

**UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
FACULDADE DE ODONTOLOGIA
PROGRAMA DE PÓS-GRADUAÇÃO-NÍVEL MESTRADO
ÁREA DE CONCENTRAÇÃO CLÍNICA ODONTOLÓGICA
DENTÍSTICA/CARIOLOGIA**

Linha de pesquisa
Biomateriais e técnicas terapêuticas em odontologia

**TRATAMENTO DE LESÕES PROFUNDAS DE CÁRIE: UM ENSAIO CLÍNICO RANDOMIZADO
COMPARANDO TRATAMENTO EXPECTANTE COM REMOÇÃO PARCIAL DA DENTINA
CARIADA**

Roberta Garcia

Orientadora: Prof^a. Dr^a. Marisa Maltz

Porto Alegre, Dezembro de 2011.

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Dissertação apresentada ao Programa de Pós-Graduação em odontologia como parte dos requisitos obrigatórios para obtenção do título de Mestre em Clínica Odontológica com ênfase em Dentística/Cariologia.

Roberta Garcia

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Dedicatória

Para minha família, base desta conquista e de todas as outras. Para Gabriel, Mariana e Raquel pelo apoio e incentivo. Para Isabelle por sempre reclamar da minha ausência durante a realização deste trabalho e requisitar minha companhia e ajuda nos temas de casa.

Para meus pais, Volnei e Maristela. Obrigada por estarem sempre ao meu lado. Vocês são meu grande exemplo e eu amo muito vocês!

Para Caio, meu amor, e com quem eu começo uma nova família. Obrigada pelo carinho e dedicação de todos os dias!

Agradecimentos

À minha orientadora, Professora Dra. Marisa Maltz. Obrigada por me dar a oportunidade de desenvolver este trabalho, por estimular meu crescimento e me incentivar a seguir em frente. Aprendi muito com a senhora durante este período em que convivemos juntas!

À minha grande amiga, Luciana Bitello Firmino, companheira de todas as horas, minha irmã de coração. Chegar ao final dessa caminhada faz muito mais sentido por estarmos finalizando juntas! Obrigada pela tua amizade, companheirismo e parceria em toda a nossa vida profissional e pessoal. Você faz parte da minha vida de forma insubstituível!

À professora Juliana Jobim Jardim, pela ajuda e por ter me acolhido na continuação do seu trabalho de doutorado. Obrigada também pelos momentos de diversão e descontração que tu trazes para o LABIM.

À professora Clarissa Fatturi Parolo, pela escuta e disponibilidade em ajudar a todos no LABIM.

À doutoranda Luana Severo Alves pela ajuda na elaboração de tabelas e disponibilidade em sempre ajudar aos colegas do LABIM.

Às queridas Camilla Ferreira do Nascimento e Bárbara Koppe, minhas bolsistas, que muito me ajudaram na realização deste trabalho. Vocês foram muito amigas comigo durante todo esse processo, e tornaram a realização deste trabalho mais leve! Contem sempre comigo para o que precisarem!

À mestranda Bruna Mua pelo companheirismo e amizade.

À minha querida Fernanda Giongo. Fê, meu agradecimento a você se resume a uma frase: eu te adoro! Obrigada por tudo!

À minha amiga Caren Bavaresco. Obrigada por me incentivar a cursar este mestrado, pela ajuda e por acreditar no meu potencial. Você é um exemplo de esforço e dedicação para nós colegas.

Aos colegas e funcionários do LABIM pela companhia e ajuda na realização deste trabalho Obrigada Lucelen, Alessandra, Natália, Vanessa, Maurício, Julio, Tânia, Luisa e Nailê.

Às professoras Lina, Sandra Berenice e Iriana pela convivência, incentivo e ensinamentos durante a realização deste trabalho.

Aos meus colegas da turma de mestrado 2009-2011. Obrigada pelos momentos de descontração e parceria!

À professora Maria Beatriz Ferreira pelos incentivos e ensinamentos durante o período que estive no mestrado. A senhora é uma pessoa muito querida!

Aos meus colegas da família CEO- CSV. Obrigada pela paciência e incentivo de todas as manhãs.

Aos meus colegas da Unidade de Saúde Nossa Senhora Aparecida. Obrigada pela paciência e colaboração de vocês durante os últimos meses.

Aos meus queridos amigos e amigas, obrigada por todo o apoio e carinho.

Sumário

Lista de abreviaturas.....	07
Resumo	08
Abstract	10
Antecedentes e Justificativa	12
Objetivos	16
Artigo.....	17
Considerações Finais.....	34
Referências Bibliográficas.....	35

Lista de Abreviaturas

TE Tratamento expectante

RPTC Remoção parcial de tecido cariado

CPO-D Número de dentes cariados perdidos e obturados

SW Stepwise excavation

PDR Partial dentine removal

Resumo

Este ensaio clínico randomizado multicêntrico avaliou a efetividade de um tratamento alternativo em lesões de cárie profundas comparado ao tratamento expectante (TE) após três anos de acompanhamento. O tratamento alternativo consistiu na remoção parcial de tecido cariado (RPTC) seguida de restauração em uma sessão. Métodos: Os critérios de inclusão foram: pacientes com molares permanentes apresentando lesões profundas de cárie (lesão alcançando metade interna de dentina ao exame radiográfico); resposta positiva ao teste térmico; ausência de dor espontânea; sensibilidade negativa à percussão vertical e ausência de lesão periapical detectada no exame radiográfico. Dentes elegíveis para participação no estudo foram randomicamente designados ao grupo teste (RPTC) e receberam remoção incompleta de tecido cariado e restauração em uma sessão (resina ou amálgama). Dentes designados ao grupo controle (TE) receberam capeamento pulpar indireto com cimento de hidróxido de cálcio e restauração temporária com cimento de óxido de zinco e eugenol modificado. Após 60 dias, as cavidades foram reabertas, o tecido cariado remanescente foi removido e os dentes foram restaurados com resina composta ou amálgama. O desfecho avaliado foi a vitalidade pulpar, determinada por sensibilidade ao teste térmico e ausência de alteração periapical ao exame radiográfico. Os dados foram submetidos à análise de sobrevivência (Kaplan Meier), teste Log Rank e análise de regressão de Cox. Resultados: Foram executados 299 tratamentos, sendo 152 RPTC e 147 TE, em pacientes com idade variando entre seis a 53 anos. Até o terceiro ano de seguimento, 209 dentes foram avaliados. Foram observadas taxas de sucesso de 94% para o grupo RPTC e de 78% para o TE ($p < 0,000$). As razões de falha foram: pulpíte (4) e necrose (1) no grupo RPTC, e pulpíte (11), necrose (5) exposição pulpar seguida de tratamento endodôntico (2), osteíte (1), exodontia (1) e fratura do dente (1) no grupo TE. Variáveis associadas com sucesso do tratamento foram o tipo de tratamento (RPTC) e número de superfícies envolvidas na restauração – uma superfície mais favorável do que duas ou mais superfícies. Os resultados sugerem que não há

necessidade de reabrir a cavidade e realizar uma segunda escavação de tecido cariado para preservar a vitalidade pulpar.

Palavras-chave

cárie dentária; ensaio clínico; dentes permanentes; tratamento expectante; tratamento; análise de sobrevivência.

Abstract

This randomized multicenter clinical trial evaluated the effectiveness of an alternative treatment on deep caries lesion's compared to stepwise excavation (SW) after three years follow up. Treatment consisted on partial caries removal (PDR) followed by tooth's restoration in one session. Methods: Inclusion criteria were: patients with permanent molars presenting deep carious lesions (lesion reaching inner half dentin on the radiographic examination); positive response to cold test; absence of spontaneous pain; negative sensitivity to percussion and absence of periapical lesion detected on radiographic exam. Teeth randomly assigned to PDR (test) received incomplete caries removal and filling in one session (resin or amalgam). Teeth assigned to SW (control) received indirect pulp capping with calcium hydroxide cement, temporary filling with a modified zinc oxide-eugenol cement. After 60 days the cavity was reopened, the remaining decayed dentine was removed and teeth were filled with composite resin or amalgam. Outcome evaluated was pulp vitality, determine by sensitivity to cold test and the absence of periapical alterations on radiographic exam. Data were submitted to Kaplan Meier, log rank test and Cox regression analysis. Results: At baseline, 299 treatments were executed, 152 PDR and 147 SW. At three years follow up, 209 teeth had been evaluated. A success rate of 94% for PDR and 78% for SW was demonstrated ($p < 0.000$). Failure reasons were: pulpitis (4), pulp necrosis (1) for PDR group, and pulpitis (11), necrosis (5), pulp exposure followed by endodontic treatment (2), osteitis (1), tooth extraction (1) and tooth fracture (1) for SW. Variables associated with treatment success were type of treatment (PDR) and number of surfaces involved in the restoration – one surface more favorable than 2 or more surfaces. Results suggest that there is no need to reopen cavity and perform a second excavation to preserve pulp vitality.

Key-words

dental caries; clinical trial; permanent teeth; stepwise excavation; treatment; survival analysis.

Antecedentes e Justificativa

A Política Nacional de Saúde Bucal busca ampliar o acesso da população brasileira aos serviços de saúde e define as diretrizes para a inserção da atenção à saúde bucal no SUS. No Brasil, o sistema público de saúde vem investindo na atenção primária como modelo ordenador de sua estrutura [Brasil, 2004].

A atenção primária caracteriza-se por apresentar pacientes com características clínicas que incluem uma variedade de problemas, sendo a responsável pela coordenação do cuidado. Seu atributo conhecido como “porta de entrada” lhe confere a responsabilidade de manejar os problemas mais prevalentes na população com ênfase nas ações de prevenção [Starfield, 2004]. Assim, do ponto de vista da saúde coletiva, e principalmente do primeiro nível de atenção, há uma valorização de manobras diagnósticas e de terapias que possam ser adaptáveis em diferentes ambientes e que dispensem maiores recursos tecnológicos. Do mesmo modo, são desejáveis técnicas que apresentem boa relação custo-efetividade e possam beneficiar um grande número de pessoas [Jardim, 2010].

Em Odontologia, a cárie dentária constitui um importante problema de saúde pública, conforme evidenciado no último levantamento epidemiológico nacional. O CPO-D da faixa etária de 35-44 anos é de 20,13 chegando a experiência de cárie da população entre 65 e 74 anos a 27,79 dentes afetados pela doença. Além da alta prevalência de doença na população adulta, assume importância também o fato de o componente perdido do índice CPO continuar sendo o mais prevalente [Brasil, 2003].

Em especial, a abordagem as lesões profundas de cárie representa um dilema na prática odontológica. Isso porque seu tratamento, realizado através da remoção total de tecido cariado (considerando o critério clínico de dureza), leva frequentemente à exposição do órgão pulpar durante o preparo cavitário, tornando o prognóstico do dente e o curso de seu tratamento menos previsível

[Leksell et al., 1996; Barthel et al., 2000]. Frente à exposição pulpar, muitas vezes é necessário o tratamento endodôntico, este mais oneroso e frequentemente envolvendo a referência do paciente da unidade de atenção primária para outro nível de complexidade dentro do sistema de saúde [Brasil, 2008]. Há que se considerar também que dentes tratados endodonticamente apresentam menor resistência a fraturas e podem determinar a realização de restaurações mais complexas [Mannocci et al., 2002; Lynch et al., 2004].

Nesse sentido, há na literatura propostas de como intervir em lesões profundas de cárie a custos mais acessíveis e preservando tanto o tecido dentário, quanto a vitalidade pulpar [Maltz et al., 2002; Leksell et al., 1996]. Essas propostas enfatizam a remoção parcial de tecido cariado como opção de tratamento uma vez que a literatura demonstra o controle do processo de desmineralização após o selamento da cavidade [Kidd, 2004; Bjørndal, 2008].

O tratamento expectante (TE) é uma dessas alternativas. Essa técnica consiste na escavação da totalidade de tecido amolecido das paredes circundantes, seguida pela remoção da dentina mais desorganizada e infectada da parede pulpar. Em seguida é feito o selamento provisório da cavidade durante um período de 2 a 9 meses. Após esse intervalo, é realizada a reabertura da cavidade, seguida da remoção da totalidade de tecido cariado da parede pulpar e finalmente a restauração do dente de maneira definitiva [Bjørndal, 2008].

De acordo com essa técnica, o principal objetivo da primeira consulta é modificar o ambiente onde a lesão está se desenvolvendo e isolar os micro-organismos cariogênicos do meio bucal. Já no momento da segunda consulta, procede-se à avaliação da reação dentária ao tratamento, através do aspecto clínico da lesão, a qual deve apresentar características de paralisação do processo de cárie (tecido endurecido e seco). Por fim, a remoção da dentina cariada remanescente é realizada [Bjørndal and Larsen, 2000].

É importante ressaltar que o tratamento minimamente invasivo para as lesões profundas, que trabalha com a remoção incompleta de cárie, está indicado apenas nos casos compatíveis com inflamações pulpares reversíveis. Isso significa que deve haver presença de sensibilidade pulpar ao teste frio,

ausência de sinais de patologia periapical e ausência de sintomatologia dolorosa espontânea antes de o tratamento ser realizado [Bjørndal, 2008].

Em estudo conduzido por Bjørndal e Thylstrup [1998], pacientes com 94 dentes com lesões profundas de cárie foram tratados com a técnica do expectante por dentistas clínico-gerais. Após realizada a primeira consulta, a reabertura da cavidade foi feita em um período médio de 6 meses. Em cinco casos ocorreu a exposição pulpar durante a escavação final. Após o período de um ano, esses pacientes foram reavaliados, tendo-se demonstrado uma alta taxa de sucesso do tratamento expectante, além da sua exequibilidade pelos cirurgiões-dentistas em sua prática diária.

Apesar dos resultados favoráveis do tratamento expectante na literatura, existem algumas questões que podem repercutir negativamente nesse tratamento. Dentre elas: a possibilidade de perda da restauração temporária no período entre as duas consultas; de perda de tecido dentário íntegro quando realizada escavação final da dentina cariada; de exposição pulpar durante a remoção da restauração provisória; de desconforto adicional para o paciente na segunda consulta ou ainda do não retorno do paciente para concluir o tratamento [Bjørndal et al., 2010]. Outra desvantagem seria o maior custo devido à necessidade de duas consultas [Jardim, 2010].

Em recente trabalho de revisão da literatura, foram abordadas a remoção completa e conservadora de tecido cariado. Seus resultados principais apontam para a redução do número de exposições pulpares frente à remoção incompleta de tecido cariado em dentes assintomáticos decíduos e permanentes. Além disso, concluiu-se que não há evidências que suportem a necessidade de reabertura da cavidade para uma segunda escavação [Ricketts et al., 2006]. Entretanto, poucos são os estudos que avaliam a remoção parcial de dentina cariada como tratamento definitivo, sem a posterior abertura da cavidade. A maioria destes estudos é realizada em dentição decídua na qual o dente tem restrito período de permanência na cavidade bucal [Falster et al., 2002; Franzon et al., 2007]. Apenas três estudos avaliaram a permanência de dentina cariada sob restaurações definitivas na dentição permanente [Mertz-Fairhurst et al., 1998; Alves et al., 2010; Bakhsandeh et al., 2011]. Não há na literatura trabalhos clínicos, randomizados e controlados que avaliem esse

tratamento em lesões profundas de dentes permanentes. Uma vez realizada a remoção incompleta de dentina cariada de maneira definitiva, e existindo a possibilidade de evolução assintomática do quadro inflamatório pulpar, faz-se necessário o acompanhamento dos pacientes tratados. Esse acompanhamento tem como objetivo verificar a presença de sintomatologia dolorosa no dente tratado, além da realização de testes clínicos e radiográficos para verificação do desfecho pulpar e reintervenção no dente, se necessário [Bjørndal, 2008].

Diante dos dados encontrados na literatura e evidenciando-se a falta de ensaios clínicos sobre esse assunto, iniciou-se no ano de 2005 o trabalho intitulado “Tratamento alternativo de lesões de cárie profundas – um estudo multicêntrico” [Jardim, 2010]. Nessa pesquisa, foram tratados 299 dentes com lesões profundas de cárie nas cidades de Porto Alegre e Brasília, sendo o desenho experimental do estudo um ensaio clínico randomizado controlado. Os indivíduos alocados para o grupo teste receberam remoção incompleta de tecido cariado e restauração definitiva em uma consulta, o que foi chamado de tratamento alternativo. Já os indivíduos pertencentes ao grupo controle receberam remoção parcial de tecido cariado e selamento provisório da cavidade na primeira consulta seguida pela remoção da dentina cariada remanescente com restauração definitiva na segunda consulta, conforme protocolo do tratamento expectante. O desfecho principal do estudo é a vitalidade pulpar após o tratamento realizado, sendo essa informação complementada a partir de testes clínicos e de radiografias. Recentemente, concluiu-se o trabalho de dois anos de acompanhamento dos indivíduos tratados [Moura, 2010]. Entretanto, em um estudo clínico de 10 anos de acompanhamento, observou-se que a taxa de sucesso da remoção incompleta pode diminuir mesmo após longos períodos após a realização do tratamento, o que justifica a necessidade de estudos que avaliem esse tratamento ao longo prazo [Maltz et al., 2011].

Frente ao exposto, são necessários estudos longitudinais que avaliem o desfecho do ponto de vista pulpar quando da remoção parcial de tecido cariado e restauração definitiva do dente permanente em única sessão.

Objetivos

Objetivo geral

Avaliar a efetividade de um tratamento alternativo em lesões profundas de cárie após três anos de intervenção clínica. Esse tratamento consiste na remoção parcial de dentina cariada e selamento definitivo da cavidade em única sessão.

Objetivos específicos

1. Comparar o sucesso clínico e radiográfico do tratamento alternativo em lesões profundas de cárie ao tratamento expectante;
2. Avaliar possíveis associações entre as variáveis: gênero, idade, renda familiar, material restaurador, número de superfícies envolvidas no preparo cavitário, falha restauradora e o desfecho vitalidade pulpar.

**Partial removal of carious dentine: a multicenter, randomized,
controlled trial: three years follow up.**

Abstract

This randomized multicenter clinical trial evaluated the effectiveness of an alternative treatment on deep caries lesion's compared to stepwise excavation (SW) after three years follow up. Treatment consisted on partial caries removal (PDR) followed by tooth's restoration in one session. Methods: Inclusion criteria were: patients with permanent molars presenting deep carious lesions (lesion reaching inner half dentin on the radiographic examination); positive response to cold test; absence of spontaneous pain; negative sensitivity to percussion and absence of periapical lesion detected on radiographic exam. Teeth randomly assigned to PDR (test) received incomplete caries removal and filling in one session (resin or amalgam). Teeth assigned to SW (control) received indirect pulp capping with calcium hydroxide cement, temporary filling with a modified zinc oxide-eugenol cement. After 60 days the cavity was reopened, the remaining decayed dentine was removed and teeth were filled with composite resin or amalgam. Outcome evaluated was pulp vitality, determine by sensitivity to cold test and the absence of periapical alterations on radiographic exam. Data were submitted to Kaplan Meier, log rank test and Cox regression analysis. Results: At baseline, 299 treatments were executed, 152 PDR and 147 SW. At three years follow up, 209 teeth had been evaluated. A success rate of 94% for PDR and 78% for SW was demonstrated ($p < 0.000$). Failure reasons were: pulpitis (4), pulp necrosis (1) for PDR group, and pulpitis (11), necrosis (5), pulp exposure followed by endodontic treatment (2), osteitis (1), tooth extraction (1) and tooth fracture (1) for SW. Variables associated with treatment success were type of treatment (PDR) and number of surfaces involved in the restoration – one surface more favorable than 2 or more surfaces. Results suggest that there is no need to reopen cavity and perform a second excavation to preserve pulp vitality.

Key-words

dental caries; clinical trial; permanent teeth; stepwise excavation; treatment; survival analysis.

Introduction

The treatment of asymptomatic teeth presenting deep caries lesions is usually based on traditional techniques which involves the complete removal of the soft demineralized dentin. It is common in these cases to have the pulp exposed during the operative procedure [Leksell et al., 1996; Magnusson and Sundell, 1977; Ricketts et al., 2006]. The conservative treatments of the exposed pulp have been studied and they are associated to a poor prognosis in follow up trials [Barthel et al., 2000; Bjørndal et al., 2010].

The stepwise excavation is an alternative option on the treatment of deep lesions. It involves a first excavation in which the necrotic and disorganized tissue is removed leaving soft tissue over the pulp wall. The cavity is sealed with a temporary restoration allowing pulp's reaction and production of tertiary dentin [Bjørndal, 2008]. After that, cavity is reopened and the remaining demineralized dentine is removed. This technique is associated with less pulp exposures when compared with complete caries removal in an only session [Leksell et al., 1996; Magnusson and Sundell, 1977]. One-year evaluation of stepwise excavation shows a survival rate of 74 to 91%. However, some problems are related to stepwise excavation as the need of two sessions to complete the treatment (providing additional costs and discomfort to the patient) and also the possibility of pulp exposure during the second appointment [Bjørndal and Thylstrup, 1998; Bjørndal et al., 2010].

Considering these problems and the evidence of lesion's arrest once the cavity is sealed [Maltz et al., 2002; Bjørndal et al., 2000], there is a discussion in the literature about the necessity of cavity's reopening [Ricketts et al., 2006]. Three clinical trials have studied partial caries removal on permanent dentition. Two of them presented lesions involving the outer half of dentin [Mertz-Fairhurst et al., 1998; Bakhsandeh et al., 2011]. The other one is a 10 year follow up study of lesions reaching the inner half of dentine [Maltz et al., 2011]. All of these papers showed no harm in leaving demineralized tissue in the cavity. In spite of that, there are not long term randomized controlled trials to support a one-step partial excavation followed by the immediately placement of a filling on permanent teeth.

The aim of this randomized multicenter trial was to evaluate the effectiveness of an alternative treatment on deep caries lesions after three years follow up. This treatment consists on partial caries removal followed by definite tooth's restoration in one session.

Subjects and Methods

Participants

From 2005 to 2007, 299 treatments were performed on a multicenter randomized trial (NCT00887952 on clinicaltrials.gov). Treatments were evaluated up to year three. Treatments were executed at two centers (Porto Alegre and Brasília) by 22 dentists working either at Public Health Services or at Brazilian's Federal Universities. Two of the investigators visited all centers presented the scientific evidences and guideline for patient selection and clinical procedures. Training regarding caries removal and restoration techniques included clinical practices.

Sample was selected at Public Health Services, Community Services and local schools. Inclusion criteria were: permanent molars presenting deep carious lesions (lesion reaching inner half dentin on the radiographic examination); positive response to cold test (performed with -20°C refrigerated gas - Aerojet, Rio de Janeiro, RJ, Brazil); absence of spontaneous pain; negative sensitivity to percussion; absence of periapical lesion detected on radiographic exam. Radiographs were made using Ektaspeed Plus n.2 (Eastman Kodak, Rochester – EUA) and the equipment available at the Services and Universities. Patients who had cuspal loss or caries lesion beneath gingival margin were excluded from the study. All individuals had their dental needs provided by the researches and all of them were informed about research's purposes and signed an informed consent. The study was approved by the Federal University of Rio Grande do Sul Ethics Committee (protocol 18/05), the Porto Alegre Municipal Ethics Committee (protocol 27/06 and registration number 001000837067), the Conceição Hospital Ethics Committee (protocol 070/05), and the Brasilia University Hospital Ethics Committee (protocol 045/2005).

Interventions

The selected participants were treated as follows: after local anesthesia and rubber dam isolation of the area, lesion was accessed with a diamond bur (if necessary). Then complete excavation from cavity walls was performed with dentine excavators or low speed burs (from 245 or 330 series) according to the hardness-tactile criteria. Partial removal of carious dentine was performed on pulp wall with manual instruments. A layer of this carious dentine was left over the pulp in order to avoid pulp's exposure. Cavity was washed with distilled water and dried with sterile filter paper. The teeth were randomized: teeth allocated to test group (PDR) received the reconstruction of surrounding walls and pulp's lining with conventional glass ionomer cement (Vitro Fil, DFL, Rio de Janeiro, RJ, Brazil). Tooth was filled with composite resin (Tetric EvoCeram + Excite + Total Etch, Ivoclar/Vivadent, Liechtenstein) or amalgam (GS-80, SDI, Bayswater WA, Australia). Teeth allocated to control group (SW) received: indirect pulp capping with calcium hydroxide cement (Dycal, Caulk/Dentsply, Rio de Janeiro, RJ, Brazil) and the temporary filling with a modified zinc oxide-eugenol cement (IRM, Caulk/Dentsply, Rio de Janeiro, RJ, Brazil). Cavity was reopened after 60 days when the remaining decayed dentine was removed and the teeth were restored according to the same technique described to PDR. All materials needed for the study's execution were supplied by research's staff.

Objectives and outcome

The primary outcome evaluated on this study was pulp's vitality evaluated based on: positive response to cold test (performed with -20°C refrigerated gas - Aerojet, Rio de Janeiro, RJ, Brazil); absence of spontaneous pain; negative sensitivity to percussion; absence of periapical lesion detected on radiographic exam (Ektaspeed Plus n.2, Eastman Kodak, Rochester – EUA) (combined outcome). The null hypothesis was that there is no difference among treatments on survival analysis three years after treatment's accomplishment. To evaluate the possible correlation of other variables and the outcome, data such as age, gender, family income, and number of surfaces involved in the filling were also collected and analyzed.

Sample size

Sample was estimated based on the difference on success rates between treatments (SW 60,9% and PDR 82% approximately in 5 years follow up) at an $\alpha = 5\%$ with a power of 90% which resulted in 76 treatments per group. A drop-out rate of 40% was considered based on a study realized with a similar population, increasing the number of restorations to 114 per group [Parolo et al., 2007; Maltz et al., 2007; Busnello et al., 2001].

Randomization/allocation concealment and blinding

Randomization procedures were performed by raffle. Each treatment group had a corresponding number printed on a paper, kept on a dark flask. A person helping the operator with clinical procedures selected one of the papers from the flask indicating which of the treatments was to be realized (test/control). Each of these groups was divided according to the filling material: amalgam or composite resin. The material's selection was realized in alternate weeks in each execution center: in one week restorations were performed using amalgam and in the next one using composite resin. Blinding of the patient was not possible due to the different number of appointments needed for each treatment. The operator was blinded until raffle was made avoiding biases on the removal of the decayed dentin in the two groups. The treatment results were assessed blindly.

Statistical Methods

Survival analyses were performed to estimate therapy success rate (Kaplan-Meier survival curves plus Log Rank test). The possible association between the variables recorded and the outcome was analyzed by Cox regression. The significance level was set in 5% and the unit of analysis was the restoration. All the analyses were made using Statistical Package for Social Science (SPSS) software, version 13.0.

Results

Participant flow and recruitment

This study was evaluated as an intention-to-treat analysis. Because of that, protocol deviations were also included in the sample. Cases of restoration

failure, secondary caries or the absenteeism in the SW second appointment were treated and followed in the survival analysis. Patients presenting filling's failure or superficial secondary caries received restoration repair. When the filling's failure involved the pulp wall, patients received the same treatment they had been enrolled in the beginning of the study. In SW group 46 treatments were not performed as planned since patients did not return for the second appointment 90 days after the first one. When contacted, they received the treatment as indicated in stepwise excavation's protocol. All patients were contacted once a year to be examined and treated. Contacts were made using phone numbers, telegrams and home visits.

Baseline data

A total of 299 treatments were performed, 147 SW and 152 PDR (figure 1) in 234 patients. Sample was composed mainly by low income individuals. Mean age was 16.37 with a standard deviation of 7.47 years. There were no differences between treatment groups regarding age, family income, filling material, number of restored surfaces and gender at enrollment.

Numbers analyzed and outcomes

A total of 209 teeth were followed up to year three, 108 belonging to PDR and 101 to SW. This number represented 70% of the sample. Results from the survival analysis are presented in figure 2. At year three, the success rates for each group were 94% and 78% for PDR and SW respectively. The long rank test showed a significantly difference among treatments, rejecting the null hypothesis ($p < 0.000$). The reasons for failure in PDR group were pulpitis (4), pulp necrosis (1). In SW group, causes of failure were pulpitis (11), necrosis (5), pulp exposure followed by endodontic treatment (2), osteitis (1), tooth extraction (1) and tooth fracture (1). The comparison of survival rates between teeth that had and had not completed SW after 90 days indicated an 89% success rate for those that completed SW and 38% for those that had not completed SW ($p < 0.000$).

Ancillary analyses

Variables as gender, age, treatment (PDR/SW), number of restored surfaces, restoration failure, filling's material and family income were tested at Cox regression bivariate analysis to find a possible influence on the outcome. Results showed p values lower than 0.2 for treatment, age and number of restored surfaces. These variables were included at Cox regression final model analysis. Significant associations were found for treatment (PDR) and number of restored surfaces – 1 surface more favorable than 2 or more surfaces (Table 1). Teeth evaluated at follow up analysis were compared to those that have not returned for evaluations. Variables as gender, filling material, number of restored surfaces and family income showed significantly differences between groups (table 2).

Discussion

A comparison was made between variables associated with teeth that were included in the survival analysis (209) and those that were lost to follow-up (90). This comparison showed statistically significant differences in gender, filling material, number of surfaces restored, and family income. In terms of gender, family income, and filling material, these variables appeared to have no major impact on the outcome when tested by Cox regression. After evaluating most of the teeth with 2 or more restored surfaces (Table 2) during follow-up appointments, it was concluded that the number of surfaces involved in restoration did not appear to compromise the results, and this parameter was highlighted as being the strongest indicator of filling failure that could potentially lead to pulp necrosis.

SW has been considered the most conservative treatment for asymptomatic teeth presenting deep carious lesions. In comparison to complete caries removal, SW leads to less pulp exposure and provides better outcomes with regard to preserving pulp sensitivity. [Bjørndal et al., 2010]. Clinical trials have demonstrated that conservative treatments performed after pulp exposure lead to a poor prognosis. Barthel and collaborators [2000] investigated 123 teeth treated with direct pulp capping. The success rates after 5 and 10 years were 44.5% and 13%, respectively. Bjørndal et al. [2010] carried out a clinical trial comparing direct pulp capping with partial pulpotomy. No difference was

found between these treatments. It is important to mention that there is little evidence from clinical trials concerning conservative treatments of the exposed pulp, and little information can be gathered during systematic reviews [Miyashita et al., 2007].

In our study, the success rates for SW were 94% and 78% after 1- and 3-year follow-up, respectively. Despite the high success rates associated with SW, it is important to point out some aspects relating to this procedure. The completion of SW necessitates 2 sessions, adding to costs and patient discomfort. Further, patients may not return to complete the treatment, as observed in our study. Among the 147 teeth allocated to SW, treatment was completed only on 101 teeth. A survival analysis was performed to compare teeth that had and had not completed SW showing a strong difference in success rates between teeth that had completed SW (89%) and those that did not complete SW (38%). Zanata and collaborators [2003] evaluated the survival of glass ionomer cement and zinc oxide-eugenol restorations in 81 caries-active women. The results indicated that zinc oxide-eugenol does not provide good cavity sealing at 2-year follow-up.

The success rates of PDR in this study after 1 and 3 years were 99% and 94%, respectively. In terms of permanent teeth, incomplete caries removal of deep lesions has previously been studied in only 1 single-arm clinical trial. In this study, success rates for PDR were 97% and 90% after 1 and 3 years, respectively [Alves et al, 2010; Maltz et al., 2011]. In our study, a comparison between SW and PDR treatments showed statistically significant differences after 3 years. This difference could be explained by the high number of incomplete SW treatments and by the type of analysis performed in the study (intention-to-treat).

Cox regression showed that PDR was associated with an 80% lower risk of pulp exposure as compared to SW. This must be considered when making treatment decisions because researchers and clinicians are still reluctant to indicate incomplete caries removal in daily practice. In a study conducted by Public Health Services in Porto Alegre (Brazil), treatment decisions for deep carious lesions were assessed. Across a total of 155 observations, the most

common was complete caries removal in a single session (61.30%). The second was complete caries removal in the first session and restoration in the second session (11.61%); this was followed by SW (18.06%), and, lastly, incomplete caries removal (9.03%) [Weber et al., 2011]. Similar results were observed in a study evaluating the North American dentist population: the majority of respondents (62%) completely removed carious dentin, even if the procedure was associated with the risk of pulp exposure, while 18% performed partial caries removal [Oen et al., 2007].

Partial dentin removal showed a statistically significant improvement with regard to the maintenance of pulp vitality as compared to SW after a 3-year follow-up period. This difference might be attributed to the low success rate of incomplete SW treatments. No adverse events relating to leaving soft demineralized dentin on the pulpal wall of the cavity were observed.

Acknowledgments

We thank the support of National Coordination of Post-graduate Education (CAPES), Brazilian Ministry of Science and Technology through its agency National Council of Research (CNPq - Process number: 40.3420/04-0), Research Support Fund of Rio Grande do Sul (FAPERGS - Process number: 04/1531-8) and the support of industries DFL (Rio de Janeiro, Brazil), Ivoclar/Vivadent (Schaan, Liechtenstein) and SDI (Bayswater WA, Australia).

Figure 1: participants flow and follow up

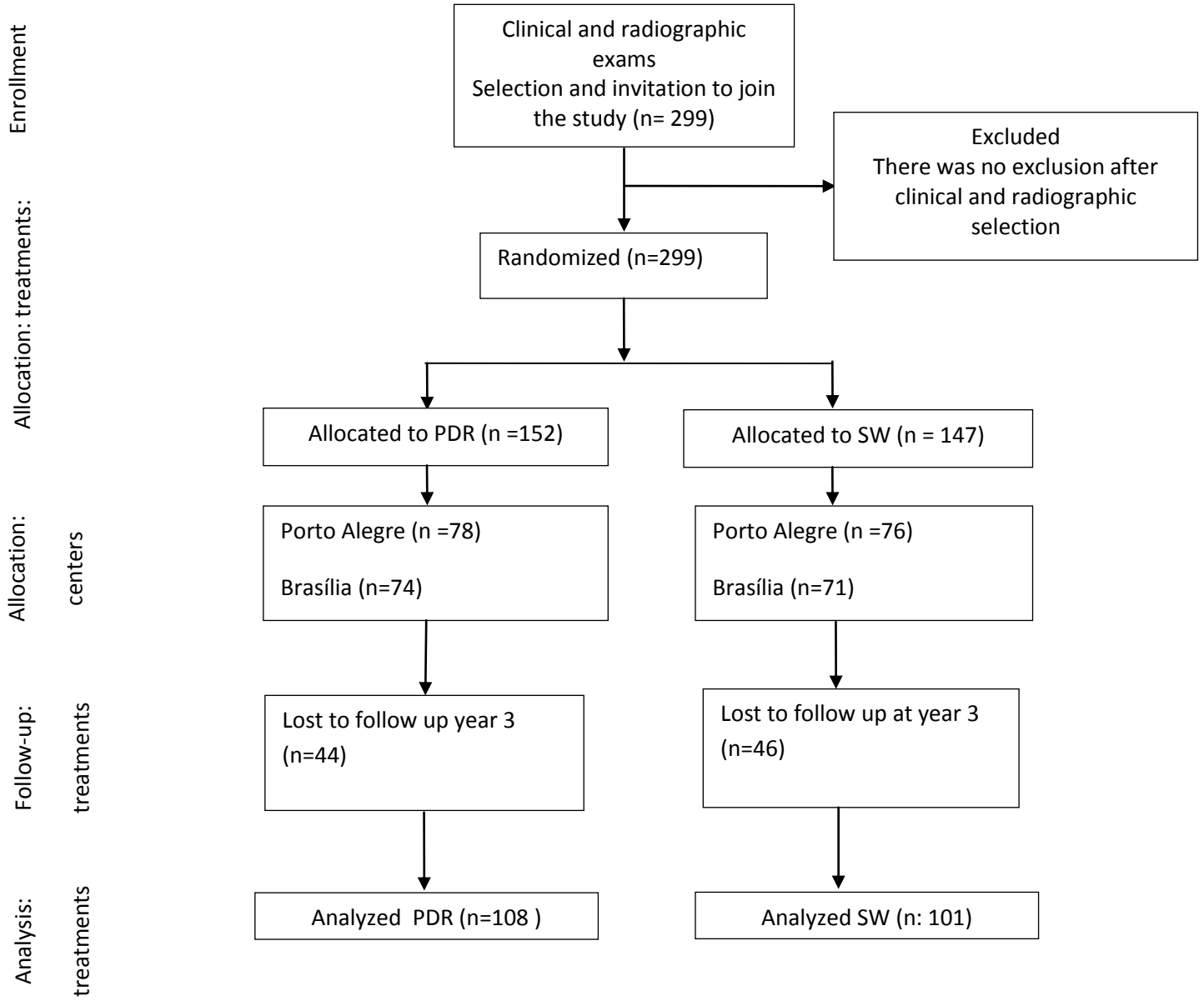


Figure 2: survival analysis comparing treatments at year 3

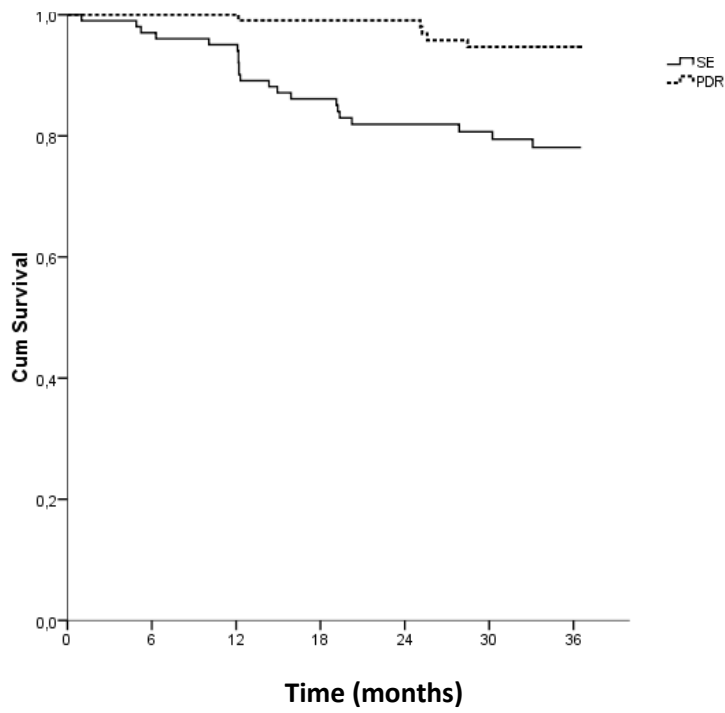


Figure 3: survival analysis comparing completed SW versus uncompleted

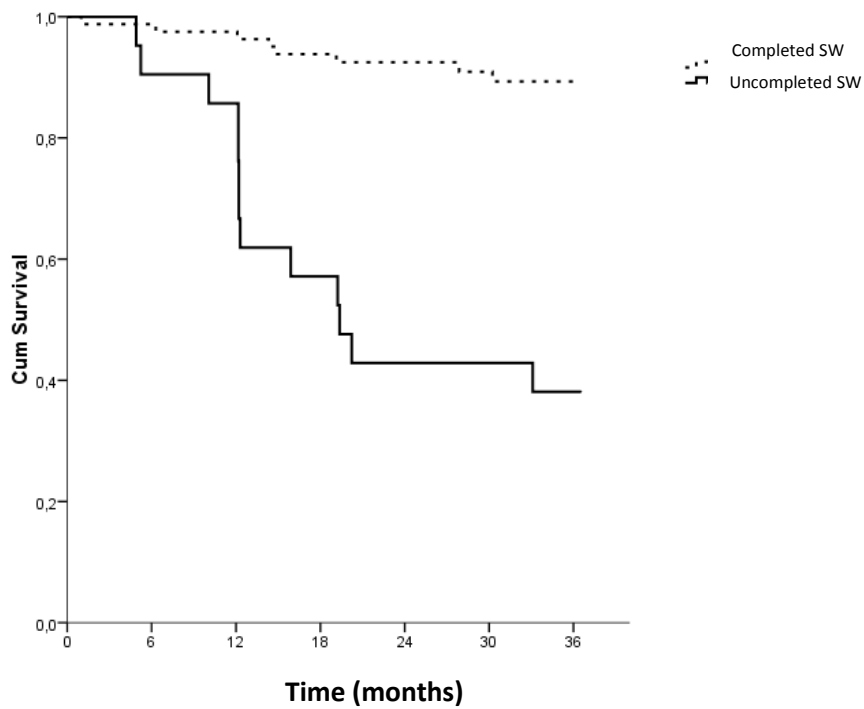


Table 1. Association between pulp necrosis and explanatory variables (Cox regression).

	n (%)	Univariable			Multivariable		
		HR	95% CI	p	HR	95%CI	p
Gender							
Male	82	1.00					
Female	127	0.90	0.41-1.96	0.79			
Age*	16.82 (±7.47)	0.95	0.89-1.01	0.13			
Family income[†]	500 (350-900)	1.00	1.00-1.00	0.74			
Treatment							
Stepwise excavation	101	1.00			1.00		
Partial dentine removal	108	0.20	0.07-0.53	0.001	0.19	0.07-0.52	0.001
Filling material							
Amalgam	75	1.00					
Composite resin	134	1.29	0.56-2.98	0.53			
Number of restored surfaces							
One	181	1.00			1.00		
Two or more	28	2.41	1.01-5.73	0.04	2.61	1.09-6.21	0.03
Restorative failure							
Absent	141	1.00					
Present	23	0.04	0.00-2892	0.57			

HR = hazard ratio; CI = confidence interval

* Mean (± standard deviation)

[†] Median (interquartile range) in local currency (R\$ 1 = US\$ 1.85)

Table 2: comparison between evaluated and non-evaluated treatments

	Evaluated	Non evaluated	p
Gender [∞]			
Male	82 (39.2%)	20(22.2%)	0.004*
Female	127 (60.8%)	70 (77.8%)	
Age *	16.82 (7.47)	15.30 (7.40)	0.109
Family income [†]	500 (350;900)	380 (62;600)	0.002*
Treatment [∞]			
Stepwise excavation	101 (48.3%)	46 (51.1%)	0.659
Partial dentine removal	108 (51.7%)	44 48.9%)	
Filling material [∞]			
Amalgam	75 (35.9%)	44 (48.9%)	0.035
Composite resin	134 (64.1%)	46 (51.1%)	
Number of restored surfaces [∞]			
One	181 (86.6%)	86 (95.6%)	0.022*
Two or more	28 (13.4%)	4 (4.4%)	

*Mean (± standard deviation); t-test

†Median (interquartile range) in local currency (R\$ 1 = US\$ 1.85); Mann-Whitney U

∞ Absolute numbers and percentiles; chi-square test

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Considerações Finais

A remoção incompleta de dentina cariada demonstrou resultados significativamente melhores do que o tratamento expectante na manutenção da vitalidade pulpar após três anos de acompanhamento. Essa diferença pode ter ocorrido devido à baixa taxa de sucesso encontrada nos tratamentos expectantes que não foram concluídos. Não ocorreram efeitos adversos relacionados à permanência de dentina cariada sobre a parede pulpar.

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