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Postoperative pain following hall technique versus pulpotomy in primary molars with deep caries: A randomized clinical trial

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***Abstract*---**Objective: to assess and compare the possible post-operative pain between both Hall Technique and Formocresol Pulpotomy. Materials and Methods: Fifty-six primary molars with deep caries were divided into two groups: Study group: Hall technique was performed in which no caries removal was done, only soft food or debris was removed with the placement of SSC. Control group: FC pulpotomy was done. Postoperative pain was recorded for 10 days postoperatively. Results: There was no statistically significant difference between both groups regarding postoperative pain. Conclusion: HT is as effective as FC pulpotomy regarding the postoperative pain.

***Keywords*---**hall technique, formecresol pulpotomy, deep caries, postoperative pain.

Introduction

Preservation of the primary dentition for as long as possible is of great importance in the orofacial development of the child, as primary teeth maintain arch length and preserve masticatory function. Unfortunately, the occurrence of cavitated

carious lesions is still a problem in developed and developing countries, with an increasing prevalence, particularly in developing communities *(1).*

The management of caries primary molars in children is problematic. Primary teeth commonly remain unrestored, especially in younger children. The high levels of dental disease in primary teeth, and its inadequate management, remains a major public health issue for children, and one with a significant impact on their well-being. Set against this background, there was a scope for the investigation of alternative methods to the management of caries primary teeth. An alternative technique that is found to be simpler and more acceptable to children and their parents than the conventional restorative approach, yet just as effective *(2).*

Pulpotomy is the most common pulp treatment of primary molars. FC pulpotomy has enjoyed long-term clinical use and success and it was considered as the gold standard dressing agent for pulpotomy. It is a cheap material compared to other materials like MTA and biodentine. Besides, FC pulpotomy is the most commonly applied treatment approach of primary molars with deep caries in Paediatric Dentistry Department - Faculty of Dentistry - Cairo University *(3).*

Treatment of deep carious lesions can be challenging in a society where the deep carious lesion is predominating, especially in young children. Although, Formocresol Pulpotomy has long been the most indicated vital pulp procedure in primary molars with deep caries and the gold standard in deep lesions approximating the pulp, but it requires local anaesthesia, rubber dam application and rotary instrumentation (*4).*

The Hall Technique for restoring teeth with deep carious lesions is a newly developed technique that is based on an old concept; in which depriving cariogenic bacteria from sugar substrate leads to caries arrest. The carious lesion needs to be detected early enough before it progresses further leading to pulpal involvement, emphasizing the importance of early diagnosis using clinical examinations coupled with radiographs. This will enable the lesion to be sealed using a stainless-steel crown. The crown could be fitted with minimal inconvenience to the child patient in a child-friendly way. This will be done without the need for local anaethesia , rubber dam, or drilling caries out *(5).*

The Hall Technique embraces changing concepts of managing dental caries, moving from the concept requiring its complete surgical excision, even at the expense of cavity size and pulpal health, to better understanding that caries in dentine can be slowed, arrested, and possibly even reversed, within a meticulously sealed environment. Owing to its non-invasive design, acceptance by patients, and rate of restoration longevity, the Hall technique may be an improved treatment option to increase access to care, decrease rates of untreated caries and provide a restoration that will allow for natural tooth exfoliation *(6).* Thus, the present study aimed to determine the efficiency of Hall Technique versus Formecresol Pulpotomy Technique regarding postoperative pain.

Materials and Methods

Sample grouping

A total of Fifty-six (56) primary molars with deep caries were enrolled in this study from the Outpatient Clinic of Paediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University according to specific inclusion criteria *(4,7).*

Inclusion criteria were

Patients

- Age of patients: five - seven years old.
- Apparently healthy children.
- Cooperative children/ compliant guardians.

Teeth

- Primary molar with deep dentin caries involving occlusal and/ or occluso-proximal surfaces.
- Vital pulp with the absence of clinical signs and symptoms of irreversible pulpitis such as spontaneous pain. Only presence of pain provoked with stimulation, such as complaints of food impaction when eating was allowed.
- Absence of clinical swelling or pus exudate/fistula of soft or periodontal tissues.
- Absence of abnormal tooth mobility.
- Absence of pain on percussion.
- Restorable tooth.
- Preoperative radiograph: Normal radiographic findings.
-

Exclusion criteria were

Patients

- Unmotivated, uncooperative patients.

Informed consent and Assent

- Once the child was identified as eligible to the study by the clinical investigator, the trial procedures, benefits from the study, and expected harms were discussed with the parent or the child's legal guardian.

Randomization and Allocation Concealment

- Fifty-six primary molars with deep caries were selected and randomly divided into two equal groups with 28 teeth in each group as follows:

Group A: Teeth were treated with HT.

Group B: Teeth were treated with FC Pulpotomy and SSC.

Intervention

- Pre-operative Diagnostic chart and diagnosis of the cases was performed by the operator.
- History of pain was recorded; A thorough and detailed history of pain was taken to ensure the absence of spontaneous pain indicative for irreversible pulpitis status.
- Clinical & radiographic examination was performed to assess the clinical & radiographic inclusion criteria.
- For Group A (Experimental group) Hall Technique: Obvious food or debris was removed from the cavity but no caries removal. The child was positioned upright in the dental chair to reduce the chance of accidental swallowing or aspiration of a loose SSC. The correct size of SSC for the tooth was selected in terms of tooth number and size. After collecting the proper SSC, it was tried passively on the tooth to make sure that it fits with gentle pressure applied to the SSC over the contact points but not completely through. The SSC should cover all cusps and give the feeling of "spring-back" when placed up to, but not through, the contact points. The tooth was rinsed and dried. The inside of the SSC was dried using a cotton roll. The SSC was filled with resin modified glass ionomer luting cement. The operator then digitally pressed the crown through the contact points so that the crown flexibly "clicks" on the tooth and fits snugly. The child was then instructed to bite down firmly on a cotton roll, until the crown is pushed down over the tooth in its correct position. If the child was unable or unwilling to bite down on the SSC, firm finger pressure by the thumb and four fingers supporting the mandible to prevent slipping or displacement was used to seat the crown. Extruded cement was wiped off, and the child was asked to keep biting on the Hall SSC until the cement had been set. Once cement had been set, excess cement was removed, floss was used to clear the proximal contacts, and post-fitting instructions were given (7,8).
- For Group B (control group) Formecresol Pulpotomy: The treated teeth were anesthetized by applying topical anaesthesia followed by local anaesthesia. A properly sized clamp, rubber dam sheet, and frame were used to ensure proper isolation. For all treated teeth in this group, caries was removed first with a large sterile slow-speed round bur. If there was no exposure, the tooth was restored and excluded from the study. Access to the pulp chamber was obtained with a sterile high-speed 330 carbide diamond bur under water irrigation. The coronal pulp was amputated and extirpated completely with a sterile sharp spoon excavator until the orifice. After pulp amputation, haemostasis was achieved using a sterile saline wet cotton pledget with gentle pressure for three minutes. If the bleeding was not stopped after five minutes, pulpectomy was done and the tooth was excluded from the study. After haemostasis, a sterile cotton pellet which was lightly moistened with a 1:5 dilution of Buckley's FC was placed against the pulpal stumps for three-five minutes then removed. After removal of the cotton pledget, a reinforced zinc oxide eugenol base was applied to cover the pulp stumps. Tooth preparation was done to receive SSC. SSC was

immediately tried on the prepared tooth and marginal adaptation was achieved. RMGI luting cement was used for cementation (3,9).

- Postoperative Pain:
  A Form related to pain with Visual Analogue Scale was delivered to the parents and they were trained to fill the form 10 days after treatment.

In this questionnaire, the degree of pain after treatment was specified with some smiles from happy to sad. The degree of pain for patients was defined in this way: painless (point 0), mild pain (points 1-3), moderate pain (points 4-6), severe pain (points 7-9). The checklists were returned to the researcher after 10 days *(10)*.

Statistical analysis

All Data were collected, checked, revised, tabulated, and entered into the computer. Categorical and ordinal data were presented as frequency and percentage values. Categorical data were compared using fisher's exact test. Intergroup comparisons for ordinal data were done utilizing Mann-Whitney U test while intragroup comparisons were done using Friedman's test followed by Nemenyi post hoc test. The significance level was set at p≤0.05 within all tests. Statistical analysis was performed with R statistical analysis software version 4.1.2 for Windows*.

Results

Intergroup comparisons

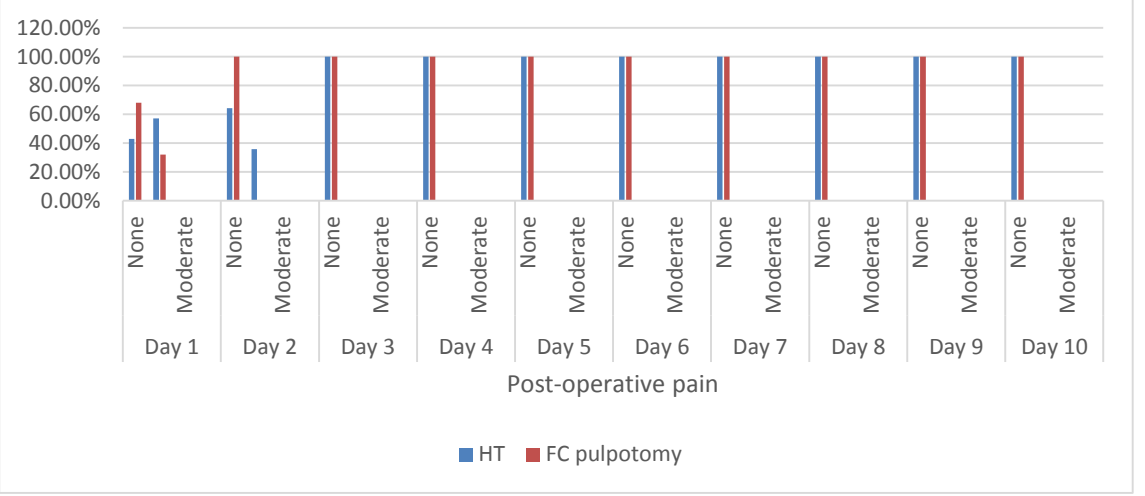
Frequency and percentage values for post-operative pain in different groups are presented in table (1) and figure (1). At day one, majority of cases in HT group had mild pain 16(57.1%), while most of the cases in FC pulpotomy group did not feel pain 19(67.9%) and the difference between both groups was not statistically significant (p=0.062). There was a statistically significant difference between both groups at day two (p=0.001), with the majority of cases in HT group 18(64.3%) and all the cases in FC pulpotomy group did not feel pain. Starting from day three until day ten, all the cases in both groups did not feel pain.

Table (1): Frequency and percentage values for post-operative pain in both groups

Time	VAS		Groups		p-value
			HT	FC pulpotomy	
Day 1	None	n	12	19	0.062ns
		%	42.9%	67.9%	
	Mild	n	16	9	
		%	57.1%	32.1%	
	Moderate	n	0	0	
		%	0.0%	0.0%	
	Severe	n	0	0	

*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/.

Time	VAS		Groups		p-value
			HT	FC pulpotomy	
		%	0.0%	0.0%	
Day 2	None	n	18	28	0.001*
		%	64.3%	100.0%	
	Mild	n	10	0	
		%	35.7%	0.0%	
	Moderate	n	0	0	
		%	0.0%	0.0%	
	Severe	n	0	0	
		%	0.0%	0.0%	
Day 3- Day 10	None	n	28	28	1ns
		%	100.0%	100.0%	
	Mild	n	0	0	
		%	0.0%	0.0%	
	Moderate	n	0	0	
		%	0.0%	0.0%	
	Severe	n	0	0	
		%	0.0%	0.0%	



Fig(1): Bar chart showing postoperative pain in both groups.

Intragroup comparisons

Frequency and percentage values for post-operative pain in different intervals were presented in table (2) and figure (2). For HT group, there was a statistically significant difference in post-operative scores measured at different follow-up intervals, with values measured at day one and day two being statistically significantly different from values of other intervals ($p<0.001$). For FC pulpotomy group, there was a statistically significant difference in post-operative scores measured at different follow-up intervals, with values measured at day one being statistically significantly different from values of other intervals ($p<0.001$).

Table (2): Frequency and percentage values for post-operative pain in different interval

Group	VAS		Time										p-value
			D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	
HT	None	n	12^{B}	18^{B}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	<0.001*
		%	42.9%	64.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	
	Mild	n	16	10	0	0	0	0	0	0	0	0	
		%	57.1%	35.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
	Moderate	n	0	0	0	0	0	0	0	0	0	0	
		%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
	Severe	n	0	0	0	0	0	0	0	0	0	0	
		%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
FC pulpotomy	None	n	19^{B}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	28^{A}	<0.001*
		%	67.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	
	Mild	n	9	0	0	0	0	0	0	0	0	0	
		%	32.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
	Moderate	n	0	0	0	0	0	0	0	0	0	0	
		%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
	Severe	n	0	0	0	0	0	0	0	0	0	0	
		%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	

Different superscript letters indicate a statistically significant difference within the same horizontal row*; significant ($p \leq 0.05$) ns; non-significant ($p>0.05$)

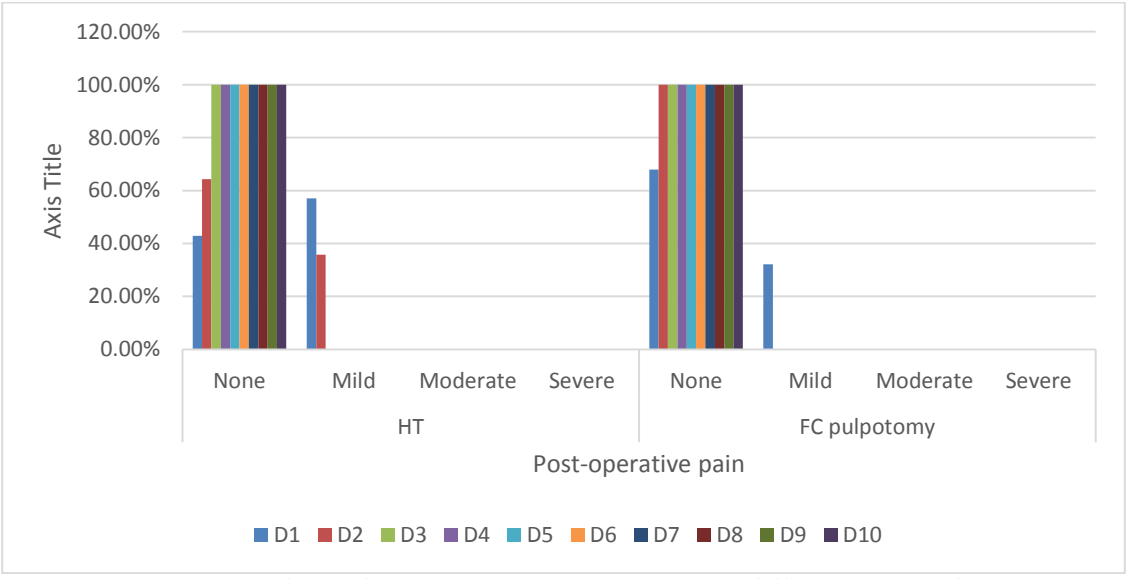


Fig (2): Bar chart showing postoperative pain in different interval

Discussion

The presence of deep carious lesions, leads to negative impact on the oral health-related quality of life of patients. Therefore, their management should be the focus of paediatric dentists *(11).* The search for the best approach for the management

of deep cavitated carious lesions resulted in many treatment modalities, which presents a challenge for paediatric dentists while searching for the best treatment option. Recommendation for further well-designed studies with decreased risk of bias, better allocation concealment, and blinding of examiners when possible was recommended to be performed to obtain reliable evidence to guide paediatric dentists in the decision-making process *(12)*. The need for LA, isolation, and drilling in FC pulpotomy makes it difficult to be applied for all children, especially the younger age group. The equipment and time needed, makes it difficult to be applied in hospitals where the flow of patients is high *(8)*.

The rationale for carrying out this study was based on the fact that sealing carious dentin beneath a SSC by HT deprives the microorganisms of nutrients, thus slowing or stopping the caries progression. In paediatric dentistry, this less invasive approach is gaining more popularity due to the difficult management of children *(4, 13)*. The HT has been shown to be successful worldwide and it has been found to be acceptable by dentists, patients and their caregivers *(14,15)*. The null hypothesis of this trial suggests that the HT is as effective as FC Pulpotomy regarding postoperative pain.

At day one, majority of cases in HT group had mild pain, while most of the cases in FC pulpotomy group did not feel pain and the difference between both groups was not statistically significant. There was a statistically significant difference between both groups at day two with the majority of cases in HT group and all the cases in FC pulpotomy group did not feel pain. Starting from day three until day ten, all the cases in both groups did not feel pain. Studying postoperative pain after FC pulpotomy versus HT was not mentioned in the literature before. Up to our knowledge, no RCT directly compared the post-operative pain in children after HT versus FC pulpotomy.

Conclusion

From the results of the present study, it was concluded that HT is as effective as FC pulpotomy regarding the postoperative pain.

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