Pulpotomy efficiency in primary molars: outcomes of 24-month randomized clinical trial

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PULPOTOMY EFFICIENCY IN PRIMARY MOLARS: OUTCOMES OF 24-MONTH RANDOMIZED CLINICAL TRIAL

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Summary. The aim of the study was to assess comparative efficiency of 3 different preparations usage for pulpotomy in primary molars in children. The randomized prospective clinical trial in the parallel groups was conducted and 58 children aged 3-9 years (mean age 6.6±0.2 years) participated. 105 primary molars with reversible pulpitis were randomized into 3 groups: in the 1st group (n=35) pulpotomy was applied using pulpotec (Pulpotec, Produits Dentaires SA, Switzerland), in the 2nd group (n=34) – using mineral trioxide aggregate (PD MTA white, Produits Dentaires SA, Switzerland), in the 3rd group (n=36) – using formocresol (Pulpevit #3, VladMiVa, Russia). After 24 months clinical efficiency of pulpotomy was high (97%) in all groups. Radiographic efficiency was 94.3% in the 1st group, 91.2% in the 2nd group, 83.3% in the 3rd group ($p>0.05$). According to radiography the treatment outcomes of pulpotec use were higher compared with MTA and formocresol but without statistical significance.

Key words: pulpotomy, primary molars, pulpotec, MTA, formocresol

Pulpitis in primary teeth is a cause for majority children's visits to dentists [5]. The methods of vital and devital pulp amputation are most often applied for pulpitis treatment in primary teeth in children [1]. However, according to the data of the majority of the authors the devital pulpotomy has low effectiveness [4,7]. Vital pulp amputation (pulpotomy) is considered to be one of the main methods for pulpitis treatments in primary teeth [6]. Different preparations are used at pulpotomy application: formocresol,

mineral trioxide aggregate (MTA), ferric sulfate, pulpotec, biodentine, sodium hypochlorite etc. [3,9,11]. The data on the efficiency of different preparations usage at pulpotomy application are conflicting, further research grounded on evidence-based medicine is needed [8,10,12].

The aim of the current study was the assessment of comparative efficiency of three different preparations used for pulpotomy in primary molars in children.

Material and methods. The permission of Regional Research Ethic Committee was obtained for performing randomized prospective clinical trial in parallel groups (Protocol #94/1, 07.09.2015). The study was conducted in Children's Clinical Dental Polyclinic #2, Volgograd. 58 children aged 3-9 years (mean age 6.6±0.2 years), in whom reversible pulpitis (initial pulpitis or chronic pulpitis, codes К.04.01 or К.04.03, according to the International Classification of Diseases, 10th Revision) had been detected in primary molars, were included into the study. Written informed consents of the legal representatives were obtained for children's participation in the study. A random number table and sealed non-transparent numbered envelopes were used for randomization of 105 cases of reversible pulpitis in primary molars (59 were the first molars, 46 – the second molars) into 3 groups for treatment by pulpotomy. In the 1st group (n=35) pulpotomy was done by using Pulpotec (Produits Dentaires SA, Switzerland), in the 2nd group (n=34) – MTA (PD MTA White, Produits Dentaires SA, Switzerland), in the 3rd group (n=36) – formocresol (Pulpevit #3, VladMiVa, Russia). All preparations were applied in accordance with the manufacturer's instructions. Liners of glass ionomer cement (Fuji-IX, GC, Japan), adhesive system (Contax, DMG, Germany) and light cure composite

(EcuSphere, DMG, Germany) were used for molars' restorations in all the cases. Follow-up examinations of the children were performed after 6, 12, 18 and 24 months. The statistical analysis consisted in calculating proportions (%), mean-values and standard errors (M±m), chi-square criterion for the assessment of the difference significance.

Results and discussion. The examinations after 6 and 12 months revealed clinical success of pulpotomy in all the cases. According to the radiographic data after 12 months signs of periodontium pathology were revealed in 1-2 cases in each group [2]. The main outcomes of pulpitis treatment in children after 24 months are presented in the table.

Table. The results of pulpotomy in primary molars in children during 24 months follow-ups

Characteristics	Number (%) in the groups:		
	1st group (n=35)	2nd group (n=34)	3rd group (n=36)
Natural tooth exfoliation	6 (17.1)	3 (8.8)	4 (11.1)
Tooth extraction due to apical periodontitis	0 (0.0)	1 (2.9)	1 (2.8)
Tooth extraction due to trauma	1 (2.8)	0 (0.0)	0 (0.0)
Pathological signs on x-rays	2 (5.7)	3 (8.8)	6 (16.7)
Clinical efficiency	34 (97.1)	33 (97.0)	35 (97.2)
Radiographical efficiency	33 (94.3)	31 (91.2)	30 (83.3)

Natural exfoliation of the treated primary molars and permanent premolars eruption were registered in 13 (12.4%) cases, mainly after 18-24 months after the

treatment, in the children aged 8-11 years (mean age 9.1±0.3 years). Among exfoliated primary teeth, 10 were the first molars and 3 were the second molars which presented 16.9% and 6.5% relatively to the total numbers of the treated first and second molars. According to the parents' information, the children did not have any complaints and complications during these teeth exfoliation. The examination revealed corresponding erupted permanent teeth without any abnormality in their structure. Healthy symmetrical primary molars were replaced by their permanent successors at the same time as the teeth treated by pulpotomy. After 24 months physiological root resorption was noticed on x-rays in 24 (22.8%) treated primary molars which corresponded to the children's age. Thus, pulpotomy did not affect the timing of primary teeth replacement.

Clinical examination of the children after 18 and 24 months revealed no complaints in children; gingiva in the area of the treated teeth had normal color and consistency, percussion and palpation were painless. Insignificant darkening of treated teeth crowns was noticed in the 2nd group (60.6% of the cases). The majority (90.5%) of the restorations were without any disturbance (90.5%) or had minor defects (7.6%) of marginal integrity, surface structure or anatomical form which did not need fillings replacement; secondary caries was not revealed. After 18 months we registered the extraction (due to apical periodontitis, according to parental information) of one tooth in the 2nd group, after 24 months – the extraction (due to trauma, according to medical records) of one tooth in the 1st group. Radiographical examination after 18 months revealed significant radiolucency in periapical area of the treated molar in one case in the 3rd group; the child was referred for tooth extraction apropos inflammatory cyst. After 24

months the signs of pathology on x-rays (periodontal ligament space increase, internal or external root resorption, and the increase of radiographic radiolucencies in furcation area) were revealed in the 1st group in 5.7% cases, in the 2nd group – 8.8% cases, in the 3rd group – 16.7% cases ($p > 0.05$). Therefore, after 24 months the clinical efficiency of pulpotomy represented by the number of primary teeth saved till natural exfoliation reached 97% in all the groups. Radiographical efficiency was 94.3% in the 1st group, 91.2% in the 2nd group, 83.3% in the 3rd group ($p > 0.05$).

Conclusions. Pulpotomy is an effective method of pulpitis treatment in primary molars in children. Pulpotomy did not significantly affect natural exfoliation of treated primary molars and the eruption of corresponding permanent premolars. According to the radiographical data, the pulpotomy outcomes after pulpotec usage were higher compared with MTA and formocresol, but without statistical significance.

REFERENCES

1. Maslak E.E. [i dr.]. E`ffektivnost` pul`potomii vo vremenny`x zubax u detej: obzor literatury` // Volgogradskij nauchno-medicinskij zhurnal. – 2018. - №4. – S.12-14.
2. Maslak E.E. [i dr.]. Rezul`taty` vital`noj pul`potomii vo vremenny`x molyarax u detej v vozraste 3-9 let: 12-mesyachnoe randomizirovannoe issledovanie // Stomatologiya detskogo vozrasta i profilaktika. – 2019. – T.19, №4. – S.37-43.
3. Shakovecz N.V., Romanova O.S. Rezul`taty` vital`noj pul`potomii pri lechenii pul`pita vremenny`x zubov // Dental Forum. – 2015. – № 4. – S. 96.

4. Shevchenko O.L., Antonova A.A. Obosnovanie e`ffektivnosti primeneniya razlichny`x preparatov dlya lecheniya pul`pita vremenny`x zubov // E`ndodontiya Today. – 2019. – T.17, №2. – S.3-7.
5. Shiryak T.Yu., Saleev R.A. Optimizaciya lecheniya pul`pita vremenny`x zubov metodom vital`noj pul`potomii // Stomatologiya. – 2016. – T. 95, № 6. – S. 80.
6. Bossù M. [et al.]. Different pulp dressing materials for the pulpotomy of primary teeth: a systematic review of the literature. J Clin Med. 2020;9(3):838.
7. Maslak E. [et al.]. Survival of primary molars after pulpotomy in 1-7-year-old children // Int. Dent. J. ‑ 2017. ‑ Vol.67, Suppl. 1. ‑ P. 230-231.
8. Mythraiye R. [et al.]. Evaluation of the clinical and radiological outcomes of pulpotomized primary molars treated with three different materials: Mineral Trioxide Aggregate, Biodentine, and Pulpotec. An in-vivo study // Cureus. – 2019. – Vol.11(6):e4803.
9. Rajasekharan S. [et al.]. Efficacy of three different pulpotomy agents in primary molars: a randomized control trial // Int Endod J. – 2017. – Vol.50(3). – P.215-228.
10. Smaïl-Faugeron V. [et al.]. Pulp treatment for extensive decay in primary teeth // Cochrane Database Syst Rev. – 2018. – Vol.5(5):CD003220.
11. Stringhini Junior E., Vitcel M.E., Oliveira L.B. Evidence of pulpotomy in primary teeth comparing MTA, calcium hydroxide, ferric sulphate, and electrosurgery with formocresol // Eur Arch Paediatr Dent. – 2015. – Vol.16(4). – P.303-312.

12. Sunitha B. [et al.]. Clinical and radiographic evaluation of four different pulpotomy agents in primary molars: a longitudinal study // Int J Clin Pediatr Dent. – 2017. – Vol.10(3). – P.240-244.