UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
FACULDADE DE ODONTOLOGIA

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INFLUÊNCIA DA REMOÇÃO QUÍMICO-MECÂNICA DO TECIDO CARIADO NO RISCO DE FALHA DE RESTAURAÇÕES: REVISÃO SISTEMÁTICA E META-ANÁLISE

Porto Alegre
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Trabalho de Conclusão de Curso apresentado ao Curso de Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal do Rio Grande do Sul, como requisito parcial para obtenção do título de Cirurgiã-Dentista.

Orientadora: Tathiane Larissa Lenzi
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RESUMO

O presente estudo teve como objetivo revisar sistematicamente a literatura e avaliar criticamente os resultados de ensaios clínicos randomizados que compararam o risco de falha de restaurações após a remoção mecânica e químico-mecânica do tecido cariado. Para isso, uma ampla busca nas bases de dados PubMed/MEDLINE, EMBASE, Scopus, LILACS, Web of Science e Cochrane Central Register of Controlled Trials (CENTRAL) e literatura cinza foi realizada até janeiro de 2022, a fim de identificar estudos relacionados à questão de pesquisa. Dois revisores selecionaram, de forma independente e em duplicata, os estudos de acordo com os critérios de elegibilidade, extraíram os dados, avaliaram o risco de viés e a certeza da evidência. Os critérios de inclusão foram estudos clínicos que investigaram o uso de remoção químico-mecânica de tecido cariado em lesões em dentina coronária de dentes decíduos ou permanentes antes dos procedimentos restauradores. Após leitura de texto na íntegra, foram excluídos os estudos que não apresentaram grupo controle (remoção mecânica do tecido cariado), não utilizaram o mesmo material restaurador em ambos os grupos, que apresentaram período de acompanhamento menor do que 6 meses, taxa de perda amostral ≥ 30%, cujos participantes não foram avaliados da mesma forma e pelo mesmo período e não avaliaram falha restauradora como desfecho. A meta-análise foi realizada através do programa RevMan 5.3, usando um modelo de efeitos aleatórios, para comparar o efeito da remoção químico-mecânica e mecânica na falha restauradora, considerando como subgrupos o tipo de remoção do tecido cariado (seletiva e completa – não seletiva). Dos 443 estudos potencialmente elegíveis após a remoção das duplicatas, 58 foram selecionados para leitura de texto na íntegra e 6 foram incluídos na revisão sistemática. Não houve diferença estatisticamente significante no risco de falha de restaurações realizadas após remoção químico-mecânica e mecânica (p=0,14) seja para remoção completa (p = 0,97) ou seletiva (p = 0,11) do tecido cariado. A heterogeneidade foi nula. O risco de viés foi alto e a certeza da evidência foi baixa. Com base na baixa certeza da evidência, conclui-se que o risco de falha das restaurações realizadas após a remoção químico-mecânica e mecânica do tecido cariado é semelhante. Novos estudos são necessários para que conclusões mais consistentes possam ser feitas.

Palavras-chave: Revisão Sistemática. Cárie Dentária. Falha de Restauração Dentária.

ABSTRACT

The present study aimed to systematically review the literature and critically evaluate the results of randomized clinical trials that compared the risk of failure of restorations after mechanical and chemomechanical carious tissue removal. Fo that, a comprehensive search was performed using PubMed/MEDLINE, EMBASE, Scopus, LILACS, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) databases and grey literature until January 2022 to identify studies related to the research question. Two reviewers independently and in duplicate selected the studies according to the eligibility criteria, extracted the data, assessed the risk of bias and the certainty of evidence. Inclusion criteria were clinical studies that investigated the use of the chemomechanical removal for excavation of coronal dentin carious lesions in primary or permanent teeth before restorative procedures. After reading the full-texts, studies that did not present a control group (conventional carious tissue removal – mechanical excavation), did not use the same restorative material in both groups, had follow-up lower than six months, dropout rate ≥ 30%, absence of similar follow-up for patients in both groups evaluated in the same way, and did not evaluate restoration failure as outcome were excluded. Meta-analysis was performed using RevMan 5.3 software, using a random effects model, to compare the effect of chemomechanical and mechanical carious tissue removal on the restorative failure, considering the type of carious tissue removal (selective and complete - non-selective) as subgroups. Of the 443 potentially eligible studies after removal of duplicates, 58 were selected for full-text analysis and 6 were included in the systematic review. There was no statistically significant difference in the risk for failure of restorations performed after chemomechanical and mechanical excavation ($p=0.14$) either for complete ($p = 0.97$) or selective ($p = 0.11$) carious tissue removal. The heterogeneity found was null. The risk of bias was high and the certainty of evidence was low. Based on the low certainty of evidence, it can be concluded that the risk of failure of restorations performed after chemomechanical and mechanical carious tissue removal is similar. Further studies are needed before more consistent conclusions can be made.

Keywords: Systematic Review. Dental Caries. Dental Restoration Failure.

SUMÁRIO

1 INTRODUÇÃO

Lesões de cárie não tratadas representam uma condição prevalente na população mundial e de difícil resolução (KASSEBAUM et al., 2017). Os procedimentos restauradores visam ao controle da progressão das lesões, minimizando o risco de complicações pulpares e perdas dentárias precoces, além do restabelecimento de forma e função (SCHWENDICKE et al., 2016). Preparos cavitários mais biológicos por priorizar a realização de remoção seletiva do tecido cariado devem ser realizados, possibilitando a preservação de estrutura dentária (INNES et al., 2016).

A literatura tem demonstrado que a ansiedade e o medo frente ao atendimento odontológico são variáveis (LU et al., 2022; SILVEIRA et al., 2021) e que podem chegar a cerca de 80% em pacientes que passaram por situações de pulpite irreversível (DOU et al., 2018). O comportamento dos pacientes pode depender de inúmeros fatores como idade, condição de saúde bucal, intervenções odontológicas anteriores, tendência geral ao medo, meio social e influência de outras pessoas (SILVEIRA et al., 2021).

A remoção de tecido cariado é convencionalmente realizada utilizando instrumentos rotatórios. No entanto, é difícil estabelecer o quanto de tecido cariado deve ser removido, o que pode levar a uma maior remoção de dentina, aumentando o risco de complicações pulpares (SCHWENDICKE et al., 2015). Consequentemente, novas alternativas têm sido desenvolvidas com o objetivo de definir um ponto de corte para a remoção do tecido cariado (SCHWENDICKE et al., 2016). A remoção químico-mecânica permite a remoção do tecido cariado através da aplicação de um gel natural ou sintético que amolece o tecido dentinário cariado, facilitando sua remoção, seguido pela instrumentação manual (HAMAMA; YIU; BURROW, 2014). Os produtos mais relatados na literatura para a realização dessa técnica são Carisolv™ (LAGER; THORNQVIST; ERICSON, 2003; GOOMER et al., 2013) (origem sueca), Caridex™ (BIANCHI et al., 1989) (origem estadunidense), Papacárie™ (MATSUMOTO et al., 2023; BOTTEGA et al., 2018) (origem brasileira) e Carie-Care™ (origem indiana) (PURI et al., 2020).

O Caridex™ (também conhecido como GK-101E) é composto por hidróxido de sódio, cloreto de sódio, glicerina, 0,05% de hipoclorito de sódio e um grupo etil. Para seu uso, a solução deve ser preparada imediatamente antes da aplicação por

meio de um aparelho de jato pulsátil após aquecimento a 37ºC (BIANCHI; CIUFFREDA; POGGIO et al., 1989).

O Papacárie™ (Fórmula & Ação) é um produto que atua na remoção de dentina infectada, preservando a dentina afetada e o tecido sadio. O Papacárie™ é um gel composto de papaína e cloramina que, por meio da ação de enzimas proteolíticas da papaína, age na degradação parcial da dentina contaminada e desmineralizada, facilitando sua remoção e prevenindo danos ao tecido subjacente (dentina afetada). Já a cloramina apresenta propriedades desinfetantes e, dessa maneira, a combinação de ambas tem ação bactericida e bacteriostática, acelerando o processo cicatricial (BUSSADORI; CASTRO; GALVÃO, 2005).

O Carisolv™ é um gel isotônico fluído e de alta viscosidade formado pela combinação de hipoclorito de sódio (0,5%) com ácido glutâmico, lisina, leucina, carboximetilcelulose, cloreto de sódio, hidróxido de sódio e corante vermelho. Sua composição confere ao Carisolv™ características alcalinas e, quando aplicado na cavidade, permanece ativo por até 20 minutos. A presença de aminoácidos faz com que o produto não provoque a desmineralização da dentina hígida enquanto a ação do hipoclorito de sódio possibilita a degradação proteolítica do colágeno já parcialmente destruído da camada mais externa da dentina cariada (RICKETTS & PITTS, 2009; ERICSON et al.,1999).

O Carie-Care™ é um produto composto por endoproteínas, cloramina, corante (extraído do mamão) e óleos essenciais de origem vegetal, apresentando efeito anti-inflamatório e leve efeito anestésico. O Carie-Care™ não apresenta hipoclorito, nem outros agentes fortes derivados do cloro. Após a aplicação do gel na superfície dentária cariada, o produto é mantido no local durante 1 minuto até observar alteração na coloração do gel, seguido de remoção de tecido cariado com instrumentos manuais (PURI et al., 2020).

Tem sido demonstrado que a remoção químico-mecânica do tecido cariado pode reduzir a dor e o desconforto durante o tratamento (SCHWENDICKE et al., 2015), minimizando a necessidade de anestesia local. Ademais, o uso de métodos para remoção químico-mecânica pode reduzir o custo do tratamento. Um estudo mostrou que o uso do Papacárie reduziu em 42% a 58% o custo do tratamento em comparação com a remoção mecânica do tecido cariado com instrumentos rotatórios, sem e com uso de anestesia local, respectivamente (BOTTEGA et al., 2018). Esse método pode ser extremamente útil em casos de pacientes muito

ansiosos, deficientes e infantis (HAMAMA; YIU; BURROW, 2014).

Uma revisão sistemática verificou que não há diferença significativa entre a remoção químico-mecânica e a remoção completa do tecido cariado em relação ao risco de complicações pulpares (ou seja, a necessidade de realizar qualquer tratamento de acompanhamento associado à terapia original, como complicações pulpares ou uma nova restauração após complicações não pulpares) (SCHWENDICKE et al., 2015). Embora a remoção químico-mecânica pareça ser uma técnica promissora para remoção do tecido cariado em dentes decíduos e permanentes, há uma lacuna no que tange sua influência na sobrevida de restaurações (MOTTA et al., 2014; BERGMANN et al., 2005; ADHAM et al., 2021).

Tendo em vista que a remoção químico-mecânica pode ser uma alternativa viável, principalmente em pacientes infantis e/ou com medo e ansiedade frente ao tratamento dentário e que o menor custo pode impactar significativamente na escolha da técnica pelos clínicos em serviços públicos e privados de saúde, é relevante revisar sistematicamente a literatura a fim de avaliar a influência do método de remoção de tecido cariado no risco de falha de restaurações em dentes decíduos e permanentes.

2 ARTIGO CIENTÍFICO

Influence of the chemomechanical and mechanical carious tissue removal on the risk of restorative failure: a systematic review and meta-analysis

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Authors' contributions

Conceptualization/Idea: Tathiane Larissa Lenzi; **Investigation:** Natália Bregalda Rossoni, Cleber Paradzinski Cavalheiro and Tathiane Larissa Lenzi; **Methodology/ Literature Search:** Natália Bregalda Rossoni, Cleber Paradzinski Cavalheiro and Tathiane Larissa Lenzi; **Formal analysis/ Data Analysis:** Cleber Paradzinski Cavalheiro and Tathiane Larissa Lenzi **Roles/Writing - original draft:** Natália Bregalda Rossoni and Cleber Paradzinski Cavalheiro **Writing-review & editing:** Luciano Casagrande and Tathiane Larissa Lenzi.

Compliance with Ethical Standards

Conflict of interest: The authors declare that they have no conflict of interest. **Ethical approval:** Ethical approval does not apply to systematic reviews. **Informed consent:** For this type of study, formal consent is not required.

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Abstract

Objective: To summarize and evaluate critically the results of clinical trials comparing the risk of failure of restorations after chemomechanical and mechanical carious tissue removal. ***Materials and Methods:*** The PubMed/MEDLINE, EMBASE, Scopus, LILACS, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) databases, and grey literature were searched to identify studies related to the research question and published up to January 2022. Two authors independently selected the studies, extracted the data, and assessed the risk of bias and the certainty of evidence. Meta-analysis was performed using a random effects model to compare the effect of chemomechanical and mechanical excavation on the outcome (restorative failure), considering the type of carious tissue removal (selective and complete) as subgroups. ***Results:*** From 443 potentially eligible studies, 58 clinical studies were selected for full-text analysis, and 6 were included in the review. There was no statistically significant difference in the risk for failure of restorations performed after chemomechanical and mechanical excavation (RR: 1.26, 95% CI 0.93; 1.72, p=0.14) either for complete (p = 0.97) or selective (p = 0.11) carious tissue removal. The heterogeneity found was null. The risk of bias was high and the certainty of evidence was low. ***Conclusion:*** Based on the low certainty of evidence, the risk of failure of restorations performed after chemomechanical and mechanical carious tissue removal is similar. ***Clinical Relevance:*** Chemomechanical carious tissue removal may be performed before restoration placement, without jeopardizing the short-term longevity. Further studies are required before definitive conclusions can be drawn.

Keywords: *Direct restoration, Dental caries, Chemomechanical removal, Mechanical removal, Evidence-based Dentistry.*

Introduction

Restorative treatments are performed to aid biofilm control, protect the pulp-dentin complex, and restore the integrity of the dental structure. The carious tissue removal stage ensures the conditions for a long-lasting restoration, preserve healthy and remineralizable tissue, achieve adequate seal, and maintain pulpal health [1].

Caries tissue removal has conventionally been performed using rotatory instruments. However, it is difficult to establish how much carious tissue should be removed, which may lead to overextended cavities, increasing the risk of pulpal complications [2]. Consequently, new alternatives have been developed that attempt to define an end point for carious tissue removal [1]. The chemomechanical excavation allows the carious tissue removal through the application of a natural or synthetic agent that softens the affected tissue. Its mechanism of action is based on the removal of only superficial decomposed and degradable dentin, followed by manual instrumentation [3]. The most reported products in the literature to carry out this technique are Carisolv™ [4, 5] (Swedish origin), Caridex™ [6] (USA origin), and Papacarie™ [7, 8] (Brazil origin).

It has been shown that chemomechanical excavation might reduce pain and discomfort during treatment [2], since the need for local anesthetics is reduced. This method could be extremely useful in very anxious, disabled and pediatric patients [3]. No significant difference was found between chemomechanical and excavation until hard dentin (complete carious tissue removal) regarding the risk of complications (i.e., need to perform any follow-up treatment associated with the original therapy such as pulpal complications or re-restoration after non-pulpal complications) [2].

Doubts remain regarding the influence of the chemomechanical carious tissue removal on longevity of the restorative procedures [9–11]. Therefore, the aim of this systematic review was to summarize and evaluate critically the results of clinical trials comparing the risk of failure of restorations placed in primary and permanent teeth after chemomechanical and mechanical excavation.

Materials and Methods

This systematic review was conducted according to the Cochrane Handbook [12], reported following the Preferred Reporting Items for Systematic Reviews and

Meta-Analyses (PRISMA) statement [13], and registered International Prospective Register of Systematic Review (PROSPERO - CRD42021267525).

The following research question was formulated to address the literature and outline the search strategy: Does chemomechanical carious tissue removal increase the risk of failure of restorations performed in permanent or primary teeth compared with mechanical removal?

The population/problem, intervention, comparison, and outcome of the study were established according to the PICOS question. In this respect, the population consisted of patients of any age with coronal dentin carious lesions. The intervention was the use of chemomechanical carious tissue removal, and the comparison was the use of mechanical carious tissue removal. The outcome evaluated was restoration failure. The study design included nonrandomized and randomized clinical trials.

Search strategy

A comprehensive literature search was performed using the MEDLINE via PubMed, EMBASE, LILACS, Scopus, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) databases to identify studies related to the research question and published up to January 2022. The search was conducted with no publication year or language restrictions. To reduce the publication bias, the ClinicalTrials.gov (www.clinicaltrials.gov), and Brazilian Clinical Trials Registry (ReBEC) (www.rebec.gov.br) websites were checked for unpublished documents. The search strategy was developed for the PubMed/MEDLINE database and then adapted for the other databases consulted (Table 1). The following search steps were performed: computer search of databases and grey literature, review of reference lists of all included studies, and contact with authors. The results of searching the various sources were crosschecked to identify and eliminate duplicates.

Elegibility criteria

Firstly, titles and abstracts were reviewed independently and in duplicate by two authors (C.P.C. and N.B.R.) and selected for further review if they met the inclusion criteria: clinical studies that investigated the use of the chemomechanical removal for excavation of coronal dentin carious lesions in primary or permanent

teeth before restorative procedures. The calculation of inter-examiner agreement (unweighted Kappa = 0.88) indicated good agreement. Full-text versions of articles selected in the previous step were retrieved and reviewed independently by two authors (C.P.C. and N.B.R.) considering the following exclusion criteria: did not present a control group (conventional carious tissue removal – mechanical excavation), did not use the same restorative material in both groups, follow-up lower than six months, dropout rate ≥ 30%, absence of similar follow-up for patients in both groups evaluated in the same way, and did not evaluate restoration failure as outcome. Disagreements were firstly resolved by discussion between the reviewers (C.P.C. and N.B.R.). If discrepancies remained, a third author (T.L.L.) was consulted.

Data extraction

Two authors (C.P.C. and N.B.R.) separately and in duplicate collected the data using a standardized sheet in Microsoft Office Excel 2013 (Microsoft Corporation, Redmond, WA, USA). For each paper, the following data were systematically extracted: publication details (authors, year, country, and design study), methodology (sample size, commercial brands and manufacturers of the carious tissue removal methods and restorative materials, and number of operators and evaluators), outcome information (follow-up, dropout, restorative failures and clinical criteria for evaluating restorations), financial sources and conflicts of interests.

Form to avoid overlapping data, when there were multiple reports of the same study (i.e., reports with different follow-ups), only the longest follow-up or more complete study was considered.

Assessment of risk of bias and certainty of evidence

The reviewers (C.P.C. and N.B.R.) also independently and in duplicate assessed the risk of bias using the RoB2 [14] tool. The criteria were divided into five domains as follows: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. The evaluation of the studies was performed by rating each domain as low risk of bias, some concerns or high risk of bias. For the final classification of risk of bias, disagreements between the reviewers were solved by consensus.

The Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) [15] tool was used to evaluate the certainty of evidence of the results from meta-analysis. The certainty of evidence was classified as high, moderate, low, or very low, while the reason for downgrading was based on five domains: study limitations, indirectness, inconsistency, imprecision, and publication bias.

Meta-analysis

A meta-analysis was performed using the random effects model to compare the effect of chemomechanical and mechanical excavation on the outcome (restorative failure), considering the type of carious tissue removal (selective and complete) as subgroups. An intention-to-treat (ITT) analysis (analysis of participants as randomized regardless of whether they received the intervention or were available for follow-up) was performed. For ITT analysis, it was assumed that all missing participants experienced an event.

Statistical differences between groups were calculated using RevMan version 5.3 (Review Manager, Cochrane Collaboration, Copenhagen, Denmark, 2014) with relative risks (RRs) and 95% confidence intervals (CIs). Differences with $p < 0.05$ were considered to be statistically significant (Z test). Statistical heterogeneity among studies was assessed via the Cochrane Q test and inconsistency (I2). Publication bias was not assessed because few number of included studies [12].

Results

Study selection

The search strategy identified 443 potentially relevant studies, excluding 110 duplicates. After the screening of titles and abstracts, 58 studies were assessed for more detailed information. Of these, 52 clinical studies were excluded after a review of the full-text articles. No additional study was included after reviewing the grey literature. Finally, 6 clinical studies met the eligibility criteria and were included in the systematic review. Figure 1 presents a flowchart of the study selection process and the reasons for exclusions.

Characteristics of the included studies

Table 2 shows descriptive extracted data from the included studies in the

systematic review. All studies were published in English between 2005 and 2021 and conducted in Brazil [9], Denmark [10], Egypt [11], England [16], India [17] and Serbia [18]. All had a randomized design and followed the restorations for 6 [10, 11], 12 [16–18] or 18 [9] months. Two studies [11, 16] performed selective carious tissue removal and four studies [9, 10, 17, 18] performed complete carious tissue removal. Two studies [9, 10] considered only primary teeth, two studies [11, 16] included only permanent teeth, and two studies [17, 18] considered primary and permanent teeth in the sample. Three studies [10, 16, 18] used Carisolv™ (Rubicon Lifesciences or MediTeam Dental AB), two studies [9, 11] used Papacarie™ (Fórmula & Ação), and one study [17] used Carie-care™ (ND) for chemomechanical carious tissue removal. For mechanical carious tissue removal, five studies [9, 10, 16–18] reported using drilling (rotary burs or low-speed bur) and one study [11] reported using only hands instruments.

Three studies [9, 11, 17] considered only occlusal restorations, one study[16] considered occlusal and occlusoproximal restorations and two studies [10, 18] considered anterior, occlusal and occlusoproximal restorations. Two studies [17, 18] used amalgam, three studies [10, 16, 18] used resin composite, four studies [9, 11, 17, 18] used conventional glass ionomer cement and only one [10] study used resin-modified glass ionomer cement as restorative materials. Only one study [9] declared funding sources.

Assessment of risk of bias and certainty of evidence

The final assessment of the risk of bias in the included studies is summarized in Figure 2. The majority of the domains received low risk of bias. Considering the randomization process domain only two studies [11, 16] were classified with low risk of bias. Four studies [9, 10, 17, 18] were classified with some concerns risk for deviations from intended interventions domain. Only one study [16] was classified with low risk of bias for measurement of the outcome domain. Overall, five studies [9–11, 17, 18] were considered with a high risk of bias and only one article [16] with low risk of bias. A low certainty of evidence was judged according to the GRADE (Table 3).

Meta-analysis

Meta-analysis with 6 datasets was performed considering restorative failure as outcome (Figure 3). Two datasets [11, 16] performed selective carious tissue

removal (p = 0.11, I2 = 15%) and 4 datasets [9, 10, 17, 18] performed complete carious tissue removal (p = 0.97, I2 = 0%). Irrespective of the type of caries tissue removal, there was no statistically significant difference in the risk for failure of restorations performed after chemomechanical and mechanical excavation (RR: 1.26, 95% CI 0.93; 1.72, I2 = 0%).

Discussion

This is the first systematic review investigating if the use chemomechanical carious tissue removal increases the risk for restoration failure in permanent and primary teeth compared with mechanical excavation. Meta-analysis showed that there was no significant difference between carious tissue removal approaches (RR 1.26, 95% CI 0.93; 1.72, p = 0.14). Nonetheless, the outcome in the included studies most likely was affected by several confounders that we could not evaluate owing to the paucity of data.

Different products for chemomechanical removal were tested in the included studies. Overall, all materials evaluated have an affinity for collagen to perform carious tissue removal. Carisolv™ (Swedish origin) is a fluid and high viscosity isotonic gel formed by combining sodium hypochlorite (0.5%) with glutamic acid, lysine, leucine, carboxymethylcellulose, sodium chloride, sodium hydroxide and red dye. The presence of amino acids prevents the product from causing demineralization of sound dentin, while the action of sodium hypochlorite enables the proteolytic degradation of collagen already partially destroyed in the outermost layer of carious dentin [19, 20]. Papacarie™ (Brazil origin) is a gel composed of papain and chloramine that facilitates carious tissue removal and prevents damage to the underlying tissue (affected dentin), while presenting disinfectant properties, bactericidal and bacteriostatic action, and accelerating the healing process [21]. Carie-care™ (India origin) is a product composed by combining papaya extract, endoprotein, chloramines, dye, and specific percentages of essential oils from plant sources, promoting anti-inflammatory and mild anesthetic effect [22]. The application protocol of these products varies according to the manufacturers; but the process is repeated until no change in chemomechanical gel color gets noted.

We planned *a priori* subgroup analyses considering the dentition (primary and permanent) and the products used for chemomechanical carious tissue removal;

however, it was not possible due the characteristics of the selected studies. We did not restrict the type of carious tissue removal (selective or complete) as an eligibility criterion. For statistical purposes, we considered this variable in the subgroup analysis. Four studies [9, 10, 17, 18] performed complete carious tissue removal and two studies [11, 16] performed selective carious tissue removal. Although studies that performed selective carious tissue removal presented a greater number of negative events, no statistically significant difference was found in both subgroup and global analyses.

It has been well established that the selective carious tissue removal reduces the risk of experiencing pulp exposure and postoperative pulpal symptoms [23, 24]. The two studies [11, 16] that performed selective carious tissue removal included only permanent teeth. It is important to highlight that scientific literature has shown no significant difference in the risk for failure of restorations after selective and complete carious tissue removal [25]. On the other hand, there is low certainty of evidence showing that selective carious tissue removal of soft dentin may increase the risk of experiencing restoration failure in primary teeth [26].

The material (amalgam, resin composite, conventional glass ionomer cement and resin-modified glass ionomer cement) used for cavity restoration as well as the use or nonuse of lining material also might have affected the outcome. Nevertheless, the same restorative material was used after chemomechanical and mechanical excavation. In two studies[10, 18] anterior and posterior restorations were performed and were analyzed together. In one study [10] only one anterior tooth was restored in each experimental group, while other study [18] did not equally divide anterior and posterior teeth between the experimental groups.” There was no standardization regarding the depth of carious lesions in the selected trials. In addition, the follow-up periods of the included studies were shorter than desired (6 to 18 months), especially for evaluating the longevity of restorations placed in permanent teeth, which is a major shortcoming of the dataset.

Chemomechanical methods are associated with effective results regarding patient acceptance, being reported less need for previous local anesthesia and, consequently, less discomfort and anxiety when compared to conventional treatment [27, 28]. Nevertheless, the protocol results in longer treatment time compared with the conventional method [28, 29]. Conventional excavation was performed with hand instruments or burs in the included studies, and it might have influenced on the

outcome.

Only one study [11] used standardized criteria based on scores system for evaluating the restorations. Other studies performed the evaluation based on clinical parameters such as marginal discoloration, recurrent caries, pulp vitality, and retention associated or not with radiographic examination. Good clinical evaluation criteria are important to accurately determine a restorative failure. Further studies should consider use the criteria as US Public Health Service (USPHS) [30] or FDI (World Dental Federation) [31] to investigate, mainly, functional (fracture and marginal adaptation) and biological (adjacent caries) parameters.

Among the limitations, most studies were classified as high risk of bias, and the certainty of evidence was graded as low. Only one study [16] adequately reported information about evaluation of the outcome. Problems with the method of sample randomization also were detected. Finally, we must address that the small number of included studies, and the small sample size, might have influenced the absence of significant differences among carious tissue removal techniques found in this review. The quality of primary studies is of paramount importance to increase the knowledge translation to clinical practice. Therefore, there is a need for further well-designed and well-reported randomized controlled clinical trials evaluating the influence of the chemomechanical carious tissue removal on the restorations' longevity.

Conclusion

Based on the low certainty of evidence, the risk of failure of restorations performed after chemomechanical and mechanical carious tissue removal is similar. Further studies are required before definitive conclusions can be drawn.

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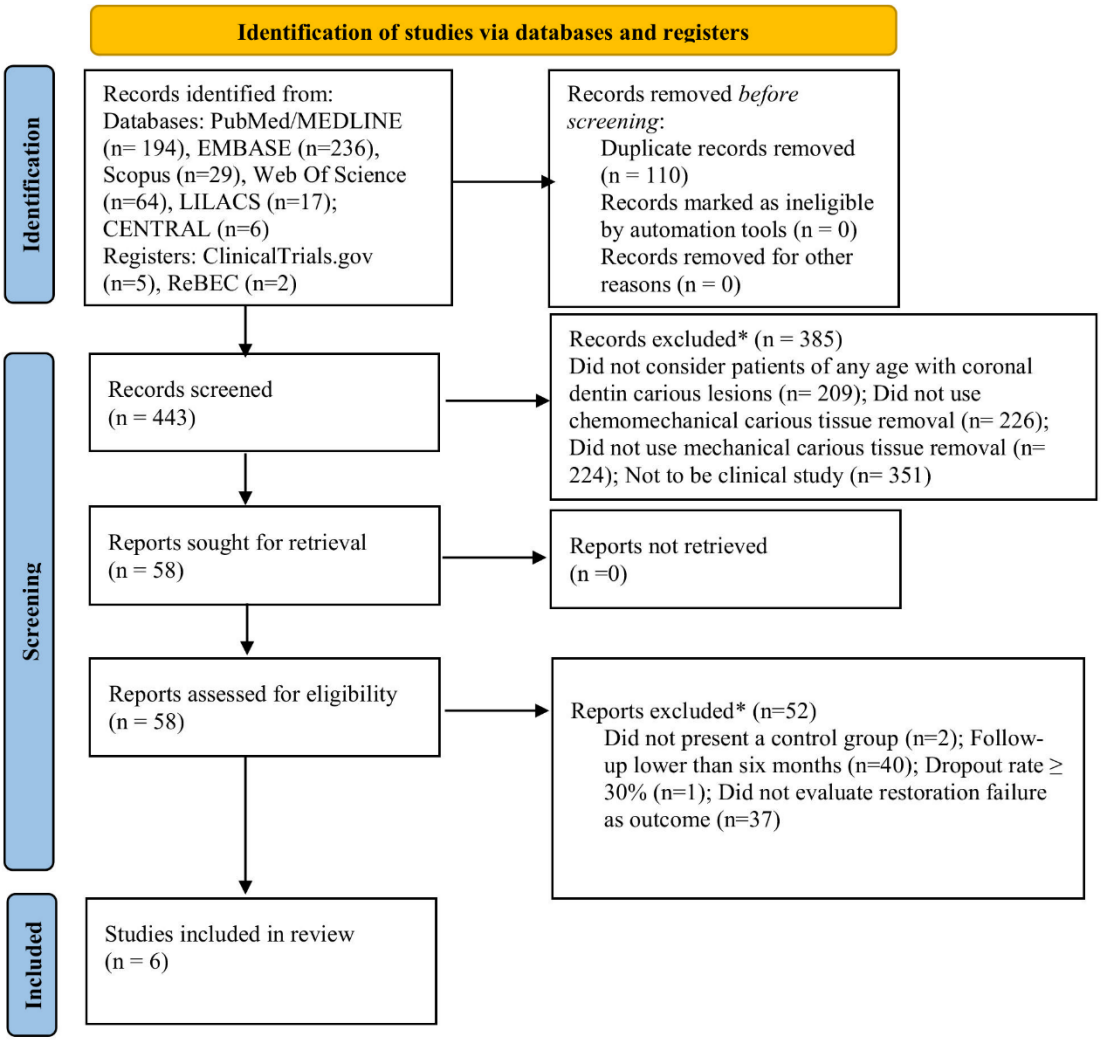

*One study could be excluded for more than one reason.

Figure 1. Flowchart of the study selection process and the reasons for exclusion.

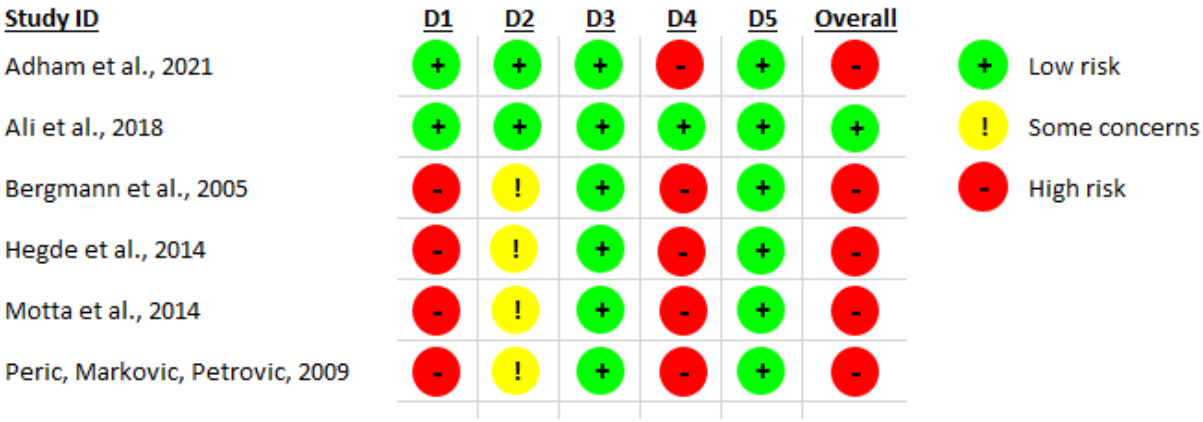

Figure 2. Summary of the final assessment of the risk of bias in the included studies.

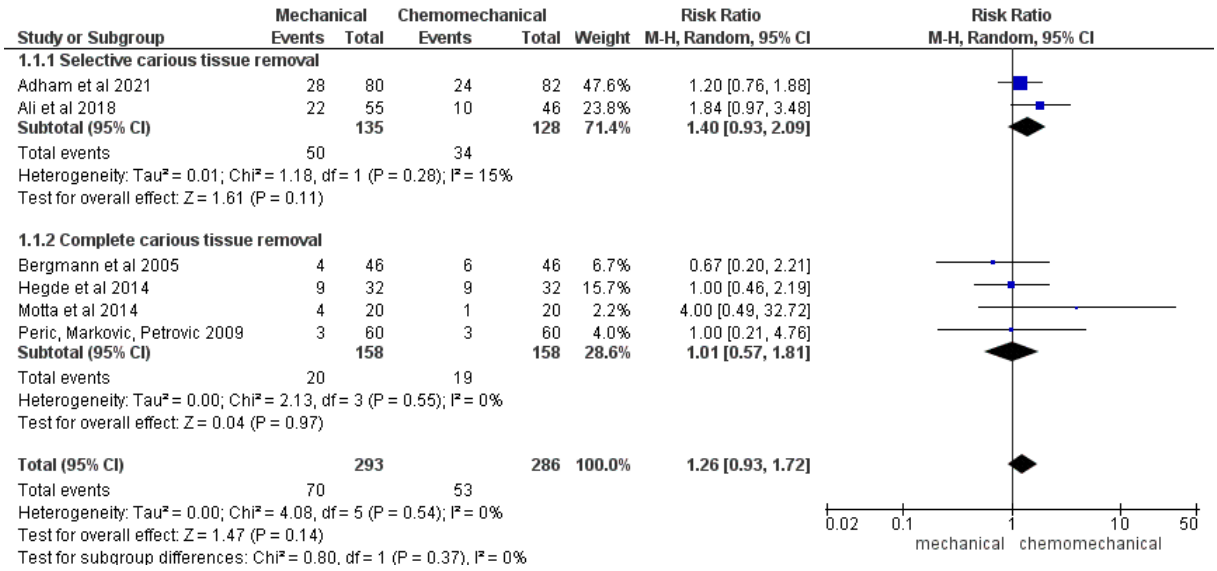

Figure 3. Meta-analysis with 6 datasets considering restorative failure as outcome.

Table 1. Search strategies used for all databases consulted.

Database	Search strategy
Pubmed/MEDLINE (https://www.ncbi.nlm.nih.gov/pubmed)	((((((((((chemomechanical[Text Word]) OR (chemo-mechanical[Text Word])) OR (chemicomechanical[Text Word])) OR (Carisolv[Text Word])) OR (Papacarie[Text Word])) OR (papain[Text Word])) OR (GK-101[Text Word])) OR (GK-101E[Text Word])) OR (Caridex[Text Word])) OR (Biosolv[Text Word])) AND (((((((mechanical removal[Text Word]) OR (conventional removal[Text Word])) OR (conventional excavation[Text Word])) OR (hand excavation[Text Word])) OR (rotary[Text Word])) OR (drilling[Text Word])))
Web of Science (https://login.webofknowledge.com)	chemomechanical removal (All fields) and mechanical removal (All fields)
LILACS (http://bases.bireme.br/)	chemomechanical OR carisolv OR papacarie AND mechanical removal OR conventional removal
EMBASE (https://www-embase.ez45.periodicos.capes.gov.br/#search)	(chemomechanical AND removal OR carisolv OR papacarie) AND mechanical AND removal OR (hand AND excavation)
Scopus (https://www.scopus.com)	(chemomechanical OR carisolv OR papacarie AND mechanical AND removal OR conventional AND removal OR hand AND excavation)
Cochrane Central Register of Controlled Trials (CENTRAL) (https://www.cochranelibrary.com/central/about-central)	chemomechanical, carisolv, papacarie
ClinicalTrials.gov (https://www.clinicaltrials.gov)	chemomechanical removal | dental caries
ReBEC (The Brazilian Clinical Trials Registry) (https:// https://ensaiosclinicos.gov.br/)	chemomechanical removal

Table 2. Main characteristics of datasets from selected studies from systematic review.

Author, year, country	Study Design	Number of Patients / Age	Type of Removal	Type of Cavity / Teeth	Chemomechanical / Mechanical	N per group	Application protocol	Restorative material	Follow-up	Drop-out	Criteria Evaluation	Cavity Liner	Competing Interests and financing
Adham et al., 2021 [11] Egypt	Randomized	162 / Papacarie-Duo: 27.06 ± 2.82 ART: 26.3 ± 3.18,	Selective	Occlusal / Permanent teeth	Papacarie-Duo (Fórmula & Ação)	82	The gel was applied in the cavities after cleaning with wet cotton pellets. When the gel turned cloudy in color, this indicated the presence of infected tissue and after 40 s the cavity was excavated and the remaining gel was removed. The process was repeated until no change in gel color was noted.	GIC (RIVA Self-Cure, SDI)	6 months	14.6%	Loe Criteria	None	None
					Hands instruments	80	Excavation was performed using Darby-Perry #220/221,			17.5%			

							#17 DE (Hu-Friedy, Chicago, USA) after proper cleaning and isolation.						
Ali et al., 2018 [16] England	Randomized	86 / 37.7	Selective	Occlusal and occlusoproximal / molars and premolars permanent teeth	Carisolv gel (Rubicon Lifesciences)	46	The gel was used to excavate carious dentin using the hand instruments supplied, until no further carious tissue was removed. All procedures undertaken using an operating microscope (G6; Global Surgical Corporation), with the magnification set at the operators' discretion.	RC (N'Durance Septodont)	12 months	15.8%	Clinical examination and Radiographic (presence/absence of PA radiolucency)	MTA (Acteon, Pierre Roland) (~2 mm) + GIC (Fuji IX, GC)	None
					Rotary burs	55	The removal of infected dentin was made using carbon-steel rose-head						

							burs (Ash Instruments) in a slowspeed handpiece.						
Bergman n et al., 2005 [10] Denmark	Randomize d	46 / 8	Complete	Small, medium and large cavities / Molars and incisors primary teeth	Carisolv (MediTeam Dental AB)	46	The carious dentin was covered with Carisolv gel, which forms a viscous droplet. After 30 s, the carious dentin was gently scraped with hand instruments to remove carious tissue. The procedure was repeated until the gel no longer became contamined with debris.	RC and RMGIC (ND)	6 months	1.1%	Clinical examination (marginal discoloration , recurrent caries, pulp vitality)	None	ND
					Rotatory burs	46	The carious lesion was removed using rotary burs						
Hegde et al., 2014 [17]	Randomize d	32 Ages of 4 to 15	Complete	Occlusal / Primary and permanent	Carie-care (ND)	32 (16 permanent and 16 primary teeth)	ND	GIC (Ketac Molar, 3M ESPE) and Amalgam (ND)	12 months	0%	Clinical examination	None	ND

India				teeth	Rotatory burs	32 (16 permanent and 16 primary teeth)	ND						
Motta et al., 2014 [9] Brazil	Randomized	20 / Ages of 4 to 7	Complete	Occlusal / Primary second molars	Papacarie™ gel (Fórmula & Ação)	20	The gel was applied, after 30 to 40 s, the softened carious tissue was removed with the blunt end of a curette. The gel was reapplied, if necessary, until the complete removal of the carious tissue.	GIC (Ketac Molar Easy Mix, 3M ESPE)	18 months	0%	Retention of the material in the cavity, presence of secondary caries and Radiographic Examination	None	Financed by FAPESP - São Paulo Research Foundation (Grant no. 2008/086423).
					Rotatory burs	20	Carious tissue removal was performed with low-speed burs						
Peric T.,					Carisolv (MediTeam		The gel was applied to the surface of the carious lesion. After 30 s, the superficial	GIC (Fuji IX, GC), RC (Point 4, Kerr			Clinical examination	Calcium Hydroxid	None

Markovic D., Petrovic B., 2009 [18] Serbia	Randomized	120 / 8.7 ± 3.0	Complete	Class I, II, III and IV / Primary and permanent teeth	Dental AB)	60	softened layer was removed with specially designed hand instruments. The procedure was repeated until the gel no longer turned cloudy and the surface was hard, as judged by clinical criteria (probing and visual inspection).	Dental) and Amalgam (Dentam Dental Amalgam Capsules, Dentam Scitem Ltd.)	12 months	0%	(integrity of the restorations, recurrent caries, and signs of pulp pathology)	e (Calcimol self-curing paste, VOCO) when indicated	
					Rotatory burs	60	Carious tissue was removed using rotary instruments until the cavity was found to be clinically caries free.						

ART: atraumatic restorative treatment; GIC: conventional glass ionomer cement; RMGIC: resin-modified glass ionomer cement; RC: resin composite; ND: not described.

Table 3. A summary of GRADE's approach to rating certainty of evidence.

Certainty assessment							№ of restorations		Effect	Certainty	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Mechanical**	**Chemomechanical**	**Relative (95% CI)**		
6	Randomized clinical trials	Serious[a]	Not serious	Not serious	Serious[b]	-	293	286	RR 1.26 [0.93, 1.72]	⊕⊕◯◯ LOW	IMPORTANT

GRADE Working Group grades of evidence **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

CI: confidence interval; RR: Risk Ratio

[a]. Problems with the form of randomization and measured of the outcome were detected.

[b]. Few studies and few restorations assessed.

3 CONCLUSÃO

Com base na baixa certeza da evidência conclui-se que o risco de falha restauradora após remoção químico-mecânica e mecânica do tecido cariado é semelhante. Novos estudos são necessários para que conclusões mais consistentes possam ser feitas.

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ANEXO A – Aprovação da Comissão de Pesquisa (COMPESQ)

Sistema Pesquisa - Pesquisador: Tathiane Larissa Lenzi

Retornar

Dados Gerais:

Projeto N°:	41223	**Título:**	INFLUENCIA DA REMOCAO QUIMICO-MECANICA DO TECIDO CARIADO NA SOBREVIDA DE RESTAURACOES: PROTOCOLO DE REVISAO SISTEMATICA		
Área de conhecimento:	Odontopediatria	**Início:**	01/09/2021	**Previsão de conclusão:**	01/09/2022
Situação:	Projeto em Andamento				
Origem:	Faculdade de Odontologia Programa de Pós-Graduação em Odontologia	**Projeto da linha de pesquisa:**	BIOMATERIAIS E TECNICAS TERAPEUTICAS EM ODONTOLOGIA		
Local de Realização:	não informado				

Não apresenta relação com Patrimônio Genético ou Conhecimento Tradicional Associado.

Objetivo:

O objetivo desta revisão sistemática será investigar a influência da remoção químico-mecânica de tecido cariado na sobrevida de restaurações em dentes decíduos e permanentes. Uma ampla pesquisa bibliográfica será realizada nas bases de dados PubMed/MEDLINE, EMBASE, Scopus, LILACS, Web of Science, CENTRAL Cochrane e nas plataformas de registros de ensaios clínicos Clinical Trials e ReBEC a fim de

Palavras Chave:

CARISOLV
PAPACÁRIE
REMOÇÃO QUÍMICO-MECÂNICA
REVISÃO SISTEMÁTICA

Equipe UFRGS:

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Ensino: doutorado - Início: 01/09/2021 Previsão de término: 01/09/2022
Nome: NATÁLIA BREGALDA ROSSONI
Técnico: zzz Outra Função zzz - Início: 01/09/2021 Previsão de término: 01/09/2022

Avaliações:

Comissão de Pesquisa de Odontologia - **Aprovado** em 16/08/2021 Clique aqui para visualizar o parecer

Anexos:

Projeto Completo **Data de Envio:** 29/07/2021