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CLINICAL AND RADIOGRAPHICAL EVALUATION OF THE EFFECT OF USING THREE DIFFERENT DIRECT PULP CAPPING MATERIALS IN PRIMARY MOLARS

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ABSTRACT

Objectives: The objective of the current study is to evaluate the efficacy of MTA, Simvastatin and 3Mixtatin (a mixture of three antibiotics combined with simvastatin) as a novel pulp capping biomaterial in primary molars.

Patients and Methods: In this randomized controlled trial (RCT), a total of 45 children were recruited from the outpatient clinic of the Pediatric Dentistry and Dental Public Health Department – Faculty of Dentistry Ain-Shams University. Children having deep caries in first or second upper and lower primary molars with normal gingival and periodontal condition, were randomly allocated into three groups. Small non-caries pulpal exposures were treated by direct pulp capping (DPC) using either simvastatin, 3Mixtatin, or MTA. Capping materials were covered with highly viscous reinforced glass ionomer capsules. Clinical and radiographic evaluation were performed at 3, 6, 9 and 12 months after treatment.

Results: By the end of 12 months follow up period, the overall success rates were 92.3% in MTA, 92.3% in 3Mixtatin and 20.0% in simvastatin groups. There was no statistically significant difference between the outcomes of MTA and 3Mixtatin groups ($P > 0.05$). 3Mixtatin and MTA had statistically superior results compared to simvastatin ($P < 0.01$).

Conclusions: Based on radiographic and clinical outcomes, 3Mixtatin can be used successfully as DPC material in primary teeth.

KEYWORDS: Direct pulp capping, primary molars, 3Mixtatin, simvastatin, MTA

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INTRODUCTION

Preservation of pulp vitality in primary teeth is one of the highest concerns in pediatric dentistry. This is because the maintenance of deciduous teeth until their normal exfoliation is vital for healthy alveolar bone development, aesthetics, mastication, pronunciations and avoiding abnormal habits [1].

Direct pulp capping of deciduous teeth is one of the most controversial treatment options. The success rates of this treatment for primary teeth were considered low since undifferentiated mesenchymal cells can differentiate into odontoclasts and cause internal resorption. For this reason, direct pulp capping has largely been phased out of primary teeth vital pulp therapy treatment modalities. However, with the recent advances of dental biomaterials, there have been several reports of improved success rates [2, 3, 4].

The size of the pulp exposure is one of the most significant factors to consider. When the pulp is exposed by a 1mm or less pinpoint exposure during cavity preparation or after a traumatic injury, a biocompatible radiopaque base such as MTA or calcium hydroxide may be used to cover the exposed pulp tissue. A microleakage resistant material is then used to restore the tooth [5].

Simvastatin has shown an improvement in odontoblastic function resulting in enhanced dentine formation in addition to pulp regeneration. Furthermore, statins have shown to reduce the levels of circulating C-reactive protein (CRP) and pro-inflammatory cytokines, indicating that they have potent anti-inflammatory properties. As a result, statins were expected to act as an ideal component that stimulate reparative dentin formation in cases of DPC [6, 7].

3 Mixtatin is a material consisting of a mixture of simvastatin and Triple Antibiotic Paste (TAP). TAP is a combination of metronidazole, minocycline, and ciprofloxacin. 3Mixtatin has recently been used in primary teeth as a direct pulp capping dressing and root canal filling material because of its essential role in preserving developmental and function capabilities of primary teeth [8].

PATIENTS AND METHODS

Study design

This is a double-blinded controlled clinical trial, with a randomization between groups in a ratio of 1:1:1. The patients in the control group received MTA, while in the test groups, the patients received 3Mixtatin or Simvastatin as a dressing DPC material.

Ethical considerations

- The study protocol was approved by the ethical committee of faculty of dentistry, Ain-Shams University. Prior to enrolment, all patients were given oral information about the aim and procedures of the study and a written informed consent/ assent was obtained from the guardians and patients respectively.
- The approval number: FDASU-REC IM 111707.

Sample Size Estimation

Based upon the results of Aminabadi 2016, [9] using overall success as the primary outcome; the effect size (w) was found to be (0.515). The alpha (α) level was set to 0.05 (5%) and Beta (β) level was set to 0.20 (20%) i.e. power = 80%. [9] The minimum estimated sample size was a total of 36 patients. To compensate for a drop-out rate of 20%; 9 subjects were added giving a total of 45 patients. Sample size calculation was performed using IBM® SPSS® SamplePower® Release 3.0.1 [9].

Patients

Patients who participated in the study were selected from the Pediatric Dentistry and Dental Public Health Department outpatient clinic at the Faculty of Dentistry- Ain-Shams University. Forty five patients (with a total of n=45 teeth) displaying

asymptomatic primary molars with deep caries were recruited to the study sample according to the following selection criteria.

Inclusion criteria

1. Age range (3 – 6) years.
2. Complete physical and mental health without any confounding medical history.
3. No allergic reactions and special use of local or systematic drugs [9]
4. Deep carious in first or second upper and lower primary molars with normal gingival and periodontal condition.

Exclusion criteria

1. Patients who had difficulties in cooperation (graded as rate 1 according to The Frankl Behavior Rating Scale) [10].
2. Non restorable molars or molars with any sign of irreversible pulp damage, periapical affection, any grade of mobility, spontaneous pain or pain elicited on percussion, furcational abscess or fistula.
3. Radiographs showing signs of bone loss or root resorption [9].

The patients were randomly allocated using random sequence generation done by a randomizer program (Excel) that generated the random sequence into three groups. To ensure allocation concealment, sequence generation was done by an investigator other than the operator or the clinician who assessed the results.

Blinding

This study was a double-blinded study. Blinding was achieved according to the following methods: patient were blinded by not knowing the used materials at each stage throughout the trial. The operator was blinded to the allocation groups and to the treatment till the step of placing the different materials in the tooth.

Procedures

Eligible children having primary molars with deep caries lesion were randomly allocated in 3 groups:

- Group **A** (Simvastatin Group)
- Group **B** (3Mixtatin Group)
- Group **C** control (MTA Group)

Then the patients were recalled in 1, 3-, 6-, 9- and 12- months intervals for clinical and radiographical examination.

Teeth with pulp exposure size of less than 1 mm that were surrounded by sound dentin were considered for DPC and were the only teeth included in the study [11]. If the exposure site was greater than 1 mm in diameter or non-stop bleeding with a moistened cotton pellet within 2-3 min, the tooth was excluded from the study and subsequently was pulpotomized [11]. Widening of the exposure was done using a new different round bur (size 3) [9].

Simvastatin, 3Mixtatin and MTA were used in this trial. The Simvastatin powder was prepared by crushing a Simvastatin tablet (Zocor® 10 mg, film-coated) using a mortar and pestle at the operating clinic. 3 Mixtatin (TAP plus statin) was prepared by adding two milligrams of simvastatin to the triple antibiotic paste which is composed of Ciprofloxacin, Metronidazole and Cefixime blended in a ratio of 1:1:1. Preparation of (3Mixtatin) was trained and supervised in Biomaterial lab. 3Mixtatin was stored in a tightly capped container, adding a small amount of silica gel in a bag inside the container to maintain low humidity [9].

Each of the three materials was mixed with normal saline to form a creamy consistency. Application of the direct pulp capping material was done by its placement on the exposure site using a small amalgam carrier to reach a thickness of

1.5–2 mm and extending it 2 mm beyond the margins of the exposure. Afterwards, a dry cotton pellet was slightly pressed against the material for better adaptation on the exposure [12]. However, in the MTA group, a moist cotton pellet was used rather than a dry one for enhanced packing of the MTA mixture.

Cavity then was conditioned using the Cavity Conditioner (3M™ Ketac™ Conditioner Refill) for 10 seconds then rinsed with water spray for 30 seconds [13]. The cavity was then gently dried before the application of glass ionomer restoration without desiccation [14].

The capping material was subsequently covered with high viscous reinforced glass ionomer (GC Fuji IX GP® Extra) capsules. Then EQUIA™ Coat was applied to protect the glass ionomer surface. All procedures were performed in one session. Periapical radiographs were taken immediately after treatment.

The patients were recalled in 1, 3, 6, 9 and 12 months intervals. Over the 5 recall visits, the clinical evaluation was done. Clinical evaluation was done to ensure primary clinical outcome success through absence of pain, and secondary clinical outcomes which are swelling, mobility, fistula, gingival inflammation, tenderness to percussion and functional impairment. Radiographical evaluation was done at only 3, 9 and12 month intervals to evaluate the success of the technique via absence of internal resorption, external resorption, furcation involvement and fracture. The technique used was parallel technique for standardization.

The Success of a treated primary molars depends on the presence of all of the following criteria: No radiographic signs of internal or external resorption and no furcation radiolucency, absence of any signs and symptoms of discomfort or tenderness from the treated tooth and proper functioning of the tooth [9].

Clinical and radiographic failures occurring during the follow-up period were treated by pulpotomy/ pulpectomy or extraction, and space maintainers were applied as necessary.

RESULTS

Statistical analysis

Numerical data were presented as mean and standard deviation values and were compared using one-way ANOVA test. Categorical data were presented as frequency and percentage values and were compared using fisher's exact test for inter-group comparisons and Cochran's q test followed for intragroup comparisons. Survival analysis was done utilizing Kaplan-Meier and log rank tests. The significance level was set at $p \leq 0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.1.2 for Windows.

A total of 45 patients were included in the study. After 12 months follow up period, 41 patients were inspected, with a retention rate of 91.1%. Three drop-outs were from the control group (MTA), while one patient dropped out from one of the intervention groups (3Mixtatin), the study flow is presented in fig(1).

Data for each patient including; postoperative spontaneous pain and swelling, in addition to, radiographic evaluation of internal resorption, external resorption and furcation involvement, were collected and subjected to statistical analysis. This was proceeded by analysing the survival probability for each group for each time interval. Outcomes of the study were summarized and presented in tables and bar charts.

Demographic data:

Summary statistics of demographic data for children were presented in table (1)

- **Clinical evaluation**
- **Post-operative spontaneous pain**

Frequency and percentage values for post-operative spontaneous pain status in different groups were presented in table (2)

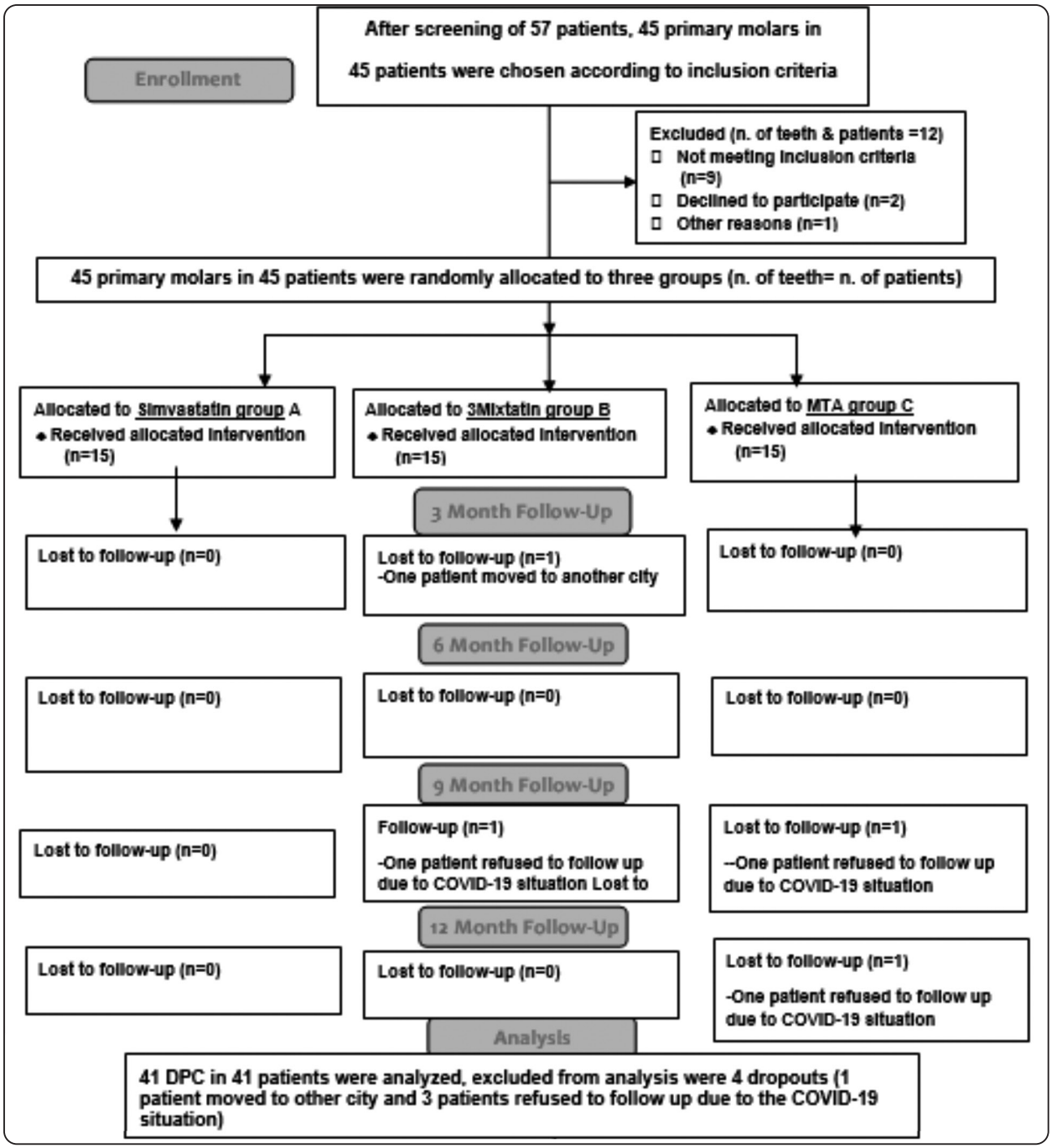

Fig. (1) Participants' flow diagram

TABLE (1) Summary statistics and results of intergroup comparisons for demographic data.

Parameter			Simvastatin	3Mixtatin	MTA	p-value
Sex	**Female**	**n**	11	9	9	**0.678ns**
		%	73.3%	60.0%	60.0%	
	Male	**n**	4	6	6	
		%	26.7%	40.0%	40.0%	
Age		**Mean ±SD**	5.31±0.70	5.20±0.77	5.37±0.72	**0.809ns**
Dental	**Upper**	**n**	5	3	3	**0.618ns**
arch		**%**	33.3%	20.0%	20.0%	
	Lower	**n**	10	12	12	
		%	66.7%	80.0%	80.0%	
Tooth	**First primary**	**n**	2	1	4	**0.306ns**
	molar	**%**	13.3%	6.7%	26.7%	
	Second primary	**n**	13	14	11	
	molar	**%**	86.7%	93.3%	73.3%	

; significant (p ≤ 0.05) ns; non-significant (p>0.05)

TABLE (2) Frequency and percentage values for post-operative spontaneous pain status in different groups

Time	Post-operative spontaneous pain		Groups			p-value
			Simvastatin	3Mixtatin	MTA	
Month	**Absent**	**n**	15	15	15	**NA**
		%	100.0%	100.0%	100.0%	
	Present	**n**	0	0	0	
		%	0.0%	0.0%	0.0%	
3 months	**Absent**	**n**	10B	14A	15A	**0.004***
Present		**%**	66.7%	100.0%	100.0%	
	Present	**n**	5	0	0	
		%	33.3%	0.0%	0.0%	
6 months	**Absent**	**n**	9	14	15	**0.226ns**
Present		**%**	90.0%	100.0%	100.0%	
	Present	**n**	1	0	0	
		%	10.0%	0.0%	0.0%	
9 months	**Absent**	**n**	5B	13A	14A	**0.001***
Present		**%**	55.6%	100.0%	100.0%	
	Present	**n**	4	0	0	
		%	44.4%	0.0%	0.0%	
12 months	**Absent**	**n**	3	12	12	**0.143ns**
		%	60.0%	92.3%	92.3%	
	Present	**n**	2	1	1	
		%	40.0%	7.7%	7.7%	
p-value			**0.092ns**	**0.406ns**	**0.406ns**	

Values with different superscript letters within the same horizontal row are significantly different *; significant (p ≤ 0.05) ns; non-significant (p>0.05), NA: Not Analyzed

- **Swelling:**

Frequency and percentage values for swelling status in different groups were presented in table (3). Photographs showing swelling after using Simvastatin as a DPC material at different follow up periods are represented in figure (2).

- **Radiographic evaluation**
- **Internal resorption:**

Frequency and percentage values for internal resorption status in different groups were presented in table (4). Radiographs showing normal radiographic appearance after using MTA as a DPC material at different follow up periods represented is figure (3).

- **External resorption:**

Frequency and percentage values for external resorption status in different groups were presented in table (5). Radiographs showing external root resorption after using Simvastatin as a DPC material at 3 months follow up represented in figure (4).

- **Furcation involvement**

Frequency and percentage values for furcation involvement status in different groups were presented in table (6).

- **Survival analysis**

Results of survival analysis results were presented in table (7) and figure (5) The mean survival time in Simvastatin group (9.47) was significantly lower than 3Mixtatin and MTA groups (12.0) ($p<0.001$).

TABLE (3) Frequency and percentage values for swelling status in different groups

Time	Swelling		Groups			p-value
			Simvastatin	3Mixtatin	MTA	
Months	**Absent**	**n**	15	15	15	**NA**
		%	100.0%	100.0%	100.0%	
	Present	**n**	0	0	0	
		%	0.0%	0.0%	0.0%	
3 months	**Absent**	**n**	10B	14A	15A	**0.004***
		%	66.7%	100.0%	100.0%	
	Present	**n**	5	0	0	
		%	33.3%	0.0%	0.0%	
6 months	**Absent**	**n**	9	14	15	**0.266ns**
		%	90.0%	100.0%	100.0%	
	Present	**n**	1	0	0	
		%	10.0%	0.0%	0.0%	
9 months	**Absent**	**n**	5B	13A	14A	**0.001***
Present		**%**	55.6%	100.0%	100.0%	
	Present	**n**	4	0	0	
		%	44.4%	0.0%	0.0%	
12 months	**Absent**	**n**	4	12	13	**0.294ns**
Present		**%**	80.0%	92.3%	100.0%	
	Present	**n**	1	1	0	
		%	20.0%	7.7%	0.0%	
p-value			**0.406ns**	**0.406ns**	**NA**	

Values with different superscript letters within the same horizontal row are significantly different *; significant ($p \leq 0.05$) ns; non-significant ($p>0.05$), NA: Not Analyzed

TABLE (4) Frequency and percentage values for internal resorption status in different groups

Time	Internal resorption		Groups			p-value
			Simvastatin	3Mixtatin	MTA	
3 months	**Absent**	**n**	15	14	15	**NA**
		%	100.0%	100.0%	100.0%	
	Present	**n**	0	0	0	
		%	0.0%	0.0%	0.0%	
9 months	**Absent**	**n**	9	13	14	**NA**
		%	100.0%	100.0%	100.0%	
	Present	**n**	0	0	0	
		%	0.0%	0.0%	0.0%	
12 months	**Absent**	**n**	5	13	13	**NA**
		%	100.0%	100.0%	100.0%	
	Present	**n**	0	0	0	
		%	0.0%	0.0%	0.0%	
p-value			**NA**	**NA**	**NA**	

Values with different superscript letters within the same horizontal row are significantly different *; significant (p ≤ 0.05) ns; non-significant (p>0.05), NA: Not Analyzed

TABLE (5) Frequency and percentage values for external resorption status in different groups

Time	External resorption		Groups			p-value
			Simvastatin	3Mixtatin	MTA	
3 months	**Absent**	**n**	15	14	15	**NA**
		%	100.0%	100.0%	100.0%	
	Present	**n**	0	0	0	
		%	0.0%	0.0%	0.0%	
9 months	**Absent**	**n**	7B	13A	14A	**0.042***
		%	77.8%	100.0%	100.0%	
	Present	**n**	2	0	0	
		%	22.2%	0.0%	0.0%	
12 months	**Absent**	**n**	4	13	12	**0.294ns**
		%	80.0%	100.0%	92.3%	
	Present	**n**	1	0	1	
		%	20.0%	0.0%	7.7%	
p-value			**0.368ns**	**NA**	**0.368ns**	

Values with different superscript letters within the same horizontal row are significantly different *; significant (p ≤ 0.05) ns; non-significant (p>0.05), NA: Not Analyzed.

TABLE (6) Frequency and percentage values for furcation involvement status in different groups

Time	Furcation involvement		Groups			p-value
			Simvastatin	3Mixtatin	MTA	
3 months	Absent	N	10^{B}	14^{A}	15^{A}	0.004*
		%	66.7%	100.0%	100.0%	
	Present	N	5	0	0	
		%	33.3%	0.0%	0.0%	
9 months	Absent	N	5^{B}	13^{A}	14^{A}	0.001*
		%	55.6%	100.0%	100.0%	
	Present	N	4	0	0	
		%	44.4%	0.0%	0.0%	
12 months	Absent	N	3^{B}	12^{AB}	13^{A}	0.035*
		%	60.0%	92.3%	100.0%	
	Present	N	2	1	0	
		%	40.0%	7.7%	0.0%	
p-value			0.135ns	0.368ns	NA	

*Values with different superscript letters within the same horizontal row are significantly different *; significant ($p \leq 0.05$) ns; non-significant ($p>0.05$), NA: Not Analyzed*

TABLE (7) Survival analysis

Parameter		Groups			p-value
		Simvastatin	3Mixtatin	MTA	
Mean survival time		9.74^{B}	12.00^{A}	12.00^{A}	<0.001*
Standard error		0.68	0.00	0.00	
95% confidence interval	Lower	8.41	12.00	12.00	
	Upper	11.07	12.00	12.00	

*Values with different superscript letters within the same horizontal row are significantly different *; significant ($p \leq 0.05$) ns; non-significant ($p>0.05$)*

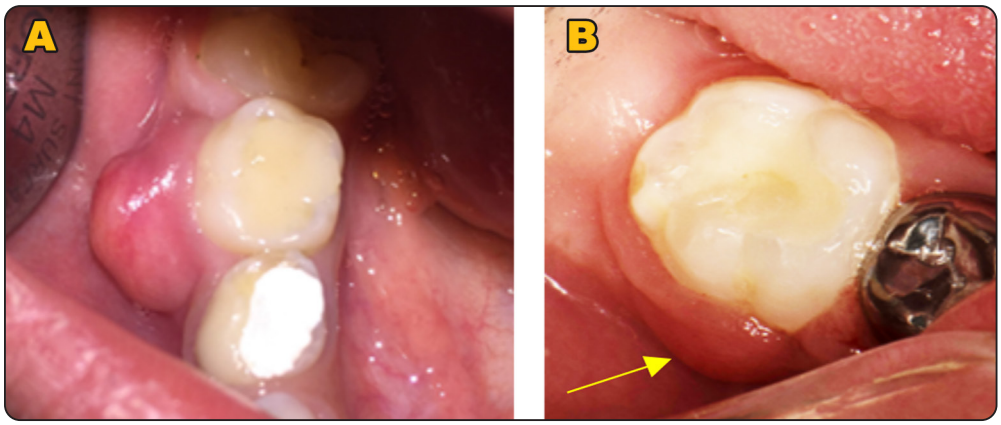

Fig. (2)(A): Lower right second molar displaying clinical swelling observed at 3 months follow up in Simvastatin group. (B): Lower right second primary molar displaying clinical swelling at 9 months follow up in Simvastatin group.

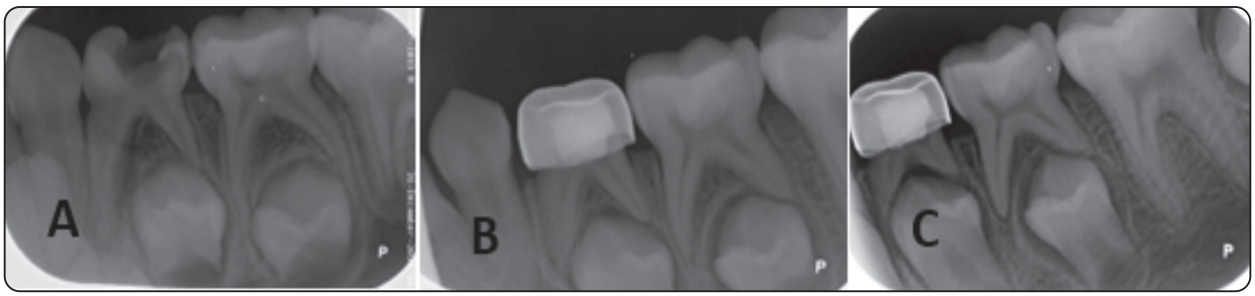

Fig (3) Radiographic images showing lower Left primary molar after DPC using MTA: (A)- after 3 months follow up (B)-after 9 months follow up (C)- after 12 months follow up

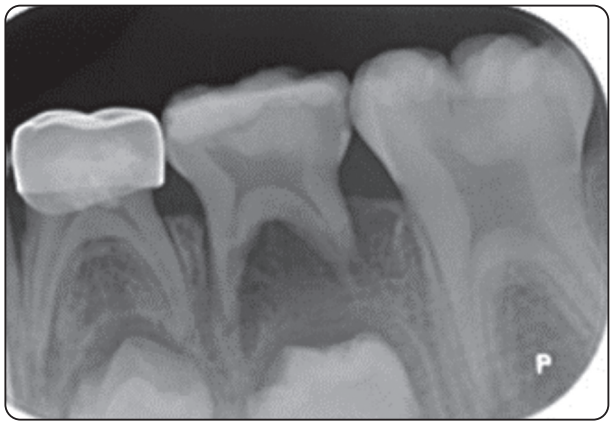

Fig. (4) Radiographic image showing external root resorption in a lower left second primary molar following DPC using simvastatin after 3 months follow up.

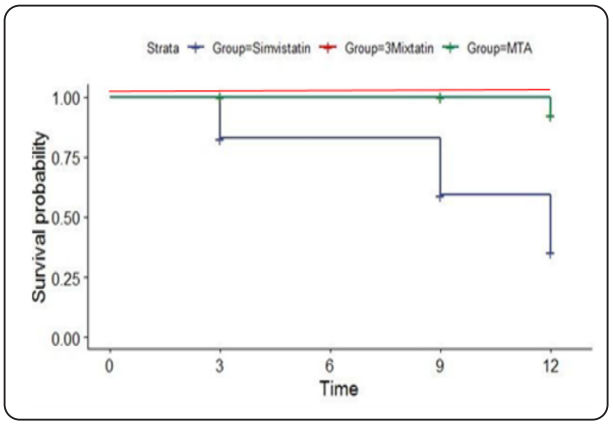

Fig. (5) Survival plot

DISCUSSION

There are some encouraging findings regarding the tested novel materials when used for DPC in primary teeth such as Simvastatin, Nano hydroxy-apatite, calcium-enriched mixture, Emdogain and calcium sulphate, yet no clear consensus exists about this treatment strategy for non-carious pulpal exposures in this dentition. In primary teeth direct pulp capping is recommended in small traumatic or mechanical pulp exposures, rather than those due to caries according to the recommendations by the **American Academy of Pediatric Dentistry 2020.** [15] However, these conditions have been challenged by some researchers who suggest that DPC might be a viable alternative for carefully selected cases with minimal to no signs of pulpal inflammation. [3,16] However there is a gap in the literature regarding DPC in primary teeth and further studies are needed to confirm the reliability of the technique.

The results of the current study showed that the simvastatin test group had an overall treatment outcome that is inferior to that of the MTA group. The clinical findings in the current study were statistically, significantly, different between both groups, where the success rate of the simvastatin group was 20%, while that of MTA was 92.3%. This disagreed with the results obtained by **Mahendran et al. 2020,**[17] who found that there was no statistically significant difference between the tested groups using different types of statins, α-tricalcium phosphate and MTA. In their study, DPC was performed on premolars which were indicated for extraction for orthodontic reasons.

The difference between the current results could be due to the fact that the authors examined the effect of those materials histologically, on permanent teeth. While the present clinical trial was on primary molars and clinical and radiographical criteria were assessed. Furthermore, the differences could be explained by using a different concentration of simvastatin powder and mixing it with α-tricalcium phosphate, which could have influenced the effect of simvastatin [17].

Regarding the radiographic findings, the current study showed no statistically significant difference between the 3Mixtatin and the MTA groups. These results are in agreement with a clinical trial done by **Aminabadi et al. 2016,**[8] who tested the effectiveness of 3Mixtatin and MTA to repair pathological, periapical, defects in primary teeth due to root resorption. The results demonstrated that no statistically significant difference was observed between both materials, upon radiographic and clinical assessment during the 24-month follow-up. This was consistent with our results, because a substantial number of teeth in the 3Mixtatin group revealed absence of radiographic signs of periapical pathosis during the follow up period [8].

Aminabadi et al. 2016,[9] performed another study which examined the efficacy of MTA, 3Mixtatin, 3Mix (TAP) and simvastatin as pulp capping biomaterials in DPC in primary molars. By the end of 12 months, the study's overall success rates were 93.8% for MTA, 91.9% for 3Mixtatin, 62.5% for 3Mix and 57.1% for simvastatin groups. These results agreed with the present study, as a comparable success rate was recorded (92.3%) in the MTA and 3Mixtatine groups. The similarity between both studies may be due to identical inclusion criteria of study subjects and a similar follow up period. On the contrary the simvastatin group in the current study showed an inadequate success rate of 20%, this can be due to the difference in sample size, as the authors included 40 primary molars in each test group, while in the current study only 15 primary molars were tested in each group [9].

The Simvastatin group showed the highest failure rate of 80.0%, which is the least recorded in all test groups through clinical and radiographical evaluation. These goes in accordance with a study carried out by **Aminabadi et al. 2013,** [18] to investigate the pulp-dentin complex reaction following DPC with calcium hydroxide (CH) and different concentrations of simvastatin in human primary molars. The histological examination revealed that pulp inflammation and necrosis was

higher in all simvastatin groups compared to the CH group. The authors attributed the higher rate of inflammation and pulp necrosis in simvastatin groups to the significant increase in the percentage of apoptotic cells due to the cytotoxic effect of statins. These results may refer to the fact that statin in high concentration results in higher rate of pulp inflammation and necrosis, in addition it also inhibits actin fibre formation and cell cycle progression, resulting in suppression of proliferation in dental pulp stem cells (DPSCs) [18].

Clinical and radiographic assessment of Simvastatin in our study revealed that the material has shown the highest failure rate which came in a disagreement with a study carried out in **2017 by Jung et al,** [19]. The study results showed a suppressing effect on lipopolysaccharide (LPS)-induced inflammatory cytokine when Simvastatin was applied on the human dental pulp cells (HDPCs) that were isolated from intact, caries-free, supernumerary, teeth that were freshly extracted from healthy children. After histological assessment the authors suggested that simvastatin might be a useful candidate as a pulp-capping agent in vital pulp therapy. This can be explained by the use of different concentrations of Simvastatin which might have yielded the difference in results between studies.

In line with our study, **Thakur et al,** [20] stated that 3Mixtatin paste is an exceptional and highly effective material with superior clinical and radiographic success, when compared to modified triple antibiotic medication with polyethylene glycol paste (3Mix-Mp) and Calcium hydroxide combined with iodoform paste. These materials were used in root canal treatment in primary teeth requiring pulp therapy and results were recorded based on a 12-month follow-up period. The success rates emphasise the anti-inflammatory and bioinductive properties of simvastatin, in addition to the antibacterial characteristic of the TAP, resulting in favourable treatment outcomes, irrespective of the vital pulp therapy procedure done. [20]

The strengths of the present study include, that it is an in-vivo, randomized clinical trial that studies a controversial procedure which is DPC in primary molar using a new material. The limitations of the current RCT are the relatively small sample size, in addition, longer follow up period is needed to assess the effect of the capping materials on the dental pulp.

CONCLUSIONS

Based on the results of our study we concluded the following:

1. MTA and 3Mixtatin yielded favourable clinical and radiographical outcomes compared to Simvastatin.
2. Simvastatin showed a significantly lower success rate than 3Mixtatin and MTA groups.
3. It can be concluded that 3Mixtatin can be used successfully as an appropriate alternative material in DPC of primary teeth in addition to MTA.

Recommendations

1. Further studies should be carried out on larger population sample of the same age group with longer follow up periods.
2. Different concentrations of Simvastatin should be tested for their efficacy.
3. Histological examination is recommended to demonstrate the tissue response to the pulp capping materials.

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