

Children's self-reported discomfort of restorative treatments for deep caries lesions in primary teeth: Results from a randomized clinical trial

Desconforto autorreferido pelas crianças sobre tratamentos restauradores para lesões de cárie profundas em dentes decíduos: Resultados de um ensaio clínico randomizado

Incomodidad autoinformado por los niños de los tratamientos restauradores para las lesiones de caries profundas en los dientes temporales: Resultados de un ensayo clínico aleatorizado

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Abstract

The aim of this study was to evaluate the impact of different restorative techniques to treat deep caries lesions of primary molars on children's self-reported discomfort. A randomized clinical trial with two parallel arms (1:1) was conducted in São Paulo, Brazil. 4-8 years-old children with at least one occlusal or occlusoproximal deep caries lesion in primary molars were selected. Molars were randomly allocated into two groups: (1) restoration performed with calcium hydroxide cement followed by high-viscosity Glass Ionomer Cement (CHC+HVGIC), and (2) HVGIC restoration. Immediately after the intervention, children reported the experienced discomfort during restoration to an external examiner using a Wong-Baker face-scale. Children's self-reported discomfort was analyzed using Poisson regression comparing both groups and assessing other variables' influence ($\alpha=5\%$). One hundred and eight children fulfilled the eligibility criteria and were randomized in the two groups ($n=54$). Most of the children who received CHC+HVGIC restorations reported none or minimal discomfort (83.3%). Similar scores (92.6%) were reported for those treated with HVGIC ($p=0.758$). The mean reported discomfort in children with CHC+HVGIC restorations was 0.37(1.01), and 0.41(1.01) for those with HVGIC restorations. Children's self-reported discomfort was associated with age, sex, children's cooperation, and intervention duration. We can conclude that CHC+HVGIC or HVGIC restorations result in none or minimal discomfort in the management of deep caries lesions, being considered a reliable option.

Keywords: Pain perception; Glass ionomer cements; Patient reported outcome measures; Tooth, deciduous.

Resumo

O objetivo deste estudo foi avaliar o impacto de diferentes técnicas restauradoras para tratar lesões de cárie profundas em molares decíduos no desconforto relatado pelas crianças. Um estudo clínico randomizado com dois braços paralelos

(1:1) foi conduzido e, São Paulo, Brasil. Crianças de 4 a 8 anos com pelo menos uma lesão de cárie oclusal ou oclusoproximal profunda em molares decíduos foram selecionadas. Os molares foram alocados aleatoriamente em dois grupos: (1) restauração realizada com cimento de hidróxido de cálcio seguida de cimento de iônomo de vidro de alta viscosidade (CHC+CIVAV), e (2) restauração de CIVAV. Imediatamente após a intervenção, as crianças relataram seu desconforto durante a técnica restauradora a um examinador externo utilizando a escala de faces de Wong-Baker. O desconforto autorreferido pelas crianças foi analisado usando regressão de Poisson comparando ambos os grupos e avaliando a influência de outras variáveis ($\alpha=5\%$). Cento e oito crianças preencheram os critérios de elegibilidade e foram randomizados nos dois grupos ($n=54$). A maioria das crianças que receberam restaurações de CHC+CIVAV relatou mínimo ou nenhum desconforto (83,3%). Escores semelhantes (92,6%) foram reportados pelas crianças tratadas com restauração de CIVAV ($p=0,758$). A média de desconforto das crianças para CHC+CIVAV foi de 0,37(1,01), e 0,41(1,01) para aquelas do grupo de restauração de CIVAV. O desconforto autorreferido pelas crianças foi associado com a idade, sexo, cooperação das crianças e tempo de intervenção. Nós podemos concluir que CHC+CIVAV ou restauração de CIVAV resultam em mínimo ou nenhum desconforto para o manejo das lesões de cárie profunda, podendo ser considerado como uma opção confiável.

Palavras-chave: Percepção de dor; Cimentos de ionômeros de vidro; Medidas de resultados relatados pelos pacientes; Dente decíduo.

Resumen

El objetivo de este estudio fue evaluar el impacto de diferentes técnicas restauradoras para el tratamiento de lesiones cariosas profundas en molares primarios sobre las molestias reportadas por los niños. Se realizó un ensayo clínico aleatorizado con dos brazos paralelos (1: 1) en São Paulo, Brasil. Se seleccionaron niños de 4 a 8 años con al menos una lesión de caries oclusal u oclusoproximal profunda en molares temporales. Los molares se asignaron al azar en dos grupos: (1) restauración realizada con cemento de hidróxido de calcio seguida de cemento de ionómero de vidrio de alta viscosidad (CHC + CIVAV), y (2) restauración CIVAV. Inmediatamente después de la intervención, los niños informaron su malestar durante la técnica de restauración a un examinador externo utilizando la escala facial de Wong-Baker. El malestar autoinformado de los niños se analizó mediante regresión de Poisson comparando ambos grupos y evaluando la influencia de otras variables ($\alpha = 5\%$). Ciento ocho niños cumplieron con los criterios de elegibilidad y fueron asignados al azar en dos grupos ($n = 54$). La mayoría de los niños que recibieron restauraciones de HCC + CIVAV informaron un malestar mínimo o nulo (83,3%). Los niños tratados con restauración CIVAV informaron puntuaciones similares (92,6%) ($p = 0,758$). El malestar medio de los niños por CHC + CIVAV fue de 0,37 (1,01) y 0,41 (1,01) para los del grupo de restauración de CIVAV. La incomodidad autoinformada de los niños se asoció con la edad, el género, la cooperación de los niños y el tiempo de intervención. Podemos concluir que la restauración de CHC + CIVAV o CIVAV resulta en una incomodidad mínima o nula para el manejo de las lesiones cariosas profundas y puede considerarse como una opción confiable.

Palabras clave: Percepción del dolor; Cementos de ionómero vítreo; Medición de resultados informados por el paciente; Diente primario.

1. Introduction

Although new studies have pointed to a reduction in the prevalence of dental caries in childhood (Srisilapanan et al., 2017; Jones et al. 2018), a systematic review reported that more than half of children are still affected by this disease (Gimenez et al., 2016), resulting in a negative impact on the quality of life of children (Abanto et al., 2014; Gradella et al., 2011), especially when in presence of extensive lesions with dentine involvement (Guedes et al., 2016a; Mickenautsch et al., 2016).

Cavitated caries lesions also present a higher risk of progression to more severe conditions, which could evolve to endodontic treatment needs or even to tooth loss (Guedes et al., 2016b). In addition to the pain and aesthetics impairment (Gomes et al., 2021), the presence of cavitation can result in discomfort during mastication, leading to a children's preference for a soft and cariogenic diet. Besides, the presence of cavities turns oral hygiene difficult to perform, resulting in biofilm accumulation. Therefore, the management of severe/cavitated caries lesions is essential.

Minimizing discomfort, anxiety, and fear of pediatric patients is one of the proposals for minimally invasive treatments (Rao & Malhotra, 2011; Walsh et al., 2013). Previous studies have focused on alternative restorative techniques for cavitated caries lesions as auxiliaries to reduce children's discomfort (Kumar et al., 2012; Eren et al., 2013). Atraumatic restorative treatment (ART), which requires fewer clinical steps, as no necessity of rubber dam isolation, and local anesthesia in most cases, is one of the main approaches that show higher acceptability of the patients (Leal et al., 2009).

Deep caries lesions, conversely, are conventionally still treated with indirect pulp capping, especially in permanent teeth, preconizing the use of biocompatible materials to protect the dentine-pulp complex (Thompson et al., 2008). In primary teeth, studies have shown that an inert material or restoration with resin-modified glass ionomer cement or adhesive systems associated with resin composites presents a similar dentine response than a restoration with a pulp capping material - calcium hydroxide cement (CHC) (Thompson et al. 2008, Casagrande et al., 2010; Kotsanos & Arizos, 2011). However, the use of high viscosity glass ionomer cement (HVGIC) on the ART, a less time-consuming material during the restorative treatment in primary teeth, since it does not require absolute isolation (Frencken et al., 1996), has not been included in studies that evaluated the impact of restorative techniques in maintaining the pulp vitality.

Moreover, the Food and Drug Administration (FDA) recently recommended the use of patient-reported outcomes (PROs) for the conduction of research studies. PROs are useful to reflect a variety of information directly reported by the patient as self-perceptions regarding the consequences of a disease or its treatment. Such outcomes should be evaluated to allow a more effective and appropriate management decision for each individual (Snyder et al., 2013). Therefore, the inclusion of PROs, as self-reported discomfort, is important and should also be considered in studies that look for the best management options for deep caries lesions.

Thus, this study aims to evaluate the children's self-reported discomfort after different restorative techniques in the management of deep caries lesions, as a patient-centered outcome. Our hypothesis was that self-reported discomfort is not influenced by the restorative technique, i.e., the HVGIC restoration does not influence the children's self-reported discomfort when compared to restorations with CHC associated with HVGIC.

2. Methodology

Study design and ethical approval

This study reports a secondary outcome from a non-inferiority randomized, controlled, double-blind (participant and examiner) clinical trial with two parallel arms (1:1 allocation rate), in which the primary outcome is the pulp vitality. It was performed at the Paediatric Dentistry Clinic - Ibirapuera University, Sao Paulo, Brazil. Ethical approval was obtained from the local ethics committee from the Faculty of Dentistry - Ibirapuera University (protocol #1.670.059), and the protocol was registered in the database for registration of clinical studies (ClinicalTrials.gov Registration number NCT02903979) and published (da Silva et al., 2019). This paper was reported according to the Consolidated Standards of Reporting Trials (CONSORT) guideline. Participants were included after their legal guardians' informed consent form signature. Children also nodded their participation.

Sample Size

The sample size calculation was conducted for the primary outcome - the pulp vitality using calcium hydroxide cement as pulp capping material (da Silva et al., 2019). Power of test was performed for this secondary outcome. Considering 54 teeth per group, the proportion of patients in both groups that reported none or minimal discomfort (score 0) and a clinically significant difference of 10% between groups, a final power of 99% was obtained.

Participant screening and eligibility assessment

Participants from 4 to 8 years old were selected from the Clinic of Paediatric Dentistry - Ibirapuera University, Sao Paulo, Brazil in the period of November 2016 to April 2018. The screening was carried out under natural light and a wooden spatula. Potentially eligible children were referred for clinical examination.

The inclusion criteria included children from 4 to 8 years old with at least one primary molar with a deep cavitated caries lesion on the occlusal/occlusoproximal surfaces. On the other hand, the exclusion criteria included children with special needs; using orthodontic devices; with systemic conditions that may influence the oral cavity; teeth presenting pulp exposure, spontaneous pain, mobility, abscess or fistula near the tooth; and teeth already restored, with sealants or enamel developmental defects.

Initial bitewing radiographs were also taken to confirm the lesion depth as well as to exclude teeth with possible pulpal involvement. A deep caries lesion was defined like that in the inner third of the dentine on the radiography.

Children with eligible teeth were examined for caries experience and oral hygiene. Caries experience was determined according to WHO criteria - decayed, missing, and filled primary teeth (dmf-t) and permanent teeth (DMF-T). The cut-off point considered the mean of dmf of Brazilian children with 5-year old (2010), being $dmf-f+DMF-T < 3$ or $dmf-t+DMF-T \geq 3$. Oral hygiene was considered in accordance with the Greene and Vermillion index as good, regular, or bad.

Randomization and allocation concealment process

Included teeth were allocated in two parallel arms: 1) Test group – High Viscosity Glass Ionomer Cement (HVGIC) restorations, and 2) Control group - restorations with calcium hydroxide cement associated with HVGIC (CHC + HVGIC). Teeth were randomly assigned into one of the groups considering the type of cavity as strata – occlusal or occlusoproximal surfaces, according to a sequence obtained by an external researcher in a specific website www.sealedenvelope.com. The generated sequence was distributed in opaque sealed envelopes, which were opened by dental assistants immediately before procedures.

Restorative procedures

Two operators were previously trained to perform both techniques (restoration with HVGIC – test group, and restoration with CHC associated with HVGIC – control group) through theoretical lectures and laboratory activities (three hours each). Due to the evident differences between techniques, blinding of operators was not possible to achieve.

Then, trained operators performed both treatments in accordance with the allocation of teeth. For the test group, teeth received initial prophylaxis, relative isolation, and selective caries removal – removing to soft dentin from the pulp wall and complete removal of the surrounding walls, using sharp spoon excavator compatible with cavity size. In occlusoproximal cavities, the dental metal matrix was used. After, the surface was conditioned with polyacrylic acid for 10 seconds, followed by washing and drying. Then, HVGIC (Fuji IX; GC Corporation, Tokyo, JP) was mixed according to the manufacturer's instructions, inserted into the cavity with an insertion spatula, and adapted by digital pressure. Occlusion was checked with carbon paper and, if necessary, adjustment was performed. Finally, restoration's superficial protection with petroleum jelly was conducted to avoid syneresis and imbibition. For the control group, the same procedure was followed but applied pulp capping material (Hydro C; Dentsply Sirona, Pennsylvania, USA) as a liner on the pulp wall. Then, restoration with HVGIC was placed as previously mentioned for the test group.

Teeth with carious lesions, not included in the study, were treated according to their diagnosis and severity by participants of CEPECO collaborative group (da Silva et al., 2019). Furthermore, all participants and their respective legal guardians received oral hygiene and diet instructions.

Outcome measures

A dental assistant asked children about the discomfort experienced during the treatment immediately after the procedure was completed. For this purpose, the Wong-Baker face scale (Wong & Baker, 1988) was used. Children pointed to the image that represented their level of discomfort after the following question: How did you feel during treatment?

Immediately after the restorative procedure, the operator indicated the children's cooperation with restorative treatment as a binary variable – yes or not. The time spent per intervention was measured by a dental assistant in seconds.

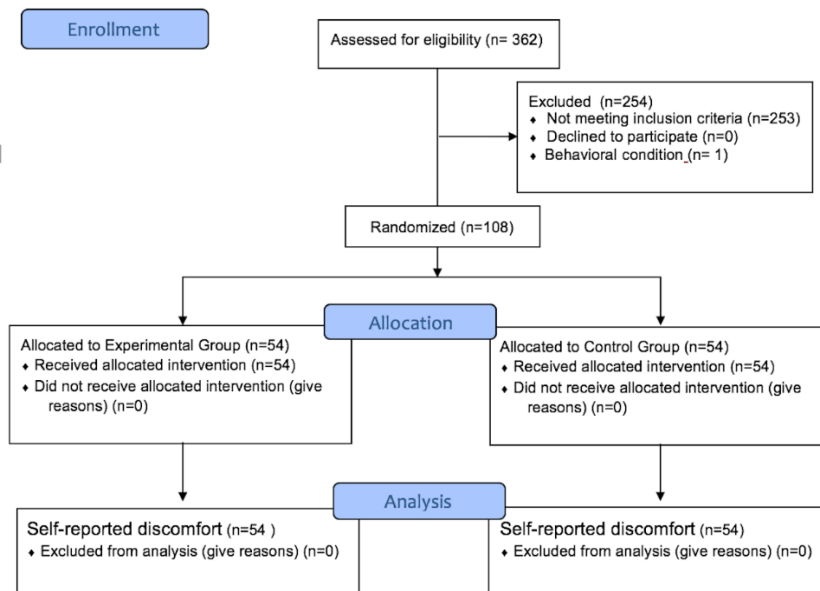
Statistical analysis

A Chi-square test was used to compare the baseline characteristics of the participants between the groups. Children's self-reported discomfort was analysed using Poisson regression comparing both groups and assessing other variables' influence (treatment group, sex, age, time spent in the intervention, and children's cooperation reported by dentists). The unit of analysis was the tooth, i.e., each child could contribute with more than one tooth. First, unadjusted Poisson regression analysis was performed per explanatory variable. Then, variables showing a $p < 0.20$ were included for the adjusted Poisson regression model. The final model only included variables showing $p \leq 0.05$. Prevalence ratios (PR) were calculated with a 95% confidence interval (CI). A one-way Analysis of variance was performed to compare spent times in the interventions. A significance value of 5% was adopted for all analyses.

3. Results

Three hundred and sixty-two (362) children were initially screened. Only 108 fulfilled the inclusion criteria and, therefore, were included in this trial. Participants were randomly allocated to receive HVGIC (n=54) or CHC+HVGIC (n=54). The participants' flow chart is presented in Figure 1.

Figure 1: Flow diagram of eligibility criteria and randomization process.



Source: Authors.

Baseline characteristics of the included participants are displayed in Table 1. Most of included children were female (54.8%), with high caries experience (89.9%) and poor oral hygiene (56.5%).

Table 1: Participants' baseline characteristics.

Characteristics		CHC + HVGIC	HVGIC	p value
Sex	Female	28	29	0.847
	Male	26	25	
Caries experience	dmf-f+DMF-T<3	6	5	0.750
	dmf-f+DMF-T≥3	48	49	
Oral Hygiene	Good: 0.0 – 0.6	11	8	0.598
	Regular: 0.7-1,8	15	13	
	Bad: 1.9-3.0	28	33	

Source: Authors.

After restorative procedures, most of the children in the CHC+HVGIC group reported none or minimal discomfort (score 0) (83.3%). A similar percentage was found in children belonging to the HVGIC group (92.6%). The mean of children's discomfort in the CHC+HVGIC group was 0.37 (± 1.01), whilst for the HVGIC group was 0.41 (± 1.01) ($p=0.758$). Spent time for the restorative procedures showed no statistical differences between CHC+HVGIC (576.0 ± 163.1 s) and the HVGIV group (541.4 ± 167.1 s) ($p=0.279$).

Table 2 displays the Poisson regression results. In the unadjusted analysis, children's self-reported discomfort was associated with age, sex, children's cooperation, and time of intervention. After adjustment, all these variables were significantly associated with the children's self-reported discomfort and were maintained in the final model. Participants from 4 to 5-years old had a four times higher rate of discomfort than older participants (4.215; 95%: 1.906-9.318). Increased time of intervention was also associated with increased children's self-reported discomfort (1.006; 95%: 1.003-1.008). Conversely, females had a lower rate of discomfort than male participants (0.342; 95%: 0.160-0.734). Cooperating children had lower levels of discomfort (0.376; 95%: 0.183-0.772).

Table 2: Poisson regression analysis between children's self-reported discomfort and independent variables.

Variables		N (%)	Self-reported discomfort			
			Unadjusted RR (95% CI)	p value	Adjusted RR (95% CI)	p value
Groups	CHC + HVGIC	54 (50)	0.909 (0.496-1.666)	0.758		
	HVGIC	54 (50)				
Age	4-5	44 (40.7)	2.364(1.268-4.406)	0.007 ϕ	4.215(1.906-9.318)	0.000
	6-8	64 (59.3)				
Sex	Female	57(52.8)	0.280 (0.137-0.569)	0.000 ϕ	0.342 (0.160-0.734)	0.006
	Male	51(47.2)				
Surface	Occlusal	54 (50)	0.680 (-1.002-0.230)	0.220		
	Occlusoproximal	54 (50)				
Jaw	Upper	48 (44.4)	0.937 (0.509-1.727)	0.836		
	Lower	60 (55.6)				
Children's cooperation dentist-reported	Yes	87(80.6)	0.434 (0.231-0.817)	0.010 ϕ	0.376 (0.183-0.772)	0.008
	No	21(19.4)				
Time of active intervention	Mean (SD)	558.70 (165.24)	1.003 (1.001-1.005)	0.001 ϕ	1.006 (1.003-1.008)	0.000

ϕ Variables considered in the adjusted analysis. Source: Authors.

4. Discussion

This study, focusing at a patient-centred outcome, aimed to investigate which would be the most appropriate restorative approach for treating deep carious lesions in primary molars from the perspective of patients' self-reported discomfort. Although

there is a fewer number of clinical steps in the HVGIC restoration without a layer of a pulp capping material in deep cavities lesion of primary teeth, no influence on children's self-reported discomfort was observed between restorative techniques.

Minimally invasive treatments aim to reduce discomfort and decrease anxiety and fear of paediatric patients (Rao & Malhotra, 2011; Walsh & Brostek, 2013). Pain and discomfort are frequently reported by patients undergoing restorative procedures (Lindsay et al., 1984; Litt, 1996). However, both restorative techniques here proposed seemed to minimize children's discomfort, since 83.3% of participants receiving CHC+HVGIC restorations and 92% HVGIC reported none or minimal discomfort. These findings can be associated with the shorter working time/ fewer clinical steps required for both techniques when compared to conventional restorative treatment, as previously reported, since they do not need local anaesthesia and/or absolute isolation (Goud et al., 2012; Ladewig et al., 2018)). These hypotheses may also explain higher discomfort more often reported when longer procedures are performed.

Notwithstanding, these results should be carefully taken since discomfort assessments are subjective measures and may consider the acceptability of the whole procedure (i.e. from the beginning of the patient's care to the final restoration, not just the restorative technique itself). However, the use of the Wong-Baker scale has been used in many studies and seems to be an effective measure for the evaluation of such outcomes (Wong & Baker, 1988; Novaes et al., 2012; Mattos-Silveira et al., 2015; Pascareli-Carlos et al., 2021).

Uncooperative children reported more discomfort. This, in fact, was expected since clinical time is extended when treating this kind of patient, needing the performance of behavior management techniques (Mattos-Silveira et al., 2015; Santamaria et al., 2015). These findings are in accordance with a previous study showing that complex techniques, with more clinical steps, may have interfered in participants' perception about treatments since they resulted in longer clinical sessions (Mattos-Silveira et al., 2015).

Participants' age is a key point to analyze. Immaturity related to age and its difficulty to establish acceptable communication and comprehension are also factors that influence reported discomfort during restorative procedures (Santamaria et al., 2015). This can explain the findings of this study since younger participants reported higher discomfort. Age increase enlarges the children's ability to understand and comprehend, allowing a better and easier dental approach and, consequently, decreasing dental fear and anxiety (Santamaria et al., 2015). Nevertheless, the type of cavity – occlusal or occlusoproximal – did not influence children's self-reported discomfort, even though the occlusoproximal cavities need to use a metal matrix and dental interproximal wedges that could result in negative acceptability of the patient.

The limitation of this study was the tooth to be considered as a unit of analysis. Thus, the same child could collaborate with more than a tooth. Since that this study focused on a patient-centered outcome, a previous restoration could impact the answer of the child. However, this is a secondary outcome from a randomized controlled trial and all planning of study was made for the primary outcome. We tried to reduce the possible influence of a previous restoration in participant answers treating one tooth per consult.

Considering a patient-centered outcome, both restorative techniques, here assessed, result in none or minimal discomfort in managing deep caries lesions and could be considered reliable options. However, it is worth highlighting that this study was designed to compare two restorative techniques concerning pulp vitality as its primary outcome, considering discomfort as a secondary outcome. Thus, considering that the deep carious lesions treatment results in a challenge for the dentist Thompson et al., 2008; Bergenholtz et al., 2013), especially in pediatric dentistry, authors suggest the conduction of new studies designed to assess the best choice to treat such lesions, including patient-centered outcomes, such as experienced discomfort, and treatment acceptability and satisfaction [da Silva et al., 2019; Santamaria et al., 2015). The treatment choice based on the patient's report is of supreme importance since it is an FDA recommendation (Snyder et al., 2013).

5. Conclusion

The application of a layer of a pulp capping material before restoration of the deep cavity does not influence the children's self-reported discomfort. CHC+HVGIC or HVGIC restorations result in none or minimal discomfort in the management of deep caries lesions and could be considered as reliable options.

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