

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
FACULDADE DE ODONTOLOGIA
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA
ÁREA DE CONCENTRAÇÃO CLÍNICA ODONTOLÓGICA/ ODONTOPEDIATRIA

**INFLUÊNCIA DA TÉCNICA DE ISOLAMENTO NA SOBREVIVÊNCIA DE
RESTAURAÇÕES REALIZADAS EM MOLARES DECÍDUOS: ESTUDO
CLÍNICO RANDOMIZADO CONTROLADO**

SABRINA WILDE

Porto Alegre

2020

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**Tese apresentada à Faculdade de Odontologia da
Universidade Federal do Rio Grande do Sul –
UFRGS, como requisito parcial à obtenção do título
de Doutor em Odontologia, Área de Concentração
Clínica Odontológica / Odontopediatria.**

Orientador: Prof. Dr. Jonas de Almeida Rodrigues

Porto Alegre

2020

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RESUMO

O objetivo desse estudo clínico randomizado controlado foi comparar as taxas de sobrevida de restaurações oclusais e ocluso-proximais realizadas com cimento ionômero de vidro modificado por resina (CIVMR) em molares decíduos sob isolamento absoluto e isolamento relativo. Além disso, objetivou-se a avaliação da paralisação clínica e radiográfica das lesões, bem como presença de sintomas pulpares. Foram selecionados pacientes entre 3 a 9 anos que procuraram atendimento na Faculdade de Odontologia da UFRGS e que apresentaram pelo menos uma lesão de cárie oclusal ou ocluso-proximal em molar decíduo, para qual o tratamento restaurador estivesse indicado. Os dentes foram aleatoriamente alocados em dois grupos: isolamento absoluto (teste) e relativo (controle). Um número amostral de 100 dentes foi calculado por grupo (total de 200 dentes). Foi realizado exame clínico inicial, momento em que se registrou os índices de placa visível (IPV) e de sangramento gengival (ISG), além do registro visual e radiográfico das lesões de cárie com relação a extensão/severidade e atividade. Os dentes incluídos no grupo teste foram restaurados com CIVMR (RIVA Light Cure – SDI, Victoria, Austrália) sob isolamento absoluto e os dentes incluídos no grupo controle foram restaurados com CIVMR sob isolamento relativo. Todas as restaurações foram realizadas após remoção seletiva de tecido cariado por dois operadores (CSS e NMS). Após 6 meses do tratamento restaurador, os mesmos exames foram realizados, além de exame radiográfico e avaliação das restaurações de acordo com os critérios do USPHS, realizado por um examinador calibrado e cego. Nesta consulta foi registrada a progressão/paralisação clínica e radiográfica da lesão e a presença de sintomas pulpares. O nível de desconforto do paciente foi avaliado pela escala de classificação da dor de Wong-Baker (WB) antes e após o procedimento. Os resultados de IPV, ISG e do exame visual foram apresentados na forma descritiva e associados com as falhas restauradoras encontradas (regressão de Cox). Para analisar as diferenças da sobrevida das restaurações entre os grupos, usou-se o método de Kaplan-Meier. O teste de long-rank foi utilizado para comparar as taxas de sucesso dos grupos isolamento absoluto e isolamento relativo. Todas as análises foram realizadas considerando-se um nível de significância de 5%, utilizando um software estatístico adequado. Uma radiografia interproximal padronizada foi realizada após 6 meses e a lesão foi classificada como 'progressão' ou 'paralisação'. Dos 179 dentes (92 sob isolamento relativo e 87 sob isolamento absoluto) avaliados no acompanhamento de 6 meses, nenhuma progressão de lesão foi observada radiograficamente. A taxa geral de

sucesso do tratamento foi de 85,47% (83,47% para o isolamento relativo e 87,35 para o isolamento absoluto). Não foi observada diferença significativa entre os tratamentos no teste log-rank ($p = 0,16$). A regressão de Cox não mostrou fatores de risco associados à falha ($p = 0,04$). Concluiu-se que o isolamento absoluto não aumentou as taxas de sobrevida das restaurações utilizando CIVMR, nem paralisou lesões de cárie dentinária em molares decíduos após 6 meses de acompanhamento.

Palavras-Chave: Cárie dentária; análise de sobrevida; dentes decíduos.

ABSTRACT

The aim of this randomized controlled clinical trial was to compare survival rates of occlusal and occlusal-proximal restorations performed with resin-modified glass ionomer cement (RMGIC) in deciduous molars under rubber dam and cotton rolls isolation. In addition, the objective was to evaluate the clinical and radiographic arrestment of the lesions, as well as the presence of pulp symptoms. Patients between 3 and 9 years who sought care at the Clinic of the UFRGS School of Dentistry, aged 3 to 9 years, who had at least one occlusal or occlusal-proximal caries lesion in the deciduous molar and that restorative treatment was indicated were selected. The teeth were randomly allocated into two groups: rubber dam (test) and cotton rolls (control) isolation. A sample number of 100 teeth was defined per group (total of 200 teeth). An initial clinical examination was performed, at which time the visible plaque index (VPI) and gingival bleeding index (GBI) indexes were recorded, besides the visual and radiographic examination of caries lesions regarding extension / severity and activity. The teeth included in the test group were restored with RMGIC (RIVA Light Cure – SDI, Victoria, Australia) under rubber dam isolation according to the selective caries removal (SRC). The teeth included in the control group were restored with RMGIC under cotton rolls isolation according to the SCR technique by two operators (CSS and NMS). The initial examination and the same records were made 6 months after the restorative treatment, besides radiographic examination and restoration assessment according to USPHS criteria, were performed by a calibrated and blinded examiner. In this follow-up appointment the clinical and radiographic progression/arrestment of the lesion as well as the presence of pulp symptoms were recorded. The patient's discomfort was assessed by the Wong-Baker scale before and after the procedure. VPI, GBI and visual examination results were presented descriptively and related to the restorative failures found (Cox regression). To analyze differences in restoration survival between the groups, the Kaplan-Meier method was used. The long-rank test was used to compare the success rates of the rubber dam and cotton rolls groups. All analyzes were performed considering a significance level of 5%, using appropriate statistical software. A standardized interproximal radiograph was taken after 6 months, and the lesion was classified as ‘progressed’ or ‘arrested’. Out of the 179 teeth (92 cotton rolls group and 87 rubber dam group) evaluated at 6-month follow-up,

no lesion progression was observed radiographically. The overall treatment success rate was 85.47% (83.47% for cotton rolls and 87.35 rubber dam group). No significant difference between treatments was observed in the log-rank test ($p = 0.16$). Cox regression showed no risk factors related to failure ($p = 0.04$). It was concluded that the rubber dam isolation does not increase the survival rates of RMGIC restorations nor arrests dentin caries lesions in deciduous molars after 6 months of follow-up period.

Keywords: Dental Caries; Survival Analysis; Tooth Deciduous.

SUMÁRIO

ANTECEDENTES E JUSTIFICATIVA	9
ARTIGO CIENTÍFICO	12
CONSIDERAÇÕES FINAIS	32
REFERÊNCIAS	33

ANTECEDENTES E JUSTIFICATIVA

O declínio na prevalência da doença cárie no mundo tem sido bem documentado. Contudo, estudos recentes relatam que a maioria das lesões de cárie localizam-se nas superfícies oclusais de dentes posteriores, na região de fósulas e fissuras. Os molares decíduos são os principais responsáveis pela experiência de cárie em crianças sendo sua superfície oclusal a mais afetada (HICKS & FLAITSZ, 1998). Além disso, a presença de lesões cavitadas não tratadas exercem um impacto negativo na qualidade de vida em crianças (FERNANDES et al., 2017).

Durante muito tempo, a terapêutica utilizada para tratar lesões de cárie foi o tratamento restaurador após remoção total de tecido cariado. Com o advento da mínima intervenção, o tratamento de lesões diagnosticadas em estágios iniciais no esmalte e/ou dentina, passou a envolver condutas de paralisação do processo cariioso e controle clínico (SCHWENDICKE et al., 2016).

Dessa forma, a remoção seletiva de tecido cariado (RSTC) constitui uma técnica contemporânea realizada durante o tratamento restaurador de lesões de cárie em dentina, exibindo bons resultados na literatura ao longo do tempo. Em contraste à abordagem tradicional, a RSTC envolve a remoção total de tecido cariado das paredes circundantes e remoção seletiva da dentina macia da parede pulpar e posterior restauração da cavidade sob isolamento absoluto (CASAGRANDE et al., 2010; SCHWENDICKE et al., 2016). Sabe-se que após a restauração o processo cariioso não se perpetua no restante do tecido infectado na base da cavidade, devido a ausência de substrato (BJORNDAL & LARSEN, 2000; MALTZ et al., 2002; PINTO et al., 2006; ORHAN et al., 2008; LULA et al., 2009; MALTZ et al., 2012).

Análises clínicas, microbiológicas, radiográficas e laboratoriais mostraram que a dentina cariada remanescente sob a restauração permanece inativa. Há também evidências do aumento da dureza clínica na região da lesão, alteração na sua coloração à semelhança de uma lesão em não-progressão, diminuição da umidade na dentina, redução na infecção bacteriana e aumento da densidade radiográfica (RIBEIRO et al., 1999; BJORNDAL & LARSEN, 2000; SANTIAGO et al., 2005; ORHAN et al., 2008; FRANZON et al., 2009; ALVES et al., 2010; BJORNDAL et al., 2010; MALTZ et al.,

2012). A RSTC também evita a exposição desnecessária de tecido pulpar (MAGNUSSON & SUNDELL, 1977; LEKSELL et al., 1996; ORHAN et al., 2010). As taxas de sucesso na retenção das restaurações não se diferem daquelas encontradas em dentes submetidos à remoção total de tecido cariado (SCHWENDICKE et al., 2013). Uma revisão sistemática realizada por PEDROTTI et al., (2019) mostrou que restaurações em dentes decíduos realizados após remoção seletiva de tecido cariado tem mais risco de falha que àquelas realizadas após remoção total de tecido cariado.

Após a RSTC, a técnica restauradora com resina composta preconiza o uso do isolamento absoluto com o intuito de reduzir a contaminação bacteriana e controlar a umidade (COCHRAN, MILLER & SHELDRAKE, 1989 e LOGUERCIO et al., 2015). O isolamento absoluto é realizado com dique de borracha, grampo dental e arco; comumente é necessário realizar algum tipo de técnica anestésica para amenizar o desconforto (HILL, 2008).

Entretanto, existem percepções negativas sobre o uso do isolamento absoluto. As mais citadas mencionam a aceitação do paciente, maior tempo de cadeira, custo dos materiais e equipamento, treinamento e desconforto do paciente (KOSHY et al, 2002; HILL et al., 2008).

Além do tipo de isolamento, o sucesso do tratamento também depende do material restaurador utilizado. Uma revisão sistemática com metanálise (PIRES et al., 2018) avaliou a sobrevida de restaurações realizadas com diferentes materiais restauradores após RSTC. Não foi observada diferença estatisticamente significativa entre a resina composta e o cimento de ionômero de vidro modificado por resina (CIVMR), os quais apresentaram taxas de sobrevida maiores do que o cimento de ionômero de vidro convencional (quimicamente ativado), sendo que nesta revisão 47,06% dos trabalhos incluídos utilizaram isolamento absoluto. Além disso, é recomendação do fabricante dos CIVMR que se realize o isolamento do campo operatório durante o procedimento restaurador, no entanto o fabricante não especifica qual o tipo de isolamento deva ser indicado. Diante da facilidade de uso e menor tempo clínico, quando se utiliza o CIVMR pode não ser necessário o uso de isolamento absoluto, realizando-se um isolamento relativo com roletes de algodão e sugador (CAJAZEIRA, SABÓIA & MAIA, 2014).

Ao considerar a dentição decídua, um fator extremamente importante no tratamento infantil é o tempo utilizado para realizar o procedimento, bem como o impacto psicológico e o desconforto que um tratamento mais invasivo pode acarretar (FRANZON et al, 2014). Por conseguinte, o uso de isolamento relativo requer menor tempo operatório e diminui o desconforto para o paciente quando comparado ao isolamento absoluto (CAJAZEIRA, SABÓIA & MAIA, 2014). Devido a ausência de estudos em dentes decíduos que avaliem estas variáveis, considera-se inescusável estudar a sobrevida das restaurações de CIVMR realizadas após RSTC sob isolamento relativo em molares decíduos.

Este é o primeiro estudo clínico controlado randomizado em molares decíduos que testou métodos de isolamento para restaurações utilizando CIVMR. A hipótese nula testada foi de que o isolamento do dique de borracha não aumenta as taxas de sobrevivência das restaurações CIVMR, nem tem associação com a paralisação de lesões de cárie dentinária em molares decíduos.

Dessa forma, o objetivo desse estudo clínico randomizado controlado foi comparar as taxas de sobrevida de restaurações oclusais e ocluso-proximais realizadas com cimento ionômero de vidro modificado por resina (CIVMR) em molares decíduos sob isolamento absoluto e isolamento relativo. Além disso, objetivou-se a avaliação da paralisação clínica e radiográfica das lesões, bem como da presença sintomas pulpares.

ARTIGO CIENTÍFICO

Influence of isolation technique on the survival of resin-modified glass-ionomer restorations in primary molars: a randomized clinical trial

Sabrina Wilde¹, Caroline Sarti¹, Julia Toniolo¹, Bethania Paludo Oliveira¹, Daiana Back Gouvea¹, Nicole Marchioro Santos¹, Jonas Almeida Rodrigues¹.

¹Pediatric Dentistry Division, School of Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, Brazil, Department of Cariology, School of Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, Brazil.

Corresponding Author:

Jonas de Almeida Rodrigues

Pediatric Dentistry Division, Faculty of Dentistry

Federal University of Rio Grande do Sul

Rua Ramiro Barcelos, 2492 – Rio Branco - 90035-003

+55 (51) 3308-5176 – Porto Alegre, RS, Brazil

E-mail: jorodrigues@ufrgs.br

ABSTRACT

The aim of this randomized controlled clinical trial was to compare the survival rates of occlusal and occlusal-proximal restorations performed with resin-modified glass-ionomer cement (RMGIC) in deciduous molars under cotton rolls and rubber dam isolation. Besides, this study aimed to assess clinic and radiographic arrestment of lesions as well as pulp vitality of restored teeth. Ninety-two patients were included and two hundred deciduous molars with cavitated dentin caries lesions on the occlusal or occlusal-proximal surfaces were randomized into two groups: cotton rolls (n = 100) and rubber dam (n = 100) in which, after the selective caries removal (SCR) the teeth were restored with RMGIC (RIVA Light Cure – SDI, Victoria, Australia). At baseline and in the follow-up visit, dental caries was registered according to the International Caries Detection and (ICDAS) and caries activity was registered according to a visual-tactile criterion by Nyvad, 2018. Two independent, blinded examiners evaluated the treated teeth using the USPHS criteria after 6 months. A standardized interproximal radiograph was taken after 6 months, and the lesion was classified as ‘progressed’ or ‘arrested’. The patient's level of discomfort during the initial treatment was assessed by the Wong-Backer (WB) scale. A standardized interproximal radiograph was taken after 6 months, and the lesion was classified as ‘progressed’ or ‘arrested’. Out of the 179 teeth (92 cotton rolls group and 87 rubber dam group) evaluated at 6-months follow-up period, no lesion progression was observed radiographically. The overall treatment success rate was 85.47% (83.47% for cotton rolls and 87.35 rubber dam group). No significant difference between treatments was observed in the log-rank test ($p = 0.16$). Cox regression showed no risk factors related to failure ($p = 0.04$). It was concluded that the rubber dam isolation does not increase the survival rates of RMGIC restorations nor arrests dentin caries lesions in deciduous molars after a 6-months follow-up period.

INTRODUCTION

Restorative treatments are performed to aid biofilm control, protect the pulp-dentin complex, and restore the integrity of the dental structure, thereby recovering functional and esthetic needs and causing no unnecessary damage. Carious tissue removal ensures the conditions for a long-lasting restoration, preserves remineralizable tissue, maintains pulp vitality, and achieves an adequate seal¹. Complete carious tissue removal of deep carious lesions has been proven to increase the occurrence of pulpal exposure and postoperative pulpal symptoms compared with selective carious tissue removal^{2,3}. The selective caries removal (SCR) is a contemporary approach for the restorative treatment of deep caries lesions in dentin, showing good results along time^{1,4}. In deep lesions, SCR of soft dentin has been recommended to avoid pulp exposure and allow the placement of a durable restoration¹. Despite the benefits of SCR, evidence regarding survival of restoration in deciduous teeth is limited².

After SCR, the restorative technique with composite resin recommends using rubber dam isolation to reduce bacterial contamination and control humidity⁵. The isolation is made with rubber dam, dental clamp and bow and usually is necessary to perform some kind of anesthetic technique to reduce the discomfort⁶.

Both rubber dam and cotton rolls are currently used in dentistry to isolate the treatment field and to exclude moisture. There are advantages and disadvantages associated with each method from the different points of view of person and dentist. Moreover, several randomized controlled trials have been conducted to determine whether the use of a rubber dam for restorative treatments influences the treatment outcomes^{7,8,9}.

In addition to the type of isolation, the success of treatment also depends on the restorative material used. A systematic meta-analysis review¹¹ assessed the survival of restorations performed with different restorative materials after RSTC. There was no statistically significant difference between composite resin and RMGIC, which had higher survival rates than conventional (chemically activated) glass ionomer cement.

Because of its ease of use and shorter clinical time, when using resin-modified glass-ionomer cement (RMGIC), rubber dam isolation may not be required, using only cottons

rolls isolations and saliva ejector¹⁰. Besides, the manufacturer of RMGIC generally recommends the use of isolation, however any specification is given about rubber dam or cotton rolls. In the study conducted by Carvalho et al (2010)⁷ restorations performed under rubber dam and cotton rolls/saliva ejector had similar survival rates, i.e. the use of rubber dam did not increase the longevity of conventional glass-ionomer restorations in deciduous teeth.

Considering deciduous dentition, an extremely important factor is the time taken to perform the procedure, as well as the psychological impact and discomfort that a more invasive treatment may cause¹². It is unquestionable that, a fundamental responsibility in pediatric dentistry is to provide comfort. Therefore, optimal pain management is critical to achieving this goal. However, without methods for quantitatively assessing pain, it is important to plan appropriate interventions and evaluate their effectiveness¹³.

Therefore, the aim of this randomized controlled clinical trial was to compare the survival of occlusal and occlusal-proximal restorations performed with RMGIC in deciduous molars using rubber dam and cotton rolls isolation. Besides, this study aimed to assess clinic and radiographic arrestment of lesions as well as pulp vitality of restored teeth and the patient's discomfort / acceptance. The null hypothesis tested was that rubber dam isolation does not increase the survival rates of RMGIC restorations nor has an association to the arrestment of dentin caries lesions in deciduous molars.

MATERIALS AND METHODS

Sample size

The sample size calculation was performed based on a previous study⁷ performed in deciduous teeth that evaluated the survival rates of occlusal-proximal atraumatic restorative treatment (ART) restorations placed in deciduous molars using cotton rolls or rubber dam as isolation methods. A sample of 100 teeth was defined by group (200 total teeth), with a power of 80% and level of significance of 5%, accepting a success rate of 61.9% in the cotton rolls isolation group and 80% in the rubber dam isolation group with a 30% sample loss rate.

Participants and recruitment

This randomized controlled clinical trial was conducted according to the CONSORT statement criteria. The treatments were carried out at the Pediatric Clinic in the Federal University of Rio Grande do Sul, School of Dentistry, Porto Alegre, Brazil, after the Local Research Ethics Committee approval (CAAE: 80465617.6.0000.5347). A written informed consent was obtained from all participants and their parents or legal guardians (REBEC Register Number: RBR-8HCG2C).

Between December 2018 and May 2019, 197 children (1576 teeth) aged between 3 to 9 years old seeking dental treatment were evaluated, and 92 (mean age = 6) were included after a complete anamnesis and clinical and radiographic examination. Standardized interproximal radiographs were taken to evaluate the pulp and periapical condition. Clinical examinations were performed by two operators (NMS and CSS) who were trained and calibrated according to the International Caries Detection System (ICDAS) and for caries activity according to visual-tactile criteria proposed by Nyvad (2018). The kappa inter-examiner value was 0,80 and the intra-examiner values were 0,69 (CSS) and 0,83 (NMS).

Inclusion criteria consisted of patients with at least one cavitated occlusal or occlusal-proximal caries lesion in a deciduous molar with a radiographically measurable depth in the outer or inner half of the dentin¹⁵ referred to restorative treatment. The included teeth should also have at least two-thirds of the root visible in the radiography. Patients with spontaneous pain, fistula, and mobility not compatible with the root resorption period and advanced rhizolysis were not included. During the study, patients who did not want to participate any longer or who moved out of the city were excluded.

Randomization and allocation confidentiality

A list of random numbers generated using the site www.randomization.com was used for the randomization process in which the tooth was the unit. The list was in the possession of a third researcher not involved with the clinical assessment or with data analysis and was revealed to the operators only when the child was already in the chair.

Clinical exams and interventions

All patients received prophylaxis prior to treatment and oral hygiene guidance with toothbrush and floss, fluoride dentifrice (1100 ppm F), and dietary counselling. The treatments were performed by two paediatric specialist dentists (CSS and NMS) following the protocol in which the tooth was allocated, as follows:

- Rubber dam group (test): After local anesthesia, the tooth was isolated using rubber dam, Ostby arch, dental floss, and appropriate clamp. The selective caries removal was performed using a slow, new, sterile, and round steel bur, according to the clinical hardness criteria. As proposed by the manufacturer, the Phosphoric Acid (Super Etch 37%, SDI, Victoria, Australia) was applied to the prepared surfaces and leave in cavity for 10 seconds, then rinsed thoroughly with water and the cavity gently air dried. For occluso-proximal cavities, a Tofflemire matrix band n° 1 with a universal Tofflemire matrix retainer was placed (Tofflemire, New York, USA). The restoration was performed with the RMGIC powder/liquid (RIVA Light Cure – SDI, Victoria, Australia) with insertion spatula, following the manufacturer's instructions. Restoration was light cured for 20s using LED light curing unit (Emitter C Schuster – intensity of 1250 mW/cm²). For cavities deeper than 1.8 mm, the material was applied in two layers. Finishing and polishing were carried out with diamond drills and silicone tips.

- Cotton rolls group (control): The tooth was isolated using cotton rolls together with suction to remove excess saliva. The selective caries removal and restorative procedure were performed exactly as done for Test Group. In both groups, the restorations were performed with four hands.

The child was also asked about the discomfort before and after the treatment performed. For this purpose, the Wong-Baker scale¹³ was used. This was showed by the dental assistant, before the procedure and immediately after the end, and the child pointed to the image that represented their level of discomfort after the following question: how are you feeling?

Follow-up assessment and radiographic analysis

Patients returned after 6 months. In this follow-up visit, after prophylaxis with Robinson bristle brushes, the dental caries was assessed according to ICDAS scores and

caries activity was assessed according to the visual-tactile criteria proposed by Nyvad (2018)¹⁴. Two blinded trained and calibrated examiners (JT and SW) evaluated the treated teeth using the USPHS criteria (Table 1)¹⁶. Based on the USPHS criteria, considering the restorative material, Criteria I (retention), III (marginal integrity), VII (postoperative sensitivity according to patient), and IX (secondary caries) were used to evaluate the survival of the treatments. The kappa inter-examiner value was 0,75 and the intra-examiner values were 0,89 (JT) and 0,92 (SW).

A standardized interproximal radiograph was followed up for 6 months. Lesions were classified as ‘progressed’ or ‘arrested’. Tertiary dentin deposition was classified as ‘present’ or ‘absent’.

Outcome

The main outcome variable was the integrity of the intervention material (longevity of the material according to USPHS criteria) and, secondarily, caries arrestment status (absence or presence). Criteria I (C), VII (C), and IX (B) were considered as clinical failure. In these cases, the teeth were submitted to the appropriate treatment (restoration, endodontic, or extraction) and the failure was registered. In cases where a failure occurred in the margin of the restoration with exposure of dentin (III - C), restoration was performed according to the group in which the tooth was allocated to continue to be evaluated. The teeth that presented radiographic progression of the caries lesion were submitted to appropriate treatment (restoration, endodontic, or extraction) and the failure was registered.

Table 1. Criteria used to evaluate USPHS ¹⁶

CRITERIA	TESTE PROCEDURE	USPHS SCORE	
I .Retention	Visual inspection with mirror at 18 inches	Complete retention of the restoration	Alpha
		Mobilization of the restoration, still present	Bravo
		Loss of the restoration	Charlie
II. Colour Match	Visual inspection with mirror at 18 inches	Restoration is perfectly matched for color shade	Alpha
		Restoration is not perfectly matched for color shade	Bravo
		Restoration is unacceptable for color shade	Charlie
III. Marginal integrity	Visual inspection with mirror at 18 inches	Absence of discrepancy at probing	Alpha
		Presence of discrepancy at probing, without dentin exposure	Bravo
		Probe penetrates in the discrepancy at probing, with dentin exposure	Charlie
IV. Marginal discoloration	Visual inspection with mirror at 18 inches	Absence of marginal discoloration	Alpha
		Presence of marginal discoloration, limited and not extended	Bravo
		Evident discoloration, penetrated toward the pulp chamber	Charlie
V. Surface texture	Visual inspection with explorer and mirror, if needed	Surface is not rough	Alpha
		Surface is slightly rough	Bravo
		Surface is highly rough	Charlie
VI. Surface staining	Visual inspection with explorer and mirror, if needed	Surface is not staining	Alpha
		Surface is slightly staining	Bravo
		Surface is highly staining	Charlie
VII. Postoperative sensitivity	Ask patients	Absence of the dentinal hypersensitivity	Alpha
		Presence of mild and transient hypersensitivity	Bravo
		Presence of strong and intolerable hypersensitivity	Charlie
VIII. Gingival bleeding	Visual inspection with explorer and mirror, if needed	Gingival tissues are perfect	Alpha
		Gingival tissues are slightly hyperemic	Bravo
		Gingival tissues are inflammation	Charlie
IX. Secondary caries	Visual inspection with explorer and mirror, if needed	No evidence of caries	Alpha
		Evidence of caries along the marginal of the restoration	Bravo

Statistical Analysis

The Visible Plaque Index (VPI), Gingival Bleeding Index (GBI), and visual examination of caries lesions were presented descriptively. Failures related to treatments were submitted for multivariate logistic regression with shared fragility (Cox regression). The Kaplan-Meier method was used to analyze differences in treatment survival rates between groups. The log-rank test was used to compare group success rates. All analyzes were performed considering a significance level of 5%, using appropriate statistical software (IBM SPSS 20.0).

RESULTS

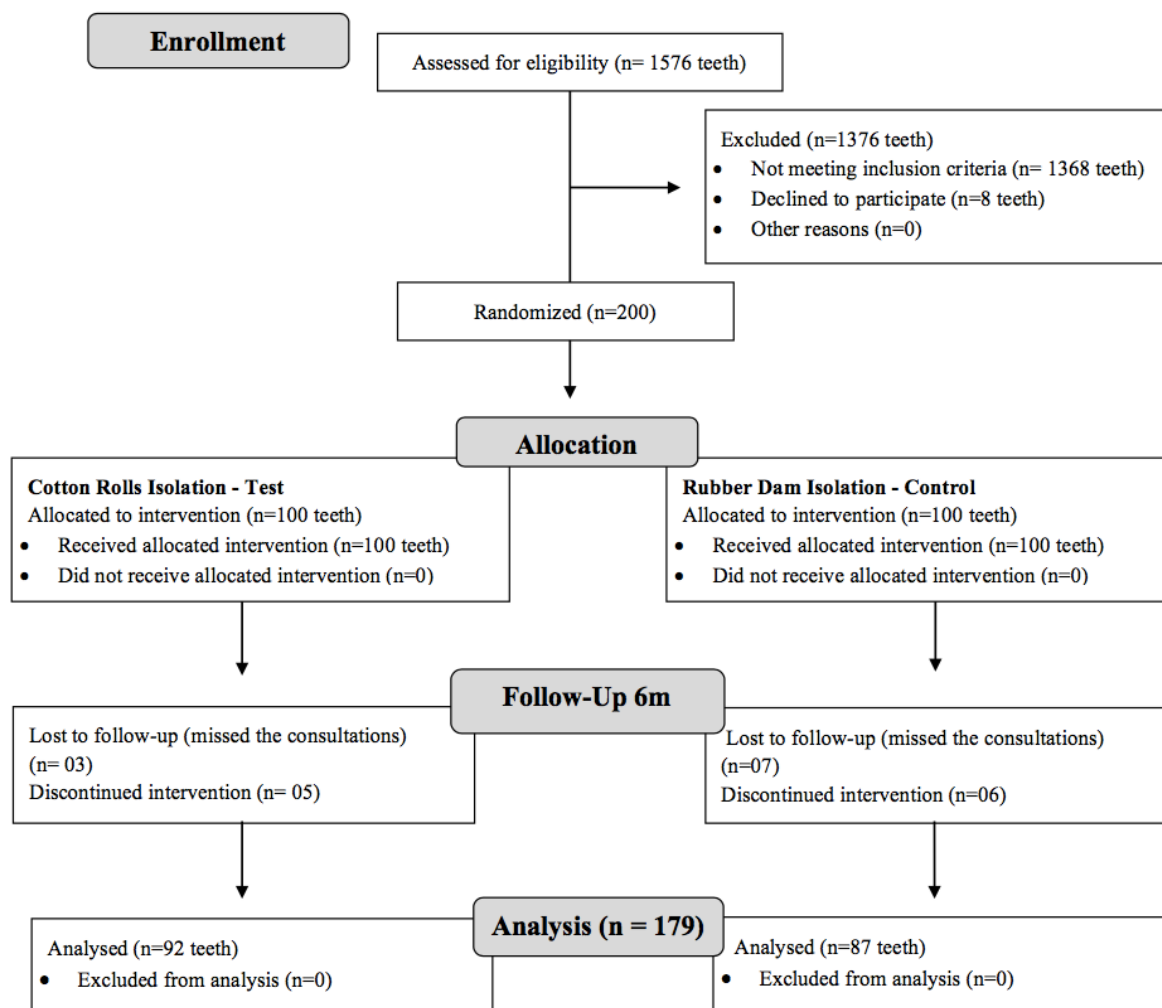
Ninety-two children were included (mean age 6.8 ± 1.37 ; 39 males (42.39%) and 53 females (57.60%)). A total of 200 dentin cavitated lesions were treated (cotton rolls group $n = 100$ and rubber dam group $n = 100$). No difference was observed between the sample characteristics (except for dmf-t and location of the lesion in the arch) as described in Table 2.

Table 2. Sample characteristics according to treatment groups at baseline (Chi-square test; *shows the variables where a statistical significance difference was observed).

		TREATMENT		p value
		Cotton Rolls	Rubber Dam	
Gender	Male	36	34	0.55
	Female	56	53	
VPI	<10%	08	14	0.10
	>11%	84	73	
GBI	<10%	40	36	0.44
	>11%	52	51	
Dmf-t	<3	43	27	0.02*
	>4	49	60	
Age (years)	<6.6	43	44	0.35
	>6.7	49	43	
Restored surfaces	1 surface	57	55	0.49
	2 surfaces	35	32	
Arch	Upper	39	49	0.04*
	Lower	53	38	
Right/Left	Right	49	44	0.41
	Left	43	43	
Molar	1° molar	39	36	0.50
	2° molar	53	51	

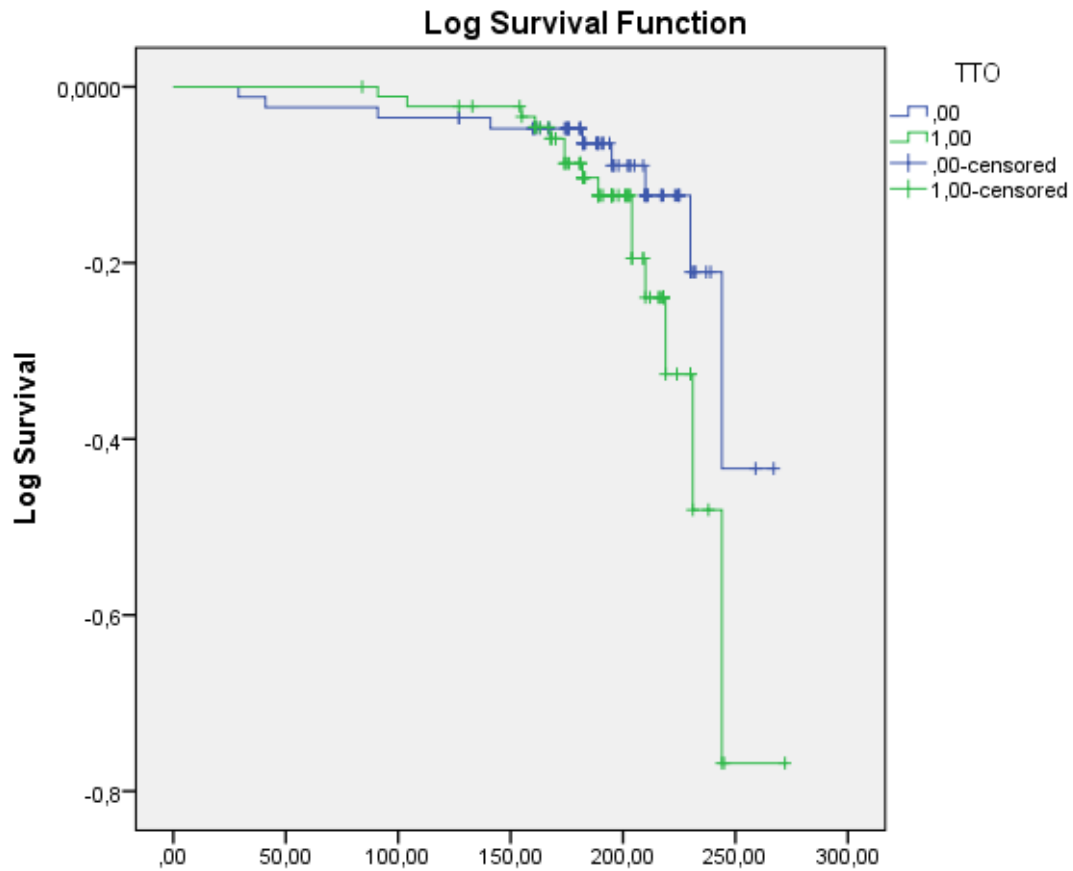
At the 6-month follow-up, 179 teeth (92 cotton rolls and 87 rubber dam) were clinically and radiographically evaluated (89.5% of baseline). The number of children, teeth allocated in each group, and drop-outs at the evaluation period can be observed in the flow diagram (Figure 1).

Figure 1. CONSORT Flow Diagram.



The overall treatment success rate was 85.47% (83.47% for the cotton rolls group and 87.35% for the rubber dam group). Kaplan-Meier survival curve is presented in Figure 2. The log-rank test was not significant ($p = 0.16$).

Figure 2. Kaplan-Meier survival curve.



According to USPHS criteria, there were 4 failures occurred in the cotton rolls group and 5 failures in the rubber dam group according to Criterion I (retention). Three failures occurred in the cotton rolls group, and 1 failure occurred in the rubber dam group, according to Criterion III (marginal integrity). Seven failures occurred in the cotton rolls group and 3 failures in the rubber dam group according to Criterion IX (secondary caries). Postoperative sensitivity (Criterion VII) was not reported by any child of both groups.

Cox regression was used to assess the risk factors related to failure (treatment; age; gender; dmf-t; teeth; location of the lesion, depth, extent of the lesion, VPI and GBI). There was no significant association with the risk factors analyzed (Table 3).

Table 3. Cox regression for risk factors for failure (p=0.05).

Risk Factors		Hazard Ratio (IC 95%)	p value	Hazard Ratio (IC 95%)	p value
Gender	Male	1.00	0.97	-	-
	Female	1.01 (0.44 – 2.32)			
Age (years)	<6.6	1.00	0.79	-	-
	>6.7	0.90 (0.40 – 2.01)			
Treatment	Rubber dam	1.00	0.17	1.00	0.14
	Cotton rolls	0.56 (0.24 – 1.28)			
Restored surfaces	1 surface	1.00	0.16	1.00	0.40
	2 surfaces	0.57 (0.26 – 1.26)			
Arch	Upper	1.00	0.88	-	-
	Lower	1.06 (0.47 – 2.39)			
Right/Left	Right	1.00	0.62	-	-
	Left	1.06 (0.36 – 1.84)			
Molar	1° molar	1.00	0.14	1.00	0.27
	2° molar	1.81 (0.82 – 3.98)			
VPI	<10%	1.00	0.28	-	-
	>11%	1.65 (0.65 – 4.19)			
GBI	<10%	1.00	0.34	-	-
	>11%	1.48 (0.66 – 3.31)			
dmf-t	<3	1.00	0.97	-	-
	>4	0.98 (0.43 – 2.26)			

A paired t test was performed to analyze inter- and intra-group IPV and GBI. There was a statistically significant improvement in the GBI group (p = 0.00). The same test also analyzed the change in behavior in relation to VPI and GBI during the 6 months for each group (rubber dam and cotton rolls). There was a statistically significant improvement for GBI in the rubber dam group (p = 0.00).

Table 4. A paired t-test was performed to analyze the change in behavior regarding VPI and GBI (*shows the variables where a statistical significance difference was observed).

		Paired Differences				Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
					Lower	Upper	
VPI	VPI initial – 6m	-0.05	0.37	0.02	-0.11	0.00	0.05
GBI	GBI initial – 6m	-0.17	0.65	0.04	-0.26	-0.07	0.00*
Dmf-t	Dmf-t initial – 6m	-0.04	0.40	0.03	-0.10	0.01	0.14
Cotton rolls	VPI initial – 6m	-0.01	0.34	0.03	-0.08	0.06	0.76
Cotton rolls	GBI initial – 6m	-0.15	0.67	0.07	-0.29	-0.01	0.03
Cotton rolls	Dmf-t initial – 6m	-0.08	0.43	0.04	-0.17	0.00	0.05
Rubber dam	VPI initial – 6m	-0.10	0.40	0.04	-0.19	-0.01	0.01
Rubber dam	GBI initial – 6m	-0.19	0.62	0.06	-0.32	-0.06	0.00*
Rubber dam	Dmf-t initial – 6m	0.00	0.37	0.04	-0.08	0.08	1.00

The analog scale Wong-Backer was used to assess the degree of discomfort during treatments. Table 5 describes the frequency of sample discomfort levels. The chi square test compared the initial and final WB of the two groups (Tables 6, 7, 8 and 9), with no statistically significant difference in relation to the discomfort levels of the sample (initial $p = 0.10$ and final 0.71).

Table 5. Frequency of sample discomfort levels at the beginning and end of the procedure.

		WBINICIAL			
		Frequency	Percent	Valid Percent	Cumulativ e Percent
Valid	No Hurt	89	49.7	57.4	57.4
	Hurts Little Bit	40	22.3	25.8	83.2
	Hurts Little More	8	4.5	5.2	88.4
	Hurts Even More	12	6.7	7.7	96.1
	Hurts Whole Lot	4	2.2	2.6	98.7
	Hurts Worst	2	1.1	1.3	100.0
	Total	155	86.6	100.0	
Missing	System	24	13.4		
Total		179	100.0		

		WBFINAL			
		Frequency	Percent	Valid Percent	Cumulativ e Percent
Valid	No Hurt	96	53.6	61.1	61.1
	Hurts Little Bit	39	21.8	24.8	86.0
	Hurts Little More	13	7.3	8.3	94.3
	Hurts Even More	2	1.1	1.3	95.5
	Hurts Whole Lot	2	1.1	1.3	96.8
	Hurts Worst	5	2.8	3.2	100.0
	Total	157	87.7	100.0	
Missing	System	22	12.3		
Total		179	100.0		

Table 6. Descriptive table of initial discomfort levels in both groups.

	WB INITIAL						Total
	No Hurt	Hurts Little Bit	Hurts Little More	Hurts Even More	Hurts Whole Lot	Hurts Worst	
Rubber Dam	40	18	5	10	2	0	75
Cotton Rolls	49	22	3	2	2	2	80
Total	89	40	8	12	4	2	155

Table 7. Chi square test comparing the initial WB of the two groups.

Chi-Square Test			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	8.992 ^a	5	0.10
Likelihood Ratio	10.251	5	0.06
Linear-by-Linear Association	1.545	1	0.21
N of Valid Cases	155		

Table 8. Descriptive table of final discomfort levels in both groups.

	WB Final						Total
	No Hurt	Hurts Little Bit	Hurts Little More	Hurts Even More	Hurts Whole Lot	Hurts Worst	
Rubber Dam	44	20	5	1	1	4	75
Cotton Rolls	52	19	8	1	1	1	82
Total	96	39	13	2	2	5	157

Table 9. Chi square test comparing the final WB of the two groups.

Chi-Square Test			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.878 ^a	5	0.71
Likelihood Ratio	3.007	5	0.69
Linear-by-Linear Association	1.082	1	0.29
N of Valid Cases	157		

DISCUSSION

This is the first randomized controlled clinical study in deciduous molars that tested isolation methods for RMGIC restorations. This study showed that the use of rubber dam isolation does not increase the survival rates of RMGIC restorations and did not show an association to the arrestment of dentin cavitated caries lesions. These findings are in accordance with the study of Carvalho et al (2010)⁷, which reported that proximal atraumatic restorative treatment (ART) restorations performed in deciduous molars with rubber dam was not statistically different than with cotton rolls/saliva ejector. Moreover, our results also showed no radiographic lesion progression in both groups.

This clinical trial showed that the survival rate of RMGIC restorations was not influenced by the type of isolation, since no statistically significant difference between the groups was found. According to Carvalho, et al (2010)⁷, saliva contamination is thought to be one of the causes of the low success rate of occluso-proximal restorations. However, the use of rubber dam isolation to avoid saliva contamination during the ART procedure does not significantly improve the survival rate of occluso-proximal restorations on deciduous teeth. The authors also suggest that the possible contamination by saliva is not the determining factor in the failure of ART occluso-proximal restorations. On the other hand, a study that evaluated⁸ the influence of relative and absolute isolation on the survival of proximal ART restorations in deciduous molars with three different types of glass ionomer cements (Fuji IX, Ketac Molar Easymix and Ketac Molar Aplicap). The authors concluded that after two years of follow-up the survival rate of restorations placed under rubber dam isolation was greater than those performed under relative isolation, however, when comparing the isolation technique and the material used, the survival of the restorations showed no difference.

Especially in pediatric dentistry, factors related to the patient can play an important role when considering behavior management. Thus, the survival of the restoration can vary due to different conditions that affect the technique^{17,18}. Poor oral hygiene and increased sugar intake are frequent in high caries risk pediatric patients and can contribute to caries development. As secondary caries or caries adjacent to restorations are subjected to the same factors as primary caries, the difficulty of the dentist or of the patients and their families to change behaviors could contribute to the early failure of restorations in pediatric dentistry. This highlights the need for professionals to work with a health-

promoting approach, which should improve treatment longevity¹⁹. In this study, it was observed that the patients had a significant improvement in the GBI, which is probably linked to the adequacy of the oral environment, and all the dental needs of the patient were performed, in addition to the oral hygiene instruction. Ammann, et al (2013)²⁰ states that the isolation using rubber dam can reduce stress in children and adolescents, as well as treatment time. In our study, we used the WB scale to measure the degree of discomfort and there was no statistically significant difference between initial and final discomfort in the same groups, not even between groups. We can then suggest that the isolation using rubber dam causes no more discomfort than the cotton rolls isolation.

In the present study no primary lesion progression was clinically and radiographically observed in both groups. Concerning failures, the systematic review of Chisini et al (2018)²¹ showed that caries near the restoration was the main reason for failures for composite or for glass ionomer materials, suggesting that the release of fluoride by GIC did not affect the longevity of restorations. This data is in accordance with the present study, where the main reason for failure was dental caries adjacent to restorations (seven failures occurred in the cotton rolls group and 3 failures in the rubber dam group). Besides, occlusal-proximal restorations showed similar risk or failure compared to occlusal restorations. However, a longer period of follow-up is needed to strengthen this evidence.

Regarding the method of assessing restorations, Wang, et al (2016)²² conducted a systematic review to assess the effects of rubber dam isolation compared with other types of isolation used for direct and indirect restorative treatments in dental patients. Three out of 4 studies reported low survival rates. However, it was not possible to group the results to address this information due to the inconsistent presentation of the data, differences in the restorative treatments performed, different monitoring moments or different criteria used to define 'survival / failure' between them. Other systematic review¹⁰, who assessed the influence of the isolation technique on direct restorations, also reported the inconsistency in the assessment of survival of restorations, because the 4 articles selected for analysis, none used the same criteria. This difference in the criteria to determine the success of dental restorations can be considered a problem as pointed out by Chadwick et al (2001)²³ who considered that inconsistencies in the application of clinical criteria could be an important source of bias in clinical trials. In our study, the USPHS criterion was

used to measure the survival of restorations. perhaps if we had used another criterion, we would not have registered so many failures due to the fact that we consider any dental caries injury to be secondary to caries.

It is important to note that the clinical decision must be based not only on the type of isolation, but also assess the degree of experience of the operator, which is probably a related factor in the survival of the restoration. Studies with longer follow-up are needed to assess the survival of restorations.

Considering the results of this clinical study, the rubber dam isolation does not increase the survival rates of RMGIC restorations nor arrests dentin caries lesions in deciduous molars. However, due to mechanical failures, this procedure might implicate more re-interventions. Therefore, closer monitoring of the patient is necessary, and a longer period of follow-up is also needed to confirm these results.

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CONSIDERAÇÕES FINAIS

Não foi observada diferença na sobrevida das restaurações utilizando isolamento absoluto. Sabendo que o CIVMR possui comprovadamente sobrevida semelhante à resina composta, este estudo nos mostra que podemos utilizar o isolamento relativo para restaurações oclusais ou ocluso-proximais em molares decíduos, sendo esta, uma forma de tratamento mais rápida e ao mesmo tempo eficaz. É importante considerar que outros fatores também influenciam a longevidade das restaurações, por isso, é necessário atentar-se àqueles relacionados ao paciente e realizar abordagens adicionais ao tratamento, como instrução de higiene oral e aconselhamento dietético. Além disso, é preciso investigações adicionais, especialmente com tempos de acompanhamento maiores, para chegar a diferentes estratégias que possam aumentar a taxa de sucesso dessas restaurações em programas de saúde bucal.

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