rate of the formocresol group was 99%. If there was truly no difference between the standard and experimental treatment, then 34 molars are required to be 80% sure that the limits of a two-sided 95% confidence interval will exclude a difference between the standard and experimental group of more than 10%. With a dropout rate of 20% the sample size was exceeded to 42 molars (21 molars in Group A in which Aloe vera gel is used as a pulpotomy agent) and (21 molars in Group B in which formocresol is used as a pulpotomy agent).

Randomization, Sequence generation, allocation concealment, and blinding

Randomization and sequence generation: Computer-generated simple randomization was carried out by the fourth investigator with the help of computer software (random.org). It randomly assigned each tooth into an experimental or control group using simple randomization. Sequence generation was done for the molars number (1 to 42; 21 numbers in each group).

Allocation - Concealment mechanism: Allocation concealment was done using sealed opaque envelopes. Each envelope contained a numbered paper folded eight folds and packed by the third investigator. The number determined the group assigned for each molar. Every participant grasped the sealed opaque envelope from a box after the diagnosis of the case. The envelope was opened after pulp extirpation so that the operator knew the type of capping material just before the application of the dressing material.

Blinding: The current study was double-blinded both participants and statistician were blinded. blinding of the operator was not possible as both materials used in this trial had different physical properties. Also, the outcome assessors couldn't be blinded because of the obvious differences between the two materials in the radiograph.

Inclusion & exclusion criteria

Inclusion criteria:

- Young cooperative patients with no history of systemic disease.
- The age range of 4-7 years.
- Patients having decayed vital second primary molars indicated for pulpotomy.
- No clinical symptoms or evidence of pulp degeneration, such as spontaneous pain,
pain on percussion, history of swelling, sinus tracts, or pathological mobility.
- The tooth is restorable.
- A tooth with at least two-third of intact root length.
- Tooth showing no radiographic signs of pulpal or inter radicular involvement
ranging from slight thinning of the trabeculae to furcal and/or periapical radiolucency.
- Children were selected independent of their gender.

Exclusion criteria:

- Patients who refused to be engaged in the follow-up protocol.
- A tooth with pre-shedding mobility.

Informed Consent

Informed consent was signed by the patient's parents, who were informed that this was a relatively new procedure and a full detailed treatment plan was explained to them. Furthermore, verbal assent was taken orally from the patient. Parents were told that follow-up appointments are obligatory to assess the outcome of initial treatment and to discuss other treatment options if this treatment failed to meet expected goals.

Preparation of Aloe vera gel

The Aloe vera gel was prepared in the laboratory of the Pharmacognosy Department, Faculty of Pharmacy by an expert professor. According to Ahmed et al.,[8] a 70% Aloe vera gel was prepared as follows: A healthy plant of Aloe barbadensis Miller, approximately 4 years old had been selected from the experimental station of medicinal plants, Faculty of Pharmacy. From the identified plant, a healthy leaf had been harvested at the level of its base. It was then cleaned with 70% ethyl alcohol and stored in distilled water for 1 h to eliminate aloin. After 1 h, with the help

of a sterile Bard-Parker blade, the outer green rind portion was removed, and a spatula was introduced to collect the Aloe vera gel. The Aloe vera gel had been removed, washed again, and collected in a sterile container [8]. The Aloe vera gel was mixed with both agar (used as a thickening agent) and preservatives including Sorbitol, Potassium sorbate, and Sodium metabisulfite. The preserved Aloe vera gel was collected in sterile containers.

Clinical procedures

All the diagnostic and clinical procedures were done by the main investigator. Pre-operative photos and radiographs had been taken to the patient. Each tooth was locally anesthetized using topical anesthesia followed by nerve block injection, then the tooth was isolated using a rubber dam. Following caries removal, a conventional access cavity had been made using a high-speed bur using copious water spray. Coronal pulp tissues had been removed using a spoon excavator then amputated sites were rinsed with normal saline. Hemorrhage was controlled by placing sterile, saline-wetted cotton pellets on the radicular pulp stumps under slight pressure, for 3 minutes.

For Group (A): According to Gupta et al.,[9] after stasis, the Aloe vera gel was placed over each pulp stump. This was followed by the application of a non-eugenol containing temporary restorative material. The final restoration of the cavity was self-cured glass ionomer restorative material. Teeth have been restored with stainless steel crowns that have been cemented by glass ionomer cement. Postoperative photos and radiographs had been taken at the same visit.

For Group (B): According to Mettlach et al.,7 after stasis, a sterile cotton pellet was lightly moistened with a 1:5 dilution of Buckley's was placed against the pulpal stumps for 3-5 minutes then removed. The pulp stumps were checked for fixation. Zinc oxide and eugenol base was placed, then the pulp chamber was filled with self-cured glass ionomer restorative material. Teeth were restored with stainless steel crowns, cemented with glass ionomer cement and an immediate postoperative radiograph was taken at the same visit.

Assessments of the outcomes

The outcomes of the materials used in this study were categorized into two main categories: primary (clinical) and secondary (radiographic) outcomes. Primary outcomes included postoperative pain, swelling, pain on percussion, swelling, development of a sinus tract, and mobility.Secondary outcomes included occurrence of radiolucent lesions at furcation or periapical region, external or internal root resorption. Clinical and radiographic evaluation was done by the third investigator in 3, 6, 9, and 12 months follow-up per protocol. A periapical radiograph was taken to assess the presence of any of the secondary outcomes to be recorded. The unit for both primary and secondary outcomes was binary. In case of the presence of adverse clinical signs (pain, a soft tissue/ dentoalveolar abscess, and/or sinus) the case was considered as failure, and the tooth was extracted. Cases with adverse radiographic signs were considered as a failure but were not extracted unless they were accompanied by clinical signs of failure.

Statistical analysis

All data were collected, checked, revised, tabulated, and saved into the computer. Data analysis was done in 3, 6, 9, and 12 months follow-up per protocol. Quantitative data were expressed as mean and standard deviation (SD) values. To test the significant differences between qualitative data, a Chi-square test was used for analysis. Statistical analysis was performed by a software program SPSS statistical version 19. The significance level was set at $p< 0.05$.

Results

Descriptive data

Mean age and gender distribution: At the time of treatment, the patients' age ranged between 4-7 years with a mean age of 5.17 + 0.64 for Group A (Aloe vera gel) and 5.43+ 0.8 for Group B (formocresol). Gender distribution was 13 (61.90 %) males and 8 (38.10 %) females for Group A while it was 12 (57.14%) males and 9 (42.86%) females for Group B. There was no statistically significant difference between age and gender distributions in the two Groups with a p-value of 0.2463 and 0.7532 respectively.

The number of patients available for follow-up: The number of patients available for follow-up at 3, 6, 9, and 12 months in both groups was illustrated in the Consort flow diagram figure (1).

Comparison between both groups regarding the clinical outcomes

Table (1) show the clinical evaluation of both groups during follow-up periods using (Chi-square test). The most frequently reported complaints in this study were pain on percussion and gingival swelling. Both complaints were significantly reported in Group A at 6, 9, and 12 months while absent in Group B throughout the follow-up period.

Comparison between both groups regarding the radiographic outcomes

Tables (2) show the clinical evaluation of both groups during follow-up periods using (Chi-square test). Furcation radiolucency was the most observed radiographic finding in Group A and the only one reported in Group B. Results showed a statistically significant difference between the two groups at 9 and 12 months.

Comparison between both groups regarding the overall clinical success rate at different follow-up periods

The number of molars showing an overall clinical success rate in Group A and Group B after 12 months was 7 (36.8%) and 13 (81.3%) respectively. There was a statistically significant difference between the two groups, (p-value 0.0081).

Comparison between both groups regarding the overall radiographic success rate at different follow-up periods

The number of molars showing an overall radiographic success rate in Group A and Group B after 12 months was 4 (21.1%) and 10 (62.5%) respectively. There was a statistically significant difference between the two groups, (p-value 0.0126).

Comparison between both groups regarding the overall success rate

The number of molars showing an overall success rate in Group A and Group B after 12 months was 4 (21.1%) and 10 (62.5%) respectively. There was a statistically significant difference between the two groups, (p-value 0.0126).

Figure (2) shows treatment of a decayed lower-left second primary molar indicated for pulpotomy using Aloe vera gel as a pulpotomy agent. Figure (3) shows treatment of a decayed lower-right second primary molar indicated for pulpotomy using formocresol as a pulpotomy agent.

Discussion

Pulpotomy is a widely applied clinical procedure for the treatment of primary teeth with deep caries approximating the pulp. Many materials and techniques are currently used to carry out primary tooth pulpotomy but still, there is not a single medicament or technique that can be used consistently to achieve ultimate clinical and radiographic success [10].

Formocresol was selected to be used in this study since it is still considered the gold standard for primary teeth pulpotomy. It is cheap, fixative, bactericidal, and has shown high clinical success rates in multiple studies. Despite the clinical success, concerns over formocresol safety had led to the search for suitable alternatives as denoted by Yousry et al.,[11].

Aloe vera is one of the oldest plants used for thousands of years for medicinal purposes. Many biological properties associated with Aloe species are contributed by the inner gel of the leaves. Aloe vera gel contains about 99.5% water and the remaining 0.5-1% solid material is a range of compounds including water- and fat-soluble vitamins, minerals, enzymes, polysaccharides, phenolic compounds, and organic acids. It is also a source of 19 out of 20 essential amino acids [12].

A few studies in the literature evaluated Aloe vera gel as a pulp dressing material. To date, there is low evidence proving Aloe vera gel as an effective pulpotomy medicament. This research was aimed to evaluate the clinical and radiographic outcomes of Aloe vera gel as a pulpotomy medicament in primary molars.

Figure 1. Consort flow diagram.

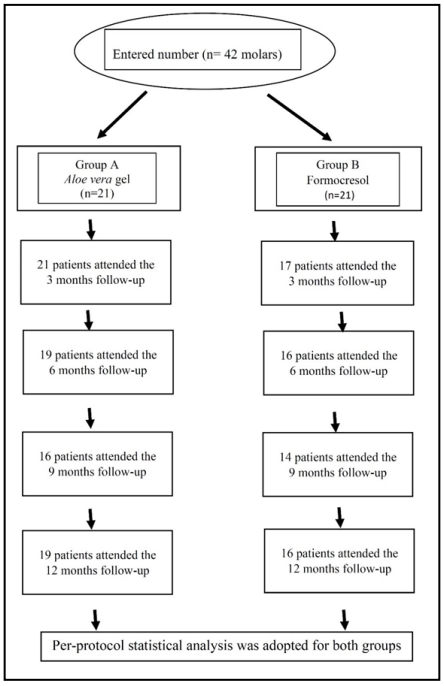

Figure 2. Showing a 6 years old girl was complaining of pain with eating related to the lower left quadrant. Pulpotomy was done to the lower-left second primary molar using Aloe vera gel as a pulpotomy agent.

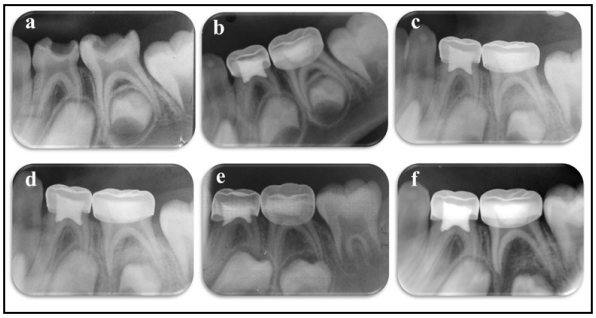

figure (2-a): preoperative x-ray, figure (2-b): post-operative x-ray, figure (2-c): 3 months post-operative, figure (2-d): 6 months postoperative, figure (2-e): 9 months postoperative, figure (2-f): 12 months postoperative

Figure 3. Showing a 5 years old girl was complaining of pain with eating related to the lower right quadrant. Pulpotomy was done to the lower right second primary molar using formocresolas a pulpotomy agent.

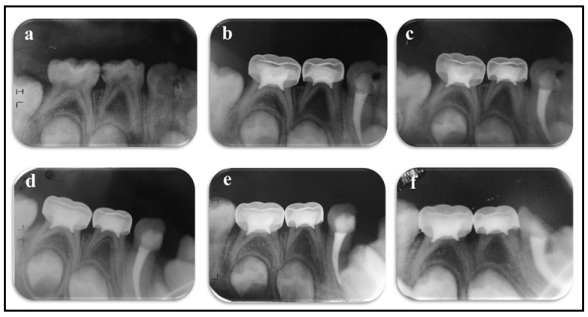

figure (3-a): preoperative x-ray, figure (3-b): post-operative x-ray,
figure (3-c): 3 months post-operative, figure (3-d): 6 months postoperative,
figure (3-e): 9 months postoperative, figure (3-f): 12 months postoperative

Table 1. Clinical evaluation of both groups during follow-up periods (Chi-square test).

Follow-up	Clinical features		Group A	Group B	p-value
3 months	Spontaneous pain	yes	1 (4.8%)	0 (0%)	0.3618 (ns)
		no	20 (95.2%)	17 (100%)	
	Pain on percussion	yes	3 (14.3%)	0 (0%)	0.1044 (ns)
		no	18 (85.7%)	17 (100%)	
	Gingivalswelling	yes	2 (9.5%)	0 (0%)	0.1911 (ns)
		no	19 (90.5%)	17 (100%)	
	Mobility	yes	0 (0%)	0 (0%)	0 (ns)
		no	21 (100%)	17 (100%)	
	Sinus tract formation	yes	0 (0%)	0 (0%)	0 (ns)
		no	21 (100%)	17 (100%)	
6 months	Spontaneous pain	yes	2 (10.5%)	1 (6.3 %)	0.6525 (ns)
		no	17 (89.5%)	15 (93.7%)	
	Pain on percussion	yes	4 (21.1%)	0 (0 %)	0.0325 (s)
		no	15 (78.9%)	16 (100%)	
	Gingivalswelling	yes	4 (21.1%)	0 (0%)	0.0511 (ns)
		no	15 (78.9%)	16 (100%)	
	Mobility	yes	0 (0%)	0 (0%)	0 (ns)
		no	19 (100%)	16 (100%)	
	Sinus tract formation	yes	1 (5.3 %)	0 (0%)	0.3518 (ns)
		no	18 (94.7%)	16 (100%)	
9 months	Spontaneous pain	yes	4 (25%)	2 (14.3%)	0.4642 (ns)
		no	12 (75%)	12 (85.7%)	
	Pain on percussion	yes	6 (37.5 %)	0 (0%)	0.0104 (s)
		no	10 (62.5%)	14 (100%)	
	Gingivalswelling	yes	5 (31.3%)	0 (0%)	0.0219 (s)
		no	11 (68.7)	14 (100%)	
	Mobility	yes	2 (12.5 %)	0 (0%)	0.1709 (ns)
		no	14 (87.5%)	14 (100%)	
	Sinus tract formation	yes	3 (18.8 %)	0 (0%)	0.0876 (ns)
		no	13 (81.2%)	14 (100%)	
12 months	Spontaneous pain	yes	5 (26.3%)	3 (18.8%)	0.5954 (ns)
		no	14 (73.7%)	13 (81.2%)	
	Pain on percussion	yes	8 (42.1%)	0 (0%)	0.0031 (s)
		no	11 (57.9%)	16 (100%)	
	Gingivalswelling	yes	8 (42.1%)	0 (0%)	0.0031 (s)
		no	11 (57.9)	16 (100%)	
	Mobility	yes	3 (15.8%)	0 (0%)	0.0964 (ns)
		no	16 (84.2%)	16 (100%)	
	Sinus tract formation	yes	4 (21.1%)	0 (0%)	0.0511 (ns)
		no	15 (78.9%)	16 (100%)	

*Significance level $p<0.05$, ns=non-significant, s= significant

Table 2. Radiographic evaluation of both groups during follow-up periods (Chi-square test).

Follow-up	Radiographic features		Group A	Group B	p-value
3 months	Periapical radiolucency	yes	1 (4.8%)	0 (0%)	0.3618 (ns)
		no	20 (95.2%)	17 (100%)	
	Furcation radiolucency	yes	4 (19%)	1 (5.9%)	0.2325 (ns)
		no	17(81%)	16 (94.12%)	
	Internal root resorption	yes	0 (0%)	0 (0%)	0 (ns)
		no	21 (100%)	17 (100%)	
	External root resorption	yes	3 (14.3%)	0 (0%)	0.1044 (ns)
		no	18 (85.7%)	17 (100%)	
6 months	Periapical radiolucency	yes	3 (16%)	0 (0%)	0.0964 (ns)
		no	16 (84%)	16 (100%)	
	Furcation radiolucency	yes	7 (36.8%)	2 (12.5%)	0.1007 (ns)
		no	12 (63.2%)	14 (87.5%)	
	Internal root resorption	yes	1 (5.3%)	0 (0%)	0.3518 (ns)
		no	18 (94.7%)	16 (100%)	
	External root resorption	yes	4 (21.1%)	0 (0%)	0.0325 (s)
		no	15 (78.9%)	16 (100%)	
9 months	Periapical radiolucency	yes	3 (18.8%)	0 (0%)	0.0876 (ns)
		no	13 (81.2%)	14 (100%)	
	Furcation radiolucency	yes	10 (62.5%)	3 (21.4%)	0.0235 (s)
		no	6 (37.5%)	11(78.6%)	
	Internal root resorption	yes	2 (12.5%)	0 (0%)	0.1709 (ns)
		no	14 (87.5 %)	14 (100%)	
	External root resorption	yes	5 (31.3 %)	0 (0%)	0.0219 (s)
		no	11 (68.7%)	14 (100%)	
12 months	Periapical radiolucency	yes	4 (21.1%)	0 (0%)	0.0511 (ns)
		no	15 (78.9%)	16 (100%)	
	Furcation radiolucency	yes	15 (78.9%)	6 (37.5%)	0.0126 (s)
		no	4 (21.1%)	10 (62.5%)	
	Internal root resorption	yes	5 (26.3%)	0 (0%)	0.0266 (s)
		no	14 (73.7%)	16 (100%)	
	External root resorption	yes	8 (42.1%)	0 (0%)	0.0031 (s)
		no	11 (57.9%)	16 (100%)	

*Significance level $p<0.05$, ns=non-significant, s= significant

A healthy Aloe barbadensis Miller plant, approximately 4 years old, has been selected to be used in this trial. Plants of this age are characterized by higher Aloe vera gel nutritional and therapeutic value. Leaves have been harvested at the level of their base and cleaned with 70% ethyl alcohol to eliminate bacterial contamination. It was then stored in distilled water for 1 h to eliminate aloin as it is an irritant laxative that is contained in the yellow sap of Aloe as reported by Ahlawat et al.,[13].

A processing technique to stabilize the gel has been conducted according to Ahmed et al.,8 in the laboratory of the Pharmacognosy Department, Faculty of Pharmacy. Stabilization of the gel by adding preservatives aimed to preserve the properties of the natural Aloe vera gel and prevent its microbial degradation as it exhibits a limited shelf-life and loses most of its biological activity when the gel is exposed to air as cited by Nazemi et al.,[14].

Agar powder has been added to the Aloe vera gel to facilitate its manipulation since the gel is semisolid in nature making its manipulation very difficult. Consequently, the concentration of the Aloe vera gel has decreased to 70% which goes in agreement with Ahmed et al.,[8] who reported that there was no statistically significant difference between 70% and 90% Aloe vera gel preparations. The preserved Aloe vera gel has been stored in sterile dark-colored containers to avoid the effect of light on sensitive bioactive agents as reported by Rahman et al.,[15].

Pulpotomies were performed by the same operator to avoid individual variations between different operators. Additionally, all procedures were performed according to the manufacturer's instructions and as per the protocol to retain treatment consistency following Dhar et al.,[16].

The clinical and radiographical evaluations were carried out by the co-supervisor at 3,6,9, and 12 months. COVID-19 pandemic lockdown hindered some patients from attending the recall visits. The effect of the lockdown was noticed in 9, and 12 months records. Consequently, the following measures have been taken to overcome the missed data for those patients. Parents were taught to do a clinical examination of the child and the results have been

collected through phone calls, parents were requested to send an intra-oral photo showing the treated tooth. Finally, a history of pain was taken from the child through a phone call. As for the radiographic record, the missed data of the 9 months recall visit was reported the same as the 12 months that was reported for the patient afterward. In some cases, the 12 months record was reported late due to the lockdown as reported by Kent et al.,[17].

The success rate of pulpotomies was measured as the percentage of teeth reaching an arbitrary point in time in absence of clinical or radiographic evidence of disease as cited by Durmus & Tanboga,[18].

Regarding clinical evaluation, the most frequently reported complaints in this study were pain on percussion and gingival swelling. Both complaints were significantly reported in Group A at 6, 9, and 12 months while absent in Group B throughout the follow-up period. Those results were following Atasever et al.,[19] who reported that pain on percussion was the most observed clinical finding in their trial. However, Yaman et al.,[20] reported no pain in all cases until the end of the follow-up period.

Pain on percussion and gingival swelling may be attributed to traumatic cutting during the pulpotomy procedure or the presence of a blood clot that might have caused chronic inflammation of the pulp that spread to the periapical tissues leading to edema and postoperative pain as denoted by Pratima et al.,[21].

Regarding Spontaneous pain, mobility, and sinus tract formation there was no statistically significant difference between the two groups throughout the follow-up period. This result was following Chakraborty et al.,[22]. In contrast, other authors as Pratima et al.,[21], reported a 100% clinical success rate with no pain reported in their trials.

In the current study, spontaneous pain was the only clinical outcome reported in Group B, this may be due to the irritating effect of formocresol on tissues of the furcation and periapical region. Regarding Group A development of spontaneous pain after pulpotomy may be attributed to chronic pulp inflammation as an adverse reaction of pulp tissues toward the Aloe vera gel as reported by Gonna et al.,[5].

Furcation radiolucency was the most observed radiographic finding in Group A and the only one reported in Group B. Results showed a statistically significant difference between the two groups at 9 and 12 months. This result was supported by Subramanyam & Somasundaram,[23]. However, Gupta et al.,[9] reported a 100% success after 1 month which may be due to the short follow-up period.

Furcation radiolucency in Group B may occur as a result of seepage of formocresol into the furcation area via accessory canals or the pulpal floor, which is thin, porous, and permeable in nature in deciduous molars. For Group A, furcation radiolucency may be due to adverse pulp reaction towards the Aloe vera gel that might have spread to the furcation area via accessory canals as cited by Al-Dahan et al.,[24], Subramanyam & Somasundaram [23].

Regarding periapical radiolucency, there was no statistically significant difference between the two groups at 3, 6, 9, and 12 months. This result was following Maqbool et al.,[6]. In contrast, Gonna et al.,[5] stated that periapical radiolucency was absent in all cases after 6-months. The development of periapical radiolucency may be due to infection of the radicular pulp which ultimately leads to apical or furcal radiolucency. This was in agreement with Chakraborty et al.,[22].

Regarding internal and external root resorption, only a few molars have been reported with internal or external root resorption in Group A, while it was absent in Group B throughout the follow-up period. The difference between the two groups was statistically significant at 12 months. This result was following Atasever et al.,[19].

The internal root resorption is generally considered a sign of chronic inflammation which might attract the osteoclastic cells and initiate the internal resorption. Another opinion was that internal resorption may be a result of undiagnosed chronic inflammation existing in the radicular pulp before pulpotomy as reported by Silva et al.,[25]. According to the AAPD [26], internal root resorption is usually self-limiting and no treatment is needed unless resorption extends to the supporting bone.

In the present study, it was observed that the clinical success in both groups was higher than the radiographic success, this finding was consistent with Al-Dahan et al.,[24] and Durmus & Tanboga, [18] who reported that the radiographic success rates are lower than the clinical success rates in their trial. Failure of pulp therapy may be detected radiographically while being unnoticed clinically until the natural exfoliation of teeth.

In the current study, the overall success rate of Group A was relatively low showing a statistically significant difference between Group A and Group B. Additionally, it was observed that as time passed the overall success rates of both groups gradually decreased which was consistent with the results reported by Yaman et al. [20], and Sajadi, [27].

Results of Group A in this study were comparable to those reported by Kalra et al.,[28] who stated that the overall success rate of Aloe vera pulpotomy by the end of 12 months follow-up was relatively low. In contrast, Gupta et al.,[9] reported a 100% overall success 1 month after using a freshly extracted Aloe vera gel as a pulpotomy agent. Maqbool et al.,6 reported a relatively high overall success rate of Aloe vera gel as a pulpotomy agent after 6 months. The gradual decrease in the success rate may be due to a decrease in the anti-inflammatory property of Aloe vera gel over time. This was following Subramanyam & Somasundaram,[23].

Comparison with previous studies may be difficult due to the limited number of clinical trials that used Aloe vera gel as a pulpotomy agent, variation in selection criteria regarding cases, methodology, materials, the concentration of the gel, and the follow-up period, which may affect the outcome.

Controversies in the results regarding the efficacy of Aloe vera gel as a pulpotomy agent may be attributed to differences in plant composition among different geographic locations, species, climate, and growing conditions. Similarly, differences in gel extraction methods and sample preparation techniques can be significant. All those factors have contributed to discrepancies in the results from the obtained studies as reported by Subramanyam & Somasundaram,[23].

Texture and color of the pulp tissue as well as the cessation of bleeding after coronal pulp amputation have been used as indicators of the status of the radicular pulp because more precise diagnostic tools are not available in the clinical situation. Consequently, pulpotomy might be performed on teeth that appear clinically suitable for pulpotomy but histologically it is contra-indicated as pulp inflammation might have extended from coronal to radicular pulp tissues, and this contributes to treatment failure as reported by Havale et al.,[29].

The high overall clinical success of Group B in this study could be attributed to the fixative and bactericidal qualities of formocresol as a pulpotomy agent. It could produce clinical success even with chronic silent inflammation because of its fixation and antimicrobial effects. However, the use of other materials in primary teeth pulpotomy has more diagnostic sensitivity as failure may occur in case of minor inflammation as denoted by Gisoure,[2].

On the other hand, the failure of some cases in Group B may be due to the effect of formaldehyde employed during pulpotomy. It could evoke inflammation of surrounding non-target tissues and exert cytotoxic, genotoxic, and mutagenic effects leading to tissue damage ranging from vascular insult and inflammation to necrotic and osteolytic changes as stated by Al-Dahan et al.,[24].

Failure in pulpotomized teeth can be attributed to the medicament placed inside the pulp chamber. Changes produced inside the radicular pulp mainly occur as a result of medicament-pulp interaction. Hence, further histological investigations should be conducted to ascertain the reaction between Aloe vera gel and human dental pulp tissues.

Conclusion

In conclusion, formocresol was found to be superior when compared to Aloe vera gel as a pulpotomy agent in second primary molars as the overall success rate of formocresol was higher than the Aloe vera gel. The clinical success in both groups was higher than the radiographic success. Radiographic failure was reported in both groups with a lower rate in the formocresol group.

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References

[1]. Abd Al Gawad RY, Hanafy RMH (2020) Success rate of three capping materials used in pulpotomy of primary molars: A randomized clinical trial. Saudi Dent J:1–8.
[2]. Gisoure EF (2011) Comparison of three pulpotomy agents in primary molars: A randomised clinical trial. Iran Endod J 6:11–14.
[3]. Mohammad SG, Baroudi K (2015) Assessment of the potential of Allium sativum oil as a new medicament for non- vital pulpotomy of primary teeth. J Int Soc Prevent Communit Dent 5:314-320.
[4]. Chakraborty R, Sen S (2017) Aloe vera-the atavistic herb used in dentistry. World J Pharm Res 6:356–365.
[5]. Gonna S, Ghoname N, Kabbash A, Yagi A (2019) Efficacy of Aloe Vera as A Pulpotomy Agent in Children Primary Teeth : Clinical and Radiographic Studies. J Gastroenterol Hepatol Res 8:2946–2951.
[6]. Maqbool H, Ali MA, Haq UU, Shah SA (2020) Comparing the efficacy of Aloe vera gel versus ferric sulphate as a pulp medicament in vital pulpotomy of deciduous. Khyber Med Univ J 12:10–14.
[7]. Mettlach SE, Zealand CM, Botero TM, Boynton JR, Majewski RF, et al. (2013) Comparison of mineral trioxide aggregate and diluted formocresol in pulpotomized human primary molars: 42-month follow-up and survival analysis. Pediatr Dent 35:1–20.
[8]. Ahmed SS, Gadalla LM, Elmeadawy SH, Badria F (2018) The Efficacy of Aloe vera Gel in Treatment of Oral Lichen Planus. Int Dent Med J Adv Res 2015:1–6.
[9]. Gupta N, Bhat M, Prabha Devi, Girish (2010) Aloe-Vera : A Nature's Gift to Children. Int J Clin Pediatr Dent 3:87–92.
[10]. Bossù M, Iaculli F, Giorgio G Di, Salucci A, Polimeni A, et al. (2020) Different Pulp Dressing Materials for the Pulpotomy of Primary Teeth : A Systematic Review of the Literature. J Clin Med 9:1–23.
[11]. Yousry YM, Abd Al Latif AE, Abd Al Gawad RY (2020) Clinical and Radiographic Evaluation of Vital Pulpotomy in Primary Molar Using Antioxidant Mix as A Novel Pulotomy Medication Versus Formcresol: Adv Dent J 3:12–23.
[12]. Samarh SN, Khalaf NA, Hajhamad MM (2017) Evidence based medical use of aloe vera extracts, short review of literature. Int J Res Med Sci 5:4198-4202.
[13]. Ahlawat S, Gulia N, Khatkar B (2013) Effect of plant maturity on leaf growth, yield and physicochemical properties of aloe vera gel. AgroFOOD Ind hi-tech 24:22–24.
[14]. Nazemi N, Khalighi-Sigaroodi F, Monfared A (2017) Processing and stabilization of Aloe Vera leaf gel by adding chemical and natural preservatives. RJP 4:24
[15]. Rahman S, Carter P, Bhattarai N (2017) Aloe Vera for Tissue Engineering Applications. J Funct Biomater 8:1-17.
[16]. Dhar V, Marghalani AA, Crystal Y, Kumar A, Ritwik P, et al. (2017) Use of Vital Pulp Therapies in Primary Teeth with Deep Caries Lesions.Pediatr Dent 39:E146-E159.
[17]. Kent DG, Knapp DJ, Kannan N (2020) Survey Says: "COVID-19 Lockdown Hits Young Faculty and Clinical Trials." Stem Cell Reports 15:1–5.
[18]. Durmus B, Tanboga I (2014) In Vivo evaluation of the treatment outcome of pulpotomy in primary molars using diode laser, formocresol, and ferric sulphate. Photomed Laser Surg 32:289–295.
[19]. Atasever G, İleri Keçeli T, Uysal S, Güngör HC, Ölmez S (2019) Primary molar pulpotomies with different hemorrhage control agents and base materials: A randomized clinical trial. Niger J Clin Pract 22:305–312.
[20]. aman E, Görken F, Erdem AP, Sepet E, Aytepe Z (2012) Effects of folk medicinal plant extract ankaferd blood stopper® in vital primary molar pulpotomy. Eur Arch Paediatr Dent 13:197–202.
[21]. Pratima B, Chandan GD, Nidhi T, Nitish I, Sankriti M, et al. (2018) Postoperative assessment of diode laser zinc oxide eugenol and mineral trioxide aggregate pulpotomy procedures in children : A comparative clinical study. J Indian Soc Pedod Prev Dent 36:308–314.
[22]. Chakraborty A, Dey B, Jana S (2018) A Nonconventional Approach to Formocresol Pulpotomy. Int J Clin Pediatr Dent 11:490–495.
[23]. Subramanyam D, Somasundaram S (2020) Clinical and Radiographic Evaluation of Aloe vera vs Formocresol as a Pulpotomy Medicament in Primary Molars : A Double Blinded Randomized Controlled Trial. Int J Clin Pediatr Dent 13:139–143.
[24]. Al-Dahan ZA, Zwain AM, Al-Assadi AH (2013) Clinical and Radiographical Evaluation of Pulpotomy in Primary Molars Treated with Pulpotec (PD), Formocresol and Mineral Trioxide Aggregate (MTA). J Baghdad Coll Dent 25:164–170.
[25]. Silva LL, Silva L, Sakai VT, Lopes CS, Silveira AP, et al. (2019) Comparison between calcium hydroxide mixtures and mineral trioxide aggregate in primary teeth pulpotomy: A randomized controlled trial. J Appl Oral Sci 27:1–8.
[26]. AAPD (2014) Guideline on Pulp Therapy for Primary and Immature Permanent Teeth. AAPD Ref Man 36:242–250.
[27]. Sajadi F (2014) Clinical and Radiographic Findings after Using Formocresol and Elaeagnus angustifolia Fruit Powder for Pulpotomy of Primary Molar Teeth. Wulfenia J21:262–278.
[28]. Kalra M, Garg N, Rallan M, Pathivada L, Yeluri R(2017) Comparative evaluation of fresh Aloe barbadensis plant extract and mineral trioxide aggregate as pulpotomy agents in primary molars: A 12-month follow-up study. Contemp Clin Dent.Jan 8(1):106–111.
[29]. Havale R, Anegundi RT, Indushekar KR, Sudha P(2013) Clinical and Radiographic Evaluation of Pulpotomies In Primary Molars With Formocresol, Glutaraldehyde and Ferric Sulphate. OHDM12(June):24–31.