UNIVERSIDADE ESTADUAL DE PONTA GROSSA
PRÓ-REITORIA DE PESQUISA E PÓS-GRADUAÇÃO
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA – DOUTORADO
ÁREA DE CONCENTRAÇÃO: CLÍNICA INTEGRADA

PRISCILA DE CAMARGO SMOLAREK

DOR E ANSIEDADE RELACIONADAS À ANESTESIA LOCAL PARA TRATAMENTO ODONTOLÓGICO EM CRIANÇAS: AVALIAÇÃO DE TÉCNICAS ALTERNATIVAS

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PONTA GROSSA
2020

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Tese apresentada como pré-requisito para a obtenção do título de doutor na Universidade Estadual de Ponta Grossa; Doutorado em Odontologia – Área de concentração: Clínica Integrada.

Orientador(a): Profª. Drª. Ana Claudia Rodrigues Chibinski

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PONTA GROSSA
2020

Smolarek, Priscila de Camargo
S666 Dor e ansiedade relacionadas à anestesia local para tratamento odontológico em crianças: avaliação de técnicas alternativas / Priscila de Camargo Smolarek. Ponta Grossa, 2020.
151 f.

Tese (Doutorado em Odontologia - Área de Concentração: Clínica Integrada), Universidade Estadual de Ponta Grossa.

Orientadora: Profa. Dra. Ana Claudia Rodrigues Chibinski.
Coorientador: Prof. Dr. Marcelo Carlos Bortoluzzi.

1. Anestesia local. 2. Odontopediatria. 3. Controle de dor. I. Chibinski, Ana Claudia Rodrigues. II. Bortoluzzi, Marcelo Carlos. III. Universidade Estadual de Ponta Grossa. Clínica Integrada. IV.T.

CDD: 617.6

Ficha catalográfica elaborada por Angela Maria de Oliveira- CRB9/1111

PRISCILA DE CAMARGO SMOLAREK

Dor e ansiedade relacionadas à anestesia local para tratamento odontológico em crianças: avaliação de técnicas alternativas

Tese apresentada ao Programa de Pós-Graduação Stricto sensu em Odontologia da Universidade Estadual de Ponta Grossa, como requisito parcial a obtenção do título de Doutora em Odontologia, área de concentração em Clínica Integrada, linha de pesquisa em Epidemiologia, Diagnóstico e Intervenção em Saúde Bucal.

Ponta Grossa, 28 de fevereiro de 2020.

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Dedico este trabalho

A

***Deus**, que permitiu que tudo pudesse ser realizado.*

*A minha família, **Antonio Carlos, Analia, André e William***

pelo apoio incondicional em todos os momentos.

*Ao meu marido, **Maycon***

Pela compreensão e incentivo

AGRADECIMENTOS

À Universidade Estadual de Ponta Grossa,

Ao Magnífico Reitor Profº. Drº. Miguel Sanches Neto.

Às coordenadoras do Programa de Pós-Graduação em Odontologia da Universidade Estadual de Ponta Grossa, no período em que estive no programa, Profª Drª Denise Stadler Wambier e Profª Drª Nara Hellen Campanha Bombarda.

À minha orientadora, Profª. Drª Ana Cláudia Rodrigues Chibinski. Pela oportunidade, incentivo, paciência, ensinamentos e disponibilidade. Muito obrigada por todo o conhecimento transmitido, e pela sua amizade

Ao meu co-orientador Profº Drº Marcelo Carlos Bortoluzzi, pelo companheirismo, confiança, conhecimento transmitido e pela sua amizade.

A todos os professores da UEPG, que fizeram parte da minha formação acadêmica por compartilhar seus conhecimentos e experiências.

À minha família, pelo amor e apoio incondicional em todos os momentos, sem vocês nada seria possível.

Ao meu marido Maycon Tadei Flores.

Aos meus alunos e amigos**,** Leonardo Siqueira da Silva, Paula Regina Dias Martins, Karen da Cruz Hartman por me acompanharem nesta jornada, pelo apoio, companheirismo e parceria. Vocês são bênçãos na minha vida.

A todos os funcionários da UEPG que sempre estiveram dispostos a nos ajudar com muito amor e competência.

E a todos que diretamente ou indiretamente contribuíram para a realização desta tese.

DADOS CURRICULARES

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RESUMO

Smolarek, PC. **Dor e ansiedade relacionadas à anestesia local para tratamento odontológico em crianças: avaliação de técnicas alternativas**. [Tese – Doutorado em Odontologia – Área de Concentração: Clínica Integrada - Universidade Estadual de Ponta Grossa; 2020].

O objetivo desta tese foi determinar a influência de diferentes técnicas de anestesia local em crianças observando a dor, ansiedade e comportamento disruptivo durante o tratamento odontológico. Foram comparadas as técnicas convencional, vibracional e computadorizada por meio de revisão sistemática e metanálise e dois ensaios clínicos randomizados (ECR). O estudo 1 foi realizado para responder o acrônimo PICO: a anestesia computadorizada gera menos dor e comportamento disruptivo em crianças quando comparada com a técnica anestésica convencional no tratamento odontológico? Foi realizada uma busca por ECR avaliaram a dor e o comportamento durante a anestesia computadorizada em crianças, em comparação à técnica convencional. Bases como PubMed, Scopus, Web of Science, LILACS, BBO, Biblioteca Cochrane e literatura cinzenta foram avaliadas. A ferramenta da Cochrane Collaboration para classificação de risco de viés foi usada para avaliação qualitativa dos estudos. Um total de 8.389 artigos foram identificados. Vinte artigos foram analisados na síntese qualitativa e quantitativa. Alta heterogeneidade foi detectada para os resultados de percepção de dor e comportamento disruptivo. Na percepção da dor, a análise geral mostrou uma diferença média padrão de -0,78 (-1,31, -0,25) a favor da computadorizada; no entanto, quando apenas estudos com baixo risco de viés foram analisados (análise de subgrupos), não houve diferença entre as duas técnicas [-0,12 (-0,46, 0,22)]. Para o comportamento disruptivo, nenhuma diferença foi detectada para dados contínuos [-0,26 (-0,68, 0,16)] ou dicotômicos [0,81 (0,62, 1,06)]. A qualidade da evidência foi considerada baixa para a percepção da dor e muito baixa para o comportamento disruptivo. O estudo 2 foi um ensaio clínico randomizado paralelo, com 105 crianças de 5 a 8 anos, que necessitavam de procedimento odontológico com anestesia local na região posterior de maxila. Cada grupo de 35 crianças recebeu apenas um tipo de anestesia: convencional (CA); vibracional (VBA) ou computadorizada (CCLAD). A autopercepção de dor foi avaliada usando as escalas de avaliação de dor de Wong-Baker Faces (WBF) e Visual Analógica (EVA). O comportamento disruptivo foi avaliado usando a Face, Legg, Activity, Cry, Consolability Scale (FLACC); a ansiedade pelo teste Venham Picture modificado (VPTm) e os parâmetros fisiológicos através de monitor multiparamétrico para pressão arterial (PAS e PAD), frequência cardíaca (FC), saturação de oxigênio (SpO2) e frequência respiratória (RR). Os dados foram analisados estatisticamente com o teste de Kruskall-Wallis e ANOVA para medidas repetidas com pós teste de Tukey. Não houve diferença entre as técnicas anestésicas na autopercepção de dor (WBF - p = 0,864; EVA - p = 0,761); no comportamento disruptivo (FLACC - p = 0,318); na ansiedade (VPTm - p = 0,274); na pressão arterial (PAS - p = 0,239; PAD - p = 0,512), na FC (p = 0,728); na SpO2 (p = 0,348), na RR (p = 0,238). O estudo 3 é um ensaio clínico randomizado que seguiu a mesma metodologia que o estudo 2, diferindo apenas pela faixa etária estudada, neste, as crianças possuíam de 9 a 12 anos. Os resultados mostraram que todos os pacientes exibiram o mesmo nível de ansiedade dental no *baseline* (Escala de Ansiedade Dental de Corah). Houve diferença na percepção de dor, a CA demonstrou menor dor do que a VBA considerando WBF = 0,018) e NRS (p = 0,006) e menor dor que CCLAD considerando WBF (p = 0,029). Não houve diferenças no comportamento disruptivo (FLACC - p = 0,573); ansiedade

(VPTm - p = 0,474); pressão arterial (PAS - p = 0,954; PAD - p = 0,899); frequência cardíaca (p = 0,726); saturação de oxigênio (p = 0,477) e frequência respiratória (p = 0,930) entre todas as técnicas anestésicas.
Segundo os resultados obtidos, a técnica convencional mostra-se mais indicada para realizar anestesia odontológica infiltrativa em crianças. A ansiedade odontológica e a faixa etária influenciam na percepção da dor das crianças à anestesia.

Palavras-chave: Anestesia local, odontopediatria, controle de dor.

ABSTRACT

Smolarek, PC. **Pain and anxiety related to local anesthesia for dental treatment in children: evaluation of alternative techniques.** [Tese – Doutorado em Odontologia – Área de Concentração: Clínica Integrada - Universidade Estadual de Ponta Grossa; 2020].

The aim of this thesis was to determine if the local anesthetic technique has influence in pain, anxiety and disruptive behavior in children, considering the conventional, vibrational and computerized techniques through systematic review, meta-analysis and two randomized clinical trial (RCT). Study 1 was conducted to answer the acronym PICO: Does computerized local anesthesia generate less pain and disruptive behavior in children compared to conventional techniques during local anesthesia for dental treatment? A search for RCT evaluating pain and behavior during computerized anesthesia in children was performed, compared to the conventional technique. Bases like PubMed, Scopus, Web of Science, LILACS, BBO, Cochrane Library and gray literature were evaluated. The Cochrane Collaboration bias risk classification tool was used for qualitative evaluation of the studies. A total of 8,389 articles were identified. Twenty articles were analyzed in the qualitative and quantitative synthesis. High heterogeneity was detected for pain perception and disruptive behavior results. In pain perception, the overall analysis showed a standard mean difference of -0.78 (-1.31, -0.25) in favor of computerized; However, when only studies with low risk of bias were analyzed (subgroup analysis), there was no difference between the two techniques [-0.12 (-0.46, 0.22)]. For disruptive behavior, no difference was detected for continuous [-0.26 (-0.68, 0.16)] or dichotomous [0.81 (0.62, 1.06)] data. The quality of the evidence was considered low for pain perception and very low for disruptive behavior. Study 2 was a parallel randomized clinical trial of 105 children aged 5 to 8 years who required a dental procedure with local anesthesia in the posterior maxilla. Each group of 35 children received only one type of anesthesia; Conventional anesthesia (CA) or vibrational anesthesia (VBA) or computerized anesthesia (CCLAD). Self-perception of pain was assessed using the Wong-Baker Faces Pain Rating Scale (WBF) and Visual Analog Scale (VAS). Disruptive behavior was evaluated using the Face, Legg, Activity, Cry, Consolability Scale (FLACC). And anxiety was assessed by the modified Venham Picture test (VPTm). The physiological parameters were evaluated using a multiparameter monitor for blood pressure (SBP and DBP), heart rate (HR), oxygen saturation (SpO2) and respiratory rate (RR). Data were statistically analyzed using the Kruskall-Wallis test and ANOVA for repeated measures with Tukey post hoc. There is no difference in pain self-perception, either in WBF ($p = 0.864$) or VAS ($p = 0.761$); the disruptive behavior in FLACC ($p = 0.318$); anxiety with VPTm ($p = 0.274$); blood pressure in SBP ($p = 0.239$) and DBP ($p = 0.512$) in HR ($p = 0.728$); SpO2 ($p = 0.348$), RR ($p = 0.238$) between anesthetic techniques. Study 3 is a randomized clinical trial that followed the same methodology as study 2, differing only by the age group studied, in this, the children were 9 to 12 years old. The results showed that all patients exhibited the same level of dental anxiety at the baseline (Corah's Dental Anxiety Scale). There was a difference in pain perception, AC showed less pain than VBA considering WBF ($p = 0.018$) and NRS ($p = 0.006$) and less pain than CCLAD considering WBF ($p = 0.029$). There were no differences in disruptive behavior (FLACC - $p = 0.573$); anxiety (VPTm - $p = 0.474$); blood pressure (SBP - $p = 0.954$; DBP – p

= 0.899); heart rate (p = 0.726); oxygen saturation (p = 0.477) and respiratory rate (p = 0.930) among all anesthetic techniques.
According to the results obtained, the conventional technique is more suitable for performing infiltrative dental anesthesia in children. Dental anxiety and age group influence children's perception of pain under anesthesia.

Key-words: Local anesthesia, pediatric dentistry, management of pain

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LISTA DE ABREVIATURAS E SIGLAS

CCLAD – anestesia computadorizada
TM – Trade Mark
VBA – anestesia vibracional
LILACS - Literatura Latino-Americana de Ciências da Saúde das Américas e Caribe
BBO - Biblioteca Brasileira de Odontologia
IADR - Internacional Association Dentistry Research
ECR - ensaios clínicos randomizados
GRADE - Grading of Recommendations Assessment, Development and Evaluation
CONSORT - Consolidated Standards of Reporting Trials
CA – anestesia convencional
CAIC - Centro de Atenção Integral da Criança e do Adolescente
UEPG – Universidade Estadual de Ponta Grossa
mL - mililitro
s - segundos
WBF – Wong Baker Faces
NRS – Numeric Rating Scale
FLACC – Faces, Legs, Activity, Consolability and Cry
VPTm – Venham Picture test modificado
PAS – pressão arterial sistólica
PAD – Pressão arterial diastólica
FC – frequência cardíaca
FR – frequência respiratória
SpO_2 – saturação de oxigênio
T1 – pré – operatório em ambiente neutro e na sala de espera
T2 – pré - operatório na cadeira odontológica
T3 – trans-operatório – aplicação da anestesia
T4 – imediatamente após a anestesia

SUMÁRIO

1 INTRODUÇÃO

A ansiedade e o medo podem atuar como uma barreira para o tratamento odontológico (Garret-Bernardin et al.[1] 2017), especialmente quando envolve a anestesia local (Gibson et al.[2] 2000). Esses sentimentos podem se originar de experiências de dor durante tratamentos anteriores. Isso demonstra a importância do controle da dor durante o tratamento odontológico pediátrico (Wambier et al.[3] 2018, Feda et al.[4] 2010).

A anestesia local é o método mais comum para se controlar a dor durante um procedimento (Kudo[5] 2005). Entretanto, para pacientes pediátricos, o medo de tratamento dentário geralmente está ligado ao trauma psicológico e físico associado a agulhas e seringas para anestesia local; uma injeção dolorosa durante a administração de anestésico local pode ser considerada a principal razão para comportamentos de ansiedade e reações defensivas (Queiroz et al.[6] 2015). Considerando que, a ansiedade severa e o medo podem aumentar a percepção da dor (Garret-Bernardin et al.[1] 2017), é fundamental explorar abordagens que têm potencial para reduzir a dor e desconforto associado à anestesia local (Baghlaf et al.[7] 2015)

Atualmente, o uso de anestesia tópica e o tempo de injeção prolongado, têm sido indicados para melhorar a experiência da anestesia local, resultando em menores níveis de ansiedade e de percepção de dor (Wambier et al.[3] 2018, Antoniazzi et al.[8] 2015). Entretanto, ao longo dos anos, diversos dispositivos auxiliares foram desenvolvidos com a promessa de diminuir a percepção de dor, o comportamento disruptivo e a ansiedade (Bilsin et al.[9] 2020).

Considerando que um dos fatores que promove a dor durante a anestesia é o estímulo sobre os nociceptores de pressão, dor e temperatura, diminuir a intensidade do estímulo parece diminuir a percepção de dor (Garret-Bernardin et al.[1] 2017). Pensando nisso, foi desenvolvido um sistema de injeção de anestésico local controlado por computador (CCLAD) (Mittal et al.[10] 2015). A tecnologia central deste sistema é fundamentada na constante e lenta taxa de administração da solução anestésica local com vazão e pressão controladas (Baghlaf et al.[7] 2015). Sendo assim, o princípio deste dispositivo sugere que, independentemente das variações anatômicas e resistência tecidual, uma injeção potencialmente indolor pode ser

realizada (Feda et al.[4] 2010). Diferentes CCLAD foram desenvolvidos, como o Wand® (versões subsequentes denominadas Wand Plus® e CompuDent®) (Milestone Scientific, Livingston, Nova Jersey, EUA), Quicksleeper™ (Dental HiTec, Cholet, França), Sleeper One™ (Dental Hi Tec, Cholet, França) e comfort Control Syringe™ (Dentsply International, York, PA, EUA) e numerosos trabalhos comparando a técnica convencional com a técnica computadorizada foram publicados (Garret-Bernardin et al.[1] 2017, Gibson et al.[2] 2000, Baghlaf et al.[7] 2015, Allen et al.[11] 2002, Asarch et al.[12] 1999, Grace et al.[13] 2000, Ram e Kassirer[14] 2006, Klein et al.[15] 2005).

A anestesia vibracional (VBA) é uma técnica que utiliza um dispositivo que busca minimizar o desconforto durante a aplicação do anestésico local (Bagherian e Sheikhfathollahi[16] 2016). De acordo com a teoria de controle de portão da dor, a vibração estimula mecanorreceptores de fibras nervosas de maior diâmetro, e como consequência ativa neurônios inibitórios, por conseguinte bloqueiam neurônios menores e resulta no bloqueio do reconhecimento da dor (Tung et al.[17] 2018). O VBA promove micro-oscilações no local da injeção e essas oscilações pulsadas fecham os portões da dor (Elbay et al.[18] 2015). Os dispositivos intra-orais utilizados para esse fim são o DentalVibe™ (Accumedix, Grayslake, IL, EUA) e Vibraject™ (ITL Dental, 31

Peters Canyon, Irvine, CA), também há estudos que utilizam a vibração manual (Tung et al.[17] 2018, Aminah et al.[19] 2017) e dispositivos extra-orais adaptados para crianças (Hegde et al.[20] 2019).

Os estudos que envolvem a comparação da anestesia convencional e anestesia vibracional ou computadorizada, possuem variabilidade no design, tamanho da amostra, faixa etária das crianças, tempo de vibração no caso da vibracional, técnica e região para aplicação da anestesia e os resultados também são discrepantes. Existem estudos que afirmam a superioridade da anestesia vibracional (Hegde et al.[20] 2019, Raslan e Masri[21] 2018, Pedersen et al.[22] 2017, Chaudhry et al.[23] 2015, Ching et al.[24] 2014, Shilpapriya et al.[25] 2015) e outros estudos que os resultados demonstram equivalência entre a anestesia vibracional e anestesia convencional (Tung et al.[17] 2018, Elbay et al.[18] 2015, Raslan e Masri[21] 2018, Sermet Elbay et al.[26] 2016, Erdogan et al.[27] 2018). Alguns estudos favorecem o uso de anestesia computadorizada (Feda et al.[4] 2010, Baghlaf et al.[7] 2015, Allen et al.[11] 2002, Klein et al.[15] 2005, Deepak et al.[28] 2017), outros não demonstram diferença entre as duas

técnicas (Asarch et al.[12] 1999, Al Amoudi et al.[29] 2008, Kuscu e Akyuz[30] 2008, Kandiah e Tahmassebi[31] 2012, Tahmassebi et al.[32] 2009, Koyuturk et al.[33] 2009).

Um aspecto importante, e comum de observar em estudos que comparam a anestesia convencional com a anestesia computadorizada ou anestesia vibracional, é a abrangencia de grandes faixas etárias, incluindo pré-escolares e adolescentes (Garret-Bernardin et al.[1] 2017, Gibson et al.[2] 2000, Asarch et al.[12] 1999, Kandiah e Tahmassebi[31] 2012). A idade é um fator que deve ser levado em consideração, pois a ansiedade relacionada ao tratamento odontológico é diferente entre as faixas etárias, pois, as crianças menores apresentam maior ansiedade dental (Oliveira et al.[34] 2012).

Considerando que a anestesia local é a primeira fase de qualquer tratamento invasivo, é imperativo que os odontopediatras realizem procedimentos anestésicos sem causar repercussão adversa no gerenciamento do comportamento (Davidovich et al.[35] 2013). Uma diminuição substancial na dor e na conseqüente ansiedade / medo, diminuindo o comportamento disruptivo, durante anestesia local é o principal fator que encorajaria os clínicos a adotar dispositivos alternativos em suas práticas diárias, uma vez que o investimento é maior em comparação à anestesia convencional. A boa prática clínica determina que todas as decisões devem ser feitas com base em fortes evidências científicas, mostrando resposta importante e significativa que poderia realmente influenciar sobre a qualidade do tratamento e melhorar as condições relacionadas à anestesia local.

As evidências atuais fornecem dúvidas sobre a efetividade de tais dispositivos existentes. Desta forma, esta tese, teve como objetivo investigar se a anestesia computadorizada, ou a anestesia vibracional diminuiem a percepção de dor, causam menor comportamento disruptivo, ansiedade e se possuem menor impacto fisiológico, em crianças, quando comparadas a anestesia convencional, realizando uma revisão sistemática e ensaios clínicos randomizados.

2 OBJETIVOS

OBJETIVO GERAL

Determinar a influência de diferentes técnicas para anestesia local no tratamento odontológico em crianças de faixas etárias distintas, realizando uma revisão sistemática e ensaios clínicos

OBJETIVOS ESPECÍFICOS

Realizar uma revisão sistemática e meta-análise comparando a anestesia convencional e a anestesia computadorizada em crianças em relação à dor e comportamento disruptivo durante a anestesia local;

Realizar ensaio clínico randomizado comparando as técnicas anestésicas convencional, vibracional e computadorizada em relação à dor, ansiedade, comportamento disruptivo e parâmetros fisiológicos nas faixas etárias de 5-8 e 9-12 anos.

3 MATERIAL E MÉTODOS

3.1 ESTUDO 1

Este estudo foi registrado no PROSPERO (CRD42016037184) (Apêndice A) e seguiu as recomendações do PRISMA *guidelines*. Foi realizado na Universidade Estadual de Ponta Grossa, Paraná, entre Maio de 2017 e Maio de 2019.

ESTRATÉGIA DE BUSCA

Uma estratégia de busca foi estabelecida com base em um vocabulário controlado (MeSH Terms) do banco de dados PubMed, em conjunto com outras palavras-chave. O operador booleano OR foi usado dentro de cada conceito de estratégia de busca. Utilizando o acrônimo PICO (população, intervenção e controle) foram pesquisados pelo operador booleano AND. Outras fontes eletrônicas de banco de dados também foram pesquisadas, adaptando a estratégia de busca às demais bases de dados (Scopus, Web of Science, Literatura Latino-Americana de Ciências da Saúde das Américas e Caribe (LILACS), Biblioteca Brasileira de Odontologia (BBO) e Biblioteca Cochrane). Listas de referências foram pesquisadas em todos os estudos primários na busca por artigos relevantes adicionais e links de artigos para cada estudo primário no banco de dados PubMed, sem restrições de datas de publicação.

Também foram utilizadas pesquisas da Internacional Association Dentistry Research (IADR) suas divisões regionais (1990-2019). O Gray e o Google Scholar foram usados para buscar a literatura cinzenta. O banco de teses da Capes foi utilizado para procurar dissertações e teses.

Nas bases de dados de registro de ensaios clínicos: Registro Brasileiro de ensaios clínicos (Rebec), European Union Clinical Trials Register, International Standard Randomised Controlled Trial Number Register (ISRCTNregister), Clinical Trials da US National Library of Medicine, foram pesquisadas para estudos em andamento ou não publicados.

No artigo 1, apresentamos a estratégia de busca e a data de busca para todos os bancos de dados. Para todas as pesquisas selecionadas, os textos

completos foram adquiridos, analisados e separados de acordo com os critérios de inclusão e exclusão para posterior extração de dados.

ESTUDOS ELEGÍVEIS

Escolhemos para esta revisão sistemática e metanálise: ensaios clínicos randomizados (ECR), com delineamento paralelo ou cruzado, em humanos, que compararam a influência da anestesia computadorizada na resposta de dor e comportamento, em crianças, em comparação com a anestesia convencional.

ESTUDOS NÃO ELEGÍVEIS

Não foram selecionados estudos que: (1) utilizaram técnicas de sedação; (2) se a amostra não incluiu apenas crianças; (3) se a anestesia computadorizada não foi comparada ao controle (a técnica convencional), (4) se estiver usando anestesia computadorizada em conjunto com técnicas de redução da dor, como eletrodos e vibrações, (5) se o artigo não for escrito em inglês, português ou espanhol.

ELEIÇÃO DO ESTUDO E EXTRAÇÃO DE DADOS

Os estudos foram escolhidos por título e resumos de acordo com os critérios descritos. Em caso de duplicata do estudo no mesmo banco de dados, ou mais bancos de dados, este foi considerado apenas uma vez. Se após a análise do título e resumo as informações não ficaram claras, o texto completo foi analisado.

Uma classificação foi gerada a partir dos estudos selecionados por dois revisores (P.C.S. e A.C.R.C.). Nessa classificação, os estudos receberam uma identificação com autor e data e as informações relevantes foram apontadas: desenho do estudo, características dos participantes, anestésicos, grupos e desfechos. Em seguida, três pesquisadores (P.C.S, A.C.R.C e L.M.W.) realizaram a extração dos dados. Se o estudo apresentasse mais de uma publicação de resultados, com diferentes seguimentos, utilizou-se um único formulário para extrair dados do mesmo estudo, evitando sobreposição de dados. Para a consistência do formulário de

extração de dados com a questão de pesquisa, foi realizado um piloto, garantindo a validade do que foi buscado nos artigos.

RISCO DE VIÉS

Os ensaios clínicos incluídos foram avaliados sobre o risco de viés, de acordo com a Ferramenta Cochrane (Higgins et al.[36] 2011), por dois revisores independentes (P.C.S. e A.C.R.C.). Para a avaliação, são considerados 6 critérios: geração de sequência adequada? Sigilo de alocação? Cegamento? Dados de resultados incompletos abordados? Livre de relatórios seletivos? E outras possíveis fontes de viés. E utilizando como guia o Manual de Revisões Sistemáticas das Intervenções 5.1.0 (http: //handbook.cochrane.org) os critérios foram qualificados em "low" (baixo risco de viés), "high" (alto risco de viés) ou "unclear" (falta de informação ou incerteza de risco de viés).

Dois domínios da Ferramenta de Polarização Cochrane (Higgins et al.[36]2011) foram considerados como domínios-chave para este estudo, sendo a geração de sequências e o sigilo de alocação.

ESTATÍSTICA DESCRITIVA E ANALÍTICA

Para a metanálise, apenas estudos classificados como "baixo risco" ou "incerto" foram incluídos. Todas as análises foram conduzidas usando o RevMan (versão 3, Cochrane Collaboration, USA). Os resultados foram submetidos ao cálculo da taxa de risco e intervalo de confiança de 95% (IC). Utilizamos modelos de efeitos aleatórios para avaliar a heterogeneidade usando o teste Q de Cochran e a estatística I^2.

AVALIAÇÃO DA QUALIDADE DA EVIDÊNCIA

A qualidade da evidencia foi avaliada usando o *Grading of Recommendations Assessment, Development and Evaluation* (GRADE). Esta etapa foi realizada para determinar o poder da evidência para cada metanálise. A evidencia pode ser graduada em 4 níveis (muito baixa, baixa, moderada, alta). Os fatores que rebaixam a

qualidade da evidência incluem imprecisão, inconsistência, limitações e viés das evidências (Guyatt et al.[37]2011).

3.2 ESTUDO 2

Este artigo foi preparado de acordo com o protocolo estabelecido pela declaração *Consolidated Standards of Reporting Trials* – CONSORT (Schulz et al.[38]2010).

APROVAÇÃO ÉTICA

O Comitê de Ética em Pesquisa local envolvendo seres humanos revisou e aprovou o protocolo de pesquisa e emitiu um parecer consubstanciado (Apêndice B) para este estudo (# 1.941.369). O termo de consentimento livre e esclarecido foi obtido dos pais / responsáveis dos pacientes participantes; todas as crianças participantes alfabetizadas também assinaram formulários de assentimento.

REGISTRO DE PROTOCOLO DE PESQUISA

Este ensaio clínico foi registrado no *Clinical Trials* da *US National Library of Medicine*, sob o número de protocolo 64773417.3.0000.5689 (Apêndice C). Todos os participantes foram informados sobre a natureza e os objetivos do estudo.

DESIGN DO ESTUDO

Este foi um ensaio clínico randomizado e paralelo, com igualdade de alocação. Foram definidos três grupos de estudo, de acordo com diferentes técnicas anestésicas (anestesia convencional - CA, anestesia vibracional - VBA e anestesia computadorizada - CCLAD).

Todos os procedimentos em voluntários selecionados foram realizados de novembro de 2017 a novembro de 2018. O estudo foi realizado no consultório odontológico de uma escola de ensino fundamental denominada Centro de Atenção

Integral da Criança e do Adolescente Reitor Álvaro Augusto Cunha Rocha, na Universidade Estadual de Ponta Grossa (CAIC- UEPG) e nas clínicas odontológicas pediátricas do Departamento de Odontologia da Universidade Estadual de Ponta Grossa (UEPG), Ponta Grossa, Paraná, Brasil.

RECRUTAMENTO

Os sujeitos foram incluídos no estudo por conveniência. As crianças foram convidadas a participar quando procuravam atendimento odontológico na universidade ou na escola, de acordo com os critérios de elegibilidade.

Critérios de inclusão: Crianças de 5 a 8 anos, com condições cognitivas compatíveis com a idade cronológica e com necessidade de tratamento restaurador nos dentes posteriores superiores sob anestesia local.

Critérios de exclusão: crianças em tratamento medicamentoso ou que tomam medicamentos de uso contínuo que contraindicam a injeção de anestésicos locais, crianças com comportamento definitivamente negativo de acordo com a escala de comportamento de Frankl (Frankl et al.[39] 1962), crianças com histórico de alergia a anestesicos locais e aquelas que não foram autorizadas pelos pais ou responsáveis.

PROCEDIMENTOS ANESTÉSICOS

ANESTESIA

Todos os procedimentos anestésicos locais foram realizados por um mesmo dentista experiente. O protocolo incluiu o uso de anestesia tópica com benzocaína a 20% por 60 segundos, técnica anestésica infiltrativa e foram aplicados 1,8 mL do anestésico lidocaína a 2% com epinefrina 1: 100.000, com uma vazão média de 1,0 mL por minuto. Toda injeção de anestesia foi controlada por um cronômetro totalizando 108s.

ANESTESIA CONVENCIONAL

Para anestesiar molares superiores, a punção da agulha foi realizada com o bisel direcionado para a mucosa alveolar e, através de uma leve pressão, penetrou no tecido mole, evitando contato com o osso. Após confirmar aspiração negativa, o anestésico local foi injetado no local de interesse. Em seguida, a agulha foi removida suavemente após a conclusão da injeção.

ANESTESIA VIBRACIONAL

O VBA foi realizado com o auxílio de um dispositivo denominado DentalVibe™ (Columbia Tech, Boston, EUA). Após anestesia tópica, o dispositivo foi posicionado no local da punção e ligado, transmitindo uma vibração local. Após 10 segundos, a punção foi realizada no intervalo entre as pontas do dispositivo para aplicação do anestésico conforme descrito na técnica convencional. Após a retirada da agulha, o dispositivo foi desligado.

ANESTESIA COMPUTADORIZADA

Para o CCLAD, foi utilizado o equipamento Morpheus™ (Meibach Tech, São Paulo, Brasil). Após anestesia tópica, um programa pré-determinado foi selecionado. Em seguida, a punção foi realizada acionando o pedal de introdução; logo após, o botão de aspiração foi selecionado e, se não houvesse aspiração positiva, o pedal de injeção era acionado para aplicação do anestésico. Ao final da injeção, a agulha foi lentamente removida do sítio de injeção.

DESFECHOS E FERRAMENTAS DE AVALIAÇÃO

DESFECHOS PRIMÁRIOS

AUTOPERCEPÇÃO DA DOR

A autopercepção da dor foi avaliada com a Escala de Avaliação da Dor de Wong Baker Faces (WBF) (Wong e Baker[40] 1988) ; essa escala, inclui imagens de

expressões faciais com números correlacionados de 0 a 10 (0 sendo “não dói” e 10 sendo “pior dor”). E pela Escala de classificação numérica da dor (NRS), (0 a 10, onde 0 significa ausência de dor, 10 significa pior dor possível) (Asarch et al.[12] 1999).

COMPORTAMENTO DISRUPTIVO

Para a avaliação do comportamento disruptivo das crianças, durante a anestesia, foi utilizada a escala Face, Pernas, Atividade, Choro, Consolabilidade (FLACC) (Willis et al.[41] 2003). Os resultados variam de 0 a 10, originando a seguinte classificação: escore 0 - o paciente apresenta-se relaxado e confortável; escore 1 a 3 - desconforto leve; escore 4 a 6 - dor moderada; 7 a 10 - dor intensa.

DESFECHOS SECUNDÁRIOS

ANÁLISE DO MEDO E DA ANSIEDADE RELACIONADOS AO TRATAMENTO ODONTOLÓGICO

Todas as crianças responderam ao questionário específico denominado Dental Anxiety Scale (Corah) (Corah[42] 1969, Corah et al.[43] 1978) para identificar e classificar o nível de medo e ansiedade relacionado ao tratamento odontológico. Trata-se de um questionário de quatro itens com 4 perguntas a serem respondidas pelos pacientes e indicar sua reação emocional durante a consulta odontológica. O resultado varia de 4 a 20 pontos. Os escores classificam o paciente como “livre de ansiedade” (escore 4); “Ansiedade moderada” (escore 5-10); “Alta ansiedade” (escore 11-15) e “ansiedade severa” (16-20). O autor relatou confiabilidade no questionário (consistência interna = 0,86; teste-reteste = 0,82) (Corah[42] 1969, Corah et al.[43] 1978).

ANÁLISE DO ESTADO EMOCIONAL DE ANSIEDADE

O teste de imagens de Venham modificado (VPTm) (Ramos-Jorge e Pordeus[44] 2004) foi realizado para determinar o estado emocional da ansiedade da criança. O VPTm consiste em 8 figuras representando sentimentos que variam de ansiedade a contentamento. As crianças foram convidadas a selecionar a imagem

que descrevia seus sentimentos naquele momento específico. A soma das respostas varia de 0 a 8 e o nível de ansiedade do paciente é classificado como "livre de ansiedade" (escore 0); “Baixo nível de ansiedade” (escores 1-3); médio nível de ansiedade” (escores 4-6) e “alto nível de ansiedade” (7-8).

PARÂMETROS FISIOLÓGICOS

As crianças foram avaliados quanto à pressão arterial sistólica (PAS), pressão arterial diastólica (PAD), frequência cardíaca (FC), saturação de oxigênio (SpO_2) e frequência respiratória (FR), utilizando monitor multiparamétrico Inmax™ (Instramed, Porto Alegre, Brasil). Para PAS e PAD, os valores foram registrados no final da medição, para FC, SpO_2 e FR, os valores foram registrados a cada 15 segundos e a média foi calculada (Baghlaf et al.[7] 2015).

TAMANHO DA AMOSTRA

O cálculo do tamanho da amostra foi realizado considerando o desfecho primário “dor”. Dessa forma, foram utilizados os níveis médios de dor obtidos por Palm (2004) (Palm et al.[45] 2004). Considerando um poder de 95% e um nível de significância de 5%, em um ensaio clínico de superioridade, a amostra final foi composta por 105 crianças, com 35 sujeitos por grupo de estudo. O cálculo do tamanho da amostra foi realizado pelo software G*Power program 3.1.9.2.

RANDOMIZAÇÃO E OCULTAÇÃO DE ALOCAÇÃO

Um membro da equipe não envolvido no protocolo de pesquisa realizou os processos de randomização e alocação. Foi obtida uma tabela gerada por programa de computador, com randomização em blocos de três e igual proporção de alocação, considerando os três grupos de estudo. A ocultação da alocação foi realizada através da distribuição dos códigos obtidos em envelopes opacos pretos numerados, que foram abertos apenas no dia do tratamento odontológico, imediatamente antes da anestesia local, consequentemente, o operador estava cego até esse momento.

Esses procedimentos foram realizados também no site sealenvelope.com (Sealed Envelope Ltd, Londres, Reino Unido).

INTERVENÇÃO

O protocolo de pesquisa considerou quatro momentos para coletar dados sobre os resultados relacionados ao paciente, resultados centrados no paciente e parâmetros fisiológicos. Esses momentos foram: T1 (antes do tratamento); T2 (no consultório odontológico, quando a criança é chamada a ocupar seu lugar na cadeira odontológica); T3 (durante anestesia local) e T4 (imediatamente após anestesia local). Todos os dados obtidos foram registrados em uma ficha clínica desenvolvida especificamente para fins desta pesquisa. Um investigador assistente foi responsável pelo registro dos dados, além de garantir a confidencialidade da identificação do paciente, que foi substituída por um número. A sequência dos procedimentos está representada na Figura 1.

T1 e T2 consistiram em uma avaliação pré-operatória que teve como objetivo identificar os parâmetros *baseline* em relação ao medo e à ansiedade do voluntário relacionados ao tratamento odontológico (Corah) e estado emocional (VPTm), além dos parâmetros fisiológicos. O questionário sobre ansiedade (Corah) foi aplicado em ambiente neutro; os demais desfechos foram medidos na sala de espera do consultório odontológico (T1). Quando a criança estava sentada na cadeira odontológica (T2), as pressões sistólica e diastólica, freqüência cardíaca, saturação de oxigênio, frequência respiratória e VPTm foram registrados novamente.

Depois disso, o pesquisador principal, que foi o único operador deste estudo, abriu o envelope opaco para descobrir a técnica anestésica que deveria ser realizada naquele paciente específico. Este foi o começo do T3. Durante essa fase transoperatória, os parâmetros fisiológicos foram aferidos novamente por um pesquisador assistente e um outro pesquisador assistente gravou o procedimento anestésico; este vídeo foi avaliado posteriormente, de acordo com os critérios da FLACC.

Imediatamente após a anestesia, no T4, o VPTm foi repetido e os testes de autopercepção da dor (WBF e NRS) também foram aplicados. Ao final da coleta de dados, o tratamento odontológico seguiu normalmente. Medidas usuais de controle

comportamental, comunicação e orientação comunicativa, técnica dizer-mostrar-fazer, controle de voz, comunicação não verbal, reforço positivo e distração, foram usadas em todos os casos.

CEGAMENTO

O operador e os pacientes não estavam cegos para a técnica anestésica, pois os dispositivos necessários para executar as técnicas não podem ser ocultados. Não obstante, a análise dos dados foi realizada sem o estatístico conhecer os grupos de estudo.

AVALIADORES

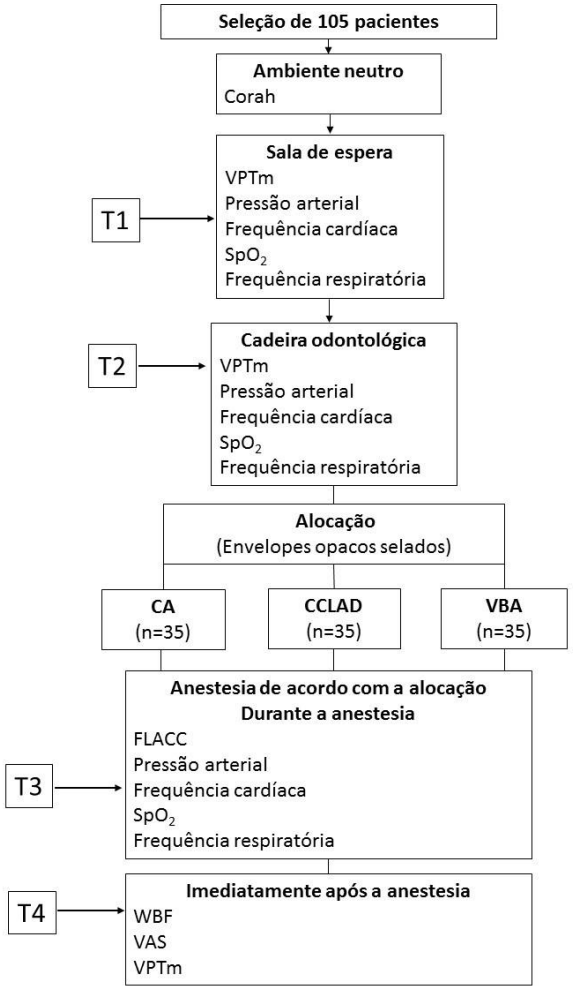
Os pesquisadores foram treinados previamente e avaliaram o medo ou ansiedade dentária, autopercepção da dor, comportamento disruptivo, ansiedade e parâmetros fisiológicos de cada paciente. Um pesquisador auxiliar específico aplicou o questionário Corah, os testes VPTm, WBF, NRS e outro pesquisador auxiliar registrou os parâmetros fisiológicos.

Para obter resultados confiáveis para o FLACC, o pesquisador foi testado pelo teste do coeficiente Kappa e obteve resultado de 0,90. Este realizou a análise dos vídeos gravados, durante a aplicação da anestesia, para determinar o índice de comportamento disruptivo.

ANÁLISE ESTATÍSTICA

A análise estatística foi realizada no programa estatístico SPSS versão 15.0 (SPSS Inc., Chicago, IL, EUA). Foi realizada análise descritiva. Os dados não paramétricos obtidos após a aplicação dos diferentes testes (Corah, WBF, NRS, FLACC) foram submetidos a Kruskal-Wallis para análise não pareada. ANOVA para medidas repetidas com post-hoc de Tukey para análises para comparar os dados de VPTm, SBP, DBP, HR, RR e SpO2 entre as fases e grupos do estudo. Também foram realizados testes de correlação de Pearson para Corah, VPTm, WBF, NRS e FLACC.

Figura 1: Diagrama das etapas do estudo 2



3.3 ESTUDO 3

Este estudo foi estruturado seguindo o protocolo estabelecido pela declaração Consolidated Standards of Reporting Trials – CONSORT (Schulz et al.[38]2010).

APROVAÇÃO ÉTICA

O Comitê de Ética em Pesquisa em seres humanos analisou e aprovou o protocolo de pesquisa, emitindo um parecer consubstanciado (Apêndice B) para esta pesquisa (# 1.941.369). O termo de consentimento livre e esclarecido foi aplicado aos pais / responsáveis dos pacientes participantes; todos os voluntários alfabetizados também assinaram formulários de assentimento.

REGISTRO DE PROTOCOLO DE PESQUISA

O *Clinical Trials* da *US National Library of Medicine* publicou o registro deste ensaio clínico sob o número de protocolo 64773417.3.0000.5689 (Apêndice C). Todos os voluntários foram informados sobre a natureza e os objetivos desta pesquisa.

DESIGN DO ESTUDO

Três grupos de estudo foram definidos: CA- anestesia convencional, CCLAD – anestesia computadorizada, VBA- anestesia vibracional, de acordo com a respectiva técnica anestésica. Este foi um ensaio clínico randomizado e paralelo, com igualdade de alocação.

O período de realização da coleta de dados foi de novembro de 2017 a novembro de 2018. A pesquisa foi executada no consultório odontológico de uma escola de ensino fundamental denominada Centro de Atenção Integral da Criança e do Adolescente Reitor Álvaro Augusto Cunha Rocha, na Universidade Estadual de Ponta Grossa (CAIC- UEPG) e nas clínicas de Odontopediatria do Departamento de Odontologia da Universidade Estadual de Ponta Grossa (UEPG), Ponta Grossa, Paraná, Brasil.

RECRUTAMENTO

As crianças foram incluídas no estudo por conveniência. Elas foram convidadas a participar quando se dirigiram a instituição para atendimento odontológico, de acordo com os critérios de elegibilidade.

Critérios de inclusão: Crianças de 9 a 12 anos, com necessidade de tratamento odontológico restaurador sob anestesia local, nos dentes maxilares posteriores, com desenvolvimento cognitivo compatível com a idade.

Critérios de exclusão: crianças com comportamento definitivamente negativo de acordo com a escala de comportamento de Frankl (Frankl et al.[39] 1962), com histórico de alergia a anestésicos locais e aquelas que não foram autorizadas pelos pais ou responsáveis, crianças em tratamento medicamentoso que contraindicam a injeção de anestésicos locais.

PROCEDIMENTOS ANESTÉSICOS

ANESTESIA

Todas as anestesias infiltrativas foram realizadas por um único cirurgião-dentista experiente. O protocolo incluiu a aplicação de anestesia tópica com benzocaína a 20% durante 60 segundos, técnica anestésica infiltrativa, foram injetados 1,8 mL do anestésico lidocaína 2% com epinefrina 1: 100.000, com uma vazão média de 1,0 mL/min. Toda injeção de anestesia foi controlada por cronômetro totalizando 108s.

ANESTESIA CONVENCIONAL

Para anestesiar os molares superiores, a punção da agulha foi realizada com o bisel direcionado para a mucosa alveolar e, através de uma leve pressão, penetrou no tecido mole, evitando contato com o osso. Após confirmar aspiração negativa, o anestésico local foi injetado no local de interesse. Em seguida, a agulha foi removida suavemente após a conclusão da injeção.

ANESTESIA VIBRACIONAL

O VBA foi realizado com o auxílio de um dispositivo denominado DentalVibe^{TM} (Columbia Tech, Boston, EUA). Após anestesia tópica, o dispositivo foi posicionado no local da punção e ligado, transmitindo uma vibração local. Após 10 segundos, a punção foi realizada no intervalo entre as pontas do dispositivo para aplicação do anestésico conforme descrito na técnica convencional. Após a retirada da agulha, o dispositivo foi desligado.

ANESTESIA COMPUTADORIZADA

Para o CCLAD, foi utilizado o equipamento Morpheus^{TM} (Meibach Tech, São Paulo, Brasil). Após anestesia tópica, um programa pré-determinado foi selecionado. Em seguida, a punção foi realizada acionando o pedal de introdução; logo após, o botão de aspiração foi selecionado e, se não houvesse aspiração positiva, o pedal de

injeção era acionado para aplicação do anestésico. Ao final da injeção, a agulha foi lentamente removida do sítio de injeção.

DESFECHOS E FERRAMENTAS DE AVALIAÇÃO

DESFECHOS PRIMÁRIOS

AUTOPERCEPÇÃO DA DOR

A autopercepção da dor foi mensurada com a Escala de Avaliação da Dor de Wong Baker Faces (WBF) (Wong e Baker[40] 1988) ; essa escala, inclui imagens de expressões faciais com números correlacionados de 0 a 10 (0 sendo “não dói” e 10 sendo “pior dor”). E pela escala de classificação numérica da dor (NRS), (0 a 10, onde 0 significa ausência de dor, 10 significa pior dor possível) (Asarch et al.[12] 1999).

COMPORTAMENTO DISRUPTIVO

Para a determinação do comportamento disruptivo das crianças, enquanto recebiam a anestesia, foi selecionada a escala Face, Pernas, Atividade, Choro, Consolabilidade (FLACC) (Willis et al.[41] 2003). Os resultados variam de 0 a 10, com a seguinte classificação: escore 0 - o paciente apresenta-se relaxado e confortável; escore 1 a 3 - desconforto leve; escore 4 a 6 - dor moderada; 7 a 10 - dor intensa.

DESFECHOS SECUNDÁRIOS

ANÁLISE DO MEDO E DA ANSIEDADE RELACIONADOS AO TRATAMENTO ODONTOLÓGICO

Todos os voluntários responderam ao questionário específico denominado Dental Anxiety Scale (Corah) (Corah[42] 1969, Corah et al.[43] 1978) para mensurar o indice de medo e ansiedade vinculado ao tratamento odontológico. Trata-se de um questionário com 4 perguntas em que os pacientes indicaram sua reação emocional de acordo com a situação odontológica. A soma do resultado varia de 4 a 20 pontos.

Os escores classificaram o paciente como “livre de ansiedade” (4 pontos); “Ansiedade moderada” (5-10 pontos); “Alta ansiedade” (11-15 pontos) e “ansiedade severa” (16-20 pontos). O autor relatou confiabilidade no questionário (consistência interna = 0,86; teste-reteste = 0,82) (Corah[42] 1969, Corah et al.[43] 1978).

ANÁLISE DO ESTADO EMOCIONAL DE ANSIEDADE

O teste de imagens de Venham modificado (VPTm) (Ramos-Jorge e Pordeus[44] 2004) foi realizado para determinar o estado emocional da ansiedade da criança. O VPTm consiste em 8 figuras representando sentimentos que variam de ansiedade a contentamento. As crianças foram convidadas a selecionar a imagem que descrevia seus sentimentos naquele momento específico. A soma das respostas varia de 0 a 8 e o nível de ansiedade do paciente é classificado como "livre de ansiedade" (escore 0); “Baixo nível de ansiedade” (escores 1-3); médio nível de ansiedade” (escores 4-6) e “alto nível de ansiedade” (7-8).

PARÂMETROS FISIOLÓGICOS

As crianças foram avaliados quanto à pressão arterial sistólica (PAS), pressão arterial diastólica (PAD), frequência cardíaca (FC), saturação de oxigênio (SpO_2) e frequência respiratória (FR), utilizando monitor multiparamétrico Inmax^{TM} (Instramed, Porto Alegre, Brasil). Para PAS e PAD, os valores foram registrados no final da medição, para FC, SpO_2 e FR, os valores foram registrados a cada 15 segundos e a média foi calculada (Baghlaf et al.[7] 2015).

TAMANHO DA AMOSTRA

O cálculo do tamanho da amostra foi realizado considerando o desfecho primário “dor”. Dessa forma, foram utilizados os níveis médios de dor obtidos por Palm (2004) (Palm et al.[45] 2004). Considerando um poder de 95% e um nível de significância de 5%, em um ensaio clínico de superioridade, a amostra final foi composta por 105 crianças, com 35 sujeitos por grupo de estudo. O cálculo do tamanho da amostra foi realizado pelo software G*Power program 3.1.9.2.

RANDOMIZAÇÃO E OCULTAÇÃO DE ALOCAÇÃO

Um membro da equipe não envolvido no protocolo de pesquisa realizou os processos de randomização e alocação. Foi obtida uma tabela gerada por programa de computador, com randomização em blocos de três e igual proporção de alocação, considerando os três grupos de estudo. A ocultação da alocação foi realizada através da distribuição dos códigos obtidos em envelopes opacos pretos numerados, que foram abertos apenas no dia do tratamento odontológico, imediatamente antes da anestesia local, consequentemente, o operador estava cego até esse momento. Esses procedimentos foram realizados também no site sealenvelope.com (Sealed Envelope Ltd, Londres, Reino Unido).

INTERVENÇÃO

O protocolo de pesquisa considerou quatro momentos para coletar dados sobre os resultados relacionados ao paciente, resultados centrados no paciente e parâmetros fisiológicos. Esses momentos foram: T1 (antes do tratamento); T2 (no consultório odontológico, quando a criança é chamada a ocupar seu lugar na cadeira odontológica); T3 (durante anestesia local) e T4 (imediatamente após anestesia local). Todos os dados obtidos foram registrados em uma ficha clínica desenvolvida especificamente para fins desta pesquisa. Um investigador assistente foi responsável pelo registro dos dados, além de garantir a confidencialidade da identificação do paciente, que foi substituída por um número. A sequência dos procedimentos está representada na Figura 2.

T1 e T2 consistiram em uma avaliação pré-operatória que teve como objetivo identificar os parâmetros *baseline* em relação ao medo e à ansiedade do voluntário relacionados ao tratamento odontológico (Corah) e estado emocional (VPTm), além dos parâmetros fisiológicos. O questionário sobre ansiedade (Corah) foi aplicado em ambiente neutro; os demais desfechos foram medidos na sala de espera do consultório odontológico (T1). Quando a criança estava sentada na cadeira odontológica (T2), as pressões sistólica e diastólica, freqüência cardíaca, saturação de oxigênio, freqüência respiratória e VPTm foram registrados novamente.

Depois disso, o pesquisador principal, que foi o único operador deste estudo, abriu o envelope opaco para descobrir a técnica anestésica que deveria ser realizada naquele paciente específico. Este foi o começo do T3. Durante essa fase transoperatória, os parametros fisiológicos foram aferidos novamente por um pesquisador assitente e um outro pesquisador assistente gravou o procedimento anestésico; este vídeo foi avaliado posteriormente, de acordo com os critérios da FLACC.

Imediatamente após a anestesia, no T4, o VPTm foi repetido e os testes de autopercepção da dor (WBF e NRS) também foram aplicados. Ao final da coleta de dados, o tratamento odontológico seguiu normalmente. Medidas usuais de controle comportamental, comunicação e orientação comunicativa, técnica dizer-mostrar-fazer, controle de voz, comunicação não verbal, reforço positivo e distração, foram usadas em todos os casos.

CEGAMENTO

O operador e os pacientes não estavam cegos para a técnica anestésica, pois os dispositivos necessários para executar as técnicas não podem ser ocultados. Não obstante, a análise dos dados foi realizada sem o estatístico conhecer os grupos de estudo.

AVALIADORES

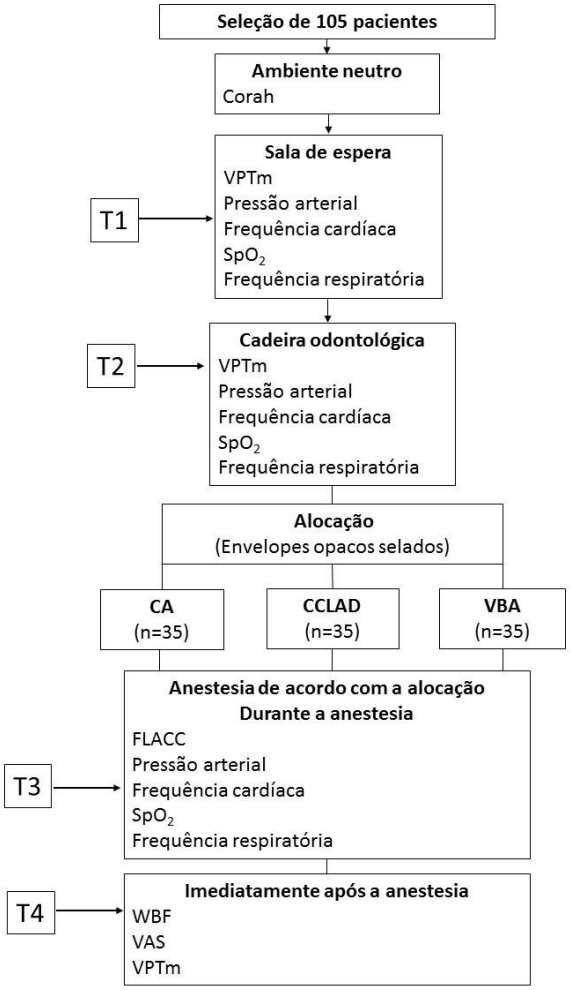
Os pesquisadores foram treinados previamente e avaliaram o medo ou ansiedade dentária, autopercepção da dor, comportamento disruptivo, ansiedade e parâmetros fisiológicos de cada paciente.

Um pesquisador auxiliar específico aplicou o questionário Corah, os testes VPTm, WBF, NRS e outro pesquisador auxiliar registrou os parâmetros fisiológicos. Para obter resultados confiáveis para o FLACC, o pesquisador foi testado pelo teste do coeficiente Kappa e obteve resultado de 0,90. Este realizou a análise dos vídeos gravados, durante a aplicação da anestesia, para determinar o índice de comportamento disruptivo.

ANÁLISE ESTATÍSTICA

A análise estatística foi realizada no programa estatístico SPSS versão 15.0 (SPSS Inc., Chicago, IL, EUA). Foi realizada análise descritiva. Os dados não paramétricos obtidos após a aplicação dos diferentes testes (Corah, WBF, NRS, FLACC) foram submetidos a Kruskal-Wallis para análise não pareada. ANOVA para medidas repetidas com post-hoc de Tukey para análises para comparar os dados de VPTm, SBP, DBP, HR, RR e SpO2 entre as fases e grupos do estudo. Também foram realizados testes de correlação de Pearson para Corah, VPTm, WBF, NRS e FLACC.

Figura 2: Diagrama das etapas do estudo 3



4 ARTIGOS

4.1 ARTIGO 1

REVISTA

International Journal of Paediatric Dentistry

Does computerized anaesthesia reduce pain during local anaesthesia in paediatric patients for dental treatment? A systematic review and meta-analysis

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ABSTRACT

This systematic review and meta-analysis analysed whether pain and disruptive behaviour can be decreased by the use of computerized local dental anaesthesia (CDLA) in children. The literature was screened to select randomized clinical trials that compared computerized and conventional anaesthesia. The primary outcome was pain perception during anaesthesia; the secondary, disruptive behaviour. The risk of bias of individual papers and the quality of the evidence were evaluated. After search, 8389 records were found and 20 studies remained for the qualitative and quantitative syntheses. High heterogeneity was detected for both outcomes. For the pain perception, the overall analysis showed a standard mean difference of −0.78 (−1.31, −0.25) favouring CDLA; however, when only studies at low risk of bias were analysed (subgroup analysis), there was no difference between the two techniques [−0.12(−0.46, 0.22)]. For disruptive behaviour, no differences were detected for

continuous [−0.26 (−0.68, 0.16)] or dichotomous data [0.81 (0.62, 1.06)]. The quality of evidence was judged as low for pain perception and very low for disruptive behaviour. It is concluded that there is no difference in the pain perception and disruptive behaviour in children subjected to computerized or conventional dental local anaesthesia. Notwithstanding, the quality of the available evidence is low.

KEYWORDS: anaesthesia, child, dental, meta-analysis, pain, systematic review

INTRODUCTION

Anxiety and fear may act as a barrier for dental treatment,[1] especially when local anaesthesia is involved.[2] These feelings probably have originated from experiences of pain during previous dental treatments, which demonstrate the importance of pain control during paediatric dental treatment.[3] Local anaesthesia is the most common method to do so, but it is also one of the factors that can trigger fear and anxiety, leading to difficulties for behaviour management in paediatric patients.[4] Considering that severe anxiety and fear may enhance pain perception,[1] it is fundamental to explore approaches that have potential to reduce the pain and discomfort associated with local anaesthesia.[5]

Currently, the use of topical anaesthesia, prolonged injection time,6 vibrotactile devices, and jet injectors[7] are the available tools for this purpose. Considering that the pain during anaesthesia is caused by the stimulus to the sensors of pressure, pain, and temperature, on the tissues when injected, as well as the speed of injection is one approach that has good potential to reduce the pain during anaesthesia.[8] Based on this finding, the computer-controlled local anaesthetic delivery (CCLAD) was developed. The central technology of this system is a constant and slow delivery rate of the local anaesthetic solution with pressure control, at a rate below the pain threshold, since the flow rate of the local anaesthetic is controlled by a computer controlled pump.[5] This device allows that, regardless of the variations in tissue resistance, a potentially painless injection can be done.[3] This can be challenging to accomplish with the conventional anaesthesia6 since manual injection is subjected to individual variations regarding the pressure and volume of the anaesthetic solution that is being injected.[9] The control of velocity and pressure during the anaesthetic solution

injection is one possible reason that could stimulate a paediatric dentist to incorporate a CCLAD device in his/her daily practice.

Different CCLAD have been developed, such as The Wand™ (subsequent versions named as Wand Plus® and CompuDent®) (Milestone Scientific,Livingston, New Jersey, USA), Quicksleeper™ (Dental HiTec, Cholet, France), Sleeper One™ (Dental Hi Tec, Cholet, France), and Comfort Control Syringe™ (Dentsply International, York, PA, USA)[7] and numerous papers comparing the conventional technique with the computerized technique have been published.[1,2,5,6,9-21] These studies differ in the design, sample size, and anaesthesia region/technique. As a consequence, there are divergent results, favoring the use of computerized anaesthesia[3,5-7,13] or showing no difference between the two techniques.[9,16-19,22]

We are aware that a literature review[23] and a recente systematic review[24] on this subject have been published. Both papers evaluated the use of CCLAD in children and adults. The first one is a narrative review of randomized clinical trials, and the second one is a systematic review and meta-analysis, with some shortcomings in the methodology, particularly regarding the assessment of the risk bias of the included papers. Therefore, we understand that a systematic review focused on children is the best way to provide evidence in order to subsidize a clinical decision in paediatric dentistry.

A substantial decrease in the pain, and in the consequent anxiety/fear, during local anaesthesia is the main factor that would encourage the clinicians to adopt the computerized anaesthesia in their daily practices, since the equipment is costly when compared to the conventional anaesthesia. The good clinical practice dictates that all decisions should be made based on strong scientific evidence, showing an important and significant response that could actually influence on the quality of the treatment and the patient's behavior related to local anaesthesia. The best evidence to support this decision is a systematic review and meta-analysis.

However, to the knowledge of the authors, this is the first systematic review that addresses this topic related to the paediatric dental practice, which justifies the completion of this study.

Therefore, this systematic review and meta-analysis aims to investigate whether local computerized anaesthesia decreases the pain and disruptive behavior in children when compared to conventional anaesthesia.

MATERIAL AND METHODS

PROTOCOL AND REGISTRATION

This study was registered in PROSPERO (CRD42016037184) and followed the PRISMA guidelines.[25] It was carried out at the State University of Ponta Grossa, Parana, between May 2017 and May 2019.

INFORMATION SOURCES AND SEARCH STRATEGY

The controlled vocabulary (MeSH terms) and free words in the search strategy were defined based on the following PICOS strategy:

a) population (P): children undergoing dental treatment under local anaesthesia;

b) intervention (I): computerized local anaesthesia;

c) comparison (C): conventional local anaesthesia;

d) primary outcome (O): pain perception and children's behaviour during local anaesthesia;

e) study design (S): randomized clinical trials.

The search strategy was initially established for PubMed database, associating controlled vocabulary (MeSH terms). The boolean operator OR was used to combine the terms in each PICO concept; the operator AND was used to combine the different PICO concepts (population, intervention, and comparison). The strategy was adapted to other electronic databases (Scopus, Web of Science, Latin American Literature of Health Sciences of the Americas and Caribbean—LILACS, Brazilian Library of Dentistry—BBO and Cochrane Library) (Table 1). The grey literature was searched using the databases System for Information on Grey Literature in Europe (SIGLE) and Scholar Google. Abstracts from the annual conference of the International Association for Dental Research (IADR) (1990-2018) were also searched. Dissertations and theses were searched using the ProQuest Dissertations and Theses Full- Text databases and the Periodicos Capes Thesis database.

ELIGIBILITY CRITERIA

The studies included in this systematic review and meta-analysis were randomized controlled trials (RCTs) with a parallel or cross-over design that analysed the influence of computerized anaesthesia on the intensity of pain and on the children's behaviour during local anaesthesia when compared to conventional anaesthesia technique.

Studies were excluded if:

a) sedation techniques were used associated with local anaesthesia;

b) the sample included teenagers and adults;

c) computerized anaesthesia was not compared to a control (the conventional technique);

d) computerized anaesthesia was used in conjunction with other pain reduction techniques such as electrodes and vibrations;

e) the paper was not written in English, Spanish, or Portuguese.

SELECTION OF THE STUDY AND DATA EXTRACTION

The first phase of the selection of the papers to be included in the systematic review consisted in a screening of the retrieved papers based on title and abstracts according to the criteria already described. This was accomplished by two reviewers (PCS and ACRC). In case of duplicated papers, the study was considered once. If the analysis of the title and abstract prevented a decision for inclusion or exclusion of the paper, the full text was analysed.

The full text of the eligible papers was retrieved, and these studies received an identification code that consisted in the author's name and year of publication. The relevant information about the studies (study design, characteristics of the participants, type of anaesthetics, study groups, and outcomes) is shown on Table 2. It was collected in specific forms that were developed for this research and pilot tested to certify that the retrieved data were consistent with the research question. Three researchers took part in the data extraction (PCS, ACRC, and LMW).

RISK OF BIAS IN INDIVIDUAL STUDIES

The Cochrane Collaboration tool for assessing risk of bias in randomized trials was used for the quality assessments of the trials, following the recommendations described in the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0[26,27] this was accomplished by two independent reviewers (PCS and ACRC).

The Cochrane tool is based on six domains: adequate sequence generation, allocation concealment, blinding of the outcome assessors, incomplete outcome data, selective outcome reporting, and other possible sources of bias. The judgment for each domain consisted of recording ‘yes’ (low risk of bias), ‘no’ (high risk of bias), or ‘unclear’ (either lack of information or uncertainty about the potential for bias).

Two of the six domains in the Cochrane risk of bias tool were considered as key domains for this systematic review (sequence generation and allocation concealment).[26]

The papers were judged to be at ‘low’ risk of bias if they were judged as ‘low’ risk in both key domains. If one key domain was classified as ‘unclear’ or ‘high’ risk of bias, the study was considered at ‘unclear’ or ‘high’ risk of bias, respectively. If there was any disagreement between the reviewers in judging the key domains, it was solved through discussion or by consulting a third reviewer (L. M. W.).

SUMMARY MEASURES AND SYNTHESIS OF THE RESULTS

For the meta-analysis, only studies classified as ‘low’ or ‘unclear’ risk in the key domains at study level were included. Data from eligible studies about pain perception during anaesthesia were evaluated using standardized mean difference, since it was a continuous outcome, obtained using diferent scales to evaluate pain. Patient's behaviour results were reported with dichotomous or continuous data; therefore, this outcome was analysed using risk ratio and standardized mean difference, respectively.

For all summary measures, the 95% confidence interval (CI) was used and random effects model was employed. Heterogeneity was assessed using the Cochran *Q* test and I^2 statistics. All analyses were conducted using RevMan software (version 3, the Cochrane Collaboration, USA). Subgroup analysis was performed considering two groups: studies of low and unclear risk of bias.

ASSESSMENT OF THE QUALITY OF EVIDENCE USING GRADE

The quality of the evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE)[28]. This stage was accomplished to determine the overall strength of the evidence for each meta-analysis. The evidence can be graded in four levels (very low, low, moderate, and high).

When a meta-analysis is graded as 'high quality', it means that the authors are very confident that the true effect lies close to the estimate of the effect. Factors that downgrade the quality include imprecision, inconsistency, indirectness, limitations, and bias of the evidence.[29]

RESULTS

STUDY SELECTION

We found 8389 records in the databases in the first screening. After removal of duplicates, 7344 records remained. The title analysis reduced this number to 302 papers. After abstract reading, 272 were excluded. Therefore, 30 studies remained for full-text analysis.

From these, 10 were excluded for different reasons:

a) patients were sedated with nitrous oxide (n = 2)[30,31];

b) there was no comparison between anaesthetic techniques (conventional vs. computerized) (n = 7),[4,8,10,11,17,32,33];

c) the papers were not written in English, Portuguese, or Spanish (n = 1)[34] (Figure 3).

FEATURES OF INCLUDED PAPERS

The characteristics of the 20 selected studies are listed in Table 2. Twelve studies had parallel designs[2,5-7,9,13,15,16,18-20,35] and 7 cross-over designs.[1,3,12,14,21,36,37] And one mixed design parallel and cross-over.[4] The sample size ranged from 20 to 158 children, with mean age of 8.41±2.42 years.

The anaesthesia protocol for all studies included the use of topical anaesthetics previously local anaesthesia, except one that did not report.[37] The topic

anaesthetic drug was benzocaine in five studies,[3,5,18,19,21] lidocaine spray in two,[1,20] one study used lidocaine with prilocaine,12 another one used lidocaine gel,7 and nine did not report.[2,6,9,13-16,35,36] The most used anaesthetic solution for local anaesthesia was lidocaine 2% with epinephrine 1:100 000, which was used in 12 studies [2,3,5-7,9,13,14,16,19,20]; four studies used 2% lidocaine with epinephrine 1:80 000[7,18-20]; three studies used 2% mepivacaine with epinephrine 1:100 000,[1,12,37] one used 4% articaine with epinephrine 1:100 000,[4] and two studies did not report which anaesthetic solution was used.[15,35]

As for the anaesthesia site, there was some variation between the studies. Twelve studies carried out local anaesthesia in the maxilla [1-3,6,13,14,16,18-21,37]; three in the mandible,[5,7,12] and five in the maxilla and mandible.[4,9,15,35,36] . Most of the studies that used the mandible as the anaesthesia site performed the inferior alveolar nerve block technique (IANB)[4,5,9,12,15,35]; only one used the infiltrative technique[7] for the conventional anaesthesia. For the computerized anaesthesia, three used periodontal ligament injection (PDL),[5,15,35] one infiltrative technique,[7] two IANB technique,[9,12] and one intraosseous technique.[4] When the anaesthesia site was the maxilla, fifteen used the vestibular and palatine infiltrative technique,[1-4,6,9,13-16,18-21,35] and one PDL[37] for the conventional anaesthesia; for the computerized technique, six papers used anaesthetic techniques for anterior and middle superior nerve injection (AMSA),[2,3,6,15,16,35] five used the palatal approach anterior superior alveolar nerve block (P-ASA),[2,6,13,15,35] one PDL[37] one intraosseous technique,[4] and one study did not report.[36]

There was a great divergence in the methods of evaluation and the presentation of the data between the studies. For pain perception evaluation, eight studies used visual analog scale (VAS).[1,2,4,9,12,14,15,20,35] Other scales used were Eland colour scale,[3] Wong Baker Faces,[5] Faces Pain Scale Revised,[7] FIS Image Scale modified,[36] NVRS (Numerical Visual Rating Scale).[37]

The disruptive behaviour of the patient related to the pain during anaesthesia was evaluated by seven articles using the code of behaviour of pain or disruptive behaviour[2,5,6,9,13,15,35]; two articles used ‘Sound, Eyes and Movement scale’[3,20]; the ‘The Face, Legs, Activity, Cry, Consolability scale’ (FLACC) was used by two studies.[7,36]

RISK ASSESSMENT OF BIAS

Six papers were classified as ‘low’,[4,15,18,19,35,37] and fourteen articles were classified as ‘uncertain risk’ risk of bias[1-3,5- 7,9,12-14,20,21,36](Figure 4).

META-ANALYSIS

The meta-analyzes were performed in studies classified at ‘low’ or ‘unclear’ risk of bias from which the necessary information could be extracted. The meta analyzes are shown on Figures 5, 6, and 7. We also performed a subgroup analysis to explore if the quality of included studies had any effect on the combined results. A total of 16 articles were eligible for a meta-analysis on pain perception during local anaesthesia, but the great variability on data report prevented us from using all of them.

Therefore, only ten papers were used for this purpose; four were classified at low risk of bias,[4,15,35,37] and six at unclear risk of bias.[3,5,7,13,20,36] There was some incompatibility in the way the results were showed in some papers, which prevented us from collecting the data and made them unsuited for the meta-analysis on pain perception and these papers were excluded. [1,2,9,14,18,19]

For the presence of patient's disruptive behaviour related to anaesthesia,11 studies were eligible for meta-analysis. For this outcome, five papers reported the outcome using continuous data and they were grouped in one meta-analysis that used the standard mean differences [3,7,20,35,36] and the other five studies reported as dichotomic data and they were analyzed using risk ratio as effect measure. [2,5,6,9,15] Among them, two were classified as low risk of bias[15,35] and eight classified as unclear risk of bias.[2,3,5-7,9,20,36] The excluded paper showed different methodology for determination of disruptive behavior, and the data were not used in the meta-analysis.[13]

PERCEPTION OF PAIN

This analysis was based on 10 papers comparing computerized to conventional anaesthesia.[3-5,7,12,15,20,35-37] The overall analysis resulted in a standard mean difference of −0.78 (95% CI = −1.31 to −0.25; I^2 = 94%). The standard mean difference was −0.12 (95% CI = −0.46 to-0.22; p = .48) for the subgroup 'low

risk'[4,15,35,37] (Figure 5); data were heterogeneous (χ2 = 13.24; *df* = 3, *p* = .004; *I*2 = 77%). When only the papers judged as 'unclear', risk were analyzed, the standard mean difference was −1.27 (– 95% CI = −2.21 to −0.33; *p* = .008); data were also heterogeneous (χ^2 = 115.74, *df* = 5, *p* < .00001; I^2 = 96%) 3,5,7,12,20,36 (Figure 5). A sensitivity test was also performed in the 'low risk' subgroup. It was observed that two papers[4,37] were responsible for the heterogeneity of the data. When these papers were removed from the meta-analysis, no difference was observed in the final results of the meta-analysis and the heterogeneity was reduced to 0% (χ^2 = 0.02, *df* = 1, *p* = .90; I^2 = 0%).

BEHAVIOUR OF THE PATIENT RELATED TO ANAESTHESIA

This analysis was based on 10 articles.[2,3,5-7,9,15,20,35,36] Considering the results presented by the authors in continuous data (means),[3,7,20,35,36] the mean difference was −0.26 (95% CI = −0.68 to 0.16; *p* = .23), the data were heterogeneous (χ^2 = 23.69; *P* < .00001; I^2 = 83%) (Figure 6). Considering the results presented by the authors in dichotomy data (events),[2,5,6,9,15] the risk ratio was 0.81 (95% CI = 0.62 to 1.06; *p* =.13), the data were also heterogeneous (χ^2 = 9.72, *df* = 4 (*p* = .05), I^2 = 59%) (Figure 7). This result showed that there is no difference in disruptive behaviour in children during local anaesthesia, regardless the type of local anaesthesia. The subgroup analysis based on the risk evaluation of the papers also showed no difference between the two anaesthetic techniques (Figures 6 and 7).

ASSESSMENT OF THE QUALITY OF EVIDENCE USING GRADE

For the primary outcome 'pain perception', the quality of evidence was low as 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. For the secondary outcome 'Disruptive behavior related to computerized and conventional anesthesia', the evidence was graded as very low, since any estimate of effect is very uncertain (Table 3).

In both outcomes, the evidence was downgraded due to risk of bias and inconsistency, which is related to the lack of 'allocation concealment' and 'sequence generation' and unexplained heterogeneity.

DISCUSSION

This systematic review and meta-analysis showed that local anaesthesia with conventional or computerized methods result in similar levels of pain perception and disruptive behaviour in children, but this conclusion should be taken cautiously, considering that the evidence was graded as low.

Pain perception was considered the primary outcome, since disruptive behaviour may be triggered by pain.[7] The method of evaluating pain is a very complex scientific question.[38] It is a patient-reported outcome, and therefore, the subjective response obtained must be converted into quantitative data to enable interpretation. Also, it is directly related to the individual's experiences like stress, anxiety, and fear that can alter the perception of pain. In the infant universe, it is even more difficult to understand how much pain the child feels at any given moment or stimulus, how anxious, stressed, or frightened he/she is, and how it will influence the pain perception.[1] Therefore, perception of pain and behaviour during local anaesthesia is related to children's emotional factors. These factors, by themselves, may be responsible for some degree of the inherent clinical heterogeneity of the trials. However, we can also list a few other features that probably contribute to the high degree of heterogeneity and the poor quality of evidence found in our meta-analysis of pain during local anaesthesia, such as the variety of pain measurement scales and the age range studied.

The studies reported here measured pain during local anaesthesia using different pain scales, all of them dependente on the patient's report. This is the method taken as the ‘gold standard’ for pain assessment in children.[39] The pain scales consisted of various versions of the visual analog scales,[1,2,4,9,12,14,15,18-20,35] Wong Baker FACES,[5] Faces Pain Scale—revised,[7] Eland Colour Scale,[3] numerical verbal rating scales,[37] and Facial Image Scale.[36] They are designed to assess different levels of pain, and they are all validated to evaluate pain in children.[9] Even considering the different scales used by the authors, the results of the studies could be grouped because they were summarized by calculating the Hedge's g standardized mean difference. By doing so, all the results are transformed to a common scale and they become comparable.

However, it can contribute to increase heterogeneity. For the perception of pain, the meta-analysis showed a lower perception of pain in children who received

computerized anaesthesia. However, a high level of heterogeneity was detected (*I*2 = 94%). The better performance of the computerized anaesthesia regarding pain perception was not observed when only studies with low risk of bias were included, and the heterogeneity was reduced (*I*2 = 77%; 95%), as well as the 95% confidence interval for the standard mean difference (−0.12; 95% CI = −0.46 to 0.22). In the subgroup of the studies considered at unclear risk of bias, we detected a decreased number of patients associated to increased degree of the heterogeneity (*I*2 = 96%) and larger confidence interval (−1.27; 95% CI = −2.21 to 0.33), which reduced our confidence on the effect size. To corroborate our decision, sensitivity analysis was done, in order to identify the reasons for the heterogeneity in the 'low risk' subgroup. By doing so, when removing two papers,[4,37] the heterogeneity was eliminated and the final result remained unchanged. It strengthens the findings showing no difference between the two local anaesthetic techniques. Taking all of this together, we choose to accept the results from the low-risk studies analysis, until others randomized clinical trials are available for analysis. Therefore, we graded the quality of evidence for this particular outcome as low, due to problems of inconsistency.

Observing children's behavior during dental treatment is essential in pain evaluation, as their facial expressions or body movements are important diagnostic criteria that indicate discomfort or pain.[16] In this way, the disruptive behavior was considered as a secondary outcome. No differences were observed for this variable when comparing the different modalities of anaesthesia, irrespective of the risk of bias of the studies. It was observed heterogeneity of the data, but it was lower than the one observed in the perception of pain. In these criteria, only three scales were used and it is a patient centered outcome, which may have led to a decreased degree of subjectivity. The pain related behaviors commonly evaluated (for instance: body movement, muscle tension, crying or screaming, verbal protest, and bodily resistance) are very explicit situations; however, there is always the possibility of adding bias to the study during the evaluation process. This is a relevant topic to be considered, since the characteristics of the two evaluated anaesthetic techniques make it impossible to have a blind evaluator and the included papers did not report any kind of training or calibration of the evaluators, which would be the optimal situation for randomized controlled trials. This is a step that we strongly suggest to be included in the research protocol for future clinical trials on this subject. The overall quality of the papers for

disruptive behavior outcome was downgraded for inconsistency (due to the degree of heterogeneity) and imprecision (due to the range of the confidence interval), which was associated to the number of studies at unclear risk of bias.[2,3,5-7,9,20,36]

The blocking of the nervous stimulation by dental anaesthesia decreases the central nervous system response to painful stimuli, also decreasing the patient's anxiety during dental treatment. Nevertheless, the greater the dental anxiety, the greater the noncooperative behavior[40] and the difficulty to manage children's behaviour. Considering this, some authors also evaluated the stress and anxiety during conventional and computerized anaesthesia[1,15,18,21,35] and no difference was reported. It was found that high anxious children tend to feel more pain during local anaesthesia, irrespective the anaesthetic technique used.[35] Unfortunately, it was not possible to extract the data related to stress and anxiety from these papers, since evaluation criteria were very different from one to another, which prevented the meta-analysis.

In addition to the factors already described, there are conditions that can influence the pain response and disruptive behaviour,[36] such as the site of the anaesthesia. For example, the IANB method is considered very painful; an injection into the palate is even more painful.[33] This may affect the child's behavior and perception of pain. In the included studies, the majority of the papers compared the injections in the maxilla.[1-4,6,13,14,16,18-21,37] It is a less challenging anaesthetic technique to perform when compared to the IANB, since there are fewer anatomical variations in the maxilla. However, there were studies that compared not only different anaesthetic methods, but also different anaesthetic techniques,[2-4,6,9,13,15,16,18,35,36] which interfere in pain perception and disruptive behavior in children. By doing so, the study design added not only another variable, but also a possible bias; therefore, the results should be interpreted cautiously. This may be another source of heterogeneity, as detected by the meta-analysis. Therefore, if the focus is the evaluation of the anaesthetic method (for instance computerized vs. conventional), future clinical trial must considered the use of the same anaesthetic technique.

Irrespective of the selected anaesthetic technique or anaesthetic method, a suitable approach for managing the infant patient is essential. The expertise and training of the dentist in anaesthetizing a child are very important and may modify the perception of pain during the procedure. The paediatric dentist should establish a dialogue with the child so that he/she feels safe and confident. It is necessary to recognize the child's psychological profile and to use the most appropriate behaviour

management techniques in dental treatment, improving the child's coping skills,[41] since manipulating attention or emotion can positively affect the experience of pain.[42] Likewise, anaesthesia should be performed according to the protocol of each technique, negligence the recommendations may contribute to fear and dental anxiety.

According to this systematic review and meta-analysis, we do not consider that investing on a CCLAD, with the objective of reducing pain and disruptive behaviour related to local anaesthesia in children, is a wise choice, since conventional injection performed correctly may have similar results. We strongly suggest that new randomized clinical trials should be accomplished with well-defined methodology in order to improve the quality of the evidence.

CONCLUSION

There is no difference in the perception of pain and disruptive behaviour in children subjected to computerized or conventional dental local anaesthesia. Notwithstanding, the quality of the available evidence is low and further research is needed to corroborate this finding.

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Table 1 – Electronic database and search strategy.

Pubmed= 6269 (05/04/2019)			
#1 "primary dentition"[Title/Abstract]) OR "primary teeth"[Title/Abstract]) OR "primary tooth"[Title/Abstract]) OR "first teeth"[Title/Abstract]) OR "first tooth"[Title/Abstract]) OR "primary molars"[Title/Abstract]) OR "permanent teeth"[Title/Abstract]) OR dentition, permanent[MeSH Terms]) OR "permanent tooth"[Title/Abstract]) OR "paediatric dental patient"[Title/Abstract]) OR "pediatric dental patients"[Title/Abstract]) OR pediatric dentistry[MeSH Terms]))	#2] (((“computerized injection”[Title/Abstract]) OR “computerized anesthesia”[Title/Abstract]) OR “computerized anaesthesia”[Title/Abstract]) OR “eletronic anesthesia”[Title/Abstract]) OR “electronic anaesthesia”[Title/Abstract]) OR “the wand”[Title/Abstract]) OR “quicksleeper”[Title/Abstract]) OR “Morpheus”[Title/Abstract]))	#3 ((((Anesthesia, dental[mh:noexp]) OR "Dental anesthesia"[Title/Abstract]) OR "Dental anaesthesia"[Title/Abstract]) OR "Local anesthetics"[Title/Abstract]) OR "Local anaesthetics"[Title/Abstract]) OR "Injectable anesthesia"[Title/Abstract]) OR "Injectable anaesthetic"[Title/Abstract]) OR "Infiltration anesthesia"[Title/Abstract]) OR "Injectable anesthetic"[Title/Abstract]) OR "Infiltration anaesthesia"[Title/Abstract]) OR "Injectable anaesthesia"[Title/Abstract]) OR "Traditional anesthesia"[Title/Abstract]) OR "Traditional anaesthesia"[Title/Abstract]))	#4 (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies as topic[mh] OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospective*[tw] OR volunteer*[tw]) NOT (animals[mh] NOT humans[mh]))
	#1 AND #2 OR #3 AND #4		
Scopus= 914 (05/04/2019)			
((TITLE-ABS-KEY (**"primary dentition"**) OR TITLE-ABS-KEY (**"primary teeth"**) OR TITLE-ABS-KEY (**"primary tooth"**) OR TITLE-ABS-KEY (**"first teeth"**) OR TITLE-ABS-KEY (**"first tooth"**) OR TITLE-ABS-KEY (**"primary molar*"**) OR TITLE-ABS-KEY (**"permanent teeth"**) OR TITLE-ABS-KEY (**"permanent dentition"**) OR TITLE-ABS-KEY (**"permanent tooth"**) OR TITLE-ABS-KEY (**"paediatric dental patient*"**) OR TITLE-ABS-KEY (**"pediatric dental patient*"**) OR TITLE-ABS-KEY (**"pediatric dentistry"**)))	((TITLE-ABS-KEY (**anesthesia**) OR TITLE-ABS-KEY (**anaesthesia**) OR TITLE-ABS-KEY (**the wand**) OR TITLE-ABS-KEY (**quicksleeper**) OR TITLE-ABS-KEY (**morpheus**)	TITLE-ABS-KEY (**"dental anesthesia"**) OR TITLE-ABS-KEY (**"dental anaesthesia"**) OR TITLE-ABS-KEY (**"Local anesthetic*"**) OR TITLE-ABS-KEY (**"Local anaesthetic*"**) OR TITLE-ABS-KEY (**"injectable anesthetic"**) OR TITLE-ABS-KEY (**"injectable anaesthetic*"**) OR TITLE-ABS-KEY (**"Infiltration**

		anesthesia") OR TITLE-ABS-KEY (**"Infiltration anaesthesia"**) OR TITLE-ABS-KEY (**"traditional anesthesia"**) OR TITLE-ABS-KEY (**"traditional anaesthesia"**)))
#1 and #2 or #3		
Web of Science- 264 (05/04/2019)		
Tópico: ("primary dentition") *OR* **Tópico:** ("primary teeth") *OR* **Tópico:** ("primary tooth") *OR* **Tópico:** ("first teeth") *OR* **Tópico:** ("first tooth") *OR* **Tópico:** ("primary molars") *OR* **Tópico:** ("permanent teeth") *OR* **Tópico:**("permanent dentition") *OR* **Tópico:** ("permanent tooth") *OR* **Tópico:** ("paediatric dental patient*") *OR* **Tópico:**("pediatric dental patient*") *OR* **Tópico:** ("pediatric dentistry") *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos*	TS=(anesthesia) OR TS=(anaesthesia) OR TS=(Morpheus) OR TS=(Quicksleeper) OR TS=(the wand) *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos*	OR TS=("dental anesthesia") OR TS=("dental anaesthesia") OR TS=("local anesthetic") OR TS=("local anaesthetic") OR TS=("injectable anesthetic") OR TS=("injectable anaesthetic") OR TS=("infiltration anesthesia") OR TS=("infiltration anaesthesia") OR TS=("traditional anesthesia") OR TS=("traditional anaesthesia") *Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos*
1 and 2 or 3		
Lilacs and BBO= 730 (05/04/2019)		
#1 (tw:((tw:("primary dentition")) OR (tw:("primary teeth")) OR (tw:("primary tooth")) OR (tw:("first teeth")) OR (tw:("first tooth")) OR (tw:("primary molars")) OR (tw:("permanent teeth")) (tw:("permanent tooth")) OR (tw:("paediatric dental patient")) OR (tw:("paediatric dental patients")) OR (tw:("pediatric dentistry")) OR (Tw :("dentición primaria")) OR (tw :("dientes de leche")) OR (tw :("diente primario")) OR (tw :("primeros dientes")) OR (tw :("primera diente ")) OR (tw :(" molares primarios ")) OR (tw :(" dientes permanentes ")) OR (tw :(" diente permanente ")) OR (tw :(" paciente dental pediátrica")) OR (tw:("pacientes pediátricos	#2 (tw:((tw:(anesthesia)) OR (tw:(anaesthesia)) OR (tw:("the wand")) OR (tw:("quicksleeper")) OR (tw:("Morpheus")) OR (tw:(anestesia))))	#3 (tw:("Anestesia dental")) OR (tw:("Dental Anesthesia")) OR (tw:("Dental anaesthesia")) OR (tw:("Local anesthetic")) OR (tw:("Local anaesthetics")) OR (tw:("Injectable anesthesia")) OR (tw:("Injectable anaesthetic")) OR (tw:("Infiltration anesthesia")) OR (tw:("Injectable anesthetic")) OR (tw:("Infiltration anaesthesia")) OR (tw:("Injectable anesthesia")) OR (tw:("Traditional anesthesia")) OR (tw:("Traditional

dentales")) OR (tw:("odontología pediátrica")) OR (tw:("dentição decídua")) OR (tw :("dentes decíduos")) OR (tw :("dente primário")) OR (tw :("primeiros dentes")) OR (tw :("primeiro dente ")) OR (tw :(" molares decíduos ")) OR (tw :(" dentes permanentes ")) (tw :(" dente permanente ")) OR (tw :(" paciente dental pediátrica ")) OR (tw :("pacientes odontológicos pediátricos")) OR (tw :("odontopediatria"))))		anaesthesia")) OR (tw:("anestesia dental")) OR (tw:("anestésico local")) OR (tw:("Los anestésicos locales")) OR (tw:(" anestesia inyectable ")) OR (tw:(" anestésico inyectable ")) OR (tw:("anestesia de infiltración ")) OR (tw:("anestesia tradicional")) OR (tw:("anestesia dental")) OR (tw:("anestésico local")) OR (tw:("anestésicos locais")) OR (tw:("anestesia injetável")) OR (tw:("anestésico injetável")) OR (tw:("anestesia infiltrativa"))
	#1 AND #2 or #3	
Cochrane Library = 212 (05/04/2019)		
#1 "primary dentition"	#13 "anesthesia"	
#2 "primary teeth"	#14 "the wand"	
#3 "primary tooth"	#15 "quicksleeper"	
#4 "first teeth"	#16 "Morpheus"	
#5 "first tooth"	#17 "dental anesthesia"	
#6 "primary molars"	#18 "Dental anaesthesia"	
#7 "permanent teeth"	#19 "Local anesthetics"	
#8 "dentition permanent"	#20 "Local anaesthetics"	
#9 "permanent tooth"	#21 "Infiltration anaesthesia"	
#10 "paediatric dental patient"	#22 "Injectable anesthesia"	
#11 "pediatric dentistry"	#23 "Injectable anaesthetic"	
#12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11	#24 "Infiltration anesthesia"	
	#25 "Injectable anesthetic"	
	#26 "Injectable anesthesia"	
	#27 "Traditional anesthesia"	
	#28 "Traditional anaesthesia"	
	#29 #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28	
	#30 #12 and #29	

Table 2: Relevant information about the studies

Author/Date	Design	Age	Number	Topical anesthetic/ time (s)	Local anesthetic/ volum (mL)	Computerized Anesthesia Arm	Conventional Anesthesia Arm	Outcomes
Al Amoudi et al., 2008	Parallel	5-8	80 36 male	Ni/60	2% Lidocaine with epinephrine 1:100000/ 1	Maxilla: AMSA	Maxilla: Infiltrative Buccal and Palatal	- Disruptive behaviour in treatement SEM Scale
Allen et al., 2002	Parallel	2-5	40 31 male	Ni/30	2% Lidocaine with epinephrine 1:100000/ 1	Maxilla: AMSA ou P-ASA	Maxilla: Infiltrative Buccal and Palatal	- Disruptive behaviour Pain behavior code
Asarch et al., 1999	Parallel	5-13	57 Ni male	Ni/30 a 45	2% Lidocaine with epinephrine 1:100000/ 1,1	Mandible: IANB Maxilla: Infiltrative buccal and palatal	Mandible: IANB Maxilla: Infiltrative buccal and palatal	- Pain perception VAS - Disruptive behaviour Disruptive behavior code
Baghlaf et al., 2015	Parallel	5-9	91 Ni male	Benzocaine/ Ni	2% Lidocaine with epinephrine 1:100000/ 1,8	Mandible: IANB or Intraligamentary	Mandible: IANB	- Pain perception Wong Baker FACES - Disruptive Behaviour Pain behavior code
Deepak et al., 2017	Parallel	6-10	100 51 male	Lidocaine gel/ 60	2% Lidocaine with epinephrine 1:80000/ 1	Mandible: Infiltrative	Mandible: Infiltrative	-Pain perception FPS-R - Disruptive behavior FLACC - Anxiety MCDAS
Feda et al., 2010	Cross-over	7-10	40 18 male	Benzocaine/ 60	2% Lidocaine with epinephrine 1:100000/ 1	Maxilla: AMSA	Maxilla: Infiltrative buccal and palatal	-Pain perception Eland Color Scale - Disruptive Behaviour SEM Scale

Garret-Bernardin et al.,2017	Cross-over	7-15	67 38 male	Lidocaine spray/Ni	2% Mepivacaine with epinephrine 1:100000/ 1,8	Maxilla: Infiltrative buccal and palatal or lingual	Maxilla: Infiltrative buccal and palatal or lingual	- Pain perception VAS -Heart rate -Stress and anxiety Modified Venham Scale - Satisfaction of patients
Gibson et al.,2000	Parallel	5-13	62 32 male	Ni/60	2% Lidocaine with epinephrine 1:100000/ 1,4	Maxilla: AMSA ou P-ASA	Maxilla: Infiltrative buccal and palatal	-Pain perception VAS - Disruptive Behaviour Pain Behavior code
Kandiah & Tahmassebi, 2012	Parallel	8-16	30 11 male	Benzocaine 20%/120	2% Lidocaine with epinephrine 1: 80000/ 1,8	Maxilla: Infiltrative of first molar	Maxilla: Infiltrative of first molar	- Pain perception VAS - Pulpar anesthesia Pulp test
Klein et al.,2005	Parallel	3-5	21 11 male	Ni/30	2% Lidocaine with epinephrine 1:100000/ 1,8	Maxilla: P-ASA	Maxilla: Infiltrative buccal and palatal	- Disruptive behaviour ADBC - Disruptive behaviour in treatment ADBC
Mittal et al., 2015	Parallel	8-12	100 54 male	Lidocaine spray/60	2% Lidocaine with epinephrine 1:80000/ 1,1	Maxilla: Infiltrative buccal and palatal	Maxilla: Infiltrative buccal and palatal	- Pain perception VAS - Disruptive behaviour SEM Scale
Palm et al.,2004	Cross-over	7-18	33 15 male	Lidocaine + Prilocaine/60	2% Mepivacaine with epinephrine 1:100000/ 1,5	Mandible: IANB	Mandible: IANB	- Pain perception VAS
Patini et al., 2018	Cross-over	5-12	76 38 male	Ni	2% Mepivacaine with epinephrine 1:100000/ 1,8	Maxilla: Intraligamentary	Maxilla: Intraligamentary	-Pain perception NVRS (Numerical Visual Rating Scale) - Heart rate

Queiroz et al., 2015	Cross-over	7-12	20 Ni male	Benzocaine/ 180	4% Articaine with epinephrine 1:100000/ 1,8	Maxilla: Infiltrative of first molar	Maxilla: Infiltrative of first molar	- Stress and anxiety Cortisol salivar STAIC
San Martín Lopez et al., 2005	Cross-over	9-12	64 30 male	Ni/60	2% Lidocaine with epinephrine 1:100000/ 1,35	Maxilla: Infiltrative of buccal and palatal	Maxilla: Infiltrative of buccal and palatal	-Pain perception VAS -Heart hate
Smail-Faugeron et al., 2019	Parallel and cross-over	7-15	158 62 male	Xylocaine 2%/ 60-120	4% Articaine with epinephrine 1:100000	Maxilla: Intraosseous Mandible: Intraosseous	Maxilla: Infiltrative Mandible: IANB	-Pain perception VAS
Tahmassebi; Nikolaou; Duggal, 2009	Parallel	3-10	38 Ni male	Benzocaine/ 120	-2% Lidocaine with epinephrine 1:80000/ Ni	Maxilla: Infiltrative of buccal and palatal	Maxilla: Infiltrative of buccal and palatal intrapapillary	-Pain perception VAS modificada - Stress and anxiety VPT
Thoppe-Dhamodharan et al., 2015	Cross-over	7-11	120 71 male	Ni/ 30	2% Lidocaine with epinephrine 1:100000/Ni	Maxilla: Ni Mandible: Ni	Maxilla: Ni Mandible: Ni	-Pain perception FIS modified - Disruptive behavior FLACC -Heart hate
Versloot et al., 2005	Parallel	4-11	125 68 male	Ni/ Ni	Ni/ Ni	Maxilla: AMSA ou P-ASA Mandible: PDL	Maxilla: Infiltrative of buccal and palatal Mandible: IANB	- Pain perception VAS - Disruptive Behaviour Pain Behavior code - Stress e ansiedade VPT CFSS-DS
Versloot et al., 2008	Parallel	4-11	152 76 male	Ni/ Ni	-Ni/ Ni	Maxilla: AMSA ou	Maxilla:	- Pain perception VAS

		P-ASA Mandible: PDL	Infiltrative of buccal and palatal Mandible: IANB	- Disruptive behaviour Pain Behavior code - Stress and anxiety VPT CFSS-DS

Ni – not informed
ADBC - Anxious and disruptive behavior code
AMSA – Anterior and middle superior alveolar nerve block
P-ASA – Palatal approuch anterior superior alveolar nerve block
IANB – Inferior alveolar nerve block
SEM Scale – Sound, eyes and movement scale
VAS – Visual analogue scale
CFSS-DS – Dental Subscale Children's Fear Survey Shedule
VPT – Venham picture test
PDL – Periodontal ligament injection
STAIC – State Trait Anxiety Inventory for Children
FLACC - Face, Legs, Activity, Cry, Consolability
FPS-R - Faces pain scale-Revised (FPS-R)
MCDAS - Modified Child Dental Anxiety Faces Scale simplified
FIS - Facial Image Scale

Table 3: Summary of findings table—GRADE

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	computerized	convencional anesthesia	Relative (95% CI)	Absolute (95% CI)		
Pain perception related with computerized and convencional anesthesia - patient related outcome (assessed with: Visual Analogue Scale (VAS), Faces Pain Scale-Revised (FPS-R), Wong-Baker FACES Pain Rating Scale, Modified Facial Image Scale (FIS), Visual Rating Scale and Numerical Rating Scale (VNRS))												
10	randomised trials	serious [a]	serious [b]	not serious	not serious	none	565	567	-	SMD **0.76 SD lower** (1.29 lower to 0.23 higher)	⊕⊕◯◯ LOW	CRITICAL
Disruptive behaviour related to computerized and convencional anesthesia - dichotomous data (assessed with: Disruptive behaviour code, Pain behaviour code)												
5	randomised trials	serious [a]	serious [c]	not serious	serious [d]	none	137/276 (49.6%)	155/268 (57.8%) 0.0%	not estimable		⊕◯◯◯ VERY LOW	IMPORTANT
Disruptive behaviour related to computerized and conventional anesthesia - continuous data (assessed with: FLAAC, SEM Scale, Pain Behaviour code)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	computerized	convencional anesthesia	Relative (95% CI)	Absolute (95% CI)		
5	randomised trials	serious [a]	serious [e]	not serious	serious [d]	none	266	274	-	SMD **0.26 SD lower** (0.68 lower to 0.16 higher)	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **SMD**: Standardised mean difference

Explanations

a. Most studies was classified as unclear for the "allocation concealment" and "sequence generation"

b. Unexplained heterogeneity ($p<0.00001$; $I^2=94\%$)

c. Unexplained heteregeneity ($p=0.05$; $I^2=59\%$)

d. Confidence interval cross the clinical decision threshold between recommending and not recommending treatment?

e. Unexplained heterogeneity ($p<0.00001$; $I^2=83\%$)

Figure 3: Flow diagram of study identification

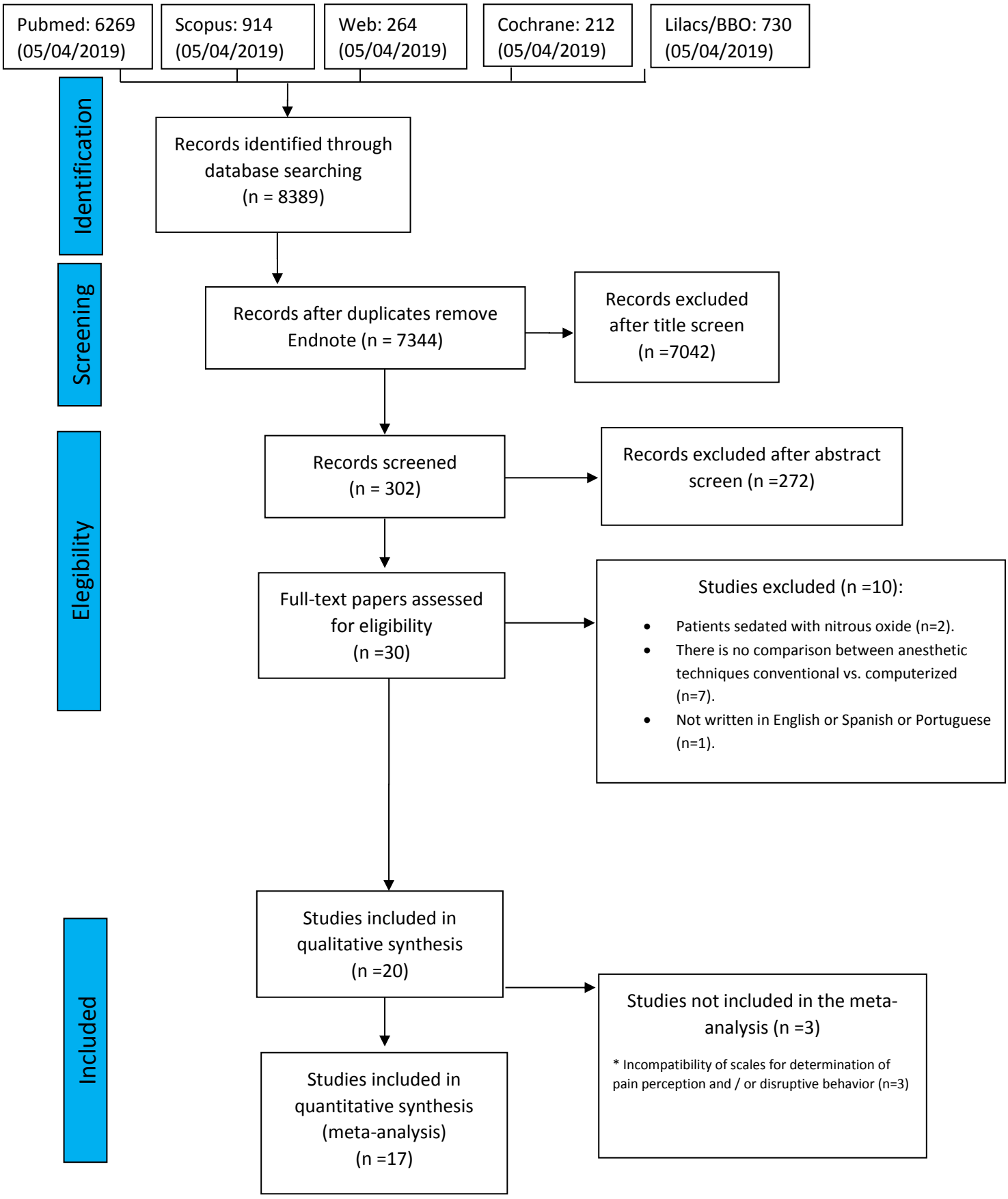


Figure 4: Summary of the risk of bias assessment according to the Cochrane Collaboration tool

Smail Faugeron et al.,2019	+	+	+	+	+
Tahmassebi; Nikolaou; Duggal, 2009	+	+	+	+	+
Thoppe – Dhamodharan et al.,2015	+	?	-	+	+
Versloot et al., 2005	+	+	-	+	+
Versloot et al., 2008	+	+	-	+	+

Figure 5: Meta-analysis of Pain perception—subgroup analysis according to the risk of bias

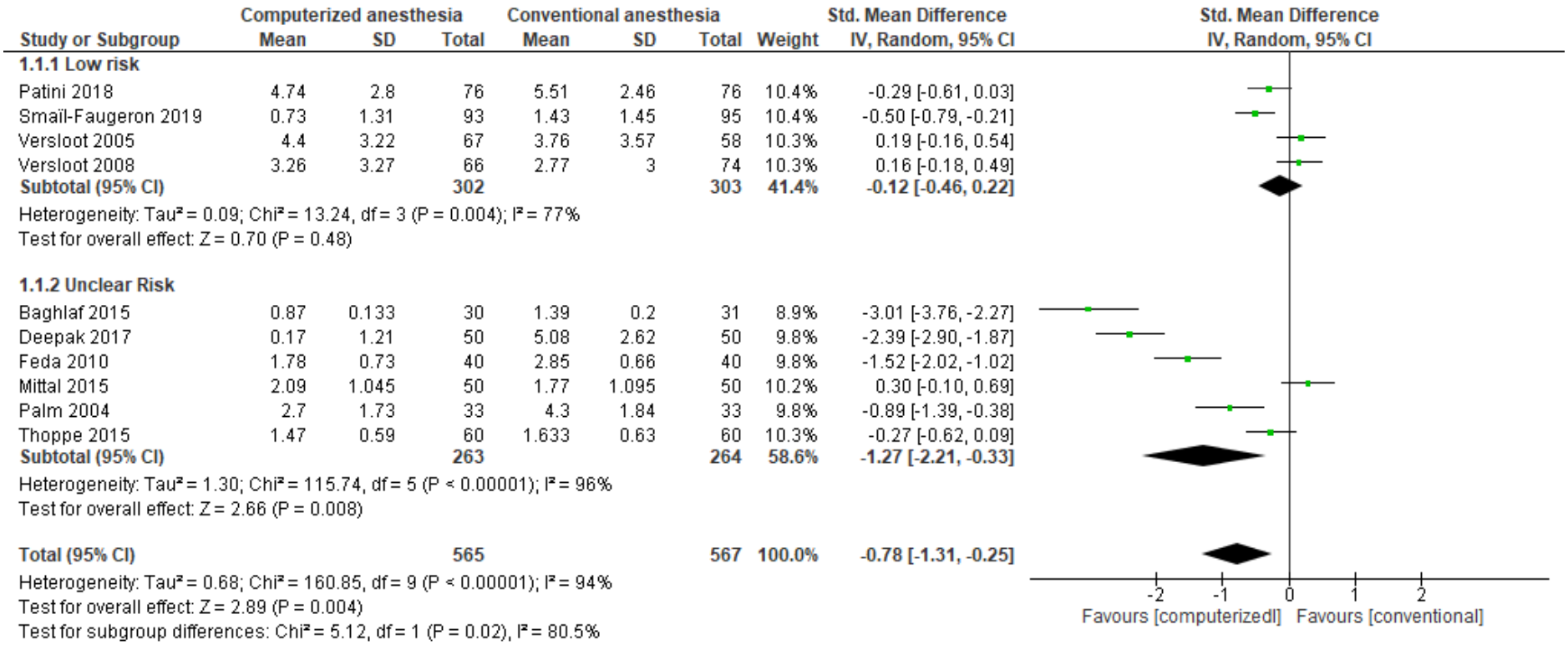


Figure 6: Meta-analysis of disruptive behaviour—continuous data—subgroup analysis according to the risk of bias

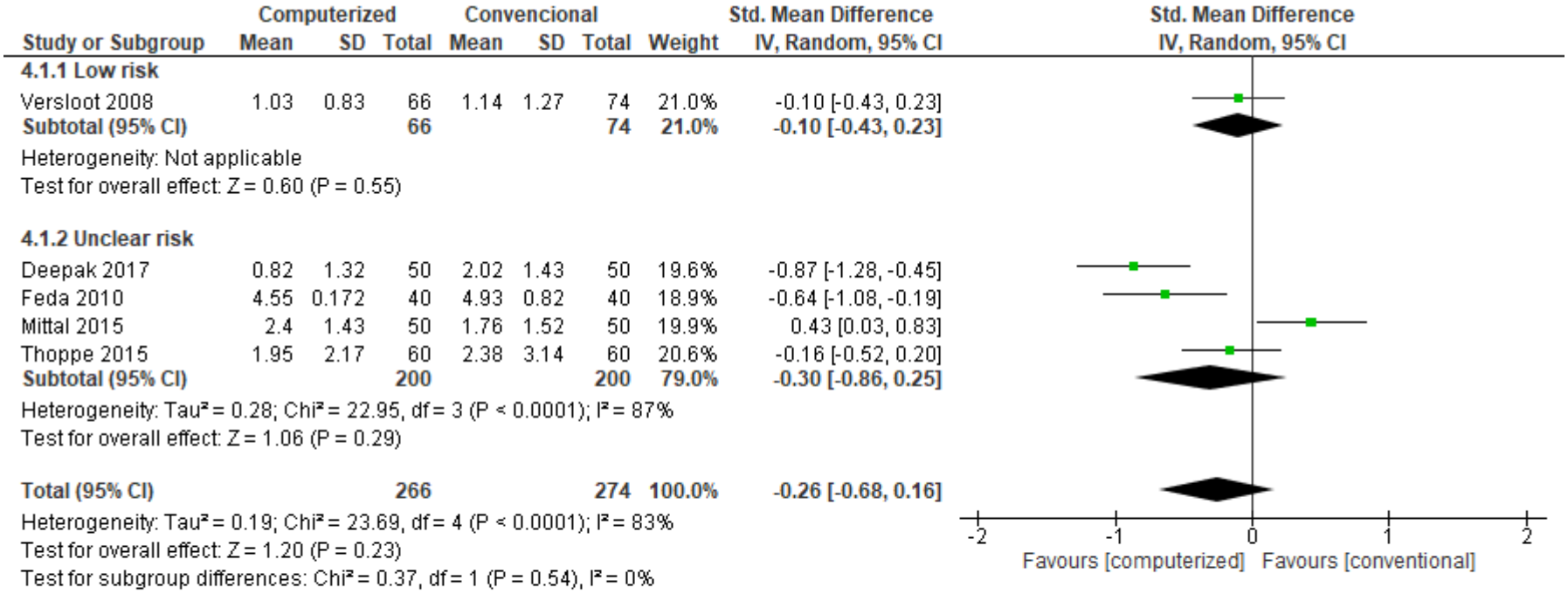
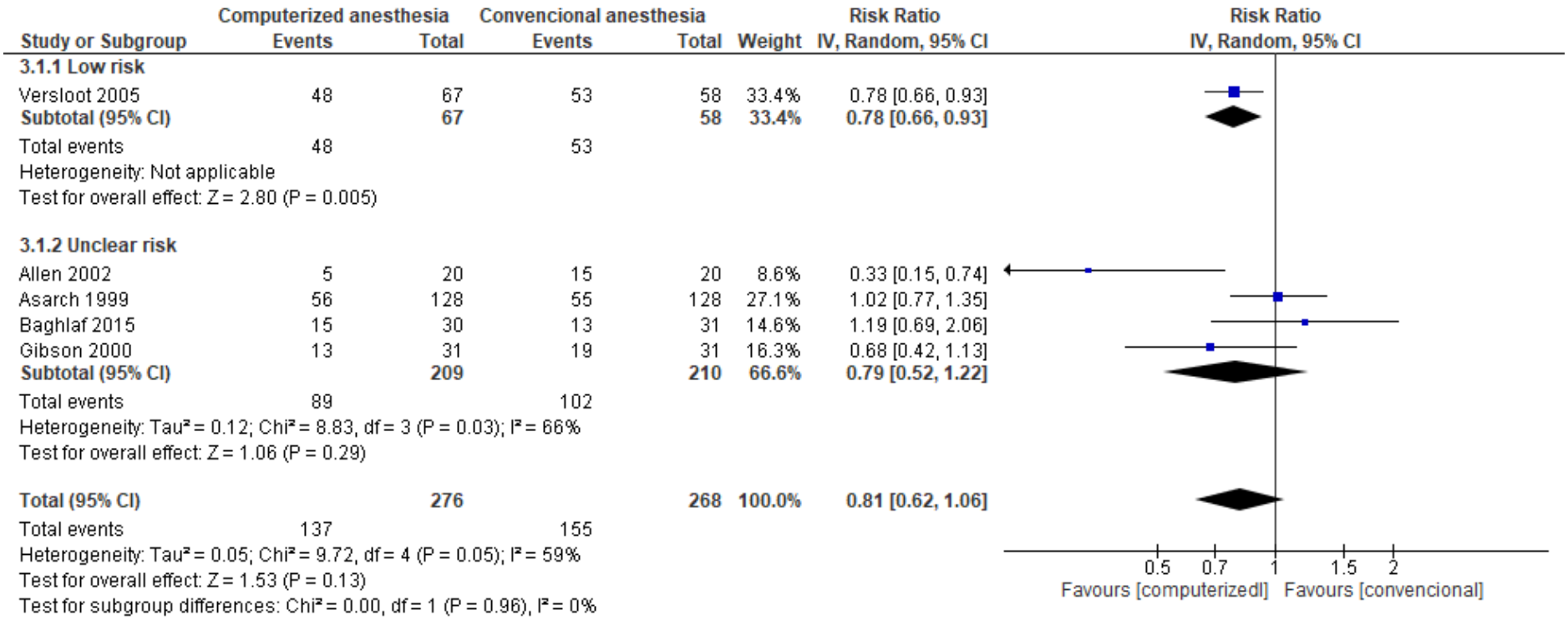


Figure 7: Meta-analysis of disruptive behaviour—dichotomy data—subgroup analysis according to the risk of bias



4.2 ARTIGO 2

REVISTA

Acta Odontologica Scandinavica

Evaluation of pain, disruptive behavior and anxiety in children of 5 at 8 years old undergoing different modalities of local anesthetic injection for dental treatment: a randomized clinical trial

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ABSTRACT

Objective: To evaluate the influence of different local anesthetic techniques in pain, disruptive behavior and anxiety in children´s dental treatment.

Material and methods: This was a randomized and parallel clinical trial. The sample consisted of 105 children (5–8 years old) that was divided in three groups (n=35) according to the anesthetic technique: conventional anesthesia (CA); vibrational anesthesia (VBA); computer controlled local anesthesia delivery (CCLAD). The outcomes were self-perception of pain (Wong-Baker Faces Pain Rating Scale – WBF; Numerical Rating Scale - NRS); disruptive behavior (Face, Legg, Activity, Cry, Consolability Scale - FLACC); anxiety (Corah's Dental Anxiety Scale; modified Venham Picture test - VPTm) and physiological parameters (blood pressure – systolic - SBP and diastolic – DBP; heart rate – HR; oxygen saturation - SpO2 ; respiratory rate - RR). Data were statistical analyzed with Kruskall-Wallis test and ANOVA for repeated measures with Tukey post hoc test (α=0.05).

Results: All the patients exhibited the same level of dental anxiety at baseline (Corah's Dental Anxiety Scale). There was no difference in self-perception pain, irrespective the evaluation tool used (WBF - p = 0.864; VAS - p=0.761). No differences were detected in disruptive behavior (FLACC - p=0.318); anxiety (VPTm - p=0.274); blood pressure (SBP - p=0.239; DBP - p=0.512); heart rate (p=0.728); oxygen saturation (p=0.348) and respiratory rate (p=0.238) between anesthetic techniques.

Conclusion: Different anesthetic dental local techniques do not affect the levels of pain, disruptive behavior, anxiety and physiological parameters in children aged five to eight years old.

Key-Words**:** local anesthesia, pediatric dentistry, pain management.

INTRODUCTION

Pain control is critical to successful pediatric patient management and dental local anesthesia is the most used method to eliminate pain during dental treatment. However, the use of needles is known as a trigger to fear and anxiety. Taking into account that local anesthesia is the first phase of any invasive treatment, it's imperative for pediatric dentists to perform anesthetic procedures without causing any adverse repercussion for behavior management [1].

A significant number of patients still perceive local anesthesia administration as a painful and anxiety-causing dental procedure [2]. For pediatric patients, the fear of dental treatment is usually linked to the psychological and physical trauma associated with needles and syringes for local anesthesia; a painful injection during local anesthetic administration may be considered the main reason for anxiety behaviors and defensive reactions [3].

In order to minimize or even to avoid the pain associated with local anesthesia, different devices have been developed, with different technical and biological approaches.

Computer-controlled local anesthetic delivery (CCLAD) has been firstly introduced in 1997 and since then it has been a topic for several clinical investigations. The theory behind the use of these computerized systems states that if the anesthetic solution is delivery in specific flow and velocity rates, it will be compatible with tissue acceptance, resulting in reduced pain perception and, consequently, decreased patient anxiety levels [4].

The vibrational anesthesia (VBA) is another alternative that seeks to minimize the discomfort during local anesthesia. According to the pain gate theory, the stimulation of larger diameter nerve fibers by vibration stimulates mechanoreceptors to activate inhibitory neurons, which blocks smaller neurons and consequently prevents pain recognition [5]. The VBA promotes micro oscillations at the injection site

and these pulsed oscillations close the gates of pain [6]. The device used for this purpose is the DentalVibe™ (Accumedix, Grayslake, IL, USA).

There are different clinical trials that studies the computerized [7- 11] or the vibrational techniques [2, 12-14] for local anesthesia in children. There are some studies that evaluate pain and anxiety related to dental anesthesia, comparing conventional anesthesia (CA) and CCLAD [3, 15, 16] and others that compare CA and VBA analyzing only pain [6, 12]. However, it is common to observe that these studies embraces large age ranges, including from preschoolers to teenagers [17-20] and age is a factor that must be taken into account because according to Oliveira et al 201221, the anxiety related to dental treatment is different between age ranges, whereas younger children have higher dental anxiety [21]. In addition, to the knowledge of these researchers, this is the first study that compares CCLAD and VBA considering patient reported outcomes and physiological parameters related to pain, disruptive behavior and anxiety caused by different anesthetic techniques in children.

Thus, the objective of this research is evaluate the influence of different anesthetic techniques in pain, disruptive behavior and anxiety in dental treatment of children from five to eight years old.

MATERIAL AND METHODS

This paper has been prepared according to the protocol established by the Consolidated Standards of Reporting Trials statement – CONSORT [22].

ETHICAL APPROVAL

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for the accomplishment of this study (#1.941.369). All participants were informed about the nature and objectives of the study. After that, Informed consent forms were obtained from parents/guardians of the participating patients; all participating children that were alphabetized also signed assent forms.

PROTOCOL REGISTRATION

This clinical trial was registered in Clinicaltrials.gov, under protocol # 64773417.3.0000.5689.

TRIAL DESIGN, SETTINGS AND LOCATIONS OF DATA COLLECTION

This was a randomized and parallel clinical trial with an equal allocation ratio. Three different study groups were defined, according to different anesthetic techniques (conventional anesthesia - CA, vibrational anesthesia – VBA and computer control local anesthesia delivery - CCLAD).

All procedures in selected volunteers were performed from November, 2017, to November, 2018. The study was conducted in the dental practice office at an elementary school called Integral Care Center for Child and Adolescent Reitor Alvaro Augusto Cunha Rocha in Ponta Grossa State University (CAIC-UEPG) and in the pediatric dental clinics from the Department of Dentistry at Ponta Grossa State University (UEPG), Ponta Grossa, Paraná, Brazil.

RECRUITMENT

The subjects were included in the study by convenience sampling. Children were invited to participate when seeking dental care at the university or at the elementary school, according to eligibility criteria.

Inclusion criteria: Children aged 5 to 8 years, with cognitive conditions compatible with chronological age and in need of restorative treatment in the upper posterior teeth under local anesthesia.

Exclusion criteria: children undergoing medical treatment at the moment of the intervention or who take drugs of continuous use that contraindicate the injection of local anesthetics, children with a history of anesthetic allergy, children with definitely negative behavior according to the Frankl behavior scale [23] and those who were not authorized by their parents or guardians.

SAMPLE SIZE

The sample size calculation was done considering the primary outcome “pain”. In this way, the mean pain levels obtained by Palm (2004) 9 were used. Considering a power of 95% and a significance level of 5%, in a superiority clinical trial, the final sample was composed of 105 children, with 35 subjects per study group. The sample size calculation was done using the site sealedenvelope.com (Sealed Envelope Ltd, London, UK).

RANDOM SEQUENCE GENERATION AND ALLOCATION CONCEALMENT

A staff member not involved in the research protocol performed the randomization and allocation processes.

Computer generated tables with blocked randomization (block size of 5) and an equal allocation ratio were obtained, considering the three study groups. The allocation concealment were accomplished by distributing the obtained codes in numbered black opaque envelopes, which were opened only on the day of the dental treatment, immediately before the local anesthesia, consequently, the operator blinded until this moment.

These procedures were accomplished also in the site sealedenvelope.com (Sealed Envelope Ltd, London, UK).

ANESTHETIC PROCEDURES

ANESTHESIA

All local anesthetic procedures were performed by the same experienced dentist (P.C.S.). The protocol included the use of topical anesthesia with benzocaine 20% for 60 seconds, infiltrative anesthetic technique with 1.8mL of lidocaine 2% with epinephrine 1:100,000 anesthetic and a flow rate of 1.0 mL per minute. All techniques used conventional short needles for anesthetic injection. For the puncture of needle, the bevel was directed toward the alveolar mucosa, and through a light pressure it penetrated the soft tissue gradually and the local anesthetic was delivered to the site

of interest, according protocol technique. All anesthetic injection procedures were controlled by a chronometer.

CONVENTIONAL ANESTHESIA

For the puncture of needle, the bevel was directed toward the alveolar mucosa, and through a light pressure it penetrated the soft tissue, with bone contact avoided as it may cause discomfort. The local anesthetic was delivered to the site of interest. Once it was confirmed negative aspiration, 1.8 mL of anesthetic solution was injected over during 108 s. The needle was removed gently after completion of the injection.

VIBRATIONAL ANESTHESIA

The VBA was performed with the aid of a device named DentalVibeTM (Columbia Tech, Boston, USA). After topical anesthesia, the device was positioned on the mucosa at the puncture site and turned on, transmitting a local vibration. After 10 seconds, the puncture was performed at the site located at the mean distance between the two ends of the vibrational device for anesthetic delivery. The injection of the anesthetic drug was done with a conventional syringe.

COMPUTERIZED ANESTHESIA

For CCLAD, the equipment MorpheusTM (Meibach Tech, São Paulo, Brasil) was used. A predetermined program with a flow rate of 1.0mL per minute was selected. After topical anesthesia, the puncture was performed with the introduction pedal activated; shortly after, the aspiration button was selected, and if there was no positive aspiration, the injection pedal was activated for anesthetic delivery. The injection of the anesthetic drug was done with a syringe provided by the Morpheus manufacturer.

OUTCOMES AND EVALUATION TOOLS

PRIMARY OUTCOMES

SELF-PERCEPTION OF PAIN

The self-perception of pain was evaluated with the Wong Baker Faces Pain Rating Scale (WBF) and Numerical Ranting Scale (NRS). The Wong Baker Faces Pain Rating Scale (WBF) is scale when including pictures of facial expressions with correlating numbers of 0–10 (0 being 'no hurt' and 10 being 'hurts worst'). The Numerical Ranting Scale (NRS), containing eleven points (0– 10, where 0 means no pain, 10 means worst possible pain) [17].

DISRUPTIVE BEHAVIOR

For the evaluation of children's disruptive behavior during anesthesia, the Faces, Legs, Activity, Cry, Consolability (FLACC) [24] was used. The results range from 0 to 10, originating the following classification: score 0 - patient is considered relaxed and comfortable; score 1 to 3 – mild discomfort; score 4 to 6 - moderate pain; 7 to 10 – severe pain.

SECONDARY OUTCOMES

ANALYSIS OF FEAR AND ANXIETY RELATED TO DENTAL TREATMENT

All the children answered a specific questionnaire named Corah's Dental Anxiety Scale (Corah) [25, 26] to identify and classify the level of fear and anxiety related to dental treatment. The author reported good reliability with the use of this questionnaire (internal consistency = 0.86; test-retest= 0.82) [25, 26].

It is a four item questionnaire with 4 questions to be answered by the patients that indicate their emotional reaction to a dental visit. The result ranges from 4 to 20. The scores classify the patient as "anxiety free" (score 4); "moderate anxiety" (scores 5-10); "high anxiety" (scores 11-15) and "severe anxiety" (scores 16-20).

ANALYSIS OF THE EMOTIONAL STATE OF ANXIETY

The Venham Picture Test modified (VPTm) [27] was performed to determine the child's emotional state of anxiety during different phases of the study.

VPTm consists of 8 pictures representing feelings ranging from anxiety to contentment. The children were asked to select the picture that better described their feelings at that specific moment. Negative feelings scored one point; positive feeling did not score. The sum of the responses ranges from 0 to 8 and the level of patient's anxiety is classified as "anxiety free" (score 0); "low anxiety level" (scores 1-3); middle anxiety levels (scores 4-6) and "high anxiety level" (7-8).

PHYSIOLOGICAL PARAMETERS

Volunteers were evaluated for systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO 2) and respiratory rate (RR) by the InmaxTM multiparametric monitor (Instramed, Porto Alegre, Brazil). SBP and DBP were rmeasured before and during the anesthetic procedures; for HR, SpO2 and RR the values were recorded every 15 seconds during the procedure and the average was calculated and recorded in the individual file of the patient [7].

INTERVENTION

The research protocol considered four moments to collect data about the patient reported outcomes, patient centered outcomes and physiological parameters. These moments were: T1 (before treatment); T2 (at dental office, when the child is called out to take his/her place at the dental chair); T3 (during local anesthesia) and T4 (immediately after local anesthesia). All obtained data were recorded in a clinical file that was developed specifically for this research purposes. One assistant investigator was responsible for recording the data, as well as to guarantee the confidentiality of the patient's identification, which was replaced by a number. The sequence of the procedures are depicted in Figure 8.

T1 and T2 consisted in a pre-operatory evaluation that aimed to identify the baseline parameters regarding the volunteer's fear and anxiety related to dental treatment (Corah) and emotional state (VPTm), as well as the physiological

parameters. The questionnaire regarding anxiety (Corah) were administered in a neutral environment; the other outcomes were measured at the waiting room of the dental office (T1). Once the child was sit on the dental chair (T2), systolic and diastolic blood pressures, heart rate, oxygen saturation, respiratory rate and VPTm scores were recorded again.

After that, the main researcher, who was the single operator of this study, opened the opaque envelope to find out the anesthetic technique that should be performed on that specific patient. This was the beginning of T3. During this trans-operatory phase, an assistant researcher recorded the anesthetic procedure; this video was evaluated later, according to the FLACC criteria. The physiological parameters were recorded again.

Immediately after anesthesia, at T4, the VPTm test was repeated and the pain self-perception tests (WBF and NRS) were also applied. At the end of the data collection, the dental treatment were done normally. Usual measures of behavioral control, namely communication and communicative orientation, and behavior management techniques such as tell-show-do, voice control, nonverbal communication, positive reinforcement and distraction, were used in all cases.

BLINDING

The operator and the patients were not blinded to the anesthetic technique, since the devices that are needed to execute the techniques are very specific and cannot be disguised or hidden. Notwithstanding, the data analysis was done without the statistician knowing the study groups.

EVALUATORS

Evaluators were trained previously to apply the evaluation tools related to dental fear/anxiety, self-perception of pain, disruptive behavior and physiological parameters. One auxiliary researcher applied the questionnaires Corah, VPTm, WBF, NRS and another one registered the physiological parameters.

A calibrated researcher performed the analysis of the recorded videos during anesthesia application to determine the index of disruptive behavior (FLACC).

To gain reliable results, the evaluator was trained and calibrated (intra evaluator Kappa = 0.90) before analysis.

STATISTICAL ANALYSIS

Statistical analysis was performed using the SPSS version 15.0 statistics program (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed. The nonparametric data obtained after the application of the different tests (Corah, WBF, NRS, FLACC) were submitted to Kruskal-Wallis for unpaired analysis. ANOVA for repeat measures with post – hoc test of Tukey was used to compare the VPTm, SBP, DBP, HR, RR and SpO 2 data between the phases and groups of the study. Pearson correlation tests were also performed for Corah, VPTm, WBF, VAS and FLACC. All tests were performed with a significance level of 0.05.

RESULTS

A total of 189 patients were examined and 84 were excluded from the sample because they didn't fulfill the inclusion criteria. A total of 105 children composed the research sample and all of them completed the study. The experimental protocols were implemented as planned (Figure 9). The mean age was 6.56 + 0.9; the gender distribution was 53 males (50.47%) and 52 females (49.52%).

DENTAL ANXIETY (CORAH'S DENTAL ANXIETY SCALE)

It's important to mention that similar levels of dental anxiety were detected in the subjects at the baseline (Table 4). The majority of the research subjects showed moderate dental anxiety (40%), without differences regarding genders (p=0.976) or between the study groups (p=0.283) (Table 5).

ANXIETY EMOTIONAL STATE (VPTM)

To identify the child's emotional state of anxiety, the VPTm test was used at T1, T2 and T4. The sample remained homogeneous, there was no difference in

emotional state at T1 (p = 0.487), T2 (p = 0.740) and T4 (p = 0.274), in the same study group (Table 6).

Notwithstanding, when considering all the patients included in the sample, without group divisions, significant differences were observed between the moment before treatment (T1), at dental office (T2) and after anesthesia (T4) (p=0.003).

SELF-PERCEPTION OF PAIN (WBF AND NRS) AND DISRUPTIVE BEHAVIOR (FLACC)

The self-perception of pain was analyzed through patient reported outcome using WBF and VAS; disruptive behavior was analyzed using FLACC as a patient centered outcome.

No difference between anesthetic techniques were observed in selfreported pain, irrespective the scale used (WBF – p= 0.864; NRS – p= 0.761) (Table 7). The same was observed regarding disruptive behavior (FLACC – p=0.318).

It was also observed that there is a poor correlation between disruptive behavior and self-perception of pain (WBF - rho=0.377, p<0.001; VAS – rho=0.300, p=0.002).

PHYSIOLOGICAL PARAMETERS

No differences were detected in systolic and diastolic blood pressures, heart rate, respiratory rate or oxygen saturation when the three different anesthetic techniques were used (p>0.05).

The analysis of the overall sample showed that there is difference in the means of SBP (p=0.022), DBP (p=0.012), HR (p<0.0001) and RR (p<0.0001) when the different moments (T1, T2, T3) of the dental appointment are considered (Table 8).

DISCUSSION

This study aimed to verify if the use of different anesthetic devices could improve the dental experience during anesthetic procedures in children regarding anxiety, pain and disruptive behavior. Also, to our knowledge, this is the first paper that compares vibrational and computerized anesthesia in children.

The obtained results favor the conventional anesthetic technique as the most cost-effective procedure.

No difference in pain perception were observed when comparing conventional, computerized and vibrational anesthesia in children aged 5 to 8 years old. This result is corroborated by several studies in the literature that compared conventional and computerized anesthesia [7, 10, 11, 17, 20] or conventional and vibrational anesthesia [6, 28]. On the other hand, there are some papers that state less pain perception with the use of computerized anesthesia [8, 18, 29, 30] or vibrational anesthesia [5, 31]. These conflicting results came from studies which samples comprised children from 3 to 15 years old, and, the large age range in some of them may be a problem for self-reporting pain levels, introducing information bias to the study.

Pain perception is a multidimensional subjective response. Having said that, it is important to discuss the different aspects in a research that can influence this response.

It is known that toddlers and preschoolers do not understand abstract concepts; therefore, it may be difficult for them to discriminate the intensity of the pain because their descending control mechanisms are immature, limiting their ability to modulate the experience. Three or 4 years old children tend to select the extreme ends of pain scales, neglecting the middle portion of continuous or multiple-item scales. The ability to quantify pain experiences will be accurate only in 5 years old children. Conversely, adolescents tend to avoid manifestations of pain, because of fear of embarrassment, which may reflect in decreased reported levels of pain [32]. That is why the present study used a narrower age range, where the pain responses tends to present similar analysis by the patients.

The level of the dental anxiety at baseline is another variable that is not assessed by the studies usually. In this research, it was detected a moderate level of dental anxiety in the patients, resulting in a homogeneous sample. This is important because dental anxiety is a significant predictor for pain perception in children and adolescents [33] and anxious children tend to overestimate the intensity of pain [33, 34], including pain from local anesthetic injection [35]. Therefore, in our sample, the reported pain data were obtained from patients with similar levels of anxiety at baseline.

Another aspect that need to be addressed is the site and the technique of the anesthesia. It is not uncommon in the literature studies that compare different anesthetic techniques using different sites of injection. For instance, there are papers that included buccal and palatal infiltration [15, 18, 29, 36] or buccal and palatal infiltration compared to inferior alveolar nerve block [11, 17, 37]. A palatal infiltration or a nerve block are much more painful than a buccal infiltration [38] and it probably would result in more intense responses. We used the infiltrative terminal anesthetic technique in the posterior region of the maxilla for all study groups. This is a site of less anatomical variation that facilitate the anesthetic procedure allowing to identify the real influence of the different anesthetic devices in the patient's response to the anesthesia.

Self-report methods are considered the gold standard for the assessment of pain [32]. Even so, to improve the assessment of pain, multiple tools, both patient reported and centered, were used for a more accurate appraisal of children's pain experience: the Wong Baker Faces, which is a nonverbal tool with pictures; NRS, a numeric dimension tool; and FLAAC, an observational tool that identify disruptive behavior related to pain. The methodology was defined to favor a multidimensional assessment of pain.

Pain activates the compensatory mechanisms of the autonomic nervous system, which results in physiological responses like tachycardia, peripheral vasoconstriction, diaphoresis, pupil dilation, and increased secretion of catecholamines and adrecorticoid hormone [32]. Therefore, physiological parameters can complement the pain self-report, although they can not be the only indicators because they are not specific for pain response.

Physiological parameters such as heart rate and systolic blood pressure tend to increase in acute pain [39] with changes of 10% to 20% [32]. There is also an increase in respiratory rate as a pain response [40]. Consequently, higher respiratory rates result in higher oxygen saturation. However, in the present study, this relation was not observed; besides, no correlations between these physiological parameters and pain self-perception were found.

It was identified that the systolic blood pressure decreased between the different moments of the study. This is probably due to the child's position. At T1, the child was sitting in a common chair; at T2 on the dental chair, but still at rest, and at T3 the child was lying down, which caused a gradual decrease in systolic blood pressure. Even without statistical differences, vibrational anesthesia resulted in higher

levels of systolic and diastolic blood pressures. This may be explained by the fact that physiological parameters are also influenced by anxiety levels, and vibrational anesthesia is the technique that introduces greater changes to the conventional anesthetic procedure when compared to computerized and traditional anesthesia.

The different anesthetic techniques did not influence the heart rate. This was corroborated by other studies that evaluated this parameter regarding computerized X conventional [10, 41] or vibrational X conventional anesthesia [5].

Taking all the former cited parameters together, we can state that the use of different local anesthetic techniques will not contribute to minimize or eliminate the pain or anxiety related to dental anesthesia in children of the 5 at 8 years old.

Notwithstanding, the emotional state of the patients is affected by the anesthetic procedure itself, without influence of the different devices used. The use of VPTm in different moments (at the waiting room, at the dental chair before anesthesia and after anesthesia) showed that anxiety increases after the local anesthesia. In a secondary analysis, it was also observed a correlation between children's emotional state/anxiety and the self-reported pain levels.

Therefore, the behavioral response of children after dental anesthesia is often a mixture of anxiety and pain [37]. Consequently, in a split mouth design, the first procedure could influence the subsequent pain report after the anesthesia in a second dental appointment. This was observed in a clinical trial with 120 patients (7-11 years old), comparing computerized and conventional anesthesia, that found difference in the disruptive behavior only in the second anesthetic procedure [42]. Considering that, a parallel design was implemented in this research.

This study aimed to analyze the majority of the factors that influence the interpretation/measurement of pain in children (disruptive behavior, anxiety, physiological parameters, as well as self - perception of pain) and how they would be related with the different anesthetic techniques. To the authors' knowledge, this is the first paper that included all these parameters in a single clinical trial and we encourage similar future researches to clarify if our findings can be applied to other anesthetic sites, techniques and age ranges.

Finally, it's important to state that the pathway to a less painful and traumatic anesthetic procedure in children will always be related to factors that overcome the technical aspects purely. The establishment of a good communication with the patient

and parents and the use of effective behavioral management strategies are measures that may reduce dental anxiety and facilitate the anesthetic procedures.

CONCLUSION

In the light of the obtained results, there is no advantages in the inclusion of vibrational or computerized anesthetic devices in pediatric dental practice, since different anesthetic dental local techniques do not affect the levels of pain, disruptive behavior, anxiety and physiological parameters in children aged five to eight years old.

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Figure 8: Flow diagram of the different phases of the study

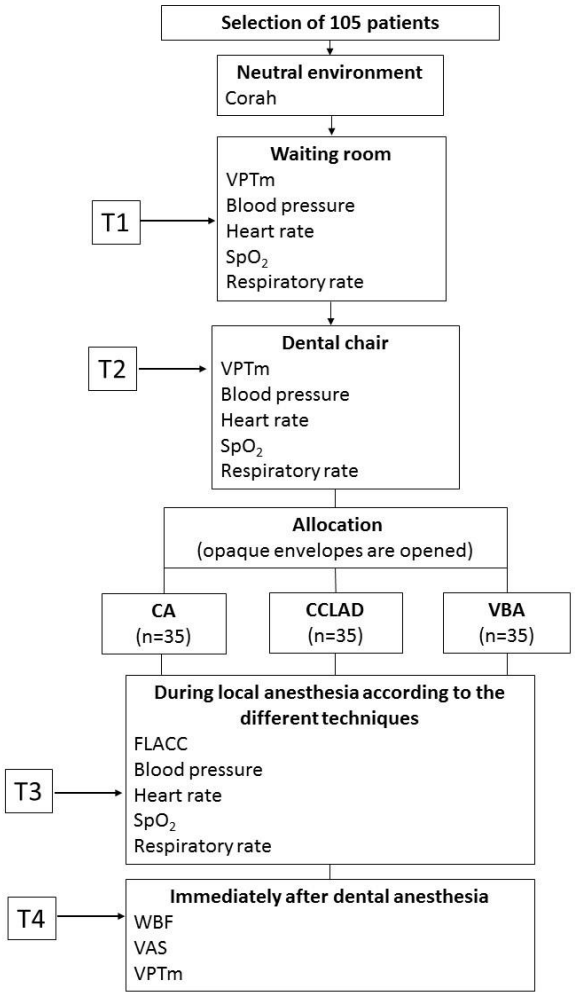

Figure 9: Sample analyzed flow diagram (CONSORT)

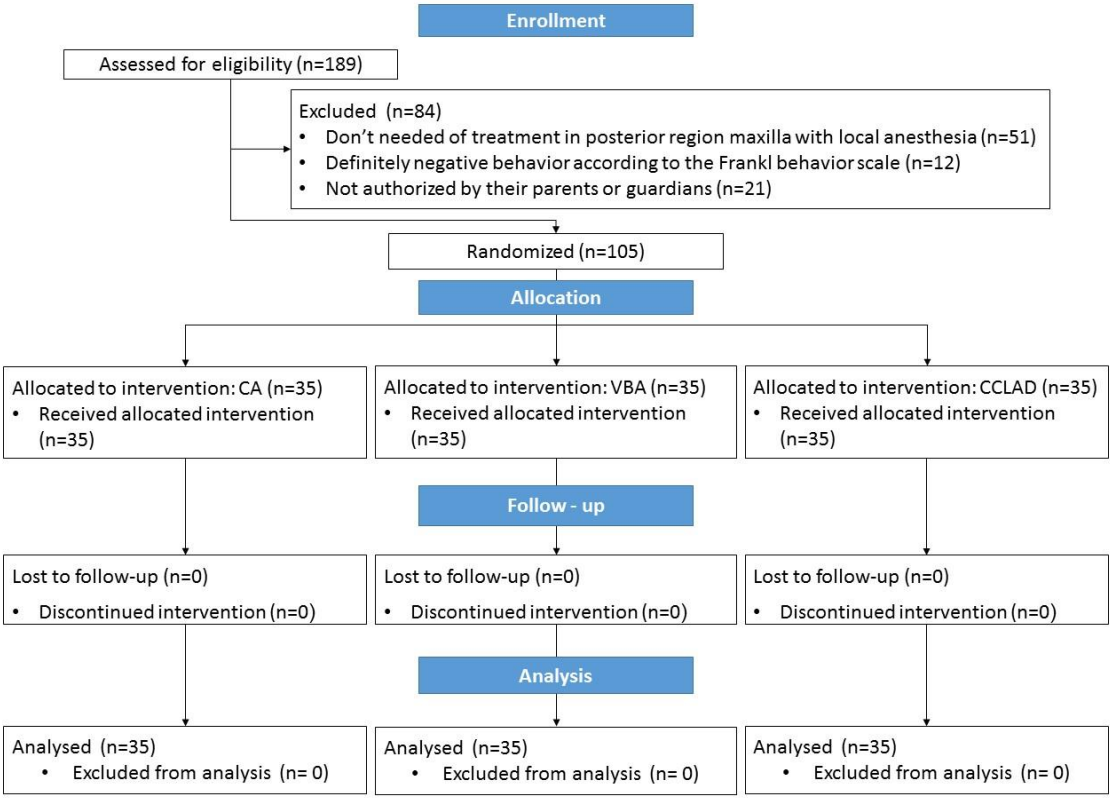

Table 4: Dental anxiety at the baseline according to the study groups (Corah's Dental Anxiety Scale)

Dental Anxiety	CA	VBA	CCLAD	*p*-value
Median (interquartile range)	2 (1-4)[a]	3 (1-4)[a]	2 (1-4)[a]	0.283
Mean ± SD	2.31±0.93[a]	2.62±0.91[a]	2.31±0.93[a]	

Lowercase letters in the same line means no significant difference between groups (p<0.05)

Table 5: Relative (absolute) frequencies of the fear and anxiety related to dental treatment (Corah) according to the patients` gender.

Dental Anxiety Levels	Gender		
	Male %(n)	Female %(n)	Total %(n)
Anxiety free	9.52% (n=10)	6.66% (n=7)	16.19% (n=17)
Moderate anxiety	18.09% (n=19)	21.90% (n=23)	40.00% (n=42)
High anxiety	17.14% (n=18)	12.38% (n=13)	52.00% (n=31)
Severe anxiety	6.66% (n=7)	7.61% (n=8)	14.28% (n=15)
p value	0.976		

Table 6: Anxiety emotional state (VPTm) according to study groups and study phases [median (interquartile range) and Mean + Standard Deviation]

	CA	VBA	CCLAD	*p*-value
T1	1(1-4)[a] 1.22±0.59[a]	1(1-3)[a] 1.31±0.52[a]	1(1-4)[a] 1.45±0.85[a]	0.487
T2	1(1-4)[a] 1.42±0.73[a]	1(1-3)[a] 1.42±0.73[a]	1(1-4)[a] 1.57±0.88[a]	0.740
T4	2(1-4)[a] 1.77±0.87[a]	1(1-4)[a] 1.54±0.88[a]	1(1-4)[a] 1.54±0.81[a]	0.274

Lowercase letters in the same line means no significant difference between groups (p<0.05)

Table 7: Self-perception of pain (Wong Baker Faces and Visual Analogue Scale) according to study groups immediately after dental local anesthesia (T4) [median (interquartile range) and Mean + Standard Deviation]

Evaluation of pain	CA	VBA	CCLAD	*p*-value
WBF	2 (0 - 10)[a]	0 (0 - 10) [a]	0 (0 - 10) [a]	0.864
	2.34±3.0 [a]	2.05±2.88 [a]	2.57±3.31 [a]	
VAS	2 (0 - 9) [a]	1 (0 - 10) [a]	1 (0 - 10) [a]	0.761
	2.54±2.94 [a]	2.45±3.22 [a]	2.88±3.39 [a]	
FLACC	1 (1-3) [a]	1 (1-3) [a]	1 (1-3) [a]	0.381
	0.80±0.63 [a]	1.08±0.78 [a]	1.00±0.93 [a]	

Lowercase letters in the same line means no significant difference between groups ($p<0.05$)

Table 8: Physiological parameters (blood pressure and heart rate) according to the different anesthetic techniques and dental appointment moments

Physiological Parameters	CA			VBA			CCLAD			*p*-value
	T1	T2	T3	T1	T2	T3	T1	T2	T3	
Systolic blood pressure	107,48±10,03[a]	102,40±12,79 [a]	102,17±12,04 [a]	106,20±13,46 [a]	105,74±12,20 [a]	106,22±12,55 [a]	103,40±11,67 [a]	102,94±10,90 [a]	99,88±9,66 [a]	0.239
Diastolic blood pressure	81,60±9,53 [a]	76,77±11,91 [a]	75,31±12,06 [a]	80,71±9,47 [a]	78,45±10,78 [a]	81,08±11,82 [a]	78,42±12,76 [a]	77,74±8,23 [a]	76,80±9,83 [a]	0.512
Heart Rate	93,45±16,62 [a]	92,00±15,71 [a]	95,20±17,69 [a]	92,02±12,53a [a]	90,68±11,65 [a]	95,88±12,66 [a]	91,88±14,29 [a]	87,48±12,98 [a]	94,02±14,26 [a]	0.728
SpO_2	96.68±0.93 [a]	96.97±0.98 [a]	96.77±1.11 [a]	95.74±2.35 [a]	96.60±1.19 [a]	96.40±1.57 [a]	96.68±1.05 [a]	96.51±0.95 [a]	96.48±1.06 [a]	0.348
Respiratory rate	20.85±3.89 [a]	21.34±3.94 [a]	23.37±5.24 [a]	20.08±3.52 [a]	20.60±3.95 [a]	24.22±5.61 [a]	19.57±2.86 [a]	20.88±3.37 [a]	21.17±4.08 [a]	0.238

Lowercase letters in the same line means no significant difference between groups ($p<0.05$)

4.3 ARTIGO 3

REVISTA

Clinical Oral Investigation

Evaluation of pain, disruptive behavior and anxiety in children of 9 at 12 years, old undergoing different modalities of local anesthetic injection for dental treatment: a randomized clinical trial

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ABSTRACT

Objective: The objective of this randomized, parallel clinical trial was to evaluate pain, disruptive behavior and anxiety in children during dental local anesthesia with different anesthetic techniques. Material and methods: One hundred and five patients took part in this trial. They were divided in 3 groups, according to the anesthetic technique used: conventional anesthesia (CA); vibrational anesthesia (VBA); computer-controlled local anesthesia (CCLAD). The distinct outcomes were evaluated with different tools: pain self-perception (Wong-Baker Faces Pain Rating Scale - WBF; Numerical Ranting Scale - NRS); disruptive behavior (Face, Legg, Activity, Crying, Consolability Scale - FLACC); anxiety (Corah's Dental Anxiety Scale; modified Venham Picture test - VPTm) and physiological parameters (blood pressure - systolic - SBP and diastolic - DBP; heart rate - HR; heart rate - HR; oxygen saturation - SpO2; respiratory rate - RR). Kruskall-Wallis test and ANOVA for repeated measures with the Tukey post hoc test (α = 0.05) were used to analyze the data. Results: All patients exhibited the same level of dental anxiety at the baseline (Corah's Dental Anxiety Scale). There was a difference in pain perception, CA demonstrated less pain than VBA in WBF (p =0.018) and NRS (p =0.006) and CCLAD in WBF (p =0.029). There were no differences in disruptive behavior (FLACC - p = 0.573); anxiety (VPTm - p = 0.474); blood pressure (SBP - p = 0.954; DBP - p = 0.899); heart rate (p = 0.726); oxygen saturation (p = 0.477) and respiratory rate (p = 0.930) between anesthetic techniques. Conclusion: The results obtained demonstrate that, under the conditions

of the present study, the conventional technique promotes less perception of pain to infiltrative local anesthesia, in dental treatment, for children from 9 to 12 years of age.

Key-Words: local anesthesia, pediatric dentistry, pain management

INTRODUCTION

A painless treatment is a goal in pediatric dental care (Veneva et al.[1] 2019). The dental local anesthesia offers a pain-free treatment, which is mandatory to obtain the cooperation of the child. Paradoxically, the application of a local anesthesia itself promotes pain and anxiety for mosto f the patients (Kuscu and Akyuz[2] 2008). Poor pain control alongside the fear and the anxiety triggered by the needle might interfere with successful behavior management (Tellez et al.[3] 2015). Also, previous negative experiences may influence the way a child faces future dental appointments (Raslan and Masri[4] 2018).

Pain is “an unpleasant sensory or emotional experience associated with actual or potential tissue damage” as defined by the World Health Organization in 2015. Discomfort from dental anesthesia is related to both the needle penetration and the tension created by tissue expansion as the anesthetic solution is injected (Elbay et al.[5] 2015).

The anxiety has been defined as “the apprehensive anticipation of future danger or misfortune accompanied by a feeling of worry, distress, and / or somatic symptoms of tension” (APA[6] 2013). Dental anxiety is a normal reaction. It is refered to an anticipation of a future concern. The feelings develop before, during and after the visit to the dentist. It is multifactorial and can be influenced by previous experiences lived by the patient. It differs from fear, that occurs in response to a specific immediate threat, for example, the visualization or the contact with the needle, which unleashes the fear of dental anesthesia (Khan et al.[7] 2016).

The disruptive behavior in pediatric dentistry patients is a consequence of pain, fear and anxiety, often related to local anesthesia and the management of children with manifestations of disruptive behavior is a challenge to the pediatric dentist, as it hinders the progress of dental care (AAPD[8] 2015).

The development of newer delivery devices and the modifications in the injection techniques for local dental anesthesia promisses the clinician an easier treatment approach associated with reduced pain during injection, essential for managing anxiety in pediatric patients (Veneva et al.[1] 2019). In this way, the vibrational technique and the computer-controlled local anesthetic delivery (CCLAD) stand out.

The concept of the vibrational anesthesia (VBA) is to reduce the pain of needle puncture and the solution injection by applying pressure, vibration, microoscillations or a combination of them in the site of the anesthesia (Sriram[9] 2014). According to the gate control theory of pain by Melzack (Melzack[10] 1996), the physical stimuli modify or interfere with pain signals by closing the neural gate of cerebral cortex, which decreases the pain perception. Based on this theory, several dental appliances have been developed — Accupal (Accupal, Hot Springs, AR, USA), DentalVibe (DV), (Columbia Tech ,, Boston, MA, USA), Vibraject (VibraJect LLC, Anaheim, CA, USA). There are different clinical trials that studied the vibrational techniques (Sermet Elbay et al.[11] 2016, Ching et al.[12] 2014, Erdogan et al.[13] 2018, Dak-Albab et al.[14] 2016) for local anesthesia in children, however the results are discrepant.

The other anesthesia system is the computer-controlled local anesthetic delivery (CCLAD). The theory behind this system is that the anesthetic solution must be delivered in a specific flow rate and continuous pressure compatible with tissue acceptance. This would result in reduced pain perception and, consequently, decreased patient anxiety levels (Grace et al.[15] 2000). There are different clinical trials that studied the computerized anesthesia for local anesthesia in children compared with conventional technique (Baghlaf et al.[16] 2015, Deepak et al.[17] 2017, Palm et al.[18] 2004, Mittal et al.[19] 2015, Versloot et al.[20] 2008). However, just like the research with vibrational anesthesia, these results are also inconsistent.

Therefore, the objective of this research is to evaluate whether computerized or vibrational anesthesia causes less pain, anxiety and disruptive behavior, than conventional anesthesia in the dental treatment of children aged nine to twelve years.

MATERIAL AND METHODS

The Consolidated Standards of Reporting Trials statement - CONSORT were followed for designing and reporting the current randomized clinical trial (RCT) (Schulz et al.[21] 2010).

ETHICAL APPROVAL

The study was reviewed and approved by the local Ethics Committee for investigations involving human beings (# 1.941.369). All volunteers and guardians were informed about the nature and objectives of the study, and the terms of informed consent were obtained from the parents / guardians of the participating patients; all participating literate children also signed terms of assent.

PROTOCOL REGISTRATION

This clinical study was registered in Clinicaltrials.gov, under protocol # 64773417.3.0000.5689.

TRIAL DESIGN, SETTINGS AND LOCATIONS OF DATA COLLECTION

This study was designed as a randomized and parallel clinical trial with an equal allocation ratio. The different anesthetic techniques defined the study groups: Group CA (conventional anesthesia), Group VBA (vibrational anesthesia) and Group CCLAD (computer controled local anesthesia delivery).

The clinical phase of the study took place at a dental office in the Center of Integral Care for Children and Adolescents Reitor Alvaro Augusto Cunha Rocha in Ponta Grossa State University (CAIC-UEPG) and at the dental clinics from the Department of Dentistry at Ponta Grossa State University (UEPG), Ponta Grossa, Paraná, Brazil. All procedures were performed from November, 2017, to November, 2018.

RECRUITMENT

The recruitment was done from August to September of 2017 at CAIC-UEPG and at the Department of Dentistry (UEPG). When seeking dental care at the institutions, children were invited to participate in the study.

The inclusion criteria comprised children in need of restorative treatment in the upper posterior teeth under local anesthesia, with normal cognitive functions and aging 9 to 12 years old.

The presence of a definitely negative behavior according to the Frankl behavior scale (Frankl et al.[22] 1962) was a motive of a child's exclusion, as well as the use of medication that contraindicate the injection of dental local anesthetic drugs or the absence of authorization by the child's parents or legal guardians to him / her participate in this study.

ANESTHETIC PROCEDURES

ANESTHESIA

All injections, irrespective the technique (conventional, vibrational or computerized) were performed as follows. After the application of a topical anesthesia with 20% benzocaine gel for 60 seconds, infiltrative anesthesia was done with short needles. The anesthetic solution used was 1.8 mL of 2% lidocaine with epinephrine 1: 100,000 at a speed of 1.0 mL per minute, totaling 108 s controlled with a stopwatch. In order to deliver the local anesthetic at the site of interest, the bevel of the needle was turned to the alveolar mucosa and slightly penetrated the soft tissue. These procedures composed the protocol for the conventional anesthetic technique. The other techniques needed additional resources, which are describe bellow. The same experienced dentist (P.C.S.) performed all local anesthetic procedures.

VIBRATIONAL ANESTHESIA

VBA was performed with a device called DentalVibe™ (Columbia Tech, Boston, USA). The device was positioned on the mucosa at the puncture site after topical anesthesia and it started the local vibration. The puncture for anesthetic

application was done 10 s after the device was turned on, at an average distance between the two ends of the vibrating device, as recommended by the manufacturer. The anesthetic was injected with a conventional syringe at a speed of 1.0 mL per minute, totaling 108 s, as previously described.

COMPUTERIZED ANESTHESIA

This anesthetic technique used na equipament named Morpheus™ (Meibach Tech, São Paulo, Brazil), which is a brazilian computerized delivery system. After topical anesthetic was applied, the puncture was performed by activating the introduction pedal followed by activation of the aspiration button.If there was no positive aspiration, the injection pedal was activated for anesthetic application, with a syringe provided by the Morpheus manufacturer and the usual needle. The delivery of 1.8 mL of anesthetic solution was accomplished with a flow rate of 1.0 mL per minute as pre-programmed in the equipment and accordingly to others techniques.

OUTCOMES AND EVALUATION TOOLS

PRIMARY OUTCOMES

SELF-PERCEPTION OF PAIN

The Wong Baker Faces Pain Rating Scale (WBF) and Numerical Rating Scale (NRS) evaluated the self perception of pain. WBF includes pictures of facial expressions with correlating numbers of 0 to 10 (0= 'no hurt' and 10= 'hurts worst') (Asarch et al.[23] 1999); NRS presents eleven points distributed at equal intervals in a straight line (0-10) (0- no pain at all, 10- worst imaginable pain) (Walker B.J.[24] 2019). The patient must choose the picture (WBF) and the number (NRS) that better represents his/her pain sensation at that given moment.

DISRUPTIVE BEHAVIOR

The children’s disruptive behavior during anesthesia was evaluated through the Faces, Legs, Activity, Cry, Consolability scale (FLACC) (Willis et al.[25]

2003). The results are classified according to the obtained scores: score 0 - patient is considered relaxed and comfortable; score 1 to 3 – mild discomfort; score 4 to 6 - moderate pain; 7 to 10 – severe pain.

SECONDARY OUTCOMES

ANALYSIS OF FEAR AND ANXIETY RELATED TO DENTAL TREATMENT

The level of fear and anxiety related to dental treatment was evaluated using Corah's Dental Anxiety Scale (Corah) (Corah[26] 1969, Corah et al.[27] 1978). The patients answered a four item questionnaire to identify and classify the levels of fear and anxiety in face of a dental visit. The possible result ranges from 4 to 20, classifying the patient as "anxiety free" (score 4); "moderate anxiety" (scores 5-10); "high anxiety" (scores 11-15) and "severe anxiety" (scores 16-20).

ANALYSIS OF THE EMOTIONAL STATE OF ANXIETY

The Venham Picture Test modified (VPTm) (Ramos-Jorge e Pordeus[28] 2004) determined the emotional state of anxiety of a child during the length ofthe study.

Eight pictures representing feelings ranging from anxiety to contentment are shown in pairs to the patient, who is asked to select the one that better described their feelings at that moment of the research. Only negative feelings score one point. The level of patient's anxiety is classified as "anxiety free" (score 0); "low anxiety level" (scores 1-3); "middle anxiety levels" (scores 4-6) and "high anxiety level" (7-8).

PHYSIOLOGICAL PARAMETERS

The physiological parameters evaluated were systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO2) and respiratory rate (RR) (Baghlaf et al.[16] 2015). A multiparametric monitor was used for this purpose (Inmax^{TM} - Instramed, Porto Alegre, Brazil).

SAMPLE SIZE

The sample size calculation was done considering the primary outcome “pain”. In this way, the mean pain levels obtained by Palm (2004) (Palm et al.[18] 2004) were used. Considering a power of 95% and a significance level of 5%, in a superiority clinical trial, the final sample was composed of 105 children, with 35 subjects per study group. The sample size calculation was done using the G*Power software program (version 3.1.9.2, University of Kiel, Germany).

RANDOM SEQUENCE GENERATION AND ALLOCATION CONCEALMENT

Randomization was accomplished by computer generated tables with blocked randomization (block size of 6) and an equal allocation ratio were obtained, considering the three study groups. The obtained codes were inserted in numbered black opaque envelopes, which were opened only on the day of the dental treatment, immediately before the local anesthesia. Consequently, the operator was blinded until this moment and the allocation concealment were achieved.

The randomization and allocation processes were done by a staff member not involved in the research protocol. These procedures were accomplished in the site sealedenvelope.com (Sealed Envelope Ltd, London, UK).

INTERVENTION

The data were collected at different moments of the research: T1 (before treatment); T2 (at dental office, when the child is called out to take his/her place at the dental chair); T3 (during local anesthesia) and T4 (immediately after local anesthesia). One assistant investigator was responsible for recording the acquired data in a specific clinical file and for guarantee the confidentiality of the patient, whose identification was replaced by a number. Figure 10 depicted all the sequence of the procedures.

The pre-operatory evaluation (T1 and T2) identified the baseline parameters of the patients (dental anxiety, emotional state of anxiety, physiological parameters). A neutral environment was used to apply the Corah questionnaire (dental anxiety); the emotional state (VPTm) and the physiological parameters were evaluated at the waiting room of the dental office (T1). After that, the child entered the dental office and

sited on the dental chair to check again the physiological parameters and the emotional state (VPTm) (T2).

After that, an opaque envelope with the designated anesthetic technique for that patient was opened by the main researcher and the T3 of the study beginned. During this phase (T3), the anesthetic procedure was recorded in video by an assistant researcher and the physiological parameters were recorded again.

At T4 (immediately after anesthesia), the VPTm, WBF and NRS tests were applied, which ended the data collection. After that, the dental treatment was done as usual, including the non pharmacological behavioral control techniques, like communication and communicative orientation, tell-show-do, voice control, nonverbal communication, positive reinforcement and distraction.

BLINDING

Operator and patients blinding was not possible because the anesthetic techniques employed very distinguished devices, which were not possible to disguise or hide. However, the data analysis was done without the statistician knowing the study groups.

EVALUATORS

All the evaluation tools were applied by two trained evaluators (L.S.S. and K.C.H.). The training consisted in a discussion about the tools with an experienced researcher and in applying the tools for 5 children who were not part of the study sample. It was useful to eliminate any evaluator's doubts or difficulties regarding the tools. At the same occasion, one evaluator was trained on the use of the multiparametrical monitor (P.R.D.M.). The Corah questionnaire, as well as VPTm, WBF, NRS scales were applied by the same evaluators (L.S.S. and K.C.H.) ; another one registered the physiological parameters.

The analysis of the recorded videos during anesthesia application to determine the index of disruptive behavior (FLACC) was done by a trained and calibrated researcher (L.S.S.). For this specific index, the training consisted in a discussion about the criteria and the analysis of treatment videos from patients not

taking place on the research. For this index, it was possible to obtain a intra evaluator Kappa value of 0.90.

STATISTICAL ANALYSIS

Descriptive analysis of the data was performed. All outcomes with were evaluated with different instruments (Corah, WBF, NRS, FLACC) resulted in nonparametric data and they were analyzed with Kruskal-Wallis test for unpaired analysis. ANOVA for repeat measures with post – hoc test of Tukey was used to compare the VPTm, SBP, DBP, HR, RR and SpO_2 data between the phases and groups of the study, after the passed the normality test (Shapiro-Wilk) Spearman correlation tests were also performed for Corah, VPTm, WBF, NRS and FLACC. All tests were performed with a significance level of 0.05 using the software SPSS version 15.0 statistics program (SPSS Inc., Chicago, IL, USA).

RESULTS

A total of 219 patients were examined and 114 were excluded from the sample because they didn't fulfill the inclusion criteria. The sample was composed by 105 children who completed all the phases of the study. The experimental protocols were implemented as planned (Figure 11). The mean age was 10.91 $\pm$ 0.8; the gender distribution was 42 males (40%) and 63 females (60%).

DENTAL ANXIETY (CORAH'S DENTAL ANXIETY SCALE)

It's important to mention that similar levels of dental anxiety were detected in the subjects at the baseline (Table 9), without differences between the study groups (p=0.856) (Table 10). The majority of the research subjects showed moderate dental anxiety (51,4%). Higher dental anxiety levels were observed in girls in comparison with boys (p=0.002) (Table 10).

ANXIETY EMOTIONAL STATE (VPTM)

The VPTm test was used at T1, T2 and T4 to identify the child's emotional state of anxiety. There was no difference in the emotional state of the patients at T1 (p = 0.967), T2 (p = 0.418) and T4 (p = 0.474), in the same study group (Table 11). Without considering the study groups, the entire sample in different moments (T1, T2, T4) of the study also showed no significant difference (p=0.127). However, when gender was considered, girls showed increased anxiety levels when compared to boys (p=0.020).

SELF-PERCEPTION OF PAIN (WBF AND NRS) AND DISRUPTIVE BEHAVIOR (FLACC)

The patient reported outcome “self-perception of pain” was analyzed using WBF and NRS; disruptive behavior was analyzed using FLACC as a patient centered outcome.

A difference between the anesthetic techniques was observed in self-reported pain, irrespective the scale used (WBF – p= 0.032; NRS – p= 0.021) (Table 12). Group CA resulted in reduced pain sensation when compared to Group VBA in the WBF (p=0.018) and NRS scales (p=0.006). The same was observed in the comparison of Group CA and Group CCLAD, but the difference was only observed for the WBF scale (p=0.029). Groups VBA and CCLAD exhibited similar levels of pain perception.

Dental anxiety and pain perception were poorly correlated. However, it was detected a positive correlation between the self reported levels of pain (WBF - p<0.001; rho=0.336 and NRS scales - p<0.001; rho=0.338) and dental anxiety (Corah), which indicate that the higher levels of dental anxiety may lead to greater perception of pain.

There was also detected a weak positive correlation between the emotional state of anxiety (VPTm) and the reported pain (WBF - p <0.001; rho = 0.469 and NRS- p <0.001; rho = 0.430). This probably indicate that, the greater the state of anxiety, the greater the perception of pain.

For the disruptive behavior, it was not observed significant differences between the anesthetic techniques tested (FLACC – p=0.573) or between gender (NRS - p=0.931; WBF - p=0.940; FLACC - p=0.118). It was also observed that there

was no correlation between disruptive behavior and self-perception of pain (WBF - rho=0.224; NRS – rho=0.243).

PHYSIOLOGICAL PARAMETERS

Considering the three anesthetic techniques, there were no differences in systolic and diastolic blood pressures, heart rate, respiratory rate or oxygen saturation ($p>0.05$).

However, the analysis of the overall sample detected significant differences in the means of systolic and diastolic blood pressures ($p<0.0001$), heart rate ($p=0.033$) and respiratory rate ($p<0.0001$) when the different moments (T1, T2, T3) of the dental appointment were evaluated (Table 13).

DISCUSSION

The development of new technologies in Dentistry brings with it the need of constant research to evaluate them and to define the cost-benefit of these devices for the everyday practice. This study sought to clarify whether investing in additional equipments for local dental anesthesia is the path to less painful anesthetic technique in children, resulting in lower levels of anxiety and easier behavior management. Our results demonstrated that, for this specific age group that composed the sample, the use of the devices did not reduce the pain perception and the manifestations of disruptive behavior of the patients.

The results evidenced that pain related to dental anestesia is, indeed, generated by the procedure itself and boosted by the existing dental anxiety and the state of anxiety at that specific moment.

Scientific evidence reveals that dental anxiety is associated with pain perception (Maulina et al.[29] 2017, Shrivastava et al.[30] 2012, Heaton[31] 2017). Dental anxiety develops in early childhood (Klingberg e Broberg[32] 2007) from past experiences of pain/anxiety in dental appointments that remain in an individual's memory (Kent[33] 1985). Cognitive reasons that influence dental anxiety include poor child-dentist relationships and negative experiences; non-cognitive reasons include fear of the unknown and vicarious learning (Carrillo-Diaz et al.[34] 2012). Therefore, we evaluated dental anxiety before the beginning of the clinical phase of the study,

because a difference in the dental anxiety level in the study groups would compromise the results of pain perception. Since the sample was homogeneous regarding this variable, we became more confident about the obtained pain perception data, that showed that the greater the dental anxiety, the greater the perception of pain. This finding is corroborated by different studies in the literature (Costa et al.[35] 2012, Sanikop et al.[36] 2011, Caltabiano et al.[37] 2018).

Notwithstanding, we hypothesized that the research data collection could generate some level of anxiety. Excessive anxiety tends to hamper patients'dental treatments, making them unable to cooperate with dentist (Kazancioglu et al.[38] 2017) and leading them to overestimate the pain experienced at the dental appointment (Kent[33] 1985). Therefore, we included the assessment of the emotional state of anxiety at different moments of the study with VPTm. The hypothesis was not comfirmed, since our data comproved that the emotional state of anxiety did not vary during the study, therefore the levels of pain were only influenced by the baseline dental anxiety, which was homogenous among the study subjects.

Pain during dental procedure is one of the major factors that have a lasting and profound impact on the behavior of the child (Oosterink et al.[39] 2008, Splieth et al.[40] 2009). Reducing pain and discomfort is essential and vital in pediatric dentistry (Jones e Dean[41] 2016). However, the evaluation of pain is a complex process. There is an inherent difficulty to distinguish between behavior resulting purely from pain and behavior resulting from fear/anxiety or a mixture of other factors (Beyer et al.[42] 1990). For this reason, we used different tools to evaluate self perception of pain. WBF and NRS are considered gold standard tests. They are tools with patient reported reponses that can suffer from external influence and by the patient perception. In order to corroborate the data obtained from these tests, we included the FLACC scale, which is a patient centered instrument. Also, physiological parameters were checked up, since they can sinalize somatic changes related to anxiety (Julian[43] 2011) Taking all the collected information together, we can say that the self perception of pain was lower when conventional anethetic technique were employed. However, the manifestations of disruptive behavior and the physiological parameters were similar regardless the used technique.

In the present study, we sought to perform the injection of the anesthetic solution by controlling the total time of injection for the three tested techniques, so that the average flow rate was 1.0 mL / min, with a volume of 1.8 mL for 108 s, which is the

CCLAD standardized time. Although in conventional anesthesia the control of the time and pressure is arbitrary, it is important to perform a slow injection on average of 1.0 mL / min, as we did in the research for conventional and vibrational anestesia techniques. Injection time control was performed with a chronometer. A fast injection can increase the level of pain, which is due to the pressure exerted on the tissue by the anesthetic solution (Klein et al.[44] 2005). It would be expected that, since the injection of the anesthetic solution was accomplished in the same way for all the anesthetic techniques, we would obtain similar results or even better results regarding self reported pain when the different anesthetic devices were used. However, the reported pain levels were higher for VBA and CCLAD when compared to the conventional technique.

There are some hypotheses that can explain this result. The vibrational device inserts other sensations to the anesthetic procedure (pressure and vibration) that may be interpreted by the child as some kind of pain or discomfort (Elbay et al.[5] 2015) and influence the final interpretation of the applied stimuli (whether painful or not) (Eli[45] 1992). Different authors suggested that the sound or the sensation of vibration can cause fear and anxiety (Raj et al.[46] 2013), being a stress triggering factor in children (Belcheva[47] 2014), even in children in this older age group like the ones that took part in this study.

It is necessary to highlight that the vibration time before the injection of the anesthetic solution probably influenced the response. We follow the manufacturer's recommendation, ie, to apply the vibration 10s before injection. Some studies found a difference favoring vibrational anaesthesia when the vibration was applied for a longer time, such as 30 s (Dak-Albab et al.[14] 2016) or 60 s (Shilpapriya et al.[48] 2015). The effect of the application time of the vibration deserves further research.

Regarding the computerized anaesthesia, our results showed that conventional anesthesia was less painful than computerized techniques. This result is not supported by the literature that compared conventional and computerized anesthesia and found no difference (Baghlaf et al.[16] 2015, Mittal et al.[19] 2015, Versloot et al.[20] 2008, Asarch et al.[23] 1999, Klein et al.[44] 2005, Kandiah e Tahmassebi[49] 2012, Thoppe-Dhamodhara et al.[50] 2015, Tahmassebi et al.[51] 2009) or less pain perception with the use of computerized anesthesia (Deepak et al.[17] 2017, Palm et al.[18] 2004, Garret-Bernardin et al.[52] 2017, Feda et al.[53] 2010, Oztas et al.[54] 2005).

There is one particularity about the other researches that justify these conflicting results. In their methodology, they didn't standardized the injection time for conventional and computerized anesthetic techniques, resulting in a shorter application time for conventional anesthesia (Deepak et al.[17] 2017, Palm et al.[18] 2004, Versloot et al.[20] 2008, Klein et al.[44] 2005). Thus, slow injection might be responsible for the high success rate of the conventional technique in the present study. However, if we consider that not always the dentists will perform the conventional technique with slow injection, the results of other studies are valid, and the use of computer-controlled local anesthesia device may be an interesting choice to minimize pain during local dental anesthesia.

The disruptive behavior was not dependent on the type of anesthesia. The children evaluated in this study showed low rates of disruptive behavior. It may be because in addition to using slower anesthesia techniques, we also use good communication with the patient and parents and effective behavioral management strategies. Therefore, in a sample with low anxiety levels, it would be expected few manifestation of disruptive behavior. For vibrational anesthesia, the literature shows conflicting results, with the manifestations of disruptive behavior being similar (Elbay et al.[5] 2015) or better (Dak-Albab et al.[14] 2016) for vibrational anesthesia when compared to the conventional technique. However, there is a difference between the vibrational device used time, which reinforce the hypothesis that the time of the vibration can influence not only the pain response but also the disruptive behavior. For computerized anesthesia, the studies that evaluated the behavior are inconsistent, some corroborate with the present study, similar levels of disruptive behavior between computerized and conventional anesthesia (Asarch et al.[23] 1999, Al Amoudi et al.[55] 2008) and others showed less disruptive behavior for computerized anesthesia (Feda et al.[53] 2010, Allen et al.[56] 2002).

Painful stimuli and anxiety are reflected in physiological responses because the autonomic nervous system prepares the body to face the situation physically (Franck et al.[57] 2000). Consequently, tachycardia, peripheral vasoconstriction, diaphoresis, pupil dilation, and increased secretion of catecholamines and adrecorticoid hormone occur (Franck et al.[57] 2000). Then there is an increase in blood pressure, heart rate (Mischkowski et al.[58] 2018), respiratory rate (Miranda et al.[59] 2011) and oxygen saturation that is compensatory by increased demand for oxygen.

When assessing the blood pressure, we found no differences between the anesthetic techniques, which is corroborated by other studies that also found no difference between conventional, vibrational (Chaudhry et al.[60] 2015) and computerized (Thoppe-Dhamodhara et al.[50] 2015) for this criterion. However, it was identified that the blood pressure decreased between the different moments of the study. This is probably due to the child's position. At T1, the child was sitting in a common chair; at T2 on the dental chair, but still at rest, and at T3 the child was lying down, which caused a gradual decrease in blood pressure.

The different anesthetic techniques did not influence the heart rate. This was corroborated by other studies that evaluated this parameter regarding computerized X conventional (Mittal et al.[19] 2015, Thoppe-Dhamodhara et al.[50] 2015, Patini et al.[61] 2018) or vibrational X conventional anesthesia (Chaudhry et al.[60] 2015, Tung et al.[62] 2018). Unlike blood pressure, which decreased, the heart rate increased between moments, probably due to the fear and anxiety generated in each situation.

Similar to heart rate, respiratory rate did not show any difference between the distinct kinds of anesthetic techniques, but, numerically, it increased along the different phases of the research, while oxygen saturation remained homogeneous and showed no difference during the study for any technique. We did not find studies that analyzed respiratory rate and oxygen saturation.

We found similar physiological parameters between anesthesia, this means that no anesthesia alone caused so much pain or anxiety that it demanded a greater physiological response compared to the others. The constant of these parameters, lead us to believe that the autonomic nervous system did not interpret the stimuli of any of the anesthesias as a potential threat of greater damage than the other anesthesias evaluated. The child’s physical, psychological and cognitive development may affect the experience and response of pain and anxiety during LA (Versloot et al.[63] 2005). The majority of the published literature about anesthetic techniques embraces large age ranges groups, including from preschoolers to teenagers (Asarch et al.[23] 1999, Kandiah e Tahmassebi[49] 2012, Garret-Bernardin et al.[52] 2017, Gibson et al.[64] 2000) and age is a factor that must be taken into account. The anxiety related to dental treatment is different between age ranges, younger children have higher dental anxiety (Oliveira et al.[65] 2012). Younger children have immature cognitive development to understanding some pain scales (Zarbock[66] 2000) and they tend to choose the extreme ends of pain scales. On the other side, teenagers tend to feel embarrassed

with manifestations of pain and chose lower pain levels (Franck et al.[57] 2000). Therefore, we selected subjects in a narrower age range, aiming to obtain a homogenous sample regarding pain responses.

Combining all the parameters mentioned above, we can say that the conventional technique is the first choice for dental local anesthesia regarding the perception of pain, disruptive behavior, anxiety and physiological response, in children aged 9 to 12 years. Anyway, it is extremely important for the professional to be aware that, when treating children, the correct technique is not enough to guarantee a successful treatment. The psychological management of the child's behavior is the paramount to lead the patients to a positive attitude toward Dentistry.

CONCLUSION

The results obtained demonstrate that, under the conditions of the present study, the conventional technique promotes less perception of pain to infiltrative local anesthesia, in dental treatment, for children from 9 to 12 years of age.

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Figure 10: Flow diagram of the different phases of the study

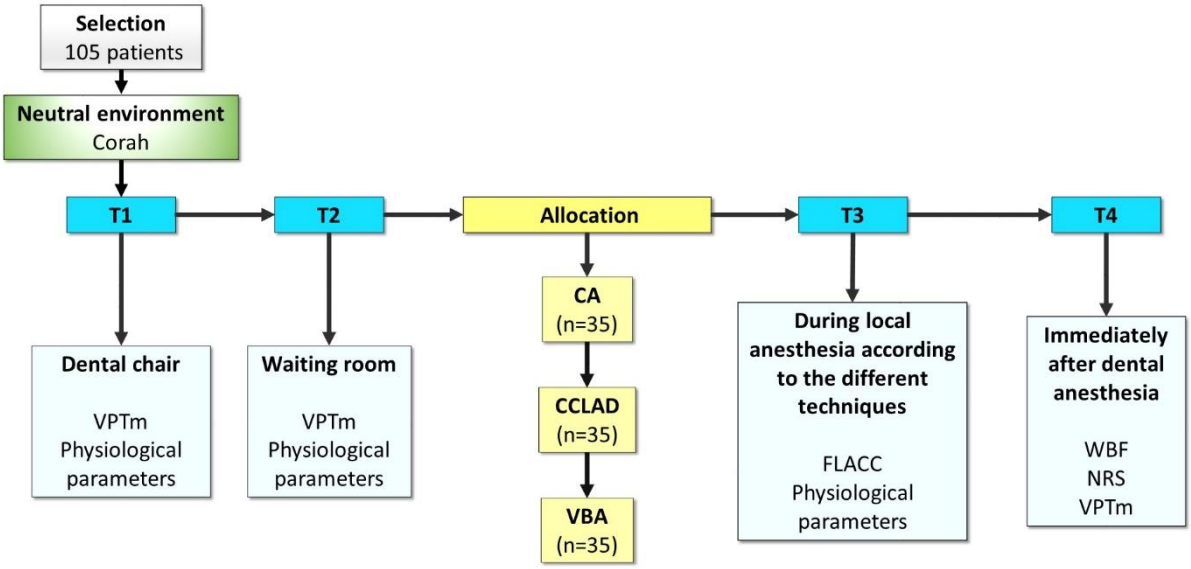

Figure 11: Sample analyzed flow diagram (CONSORT)

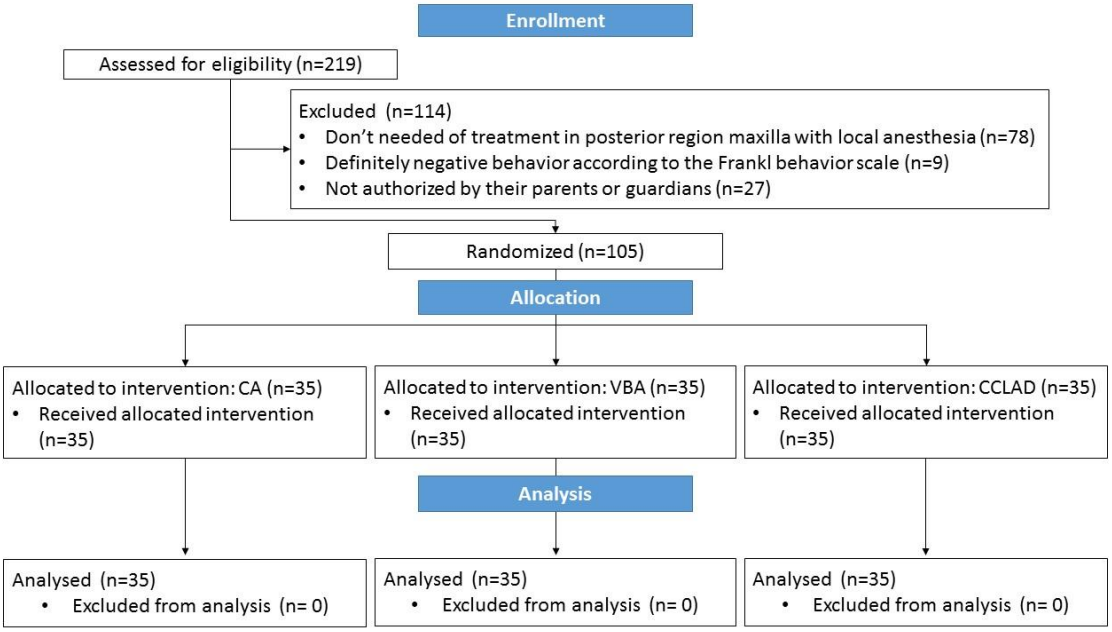

Table 9: Dental anxiety at the baseline according to the study groups (Corah's Dental Anxiety Scale)

Dental Anxiety	CA	VBA	CCLAD	*p*-value
Median (interquartile range)	2 (1-4)[a]	3 (1-4)[a]	2 (1-4)[a]	0.856
Mean ± SD	2.22±0.77[a]	2.17±0.70[a]	2.14±0.79[a]	

Lowercase letters in the same line means no significant difference between groups (p<0.05)

Table 10: Relative (absolute) frequencies of the fear and anxiety related to dental treatment (Corah) according to the patients` gender.

Dental Anxiety Levels	Gender		
	Male %(n)	Female %(n)	Total %(n)
Anxiety free	12.38% (n=13)	5.71% (n=6)	18.09% (n=19)
Moderate anxiety	20.00% (n=21)	31.42% (n=33)	51.42% (n=54)
High anxiety	7.61% (n=8)	17.14% (n=18)	24.76% (n=26)
Severe anxiety	0.00% (n=0)	5.71% (n=6)	5.71% (n=6)
p value	0.002		

With significative difference between sex (p=0.002).

Table 11: Anxiety emotional state (VPTm) according to study groups and study phases [median (interquartile range) and Mean + Standard Deviation]

	CA	VBA	CCLAD	*p*-value
T1	1(1-4)[a] 1.37±0.64[a]	1(1-4)[a] 1.40±0.73[a]	1(1-4)[a] 1.45±0.81[a]	0.967
T2	1(1-2)[a] 1.37±0.49[a]	1(1-4)[a] 1.60±0.81[a]	1(1-4)[a] 1.40±0.73[a]	0.418
T4	1(1-3)[a] 1.42±0.60[a]	1(1-4)[a] 1.71±0.89[a]	1(1-4)[a] 1.57±0.73[a]	0.474

Lowercase letters in the same line means no significant difference between groups (p<0.05)

Table 12: Self-perception of pain (Wong Baker Faces and Numerical Rating Scale) according to study groups immediately after dental local anesthesia (T4) [median (interquartile range) and Mean + Standard Deviation]

Evaluation of pain	CA	VBA	CCLAD	*p*-value
WBF	2 (0 - 4)^{A}	2 (0 - 10) ^{A}	2 (0 - 8)^{A}	0.032
	1.37±1.43^{A}	2.74±2.52^{A}	2.57±2.35^{A}	
NRS	1 (0 - 5)^{A}	2 (0 - 8)^{A}	2 (0 - 7)^{A}	0.021
	1.17±1.29^{A}	2.48±2.11^{A}	2.02±1.97^{A}	
FLACC	0 (0-1) ^{a}	0 (0-2) ^{a}	0 (0-3) ^{a}	0.573
	0.34±0.48 ^{a}	0.48±0.56 ^{a}	0.51±0.74 ^{a}	

Lowercase letters in the same line means no significant difference between groups (p<0.05)
Capital letters on the same line mean that there is a statistically significant difference (p <0.05)

Table 13: Physiological parameters (blood pressure and heart rate) according to the different anesthetic techniques and dental appointment moments

Physiological Parameters	CA			VBA			CCLAD			*p*-value
	T1	T2	T3	T1	T2	T3	T1	T2	T3	
Systolic blood pressure	113.54±11.03[a]	110.85±9.30[a]	108.25±11.08[a]	112.57±7.78[a]	111.11±11.00[a]	109.37±10.70[a]	112.60±9.88[a]	111.25±10.62[a]	107.39±9.22[a]	0.954
Diastolic blood pressure	84.62±10.16[a]	80.97±9.25[a]	79.62±9.15[a]	85.02±6.43[a]	80.91±8.73[a]	81.54±10.56[a]	85.22±9.41[a]	81.57±11.91[a]	78.11±11.85[a]	0.899
Heart Rate	83.25±12.30[a]	84.45±12.49[a]	88.05±13.99[a]	81.65±11.91[a]	83.00±12.44[a]	85.34±14.11[a]	85.85±19.22[a]	84.80±15.46[a]	87.11±18.71[a]	0.726
SpO_2	96.28±2.21[a]	97.08±0.95[a]	96.88±0.93[a]	96.82±0.95[a]	97.00±0.97[a]	96.62±1.57[a]	96.74±0.98[a]	96.88±1.25[a]	96.65±1.05[a]	0.930
Respiratory rate	20.57±3.44[a]	21.11±3.28[a]	22.62±4.45[a]	19.51±3.22[a]	20.00±3.22[a]	23.85±3.71[a]	19.00±3.53[a]	19.62±3.39[a]	21.97±3.99[a]	0.477

Lowercase letters in the same line means no significant difference between groups ($p<0.05$)

5 DISCUSSÃO

O desenvolvimento de novas tecnologias em Odontologia traz consigo a necessidade de pesquisas constantes para avaliá-las e definir o custo-benefício desses dispositivos para a prática diária. Esta tese buscou esclarecer se existe vantagens na utilização de dispositivos de anestesia computadorizada e anestesia vibracional, sobre a anestesia convencional, em crianças, considerando a autopercepção de dor, o comportamento disruptivo, a ansiedade e a resposta fisiológica.

Nossas evidências científicas por meio da revisão sistemática e metanálise, quando investigamos a anestesia computadorizada, demostraram equivalência com a anestesia convencional. E investigando a superioridade da anestesia computadorizada ou anestesia vibracional, sobre a anestesia convencional, por meio de ECR, também encontramos uma equivalência entre as técnicas em crianças de 5 a 8 anos e uma superioridade da anestesia convencional em crianças de 9 a 12 anos.

Os métodos de avaliação da dor são uma questão científica muito complexa (Johannessen[46] 2019). Trata-se de um desfecho relatado pelo paciente e, portanto, uma resposta subjetiva obtida, deve ser convertida em dados quantitativos para permitir a interpretação. Além disso, está diretamente relacionado as experiências individuais como estresse, ansiedade e medo que podem alterar a percepção da dor. No universo infantil, é ainda mais difícil entender quanta dor a criança sente naquele momento ou estímulo, quão ansioso, estressado ou assustado, ela se encontra e como isso influenciará a percepção da dor (Garret-Bernardin et al.[1] 2017). Portanto, a percepção da dor e do comportamento durante a anestesia local estão relacionados a fatores emocionais das crianças.

Considerando a revisão sistemática e metanálise, esses fatores, por si só, podem ser responsáveis por algum grau da heterogeneidade clínica inerente dos ensaios. No entanto, também podemos listar alguns outros recursos que provavelmente contribuir para o alto grau de heterogeneidade e a baixa qualidade da evidência encontrada em nossa metanálise de percepção dor durante a anestesia local, como a variedade de escalas para medir a dor e faixa etária estudada. Os estudos aqui relatados mediram a dor durante a anestesia usando diferentes escalas de dor, todas dependentes do relato do paciente. Este é o método usado como o 'Padrão ouro' para avaliação de dor em crianças (Abdellatif[47] 2011). Elas são

projetadas para avaliar diferentes níveis de dor e todos são validados para avaliar dor em crianças (Asarch et al.[12] 1999). Mesmo considerando as diferentes escalas utilizadas pelos autores, os resultados dos estudos poderiam ser agrupados porque foram resumidos calculando o valor da diferença média padronizada (*g* de Hedge). Assim, todos os resultados são transformados em uma escala comum e se tornam comparáveis. No entanto, também pode contribuir para aumentar a heterogeneidade.

Para a percepção da dor, a metanálise mostrou uma menor percepção de dor em crianças que receberam anestesia computadorizada. No entanto, um alto nível de heterogeneidade foi detectado (I^2 = 94%). O melhor desempenho da anestesia computadorizada em relação à percepção da dor não foi observado quando apenas estudos com baixo risco de viés foram incluídos, e a heterogeneidade foi reduzida (I^2 = 77%; 95%), bem como o intervalo de confiança de 95% para a média padrão diferença (-0,12; IC95% = -0,46 a 0,22). No subgrupo dos estudos considerados com incerto risco de viés, detectamos diminuição do número de pacientes associados ao aumento do grau heterogeneidade (I^2 = 96%) e maior intervalo de confiança (-1,27; IC95% = -2,21 a 0,33), o que reduziu nossa confiança no tamanho do efeito.

Uma análise de sensibilidade, a fim de identificar os motivos pela heterogeneidade no subgrupo "baixo risco", foi realizada. Ao fazê-lo, retirando dois artigos, (Smail-Faugeron et al.[48] 2019, Patini et al.[49] 2018) a heterogeneidade foi eliminada e o resultado final permaneceu inalterado, fortalecendo os achados que não mostram diferença entre as duas técnicas anestésicas.Então, escolhemos aceitar os resultados da análise de estudos de baixo risco, até outros ensaios clínicos randomizados estiverem disponíveis para análise. Portanto, classificamos como baixa qualidade da evidência para esse resultado, devido a problemas de inconsistência.

Observar o comportamento das crianças durante o tratamento odontológico é essencial na avaliação da dor, pois suas expressões faciais ou movimentos corporais são critérios diagnósticos importantes que indicam desconforto ou dor (Al Amoudi et al.[29] 2008). Dessa forma, o comportamento disruptivo foi considerado como desfecho secundário. Não foram observadas diferenças para essa variável ao comparar diferentes anestesias, independentemente do risco de viés dos estudos. Foi observada heterogeneidade dos dados, mas foi inferior ao observado na percepção da dor. Nesse critério, apenas três escalas foram usadas, e é um resultado centrado no paciente, que pode levar a um menor grau de subjetividade.

O comportamento disruptivo relacionado a dor é facilmente identificado (por exemplo: movimento corporal, tensão muscular, chorando ou gritando, protesto verbal, e resistência corporal) são situações muito explícitas. Contudo, há sempre a possibilidade de adicionar viés ao estudo durante o processo de avaliação. Este é um tópico relevante a ser considerado, uma vez que as características das duas técnicas anestésicas tornam impossível ter um avaliador cego e os artigos incluídos não relataram nenhum tipo de treinamento ou calibração dos avaliadores, que seria a situação ideal para ensaios clínicos randomizados. Isto é um passo que sugerimos fortemente que seja incluído nos protocolos de pesquisa para futuros ensaios clínicos sobre esse assunto.

A qualidade dos artigos para resultados de comportamento disruptivo foi baixa por inconsistência (devido ao grau de heterogeneidade), imprecisão (devido ao alcance do intervalo de confiança), que foi associado ao número de estudos em incerto risco de viés (Gibson et al.[2] 2000, Feda et al.[4] 2010, Baghlaf et al.[7] 2015, Mittal et al.[10] 2015, Allen et al.[11] 2002, Asarch et al.[12] 1999, Deepak et al.[28] 2017, Thoppe-Dhamodhara et al.[50] 2015).

O bloqueio da estimulação nervosa por anestesia local diminui a resposta do sistema nervoso central ao estímulo de dor, diminuindo também a ansiedade do paciente durante a tratamento. No entanto, quanto maior a ansiedade dental, maior o comportamento não cooperativo (Duskova et al.[51] 2017) e maior a dificuldade de gerenciar o comportamento das crianças. Considerando isso, alguns autores também avaliaram o estresse e a ansiedade durante o tratamento convencional e anestesia computadorizada (Garret-Bernardin et al.[1] 2017, Queiroz et al.[6] 2015, Tahmassebi et al.[32] 2009, Versloot et al.[52] 2005, Versloot et al.[53] 2008) e nenhuma diferença foi relatada. Verificou-se que crianças muito ansiosas tendem a sentir mais dor durante a anestesia local, independentemente da técnica anestésica utilizada (Versloot et al.[53] 2008). Infelizmente, não foi possível extrair os dados relacionados ao estresse e ansiedade desses artigos, uma vez que os critérios de avaliação eram muito diferentes de um para outro, o que impediu a metanálise.

Além dos fatores já descritos, existem condições que podem influenciar a resposta à dor e perturbar comportamento, 36 como o local da anestesia. Por exemplo, o método IANB é considerado muito doloroso; uma injeção no palato é ainda mais dolorosa (Wiswall et al.[54] 2014). Isso pode afetar o comportamento da criança e a percepção da dor. Nos estudos incluídos, a maioria dos trabalhos comparou as

injeções na maxila (Garret-Bernardin et al.[1] 2017, Gibson et al.[2] 2000, Feda et al.[4] 2010, Queiroz et al.[6] 2015, Mittal et al.[10] 2015, Allen et al.[11] 2002, Klein et al.[15] 2005, Al Amoudi et al.[29] 2008, Kandiah e Tahmassebi[31] 2012, Tahmassebi et al.[32] 2009, Smail-Faugeron et al.[48] 2019, Patini et al.[49] 2018, San Martin-Lopez et al.[55] 2005). É uma anestesia menos desafiadora a ser realizada quando comparada à IANB, pois há menos variações anatômicas na maxila. No entanto, houve estudos que compararam não apenas a anestesia convencional com a computadorizada, mas também diferentes técnicas anestésicas (Gibson et al.[2] 2000, Feda et al.[4] 2010, Allen et al.[11] 2002, Asarch et al.[12] 1999, Klein et al.[15] 2005, Al Amoudi et al.[29] 2008, Tahmassebi et al.[32] 2009, Smail-Faugeron et al.[48] 2019, Thoppe-Dhamodhara et al.[50] 2015, Versloot et al.[52] 2005, Versloot et al.[53] 2008) que interferem na percepção da dor e comportamento disruptivo nas crianças. Ao fazer isso, os autores adicionam um possível viés; portanto, os resultados devem ser interpretados com cautela. Essa pode ser outra fonte de heterogeneidade, conforme detectado pela metanálise. Portanto, se o foco é a avaliação de método anestésico (por exemplo, computadorizado vs. convencional), ensaios clínicos futuros devem considerar o uso da mesma técnica anestésica.

Baseado nas lacunas evidenciadas pela revisão sistemática e metanálise, decidimos elaborar um protocolo de pesquisa para ensaio clínico randomizado; afim de elucidar as correntes dúvidas sobre o uso de dispositivos acessórios na anestesia local, controlando o máximo possível de viés. Os ECR's tiveram como objetivo verificar se o uso de diferentes dispositivos anestésicos poderia melhorar a experiência odontológica durante os procedimentos anestésicos, em crianças, em relação à ansiedade, dor e comportamento disruptivo. Além disso, ao que sabemos, estes são os primeiros artigos que comparam anestesia vibracional e computadorizada em crianças. Os resultados obtidos favorecem a técnica anestésica convencional como o procedimento de melhor custo-benefício.

O nível de ansiedade dental no início do estudo é uma variável que geralmente não é avaliada por outros pesquisadores. Nestes ECR's, foi detectado um nível moderado de ansiedade dental nos pacientes, em ambas faixas etárias, resultando em uma amostra homogênea. Isso é importante porque a ansiedade dentária é um preditor significativo para a percepção da dor em crianças e adolescentes (Marsac e Funk[56] 2008) e crianças ansiosas tendem a superestimar a intensidade da dor (Kuscu e Akyuz[30] 2008, Marsac e Funk[56] 2008), incluindo dor a injeção de anestesia local

(Ortiz et al.[57] 2014). Portanto, em nossa amostra, os dados de dor relatados foram obtidos de pacientes com níveis semelhantes de ansiedade no início do estudo.

Não foi observada diferença na percepção da dor ao comparar anestesia convencional, computadorizada e vibracional em crianças de 5 a 8 anos de idade. Esse resultado é corroborado por vários estudos na literatura que compararam anestesia convencional e computadorizada (Baghlaf et al.[7] 2015, Mittal et al.[10] 2015, Asarch et al.[12] 1999, Kandiah e Tahmassebi[31] 2012, Versloot et al.[53] 2008) ou anestesia convencional e vibracional (Elbay et al.[18] 2015, Raslan e Masri[21] 2018). As crianças de 9 a 12 anos manifestaram menor percepção de dor, quando anestesiadas pela técnica convencional, não identificamos estudos com este mesmo resultado. Por outro lado, existem alguns artigos que afirmam menor percepção da dor com o uso de anestesia computadorizada (Garret-Bernardin et al.[1] 2017, Feda et al.[4] 2010, Deepak et al.[28] 2017, Oztas et al.[58] 2005) ou anestesia vibracional (Tung et al.[17] 2018, Shilpapriya et al.[25] 2015).

Esses resultados conflitantes vieram de estudos com amostras de crianças de 3 a 15 anos e, a grande faixa etária em algumas delas pode ser um problema para os níveis de autopercepção de dor, introduzindo viés de informação no estudo. Sabe-se que crianças pequenas e pré-escolares não entendem conceitos abstratos; portanto, pode ser difícil para eles discriminar a intensidade da dor porque seus mecanismos de controle descendente são imaturos, limitando sua capacidade de modular a experiência. Crianças de três ou quatro anos tendem a selecionar os extremos das escalas de dor, negligenciando a porção intermediária das escalas contínuas ou de itens múltiplos. A capacidade de quantificar as experiências de dor será precisa apenas em crianças de 5 anos de idade. Por outro lado, os adolescentes tendem a evitar manifestações de dor, devido ao medo de constrangimento, o que pode refletir na diminuição dos níveis relatados de dor (Franck et al.[59] 2000). Por isso, nestes estudos utilizamos faixas etárias mais restritas (5 a 8 anos e 9 a 12 anos), onde as respostas à dor tendem a apresentar análises semelhantes pelos pacientes.

Outro aspecto que precisa ser abordado é o local e a técnica da anestesia. Não é incomum na literatura estudos que comparem diferentes técnicas anestésicas usando diferentes locais de injeção. Como evidenciado na revisão sistemática, existem artigos que incluem infiltração bucal e palatal (Garret-Bernardin et al.[1] 2017, Feda et al.[4] 2010, Allen et al.[11] 2002, Al Amoudi et al.[29] 2008) ou infiltração bucal e palatal comparada ao bloqueio do nervo alveolar inferior (Asarch et al.[12] 1999, Versloot

et al.[52] 2005, Versloot et al.[53] 2008). Uma infiltração palatal ou um bloqueio nervoso são muito mais dolorosos do que uma infiltração bucal (Wiswall et al.[54] 2014) e provavelmente resultaria em respostas mais intensas. Utilizamos a técnica anestésica terminal infiltrativa na região posterior da maxila para todos os grupos de estudo. Este é um sitio de menor variação que facilita o procedimento anestésico, permitindo identificar a real influência dos diferentes dispositivos anestésicos na resposta do paciente à anestesia.

Nestes estudos, buscou-se realizar a injeção da solução anestésica, controlando o tempo total da injeção, para que a vazão média fosse de 1,0 mL / min, com um volume de 1,8 mL por 108 s. Uma injeção rápida pode aumentar o nível de dor, que está relacionado à pressão exercida no tecido pela solução anestésica (Klein et al.[15] 2005). Embora na anestesia convencional o controle da pressão seja arbitrário, é importante realizar uma injeção lenta em média de 1,0 mL / min. Dessa forma, juntamente com o dispositivo vibratório, a injeção da solução anestésica era controlada na realização da técnica anestésica vibracional. Seria de esperar que, como a injeção da solução anestésica foi realizada exatamente da mesma maneira que para a técnica convencional, obtivéssemos resultados semelhantes ou até melhores com relação à dor autorreferida. No entanto, os níveis de dor relatados na anestesia vibracional foram superiores aos da técnica convencional com diferença significativa somente para as crianças de 9 a 12 anos.

Existem algumas hipóteses que podem explicar esse resultado. O dispositivo vibracional insere outras sensações no procedimento anestésico (pressão e vibração) que podem ser interpretadas pela criança como algum tipo de dor ou desconforto (Elbay et al.[18] 2015) e influenciam a interpretação final dos estímulos aplicados (dolorosos ou não) (Eli[60] 1992). Diferentes autores sugeriram que o som ou a sensação de vibração podem causar medo e ansiedade (Raj et al.[61] 2013), sendo um fator desencadeador de estresse em crianças (Belcheva[62] 2014).

É necessário destacar que o tempo de vibração antes da injeção da solução anestésica provavelmente influenciou a resposta. Seguimos a recomendação do fabricante, ou seja, aplicar a vibração 10s antes da injeção. Alguns estudos encontraram uma diferença favorável à anestesia vibracional quando a vibração foi aplicada por mais tempo, como 30 s (Dak-Albab et al.[63] 2016) ou 60 s (Shilpapriya et al.[25] 2015). O efeito do tempo de aplicação da vibração merece mais pesquisas.

No caso da anestesia computadorizada, há uma particularidade nas outras pesquisas que justificam os resultados conflitantes. Em sua metodologia, eles não padronizaram o tempo de injeção para as técnicas anestésicas convencionais e computadorizadas, resultando em um menor tempo de aplicação da anestesia convencional (Klein et al.[15] 2005, Deepak et al.[28] 2017, Palm et al.[45] 2004, Versloot et al.[53] 2008). Assim, a injeção lenta pode ser responsável pela alta taxa de sucesso da técnica convencional para as crianças de 9 a 12 anos, já que nas mais novas não obtivemos diferença. No entanto, se considerarmos que nem sempre os dentistas executam a técnica convencional com injeção lenta, os resultados de outros estudos são válidos e o uso do dispositivo de anestesia local controlado por computador pode ser uma opção interessante para minimizar a dor durante a anestesia dentária local.

Os métodos de autorrelato são considerados o padrão-ouro para a avaliação da dor (Franck et al.[59] 2000). Mesmo assim, para melhorar a avaliação da dor, várias ferramentas, relatadas e centralizadas pelo paciente, foram usadas para uma avaliação mais precisa da experiência da dor infantil: o Wong Baker Faces, que é uma ferramenta não-verbal com figuras; NRS, uma ferramenta de dimensão numérica; e FLAAC, uma ferramenta observacional que identifica comportamentos disruptivos relacionados à dor. A metodologia foi definida para favorecer uma avaliação multidimensional da dor.

A dor ativa os mecanismos compensatórios do sistema nervoso autônomo, o que resulta em respostas fisiológicas como taquicardia, vasoconstrição periférica, diaforese, dilatação da pupila e aumento da secreção de catecolaminas e hormônio adrecorticóide (Franck et al.[59] 2000). Portanto, parâmetros fisiológicos podem complementar o autorrelato da dor, embora não possam ser os únicos indicadores, pois não são específicos para a resposta à dor. Parâmetros fisiológicos como frequência cardíaca e pressão arterial sistólica tendem a aumentar a dor aguda (Mischkowski et al.[64] 2018) com alterações de 10% a 20% (Franck et al.[59] 2000). Há também um aumento na frequência respiratória como resposta à dor (Miranda et al.[65] 2011). Consequentemente, taxas respiratórias mais altas resultam em maior saturação de oxigênio. No entanto, nos presentes ECR's, essa relação não foi observada; além disso, não foram encontradas correlações entre esses parâmetros fisiológicos e a autopercepção da dor em ambas faixas etárias.

Identificamos que, apesar da pressão arterial não ter sido influenciada pelas diferentes técnicas, a pressão arterial sistólica diminuiu entre os diferentes momentos

do estudo, para as crianças de 5 a 8 anos e de 9 a 12 anos. Provavelmente isso se deve à posição da criança. Em T1, a criança estava sentada em uma cadeira comum; em T2 na cadeira odontológica, mas ainda em repouso, e em T3 a criança estava deitada, causando uma diminuição gradual da pressão arterial sistólica.

As diferentes técnicas anestésicas também não influenciaram a frequência cardíaca. Isso foi corroborado por outros estudos que avaliaram esse parâmetro em relação à anestesia convencional x computadorizada (Mittal et al.[10] 2015, Patini et al.[49] 2018) ou anestesia convencional x vibracional (Tung et al.[17] 2018). Diferentemente da pressão arterial, que diminuiu, a frequência cardíaca aumentou entre os momentos do estudo, provavelmente devido ao medo e à ansiedade gerados em cada situação.

Semelhante à frequência cardíaca, a frequência respiratória não mostrou diferença entre os diferentes tipos de técnicas anestésicas, mas, numericamente, aumentou ao longo das diferentes fases da pesquisa, enquanto a saturação de oxigênio permaneceu homogênea e não mostrou diferença durante o estudo para qualquer técnica. Não foram encontrados estudos que analisaram a frequência respiratória e a saturação de oxigênio.

Encontramos parâmetros fisiológicos semelhantes entre as anestesias, o que significa que nenhuma anestesia por si só causou tanta dor ou ansiedade que exigiu uma resposta fisiológica maior em comparação com as demais. Entendemos que, a constante desses parâmetros, demonstra que o sistema nervoso autônomo não interpretou os estímulos de nenhuma anestesia como uma ameaça potencial de maior dano do que as demais anestesias avaliadas.

Juntando todos os parâmetros citados anteriormente, podemos afirmar que o uso de diferentes técnicas anestésicas locais não contribuirá para minimizar ou eliminar a dor ou a ansiedade relacionada à anestesia dentária em crianças de 5 a 8 anos e de 9 a 12 anos de idade. Os resultados demonstraram que a dor relacionada à anestesia dentária é, de fato, gerada pelo próprio procedimento e estimulada pela ansiedade odontológica existente e pelo estado de ansiedade naquele momento específico. Evidências científicas revelam que a ansiedade dental está associada à percepção da dor (Maulina et al.[66] 2017, Shrivastava et al.[67] 2012, Heaton[68] 2017). A ansiedade dental se desenvolve na primeira infância (Klingberg e Broberg[69] 2007) a partir de experiências passadas de dor / ansiedade em consultas odontológicas que permanecem na memória do indivíduo (Kent[70] 1985). Razões cognitivas que influenciam a ansiedade dental incluem relacionamentos ruins entre criança e dentista

e experiências negativas; razões não-cognitivas incluem medo do aprendizado desconhecido e vicário (Carrillo-Diaz et al.[71] 2012). No presente estudo, observamos que quanto maior a ansiedade dental, maior a percepção da dor. Esse achado é corroborado por diferentes estudos da literatura (Costa et al.[72] 2012, Sanikop et al.[73] 2011, Caltabiano et al.[74] 2018).

Não obstante, o estado emocional dos pacientes é afetado pelo próprio procedimento anestésico, sem influência dos diferentes dispositivos utilizados, pois não encontramos diferença nos níveis de ansiedade entre as técnicas anestésicas para as crianças nas faixas etárias estudadas. O uso do VPTm em diferentes momentos (na sala de espera, na cadeira odontológica antes e depois da anestesia) mostrou que a ansiedade aumenta após a anestesia local, independente da técnica, para ambas faixas etárias.

A resposta comportamental de crianças após anestesia dentária costuma ser uma mistura de ansiedade e dor (Versloot et al.[52] 2005). Segundo os presentes ECR's, não está relacionada as técnicas anestésicas. As crianças avaliadas nestes estudos apresentaram baixas taxas de comportamento disruptivo. Pode ser porque, além de usar técnicas de anestesia mais lentas, também usamos boa comunicação com o paciente e os pais, e estratégias eficazes de gerenciamento comportamental. Portanto, em uma amostra com baixos níveis de ansiedade, seria de esperar poucas manifestações de comportamento disruptivo.

Para anestesia vibracional, a literatura mostra resultados conflitantes, com manifestações de comportamento disruptivo semelhantes (Elbay et al.[18] 2015) ou melhor (Dak-Albab et al.[63] 2016) para anestesia vibracional quando comparadas à técnica convencional. No entanto, existe uma diferença entre o tempo utilizado pelo dispositivo vibracional, o que reforça a hipótese de que o tempo da vibração pode influenciar não apenas a resposta à dor, mas também o comportamento. Para anestesia computadorizada, os estudos que avaliaram o comportamento são discrepantes, alguns corroboram com o presente estudo, níveis semelhantes de comportamento perturbador entre anestesia computadorizada e convencional (Asarch et al.[12] 1999, Al Amoudi et al.[29] 2008) e outros mostraram menos comportamento disruptivo para anestesia computadorizada (Feda et al.[4] 2010, Allen et al.[11] 2002), também levando em consideração que a anestesia convencional nos presentes ECR's foi mais lenta e ofereceu menos dor, consequentemente nossas crianças não demonstraram diferença no comportamento disruptivo.

Além disso, a experiência odontológica tem alto impacto na percepção das crianças. Consequentemente, em um desenho de boca dividida, o primeiro procedimento pode influenciar a percepção subsequente da dor após a anestesia em uma segunda consulta odontológica. Isso foi observado em um ensaio clínico com 120 pacientes (7 a 11 anos), comparando anestesia computadorizada e convencional, que encontrou diferença no comportamento disruptivo apenas no segundo procedimento anestésico (Thoppe-Dhamodhara et al.[50] 2015). Considerando isso, um desenho paralelo foi implementado nesta pesquisa.

Independentemente da técnica anestésica selecionada ou anestésico, uma abordagem adequada para o gerenciamento do paciente infantil é essencial. A experiência e o treinamento do dentista em anestesiar uma criança são muito importantes e pode modificar a percepção da dor durante o procedimento. O odontopediatra deve estabelecer um diálogo com a criança para que ela se sinta segura e confiante. É necessário reconhecer o perfil psicológico da criança e usar as técnicas de gerenciamento de comportamento mais apropriadas no tratamento odontológico, melhorando as habilidades de enfrentamento da criança (Radhakrishna e Srinivasan[75] 2019), uma vez que manipular a atenção ou a emoção pode afetar positivamente a experiência da dor (Mischkowski et al.[64] 2018). Da mesma forma, a anestesia deve ser realizada de acordo com o protocolo de cada técnica, negligenciar as recomendações pode contribuir para o medo e ansiedade dental.

Este estudo teve como objetivo analisar a maioria dos fatores que influenciam a interpretação / mensuração da dor em crianças (comportamento perturbador, ansiedade, parâmetros fisiológicos, bem como a autopercepção da dor) e como eles se relacionariam com as diferentes técnicas anestésicas. Para o conhecimento dos autores, este é o primeiro artigo que incluiu todos esses parâmetros em um único ensaio clínico e incentivamos pesquisas futuras semelhantes para esclarecer se nossos resultados podem ser aplicados a outros locais, técnicas anestésicas e faixas etárias.

De acordo com esta revisão sistemática, metanálise e ensaios clínicos randomizados, nós não consideramos que investir em um CCLAD, ou VBA com o objetivo de reduzir a dor e o comportamento disruptivo durante a anestesia, em crianças de 5 a 12 anos, é uma boa escolha, uma vez que as injeções convencionais realizadas corretamente, podem ter resultados semelhantes ou melhores.

Nós sugerimos fortemente que uma revisão sistemática e metanálise avaliando a anestesia vibracional em comparação a anestesia convencional deve ser realizada. Outrossim, novos ensaios clínicos randomizados devem ser realizados com metodologia bem definida, a fim de melhorar a qualidade da evidência, e elucidar as questões pendentes sobre o procedimento anestésico e o enfrentamento das crianças.

Por fim, é importante afirmar que o caminho para um procedimento anestésico menos doloroso e traumático em crianças estará sempre relacionado a fatores que superam os aspectos técnicos puramente. O estabelecimento de uma boa comunicação com o paciente e os pais e o uso de estratégias eficazes de manejo comportamental são medidas que podem reduzir a ansiedade dentária e facilitar os procedimentos anestésicos.

6 CONCLUSÃO

De acordo com a revisão sistemática e metanálise, não há diferença na percepção de dor e comportamento disruptivo em crianças submetidas a anestesia computadorizada ou anestesia convencional odontológica. Não obstante, a qualidade da evidência disponível é baixa e mais pesquisas são necessárias para corroborar esse achado.

De acordo com os ECR's, não há vantagens na inclusão de dispositivos anestésicos vibracionais ou computadorizados na prática odontológica pediátrica.

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APÊNDICES

APÊNDICE A

PROSPERO International prospective register of systematic reviews

Does computerized anesthesia reduce pain and anxiety during local anesthesia in pediatric patients undergoing dental treatment? A systematic review

Priscila de Camargo Smolarek, Letícia Wambier, Marcelo Carlos Bortoluzzi, Alessandra Reis, Ana Claudia Chibinski

Citation

Priscila de Camargo Smolarek, Letícia Wambier, Marcelo Carlos Bortoluzzi, Alessandra Reis, Ana Claudia Chibinski. Does computerized anesthesia reduce pain and anxiety during local anesthesia in pediatric patients undergoing dental treatment? A systematic review. PROSPERO 2016:CRD42016037184 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42016037184

Review question(s)

Does computerized local anesthesia generate less pain and anxiety in children compared to conventional techniques during local anesthesia for dental treatment?

Searches

To identify trials to be included for this review, we will search on the electronic databases MEDLINE via PubMeb, Scopus, Web of Science, Latin American and Caribbean Health Sciences Literature database (LILACS), Brazilian Library in Dentistry (BBO) and Cochrane Library. We will hand-search the reference lists of all primary studies for additional relevant publications and the related articles link of each primary study in the PubMed database without restrictions to publication date or languages.

No restrictions will be placed on the publication date or languages, and all relevant studies will be translated and reviewed. We will search the abstracts of the annual conference of the

International Association for Dental Research (IADR) and their regional divisions (1990–2014) and will get in touch with authors of relevant abstracts for further information. We will explore the grey literature using the database System for Information on Grey literature in Europe (SIGLE), and dissertations and theses using the ProQuest Dissertations and Theses Fulltext database, as well as the Periódicos Capes Theses database. To locate unpublished and ongoing trials related to the review question, we will search the following clinical trials registry: Current Controlled Trials (www.controlled-trials.com), International Clinical trials registry plataform http://apps.who.int/trialsearch/), the ClinicalTrials.gov (www.clinicaltrials.gov), Rebec (www.rebec.gov.br), and EU Clinical Trials Register https://www.clinicaltrialsregister.eu). The search strategy will be appropriately modified for each database and performed by two reviewers to idebtify eligible studies. Full text versions of the papers that appeared to meet the inclusion criteria will be retrieved for further assessment and data extraction.

Types of study to be included

We will include randomized clinical trials (RCTs) that compare computerized local anesthesia and traditional anesthesia techniques and their influence in pain and anxiety during dental treatment in children. The primary outcome is the pain intensity and anxiety during local anesthesia.

Non-controlled clinical trials, editorial letters, pilot studies, historical reviews, in vitro studies, cohort, observational and descriptive studies, such as case reports and case series will be excluded. Additionally, RCT studies will be excluded if the alternative anesthesia technique is the electronic anesthesia.

Condition or domain being studied

Dental anesthesia; pain intensity; anxiety

Participants/ population
Inclusion: children undergoing dental treatment

Exclusion: children using drugs that could affect pain perception and anxiety; patients cognitively impaired

Intervention(s), exposure(s)
Patients that will receive local anesthesia for dental procedures (restorative treatment, endodontic treatment, surgical treatment, dental extraction) using computerized local anesthesia.

Comparator(s)/ control
Patients that will receive local anesthesia for dental procedures (restorative treatment, endodontic treatment, surgical treatment, dental extraction) using conventional local anesthesia.

Context
Inclusion: We will include randomized clinical trials (RCTs) that compare computerized local anesthesia and traditional anesthesia techniques and their influence in pain and anxiety during dental treatment in children. The primary outcome is the pain intensity and anxiety during local anesthesia.

Exclusion: Non-controlled clinical trials, editorial letters, pilot studies, historical reviews, in vitro studies, cohort, observational and descriptive studies, such as case reports and case series will be excluded. Additionally, RCT studies will be excluded if the alternative anesthesia technique is the electronic anesthesia.

Outcome(s)
Primary outcomes
Pain intensity and anxiety during dental local anesthesia

Different types of pain and anxiety scales will be accepted to assess pain intensity and anxiety during local anesthesia

Secondary outcomes
None

Data extraction, (selection and coding)
Articles will be selected by title and abstracts according to the previously described search strategy. Articles that appear in more than one database will be considered only once. Full-text articles will also be obtained when the title and abstract have insufficient information to make a clear decision. Subsequently, two reviewers will classify those which met the inclusion criteria. To handle such a large number of studies, we will use a study ID for each eligible study, combining first author and year of publication. Any disagreement between the reviewers over the eligibility of particular studies will be resolved through discussion with a third reviewer.

Risk of bias (quality) assessment
Quality assessments of the selected trials will be evaluated by two independent reviewers, using the Cochrane Collaboration's tool for assessing risk of bias in randomized trials (Higgins et al.20 2011). The assessment criteria contain six items: sequence generation, allocation concealment, blinding of the outcome assessors, incomplete outcome data, selective outcome reporting, and other possible sources of bias. During data selection and quality assessment, any disagreements between the reviewers will be solved through discussion, and if needed, by consulting a third reviewer. The quality assessment will be pilot tested using a sample os study reports to ensure that the criteria will be consistent to the research quesion.

Strategy for data synthesis
The extracted data will be analyzed using Revman (Review Manager version 5.3 softwar, Cochrane Collaboration, Copenhagen, Denmark). Data from eligible studies will be either dichotomous or ordinal.

Analysis of subgroups or subsets
None planned.

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Anticipated or actual start date
31 March 2016

Anticipated completion date
31 March 2017

Funding sources/sponsors
None

Conflicts of interest
None known

Language
English

Country
Brazil

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Anesthesia, Local; Anesthesiology; Anxiety; Child; Humans; Pain

Stage of review
Ongoing

Date of registration in PROSPERO
01 April 2016

Date of publication of this revision
01 April 2016

Stage of review at time of this submission	Started	Completed

Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

PROSPERO

International prospective register of systematic reviews

The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

APÊNDICE B

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da dor e ansiedade em crianças submetidas a diferentes modalidades de injeção de anestésico local para tratamento odontológico: ensaio clínico randomizado

Pesquisador: Ana Cláudia Rodrigues Chibinski
Área Temática:
Versão: 1
CAAE: 64773417.3.0000.5689
Instituição Proponente: Universidade Estadual de Ponta Grossa
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.941.369

Apresentação do Projeto:
Medo e ansiedade dental estão frequentemente associados com o uso de agulhas e seringas para anestesia local, e a percepção dolorosa durante
a administração de anestésicos locais é frequentemente a principal razão de comportamentos de ansiedade e reações defensivas. O trauma
odontológico origina-se na infância, por experiências malconduzidas. O objetivo deste estudo é avaliar a dor e ansiedade relacionadas a 4 diferentes
modalidades de anestesia em crianças. Serão selecionados voluntários com idade entre 5 a 12 anos e que necessitem de tratamento odontológico
restaurador em dentes posteriores nos 2 quadrantes superiores. Todos os pacientes receberão 1 modalidade de anestesia: Anestesia convencional
(grupo controle), Anestesia computadorizada, anestesia DentalVibe e anestesia computadorizada + anestesia DentalVibe. Serão feitas avaliações
com critérios fisiológicos e comportamentais. Para a avaliação fisiológica serão medidos a pressão arterial, frequência respiratória, frequência
cardíaca, oximetria e cortisol salivar antes e durante cada anestesia. Como critérios para avaliação da ansiedade serão aplicados os métodos, Corah

e VPT modificado antes da anestesia e VPT modificado será repetido após a anestesia. A dor será avaliada ao término de cada anestesia com
Escala Visual Analógica (VAS) e Wong Baker Faces. Os resultados serão submetidos à análise estatística paramétrica e não paramétrica, de acordo
com os dados obtidos nos diferentes critérios de avaliação.

Objetivo da Pesquisa:
Objetivo Primário:
Avaliar a dor e ansiedade de crianças submetidas a diferentes modalidades anestésicas durante o tratamento odontológico.
Objetivo Secundário:
Realizar revisão sistemática da avaliação de dor e ansiedade à anestesia odontológica convencional e computadorizada.2- Determinar o nível de
dor e ansiedade causada pela técnica convencional de anestesia 3 - Determinar o nível de dor e ansiedade causada pela técnica anestésica
computadorizada 4– Determinar o nível de dor e ansiedade causada pela técnica anestésica convencional associada a anestesia com DentalVibe 6
- Determinar o nível de dor e ansiedade causada pela técnica anestésica computadorizada associada a anestesia com DentalVibe 7 – Determinar
a diferença, entre as modalidades anestésicas, na dor e ansiedade de crianças em tratamento odontológico.

Avaliação dos Riscos e Benefícios:
Riscos:
Todos os relacionados à anestesia local, principalmente:
- Hipersensibilidade ao anestésico local;
- O paciente traumatizar a região anestesiada;
- Toxicidade;
- Injeção em vaso sanguíneo.
Acidentes ocupacionais
Benefícios:
Se a hipótese for confirmada, será possível minimizar o trauma das crianças ao tratamento odontológico quando necessitam de anestesia local

Continuação do Parecer: 1.941.369

Comentários e Considerações sobre a Pesquisa:

Pesquisa de grande importância para a área a ser estudada.

Considerações sobre os Termos de apresentação obrigatória:

Os termos estão de acordo com a Resolução 466/2012

Recomendações:

Enviar relatório parcial e final

Conclusões ou Pendências e Lista de Inadequações:

Enviar relatório parcial e final

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_838890.pdf	22/01/2017 16:12:32		Aceito
Projeto Detalhado / Brochura Investigador	Protocolo_de_Pesquisa_doutorado_Priscila.doc	22/01/2017 16:11:12	Ana Cláudia Rodrigues Chibinski	Aceito
Folha de Rosto	folha_de_rosto.docx	22/01/2017 16:06:59	Ana Cláudia Rodrigues Chibinski	Aceito
Outros	ANEXO_6_FICHA_CLiNICA_2.docx	30/12/2016 14:16:19	Ana Cláudia Rodrigues Chibinski	Aceito
Outros	ANEXO_5_FICHA_CLiNICA_1.docx	30/12/2016 14:15:45	Ana Cláudia Rodrigues Chibinski	Aceito
Outros	ANEXO_4_VPT_modificado.docx	30/12/2016 14:15:04	Ana Cláudia Rodrigues Chibinski	Aceito
Outros	ANEXO_3_Questionario_Corah.docx	30/12/2016 14:14:20	Ana Cláudia Rodrigues Chibinski	Aceito
Outros	ANEXO_2_SCARED.docx	30/12/2016 14:13:42	Ana Cláudia Rodrigues Chibinski	Aceito
Outros	ANEXO_1_Autorizacao.docx	30/12/2016 14:13:02	Ana Cláudia Rodrigues Chibinski	Aceito
TCLE / Termos de Assentimento /	ANEXO_7_TCLE.docx	30/12/2016 14:06:27	Ana Cláudia Rodrigues	Aceito

Continuação do Parecer: 1.941.369

Justificativa de Ausência	ANEXO_7_TCLE.docx	30/12/2016 14:06:27	Chibinski	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PONTA GROSSA, 23 de Fevereiro de 2017

Assinado por:
Cristiane Ansbach Pereira Mendes
(Coordenador)

APÊNDICE C

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 15, 2019

ClinicalTrials.gov ID: NCT03176446

Study Identification

Unique Protocol ID: 64773417.3.0000.5689

Brief Title: Pain and Anxiety Evaluation in Children Using Different Techniques of Local Anesthesia for Dental Treatment

Official Title: Pain and Anxiety Evaluation in Children Using Different Techniques of Local Anesthesia for Dental Treatment

Secondary IDs:

Study Status

Record Verification: October 2019

Overall Status: Completed

Study Start: October 1, 2017 [Actual]

Primary Completion: November 30, 2018 [Actual]

Study Completion: March 1, 2019 [Actual]

Sponsor/Collaborators

Sponsor: Universidade Estadual de Ponta Grossa

Responsible Party: Principal Investigator
Investigator: Priscila de Camargo Smolarek [psmolarek]
Official Title: PhD student
Affiliation: Universidade Estadual de Ponta Grossa

Collaborators:

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

Unapproved/Uncleared Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved
Approval Number: 64773417.3.0000.5689
Board Name: 5689- Faculdades Ponta Grossa
Board Affiliation: Faculdades Ponta Grossa
Phone: 554230258555
Email: cep@faculdadespontagrossa.com.br
Address:

Rua Tomazina, 710. Ponta Grossa, Paraná - Brasil

Data Monitoring:

Study Description

Brief Summary: Fear and dental anxiety are often associated with the use of needles and syringes for local anesthesia, and painful perception during the administration of local anesthetics is often the main reason for anxiety behaviors and defensive reactions. Dental trauma originates in childhood, through experience misconduct. The objective of this study is to evaluate the pain and anxiety related to 4 different modalities of anesthesia in children. Will be selected volunteers aged between 5 and 12 years who need restorative dental treatment in posterior teeth in the upper 2 quadrants. All patients will receive 1 modality of anesthesia: conventional anesthesia (control group), computerized anesthesia, Dental Vibe anesthesia and computerized anesthesia + DentalVibe anesthesia. Evaluations will be made with physiological and behavioral criteria. For the physiological evaluation will be measured the blood pressure, respiratory rate, heart rate, oximetry and salivary cortisol before and during each anesthesia. As criteria for evaluation of anxiety will be applied the methods, Corah and modified VPT before anesthesia and modified VPT will be repeated after anesthesia. The pain will be assessed at the end of each anesthesia with Visual Analogue Scale (VAS) and Wong Baker Faces. The results will be submitted to parametric and non-parametric statistical analysis, according to the data obtained in the different evaluation criteria.

Detailed Description:

Conditions

Conditions: Pediatric Dentistry
Local Anesthesia
Pain Management

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Device Feasibility

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: Single (Investigator)

Allocation: Randomized

Enrollment: 210 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Control Group The children anesthesia will be traditional technique	Device: Local anesthesia with traditional technique

Arms	Assigned Interventions
	Puncture with short needle in the region of the apical third of the tooth to be anesthetized Injection of local anesthetic, with speed 1ml / min Other Names: • Traditional anesthesia • Conventional anesthesia Drug: Topic anesthesia Application of topical anesthetic for 60 seconds with benzocaine Other Names: • Topical anesthesia Drug: Local anesthetic 2% lidocaine with epinephrine 1: 100000 1.8 mL Other Names: • Anesthetic
Active Comparator: Computerized Group The children anesthesia will be computerized technique	Device: Local anesthesia with computerized technique Puncture with short needle in the region of the apical third of the tooth to be anesthetized according to the recommendations of the manufacturer Injection of local anesthetic with computerized anesthesia equipment, with speed 0.5 ml / min Other Names: • Computerized anesthesia Drug: Topic anesthesia Application of topical anesthetic for 60 seconds with benzocaine Other Names: • Topical anesthesia Drug: Local anesthetic 2% lidocaine with epinephrine 1: 100000 1.8 mL Other Names: • Anesthetic
Active Comparator: DentalVibe Group The children anesthesia will be DentalVibe technique	Device: Local anesthesia with DentalVibe technique Use of DentalVibe in the apical region of the tooth to be anesthetized according to the manufacturer's guidelines Puncture with short needle enters the tips of the DentalVibe Injection of local anesthetic with traditional carpule, with speed 1 ml / min Other Names: • DentalVibe anesthesia Drug: Topic anesthesia Application of topical anesthetic for 60 seconds with benzocaine Other Names: • Topical anesthesia Drug: Local anesthetic 2% lidocaine with epinephrine 1: 100000 1.8 mL Other Names: • Anesthetic

Outcome Measures

Primary Outcome Measure:

1. Self-perception of pain
   The pain will be analyzed by the Wong Baker Faces scales, and VAS scale.

   [Time Frame: Immediately after anesthesia]
2. Pain Behavior
   The pain will be analyzed by the FLACC

   [Time Frame: During the anesthetic procedure]

Secondary Outcome Measure:

3. SCARED Questionnaire
   Children will be evaluated for the anxiety behavior prior to any anesthesia by answering the SCARED questionnaire

   [Time Frame: Before anesthesia]
4. Corah Questionnaire
   Children will be evaluated for the dentistry anxiety prior to any anesthesia

   [Time Frame: Before anethesia]
5. VPT modified
   Children will be evaluated for the anxiety after to any anesthesia

   [Time Frame: Before anethesia and immediately after anesthesia]
6. Blood pressure
   The physiological response of anxiety to local dental anesthesia will be evaluated by parameters of blood pressure

   [Time Frame: Immediately before anesthesia, during anesthesia]
7. Respiratory rate
   The physiological response of anxiety to local dental anesthesia will be evaluated by parameters of respiratory rate

   [Time Frame: Immediately before anesthesia, during anesthesia]
8. Heart rate
   The physiological response of anxiety to local dental anesthesia will be evaluated by parameters of heart rate

   [Time Frame: Immediately before anesthesia, during anesthesia]
9. Oxygen saturation
   The physiological response of anxiety to local dental anesthesia will be evaluated by parameters of oxygen saturation

   [Time Frame: Immediately before anesthesia, during anesthesia]
10. Salivary cortisol
    The physiological response of anxiety to local dental anesthesia will be evaluated by parameters of salivary cortisol

    [Time Frame: Immediately before anesthesia, during anesthesia]

Eligibility

Minimum Age:	5 Years
Maximum Age:	12 Years
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- Children of both sexes, aged between 5 and 12 years, requiring dental treatment under local anesthesia in the first permanent molars or deciduous maxilla.

Exclusion Criteria:

- The person responsible does not authorize the participation of the child as a research volunteer.
- Be using pain modulating drugs.
- Be using anxiety modulating drugs.
- Patients with a history of hypersensitivity to local anesthetics.
- Patients with a history of systemic diseases.

Contacts/Locations

Central Contact Person: Priscila C Smolarek, Ms
Telephone: 42999290452 Ext. 55
Email: pcsmolarek@gmail.com

Central Contact Backup:

Study Officials:

Locations: **Brazil**
Ponta Grossa State University
Ponta Grossa, Paraná, Brazil, 84030900
Contact: Priscila C Smolarek, Master 42999290452 Ext. 55
pcsmolarek@gmail.com

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: Type: Other [Approval of the ethics committee]
URL: http://plataformabrasil.saude.gov.br
Identifier: 1.941.369