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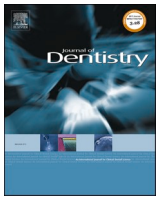

Comparison of three management approaches for dental caries in primary molars: A two-year randomized clinical trial

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ABSTRACT

Aim: to compare two-year clinical success rates of caries management in children (Hall Technique HT, Non-restorative caries treatment NRCT, Conventional restorations CR), and to evaluate pain perception, behaviour, technique acceptability by patients, parents and dentists.

Methods: 122, 3–8–year-olds were enrolled in 2-year parallel group randomised controlled trial (CR, $n = 52$, HT, $n = 35$, NRCT, $n = 35$). Caries was recorded using Nyvad criteria to measure clinical success/ failure rates. Child's pain perception (Visual Analogue Scale of Faces), child behaviour (Frankl scale), parents' and dentists' treatment opinions (5-point Likert scale) were assessed. Statistical analysis included Chi-square, non-parametric Kruskal–Wallis, Bonferroni-corrected Mann-Whitney U tests ($p < 0.05$), absolute risk reduction (ARR) and number needed to treat (NNT).

Results: After two years, with 116 participants, clinical success rates were: CR=60.8 % ($n = 31$), HT=93.8 % ($n = 30$), NRCT=42.5 % ($n = 14$) ($p < 0.001$). Major/minor failure rates differed: CR=17.6 % ($n = 9$) / 21.6 % ($n = 11$); HT=6.2 % ($n = 2$)/ 0 %, NRCT=33.3 % ($n = 11$)/ 24.2 % ($n = 8$), ($p < 0.05$). When comparing HT to CR, ARR = 0.33; NNT= 3 (95 % CI 0.02 -0.58); NRCT to CR, - no observed benefit from NRCT. More than 70 % of children demonstrated "positive/definitely positive" behaviour during treatment. Pain intensity was "very low/ low" in 92.3 % of cases for CR, 88.6 % for HT, and 77.1 % for NRCT . NRCT was "very easy" to perform for 82.9 % of participants, compared to 42.3 % for CR and 17.1 % for HT ($p < 0.05$). CR were reported to take longer than NRCT and HT ($p < 0.05$).

Conclusion: Clinical success rates of HT were superior to CR and NRCT. All treatment techniques were well tolerated by children, CR was more time-consuming and HT – technically more difficult to perform.

Clinical significance: caries management in primary molars can be successfully performed using minimal intervention, particularly, sealing in caries lesions with Hall technique. NRCT can prevent caries progression when adequate access to mechanical plaque disruption and fluoride is provided. However, occasional fluoride application, and uncontrolled toothbrushing with fluoride toothpaste cannot replace restorative procedures.

1. Introduction

Despite the overall caries decline on a global level dental caries in primary dentition is still a common oral health issue for millions of children worldwide [1,2]. This indicates that the traditional methods of disease management focused on restoration of the cavitated stages of dental caries are ineffective. The current understanding of the biological mechanisms behind the caries process implies that the key to successful disease control lies in the early detection of the caries lesions at the non-cavitated stage, along with controlling the lesion activity [3]. Moreover, the progression of caries lesions can be arrested at both non-cavitated and cavitated stages, by maintaining the dynamic stability

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of the microbial biofilm [4]. Thus, the contemporary approach of caries treatment follows the principles of minimal intervention including non-operative and operative measures [5,6,7].

Management of dentine caries in the primary dentition can be particularly challenging, due to several features, including the anatomy of the primary teeth (close lesion proximity to the pulp), pain perception and low levels of cooperation in children as they develop cognitively, difficulties in moisture control, etc. Following the contemporary approach, the use of less invasive techniques involving selective or no caries removal with or without restoration over conventional restorative treatment, for patients presenting with vital, carious lesions in primary teeth is recommended [7,8]. In particular, the Hall Technique (HT) - a method where no caries is removed and a preformed (stainless steel) crown is cemented over the tooth has been recognised as a superior treatment modality, in comparison with conventional restorations, in several studies [9]. The biological rationale of this technique is based on the principle of sealing in the caries lesion and its isolation from the biofilm [10].

Another promising alternative, the non-restorative caries treatment (NRCT) based on no caries removal and on cavity access to effective plaque removal and fluoride action has been less investigated. Peretz and Gluck 18 years ago [11] demonstrated that it was possible to arrest approximal caries lesions in anterior teeth by slicing the lesions and applying professional topical fluoride applications along with other preventive measures such as improved dental plaque control and reduced sugar intake. Later, this method proved to be successful in other studies with varying frequency of fluoride treatment and duration [12, 13,14,15]. However, NRCT is still rarely used in clinical practice, and further evidence is needed to support its effectiveness.

The present study in a Lithuanian population of 3–8-year-old children was planned in parallel to the earlier reported study in Germany [12,13], in order to compare the long-term clinical effectiveness of three different dental caries treatment approaches - the Hall Technique (HT), the non-restorative caries treatment (NRCT), and the conventional caries removal followed by a restoration, to the management of class II cavitated caries lesions. In addition to the outcomes of caries treatment, the perceptions of children, their parents, and the treatment providers (dentists) about pain, discomfort, ease, and duration of treatment procedures were evaluated. The follow up period of 24 months was chosen, with an interim assessment of the study results after 1 year.

The idea of conducting parallel studies in two countries was to observe how the selected treatment approaches function in different environments, considering cultural differences in the populations as well as potential variations in the clinical education and experience of the dentists. Ultimately, the data from these studies were expected to offer deeper insights into the generalizability of the findings.

2. Material and methods

2.1. Study design

The study was conducted as a 2-year three-arm, parallel-group, randomised controlled trial involving 3- to 8-year-old patients referred for dental treatment to the Clinic for Preventive and Paediatric Dentistry of Lithuanian University of Health Sciences, during the period 2013 - 2017. The trial compared three treatment modalities for managing cavitated caries lesions:

1) Complete caries removal and conventional cavity restoration, CR; 2) Sealing the caries lesion with a stainless-steel crown using the Hall Technique, HT; 3) Non-restorative caries treatment performed as cavity opening and fluoride application (at baseline and after 1 year), NRCT.

Nine dentists (1 paediatric specialist and 8 postgraduate paediatric students) were trained to perform all three treatments. The experienced paediatric dentist (JN) was responsible for conducting the training. Prior patient recruitment, the study protocol was explained and discussed with the treating dentists. The training provided detailed instructions on performing the interventions for each treatment arm. Video demonstrations and hands-on practice were provided, especially for areas where the dentists felt less confident, such as the Hall technique and NRCT.

A total of 122 children with the mean age of 5.7 (SD = 1.2) yrs, were recruited based on the following inclusion criteria: 1) At least one primary molar with occluso-proximal active cavitated caries lesion into the dentine [16]; 2) Willingness to participate based on informed consent signed by the parents. Children were excluded if they had pain or symptoms of pulpal or peri-radicular pathology in the dentition, or systemic diseases requiring special care during dental treatment. If a child had multiple carious molars, only one tooth was included in the study according to the order list (upper left first/second molar, upper right first/second molar, lower right first/second molar, lower left first/second molar).

2.2. Study sample

Comparison of failure rates of stainless-steel crowns versus conventional fillings was used for sample calculation. No reliable failure rate data for NRCT was available. According to Innes et al. [10], minor failure rates were 5 % for HT compared to 46 % for CR. Assuming failure rates of 5 % for HT and 25 % for CR, the sample size was calculated using the program G*Power version 3 [17]: two-tailed test, $\alpha = 0.05$ divided by three for multiple testing, resulting in 0.016; $\beta = 0.20$. Thus, a reasonable sample size to detect clinically significant differences was estimated to be 116 children, divided into three groups (33 HT + 33 NRCT + 50 CR).

The study participants were sequentially randomized using a computer-generated random number list with allocation concealment, into one of three arms. The patients were not informed of which arm they had been assigned to before the treatment was administered.

Patient recruitment and follow-up are presented in the CONSORT diagram (Fig. 1) [18]. The baseline distribution of the participants by treatment modality was as follows: CR = 52, HT = 35, NRCT = 35. Of the 122 baseline participants, 120 were examined at one year, and 116 returned at two years.

The reasons for dropout (6 participants over two years) were failure to return ($n = 4$) and moved away ($n = 2$).

2.3. Treatment procedures

All study participants have received recommendations to use fluoride toothpaste for daily tooth brushing and dietary instructions.

2.3.1. Conventional restorations (CR)

The cavitated caries lesions were accessed using a small round diamond bur in a high-speed handpiece. Complete removal of carious dentine (to hard dentine, [6]) from the cavity was performed with a small round bur in a slow handpiece or, by hand, using sharp spoon excavator. Local anaesthesia, continuous aspiration and cotton roll isolation were used as needed. The restorative material used was hand-mixed Glass Ionomer Cement (GC Fuji IX®, GC Corporation, Tokyo, Japan), and a cavity conditioner was applied for pre-treatment in accordance with the manufacturer's instructions. Dental matrix, matrix band (Henry Schein Inc., Melville, NY, USA) and wedge (Interdental wedge, Kerr, Biogglo, Switzerland) were used to restore the proximal surfaces.

2.3.2. Hall technique (HT)

The cavitated caries lesions were sealed with a prefabricated stainless-steel crown (3 M ESPE®, USA) without tooth preparation, anaesthesia, or caries removal. The appropriate crown size was selected

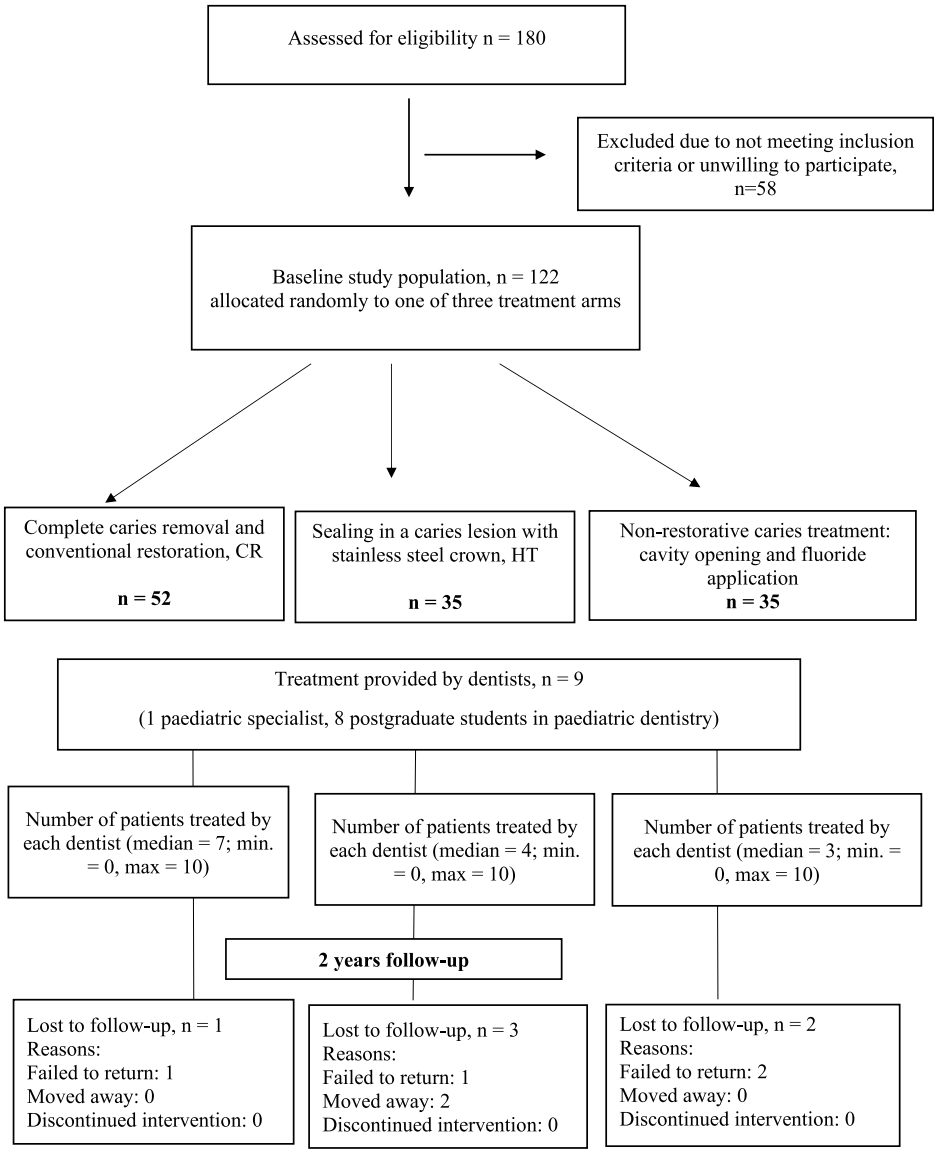

Fig. 1. Study CONSORT diagram.

and cemented with glass ionomer luting cement (GC Fuji I®, GC Corporation, Tokyo, Japan). Cotton wool rolls and continuous aspiration were used for isolation. In case of tight contact points, orthodontic separator elastics were inserted for 2–3 days prior to crown placement at subsequent appointment.

2.3.3. Non-restorative caries treatment (NRCT)

Unsupported enamel margins of the cavitated caries lesions were removed using a high-speed flame-shaped or cylindrical bur to make the lesions accessible for plaque removal. Residual biofilm in the cavity was eliminated using a rotary bristle brush. Fluoride varnish 22 600 ppm (Duraphat®, GABA, Lörrach, Germany) was applied immediately after cavity preparation. The parents received site–specific toothbrushing instructions. The patients were advised to brush with fluoridated toothpaste (1000 ppm fluoride) twice daily using a single tufted toothbrush as per Guidelines of Lithuanian Dental Chamber [19]. Though fluoride varnish was scheduled for application every three months, the dentists did not realise this was the instructions as it differed from usual practice and the fluoride varnish applications were repeated at next follow-up session (after 12 months) only in line with usual practice. This deviation from the original protocol was not detected until after the treatment sessions were complete.

Regular caries treatment was offered to all study participants in the event of failure in any of the treatment arms.

2.4. Treatment perceptions of study participants, parents, and dentists

Immediately after treatment, perceptions and opinions were collected from the study participants and their parents by the treating dentists in the treatment room. The dentists also filled in the questionnaire regarding the treatment procedures. The following instruments were used:

- Frankl Behaviour Rating Scale [20]. Dentists assessed the child's behavior during treatment on a four-point scale ranging from completely uncooperative (refuses treatment) to completely cooperative.
- Visual Analogue Scale of Faces (VASOF) scale for pain perception [21]. Children selected a face from a five-point scale representing varying pain levels from very mild to very intense.
- 5-point Likert scales. The parents evaluated their child's behavior, comfort, and satisfaction with the treatment while the dentists

assessed the ease of treatment, patient discomfort, and duration of the treatment. The parents were also asked if they would choose the same treatment again, and the dentists were asked about their preferred treatment option in routine practice.

2.5. Clinical examinations

The clinical dental examination of the study participants was performed at baseline, after one and two years using the caries diagnostic system that included caries lesion activity (Nyvad criteria) [16]. Trained dentists performed the examinations and recorded the data on specially designed paper forms. Follow-up examinations included inquiries about pain and any required emergency treatments.

2.6. Study ethics

Kaunas Regional Committee on Biomedical Research Ethics, Lithuania granted their approval of the study (reference BE-2–54; trial registration No NCT01797458). Informed consent was obtained from the parents for their children to participate.

2.7. Data analysis

Data analysis was performed using SPSS for Windows (version 20.0, SPSS Inc., Chicago, IL, USA). Nonparametric Kruskal-Wallis analysis of variance and Bonferroni-corrected Mann-Whitney U tests were used to compare clinical outcomes (success, minor failure, major failure). A p-value ≤ 0.05 indicated statistical significance. Chi-square and Kruskal-Wallis tests were also used for statistical analysis. Outcome measures included clinical success and failure rates, defined as minor failures (restoration loss/need for replacement, reversible pulpitis, caries progression) and major failures (irreversible pulpitis, abscess, non-restorable/broken crown). Absolute risk reduction (ARR); absolute difference between the risk of the event in the control group (control event risk [CER]) and experimental group (experimental event risk [EER]); ARR = CER – EER and the number needed to treat (NNT); NNT=1/ARR were also calculated, comparing control therapy (CR) with experimental treatments (NRCT and HT).

3. Results

3.1. Baseline characteristics

The baseline study sample comprised 122 children aged 3–8 yrs, 60 (49 %) boys and 62 (51 %) girls (Fig. 1). The mean age of the participants was 5.7 (SD=1.2) years. No significant difference for gender and age between the three treatment groups was observed. The first primary molars comprised two-thirds of all teeth subjected to treatment using all techniques while the remaining teeth treated during the study were the primary second molars (Table 1). No significant difference between any of the three treatment modalities, with respect to the tooth type was registered.

Dental caries was recorded at surface and tooth levels and included non-cavitated as well as cavitated lesions. At baseline, no significant difference regarding dental caries experience was found between the treatment groups (Table 2).

Slight, but non-significant increase of the mean dmft and dmfs values was observed throughout the study period in all study groups. No significant difference was observed within treatment techniques as well (Table 2).

3.2. Treatment success and failure rates

After one year, treatment success rates in NRCT and CR arms were 53 % and 73.3 %, and after two years 42.5 % and 60.8 %, respectively (Table 3 and 4). In the third treatment arm (HT), the treatment outcome was successful in 93.8 % of cases, after two years (Table 3).

The treatment success rates differed significantly between all three treatment modalities, the HT arm showing the best result and the NRCT arm – the lowest result ($p < 0.05$) after one and two years of follow up. Most minor failures were recorded during the first year of the study: in NRCT arm (29.4 %, all due to caries progression), followed by the CR arm (15.7 %) (7 cases of lost filling and one case with secondary caries). No minor failures were recorded in HT arm throughout the entire study period (Table 3). More major failures occurred in NRCT and in CR than in HT arm ($p < 0.05$) during the first year of the study. After two years, the overall number of minor failures decreased in the NRCT arm while the rate of major failures increased by 33.3 % mostly recorded as irreversible pulpitis or abscess formation (Table 4). Respectively, in CR arm irreversible pulpitis was recorded in three patients, abscess formation - in four patients, and two cases of non-restorable tooth crown during the

Table 1
Baseline characteristics of study participants ($n = 122$).

Baseline Characteristics	Treatment Modality			
	CR	HT	NRCT	Total
Gender	21/31	21/14	18/17	60/62
boys/girls, n (%)	(40/60)	(60/40)	(51/49)	(49/51)
Age				
3–5-yr-olds, n (%)	31(60)	22 (63)	20 (52)	73 (60)
6–8-yr-olds, n (%)	21(40)	13 (37)	15 (43)	49 (40)
All, Mean age, years (SD)	5.6(1.2)	5.2 (1.4)	5.6 (1.2)	5.7 (1.2)
Tooth type				
1st primary molar, n (%)	39 (75)	23(66)	25 (71)	87 (71)
2nd primary molar, n (%)	13 (25)	12 (34)	10 (28)	35 (29)

HT, Hall Technique; NRCT, non-restorative caries treatment; CR, conventional restoration.

Table 2
Caries experience of study participants at baseline, after one and two years of follow- up.

Caries experience, Mean [CI]	Treatment Modality			
	CR	HT	NRCT	Total
At baseline ($n =$ 122)				
dmft (noncav+cav)*	7.0 [4.0–10.0]	5.0 [4.0–10.0]	7.0 [4.25–9.0]	7.0 [4.0–9.0]
dmft (cav)*	5.0 [4.0–8.0]	5.0 [3.0–8.0]	6.0 [3.0–8.0]	5.0 [3.0–8.0]
dmfs (noncav+cav)*	11.0 [8.0–16.75]	11.0 [6.0–19.0]	11.0 [6.0–20.0]	11.0 [7.0–18.0]
dmfs (cav)*	9.5 [7.0–16.5]	10.0 [6.0–18.0]	10.0 [6.0–18.0]	10.0 [6.0–18.0]
After 1 year ($n =$ 120)				
dmft (noncav+cav) *	7.0 [5.0–9.0]	5.0 [3.0–9.0]	7.0 [3.75–9.0]	7.0 [4.0–9.0]
dmft (cav) *	6.0 [5.0–9.0]	4.0 [2.0–7.0]	6.0 [3.0–8.0]	6.0 [4.0–8.0]
dmfs (noncav+cav) *	14.0 [9.0–19.0]	10.0 [5.0–18.0]	11.0 [7.75–21.0]	12.0 [8.0–18.8]
dmfs (cav) *	12.0 [8.0–18.0]	10.0 [5.0–17.0]	10.5 [6.75–18.8]	11.0 [7.0–18.0]
After 2 years ($n =$ 116)				
dmft (noncav+cav) *	8.0 [6.0–9.0]	5.0 [4.0–9.0]	7.0 [5.0–10.0]	7.0 [5.0–9.0]
dmft (cav) *	7.0 [5.0–8.0]	5.0 [3.0–7.0]	7.0 [4.5–8.0]	6.0 [4.0–8.0]
dmfs (noncav+cav) *	17.0 [10.0–23.0]	10.5 [6.0–19.0]	16.0 [10.0–20.0]	15.5 [9.0–20.0]
dmfs (cav only) *	16.0 [9.0–20.0]	10.0 [5.0–19.0]	14.0 [10.0–19.5]	14.0 [8.0–20.0]

HT, Hall Technique; NRCT, non-restorative caries treatment; CR, conventional restoration.
* Abbreviations: noncav - noncavitated lesions; cav - cavitated lesions.

Table 3
Treatment success rates after one and two years, by treatment modality, n (%).

Treatment outcome	Treatment modality				
	CR	HT	NRCT	Total	P-value
Success and failure rates after 1 year					
Successful	37 (72.5 %) [a]	33 (94.3 %) [b]	18 (53 %) [c]	88 (73.3 %)	$p < 0.001$
Minor failure	8 (15.7 %) [a]	0 (0) [b]	10 (29.4 %) [c]	18 (15 %)	
Major failure	6 (11.8 %) [a]	2 (5.7 %) [a]	6 (17.6 %) [a]	14 (11.7 %)	p< 0,05
Total	51	35	34	120	
Success and failure rates after 2 years					
Successful	31 (60.8 %) [a]	30 (93.8 %) [b]	14 (42.5 %) [a]	75 (64.6 %)	$p < 0.001$
Minor failure	11 (21.6 %) [a]	0 (0) [b]	8 (24.2 %) [a]	19 (16.4 %)	
Major failure	9 (17.6 %) [ab]	2 (6.2 %) [b]	11 (33.3 %) [a]	22 (19 %)	p <0.05
Total	51	32	33	116	

Categories marked with the same superscript letter do not differ significantly from each other within the same row at the 0.001 or, 0.05 significance level.
HT, Hall Technique; NRCT, non-restorative caries treatment; CR, conventional restoratio.

Table 4
Treatment success/failure analysis in NRCT and CR arms, based on caries lesion transitions after one and two years.

Transition type*	NRCT	
	Baseline – 1 year ($n = 34$)	Baseline - 2 years ($n = 33$)
Active - inactive	12	10
Inactive – inactive	6	4
Active – active	10	3
Inactive- active	2	0
Active – filled/extracted	2/0	7/4
Inactive – filled/ extracted	0/2	1/4
Success/failure	18/16	14/19
	CR	
	Baseline – 1 year ($n = 51$)	Baseline - 2 years ($n = 51$)
Filled - filled	37	31
Filled– lost filling	7	11
Filled– secondary caries	1	0
Filled – pulpitis/extracted	4/2	3[x]/6
Success/failure	37/14	31/20
Risk of Failure (%)**	27	39
Absolute risk reduction (ARR)	20	19
Number needed to treat (NTT)	5	5.3

NRCT, non-restorative caries treatment; CR, conventional restoration.
Extracted includes cases with acute periodontitis/abscess and non-restorable, due to considerable breakdown.
* *Active* and *Inactive* include all cavities in enamel and dentine;.
[x] one new case with pulpitis in year 2, and two from the first year were extracted.
** Risk of Failure = (n of failures/total n of treated cases)*100.

second year of the study (Table 4). In two cases of major failures in HT arm abscess formation was recorded during the first year of follow up, and no more major failures occurred during the second study year.

At the 1-year follow-up, 27 % of patients in the CR arm, 47 % in the NRCT arm, and 5 % in the HT arm experienced an adverse outcome (failure). When comparing HT to CR, the ARR was 0.20, with an NNT of 5 (95 % CI = 0.03 to 0.14). This indicates that for every five patients treated with HT one more would benefit (not experience the adverse event) compared to if the CR had been used. Conversely, when comparing NRCT to CR, there was no evidence of benefit from NRCT (95 % CI = −0.012 to 0.04) (Table 4).

At the 2-year follow-up, 39 % of patients in the CR arm, 57 % in the NRCT arm, and 6 % in the HT arm experienced an adverse outcome (failure). When comparing HT to CR, the ARR was 0.33, with an NNT of 3 (95 % CI = 0.02 to 0.58). This suggests that for every three patients treated with HT, one more would benefit (not experience the adverse event) compared to if the CR had been used. However, when comparing NRCT to CR, there was no evidence of benefit from NRCT (95 % CI = −0.032 to 0.04) (Table 4).

The analysis of potential associations between the patient-related factors (gender and age) and treatment success did not reveal any significant correlations, either in the overall participant group or in relation to the specific treatment modalities (data not shown).

3.3. Treatment perceptions

Most children in all three treatment arms were rated by the dentists as having "positive" or "definitely positive" behaviour during treatment: 90.4 % of those who received CR, 88.6 % of those treated with HT, and 71.4 % of those who received NRCT ($p < 0.252$).

Regarding patients' pain perceptions/pain intensity rated by themselves, four patients in NRCT arm reported pain during treatment procedure being intense while none did so in the other two treatment arms (Table 5). A statistically significant difference was estimated between the NRCT and CR arms with more children rating the pain intensity as "very low" and "low" in CR than in NRCT ($p < 0.05$).

Asked about their opinion regarding the treatment procedures, most dentists (86 - 100 %, in all treatment arms, (Table 6) rated the treatment procedures as "very easy" and "easy" to perform, with no difference between the techniques. However, when considering the categories "very easy" and "easy" separately, NRCT was superior to other techniques, followed by CR and HT ($p < 0.05$; Table 6).

Evaluation of treatment duration differed between the treatment arms, NRCT being rated as "very short" and "short" by 100 % of the dentists while the corresponding values for CR and HT were 65.4.% and 77.1 %, respectively ($p < 0.05$). Thus, CR procedures were reported being significantly longer compared to NRCT and HT ($p < 0.05$; Table 6).

Significant differences were observed in the child's discomfort levels accross different treatment types. NRCT resulted in more reports of "no apparent" and "very mild" discomfort (91.4 %) compared to CR (84.6 %) and HT (62.9 %) ($p < 0.05$, Table 6).

Parental satisfaction with the procedures was mostly rated as "very satisfied" and "satisfied" accross all treatment arms (98 % in CR, 100 % in HT, and 89 % in NRCT).

4. Discussion

This clinical trial investigated the 2-year clinical success/failure rates for three treatments of cavitated dentine carious lesions in the primary dentition: conventional restorations; the Hall Technique; and the non-restorative cavity treatment method based on the lesion accessibility to biofilm removal and supplemented with regular topical application of fluoride varnish. We found significant differences between the treatment

Table 5
Pain perception of children during treatment ($n = 122$).

	CR n (%)	HT n (%)	NRCT n (%)
Very low/Low	48 (92.3 %) [a]	31 (88.6 %) [ab]	27 (77.1 %) [b]
Moderate	4 (7.7 %) [a]	4 (11.4 %) [a]	4 (11.4 %) [a]
Intense/ Very intense	0 [a]	0 [a]	4 (11.4 %) [b]

Categories marked with the same superscript letter do not differ significantly from each other within the same row at the 0.05 significance level.
HT, Hall Technique; NRCT, non-restorative caries treatment; CR, conventional restoration

Table 6
Dentists' opinion about treatment methods ($n = 122$).

	CR n (%)	HT n (%)	NRCT n (%)	P-value
Procedure undertaken				
Very easy	22(42.3 %) [a]	6 (17.1 %) [b]	29 (82.9 %) [c]	$p < 0.05$
Easy	29 (55.8 %) [a]	25 (71.4 %) [a]	5 (14.3 %) [b]	
Manageable	1(1.9 %) [a]	4 (11.4 %) [a]	1(2.9 %) [a]	
Difficult	0	0	0	
Very difficult	0	0	0	
Technique difficulty to handle				
Very easy	24 (46.2 %) [a]	11(31.4 %) [a]	29 (82.9 %) [b]	$p < 0.05$
Easy	27 (51.9 %) [a]	22 (62.9 %) [a]	6 (17.1 %) [b]	
Manageable	1 (1.9 %) [a]	2 (5.7 %) [a]	0 [a]	
Difficult	0	0	0	
Very difficult	0	0	0	
Treatment duration				
Very short	11(21.2 %)	5 (14.3 %) [a]	22 (62.9 %) [b]	$p < 0.05$
Short	23 (44.2 %) [ab]	22 (62.9 %) [b]	13 (37.1 %) [a]	
Time-efficient	18 (34.6 %) [a]	7(20 %) [a]	0 [b]	
Long	0 [a]	1(2.9 %) [a]	0 [a]	
Very long	0	0	0	
Child's level of discomfort				
No apparent	22 (42.3 %) [a]	4 (11.4 %) [b]	19 (54.3 %) [a]	$p < 0.05$
Very mild	22 (42.3 %) [a]	18 (51.4 % [a]	13 (37.1 %) [a]	
Mild	6 (11.5 %) [a]	12 (34.3 %) [b]	2 (5.7 %) [a]	
Moderate	2 (3.8 %) [a]	1 (2.9 %) [a]	0 [a]	
Unacceptable	0 [a]	0 [a]	1(2.9 %) [a]	

Categories marked with the same superscript letter do not differ significantly from each other within the same row at the 0.05 significance level.
HT, Hall Technique; NRCT, non-restorative caries treatment; CR, conventional restoration.

groups with adverse outcomes (failures) experienced by 39 % of patients in the CR arm, 57 % in the NRCT arm, and only 6 % in the HT arm.

The study originally followed a protocol used by Santamaría at al, in Germany [12,13] but was modified mainly due to misinterpretation of the procedure by the dentists involved in the study. In the NRCT arm, fluoride applications were standardized to once a year, not quarterly as in the earlier study of Santamaria et al. [12]. All study participants received instructions to use fluoridated toothpaste for tooth brushing at home, and most of the toothpaste available at the Lithuanian market contains regular amounts of fluoride ($\geq$ 1000 F^- ppm). In fact, the study scenario was close to the natural life course of a cavitated caries lesion made accessible for cleaning.

The study's deviation from the protocol may explain differences between this trial and the German study. The Lithuanian NRCT success rate was 43 % after two years, compared to 71 % at 2.5 years in Germany where NRCT performed as well as CR [12,13]]. In this study, the NRCT approach was inferior to both, the CR, and the HT. It is noteworthy that the results of this study align with the earlier findings by Hansen and Nyvad [14], where 50 % of non-operatively treated primary teeth with the cavities in dentine survived without pain, pulpal or periapical pathology for an average of 26 months.

Other factors may account for the remarkable differences in the treatment success rates observed between the German and Lithuanian studies, such as the use of different caries recording criteria: the German study employed the ICDAS while the Lithuanian study used the Nyvad criteria. Thus, activity status of the lesions rather than the lesion depth was considered in the Lithuanian children when evaluating treatment success. Particularly, this was important in the NRCT group as the lesion transition from active to inactive and, remaining inactive at two examination sessions were regarded as successful outcomes. Most of the successful outcomes (lesion arrest) occurred within the first year of the follow-up indicating a 50 % probability in preventing lesion progression by merely exposing its surface to mechanical cleaning and daily use of fluoride toothpaste. Fluoride toothpaste is well-established for controlling dental caries [22], but NRCT outcomes may have been influenced by behavioral factors like adherence to home care, which was not assessed in either the Lithuanian or German. As suggested by Hansen and Nyvad [14] lack of compliance with preventive interventions including high quality, regular toothbrushing at home, was associated with failed NRCT. Although the caries preventive efficacy of the NaF varnish is well-documented [23], its superiority in arresting active caries lesions remains debatable. A 30-month clinical trial involving Chinese pre-school children, found no significant effect of regularly applied (4 times per year) 5 % NaF varnish in arresting dentine caries in anterior primary teeth, though it did prevent development of new lesions [24]. Moreover, the preventive fractions of 5 % fluoride varnish application in the primary dentitions seem to fall within the same range, regardless of the frequency of application throughout the year [25]. An meta-analysis of nonrestorative caries treatments also found limited effectiveness of 5 % NaF varnish in arresting caries lesions on approximal surfaces although the concept of exposing the lesions to mechanical cleaning was not considered [26].

The HT approach using preformed metal crowns to seal the lesions proved superior in this study, with considerably lower failure rates than NRCT and CR. These findings align with earlier studies reporting HT high success rates of 92–100 % [12,13,27,28,29] and support a general notion about HT resulting in lower treatment failure rates in primary dentition than other minimally invasive techniques [7,30].

Regarding acceptability of the treatment procedure, several clinical trials have shown that the Hall technique is either superior to or, equally acceptable as conventional restorations, from both patients' and dentists' perspectives [10,31,]. The present results partly support this showing no significant differences in children's behaviour across the three treatment modalities. However, unlike Santamaría et al. [32], we found that pain perception differed between CR and NRCT, with more children being comfortable with CR. Still, most participants (77–90 %) reported very low or low pain levels, with the statistical difference arising from four NRCT participants reporting some pain. Dentists' opinions differed on the technical aspects of the procedures, rating CR as the most time-consuming, and HT as more complex and less comfortable compared to the other two techniques. This again, aligns with Santamaría et al. [32] who found CR the least favourable in terms of duration and ease of performance. The authors mentioned the CR group being slightly younger while the participants in the present study were equally distributed between the study groups, by age. The reported technical difficulties in applying the HT may be attributed to the operators' limited experience as this technique is still rarely used in Lithuania.

Overall, all three treatment techniques were generally well accepted by the participants, their parents and the dentists involved in the present study. While the small numbers of the participants in each treatment arm made the percentage of the less positive responses seem significant, only a few individuals contributed to it. Thus, the study suggests that all types of caries treatments can be well tolerated by both patients and care providers, although individual factors such as the patient's temperament, emotional state, past treatment experiences, and dentist communication etc., may affect treatment success [33]. Within the limitations of this study, we conclude that minimal intervention techniques, especially sealing caries with stainless steel pre-formed crowns (HT), offer effective management of dental caries in the primary molars. The longevity and success rate of HT exceeding 90 % over two years, is significantly higher than that of other techniques.

The conventional restorations using glass ionomer cement did not perform well in the present study, with failure rates reaching as high as 39 % after two years. Notably, most restorations were performed without local anaesthesia and rubber dam application as children refused these options. Evidence shows that the success of restorative treatments varies significantly across different settings and depends on several factors, including the type of materials chosen, the restoration technique and individual patient characteristics [34]]. This is crucial for clinical practice, and recent recommendations to incorporate minimal intervention techniques in the management of carious primary teeth as a standard approach should be considered [35].

For NRCT, from first principles, it should have the potential to

prevent progression of the lesions when ~~proper~~ adequate access to mechanical plaque disruption and fluoride is provided. However, occasional application of topical fluorides, and uncontrolled toothbrushing with fluoride toothpaste does not provide the desirable result and cannot replace restorative procedures, even though the conventional treatment failed in 40 % of the cases in a two-year term as observed in the present study. Like other randomized control studies, our findings support the HT as a successful caries management option for treating dentine carious primary molars. This recommendation is based on the lower incidence of adverse outcomes compared with other management options.

CRediT authorship contribution statement

Julija Narbutaite: Writing – original draft, Investigation, Data curation. **Ruth M. Santamaría:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Nicola Innes:** Writing – review & editing, Methodology, Conceptualization. **Christian H. Splieth:** Writing – review & editing, Methodology, Conceptualization. **Vita Maciulskiene:** Writing – review & editing, Writing – original draft, Methodology, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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