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INDIRECT PULP CAPPING VERSUS PULPOTOMY WITH MTA FOR TREATMENT OF PRIMARY MOLARS WITH DEEP CARIES: AN EQUIVALENT PARALLEL RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Aim: to compare the clinical and radiographic outcomes of pulpotomy versus indirect pulp capping (IPC) using mineral trioxide aggregate (MTA) to treat deeply carious primary molars without signs or symptoms of irreversible pulpitis.

Subjects and methods: A parallel-arm randomized controlled clinical trial (RCT), with a 1:1 allocation ratio, was conducted on 89 children with 100 deep-carious primary molars without signs or symptoms of irreversible pulpitis. They were between the ages of three and six. Teeth were assigned into two groups; group (I) received IPC treatment and group (II) received pulpotomy treatment, both of which used MTA. Treated teeth were finally restored with stainless steel crowns (SSCs). Follow-up was conducted for radiographic and clinical evaluation at three, six, and twelve months.

Results: Following a 12-months follow-up period, both groups' clinical success rates were 100%. Radiographically, IPC group revealed no failure throughout the duration of follow up, while in the pulpotomy group, one tooth out of fifty displayed external root resorption (ERR) and periapical radiolucency after a period of 12 months. The success rates for IPC and pulpotomy were 100% and 98%, respectively, with no statistically significant differences between the two groups (p=0.65).

Conclusion: IPC and pulpotomy with MTA can be used successfully for treatment of primary molars with deep carious lesions without signs or symptoms of irreversible pulpitis.

KEYWORDS: deciduous, VPT, IPC, pulpotomy and MTA

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INTRODUCTION

Dental caries is the most prevalent worldwide chronic disease in children**.** It is a major public health concern worldwide since it has a significant socioeconomic burden on families and society, especially when affecting very young children**.** Therefore, it is crucial to implement a suitable treatment plan, for carious primary teeth, that heavily relies on pulp diagnosis ***(Miller et al., 2012)***.

When clinical and radiographic examinations of deep carious primary molars reveal normal pulp or reversible pulpitis, vital pulp therapy (VPT) is recommended. VPT has the advantage of keeping the pulp healthy and functional till the exfoliation of the primary molars. There are various VPT treatment options for primary molars, including indirect pulp capping (IPC), direct pulp capping (DPC) and pulpotomy ***(AAPD 2023).***

IPC procedures particularly have attracted a lot of interest in pediatric dentistry, primarily because children need a fast and accurate treatment. It involves infected dental tissues removal, leaving the hard affected dentine. The dentine that is left is allowed to be remineralized by a biocompatible material that is applied in thin layer between the restorative material and the dentin–pulp complex ***(Kuhn et al,. 2014)***.

Pulpotomy is a procedure that aim to remove the inflamed infected coronal pulp tissue, and a material is applied on the remaining healthy radicular pulp to help maintain its vitality. When the coronal tissue is removed, the remaining radicular tissue must be assessed to be vital without suppuration, purulence, necrosis, or excessive hemorrhage that cannot be controlled by a cotton pellet after several minutes ***(AAPD 2023).***

Ideal requirements for VPT dressing material are biocompatibility, capability of hard tissue formation, have disinfectant properties and lack of cytotoxicity ***(Chen et al., 2021).*** MTA has the following advantages: an excellent biocompatibility, a high sealing capacity, an alkaline pH, and antimicrobial effects. Previous studies have demonstrated the potential of MTA to stimulate tissue regeneration during VPT ***(Guo et al., 2023), (Thomas et al., 2024).***

All previous studies compared IPC with pulpotomy but with materials other than MTA ***(Roberts et al., 2009), (Vidya et al., 2015), (Fang et al., 2019), (Chen et al., 2021).*** According to ***American academy of pediatric dentistry (AAPD) (2024)*** there is lack of studies directly comparing IPC and pulpotomy. Therefore the current RCT was conducted to compare IPC and pulpotomy techniqu e directly using MTA as a medicament.

SUBJECTS AND METHODS:

Ethical approval:

The Faculty of Dentistry at Minia University's Ethical Regulations Committee gave its approval to the study protocol (526/2021). Clinicaltrials.gov has the study registered (NCT05554952). Informed consent was signed by the parents /guardians of the patients prior to any clinical procedure**.**

Study design:

A randomized controlled clinical trial with two parallel arms and a 1:1 allocation ratio was performed. This study was conducted and reported following the CONSORT checklist 2010.

Sample size calculation:

$$N = \frac{\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^2 \times P_1(1-P_1) + P_2(1-P_2)}{d^2} \times 2$$

***N= (1.64+0.84)^2 × 0.95(1-0.95) + 0.81(1-0.81)) /0.14^2 ×2=* 45 per group**

N= number of participants per group

$Z_{\frac{\alpha}{2}}$= z value corresponding level of significance

Z_β =z value corresponding level of power

P 1= proportion of outcome from group 1

P 2= proportion of outcome from group 2

D= Difference between 2 groups outcomes

Additionally, an additional 10% of each group was included to adjust for potential bias resulting from drop-off.

Randomization, Allocation and blinding:

Eligible patients were randomly allocated using an online website (https://www.sealedenvelope.com/simplerandomiser/v1/lists) to create two balanced groups according to the technique used Group (I): indirect pulp capping (IPC) using MTA and Group (II): pulpotomy using MTA.

Allocation was carried out with a printed letter including the child's ID, the date, the time, and the technique to be employed. To hide the print, the letter was wrapped in aluminum foil and securely placed within an opaque envelope with a serial number on the outside. At the time of treatment (prior to the removal of caries), an independent nurse opened the envelope. The statistician and the patients and their guardians were blinded of the technique applied.

Inclusion Criteria *(Roberts et al., 2009), (Chen et al., 2021)*:

1. Apparently healthy children (ASA I, II classification).
2. Cooperative children (Classified as a 3 or 4 on the Frankle Behavior Rating Scale.).
3. Children aged 3 to 6 years.
4. Children with primary molars with deep caries without signs or symptoms of irreversible pulpitis.

Exclusion criteria *(Coll et al., 2017)*:

1. Primary molars that could not be restorable.
2. Gingival swelling, sinus tract or fistulous tract exist.
3. Presence of mobility.
4. Primary molars tender to percussion.
5. Presence of spontaneous Pain.
6. Preoperative radiographs demonstrating periapical radiolucency, furcal radiolucency, internal root resorption (IRR), ERR, or a widened periodontal ligament space.

The study flow is showed in figure (1):

Clinical steps:

A comprehensive clinical examination was conducted after a thorough medical and dental history was documented. Preoperative radiographs were taken after the clinical evaluation. The entire clinical procedure was carried out by a single operator. Four percent articaine and a 1:100,000 dose of epinephrine were used to anesthetize the teeth. Low volume suction and a rubber dam were then employed for isolation.

In group I: IPC with MTA

The gross caries were removed as part of the clinical process, with high speed contra-angle handpiece with a large round bur or with spoon excavator. However, in order to prevent pulp exposure, enough decay must be left over the pulp horn. Because carious enamel and dentin at the cavity's edges might hinder the formation of a sufficient seal during the repair process, the cavity's walls were expanded to sound tooth structure. MTA material was used to cover the thin layer of caries that remained at the cavity's base. The teeth were prepared for full-coverage restoration and a SSC was cemented using glass ionomer cement (GIC).

In group II: pulpotomy with MTA

Throughout the treatment, a surgically clean method was employed. The overhanging enamel and any remaining tooth decay were eliminated. Bur No. 330, which was mounted to a water-cooled high-speed contra-angle handpiece, was used to

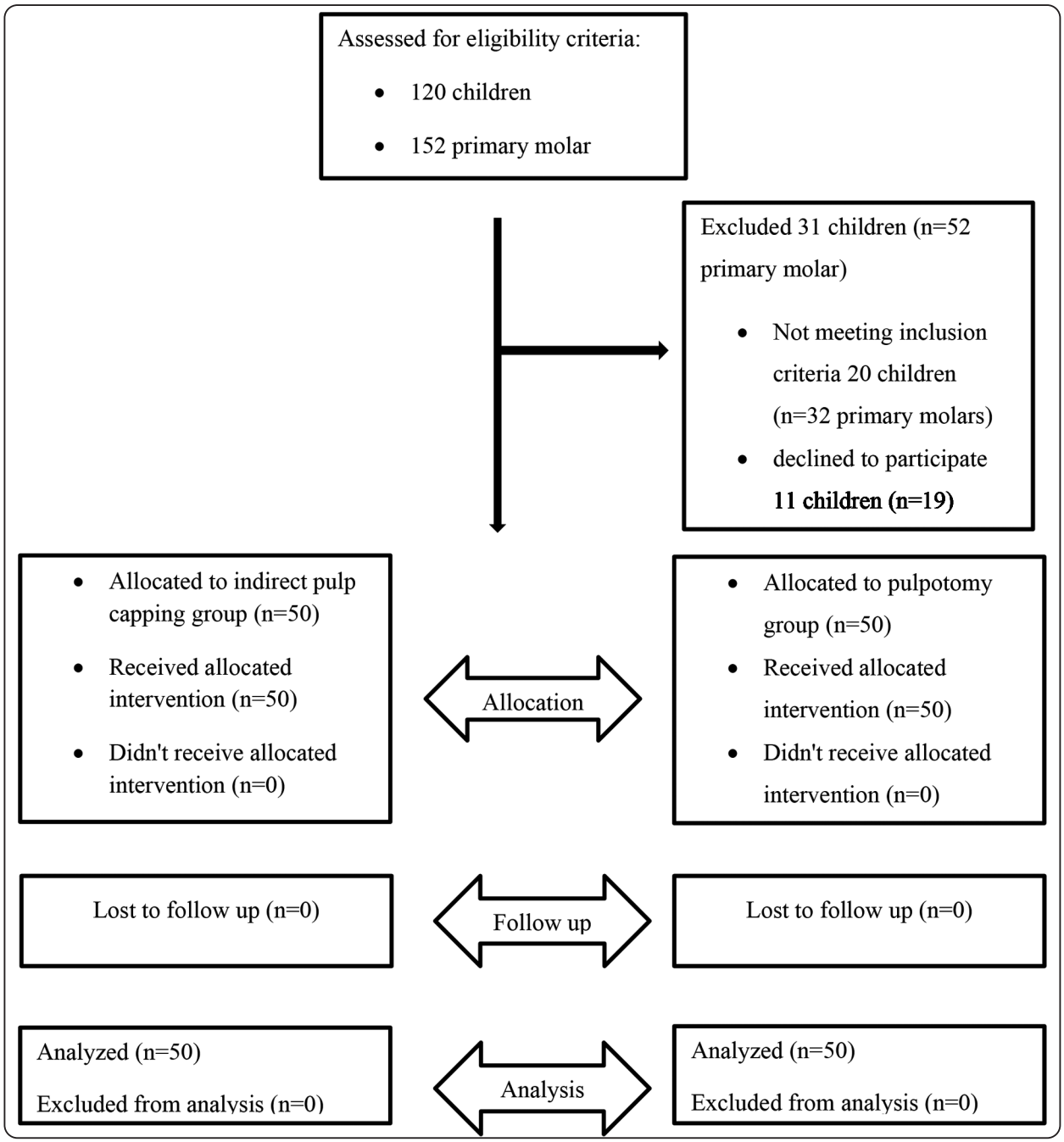

Fig. (1) Consort Flowchart of the trial design.

remove the pulp chamber's complete roof. The coronal pulp was amputated at the entry into each root canal using a sharp spoon excavator that was large enough to reach across the entrance. Until the coronal pulp was removed, no effort was made to stop the bleeding. Water-moistened cotton pellets were put in the pulp chamber and left on top of the pulp stumps until a clot formed. MTA was placed over the pulp tissue. The teeth were prepared for full-coverage restoration and a SSC was cemented using GIC.

Outcome assessment

At 3, 6, and 12 months, two calibrated pediatric dentistry specialists conducted clinical and radiographic outcome assessments. They recorded the results separately at the same appointment. Inter-observer reliability using the Kappa coefficient (x) was high at each examination time (x≥ 0.85). Whether a missed appointment was successful or not, it was counted toward the following appointment score. Clinical failures were identified based on the following criteria: pain, tenderness to percussion, draining fistula, abscess, or pathological tooth mobility. Digital periapical radiographs using parallel technique were taken at 3, 6 and 12 months to detect any periapical radiolucency, the interradicular radiolucency, widened periodontal ligament space, resorption of the roots either internally or externally.

Statistical analysis

Statistical analysis was done using IBM SPSS, Version 20 Inc., Chicago, Ill., USA). The binary outcomes of clinical and radiographic criteria (present or absent) were tested using Fisher -exact test. The alpha level of significance was adjusted at 5%.

Age Distribution: Tested for normality using the Shapiro-Wilk test.The study included 89 patient (58 boys (65.2%) and 31 girls (34.8%), with 100 primary molars that were randomly distributed into two groups with 1:1 allocation ratio group (I): IPC and group (II) pulpotomy both using same material MTA. The mean age was 5.0 ± 0.96 years for the IPC group and 4.75 ± 1.03 years for the Pulpotomy group. Age distributions in both groups were non-normal (Shapiro-Wilk test: $W = 0.87$, $p < 0.001$ for IPC; $W = 0.90$, $p < 0.001$ for Pulpotomy). The difference in mean age between groups was not statistically significant ($t = 1.26$, $p = 0.21$; 95% CI: -0.15 to 0.65). The interquartile range (IQR) was 2.0 years for IPC and 1.88 years for Pulpotomy. Both groups were well-matched in terms of age, with no evidence of age acting as a confounding factor for treatment outcomes.

Effect Size Measure Analysis

The effect size measures were calculated to assess the association between treatment type and outcomes. The Odds Ratio was 100, indicating a strong association favoring the IPC group. The Relative Risk was 1.02, suggesting a slightly higher likelihood of success in the IPC group compared to the Pulpotomy group. Phi Coefficient and Cramer's V were both 0, reflecting no significant association, likely due to the small sample size and low event rates. Cohen's h was 0.28, indicating a small to medium effect size in terms of proportions. Overall, these results highlight a strong association with IPC as indicated by the Odds Ratio, while other measures suggest comparable effectiveness between the treatments.

RESULTS

Our study's findings showed that both IPC and pulpotomy with MTA had good clinical and radiographic success rates. After a 12-month follow-up period, the clinical success rate for both methods was 100%, while the radiographic success rates for IPC and pulpotomy were 100% and 98%, respectively. In pulpotomy group one tooth out of fifty displayed external root resorption (ERR) and periapical radiolucency after a period of 12 months. This case was managed by extraction and placing band and loop space maintainer by same

operator (figure: 2). There was no statistically significant difference between the two techniques (p-value >0.05).

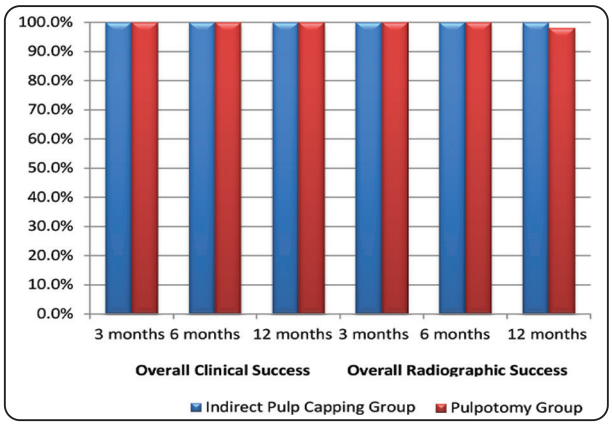

Fig. (2) Overall Clinical and Radiographic Success Rate of IPC and Pulpotomy at 3, 6 and 12 months

DISCUSSION

Approximately 50% of children still require treatment for at least one primary tooth, even with the deployment of preventive treatments for dental caries. Patients' quality of life in relation to their oral health is negatively impacted by the presence of caries lesions, particularly the more severe ones ***(Tedesco et al., 2020).***

IPC treats the dentin-pulp complex conservatively ***(Marchi et al., 2008).*** According to ***Duque et al. (2009)***, the IPC for primary teeth produced satisfactory results when given in conjunction with a thorough dental history, manageable caries activity, and with appropriate capping materials.

Pulpotomy has been regarded as the most common treatment modality for carious- pulp exposed and symptom free primary molars.. It offers major benefits for preserving the affected tooth at the normal exfoliation stage, reducing pain and inflammation, and maintaining the radicular pulp's vitality ***(Guo et al., 2023).***

IPC or pulpotomy using calcium silicate cements as VPT techniques, are more successful than DPC and pulpotomy using other materials for treatment of primary molars with deep caries. Several studies addressed the success rate of IPC and pulpotomy showing high success rate of both techniques with overall success rate 94.4%, 82.6% for IPC and pulpotomy respectively. The success of IPC technique was unaffected by using different materials while MTA and formocresol had the best success rates when utilized as materials for pulpotomy in comparison to other materials ***(Coll et al., 2024).***

In the current RCT, two treatment modalities were tested: IPC group and pulpotomy group using the same material; MTA. For both groups, MTA was selected since it's a biocompatible material that has a dentinogenic potential and excellent sealing ability. It promotes tissue regeneration during VPT. It's also applicable as a pulp capping agent ***(Guo et al., 2023, Thomas et al., 2024).***

The current study was designed as parallel RCT since RCTs represent the optimal most reliable study design to determine the effectiveness of healthcare intervention. It sits atop the research design hierarchy with highest grade of evidence at the level of primary studies. It has long been considered the gold standard for conducting evidence-based clinical research because they minimize bias in addition to that experimental and control groups support cause and effect relationship ***(Sharma et al., 2020).***

Participants were randomly selected and randomly divided into both groups this random allocation reduced selection bias and allocation bias, balancing both known and unknown prognostic factors, in the assignment of treatments ***(Moher et al., 2010).***

Eligible patients were children that were healthy and cooperative, aged from 3 to 6 years old with one or more primary molar with deep carious lesion that didn't show any clinical nor radiographic signs or symptoms of irreversibly diseased pulp. Similar eligibility criteria were followed by ***Roberts et al., (2009)*** and ***chen et al., (2021)***.

Both techniques were performed by standard protocol after administering local anesthesia and placement of rubber dam. As isolation is necessary to minimize bacterial contamination and to protect soft and hard tissues. Use of rubber dam isolation is considered a gold standard for pulp treatment. It provides a throat partition and protects the oral tissues from exposure to medicaments or injury with the bur or instruments ***(AAPD 2023).***

The entire clinical procedure was carried out by a single operator ***(Thomas et al., 2024).*** Follow up extended over a period of 12 months by two skilled operators, on IPC group a total of 50 primary molars were followed up and none of them exhibited neither clinical nor radiographic failure criteria at 3 , 6 and 12 month follow up, with 100% success rate. This result was similar to ***Menon et al., (2016) Chauhan et al., (2018) Thomas et al., (2024)*** after a period of 6 month. While success rate on ***Petrou's et al., (2014)*** prospective study that compared MTA, portland cement and calcium hydroxide with two-step IPC was 94% for MTA group at 6 month follow up. This lower success rate could be attributed to the delay of final restoration placement that was placed after 6 months. ***Petrou et al., (2014)*** concluded at the end of his study that IPC as a one-step treatment of deep carious lesions may promote higher results than two-step technique.

In addition ***George et al., (2015)*** conducted clinical trial over a period of 6 months that compared MTA as a material for IPC with calcium hydroxide and followed up cases for 6 months, in MTA group one tooth out of 16 failed after 6 month due to development of sinus discharge. Unlike the current study, GIC was used as a final restoration not SSC ***(Van der zee et al., 2010).*** It's noteworthy that an accurate assessment of the pulp's health, a caries-free dentino-enamel junction, proper isolation technique and a restoration with good sealing ability as SSC are fundamental requirements for treating teeth with deep caries lesions with IPC and maintaining the pulp's vitality ***(Coll. 2023).***

AAPD (2024) stated that different liners do not affect IPC success. As the application of cavity lining was predicated on its capacity to decrease the quantity of live bacteria that remained, restore demineralized hard tissues, trigger reactive dentin, and preserve pulp integrity [19]. Although some studies showed superiority of calcium silicate cements over other materials as calcium hydroxide as it forms more dentinal bridging with superior quality ***(George et al., 2015, Menon et al., 2016, Santos et al., 2017).***

For pulpotomy group, procedures were executed according to standard protocol [21]. In the current investigation, all 50 teeth that had MTA pulpotomy were successful at the 3- and 6-month follow-up periods. achieving complete clinical and radiological success. A single patient at the 12-month follow-up period had radiographic failure, meaning that there was 100% clinical success and approximately 98% radiographic success. These findings were comparable to those of (***godhi et al., 2011***), (***vidya et al., 2015), (Bani et al., 2017)***, ***(chen et al., 2021).***

Bacterial contamination during treatment is thought to be less harmful to the result than bacterial leaking through the final restoration. This result emphasizes the necessity of an effective seal in the final restoration following pulp treatment ***(George et al., 2015). Kim et al., (2021)*** reported that a greater failure rate was noted when pulpotomized teeth were repaired using amalgam or resin modified glass ionomer (RMGI) as opposed to SSC. In order to guarantee a biological seal, which is essential for long-term effectiveness, SSCs are typically advised as a final restoration after pulp therapy ***(Coll et al., 2015).***

The results of this study show a comparable clinical outcome with IPC using MTA when compared with the MTA pulpotomy. As both techniques showed 100% clinical success rate after 12 month follow up. While for radiographic success IPC with MTA showed 100% success and in MTA

pulpotomy 1 out of 50 molars showed ERR and periapical radiolucency with 98% success rate at 12 month. The present study showed good clinical and radiographic outcome with both techniques. The difference in the rate of clinical and radiographic success in the two groups was not statistically significant [$p > 0.05$].

The results of this study show that a child diagnosed with reversible pulpitis can be successfully treated with either IPC or pulpotomy using MTA as a material. In such teeth, 100% of those treated with IPC were successful versus 98% with pulpotomy. Therefore, a dentist can prioritize IPC as a biological, more conservative with less chair time and cost-effective option for primary teeth with deep caries ***(Coll et al., 2024).***

Limitations:

Limitations of the current study included short duration of follow up and including specific age groups. Therefore, further studies are recommended with longer follow up periods and different age groups.

CONCLUSION

According to the results of the current study, IPC and pulpotomy with MTA can be successfully used for the treatment of primary molars with deep carious lesions without signs or symptoms of irreversible pulpitis.

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