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Post-operative pain after vital pulpotomy of primary molars using allium sativum oil versus mineral trioxide aggregate: A randomized pilot clinical study

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***Abstract*---**Aim: To evaluate clinical and radiographic performance of Allium Sativum oil dressed in Zinc Oxide versus Mineral trioxide aggregate as pulp dressing agent in pulpotomized lower primary molar teeth. Methodology: This randomized pilot clinical trial included 30 lower primary molars indicated for vital pulpotomy and randomly allocated into two equal groups (n=15): Group (I): pulpotomy using A. Sativum oil dressed in ZnO and Group (II): pulpotomy using Mineral trioxide aggregate as pulpotomy agent. All molars were covered with stainless steel crowns and clinical and radiographic assessment was done at 3, 6, 9 and 12 months interval by help of predetermined criteria. Results: Overall clinical success rate of Group (I) and Group (II) at the end of 12 months follow-up was (93.3%) and (100.0%) respectively. There was no statistical significance difference between two groups regarding overall clinical success rate. The overall radiographic success rate at the end of 12 months was (40.0%) and

(100.0%) respectively. There was a statistical significant difference regarding overall radiographic success rate at 9 and 12 months follow-up. The overall success rate of Group (I) and Group (II) at the end of 12 months was (40.0%) and (100.0%) showing a statistically significant difference between the two groups. Conclusion: Mineral trioxide aggregate was found to be superior when compared to A.Sativum oil as pulpotomy agent in primary molar teeth.

***Keywords*---**Allium Sativum oil, Mineral trioxide aggregate, primary molars, Pulpotomy, Zinc Oxide.

Introduction

Pulpotomy is one of the procedure that aims to preserve the primary teeth in anatomical position and functioning condition until physiological exfoliation and eruption of succedaneous teeth (1). Saving primary teeth is important to preserve the mesiodistal space and the vertical dimension that guides the physiological position of the normal eruption of succedaneous teeth, in addition, it also helps in maintaining aesthetics, mastication, speech, alleviation of pain, swelling and abnormal habits (2).Pulpotomy procedure entails the removal of the coronal part of the affected or infected dental pulp tissue, treatment of the remaining vital radicular pulp tissue surface should maintain the vitality and function of the remaining radicular pulp and ultimately to preserve tooth (3).

Mineral trioxide aggregate (MTA) is a novel endodontic cement that is the gold standard as pulpotomy medicament because of high clinical and radiographic success in primary molar teeth pulpotomy (4, 5). However, *MTA* possesses some drawbacks including, high cost, struggling in handling, long setting time, slower resorption rate than physiologic root resorption and suppresses some toxic impurities like *Arsenic* (6). Thus, forcing researchers to explorate and investigate the use of natural products as dressing agents in the pulpotomy procedure of primary teeth.

The use of natural materials for the curing of various infections and diseases is practiced all over the world for many years. The significant merits of using herbal products are availability, cost-effectiveness, long shelf life, low cytotoxicity and absence of microbial resistance (7, 8, 9, 10).*Garlic oil (Allium Sativum) (A.Sativum)* was launched recently in the field of dentistry due to its potent antioxidant, antibacterial, antiviral, antifungal, antitumor, anti-inflammatory and immunomodulatory effects. Sulfur-containing compounds, the main compositions of *Garlic oil*, are thought to be responsible for their variable therapeutic effects. *Garlic oil* had been also launched as a pulpotomy medication in primary molars due to its biological properties offering a good environment for healing and leaving the remaining pulp tissue healthy and functioning (9, 11, 12).

However, few researches had examined the use of *Garlic oil* in pediatric dentistry as vital pulpotomy medicament in primary molar teeth and revealed discrete clinical and radiographic success rate (13,14).Due to lack of evidence regarding *Garlic oil* efficacy as a pulpotomy medicament in primary molar teeth, the present

study was conducted to assess the clinical and radiographic consequences of using *Garlic oil* dressed in *Zinc Oxide (ZnO)* as a pulpotomy medicament following coronal pulp removal in lower primary molars and contrast them to the results of using *MTA*.

Subjets & Methods

Study design

This study was a randomized controlled trial (RCT), a parallel group with a 1:1 allocation ratio and equivalence framework. Triple blinded (patient, radiographic assessors, and statistician).

Sample size

This intervention is new and was not used before for long follow up period in vital pulpotomy of primary molar teeth, therefore, a pilot study was recommended. The suggested total sample size is 25 molars in both groups. This was increased by 20 % to compensate for losses during follow-up. The total sample size after increasing by 20% was 30 molars, fifteen molars in each group (15). The research was approved by the evidence- based committee, on 22-5-2019. It was approved by the Ethics committee, on 25-6-2019. The protocol was then registered on the clinical trial website, (http://www.clinicaltrial.com.gov), ClinicalTrials.gov ID: (NCT03908489) and was verified on August 17, 2021

Subject selection

Thirty primary lower molars in eighteen children were recruited to participate in this study. Patient were chosen from outpatient diagnosis clinic. *CONSORT* flow chart outlining this study design (Figure 1).

Eligibility criteria:
Inclusion criteria

- Healthy cooperative children patient having deep decayed mandibular deciduous molars nesseciating vital pulpotomy.
- Aged between 4 to 7 years.
- Both sexes were involved.
- Patients with provoked pain were involved.
- Residual radicular tissue is vital with no suppuration or purulence.
- Restorable teeth.

Exclusion criteria

- Increased bleeding that cannot controlled by a wet cotton pellet after few minutes.
- Clinical or radiographic finding of pulp necrosis.
- With congenital abnormalities in teeth e.g., taurodontism, concrescence or fusion.
- Patients who revealed allergic response to any agent was used in this study.

- Patients did not accept to adhere to follow-up protocol in the study and reject to give communication information.
- Patient's parents reject to sign up an informed consent before contributing in this study.

Researcher discussed the trial with legal guardian of each participating child. Verbal assent was taken orally from participating child. Written informed consent was taken from the legal guardian of each willing participating child. All consent forms had been translated into Arabic. Parents were informed that follow up visit are mandatory to evaluate the effect of treatment and to discuss other treatment option if this treatment failed to meet anticipated targets. All consent forms had been translated into Arabic.

Patients were chosen from the outpatient clinic. Examination of patients sustained until the objective population was attained. The thirty lower deciduous molars were randomly allocated into two equal groups (n=15). Group I involved deciduous molars treated with *A. Sativum* as pulpotomy agent but group II involved deciduous molars treated with *MTA* as pulpotomy agent.

Eligible consented participants were assigned to either the intervention or comparator group by simple randomization with help of computer software (Random.com) according to a sequence generated on a Microsoft Excel sheet where the intervention (Group I) and the control (Group II). The table of sequence generation was kept with the co-supervisor. Every participant grasped an opaque sealed envelope and opened after pulp extirpation so that the operator knew the type of capping material just before application of dressing material. Co-supervisor was allocated which primary molar tooth was involved to either control or intervention groups regarding to the generated random sequence. Participants and their parents were blind in this study in addition to the statistician and radiographic outcomes assessor.

Operative procedure

Diagnosis of the molars was done along with to guidelines of *AAPD, 2017* for management primary molar teeth with deep caries needing vital pulp therapy (16). A full diagnostic dental chart specially designed for purpose of the study was filled for every patient by the researcher to record; personal history, medical history, dental history, clinical and radiographic examination, treatment plan and follow-up.

Clinical examination

Clinical examination was done on the dental clinic using light of dental unit *(Knight by Midmark)* of department using autoclavable mirror *(no.5, EC aktiv, Röder Dental Instruments, Germany)* and sickle probe (*no.23, Nordent Manufacturing 610 Bonnie Lane Elk Grove Village USA*) to assess inclusion and exclusion criteria.

Radiographic examination

Preoperative periapical radiograph was taken, using size-1 digital radiographic sensor*([4]Digora Optime, Soredex, Tuusula, Finland)* and x-ray machine (Minray, Soredex, Tuusula, Finland) with the following exposure parameters 70 kVp, 7 mA and .050 second exposure time and Digora software (Digora for windows 2.7, Soredex, Tuusula Finland) for windows through Digora Optime system scanner (Digora Optime, Soredex, Tuusula, Finland) to evaluate the extent of the carious lesion, as well as to detect presence or absence of any unfavorable radiographic results (e.g. internal or external root resorption or other pathologic changes). An alginate impression *(Cavex CA37 Holland BV, Fast set, Dust free, Fustweg 5, 2031 CJ Haarlem, The Netherlands)* was taken, then acrylic radiographic stent was fabricated on the cast for each patient. The stent placed around the Extension Cone Paralleling (XCP) plastic tip *XCP (KIT RINN FPS 3000, Dentsply, United Kingdom)*

Intra-operative procedure (Figure 2)

All clinical and diagnostic procedures were done by main investigator. Pre-operative photographs and radiographs had been taken to the targeted molars. Each tooth locally anesthetized by topical anesthesia (Topical Anesthetic *Gel* Benzocaine 20*%,* Miami*, Florida,* United States) followed by nerve block using articaine *(Septanest® Injections, Septodont Saint-Maur-des Fossés, France)* HCL 4% with 1:100000 epinephrine was administered at the side of affected teeth. Teeth were isolated by rubber dam Sanctuary powder free latex dental dam *(Sanctuary Health Sdn Bhd, Malaysia).* Dental caries and undermined enamel had been eliminated. Following caries removal, a conventional access cavity had been performed exploiting a high- speed bur *(Komet, Germany and Dia-Burs, Mani, INC, Japan)* using copious water jet. Coronal pulp tissue had been excised exploiting a spoon excavator *(NOVA leading edge dental instruments, England)*, then amputated sites rinsed by normal saline. *Bleeding* was stopped by adding a sterile, moistened cotton pellets on radicular pulp tissue under low pressure for 5 minutes*)*.

Group (I) Figure 2 (A-F)

After hemostasis, a cotton pellet damped with *A. sativum oil (Captin company (CAPpharm) registration No 952/94 Cairo, Egypt)* was placed over each pulp stump for 5 minutes followed by application *A. Sativum* dressed in *ZnO powder (Prevest Denpro Limited, Sidco Industrial Complex Bari Brahmana, Jammu, Jammu & Kashmir)* of thick doughy consistency that was condensed over radicular pulp**.**

Group (II) Figure 2: (G-K)

After hemostasis, powder and liquid of *White MTA Angelus™ (Angelus, Londrina, Parana, Brazil)* were mixed according to manufacturer instructions in a 3:1 powder/liquid to obtain putty like consistency, then carried using amalgam carrier, placed and condensed over pulp stump using suitable size condenser.

For both groups

Zinc phosphate (Zn-ph) cement (Adhesor ® Phosphate Cement, Pentron, USA) was mixed according to manufacturer instructions (powder/liquid = 3.5: 1) till base of doughy consistency was formed and were used as base to fill remaining cavity and condensed using large condenser *(NOVA leading edge dental instruments, England).* All molars were finally restored with stainless steel crown *(Kids Crowns shunghung company ltd korea)* and cemented by *glass ionomer cement (GIC) (Meron ® Glass Ionomer Cement, VOCO GMbH Company, Germany).* Post-operative baseline photograph and radiograph after placement of stainless steel crown had been taken at the same visit.

Follow up

Follow up was performed at 3, 6, 9 and 12 months according to AAPD, 2017 guidelines for clinical and radiographic evaluation (16). Clinical examination was done by the researcher to examine the patient for presence and absence of pain, mobility, sinus or fistula and swelling. Radiographic examination was done by Co-Supervisor using periapical radiographs to assess the presence and absence of normal bone trabeculation, development of radiolucency in periapical region or furcation area, external or internal root resorption. Photographs for the patient and the oral cavity were taken using a digital camera.

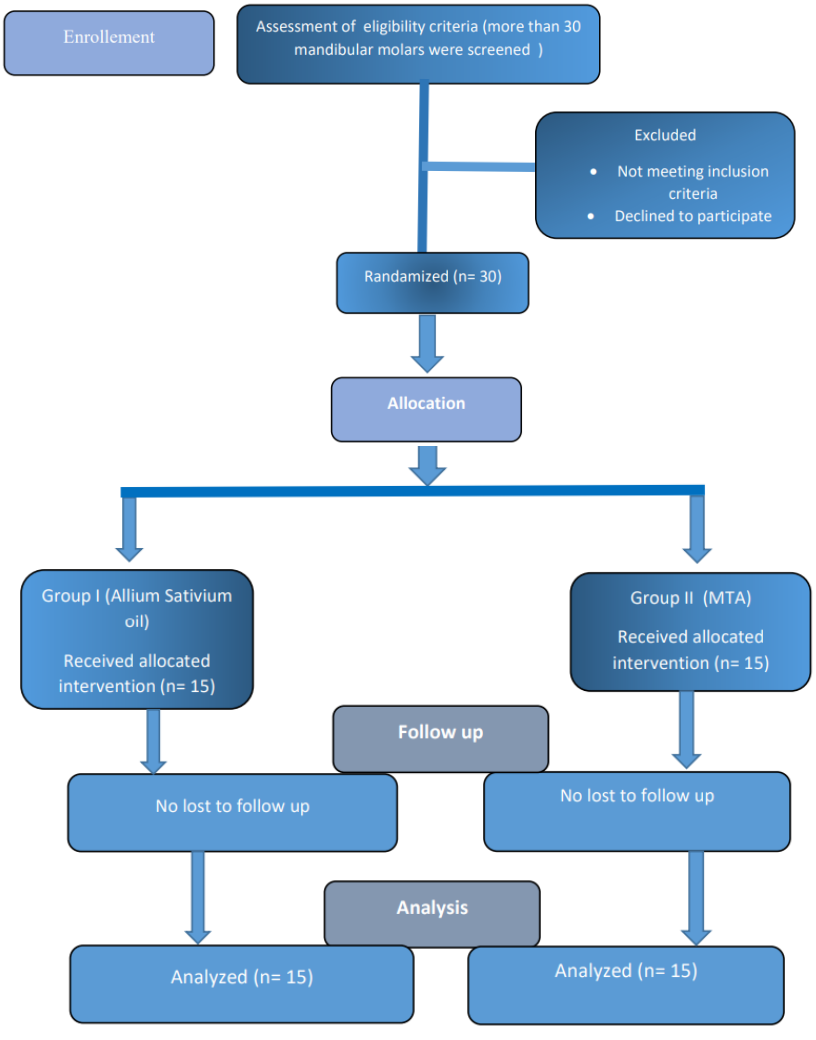

Figure1: CONSORT flow chart outlining the study design

Figure 2: (A): Molars were isolated by rubber

Figure 2: (B): After hemostasis

Figure 2 :(C) Placement of *A. Sativum oil* cotton pellet for 5 min on pulp stump after hemostasis

Figure 2 :(D) Placement of *A. Sativum* dressed in

Figure 2 :(E) Placement *of Zn-ph* base

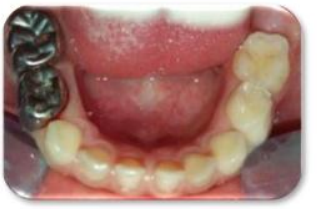

Figure 2 : (F) Immediate post-operative photograph after placement of

Figure 2 (*A-F): Clinical picture of lower primary molars in Allium Sativum oil group*

Figure 2: (G) Molar was isolated by rubber dam

Figure 2: (H) After hemostasis

Figure 2: (I) Placement of *MTA* on pulp stump

Figure 2: (J) Placement of *Zinc phosphate* base

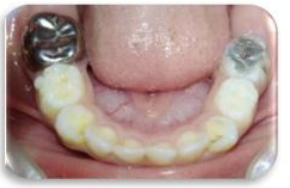

Figure 2: (K) Immediate post-operative photograph

Figure 2: *(G-K): Clinical pictures of the lower primary molars in Angelus MTA ™ group*

Outcomes
1ry outcome:

Post-operative pain

Spontaneous pain and pain on biting was reported by asking the patient using *Wong-Baker FACES Pain Rating Scale which is* Self-report faces scale for acute pain. Scale ranges from (0-10) according to the severity of pain. Six line drawn faces range from no hurt to hurts worst. Scores of pain were recorded to affected tooth at 3, 6, 9 and 12 months respectively (17).

2ry outcomes:

- Pain on percussion: were reported by asking the patient using *Wong-Baker FACES Pain Rating Scale which is* Self-report faces scale for acute pain. Scores of pain were recorded to affected tooth at 3, 6, 9 and 12 months respectively (17).
- Swelling (Binary outcome): Presence or absence of swelling related to the affected tooth was detected by visual intra-oral clinical examination at 3, 6, 9 and 12 months respectively (18).
- Sinus or fistula (Binary outcome): Presence or absence of sinus or fistula related to the affected tooth was detected by visual intra-oral clinical examination at 3, 6, 9 and 12 months respectively (19).
- Furcation involvement: Furcation involvement was evaluated radiographically by visual interpretation of DIGORA software using furcation involvement scores: 0 - no radiolucency; 1 - radiolucency between ¼ of furcation to periapical areas; 2 - radiolucency between ¼ to ½ of furcation to periapical areas; 3 - radiolucency more than ½ of furcation to periapical areas. Furcation involvement was evaluated at 3, 6, 9 and 12 months according to guidelines for radiographic evaluation (19).
- Periapical radiolucency: Presence or absence of periapical radiolucency was evaluated radiographically by visual interpretation of DIGORA software at 3, 6, 9 and 12 months (20).
- Pathological internal or external root resorption: Presence or absence of pathological internal or external root resorption treated teeth was evaluated radiographically by visual interpretation of DIGORA software at 3, 6, 9 and 12 months (21).
- Widening of periodontal membrane space: Widening of periodontal membrane space was evaluated radiographically by visual interpretation of DIGORA software for presence or absence of widening in periodontal membrane space at 3, 6, 9 and 12 months (22).

Statistical analysis

Data were collected, revised for completeness and logical consistency, tabulated, and statistically analyzed. For the two groups, clinical and radiographic findings at 3, 6, 9 and 12 months postoperatively were assessed. Statistical analysis was performed with R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.Categorical and ordinal data were presented as

frequency and percentage values. Numerical data were presented as mean and standard deviation values. Categorical data were analyzed using fisher's exact test for intergroup comparisons and Cochrane q test followed by pairwise comparisons utilizing multiple mcnemar tests with bonferroni correction.Parametric data of age were analyzed using independent t-test. Ordinal data were analyzed using Mann-Whitney U test for intergroup comparisons and Freidman's test followed by Nemenyi post hoc test for intragroup comparison.To test the significant differences between two groups at different follow-up period Chi-square test was used for qualitative analysis. Statistical analysis was performed by a software program.

Results

1-Demographic data
Age

The mean age of the participants in **group I (*A. Sativum*)** was (5.63±0.35) years. The mean age of the participants was **Group II (*MTA*)**: (5.67±0.31) years. There was no significant difference between both groups (p=0.462).

Gender

In **Group I (*A. Sativum*):** Five (33.3%) of the participants in group (I) were males and 10(66.7%) were females but in **Group II *(MTA*)**: Eight (53.3%) of the cases were males and 7(46.7%) were females. There was no significant difference between both groups (p=785).

Lower primary molars

Thirty molars included in the clinical trial and were randomly and equally allocated to one of the studied groups (n= 15). In **Group I (*A. Sativum*):** Six (40%) of the treated teeth were first primary molars while 9 (60%) were second primary molars. In **Group II *(MTA*)**: Seven (46.7%) of the treated teeth were first primary molars and 8(53.3%) were second primary molars. There was no significant difference between both groups (p=0.713).

Success rate of both groups

A. Clinical success rate:

Frequency and percentage values of clinical success rate for different groups were presented in Figure 3 (A). At 3 and 6 months all molars in both groups showed 100% clinical success rate. At 9 months, clinical success rate in group (I) and group (II) was 93.3% and 100 % respectively and there was no significant difference between both groups (p=1). At 12 months, clinical success rate in group (I) and group (II) was 93.3% and 100 % respectively and there was no significant difference between both groups (p=1).

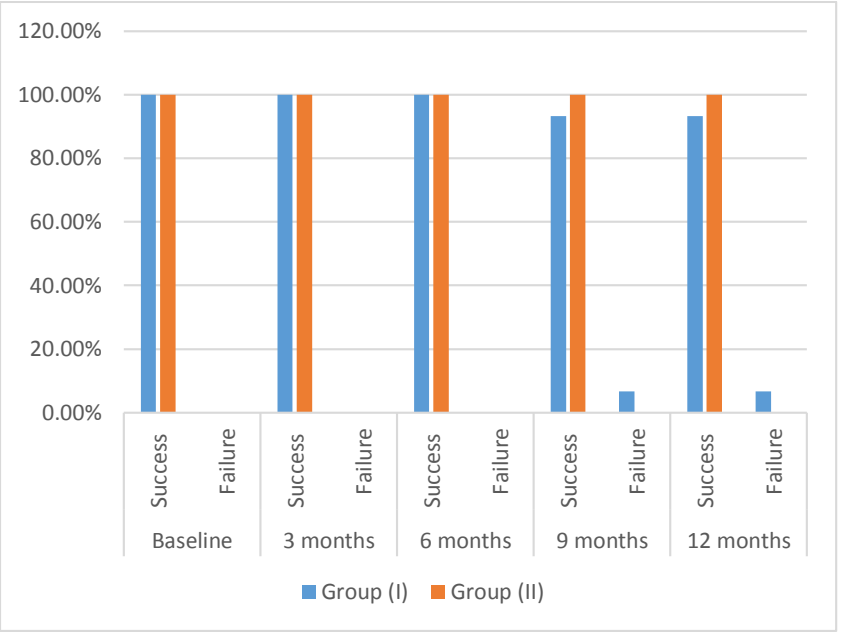

Figure 3 (A): Bar chart showing clinical success rate at different follow-up intervals among both groups

B. Radiographic success rate:

Frequency and percentage values of radiographic success rate for different groups were presented in Figure 3 (B). At 3 months, radiographic success rate in group (I) and group (II) was 93.3% and 100% respectively and there was no significant difference between both groups (p=1).At 6 months, radiographic success rate in group (I) and group (II) was 80% and 100% respectively and there was no significant difference between both groups (p=0.224). At 9 months, radiographic success rate in group (I) and group (II) was 46.7% and 100% respectively and there was a significant difference between both groups (p=0.002). At 12 months, radiographic success rate in group (I) and group (II) was 40% and 100% respectively and there was a significant difference between both groups (p=0.001). Figure 3 (C, D, E) showed radiographic success rate of different cases in both groups.

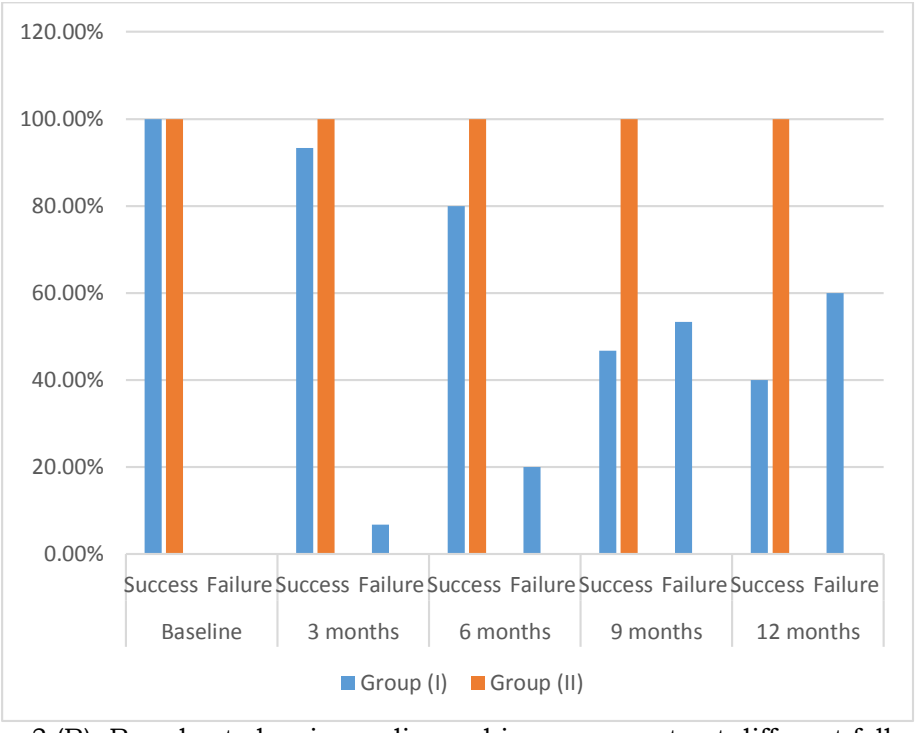

Figure 3 (B): Bar chart showing radiographic success rate at different follow-up intervals between both groups

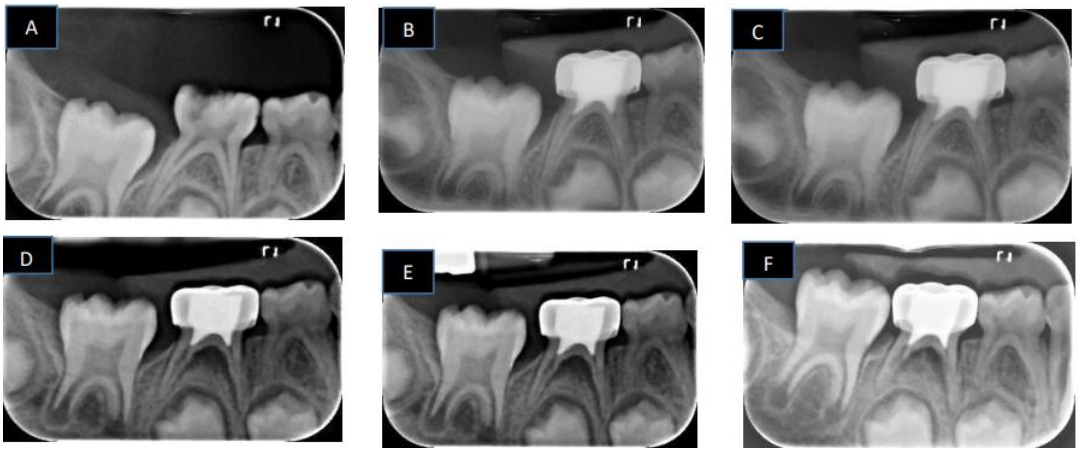

Figure 3 (C): Periapical radiographs of Group I (case1): A-Preoperative radiograph showing carious lower right primary molar. **B-**Post-operative baseline radiograph after placement of stainless steel crown. **C-**Radiograph showing 1th follow-up after 3 months. **D-** Radiograph showing furcation involvement in 2nd follow-up after 6 months. **E-** Radiograph of 3rd follow-up after 9 months showing furcation involvement and external root resorption in second primary molar. **F-** Radiograph of 4th follow-up after 12 months showing Furcation involvement and external root resorption in second primary molar.

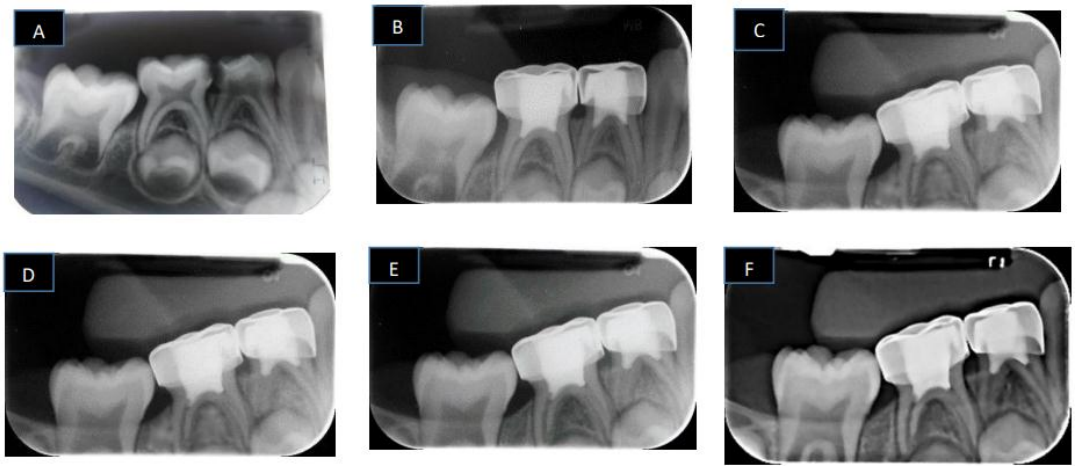

Figure 3 (D): Periapical radiographs of Group I (case2): A-Preoperative radiograph showing carious lower right primary second molar. **B-**Post-operative baseline radiograph after placement of stainless steel crown. **C-**Radiograph showing 1th follow-up after 3 months. **D-** Radiograph in 2nd follow-up after 6 months. **E-** Radiograph of 3rd follow-up after 9 months. .**F-** Radiograph of 4th follow-up after 12 months.

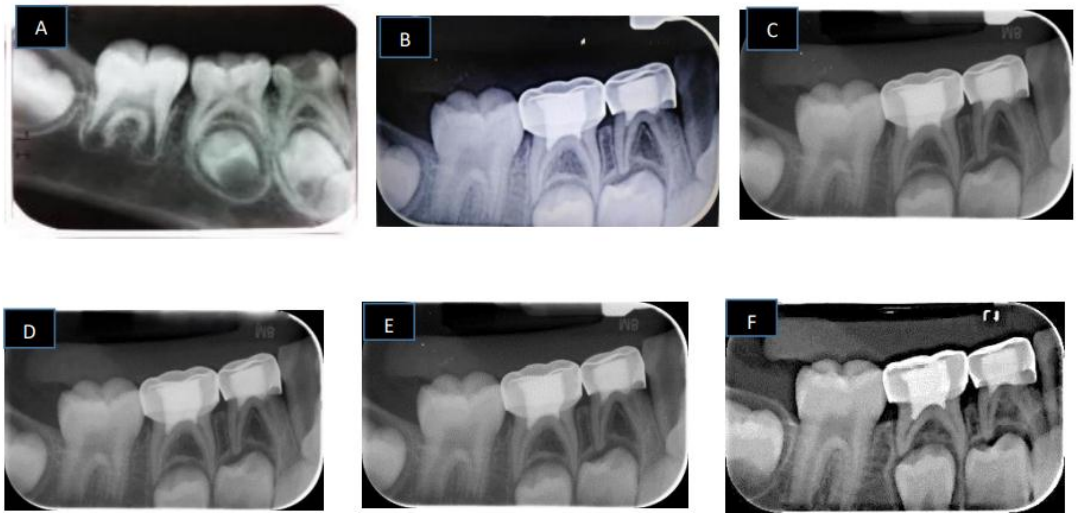

Figure 3 (E):): Periapical radiographs of Group II (case1): A-Preoperative radiograph showing carious lower right primary molars. **B-**Post-operative baseline radiograph after placement of stainless steel crowns. **C-**Radiograph showing 1th follow-up after 3 months. **D-** Radiograph of 2nd follow-up after 6 months. **E-** Radiograph of 3rd follow-up after 9 months. .**F-** Radiograph of 4th follow-up after 12 months.

Overall success rate:

Frequency and percentage values of overall outcome for different groups were presented in Figure 3 (F). At 3 months, overall success rate in group (I) and group (II) was 93.3% and 100% respectively and there was no significant difference between both groups (p=1). At 6 months, overall success rate in group (I) and group (II) was 80% and 100% and there was no significant difference between both groups (p=0.224). At 9 months, overall success rate in group (I) and group (II) was 46.7 % and 100% respectively and there was a significant difference between both groups (p=0.002). At 12 months, overall success rate in group (I) and in group (II) was 40% and 100% respectively and there was a significant difference between both groups (p=0.001). \

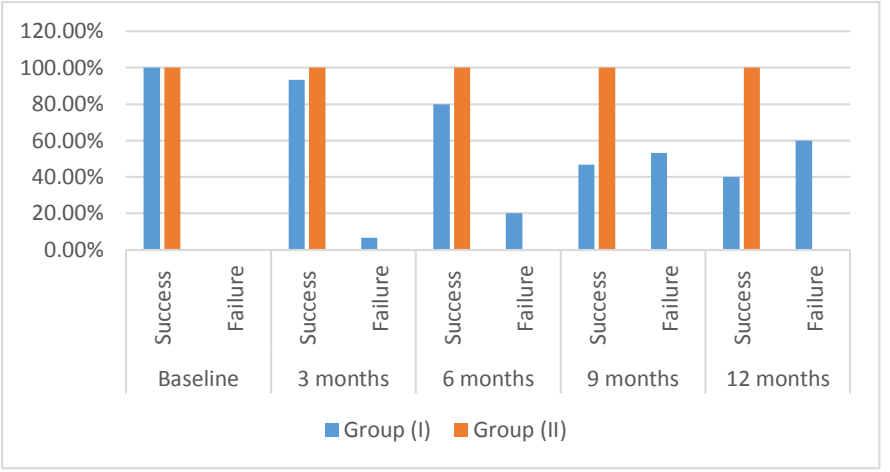

Figure 3 (F): Bar chart showing overall outcome at different follow-up intervals among both groups

Discussion

Pulpotomy is a widely used clinical procedure for the treatment of deciduous teeth with deep caries approximating pulp (23).*Mineral trioxide Aggregate* was selected as control group as it is the gold standard material used in primary molars pulpotomy. Previous studies showed that *MTA* has a higher clinical and radiographic success rate as vital pulpotomy material and is more biocompatible to vital pulp saving its vitality till shedding time of the teeth. Despite its clinical and radiographic success over years and proven favorable histological response, *MTA* does not gain much clinicians acceptance regarding manipulation difficulties, poor complicated handling characteristics and slow setting where it takes about 24 hours to reach the final setting; rendering the technique sensitive procedure, expensive and even more difficult and restricted its use to specialists (4, 24).

In recent decades, the use of natural products has grown significantly in dentistry. *Garlic*, with the scientific name *A. Sativum*, has been used extensively in medical fields. *Garlic* has antimicrobial, anti-inflammatory, antioxidant effects and regulates the immune system and can contribute to wound healing. This characteristic is due to its main components called *Allicin* as well as *thiosulfonates*. *Garlic* is also effective in a wide range of gram-positive and gram-negative bacteria. The use of *Garlic* in dentistry involves the use of *Garlic* solution as a pulpotomy medicament, root canal detergent and mouthwash (14, 25, 26). Mohamed et al S G., 2014 was used *Garlic oil* in the pulpotomy of the primary teeth and its clinical and radiographic success rate was reported as 90%. Mohamed S G et al., 2015 found that the histological success rate of garlic oil in pulpotomy was higher than that of *FC* (27).

Children in the present study was in the age range from 4 to 7 years with decayed mandibular primary molars requiring pulpotomy procedure. Patients were selected irrespective of their gender. The age range was carefully chosen taking into consideration the lack of cooperation of younger children and physiologic root

resorption in elder ones (12, 14, 23). Mandibular molars were chosen in the study as they are accessible and easier in pulpotomy technique and more accurate radiographic interpretation than maxillary ones due to less superimposition on mandibular radiographs than maxillary teeth as the radiographic interpretation of maxillary molars as denoted by Ahmed HM & Abbott PV, 2012 (28). The patients were healthy with no physical or mental disorder that could alter the treatment procedure and without systemic diseases that could influence the dental pulp reaction to the capping material. The selected teeth were met the following criteria; restorable lower primary molars with deep caries, without a history of spontaneous, persistent pain or sensitivity to palpation/percussion and/or other clinical signs of inflammation (abscess, sinus tract, and abnormal mobility). Radiographically, the absence of signs of periapical or furcation pathology and/or of pathological resorption to ensure proper dental pulp reaction to pulpotomy materials (29).

An alginate impression was taken, then an acrylic radiographic stent or block was fabricated on the cast for each patient which was placed around the Extension cone paralleling *(XCP)* plastic tip to standardize the radiographic technique, paralleling technique on the same radiographic unit with the same exposure parameters using individual bite blocks of acrylic resin attached to the individual XCP. Thus, consistent comparison of the standardized radiographs would be possible this was in agreement with Sharma et al., 2014 (30). However, the acrylic radiographic stent was unpleasant for most of the children in this study. In the present study, randomization was done with Computer generated simple randomization by a co-supervisor with the help of computer software (Random.com). Randomly assigned each tooth into Group (I) or Group (II) using simple randomization. Simple randomization was selected because it is easy to use, accurate representation of the larger population and produce comparable treatment group (31). Blinding of outcome assessors and statisticians reduced detection bias as it eliminates discrepancies. Also blinding of the operator was not possible as both materials used in this trial had different physical properties (32, 33).

Pulpotomies were performed by the same operator to avoid individual variation between different operators. (34). The inferior alveolar nerve block was the technique used for administration of local anesthetic agent with all patients to enable the operator to treat multiple teeth in the same quadrant at one appointment as most of the patients has 1 or 2 decayed adjacent teeth that needed to be treated (35, 36). Rubber dam isolation was done to ensure a good field isolation and minimize bacterial contamination at the treatment site that would lead to failure of the pulpotomy procedure. After caries removal, coronal pulp tissues have been removed using a sharp spoon excavator to avoid mechanical injury to the pulp which subsequently affects the success of pulpotomy. Initial pulp bleeding was arrested by the application of pressure over the root canal orifices with a saline cotton pellet for 5 minutes (37, 38). All teeth were finally restored with *SSC* that have been cemented by *GIC* to ensure bacterial seal to avoid failure of pulp therapy as *SSC* showed superior clinical performance and the most effective long term restoration in comparison to amalgam or composite restoration based on the assumption that there is less leakage in crowned teeth than those restored with amalgam (39).

An immediate postoperative photographs and radiograph were obtained to document the quality of treatment and to help determine the prognosis and serving as a comparative baseline for clinical evaluation in future follow-ups. (40). Success rate of pulpotomy was measured traditionally as the percentage of teeth reaching an arbitrary point in time with the absence of clinical or radiographic evidence of disease. Similarly, in the present study, the success rate of pulpotomy treatment was defined as the absence of clinical or radiographic pathology at follow-up appointments as reported by Durmus & Tanboga, 2014, Dean et al., 2015 and Fuks et al., 2019 (41, 42, 43).

In the present study, it was observed that clinical success in the Group (I) is higher than radiographic success. Clinical success was 100% at 3 and 6 months and 93.3% success rate at 9 and 12 months with no significant difference between different follow-up intervals. Regarding Group (II), both clinical and radiographic success were 100%.Clinical success rate in the Group (I) was 100% at 3 and 6 months was in agreement with randomized clinical trials conducted by Kahvand et al., 2019, Abirami, 2020 and Gomaa & Allam, 2020 (14, 26, 44). Clinical success rate at 9 and 12 months follow-up intervals was 93.3 % agreed with Mohammad SG et al., 2014, and Hashem et al., 2019 (12, 22) who reported 90%, and 95% clinical success rate of pulpotomy using *A. Sativum* at 1, 3 and 6 months respectively. Clinical success of Group (II), the result was in agreement with a randomized clinical trials conducted by Junqueira et al., 2018, Meslmani et al., 2019 and Zewail et al., 2019 who reported 100% clinical success of *MTA* pulpotomy in primary molars (45, 46, 47). However, Odabaş et al., 2012 (48) conducted a randomized clinical trial and reported 94.7% clinical success rates of *MTA* pulpotomy, Cuadros-Fernández et al., 2016 (49) reported 92% clinical success rate of *MTA*, Perea et al., 2017 (50) reported 89.9% clinical success rate and Swarnalatha et al., 2021 (51) reported 90%, 84.21% and 88.23% clinical success rate at 3, 6 and 9 months follow-up intervals.

Regarding the radiographic success of Group (II), the result was in contrast with randomized clinical trials conducted by Sunitha et al., 2016, Carti & Oznurhan, 2017 and Mythraiye et al., 2019 (52, 53, 54) who reported 94%, 96% and 80% radiographic success rates of *MTA* pulpotomy in primary molars respectively. In the current study, regarding overall success rate for Group (I) and Group (II) at 3, 6, 9 and 12 months were (93.3% and 100.%), (80.0% and 100.0%), (46.7% and 100.0%) and (40.0% and 100.0%) respectively. The overall success rate in the Group (I) agreed with Mohammad SG et al., 2014 and Mohammad & Baroudi, 2015 (12, 13) who reported a 90% and 95% success rate of *A. sativum oil.* Comparison with previous studies may be difficult due to the limited number of clinical trials that used *A. Sativum* as pulpotomy agent, variation in selection criteria regarding cases, methodology, preparation and concentration of *A. Sativum* and the follow-up period, which may affect the outcome.

The high overall success rate in the Group (I) at 3 and 6 months due to antibacterial, anti-inflamatory, analgesic, immune regulatory and antioxidant properties of *A. Sativum*. The gradual decrease in the overall success rate in the Group (I) at 9 and 12 months may be due to a decrease in anti-inflammatory and antibacterial and antioxidant properties of *A. Sativum* over time. This was in agreement with a randomized clinical trials conducted by Mohammad SG et al.,

2014, Kahvand et al., 2019 and Subramanyam & Somasundaram, 2020 (10, 12, 14). The overall success rate in the Group (II) was in agreement with randomized clinical trials conducted by Çelik et al., 2019 and Fouad & Abd El Gawad., 2019 (23, 55). However the result was in contrast with Neamatollahi & Tajik, 2006, Jamali et al., 2018, Swarnalatha et al., 2020 and Vilella-Pastor et al., 2021 (56, 57, 58 , 59) who reported (69.2%), (90%), (80%) and (97.2%) overall success respectively. The high overall success of Group (II) may be attributed to *MTA* has a biocompatible, high alkalinity, antibacterial, less cytotoxic, non-mutagenic, stimulation of healing in the pulpal tissue, excellent sealing ability and induction of hard tissue formation as reported by Fouad & Abd El Gawad, 2019 and Swarnalatha et al., 2021 (23, 58).

The limitations of this study:

- Compostion of *Garlic oil* used in the present study did not subject to such *Gas chromatography–mass spectrometry (GC-MS) analysis. Gas chromatography–mass spectrometry* is an analytical method that combines the features of gas-chromatography and mass spectrometry to identify different substances within a test sample.
- Digital radiography resolution is less than conventional radiography, requires equipment like computers and specific receptors that may not always be available and annoying to younger patients.
- The most significant limitation is a small sample size as too small sample size reduces the power of the study and increases the margin of error, which can render the study meaningless.

Conclusions

Based on this study results the following are concluded: *Mineral trioxide aggregate* continues to be the material of choice as pulpotomy agents in primary molars. *Allium Sativum* oil dressed in *ZnO* could be a successful alternative to *MTA* when used as pulpotomy agents in primary molars. *Allium Sativum* oil dressed in *ZnO* showed better clinical success rate than radiographic one. Radiographic failure in *A. Sativum* oil group was presented as periapical radiolucency, furcation involvement, internal and external root resorption.

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