Universitat Autònoma de Barcelona

CALIDAD DE VIDA RELACIONADA CON LA SALUD ORAL EN NIÑOS Y ADOLESCENTES

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DOCTORADO EN METODOLOGÍA DE LA INVESTIGACIÓN BIOMÉDICA Y SALUD PÚBLICA.

Departamento de Pediatría, Obstetricia y Ginecología y de Medicina Preventiva

TESIS DOCTORAL

CALIDAD DE VIDA RELACIONADA CON LA SALUD ORAL EN NIÑOS Y ADOLESCENTES

Doctorando: Carlos Zaror Sánchez

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Barcelona, Junio 2019

CERTIFICADO DE SUPERVISIÓN DE TESIS

Montserrat Ferrer Forés, PhD, MD, investigadora del Grupo de Investigación en Servicios Sanitaios del IMIM (Instituto de Investigación Médica del Hospital del Mar) y profesora del Departamento de Pediatría, Obstetricia y Ginecología y Medicina Preventiva de la Escuela de Medicina de la Universidad Autónoma de Barcelona, España, y

María José Martínez Zapata, PhD, MD, investigadora del Centro Cochrane Iberoamericana, Barcelona, España.

CERTIFICAN:

Que Carlos Elías Zaror Sánchez ha realizado bajo su supervisión la tesis titulada "Calidad de vida relacionada con la salud oral en niños y adolescentes", la cual reúne las condiciones necesarias para su presentación como tesis doctoral.

Montserrat Ferrer, PhD, MD
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RESUMEN

Las enfermedades orales son altamente prevalentes a nivel mundial a pesar de la mejora en los índices de salud oral en las últimas décadas del siglo XX. Es bien sabido que sus consecuencias en los niños son graves y pueden afectar la calidad de vida relacionada con la salud oral.

El objetivo general de esta tesis doctoral fue estimar el impacto de las patologías orales más prevalentes y de sus tratamientos en la calidad de vida relacionada con la salud oral de la población pediátrica.

Se realizaron cuatro trabajos de investigación, tres de ellos fueron revisiones sistemáticas cuyos objetivos específicos fueron: 1) Obtener una evaluación sistemática y estandarizada de la evidencia actual sobre el proceso de desarrollo, las propiedades métricas y los problemas de administración de los instrumentos de calidad de vida relacionada con la salud oral disponibles para niños y adolescentes; 2) Evaluar el impacto de los traumatismos dentoalveolares en la calidad de vida relacionada con la salud oral de preescolares y escolares; y 3) Evaluar los efectos del tratamiento restaurador atraumático en comparación con el tratamiento convencional para el tratamiento de las lesiones de caries dentales en dientes primarios y permanentes de niños y adultos. Finalmente se realizó la adaptación transcultural de la Early Childhood Oral Health Impact Scale (ECOHIS) para obtener la versión en español para Chile, y un estudio transversal para evaluar su aceptabilidad, fiabilidad y validez en población preescolar.

La revisión sistemática sobre los instrumentos de calidad de vida relacionada con la salud oral, identificó 18 instrumentos, siendo la edad un factor clave al momento de elegir entre los instrumentos genéricos de calidad de vida relacionada con la salud oral: el ECOHIS

fue el más recomendable para preescolares, el Child Perceptions Questionnaire el más recomendable para escolares y el Child Oral Impact on Daily Performance para adolescentes. Entre los instrumentos genéricos desarrollados para cualquier edad, la Family Impact Scale (FIS) fue el mejor evaluado.

La síntesis de la evidencia disponible mostró que los niños que presentan traumatismos dentoalveolares tienen una probabilidad significativamente mayor de afectación de la calidad de vida relacionada con la salud oral en comparación con los controles tanto en edad preescolar como escolar. Sin embargo, se requieren estudios de cohortes prospectivos para confirmar estos resultados y describir su evolución temporal.

Los estudios de niños con caries en su dentición primaria que son tratados con el método restaurador atraumático usando cemento de ionómero de vidrio de alta viscosidad mostraron mayor riesgo de fracaso que los que reciben un tratamiento convencional con el mismo material. En futuros ensayos clínicos se debería aportar datos sobre resultados reportados por los pacientes como dolor, incomodidad o calidad de vida relacionada con la salud oral a través de cuestionarios validados, dado que hasta el presente no se dispone de suficiente información.

La versión Chilena de la ECOHIS mostró resultados de fiabilidad y validez similares a los de la versión original desarrollada en Estados Unidos. Estos resultados sugieren que la versión Chilena es equivalente a la original, y puede ser utilizada para medir la calidad de vida relacionada con la salud oral de los preescolares en Chile, tanto en la práctica clínica como para la investigación.

ABSTRACT

Despite a significant improvement in oral health rates during the last decades of the twentieth century, oral diseases continue to be highly prevalent worldwide. It is an undeniable fact that its consequences in children are serious, and can affect their oral health-related quality of life. The general objective of this doctoral thesis was to estimate the impact of the most prevalent oral diseases and their treatments, regarding to the oral health-related quality of life in the pediatric population.

Four research studies were carried out, three of which were systematic reviews with the following specific objectives: 1) To obtain a systematic and standardized evaluation of the current evidence on development process, metric properties, and administration issues of oral health-related quality of life instruments available for children and adolescents; 2) To assess the impact of traumatic dental injuries on the oral health-related quality of life of preschoolers and schoolchildren; and 3) To assess the effects of atraumatic restorative treatment compared with conventional treatment for managing dental caries lesions in the primary and permanent teeth of children and adults. Finally, the cross-cultural adaptation of the Early Childhood Oral Health Impact Scale (ECOHIS) was performed to obtain the Spanish version for Chile, and a cross-sectional study was carried out to evaluate its acceptability, reliability and validity in the preschool population.

The systematic review on oral health-related quality of life instruments identified 18 instruments, with age considered as a key factor when choosing among the generic oral health-related quality of life instruments: ECOHIS was the most recommended for preschool children, the Child Perceptions Questionnaire the most recommended for schoolchildren and

the Child Oral Impact on Daily Performance, for adolescents. Among the generic instruments developed for any age, the Family Impact Scale (FIS) was the best rated.

Synthesis of the available evidence showed that children who present traumatic dental injuries have a significantly higher chance of reporting any impact on oral health-related quality of life, compared to controls in pre-school age and schoolchildren. However, prospective cohort studies are required to confirm these results and describe their evolution along time.

Studies on children with caries in their primary dentition who are treated with the atraumatic restorative method, using high viscosity glass ionomer cement, showed a higher risk of failure than those who received conventional treatment with the same material. Future clinical trials should provide detailed data on patient-reported outcomes, such as pain, discomfort or oral health-related quality of life through validated questionnaires, since to date there is not enough information available.

The Chilean version of ECOHIS showed similar reliability and validity results to the original version developed in the United States. These results suggest that the Chilean version is equivalent to the original version, and can be used to measure the oral health-related quality of life of preschool children in Chile, in clinical practice as well as in research.

AGRADECIMIENTOS

Quiero comenzar agradeciendo de manera muy especial a las directoras de mi tesis, Montse Ferrer y María José Martínez. Me siento afortunado de haber enfrentado este desafío académico bajo su valiosa supervisión. No sólo conocí a dos importantes docentes e investigadoras, sino también a dos excelentes personas. No sólo me entregaron las competencias técnicas para poder llevar este proceso de manera óptima, sino también me enseñaron la importancia del trabajo en equipo. Creo sin duda que sin su apoyo constante, preocupación y dedicación no hubiese podido finalizar este proceso de manera exitosa.

Al Centro Cochrane Iberoamericano y al Instituto Hospital del Mar de Investigaciones Médicas quienes me hicieron sentir confortable y parte de su equipo en cada una de mis estadías en Barcelona. Me dieron además la oportunidad de participar de proyectos de investigación que sin duda fueron una parte importante de mi aprendizaje.

Al Dr. Xavier Bonfill, Director de Doctorado en Metodología Investigación Biomédica y Salud Pública, quien siempre estuvo preocupado de facilitar mi trabajo en el Doctorado. Sin duda una de las grandes persona que conocí durante este proceso.

A la Universidad de La Frontera, su Facultad de Odontología y al Centro de Excelencia CIGES por permitir que me desarrolle en al ámbito académico y darme los espacios para potenciar las competencia adquiridas durante estos años de Doctorado.

Al Servicio de Salud del Reloncaví y en especial al Hospital de Calbuco donde ejerzo profesionalmente como Odontopediatra, por confiar en mi y darme la posibilidad de ausentarme del establecimiento para realizar mis pasantías del Doctorado.

No puedo terminar sin agradecer a mis padres Carlos y Corina quienes siempre me han apoyado en mi desarrollo profesional y por entregarme los valores que me han guiado durante mi vida.

A mi hermana Loreto por su apoyo y estimulo constante durante toda nuestra vida.

A Daniela por su compañía, apoyo incondicional y paciencia…. Gracias por asumir las responsabilidades familiares durante mis ausencias.

A Renata quién nació cuando inicié este proceso, alegró mi vida y me dio la inspiración para afrontar este desafío.

TABLA DE CONTENIDOS

PRESENTACIÓN

La presente tesis doctoral titulada "CALIDAD DE VIDA RELACIONADA CON LA SALUD ORAL EN NIÑOS Y ADOLESCENTES" fue desarrollada por medio de compendio de publicaciones.

En las primeras páginas se pone en contexto la importancia de la salud oral, las patologías orales que afectan más frecuentemente a niños y adolescentes y la importancia de medir no sólo los indicadores clínicos sino también las percepciones de los mismos pacientes sobre su estado de salud oral.

Se define además, calidad de vida relacionada con la salud oral, su importancia tanto para la clínica e investigación y cuales son las brechas en el conocimiento que justifican los trabajos presentados en esta tesis doctoral.

Finalmente la tesis quedó constituida por las siguientes 4 publicaciones que abordan tanto aspectos metodológicos como clínicos del problema de estudio:

Artículo 1: Zaror C, Pardo Y, Espinoza-Espinoza G, Pont A, Muñoz-Millán P, Martínez-Zapata MJ, Vilagut G, Forero C, Garin O, Alonso J, Ferrer F. Assessing oral health-related quality of life in children and adolescents: A systematic review and standardized comparison of available instruments. Clin Oral Invest 2019;23(1):65-79. (IF: 2.386; Q1)

Artículo 2: Zaror C, Martínez-Zapata MJ, Abarca J, Díaz J, Pardo Y, Pont À, Ferrer M. Impact of Traumatic Dental Injuries on Quality of Life in Preschoolers and Schoolchildren: A Systematic Review and Meta-Analysis. Community Dent Oral Epidemiol 2018;46(1):88-101. (IF:2.302; Q1)

Artículo 3: Dorri M, Martinez-Zapata MJ, Walsh T, Marinho VCC, Sheiham A, Zaror C. Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries. Cochrane Database Syst Rev 2017;12:CD008072. (IF:6.264; Q1)

Artículo 4: Zaror C, Atala-Acevedo C, Espinoza-Espinoza G, Muñoz-Millán P, Muñoz S, Martínez-Zapata MJ, Ferrer F. Cross-cultural adaptation and psychometric evaluation of the early childhood oral health impact scale (ECOHIS) in Chilean population. Health Qual Life Outcomes 2018;16(1):232. (IF:2.278; Q2)

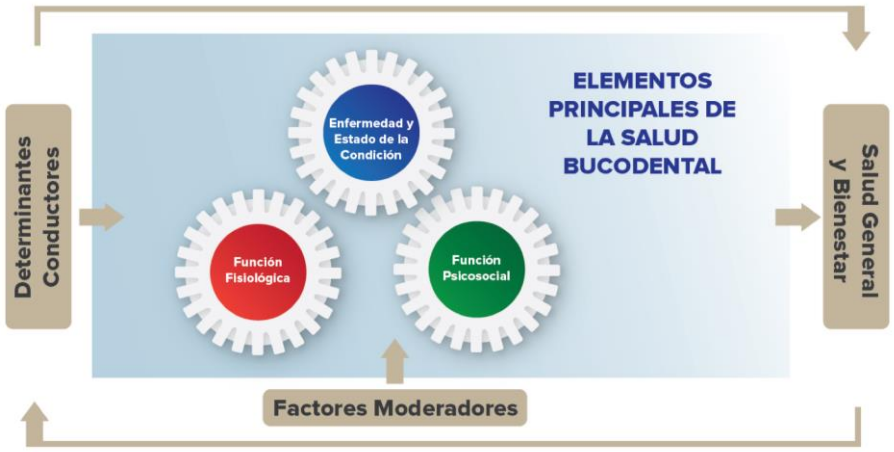
INTRODUCCIÓN

SALUD ORAL

La Organización Mundial de la Salud (OMS) reconoce la salud oral como un factor esencial para la salud general y la calidad de vida y la define como "la ausencia de dolor bucal o facial, de cáncer oral o de garganta, de infecciones o úlceras, de enfermedades periodontales, caries, pérdida dentaria así como de cualquier otra enfermedad o alteración que limite la capacidad del individuo de morder, masticar, reír, hablar o que comprometa el bienestar psicosocial" (1).

En septiembre del 2016, la Asamblea General de la Federación Dental Mundial aprobó una nueva definición de salud oral: "concepto multifacético que incluye la capacidad de hablar, sonreír, oler, saborear, tocar, masticar, tragar y transmitir una variedad de emociones a través de las expresiones faciales con confianza y sin dolor, incomodidad y enfermedad del complejo craneofacial" (2). Reconociendo así su naturaleza multifactorial que refleja los atributos esenciales para una adecuada calidad de vida (fisiológicos, sociales y psicológicos). Además la destaca como un componente fundamental de la salud y el bienestar físico y mental, el cual es influenciado por las experiencias, percepciones, expectativas y capacidad de adaptación de las personas a las circunstancias.

La figura 1 muestra la estructura de la definición de salud oral de la FDI.



A pesar de estas definiciones, los métodos tradicionales para medir la salud oral se basan en estándares clínicos que no consideran sus aspectos psicosociales y funcionales, y que muestran una relación pobre con las percepciones individuales sobre la calidad de vida relacionada con la salud (3).

Los procesos de enfermedad están influenciados por factores culturales y económicos que afectan los resultados de la atención de la salud oral (4). La evidencia muestra una asociación débil entre indicadores clínicos de la enfermedad oral (como la presencia de caries dental o pérdida de inserción periodontal) y las opiniones de los pacientes sobre su estado oral (5). Por lo tanto, la medición de la percepción del paciente junto con indicadores clínicos puede proporcionar una evaluación más completa de la salud oral del paciente (6).

EPIDEMIOLOGÍA DE LAS PATOLOGÍA ORALES

Las enfermedades que afectan la cavidad oral son altamente prevalentes a pesar de la indiscutible mejora de las últimas décadas (7-9). Estudios epidemiológicos indican que la prevalencia de caries dental, anomalías dento-maxilares y enfermedad periodontal puede llegar al 90% en la población infantil, y cercanas al 40% en el caso de los traumatismo dento-alveolares (7, 9-12).

A continuación se describen las características de las patologías orales más prevalentes en niños y adolescentes.

CARIES

La caries dental es una enfermedad crónica no transmisible mediada por bacterias, en la cual un desequilibrio ecológico entre los minerales de los dientes y los fluidos del biofilm resultan en una pérdida de minerales del diente y la consecuente lesión de caries (13). Este desequilibrio ecológico es producido por una dieta rica en azúcares o carbohidratos. El ácido producido por la fermentación de azúcares de la dieta causa descenso del pH y un cambio en el ecosistema bacteriano con un mayor predominio de bacterias patógenas. Esto lleva a un desequilibrio iónico que se traduce en una pérdida de minerales, iones calcio y fosfato, de las zonas superficiales y subsuperficiales del diente con la consecuente desmineralización del esmalte dentario. Si ese proceso continua, la pérdida de los componentes minerales del diente, pueden guiar a la pérdida de estructura y la consecuente cavitación (14). Esta cavitación es importante desde el punto de vista clínico, ya que marca el momento en que la desmineralización es irreversible (15).

La caries dental es la enfermedad crónica más prevalente, tanto a nivel oral como sistémico, afectando a una proporción importante de la población mundial (16). En la dentición permanente es la condición más prevalente evaluada en el estudio de carga de morbilidad mundial del año 2010 (16), afectando al 35% de la población mundial (2.4 billones de personas). En dentición primaria es la 10ª condición más prevalente afectando a un 9% de la población, es decir, a 621 millones de niños a nivel mundial (17). Es más prevalente en la población de nivel socioeconómico bajo y medio (18, 19).

Las consecuencias de la caries dental en los niños son graves y producen una serie de alteraciones como dolor, dificultades funcionales, desordenes de salud general, problemas psicológicos, hospitalizaciones y atenciones de urgencia (20-22). Las lesiones de caries pueden tener efectos a largo plazo, aumentando el riesgo de problemas dentales tanto en la dentición primaria como en la dentición permanente (23). La alteración de la salud oral interfiere en el desarrollo físico y social del niño (24, 25) lo que conlleva finalmente a una menor calidad de vida (26, 27).

Algunos autores afirman que la alimentación y sueño son las funciones más afectadas y estiman que 60 millones de horas escolares se pierden cada año debido al dolor dental (26, 28). Además del efecto en los niños, la caries dental no tratada también puede ejercer una influencia negativa en la dinámica familiar debido a la interrupción de las actividades diarias de los cuidadores, la ausencia en el trabajo y el gasto de tiempo y dinero en atención dental (29, 30).

ENFERMEDAD PERIODONTAL

La enfermedad periodontal es un grupo de afecciones inflamatorias crónicas que afectan los tejidos de soporte del diente, como la encía (el tejido blando que rodea los dientes), el hueso alveolar y/o el ligamento periodontal (las fibras de colágeno del tejido conectivo que anclan un diente al hueso alveolar) (31). Su prevalencia varía de una población a otra con estimaciones que van desde un 25% a un 100% (9, 32, 33).

La enfermedad periodontal comienza con la gingivitis, inflamación localizada de la encía que es iniciada por bacterias del biofilm dental (biopelícula microbiana que se forma en los dientes y la encía) (31).

La gingivitis más prevalente en niños y adolescentes es la inducida por una placa bacteriana (biofilm) (9, 34). Si bien este tipo de gingivitis se caracteriza por ser causada por una infección bacteriana no específica, en niños se ha encontrado un aumento en los niveles de Actinomyces sp, Capnocytophaga sp, Leptotrichia sp. y Selenomonas sp. al compararlo con la gingivitis en adultos (34, 35). La gingivitis alcanza su máxima prevalencia en la pubertad (36, 37). Este incremento con la edad, es atribuido al aumento de los sitios de riesgo, la acumulación de placa asociada con la erupción y exfoliación dental y a la influencia de los factores hormonales durante la pubertad. Otros factores que pueden afectar la ocurrencia y gravedad de gingivitis en niños son respuesta inmunológica de las células inflamatorias, cambios en la composición bacteriana del biofilm, diferencias morfológicas en la dentición primaria, presencia de apiñamiento, factores demográficos, socioeconómicos y estrés (37-39).

Durante la adolescencia existe una disminución en la prevalencia de la patología asociada a un aumento en la conciencia social y mejor higiene oral (9).

Si la gingivitis no es tratada, ésta progresa destruyendo la encía, el hueso alveolar y el ligamento periodontal, forman "sacos" periodontales profundos que pueden conducir a la pérdida de los dientes (31).

La enfermedad periodontal es una enfermedad silenciosa, a menudo subclínica, pero puede afectar negativamente la alimentación, la estética y el habla en particular. La pérdida de función debido a la pérdida de dientes afecta la masticación y, por lo tanto, la digestión y puede afectar en gran medida la nutrición y la dieta (31). La halitosis producida a consecuencia de la necrosis, puede generar problemas de interacción social. Además, la enfermedad periodontal puede contribuir a la carga inflamatoria general del cuerpo, empeorando condiciones como la diabetes mellitus y la aterosclerosis (31).

MALOCLUSIONES

Las maloclusiones son un grupo de patologías caracterizadas, tanto por una alteración del crecimiento y desarrollo de los maxilares como por alteraciones a nivel dentario que repercuten en la forma, función y estética del sistema estomatognático (40). Se consideran variaciones significativas de la fluctuación normal del crecimiento y de la morfología, que en la mayoría de los casos, resultan de una discrepancia entre el tamaño de los dientes y de los huesos, o de una desarmonía en el desarrollo de las bases óseas maxilares (41).

Las maloclusiones pueden expresarse en los planos del espacio, por ejemplo, el “overjet” o resalte incisal indica una desviación anteroposterior en la oclusión, mientras que la mordida profunda y la mordida abierta muestran desviaciones verticales, y la mordida cruzada posterior o la mordida en tijera sugieren desviaciones transversales de las relaciones oclusales normales (42).

La etiología de la malaoclusión es multifactorial y confluyen tanto factores generales (genética, los defectos congénitos o del desarrollo, hábitos orales disfuncionales y las deficiencias nutricionales) como factores locales (anomalías en el número y tamaño dentario, pérdida prematura de piezas dentarias, retención prolongada de dientes temporales, caries dental, entre otros) (43).

La OMS posiciona a las maloclusiones en tercer lugar de prevalencia en las patologías orales, después de la caries dental y la enfermedad periodontal. La prevalencia es superior al 60% en niños en edad preescolar y entre el 43 y el 78% en escolares (44). Las maloclusiones más comunes son la mordida abierta anterior, la sobremordida excesiva, las maloclusiones de Clase II y la mordida cruzada posterior (11).

Debido a sus consecuencias tanto estéticas como funcionales, las maloclusiones generan un impacto psicológico en la calidad de vida de quienes las padecen (45). Dentro de las alteraciones en las actividades de la vida diaria que sufren los jóvenes a causa de las maloclusiones se encuentran la forma en que ríen o sonríen, aislarse de grupos sociales, evitar aparecer en fotografías, sufrir de hostigamiento y burlas, sentimientos de inseguridad que les impiden hacer amigos, e incluso dificultad para morder algunos alimentos, y estar más propensos a sufrir traumatismos dentoalveolares (46, 47).

TRAUMATISMOS DENTALES

El Trauma Dentoalveolar corresponde a una lesión que afecta al diente propiamente, y/o a las estructuras de soporte que lo rodean (hueso alveolar, ligamento peridontal y encía) como consecuencia de un impacto violento (48). La presentación clínica de estas lesiones depende de la cantidad de energía del impacto, la forma y dirección del objeto que causa el trauma y de la resiliencia de las diversas estructuras orales (48).

Los traumas de la región oral constituyen hasta el 5% de las lesiones corporales, de los cuales el 92% corresponden a lesiones de los dientes (49). Una reciente revisión sistemática estima que cerca de un billón de personas han sufrido traumatismos dentoalveolares en todo el mundo (50).

La prevalencia de traumatismos dentoalveolares varía entre 6% y 59% en estudios con individuos de todas las edades (51), siendo más prevalente en dentición permanente (58,6%) (52) que en dentición primaria (36,8%) (53). Estudios previos muestran que el 92% de las lesiones dentales traumáticas ocurren antes de los 34 años (51). Generalmente los varones sufren lesiones dentales traumáticas al menos dos veces más que las mujeres, lo que se puede atribuir a una mayor participación de niños, adolescentes y adultos jóvenes en deportes de contacto, peleas y accidentes automovilísticos (54).

Dentro de las principales causas de traumatismos dentoalveolares se encuentran las caídas con una frecuencia entre un 31.7% y un 64.2%, seguidas por actividades deportivas (hasta 40.2%), accidentes de bicicleta (hasta 19.5%), accidentes de tráfico (hasta 7.8%) y la violencia física (hasta 6.6%) (54).

Los factores de riesgo de traumatismos más consistentes en la literatura son el resalte aumentado, una relación esqueletal de clase II con protrusión incisiva y la incompetencia labial (55), cuya asociación ha sido confirmada por revisiones sistemáticas (56, 57). La

incompetencia labial presentó un aumento de riesgo de un 81% de sufrir un trauma dentoalveolar en relación a los que no lo tienen (OR: 1.81; 95%IC 1.50–2.17) (56). El resalte de 3-4 mm en dientes primarios presentó un OR de 2.72 (95% IC 1.10-6.74), muy similar al reportado en dientes permanentes (OR 2.39;95% IC 1.62-3.51) y el resalte mayor a 6 mm. presentó un OR de 2.61 (95% IC 1.78-3.83) (57). Además, Correa-Feira y Petti el 2015 observaron un mayor riesgo de sufrir traumatismos en niños obesos (1.30; 95% CI 1.11–1.53), y desarrollaron la hipótesis de que la menor destreza y agilidad de los comportamientos actuarían como factores predisponentes del trauma (58).

La evidencia sobre la relación del trauma dentoalveolar con el nivel socioeconómico es contradictoria, en una reciente revisión sistemática no se encontró asociación significativa con ningún de los indicadores: alto vs bajo nivel socioeconómico (OR 0,77, 95% IC 0,43-1,36), dueño o arrendatario de vivienda (OR 1.28; 95% IC 0.98-1.66), educación de la madre (OR 0.89;95%IC 0.74-1.08), o educación del padre (OR 1.01; 95%IC 0,62-2,74) (59).

Las consecuencias de los traumatismos dentoalveolares incluyen alteraciones estéticas, funcionales (fonación, masticación, etc.), socio-psicológicas (autoestima, relaciones interpersonales), tratamientos complejos y costosos (60). El costo anual del tratamiento de las lesiones dentales, independientemente de la edad, puede oscilar entre los 2 y 5 millones de dólares anuales por cada millón de habitantes (61).

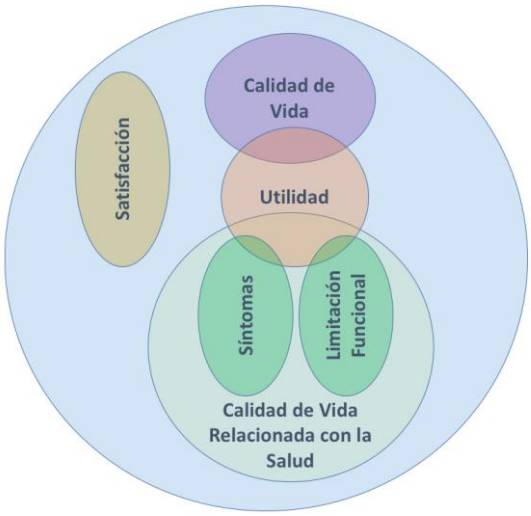
RESULTADOS PERCIBIDOS POR LOS PACIENTES

La Food and Drug Administration (FDA) definió los resultados percibidos o reportados por los pacientes (PRO de las siglas en ingles de 'Patient Reported Outcomes') como "una medida de cualquier aspecto del estado de salud del paciente que proviene directamente del él, sin la interpretación de sus respuestas por parte de un clínico u otra persona" (62).

Esta definición, enfatiza la importancia de la propia perspectiva del individuo al hacer la evaluación (63). La importancia de evaluar la propia percepción del paciente radica en la relevancia de la experiencia, que evita sesgos relacionados con la administración por parte del clínico (64). Los pacientes tienen la capacidad de informar con exactitud sobre muchos dominios que son importantes para la evaluación de una intervención, o del impacto de la enfermedad.

Los PRO son instrumentos que miden los síntomas, el estado funcional, el estado de salud, la calidad de vida relacionada con la salud y con la salud oral, el bienestar o la satisfacción respecto al cuidado o tratamiento recibido, desde la perspectiva del paciente (6). Por lo tanto, incluyen tanto medidas de dimensión única (por ejemplo la satisfacción del paciente) como multidimensionales (por ejemplo calidad de vida relacionada con la salud oral) (Figura 2) (63, 65).

Figura 2: Esquema sobre los diferentes tipos de PRO. Traducido de Mackenna, SP. (66).



Existen varios tipos de instrumentos que se diferencian principalmente por su carácter genérico o especifico y su orientación psicométrica o econométrica (6).

Instrumentos genéricos

Permiten evaluar y comparar tanto a pacientes con una amplia variedad de enfermedades, como a individuos de la población general, mayoritariamente sana, lo que permite comparar la carga de diferentes enfermedades. Sin embargo, pueden no detectar adecuadamente los cambios clínicos en poblaciones específicas.

Instrumentos específicos

Estos instrumentos son diseñados para poblaciones específicas, habitualmente pacientes con una enfermedad concreta y pretenden medir de manera más detallada el impacto de una determinada enfermedad sobre la salud percibida por el paciente.

Perfiles de salud (psicométricas)

Estas medidas pueden ser genéricas o específicas y generalmente tienen como objetivo evaluar múltiples aspectos de la percepción del paciente sobre su estado de salud (perfil multidimensional).

Medidas de utilidad (econométricas)

Se desarrollaron desde el ámbito de la economía y desde la teoría de la decisión. Este tipo de instrumentos proporcionan una estimación de las preferencias sociales (utilidad) para diversos estados de salud (índice sumario). Este tipo de instrumentos son esenciales para realizar evaluaciones económicas mediante análisis de costo-utilidad. En estas evaluaciones económicas todos los beneficios se miden en una unidad común tanto la calidad de vida como la cantidad o largo de vida obtenida como consecuencia de una intervención (67).

CALIDAD DE VIDA RELACIONADA CON LA SALUD ORAL

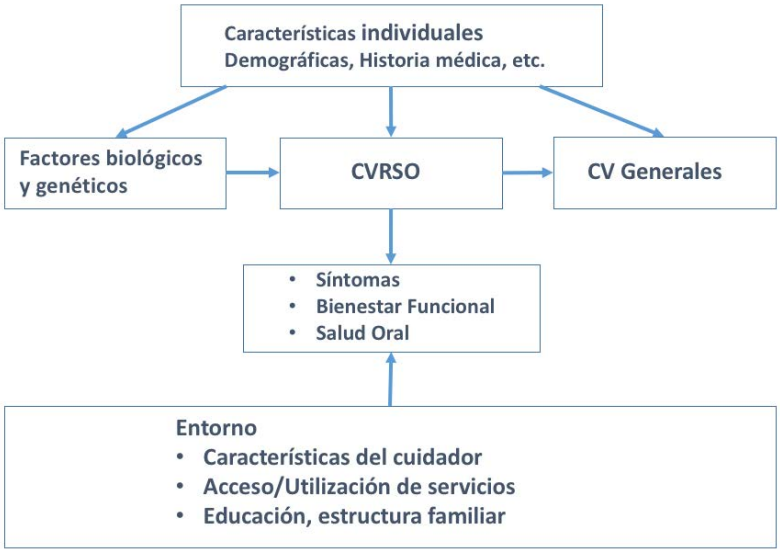
En el ámbito de la salud oral, las medidas que se basan en la perspectiva del paciente se conocieron originalmente como indicadores socio-dentales, medidas del estado de salud oral, salud oral subjetiva o como impactos sociales de la enfermedad oral. Posteriormente, estos términos fueron reemplazados con el término Calidad de Vida Relacionada con la Salud Oral (CVRSO), independientemente de su contenido (68). Este concepto se relaciona con el impacto que la salud oral o las patologías orales tienen en el desempeño diario de la persona, el bienestar o calidad de vida (46).

Una de las primeras definiciones de CVRSO fue realizada por Kressin: "una concepción amplia de la salud, que abarca la definición tradicional de salud, así como el impacto subjetivo individual de la salud sobre el bienestar y el funcionamiento en la vida cotidiana" (69).

Posteriormente otras definiciones publicadas fueron: “la medida en que los trastornos orales afectan el funcionamiento y el bienestar psicosocial”; “los síntomas y los impactos funcionales y psicosociales que emanan de las enfermedades y trastornos orales” (70, 71).

Una de las definiciones actualmente más aceptadas considera la CVRSO como un “constructo multidimensional que incluye una evaluación subjetiva de la salud bucal de la persona, el bienestar funcional, las expectativas y la satisfacción con la atención” (72). Esta definición está basada en el modelo biopsicosocial de la salud que incorpora factores biológicos, sociales, psicológicos y culturales (Figura 3).

Figura 3: Modelo teórico para CVRSO. Traducido de Sischo L. et al. (73)



Este modelo conceptual vincula el estado de salud o las variables clínicas (por ejemplo, tipo/extensión del defecto), el estado funcional (por ejemplo, el habla), la apariencia oral y facial, el estado psicológico, la CVRSO y la calidad de vida general. El modelo reconoce los efectos de los factores ambientales o contextuales (por ejemplo, factores socioculturales, educación, estructura familiar) y el acceso a la atención sobre las percepciones de salud oral y la calidad de vida (73).

INSTRUMENTOS PARA MEDIR CVRSO

Desde que Cohen y Jago (1976) abogaron por primera vez por el desarrollo de indicadores socio-dentales, los esfuerzos se han centrado en el desarrollo de instrumentos para medir la CVRSO (73, 74)

Fundamentalmente, se distinguen tres categorías de medida de CVRSO según Slade (69): indicadores sociales, autoevaluaciones globales de CVRSO y cuestionarios de ítems múltiples de CVRSO.

Los indicadores sociales se utilizan para evaluar el efecto de las patologías orales a nivel comunitario. Su utilidad radica principalmente en las grandes encuestas de salud para expresar la carga de las enfermedades bucodentales en toda la población por medio de indicadores tales como: días de actividades restringidas, pérdida de trabajo y ausencia escolar debido a afecciones orales (75). Si bien los indicadores sociales son útiles para la planificación de políticas, tienen limitaciones ya que los síntomas de las patologías orales no siempre conllevan una ausencia laboral, y que por otra parte no serían aplicables a los que no trabajan (76).

Las autoevaluaciones globales de CVRSO, también conocidas como cuestionarios de ítem único, consisten en hacer una pregunta general a las personas acerca de su salud oral. Por ejemplo, "¿Cómo calificaría la salud de sus dientes, encías y boca?" y las opciones de respuesta a esta pregunta global pueden estar en un formato de escala visual numérica, categórica o analógica. Una característica de la evaluación global es que ofrece también respuestas positivas y no se limita a medir solo el impacto adverso de la salud oral (76).

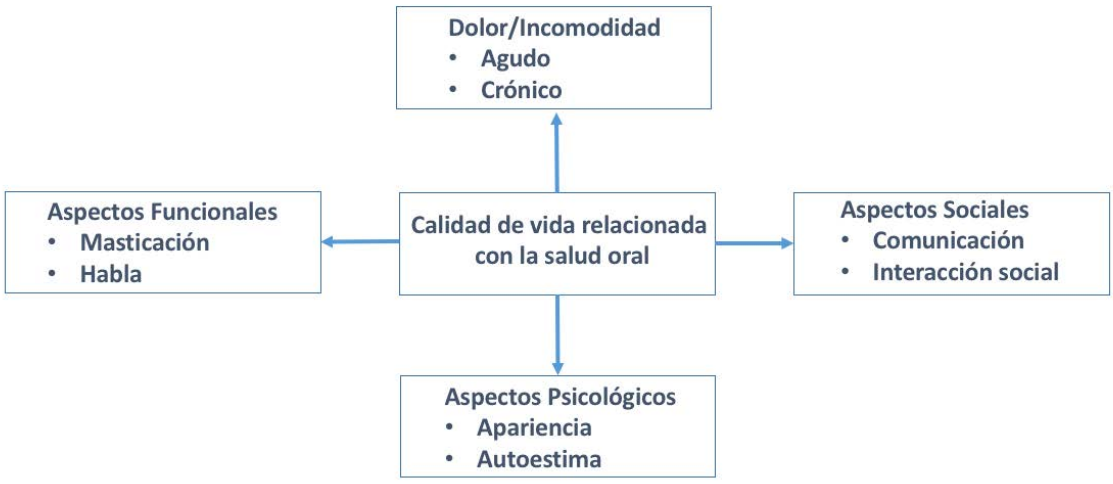
Finalmente, los cuestionarios que evalúan múltiples dimensiones de la CVRSO son los más ampliamente utilizados. Por ejemplo, algunas preguntas pueden ir enfocadas a la función, dolor o malestar mientras otras evalúan la interacción social (76).

Estas medidas se pueden clasificar en instrumentos genéricos que miden la salud oral en general o en instrumentos diseñados para medir dimensiones o síntomas específicos de salud oral como la ansiedad dental (77) o el dolor (78). Otros instrumentos están orientados en medir el impacto de una condición específica como aquellos que evalúan la CVRSO en pacientes con cáncer de cabeza y cuello (79), deformidad dentofacial (80), maloclusiones (81) o hipodoncia (82). Existen también instrumentos destinados a evaluar poblaciones

específicas (niños (83, 84) o adultos mayores (85)) y finalmente otros destinados a evaluar el impacto de los tratamientos dentales en la calidad de vida (86).

Un instrumento ideal que mida CVRSO debe ser capaz de abarcar aspectos sociales y psicológicos a través de la autopercepción del impacto de la salud bucal en la calidad de vida (3). La figura 4 muestra las dimensiones comunes en los instrumentos de CVRSO, junto con ejemplos específicos de elementos asociados con cada dimensión. Si bien aparecen los factores tradicionales como los síntomas de salud oral, también aparecen otros factores como el bienestar social y emocional que incorporan estados de salud positivos como la felicidad y la confianza (73).

Figura 4: Principales dimensiones de los instrumentos de CVRSO. Traducido de Sischo L. et al. (73)



IMPLICACIÓN DE CVRSO EN INVESTIGACIÓN Y CLÍNICA

En los últimos 30 años, los indicadores epidemiológicos han sido ampliamente usados para evaluar el estado de la salud oral individual y poblacional, en la mayoría de casos aportando una evaluación muy parcial de la salud oral del paciente.

Como respuesta a este vacío, la investigación odontológica sobre la CVRSO se ha desarrollado fuertemente en la última década, principalmente debido: 1) al rol más activo del paciente como miembro del equipo de tratamiento; 2) a la necesidad de enfoques basados en la evidencia en las prácticas de salud; y 3) al hecho de que muchos tratamientos para las enfermedades orales no logran resolver la afección (ej: pérdida dentaria), elevando así la importancia de la CVRSO como una variable de resultado valiosa (73).

Junto con los indicadores clínicos, conocer el impacto que las patologías orales tienen en la CVRSO, permite la evaluación de sentimientos y percepciones a nivel individual, incrementando la posibilidad de una comunicación efectiva entre profesionales y pacientes, y una mejor comprensión del impacto de la salud oral en la vida del sujeto y la familia (87).

Es decir, la evaluación de CVRSO permite un cambio de los criterios médicos/dentales tradicionales, a la evaluación y la atención que se centran en la experiencia emocional y social de la persona y el funcionamiento físico en la definición de los objetivos y resultados del tratamiento apropiados (73).

En salud pública, evaluar la CVRSO puede contribuir a una mejor comprensión de la desigualdad, a identificar los grupos con mayor nivel de necesidad y riesgo, priorizar programas de salud pública y mejorar así el acceso a la atención (3). También se utiliza en la investigación de servicios de salud para examinar las tendencias en la evaluación de la salud oral y de las necesidades basadas en la población (73). En resumen, la investigación de la

CVRSO puede ser utilizada para la elaboración de políticas públicas basadas en la población y contribuir a erradicar las disparidades de salud oral (88).

La CVRSO es una importante medida de resultado para evaluar la efectividad del tratamiento. Su uso como medida de resultado es congruente con la atención centrada en el paciente, siendo crucial para entender la efectividad del tratamiento desde la perspectiva de los pacientes y las interrelaciones entre las cuestiones específicas sobre salud oral con la salud general a través del tiempo (73). Por lo tanto, el análisis de los datos de la investigación que utiliza la CVRSO como medida de resultado también ayudará a los pacientes a a tomar decisiones sobre el tratamiento (73).

Por otro lado, con la CVRSO se evalúa con más precisión los riesgos y beneficios asociados a cualquier tratamiento (89). Además, facilita la valoración de si los costos asociados con los protocolos de tratamiento valen la pena cuando estos logran mejorar la CVRSO de los pacientes (90) mediante análisis de coste-utilidad.

EVIDENCIA DEL IMPACTO DE LAS PATOLOGIA ORALES EN LA CVRSO DE NIÑOS Y ADOLESCENTES

En la última década la investigación que evalúa el impacto de las condiciones orales sobre la CVRSO se ha ido incrementando de manera notable.

Algunos estudios muestran que la caries dental tiene un impacto negativo sobre la calidad de vida y se correlaciona fuertemente con los síntomas orales, la limitación funcional y, el bienestar social y emocional (91). A mayor daño oral, mayor es el impacto en la calidad de vida de los niños afectados (26). Una reciente revisión sistemática que incluyó 5.035

participantes reportó que los preescolares cuyo índice ceod fue ≥1 presentaron peor calidad de vida que aquellos sin historia de caries (-3,57 IC 95% -5,16 a -1,98). Además el impacto fue mayor si el índice ceod fue mayor a 6 (diferencia de medias -9,19; IC 95% -13,00 a -5,38) (27).

Los estudios sobre las maloclusiones sugieren que el impacto más significativo en la calidad de vida es psicosocial, y en menor grado en síntomas orales y limitaciones funcionales. Además, la dificultad de sonreír debido a la mala posición de los dientes ha sido considerada unos de los motivos de mayor impacto en la CVRSO de niños (46). Un metanálisis que incluyó 7.772 participantes con mal maloclusión y 6.549 con normoclusión, mostró evidencia de una asociación inversa muy fuerte entre maloclusión y CVRSO (diferencia de medias estandarizada 0.29; IC 95% 0.19 a 0.38). Además los autores concluyeron que la fuerza de la asociación depende de la edad de los niños y de su entorno cultural (92).

Algunos estudios han revelado que los traumas dentarios y la enfermedad periodontal en niños tienen el potencial de influir en la CVRSO, sin embargo la evidencia es aún escasa y contradictoria (93). Una reciente revisión sistemática con metanálisis de los traumatismo dentales se centró en estudios de niños en edad preescolar que utilizaron el instrumento Early Childhood Oral Health Impact Scale (ECOHIS). Los autores concluyeron que hay una moderada calidad de la evidencia que sugiere un significativo impacto en la CVRSO de niños en dentición primaria (odds ratio 1.23; IC 95% 1.07 a 1.41;3270 participantes), sin un impacto significativo en la familia (odds ratio 1.09; IC 95% 0.90 a 1.32; 7012 participantes) (94).

Con respecto a la enfermedad periodontal, una revisión sistemática que incluyó 10 estudios para su síntesis cualitativa concluye que todos los estudios realizados en población

infantil y adolescentes mostraron que la gingivitis presenta un impacto negativo en la calidad de vida, independiente del criterio diagnóstico utilizado (95).

Las alteraciones del desarrollo dentario, como la hipomineralización molar incisal, han sido asociadas con un mayor impacto en la calidad de vida de quienes la presentan, sin embargo la evidencia es aún escasa. Ésta fue asociada a un mayor impacto en la calidad de vida de escolares en los dominios sintomáticos (riesgo relativo 1.30; IC 95% 1.06–1.60) y funcional (riesgo relativo 1.42; IC 95% 1.08–1.86) (96).

La literatura científica muestra que niños que presentan fisura de labio y/o palatina no sindrómica tendieron a tener una más baja CVRSO que la población infantil sin fisuras (97).

La evidencia sobre el efecto de los tratamientos odontológicos sobre la CVRSO es aún escasa en niños y adolescentes (89) a pesar del aumento de nuevas tecnologías sanitarias que tienen como fin una mejora en la calidad de vida de niños y adolescentes que padecen patologías orales.

Una revisión sistemática con metanálisis que incluyó 6 estudios muestra que pacientes pediátricos que presentan maloclusiones no asociadas a síndromes, reportan un moderada mejora en la CVRSO una vez finalizado su tratamiento de ortodoncia (diferencia de medias estandariza -0.75; IC 95% , -1.15 to -0.36), particularmente en los aspectos emocionales (diferencia de medias estandariza -0.61; IC 95%, -0.80 to -0.41) y sociales (diferencia de medias estandariza -0.62; IC 95%,-0.82 to -0.43) (98).

Otra revisión sistemática evaluó el cambio en la CVRSO en niños menores de 16 años entre antes y después del tratamiento con anestesia general para el manejo de la caries dental. Sus resultados mostraron que el tratamiento con anestesia general parecía mejorar la CVRSO, sin embargo, dada la gran heterogeneidad de los estudios incluidos, los autores recomendaron

realizar estudios de mejor calidad utilizando instrumentos validados (99). Un reciente meta-análisis que incluyó 22 estudios confirmó la mejora en la calidad de vida con el tratamiento realizado bajo anestesia general en preescolares con una diferencia de medias de 1.62; IC 95% 1.52–1.71 y de 0.86; IC 95% 0.74–0.99 en escolares y adolecentes (100). Este mismo estudio mostró que la mejora en la CVRSO fue mayor en niños mayores de 6 años (diferencia de medias 1.84; IC 95% 0.36–3.32) (100).

El tratamiento de la caries dental también ha mostrado mejorar la calidad de vida independiente de si el tratamiento fue otorgado mediante un enfoque convencional o biológico (101, 102). Sin embargo falta evidencia que compare los diferentes enfoques terapéuticos en población pediátrica.

JUSTIFICACION

Las enfermedades orales son altamente prevalentes en todo el mundo a pesar de la mejora en los índices de salud oral en las últimas décadas del siglo XX. Es bien sabido que sus consecuencias en los niños son graves y pueden afectar su calidad de vida.

En respuesta a esto, se han desarrollado un gran número de cuestionarios para evaluar la calidad de vida relacionada con la salud oral en niños y adolescentes. Desafortunadamente, la información sobre su proceso de desarrollo, propiedades métricas y problemas de administración es dispersa. Sólo se había publicado una revisión sistemática centrada en los tres instrumentos actualmente más utilizados en niños, el Child Perceptions Questionnaire, Child Oral Impacts on Daily Performances, y el Child Oral Health Impact Profile. Por lo tanto, planteamos una revisión sistemática extendida a todos los instrumentos disponibles para evaluar calidad de vida relacionada con la salud oral durante la infancia y la adolescencia, sus características, ventajas e inconvenientes con el fin de facilitar la selección según los requisitos clínicos o de investigación. Además, muy pocos de estos instrumentos han sido adaptados y validados para su uso en Latinoamérica.

Por otro lado, la investigación que evalúa el impacto de un amplio rango de condiciones orales y orofaciales sobre la calidad de vida relacionada con la salud oral se ha incrementado de manera significativa y se han llevado a cabo revisiones sistemáticas de maloclusión, labio leporino y/o fisura palatina y traumatismos dentoalveolares en dentición primaria. Sin embargo, en el momento en que se inició el trabajo de tesis doctoral no habían estudios que resumiesen el impacto del trauma dentoalveolar en dentición permanente en la calidad de vida relacionada con la salud oral en población pediátrica.

Finalmente, a pesar del aumento en estudios que evalúan el impacto en la calidad de vida relacionada con la salud oral de las diferentes condiciones orales, hay una escasez de estudios que evalúen la efectividad de nuevas o existentes tecnologías sanitarias desde la perspectiva del paciente y a través del impacto en su calidad de vida relacionada con la salud oral.

Es importante conocer el impacto que tienen las patologías orales y sus tratamientos tanto en la población pediátrica como en su familia, dado que tal conocimiento contribuirá a la identificación de los grupos con mayor nivel de necesidad y a una mejor comprensión de la desigualdad en salud oral. Permitiendo priorizar programas de salud pública dirigidos a la atención de niños y adolescentes y por lo tanto mejorar el acceso a su atención.

OBJETIVOS DE LA TESIS DOCTORAL

OBJETIVO GENERAL

Evaluar el impacto de las patologías orales más prevalentes en población pediátrica y de sus tratamientos en la calidad de vida relacionada con la salud oral de los niños pre-escolares, escolares y adolescentes.

OBJETIVOS ESPECÍFICOS

1. Obtener una evaluación sistemática y estandarizada de la evidencia actual sobre el proceso de desarrollo, las propiedades métricas y los problemas de administración de los instrumentos de calidad de vida relacionados con la salud oral disponibles para niños y adolescentes
2. Evaluar el impacto de los traumatismos dentoalveolares en la calidad de vida relacionada con la salud oral de preescolares y escolares, mediante la síntesis de la evidencia disponible
3. Evaluar los efectos del tratamiento restaurador atraumático en comparación con el tratamiento convencional para el tratamiento de las lesiones de caries dentales en dientes primarios y permanentes de niños y adultos.
4. Desarrollar la versión Chilena en español de la Early Childhood Oral Health Impact Scale que sea conceptualmente equivalente al original y evaluar su aceptabilidad, fiabilidad y validez en población preescolar de Chile.

PUBLICACIONES

Artículo 1: Zaror C, Pardo Y, Espinoza-Espinoza G, Pont A, Muñoz-Millán P, Martínez-Zapata MJ, Vilagut G, Forero C, Garin O, Alonso J, Ferrer F. Assessing oral health-related quality of life in children and adolescents: A systematic review and standardized comparison of available instruments. Clin Oral Invest 2019;23(1):65-79. (IF: 2.386; Q1)

Clinical Oral Investigations
https://doi.org/10.1007/s00784-018-2406-1

ORIGINAL ARTICLE

Assessing oral health-related quality of life in children and adolescents: a systematic review and standardized comparison of available instruments

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Received: 7 August 2017 / Accepted: 28 February 2018

Abstract

Objectives To obtain a systematic and standardized evaluation of the current evidence on development process, metric properties, and administration issues of oral health-related quality of life instruments available for children and adolescents.

Materials and methods A systematic search until October 2016 was conducted in PubMed, Embase, Lilacs, SciELO, and Cochrane databases. Articles with information regarding the development process, metric properties, and administration issues of pediatric instruments measuring oral health-related quality of life were eligible for inclusion. Two researchers independently evaluated each instrument applying the Evaluating Measures of Patient-Reported Outcomes (EMPRO) tool. An overall and seven attribute-specific EMPRO scores were calculated (range 0–100, worst to best): measurement model, reliability, validity, responsiveness, interpretability, burden, and alternative forms.

Results We identified 18 instruments evaluated in 132 articles. From five instruments designed for preschoolers, the Early Childhood Oral Health Impact Scale (ECOHIS) obtained the highest overall EMPRO score (82.2). Of nine identified for schoolchildren and adolescents, the best rated instrument was the Child Perceptions Questionnaire 11–14 (82.1). Among the four instruments developed for any age, the Family Impact Scale (FIS) obtained the highest scores (80.3).

Conclusion The evidence supports the use of the ECOHIS for preschoolers, while the age is a key factor when choosing among the four recommended instruments for schoolchildren and adolescents. Instruments for specific conditions, symptoms, or treatments need further research on metric properties.

Clinical relevance Our results facilitate decision-making on the correct oral health-related quality of life instrument selection for any certain study purpose and population during the childhood and adolescence life cycle.

Keywords Oral health · Quality of life · Questionnaires · Psychometrics · Outcome assessment · Child

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00784-018-2406-1) contains supplementary material, which is available to authorized users.

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Introduction

Oral diseases are highly prevalent worldwide despite the improvement in oral health indices initiated in the last decades of the twentieth century [1–4]. It is well known that their consequences on children are serious and can affect their quality of life [5–10]. Patient-reported outcomes, together with clinical indicators, can jointly provide a more comprehensive assessment of the patient's oral health [11]. The oral health-related quality of life has been defined as a multidimensional concept which includes a subjective evaluation of the individual's oral health, functional well-being, expectations and satisfaction with care, and sense of self [11].

As the increase in the development of patient-reported outcomes is a general phenomenon, several attempts have been made to systemize evaluation criteria. One of the first approximations was performed by the Medical Outcomes Trust, which published an exhaustive series of recommendations regarding the ideal attributes of patient-reported outcomes [12]. Nowadays, the most established tools are the Evaluating Measures of Patient-Reported Outcomes (EMPRO) [13], based on the Medical Outcomes Trust proposal [12], and the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) [14]. While the latter was originally developed as a checklist for evaluating the methodological quality of each study focused on measurement properties, the EMPRO was designed to carry out an overall assessment of each instrument by taking into account both the methodology applied and the results obtained, based on all the available evidence. The EMPRO is a valid and reliable tool that has proven its usefulness in comparing the performance of generic [13] and disease-specific patient-reported outcomes [15–19].

In the last decade, a large number of oral health-related quality of life questionnaires have been developed for children and adolescents. Unfortunately, information about their development process, metric properties, and administration issues is dispersed. To the best of our knowledge, only one systematic review has been published and it was centered on the three instruments currently most used for children, [20] the Child Perceptions Questionnaire, the Child Oral Impacts on Daily Performances, and the Child Oral Health Impact Profile. Therefore, an extended systematic review of all the available instruments to assess oral health-related quality of life during childhood and adolescence is necessary in order to know the characteristics, pros, and cons of each one and to facilitate selection according to clinical or research requirements.

Accordingly, the research question to answer is as follows: to what extent is each instrument metrically robust and suitable to assess children's and adolescents' oral health-related quality of life? The aim of our study was to obtain a systematic and standardized evaluation of the current evidence on the development process, metric properties, and administration issues of the oral health-related quality of life instruments available for population aged 0–18 years, by applying the EMPRO tool.

Methods

Protocol

We used the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines for the reporting of this systematic review [21].

Eligibility criteria

Articles presenting information on the development process, the psychometric properties, and the administration of oral health-related quality of life instruments in children and adolescents were eligible for inclusion. Articles written in English, Spanish, Portuguese, French, German, and Italian were eligible, including both studies of original instruments as well as those of other country versions. Studies were excluded if they had used generic instruments to measure oral health, or applied oral health-related quality of life tools developed for the adult population in studies with children. Articles describing protocols, conference summaries, and case studies, as well as letters to the editor, were also excluded.

Information sources and search

A systematic search until October 2016 was conducted, with initial dates depending on database: from 1966 in Medline, 1974 in Embase, 1982 in Lilacs, 1998 in SciELO, and 2008 in the Cochrane Library. It was complemented by a manual review of the references of the included articles and in two online databases of patient-reported outcome instruments: patient-reported outcomes and quality of life instruments database (https://eprovide.mapi-trust.org) and BiblioPRO (www.bibliopro.org). The details of the search strategy used in Medline are listed in supplementary data (Online Resource 1).

Study selection

Titles, abstracts, and full-text articles were selected independently by two investigators (CZ and either PM or GE) to verify their eligibility. In cases of discrepancy, the decision was made by a third reviewer (YP).

Data collection process

Each oral health-related quality of life instrument was evaluated independently by two reviewers, which is the minimum recommended instrument when assessing information that

involves subjective interpretation [22]. Concordance between pairs of reviewers was examined by calculating the one-way random effects intraclass correlation coefficient (ICC) for absolute agreement. In case of evaluation discrepancies, they were first resolved through consensus and then, if necessary, by a third reviewer. Experts were identified and invited because of their knowledge and experience in patient-reported outcomes measurement: 14 belonged to the team that developed the EMPRO and 18 were researchers who participated in a training course focused on how to support selection of the

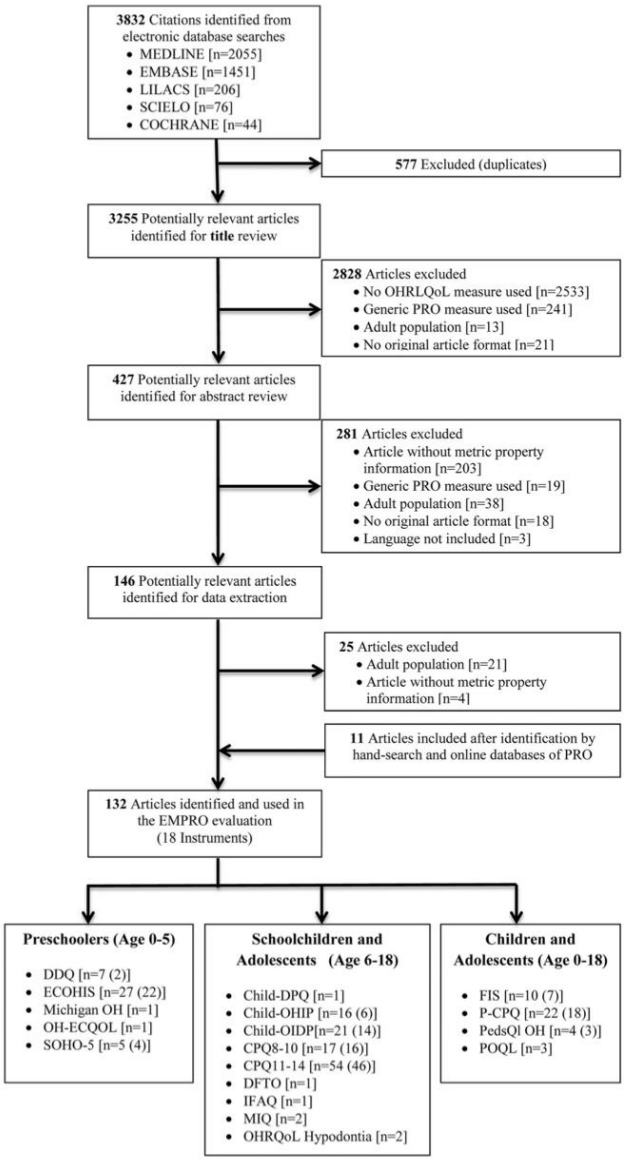


Fig. 1 Flowchart of the systematic literature review, instruments identified. Total number of articles per instrument (articles evaluating cross-cultural versions in brackets)

Table 1 Summarized characteristics of instruments designed for preschoolers, in alphabetical order

Instrument	Purpose of development (age)	Administration mode	Dimensions (no. of items)	Response options	Scores (range)	Original and adapted languages
1. The Dental Discomfort Questionnaire (DDQ) [23]	Dental discomfort/dental pain (2–5 years)	Proxy-administered	Occurrence of toothache (3) Behavior-associated discomfort (12)	1st part: the 4-point Likert scale 2nd part: the 3-point Likert scale	Global score (0–24)	English Dutch Portuguese
2. The Early Childhood Oral Health Impact Scale (ECOHIS) [24]	Oral diseases (0–5 years)	Proxy-administered	Symptom (1) Function (4) Psychology (2) Social (2) Parental distress (2) Family function (2)	The 5-point Likert scale	Global score (0–52) Scores by dimension	English Chinese Spanish Portuguese (Portugal, Luanda) French Persian Arabic Turkish Lithuanian Kiswahili Kannada Malayalam Malay
3. The Michigan Oral Health-Related Quality of Life (Michigan-OHRQoL) [25]	Oral diseases (1–5 years)	Self-administered Proxy-administered	Unidimensional Child version (9) Parent version (10)	Child version: yes/no Parent version: the 5-point Likert scale	No information	English
4. The Oral Health-related Early Childhood Quality of Life (OH-ECQOL) [26]	Oral diseases (2–5 years)	Proxy-administered	Unidimensional - Child impact (12) - Family impact (4)	The 3-point Likert scale	Global score (16–48)	Hindi
5. The Scale of Oral Health Outcomes for 5-year-old children (SOHO-5) [27]	Oral diseases (5 years)	Self-administered Proxy-administered	Unidimensional (7)	Child version: the 3-point Likert scale Parental version the 5-point Likert scale	Global Score (Child version 0–14) (Parental version 0–28)	English Portuguese (Brazil)

Table 2 Summarized characteristics of instruments designed for schoolchildren and adolescents, in alphabetical order

Instrument	Purpose of development (age)	Administration mode	Dimensions (no. of items)	Response options	Scores (range)	Original and adapted languages
1. The Child Dental Pain Questionnaire (Child-DPQ) [28]	Dental pain (8–9 years)	Self-administered	Prevalence (2) Severity (2) Impact (2)	Different types of responses	Global score (0–15)	English
2. The Child Oral Health Impact Profile (Child-OHIP) [29]	Oral diseases (8–15 years)	Self-administered	Oral health (10) Functional (6) Social-emotional Well-being (8) School environment (6) Self-images (4)	The 5-point Likert scale	Global score (34–170)	English Persian Dutch Chinese German Korean French
3. The Child Oral Impact on Daily Performance Index (Child-OIDP) [30]	Oral diseases (11–15 years)	Self-administered Interview administered	Physical (4) Psychological Social (4)	The 3-point Likert scale	Global score (0–100)	10*
4. The Child Perceptions Questionnaire 8–10 (CPQ8–10) [31]	Oral diseases (8–10 years)	Self-administered Interview administered	Oral symptoms (5) Functional limitations (5) Emotional well-being (5) Social well-being (10)	The 5-point Likert scale	Global score (1–55)	English Spanish Portuguese Bosnian Cambodian Danish Korean Japanese
5. The Child Perceptions Questionnaire 11–14 (CPQ11–14) [32]	Oral diseases (11–14 years)	Self-administered Interview administered Telephone interview	Oral symptoms (6) Functional limitations (9) Emotional well-being (9) Social well-being (13)	The 5-point Likert scale	Global score (1–80)	12**
6. The Dental Freetime Trade-Off scale (DFTO) [33]	Utility (14–19 years)	Self-administered	Unidimensional (5)	Different types of responses	Global score (minutes)	English
7. The Impact of Fixed Appliances Questionnaire (IFAQ) [34]	Fixed orthodontic appliances (10–18 years)	Self-administered	No information	The 5-point Likert scale	Global score (0–34)	English
8. The Malocclusion Impact Questionnaire (MIQ) [35]	Malocclusion (10–16 years)	Self-administered	Appearance of teeth Effect on social interactions Oral health and function Global (28)	The 3-point Likert scale	Global score (0–64)	English
9. The Oral Health-Related Quality of Life for Patients with Hypodontia (OHRQoL-Hypodontia) [36]	Hypodontia-anodontia (11–18 years)	Self-administered	No information	No information	No information	English

*Child-OIDP is in 10 languages: Thai, English, Kannada, Spanish, Portuguese, Kiswahili, Arabic, French, Malay, and Hindi

**CPQ11–14 is in 12 languages: English, Spanish, Portuguese, German, Arabic, Malay, Thai, Italian, Cambodian, Danish, Korean, and Telugu

Table 3 Summarized characteristics of instruments designed for the whole childhood and adolescence cycle

Instrument	Purpose of development (age)	Administration mode	Dimensions (no. of items)	Response options	Scores (range)	Original and adapted languages
1. The Family Impact Scale (FIS) [37]	Family impact of oral disease (2–14 years)	Proxy-administered	Parental/family activity (5) Parental emotions (4) Family conflict (4)	The 5-point Likert scale	Global score (0–33)	English Portuguese Chinese Telugu
2. The Parental-Caregiver Perceptions Questionnaire (P-CPQ) [38]	Oral diseases (2–14 years)	Proxy-administered	Oral symptoms (6) Functional limitations (8) Emotional well-being (7) Social well-being (10)	The 5-point Likert scale	Global score (0–124)	English Spanish Portuguese Chinese Telugu
3. The Pediatric Quality of Life Inventory™ Oral Health Scale™ (PedsQL™ Oral Health Scale™) [39]	Oral diseases (2–18 years)	Self-administered Proxy-administered	Unidimensional (5)	The 5-point Likert scale	Global score (0–100)	English Portuguese (Brazil) Persian
4. The Pediatric Oral Health-Related Quality of Life (POQL) [40]	Oral diseases (2–16 years)	Self-administered Proxy-administered	Physical functioning Role functioning Emotional impact Social impact Global (10)	The 4 and 5-point Likert scale	Global score (0–100)	English Spanish

most adequate patient-reported outcome through a standardized assessment of metric properties and issues related to its administration with the EMPRO system.

Evaluating measures of patient-reported outcomes

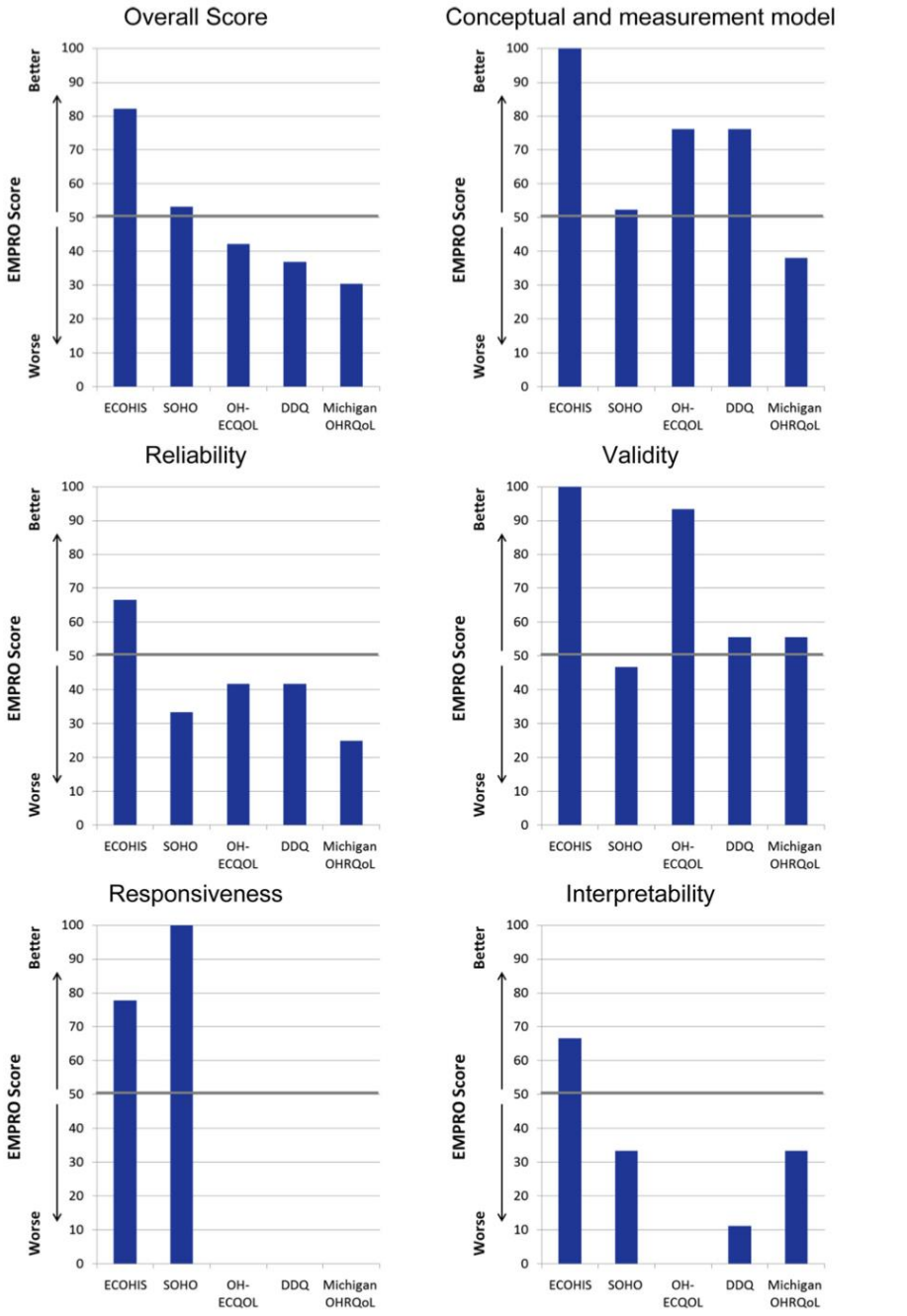
The EMPRO tool is composed of 39 items divided into 8 attributes: "conceptual and measurement model" (concepts and population intended to assess), "reliability" (to what degree an instrument is free from random error), "validity" (to what degree an instrument measures what it intends), "responsiveness" (ability to detect change over time), "interpretability" (assignment of meanings to instrument scores), "burden" (time, effort, and other demands for administration and response), "alternative modes of administration" (i.e., self- or interviewer-administered and telephone- or computer-assisted interview), and "cross-cultural and linguistic adaptations" (equivalence across translated versions) [13]. The last attribute was not completed because it was beyond the scope of this study.

All EMPRO attributes and items are accompanied by a short description, to facilitate understanding and to guarantee a standardized application during the evaluation process. Agreement with each item can be answered on a four-point Likert scale, from 4 (strongly agree) to 1 (strongly disagree), and there is also a "no information" option. Five items allow a "not applicable" reply. Items for which the response option was "no information" were assigned a score of 1 (lowest possible score).

Statistical analysis

Attribute-specific scores and an overall score were calculated for each instrument. The mean score of the applicable items was calculated for each attribute when at least 50% of them were rated. Mean responses were linearly transformed into a range from 0 (worst possible score) to 100 (best possible score). Separate subscores for the "reliability" and "burden" attributes were calculated, as they are composed of two components each: "internal consistency" and "reproducibility" for reliability and "respondent" and "administrative" for burden. For reliability, as the two components represent different approaches to examine one same attribute, the highest subscore was chosen. For burden, however, as the two components

Fig. 2 The overall EMPRO ranking and attribute-specific scores of instruments designed for preschoolers (age 0–6 years). The gray line on 50 (half of the 100 maximum theoretical points) represents the reasonably acceptable cut-off defined for EMPRO scores. The Dental Discomfort Questionnaire (DDQ), the Early Childhood Oral Health Impact Scale (ECOHIS), the Michigan Oral Health-Related QoL scale (Michigan-OHRQoL), the Oral Health-related Early Childhood Quality of Life tool (OH-ECQOL), the Scale of Oral Health Outcomes for 5-year-old children (SOHO-5)


Overall Score
Conceptual and measurement model
Reliability
Validity
Responsiveness
Interpretability
EMPRO Score
Better
Worse
100
90
80
70
60
50
40
30
20
10
0
ECOHIS
SOHO
OH-ECQOL
DDQ
Michigan OHRQoL

assess different aspects of the same attribute, the final score was calculated as their mean.

In addition, an overall score was computed by calculating the mean of the five metric-related attributes: "conceptual and measurement model," "reliability," "validity," "responsiveness to change," and "interpretability." The overall score was only calculated when at least three of these five attributes had a score.

EMPRO scores were considered reasonably acceptable if they reached at least 50 points (half of the 100 maximum theoretical points). This threshold was chosen based on the global recommendations made by the reviewers in the first two EMPRO studies [13, 15].

Oral health-related quality of life instruments were examined separately according to the target population: preschoolers (< 6 years old), schoolchildren and adolescents (6–18 years old), and the whole childhood and adolescence life cycle (0–18 years old).

Results

Results of the search

The search identified 3832 references (Fig. 1). After excluding 577 duplicates and reviewing titles and abstracts, 146 articles were read in full text. Subsequently, 25 were excluded, 21 because they included only adult samples and 4 due to their lack of metric property information. Eleven articles were identified by hand search and online patient-reported outcomes databases. Thus, a total of 132 full-text articles were considered at the EMPRO evaluation of 18 instruments (see list of references in Online Resource 2). The number of articles found per instrument ranged from 1 to 54, with some articles providing information on more than one instrument. The intraclass correlation coefficient for the overall EMPRO score between pairs of reviewers was 0.84 indicating a high agreement before consensus process.

Characteristics of instruments

Table 1 shows in alphabetic order the five instruments applicable to preschoolers, which were published between 2002 and 2014. All were designed for oral diseases in general, proxy administration and were developed in English-speaking countries, except for the Dental Discomfort Questionnaire (DDQ) symptom-specific scale, which focused on discomfort and/or pain, and the Oral Health-Related Early Childhood Quality of Life (OH-ECOQOL) developed in India. Only two scales, the Michigan Oral Health-Related Quality of Life scale (Michigan-OHRQoL) and the Scale of Oral Health Outcomes for 5-year-old children (SOHO-5), have a version for child self-administration.

For schoolchildren and adolescents, nine instruments were identified (Table 2): four were generic, two condition-specific (for hypodontia and malocclusion), one symptom-specific for pain, one treatment-specific for fixed appliances, and one econometric. They were developed between 1998 and 2016, in English, and to be self-administered, with the exception of the Child Oral Impact on Daily Performance Index (Child-OIDP), developed in Thai to be interviewer-administered.

Four instruments designed for children and adolescents of any age (0–18 years) were published after 2002 (Table 3). They were all designed in English, adapted to different cultures and administered through a parent or caregiver, although Pediatric Quality of Life Inventory™ Oral Health Scale™ (PedsQL-OH™) and Pediatric Oral Health-Related Quality of Life (POQL) had also a self-administered version for specific children's ages.

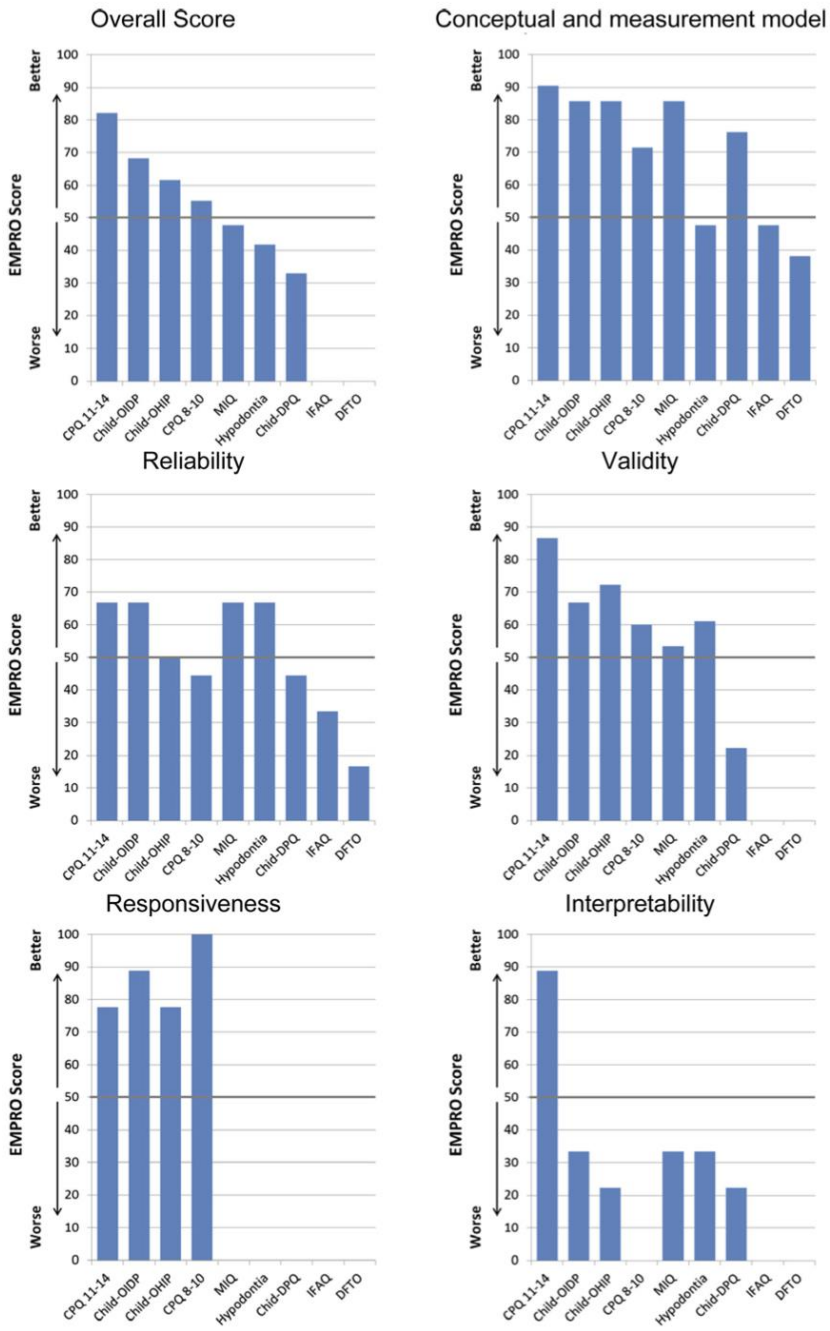
It is important to clarify that four of the abovementioned instruments form part of the Child Oral Health Quality of Life, which considers not only the children's perception measured with Child Perceptions Questionnaires (CPQ8–10 or CPQ11–14), but also that of the parents with the Parental-Caregiver Perceptions Questionnaire (P-CPQ), and the impact of the child's oral problems on the family with the Family Impact Scale (FIS). Each one of these four instruments has been evaluated separately within their target population group.

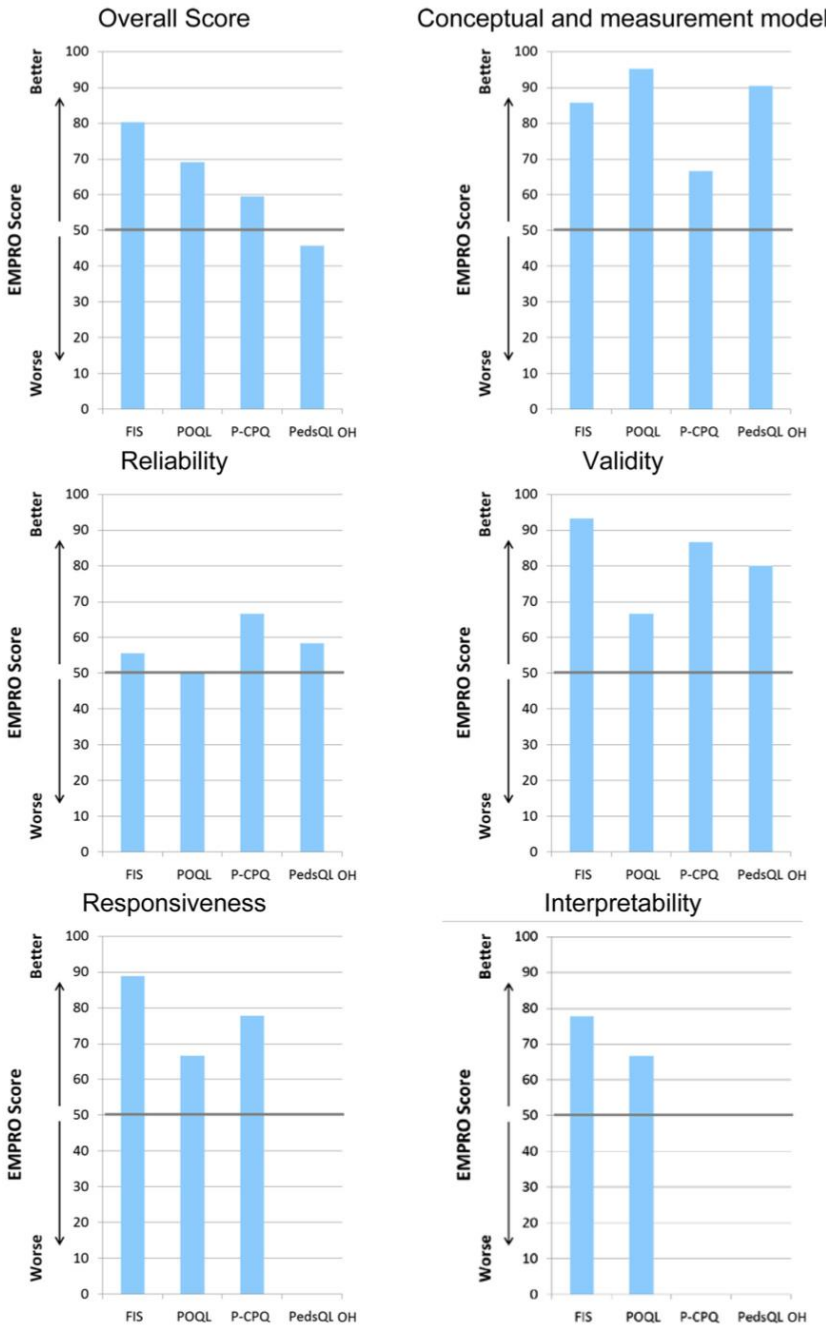
Results of the EMPRO ratings

The instrument with the highest overall score in preschoolers (Fig. 2) was the Early Childhood Oral Health Impact Scale (ECOHIS) with 82.2 points; in schoolchildren, it (Fig. 3) was the CPQ11–14 with 82.1, and for children and adolescents of any age (Fig. 4), the FIS with 80.3 points. Detailed EMPRO results for any specific criteria and attributes are presented in supplementary material (Online Resource 3).

All the questionnaires were scored over 50 in the conceptual model attribute, except for the Michigan-OHRQoL (Fig. 2), Oral Health-Related Quality of Life for Patients with Hypodontia (OHRQoL-Hypodontia), Impact of Fixed Appliances Questionnaire (IFAQ), and Dental Freetime Trade-Off Scale (DFTO) (Fig. 3). Reliability scores ranged from 16.7 to 66.7 with eight instruments below 50.

Fig. 3 The overall EMPRO ranking and attribute-specific scores of instruments designed for schoolchildren and adolescents (Age 7–18 years). The gray line on 50 (half of the 100 maximum theoretical points) represents the reasonably acceptable cut-off defined for EMPRO scores. The Child Dental Pain Questionnaire (Child-DPQ), the Child Oral Health Impact Profile (Child-OHIP), the Child Oral Impact on Daily Performance Index (Child-OIDP), the Child Perceptions Questionnaire 8–10 (CPQ8–10), the Child Perceptions Questionnaire 11–14 (CPQ11–14), Dental Freetime Trade-Off Scale (DFTO), the Impact of Fixed Appliances Questionnaire (IFAQ), the Malocclusion Impact Questionnaire (MIQ), and the Oral Health-Related Quality of Life for Patients with Hypodontia (OHRQoL-Hypodontia)


Overall Score
Conceptual and measurement model
Reliability
Validity
Responsiveness
Interpretability
EMPRO Score
Better
Worse
0
10
20
30
40
50
60
70
80
90
100
CPQ 11-14
Child-OIDP
Child-OHIP
CPQ 8-10
MIQ
Hypodontia
Chid-DPQ
IFAQ
DFTO


Overall Score
Conceptual and measurement model
Reliability
Validity
Responsiveness
Interpretability
EMPRO Score
Better
Worse
100
90
80
70
60
50
40
30
20
10
0
FIS
POQL
P-CPQ
PedsQL OH

◀ **Fig. 4** The overall EMPRO ranking and attribute-specific scores of instruments designed for children and adolescents (age 0–18 years. The gray line on 50 (half of the 100 maximum theoretical points) represents the reasonably acceptable cut-off defined for EMPRO scores. The Family Impact Scale (FIS), the Parental-Caregiver Perceptions Questionnaire (P-CPQ), the Pediatric Oral Health-Related Quality of Life (POQL), and the Pediatric Quality of Life Inventory™ Oral Health Scale™ (PedsQL-OH™)

Regarding validity, the SOHO-5 (Fig. 2) and the Child Dental Pain Questionnaire (Child-DPQ) (Fig. 3) did not reach this threshold, while insufficient information was found for the IFAQ and DFTO (Fig. 3) to calculate this score. Only in half the instruments was it possible to calculate an EMPRO responsiveness score, as the information was insufficient in the other nine. Interpretability scores were high for ECOHIS (66.7 in Fig. 2), CPQ11–14 (88.9 in Fig. 3), FIS, and POQL (77.8 and 66.7 in Fig. 4) and below 50 for eight instruments, and it was not possible to calculate them for six instruments.

The interview administration version of the CPQ11–14 and CPQ8–10, as well as versions for telephone interview administration of CPQ11–14 and self-administration of Child-OIDP, obtained 83 points in the EMPRO evaluation of the "Alternative forms of administration" (Online Resource 4) because most metric properties were evaluated and scores were similar to those from the original administration versions. Similarly, short forms derived from Child Oral Health Impact Profile (Child-OHIP with 19 items), CPQ11–14 (with 16 and 8 items), FIS (with 8 items), and P-CPQ (with 16 items) were well rated, with scores over 80. The DDQ, with eight items, is the only short form which has not yet demonstrated suitable metric properties or enough comparability with the original instrument scores.

Discussion

This review provides exhaustive information about the oral health-related quality of life instruments designed for preschoolers, schoolchildren, adolescents, and the whole childhood and adolescence cycle, in order to facilitate an informed decision about the optimum instrument for a specific study according to metric properties and purpose of application. The most highly rated ones, according to the EMPRO tool's standard criteria, were the ECOHIS in preschoolers and the CPQ11–14 in schoolchildren. The FIS was shown to be an excellent instrument to measure the impact of oral health on the family. Results obtained by the Child-OIDP and Child-OHIP in schoolchildren, as well as POQL and P-CPQ for any age, also make them recommendable. The SOHO-5 in preschoolers and the CPQ8–10 in schoolchildren scored just above the threshold, indicating reasonably acceptable results, while instruments specific for malocclusion and hypodontia are only slightly below this.

In preschoolers, the five identified questionnaires showed generally an adequate process in their development and were valid; however, only the ECOHIS presented good reliability, responsiveness, and interpretability. The SOHO-5, despite its high responsiveness (100 points), would need more research on reliability and interpretability. Furthermore, the ECOHIS is the only questionnaire that has been culturally adapted to 14 languages or countries (allowing international studies) and has a section assessing the impact of oral problems on the family, making it the most complete instrument. Although the ECOHIS and SOHO-5 were originally developed to assess the impact of dental caries, they have both been widely used to evaluate several oral pathologies [5, 41] and are currently considered generic oral health-related quality of life instruments.

Among the nine instruments developed for schoolchildren and adolescents, the CPQ 11–14, Child-OIDP, and Child-OHIP scored the highest in the overall EMPRO assessment and also obtained good results for conceptual model, reliability, validity, and responsiveness. Furthermore, the CPQ11–14 presented a high EMPRO score for interpretability (88.9) and has been validated for a number of dental and orofacial pathologies, such as caries [42], enamel defects [43], dental fluorosis [44], malocclusion [45, 46], and craniofacial disorders [32, 47]. Although the CPQ11–14 is long (37 items), its short versions (8 and 16 items) allow to minimize administration burden and facilitate its applicability. Unexpectedly, the CPQ 11–14 and the CPQ 8–10, developed by the same research group using the same strategy for each age stratum, presented substantially different EMPRO overall scores (82.1 vs 55.2). However, the worse results obtained by CPQ8–10 are mostly explained by the lack of studies on its interpretability, which penalizes substantially the overall EMPRO score since it is one of the five components. Finally, the two condition-specific instruments designed for malocclusion and hypodontia were well rated for conceptual model, reliability, and validity, but needed further research for responsiveness and interpretability.

In children and adolescents of any age, the FIS, P-CPQ, and POQL were those with the best EMPRO evaluation. However, it is important to remember that the FIS measures the impact on the family, the P-CPQ measures the impact on the child from the parent's perspective, and the POQL has been validated only for dental caries. The FIS and P-CPQ were developed for children between 6 and 14 years old, but their psychometric properties have been evaluated on children from 3 years of age onwards. Both instruments have derived short versions (8 and 16 items, respectively) validated for several conditions, such as caries [48, 49], orofacial conditions [37, 38], dental fluorosis [48], or orthodontic treatment [37, 38], and have been adapted in 5 languages.

Our results are consistent with those reported by the previous systematic review [20] of the Child-OIDP, Child-OHIP,

and P-CPQ showing acceptable evidence on validity. However, our EMPRO results in reliability, responsiveness, and interpretability are more favorable for these instruments. These differences could be explained by the larger number of studies analyzed in our review than in theirs [20]: 54 studies vs 7 for CPQ11–14, 17 vs 2 for CPQ8–10, 21 vs 2 for the Child-OIDP, and 16 vs 4 for the Child-OHIP. Furthermore, the EMPRO uses several criteria covering different aspects of methods and the quality of the results for each evaluated attribute (from three criteria in responsiveness or interpretability to seven in measurement model) [13]. The previous review, instead, synthesized the evaluation of each attribute's quality in a single criterion [14].

Age is a key issue in the assessment of patient-reported outcomes in children: it determines not only the direct or proxy sources of information, but also the way they experience oral health-related quality of life [50], which generates the need to develop instruments for each age strata. Only the PedsQL-OH has specific age versions [39] allowing to measure with the same instruments the whole childhood and adolescence cycle without missing age-specific information. Proxy reporting is the standard in preschoolers [50] due to their difficulties in fully comprehending and/or communicating their perceptions. In this sense, the self-reported versions of the SOHO-5 and Michigan-OHRQoL are especially valuable, providing the children's own perspective in preschoolers [51]. A SOHO-5 study [52] obtained similar oral health-related quality of life results from parents and their children. Children usually start abstract thinking and compare their physical features and personality traits with their peers at the age of six, which allows self-reporting from this age on [53]. In general, evidence shows that parents underestimate the impact of children's oral problems, since they have a different perspective and limited knowledge, particularly related to social and emotional well-being [54]. Oral health-related quality of life domains directly observable by parents, such as physical complaints and functionality, concur better with children's perceptions [55, 56]. In this sense, it is noteworthy that self-reporting was chosen for all instruments identified for schoolchildren and adolescents in our review.

In general, specific instruments scored worse than generic instruments according to the EMPRO evaluation. Then again, their potential advantages for certain study purposes or populations make them worthy of further comment. Condition-specific instruments for malocclusion and hypodontia, symptom-specific for pain (the DDQ and Child-DPQ), and treatment-specific for fixed appliances (the IFAQ) have something in common, that is, not reporting any information on responsiveness and presenting poor results on interpretability. This is important for longitudinal studies and clinical trials, where responsiveness and reproducibility are key attributes, as it cannot be assumed that a measure shown to be reliable and valid in cross-sectional studies will necessarily be sensitive to changes over time in a clinical intervention. Therefore, if responsiveness is not demonstrated prior to its application, it is not sure whether this change is real or generated by measurement error [57, 58]. On the other hand, developing strategies to facilitate the interpretation of scores (such as estimating the minimal important difference by using anchor-based or distribution-based strategies) may help to extend the use of these instruments. Finally, it is also noteworthy that the Dental Freetime Trade-Off (DFTO) scale is the only econometric instrument identified in our search, designed as a preference-based health index [33]. However, its poor results in our metric quality evaluation indicate the need of future research, mainly to confirm the validity, reliability, and responsiveness of the utilities for economic evaluation of oral health interventions.

The main strengths of this study are that the information regarding development process, metric properties, and administrative issues of oral health-related quality of life instruments in children and adolescents was obtained in a systematic review of the literature and was evaluated by experts using a standardized tool. The EMPRO combines two fundamental aspects: well-described and established criteria for the assessment of attributes, taking into account the quality of the methodology as well as the results obtained; and scores that allow for a direct comparison of attributes and overall performance among the evaluated instruments.

Our findings should be interpreted taking into account some limitations that deserve to be addressed. Firstly, we may have failed to identify all oral health-related quality of life instruments or relevant articles. However, to minimize this, we applied a sensitive search strategy, an additional hand search of references along with two online databases of patient-reported outcomes, and a double independent review process. Secondly, the EMPRO evaluation is based on the quantity and quality of published evidence on each instrument. A lack of information for a few EMPRO items or attributes penalizes the EMPRO scores, because the scoring algorithm counts any missing information as the worst possible rating. Nevertheless, to minimize such penalization, the EMPRO score was not calculated if information on half or more items/attributes was missing. For example, the IFAQ and DFTO reported information only for conceptual model and reliability; therefore, their overall EMPRO score was not calculated. This should be interpreted as the need to produce such information before an evidence-based decision can be made. Thirdly, EMPRO ratings may be biased by evaluators. It is important to notice that, to avoid this bias, each item of the EMPRO tool includes a comprehensive description which facilitates rating standardization, and we carried out a double independent evaluation followed by a consensus, as in the majority of previous EMPRO studies [16, 17, 59, 60]. Fourthly, selecting the cut-off point of 50 as the threshold to consider the EMPRO scores acceptable for any purpose and setting is questionable. This threshold was obtained with data from the first two EMPRO studies [13, 15]: the area under the receiver operating

characteristic (ROC) curve evaluating the agreement between EMPRO attribute scores and the reviewers' global recommendations was of 0.87 (data not shown but available upon request). Therefore, this cut-off point should be used only as a guide to identify potential gaps. Fifthly, studies on the metric properties of the original instrument and the country versions derived from it were considered in our EMPRO evaluation. These studies contribute with information and provide valuable data about the generalization of the instruments' psychometric data. Finally, although clinical trials can provide indirect evidence on some metric properties such as validity, sensitivity to change, or interpretability, none were included in our study, because they were not specifically designed for the assessment of metric properties nor included this as a secondary objective.

Conclusions

This is the first study to provide a systematic and reliable expert-based evaluation of all available oral health-related quality of life instruments in preschoolers, schoolchildren, and adolescents. Our results support the selection for preschoolers of the Early Childhood Oral Health Impact Scale (ECOHIS) or the Scale of Oral Health Outcomes for 5-year-old (SOHO-5) in the case of preferring the children reporting themselves. When evaluating schoolchildren and adolescents, the age of the target population is a key factor in choosing among the following recommended instruments: the CPQ11–14, Child-OIDP (11–15 years), Child-OHIP (8–15 years), or CPQ8–10. The administration of the Child Perceptions Questionnaires (CPQ11–14 or CPQ8–10) together with the Parental-Caregiver Perceptions Questionnaire (P-CPQ) and the Family Impact Scale (FIS) can provide a complete evaluation of the patient's oral health-related quality of life, by measuring both the parents' and children's perceptions and also the impact on the family. The Pediatric Oral Health-Related Quality of Life (POQL) is also recommended for ages 2–16 years, both with proxy and self-completion. However, the instruments designed to assess a specific condition, symptom, or treatment, as well as the only questionnaire developed for economic evaluation, need further research on their metric properties before taking advantage of their specificity. Our results may facilitate the decision-making process regarding the correct instrument selection and its use for each study purpose.

Acknowledgements We would like to acknowledge Aurea Martin for her help in the English editing process and figure edition of this manuscript.

Funding Carlos Zaror is a PhD candidate in Methodology of Biomedical Research and Public Health program, Universitat Autònoma de Barcelona, Barcelona, Spain.

Ma. José Martínez is funded by a Miguel Servet research contract from the Instituto de Salud Carlos III and European Social Fund (CP15/00116).

Montse Ferrer is partially funded by the Departament d'Innovació, Universitats i Empresa, Generalitat de Catalunya (2014 SGR 748).

This project was funded by a grant from the Convenio de Desempeño Regional, FRO 1301, Universidad de La Frontera, No. UNT15-0012.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study, formal consent is not required.

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Artículo 2: Zaror C, Martínez-Zapata MJ, Abarca J, Díaz J, Pardo Y, Pont À, Ferrer M. Impact of Traumatic Dental Injuries on Quality of Life in Preschoolers and Schoolchildren: A Systematic Review and Meta-Analysis. Community Dent Oral Epidemiol 2018;46(1):88-101. (IF:2.302; Q1)

Received: 13 January 2017 | Accepted: 6 August 2017

DOI: 10.1111/cdoe.12333

ORIGINAL ARTICLE

WILEY Community Dentistry and Oral Epidemiology

Impact of traumatic dental injuries on quality of life in preschoolers and schoolchildren: A systematic review and meta-analysis

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Funding information
Comisión Nacional de Investigación Científica y Tecnológica, Grant/Award Number: MEC 800140042; Miguel Servet research contract from the Instituto de Salud Carlos III; European Social Fund, Grant/Award Number: CP15/00116; Departament d'Innovació; Universitats i Empresa; Generalitat de Catalunya, Grant/Award Number: 2014 SGR 748

Abstract

Objectives: Traumatic dental injuries (TDIs) in childhood and adolescence are a potential public health problem given their prevalence and consequences. The aim of this study was to assess the impact of TDIs on the oral health-related quality of life (OHRQoL) of preschoolers and schoolchildren, by synthesizing the available evidence.

Methods: A systematic search was conducted in MEDLINE, EMBASE, Cochrane, ScieLo and Lilacs databases since January 1966 until March 2016. The included studies compared OHRQoL between groups with and without TDIs, using validated instruments. The selection process and data extraction were carried out by two researchers independently. A third reviewer resolved discrepancies. Methodological quality was assessed with the Effective Public Health Practice Project's Quality Assessment Tool. Meta-analyses were performed using random effect models, separately for preschoolers and schoolchildren.

Results: Of 213 identified articles, 26 studies (involving a total of 4582 patients and 13 601 controls between the ages of 1 and 15 years) met the inclusion criteria. Most of the studies had been published in the last 5 years, and their methodological quality was judged to be moderate. The TDIs group had a significantly higher chance of reporting any impact on OHRQoL than controls for both preschoolers (OR = 1.44; 95% confidence interval [CI]: 1.28-1.63; I^2 = 0%) and schoolchildren (OR = 1.31; 95% CI: 1.04-1.66; I^2 = 70%). In preschoolers, the OR for OHRQoL impact for complicated vs uncomplicated TDIs was 1.53 (95% CI: 1.04-2.26; I^2 = 0%). The social domain was the most affected one in schoolchildren (standard mean difference = 0.34; 95% CI: 0.13, 0.55; I^2 = 68%).

Conclusion: Traumatic dental injuries have a negative impact on OHRQoL of both preschoolers and schoolchildren. Outcome standardization to measure OHRQoL impact, such as mean score differences and cut-off points, is needed. Prospective cohort studies are recommended to confirm these findings and to understand how TDIs' impact changes with time.

KEYWORDS
adolescent, child, preschool, quality of life, tooth injury

1 | INTRODUCTION

Traumatic dental injuries (TDIs) are a common condition in up to 20% of children and adolescents, given their greater participation in recreational and sports activities.[1,2] Given their relevant prevalence and consequences, they are a public health issue to be taken into consideration.[3]

Oral injuries can cause aesthetic, psychological, social, functional and therapeutic problems, not only at the time of the accident, but also during later treatment.[4] Children with TDIs can experience emotional stress, pain and discomfort affecting their oral health-related quality of life (OHRQoL).[5-7]

Oral health-related quality of life is defined as a multidimensional concept which includes a subjective evaluation of the individual's oral health, functional well-being, expectations and satisfaction with care, and sense of self.[8] The measurement of OHRQoL together with clinical indicators can provide a more comprehensive assessment of the patient's oral health.[9] The first OHRQoL questionnaire designed for children was the child oral health quality of life questionnaire (COHQoL), which is composed by the child perceptions questionnaire (CPQ) for ages 11-14, published in 2002,[10] with a version for younger children aged 8-10[11]; the Parental Perceptions of Child Oral Health-related Quality of Life (P-CPQ)[12]; and the Family Impact Scale (FIS).[13] Later, the Child Oral Impact on Daily Performance Index (Child-OIDP) and the child oral health impact profile (Child-OHIP) were developed for schoolchildren.[14,15] Questionnaires for preschoolers using parental proxy report have appeared more recently: the Early Childhood Oral Health Impact Scale (ECOHIS) was published in 2007 and the Scale of Oral Health Outcomes for 5-year-olds (SOHO-5) in 2012.[16,17]

Investigators are increasingly measuring OHRQoL to assess the impact of a wide range of oral and orofacial conditions in children. As a consequence of this interest, systematic reviews of malocclusion,[18] cleft lip and/or palate,[19] orthodontic treatment[20] and TDIs[21] have been undertaken. The latter focused on studies of the preschool children using the ECOHIS questionnaire. The review authors concluded that there is a moderate quality of evidence suggesting a significant impact on OHRQoL of TDIs in the primary dentition.[21] However, it neither evaluated schoolchildren, nor considered studies measuring OHRQoL with other questionnaires developed for this purpose.

Accordingly, the research question to answer is: How do TDIs affect the OHRQoL of preschoolers and schoolchildren, and which specific OHRQoL domains are affected? The aim of this study was to assess the impact of TDIs on preschoolers' and schoolchildren's OHRQoL by synthesizing the available evidence through a systematic review approach.

2 | MATERIALS AND METHODS

Systematic review of the literature reported according to the guidelines of the preferred reporting items for systematic reviews and meta-analyses (PRISMA).[22]

Searches for eligible articles were undertaken in MEDLINE (January 1966-March 2016), EMBASE (January 1974-March 2016), Cochrane Library (The Cochrane Library 2016), Lilacs (January 1982-March 2016) and SciELO (January 1998-March 2016). The search strategy used in PubMed was as follows: (((((((tooth) OR dental)) AND (((((injur*) OR traumatology) OR "Traumatology"[Mesh]) OR ("Wounds and Injuries"[Mesh])) OR trauma)))) AND (((((((QoL[tiab]) OR HQoL[tiab]) OR OHQoL[tiab]) OR OHRQoL[tiab]) OR HRQoL[tiab]) OR Quality of Life[tiab]) OR "Quality of Life"[Mesh])) AND ((((((adolescent*[tiab]) OR teen*[tiab]) OR child*[tiab]) OR infant*[tiab]) OR "Adolescent"[Mesh]) OR "Child"[Mesh]) OR "Infant"[Mesh]). All references identified were extracted to an EndNote X6 Database to facilitate their management and delete duplicates.

Included in the review were studies comparing OHRQoL between groups with and without TDIs, or complicated and uncomplicated TDIs; study samples composed of children and/or adolescents under 18 years of age; using validated instruments to measure OHRQoL; established criteria for the diagnosis of TDIs; and publications in English, Spanish, Portuguese, German or French.

Studies were excluded if they considered medically compromised participants; they measured only health-related quality of life without assessing OHRQoL; the study sample comprised adults and children without age group stratification; the study design was case report or case series with a sample of fewer than 10 patients; or they were not primary studies.

Two members of the study team (CZ and JA) independently reviewed articles found in the literature searches by examining them in the three consecutive phases of titles, abstracts and full-text revision. A third reviewer (MMZ) resolved discrepancies. Data extraction and methodological quality assessment of the studies were conducted by agreement of two reviewers (CZ and JA) using a standardized, predefined data collection form. A pilot test using six potentially eligible articles was performed to homogenize criteria among reviewers throughout the whole process. Neither authors nor journals were blinded to reviewers. Finally, the reference lists of the selected articles and those of previous systematic reviews were checked to identify other possible studies that could be included. Coding for inclusion and exclusion criteria was defined and recorded for each phase.

The information extracted was publication data, study design, sample size, patient characteristics, TDI diagnostic criteria, OHRQoL instrument used and findings obtained from each group (event frequency, mean and standard deviation of global and domain scores, odds ratios and confidence intervals [CIs]). Finally, to take into account TDI severity, "complicated TDIs" were defined as injuries involving exposure of the pulp tissue and/or dislocation of the tooth, and "uncomplicated TDIs" as those in which the pulpal tissue was not exposed and the tooth was not dislocated (crown fracture of only enamel, crown fracture of enamel, and dentine or tooth discoloration).

We contacted study authors by e-mail to obtain additional information when data were missing or unclear. The studies' methodological quality was assessed with the Effective Public Health Practice

Project's (EPHPP) Quality Assessment Tool for Quantitative Studies, which has the six components of selection bias, study design, confounders, blinding, data collection methods and withdrawals/dropouts. Each component was classified as "strong," "moderate" or "weak," and a global rating was obtained according to the number of components rated as weak (0, 1, or >1).[23]

2.1 | Data synthesis

When OHRQoL results were reported as scores (continuous variables) in the included studies, the standard mean difference (SMD) between the group of individuals with TDIs and controls was calculated and pooled by meta-analysis. The SMD allows combining data from studies using different OHRQoL instruments.[24] When the authors reported OHRQoL data as a dichotomous variable describing the presence or absence of any negative impact, the odds ratios (OR) were calculated and pooled. We combined adjusted OR published in the studies using the generic inverse variance method.

For all measures, forest plots were constructed showing the summary and 95% CI estimated in the meta-analyses, together with results from individual studies. We used a random effect model (DerSimonian-Laird method), as we expected variation in effects due to differences in study populations, questionnaires and methods. Meta-analyses were conducted separately for preschoolers (<6 years old) and schoolchildren (6-15 years old). Testing by the studies' subgroups was performed according to the OHRQoL questionnaire used, because it could be a relevant source of heterogeneity, and a sensitivity analysis, excluding studies that used OHRQoL questionnaires designed for adults and weak methodological quality, was planned.

Heterogeneity among studies was evaluated using the I^2 statistic categorized as follows: <30% not important; 30%-50% moderate; 50%-75% substantial; and 75%-100% considerable.[24] Data were not pooled if I^2 was over 75%. To explore possible publication bias, a funnel plot was planned when the number of studies pooled was ≥10. The software used was Review Manager 5.3 (Cochrane IMS, Copenhagen, Denmark).

3 | RESULTS

Figure 1 shows the PRISMA diagram of the literature flow chart in our review. The search identified 237 citations. Once 24 duplicates were excluded, 213 titles and 68 abstracts were reviewed, 39 articles were fully read, and finally 30 articles were included. Of the 39 full-text articles reviewed, three were excluded due to the lack of a suitable control group,[5,25,26] two because TDIs diagnostic criterion was not specified,[27,28] two for only assessing family impact,[29,30] and two studies because they also included adults and results were not stratified by age.[31,32] Agreement between the two reviewers during the 3 phase process was good (k = 0.735).

The main characteristics of the included studies are presented in Table 1 (ordered by year of publication). The 30 articles identified correspond to 26 studies, because 4 studies were reported in more than one article.[35,39,49,53] Most were published after 2011, 21 were cross-sectional studies comparing groups with and without TDIs, 4 were case-control, and 1 was a case-control nested in a cross-sectional study. Most studies were carried out in Brazil, two in Canada and Peru and only one study from India and the United Kingdom. Ten studies were conducted on preschoolers (<6 years) and 16 on schoolchildren aged 8-15 years. Andreasen's TDIs diagnostic criterion was most commonly applied (12 studies), followed by O'Brien (8 studies), WHO (4 studies) and Glendor criteria (2 studies).

All preschooler studies used the ECOHIS, except one with the SOHO-5. In schoolchildren, the most frequent OHRQoL questionnaire was the CPQ11-14 (10 studies): the full version, the 16-item and the 10-item short forms in 4, 4 and 2 studies, respectively. The CPQ8-10 was implemented in two studies, the Oral impact on daily performance for children (Child-OIDP) in three and the original OIDP designed for adults in one.

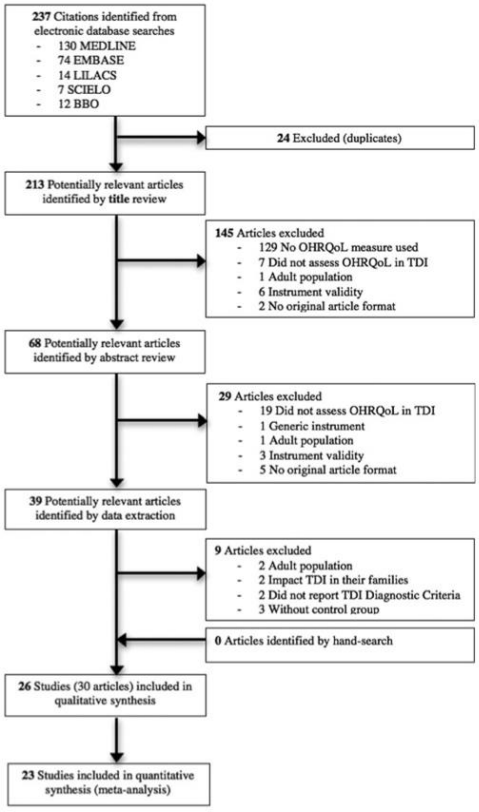

FIGURE 1 Flow chart of systematic literature review

TABLE 1 Characteristics of included studies

References	Country	Study design	Setting	Age range	Sample size (response rate; %)	TDIs diagnostic criteria	OHRQoL instrument (Age)	End points provided (measure of effects)
Cortes et al[33]	Brazil	CC	School	12-14	204	O'Brien	OIDP (>18 y)	Any impact (OR)
Locker et al[34]	Canada	CS	Hospital	11-14	370	O'Brien	CPQ11-14 ISF 10 (11-14 y)	None
Fakhruddin et al[7]	Canada	CC	School	12-14	270	O'Brien	CPQ11-14 ISF 10 (11-14 y)	Any impact (OR)
Aldrigui et al[35] Abanto et al[36]	Brazil	CS	Dental school	2-5	260 (85.2)	Andreasen	ECOHIS (0-5 y)	Global score (SMD) Scores of 4 dimensions (SMD)
Castro et al[37]	Brazil	CS	School	11-14	571 (89.2)	Andreasen	Child-OIDP (11-12 y)	Global score (SMD)
Piovesan et al[38] Piovesan et al[39]	Brazil	CS	School	12	792 (90)	O'Brien	CPQ11-14 (11-14 y)	Global score (SMD) Scores of 4 dimensions (SMD)
Paula et al[40]	Brazil	CS	School	12	515	WHO	CPQ11-14 (11-14 y)	None
Traebert et al[41]	England	CS	School	11-14	403 (98.5)	O'Brien	CPQ11-14 ISF 16 (11-14 y)	Any impact (OR) Global score (SMD) Scores of 4 dimensions (SMD)
Viegas et al[42]	Brazil	CS	Preschool	5	388 (94)	Andreasen	ECOHIS (0-5 y)	Any impact (OR)
Antunes et al[43]	Brazil	CC	School	10-15	50	WHO	CPQ11-14 ISF 16 (11-14 y)	Any impact (OR) Global score (SMD) Scores of 4 dimensions (SMD)
Basavaraj et al[44]	India	CS	School	12-15	900 (100)	WHO	Child-OIDP (11-12 y)	Any impact (OR)
Dame-Teixeira et al[45]	Brazil	CS	School	12	1528 (83.2)	O'Brien	CPQ11-14 ISF 16 (11-14 y)	Global score (SMD) Scores of 4 dimensions (SMD)
Kramer et al[46]	Brazil	CS	Preschool	2-5	1036 (90.2)	Andreasen	ECOHIS (0-5 y)	Any impact (OR) Global score (SMD) Scores of 4 dimensions (SMD)
Siqueira et al[47]	Brazil	CS	Preschool	3-5	814 (94.2)	Andreasen	ECOHIS (0-5 y)	Any impact (OR)
Abanto et al[6]	Brazil	CS	Dental school	1-4	1215 (94)	Glendor	ECOHIS (0-5 y)	Global score (SMD) Scores of 4 dimensions (SMD)
Abanto et al[48]	Brazil	CS	Dental school	5-6	335 (85)	Glendor	SOHO-5 (5 y)	Global score (SMD)
Bendo et al[30] Bendo et al[49]	Brazil	CC nested in CS	School	11-14	1215 (86.2)	Andreasen	CPQ11-14 ISF 16 (11-14 y)	Any impact (OR)
Gomes et al[50]	Brazil	CS	Preschool	3-5	843 (97.5)	Andreasen	ECOHIS (0-5 y)	Any impact (OR) Global score (SMD) Scores of 4 dimensions (SMD)
Ramos-Jorge et al[51]	Brazil	CS	School	11-14	668 (94.1)	O'Brien	Child-OIDP (11-12 y)	Any impact (OR)
Schuch et al[52]	Brazil	CS	School	8-10	750 (69)	O'brien	CPQ8-10 (8-10 y)	Global score (SMD)
Viegas et al[53] Scarpelli et al[54]	Brazil	CS	Preschool	5	1632 (96.28)	Andreasen	ECOHIS (0-5 y)	Any impact (OR) Global score (SMD) Scores of 4 dimensions (SMD)

(Continues)

TABLE 1 (Continued)

References	Country	Study design	Setting	Age range	Sample size (response rate; %)	TDIs diagnostic criteria	OHRQoL instrument (Age)	End points provided (measure of effects)
Apaza-Ramos et al[55]	Perú	CS	School	11-14	131	WHO	CPQ11-14 (11-14 y)	Global score (SMD) Scores of 4 dimensions (SMD)
Feldens et al[56]	Brazil	CS	Preschool	1-5	1275 (88.4)	Andreasen	ECOHIS (0-5 y)	Any impact (OR) Global score (SMD)
Freire-Maia et al[57]	Brazil	CS	School	8-10	1210 (83.8)	Andreasen	CPQ8-10 (8-10 y)	None
Pulache et al[58]	Peru	CS	School	11-14	473 (93.8)	Andreasen	CPQ11-14 (11-14 y)	Global score (SMD) Scores of 4 dimensions (SMD)
Vieira-Andrade et al[59]	Brazil	CC	Preschool	3-5	335	Andreasen	ECOHIS (0-5 y)	Any impact (OR)

OHRQoL - Oral Health-related Quality of Life; TDI - Traumatic dental injurie; CC - Case Control; CS cross-sectional.

The methodological quality (Figure 2) was qualified as moderate in most studies. "Selection bias" and "Data collection methods" were the best evaluated components (mostly strong), because the sample was randomly selected from schools in most studies, and all of them used a valid and reliable instrument to assess the primary outcome, OHRQoL (considered an eligibility criterion). "Study design" was predominantly qualified as weak because it was cross-sectional, except for the five case-control studies (moderate). None was qualified as strong because no longitudinal study was identified, and subsequently, the "Withdrawal/dropout" component was not applicable. The quality of "Confounders" component was qualified as strong for the five case-control studies, which were controlled by matching. All cross-sectional studies were adjusted for confounders in the analysis: fifteen performed adjusted analysis for TDIs (strong), although adjusted estimators of five could not be included in any meta-analysis due to outcomes underreporting; and the other six studies were qualified as moderate because the specific analysis for TDIs was not adjusted. Finally, "Blinding" was qualified as moderate due to most studies not reporting whether the dental examination and OHRQoL questionnaire administration were independently performed.

3.1 | Global impact on OHRQoL

Figure 3A shows results from studies with preschoolers. Six studies reported the mean of ECOHIS total score and one study the mean of SOHO-5 total score from preschoolers including 1841 patients and 4582 controls. Test for subgroups showed that the difference in results from these two questionnaires was not significant ($P = .95$). The pooled SMD between the TDIs group and the control was not significant (0.06; 95% CI: −0.02 to 0.13), and heterogeneity was moderate ($I^2 = 36\%$). Seven studies, all performed with the ECOHIS instrument, analysed the dichotomous variable presence/absence of any impact on OHRQoL in 2049 patients and 4270 controls: the pooled OR (1.38) was statistically significant (95% CI: 1.10-1.73) and heterogeneity was substantial ($I^2 = 68\%$). The meta-analysis from adjusted data confirmed this result (OR: 1.44; 95% CI: 1.28-1.63; $I^2 = 0$).

Figure 3B shows forest plots for studies with schoolchildren. No pooled data of the meta-analyses carried out with all these studies was provided because the heterogeneity was considerable when calculating pooled SMD ($I^2 = 80\%$) and OR ($I^2 = 86\%$). In the sensitivity analysis of ORs meta-analysis, the heterogeneity diminished to $I^2 = 59\%$ after excluding one study which had been performed with the OIDP designed for adults.[33] In this case, data showed that OHRQoL was significantly affected by TDIs (OR: 1.61; 95% CI: 1.16-2.23). Results from adjusted data confirmed that TDIs have more chance of reporting any impact in OHQoL than controls (OR: 1.31; 95% CI: 1.04-1.66; $I^2 = 70\%$).

3.2 | Domains affected

Eleven studies in total were included in the meta-analyses of the four OHRQoL domains (Figure 4). The instrument used was the ECOHIS in 5 studies with preschoolers (1566 patients and 3416 controls) and the CPQ11-14 in 6 studies with schoolchildren (462 patients and 2870 controls). No OHRQoL domain score presented statistically significant differences between the TDIs group and controls in studies with preschoolers (Figure 4A). In studies with schoolchildren (Figure 4B), the pooled SMD was statistically significant for the social domain (0.34; 95% CI: 0.13-0.55; $I^2 = 68\%$) but not for the symptom one. Due to high heterogeneity, pooled SMD was not shown for symptom domain in preschoolers and for functional and psychological domains in schoolchildren (I^2 was 79%, 78% and 85%, respectively).

3.3 | Severity of traumatic dental injuries

Figure 5 shows meta-analyses carried out with studies on preschoolers, which showed negligible heterogeneity ($I^2 = 0\%$): the complicated TDI group was significantly more likely to have any impact on OHRQoL than the group without TDIs (pooled OR = 1.58, 95% CI:

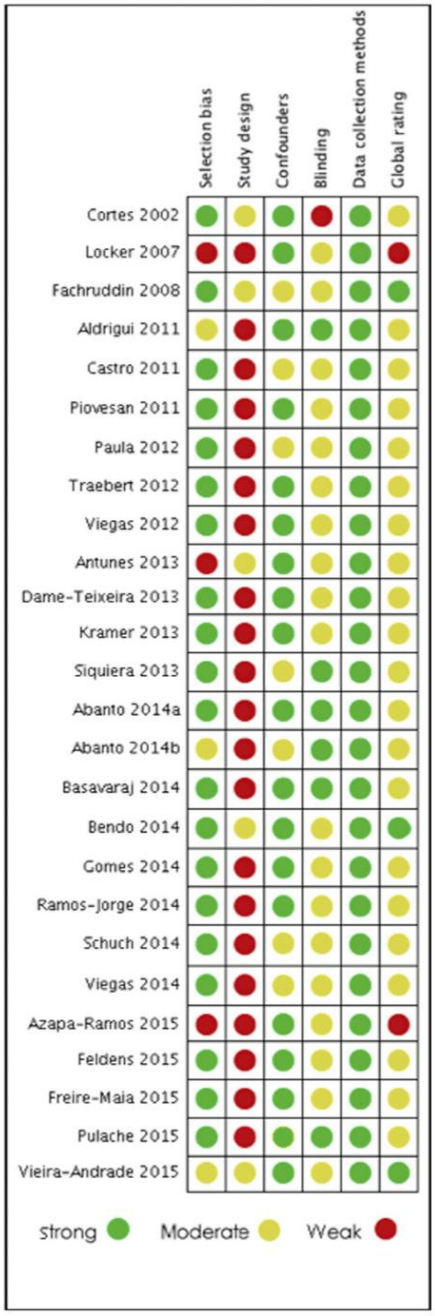

FIGURE 2 Summary of risk of bias of the included studies

1.08-2.31) and the group with uncomplicated TDIs (pooled OR = 1.53, 95% CI: 1.04-2.26). The only study which compared complicated TDIs with controls in schoolchildren[49] also showed that they had a greater chance of having a highly negative impact on OHRQoL. This study, however, defined complicated TDIs as those with fractures involving dentine and/or the pulp, which differs slightly from the definition used in our systematic review (injuries involving exposure of the pulp tissue and/or dislocation of the tooth).

4 | DISCUSSION

The evidence linking OHRQoL with TDIs has been mostly published in the period 2011-2015. This systematic review identified 26 studies that met the inclusion criteria with 18 183 participants in total: 4582 patients with TDIs and 13 601 controls. Both meta-analyses performed in preschoolers and schoolchildren studies (with 3745-6423 and 3310-3332 participants, respectively, according to the outcome considered) showed the impact of TDIs on OHRQoL. Our findings also identify the social domain as the most affected in schoolchildren, and the association between OHRQoL and severity of TDIs. Furthermore, their increasing prevalence during the past few decades has made TDIs one of the most common reasons for seeking emergency treatment.[2,3,60]

Preschoolers with TDIs did not have worse OHRQoL total or domain scores than controls, but the significantly higher pooled OR indicate a greater chance of reporting any OHRQoL impact. This agrees with the systematic review by Borges et al[21], which concluded that TDIs negatively impact on the OHRQoL of preschool children, but TDIs do not seem to have an impact on the family. Furthermore, confirming our hypothesis, complicated TDIs were associated with a higher OHRQoL impact chance: 53% and 58% relative to uncomplicated TDIs or controls, respectively. Patients with complicated TDIs suffer more symptoms, require multiple and complex procedures and need a higher number of clinical and radiographic follow-up.[61]

Generally, preschoolers do not self-complete the OHRQoL questionnaires; instead, they are usually answered by parents as main caregivers. On the one hand, a previous systematic review[62] has shown that parents may underestimate the impact of children's oral problems, because they have a different perspective and limited knowledge about some aspects, particularly those related to social and emotional well-being. Additionally, parents underestimate the importance of primary teeth, unless the children suffer severe TDIs involving other tissues.[62] On the other hand, oral conditions have an indirect impact on parents and family members, because they result in lost workdays or in having to spend time and money on dental care.[63] It is important to highlight that the SOHO-5 is the only questionnaire which has a child self-report and a parental report to be used in children 5-6 years of age who are able to participate in an interview. In contrast with the impact underestimation by parents highlighted in the previous systematic review,[62] a study with the SOHO-5 questionnaire has obtained similar OHRQoL rates from parents and their children.[64]

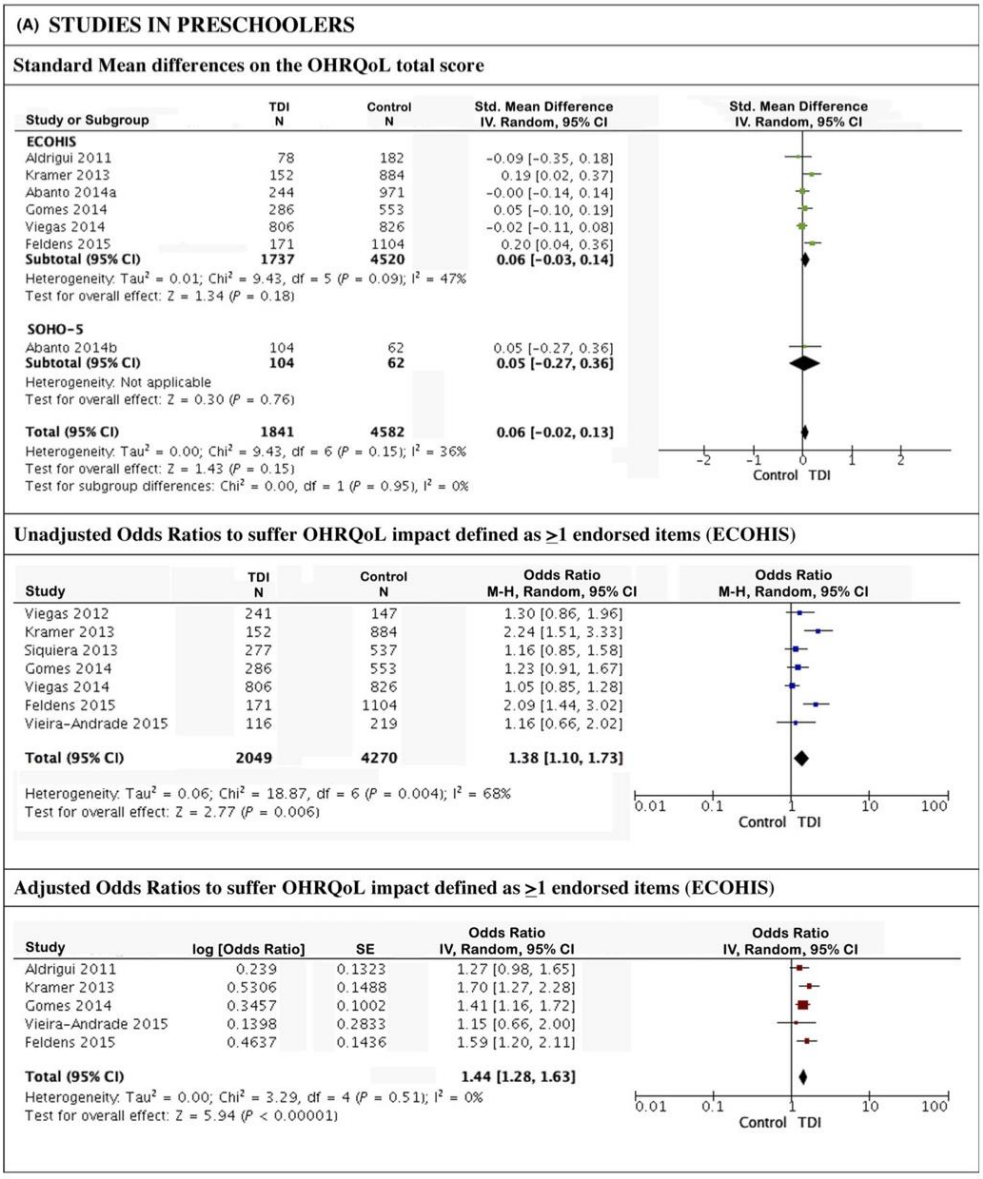

FIGURE 3 Synthesis of comparison between traumatic dental injuries and control groups by meta-analysis of results using the total score oral health-related quality of life instrument

Turning to the schoolchildren, the meta-analyses showed that their OHRQoL was significantly affected by TDIs, especially in the social domain. The pooled OR indicates that patients with TDIs presented 31% more chance of reporting any OHRQoL impact than controls, and the pooled SMD in the social score (0.34) shows that the magnitude of impact in this domain is between small and moderate (0.2-0.5). An a

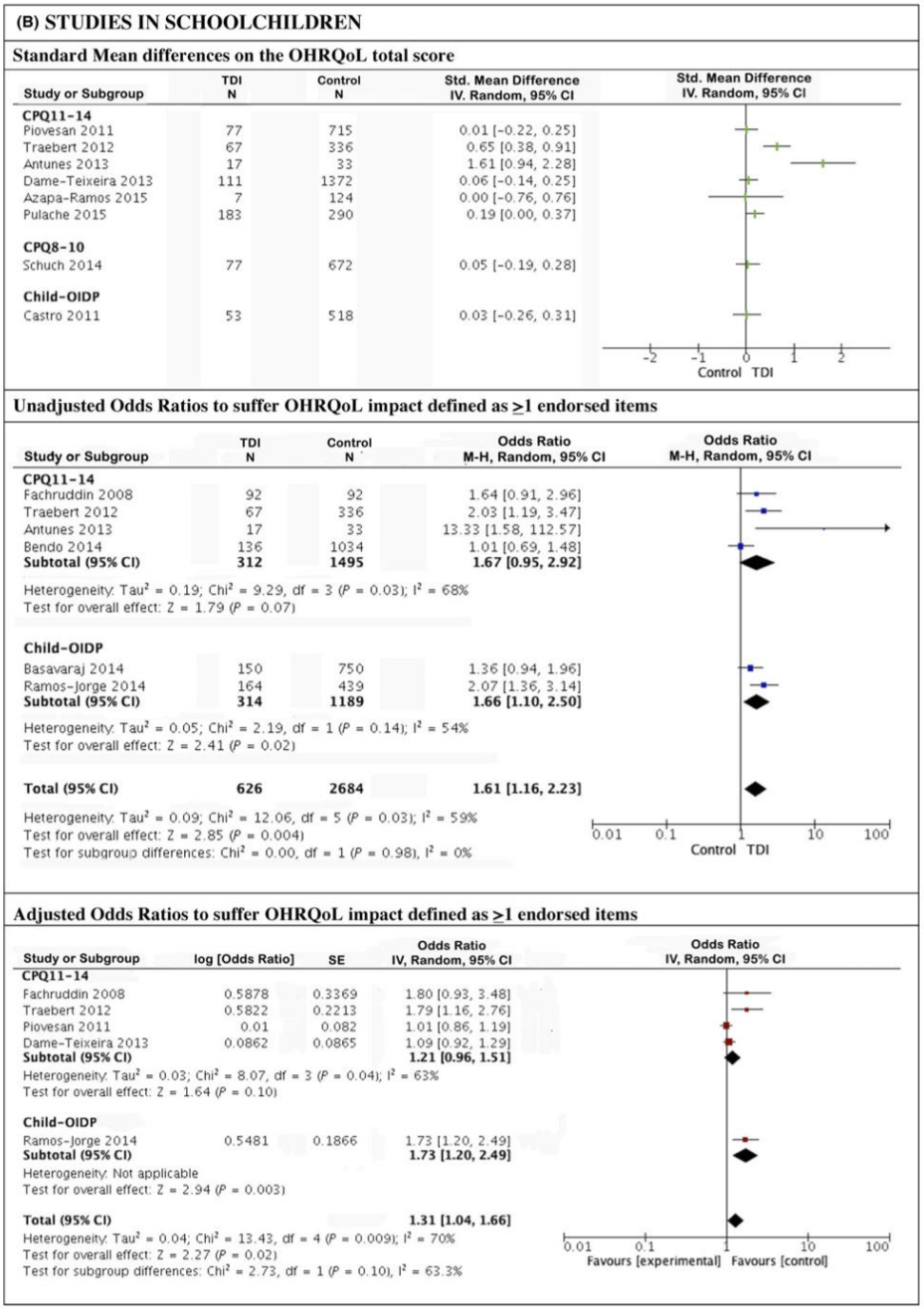

FIGURE 3 Continued

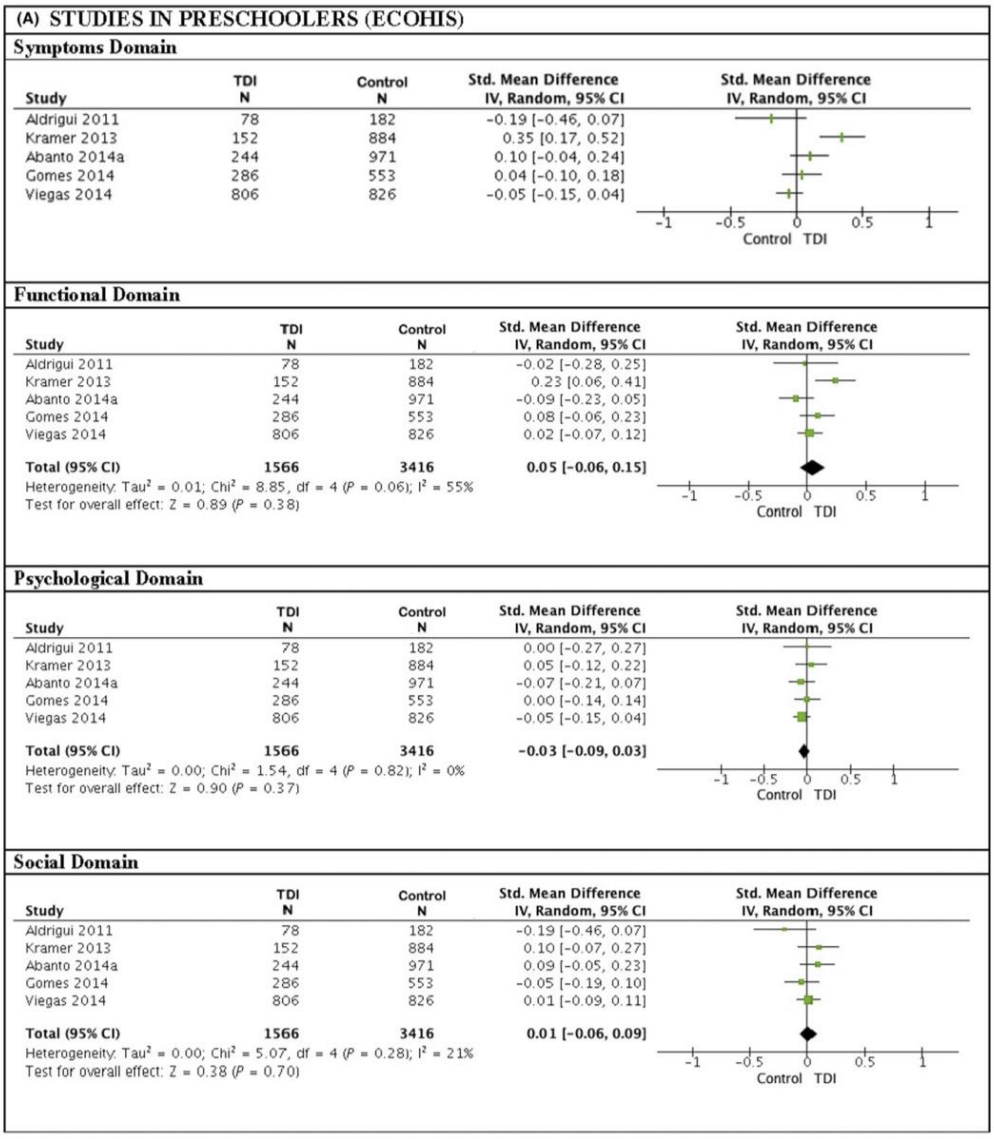

FIGURE 4 Meta-analysis of standard mean differences on oral health-related quality of life domains' scores between traumatic dental injuries and control groups

priori hypothesis of the psychological domain as the one mainly affected could not be tested due to the high heterogeneity of this meta-analysis, which prevented the interpretation of a pooled estimator: two studies reported significant differences of large magnitude (SMD > 0.7), while the other four described negligible ones (−0.03 to 0.13). Unlike preschoolers, schoolchildren complete their own OHRQoL questionnaire in the studies included. The evidence shows that adolescents report a worse OHRQoL than their parents, especially in functional and social domains.[65] This is expected, since it is during adolescence that children integrate the idea of aesthetic health as part

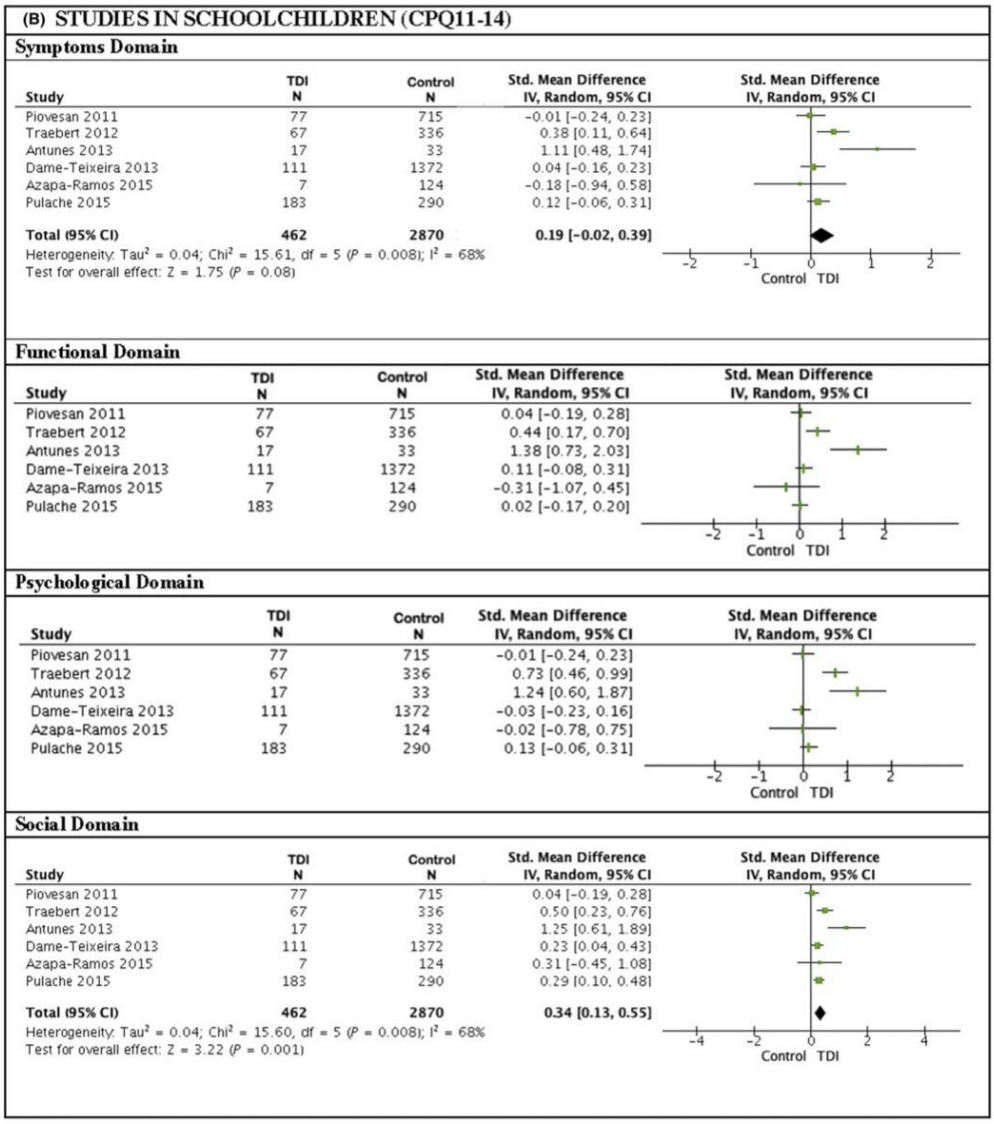

FIGURE 4 Continued

of their self-esteem.[66] On the other hand, a gap that merits being highlighted is the lack of knowledge concerning schoolchildren aged 6-10 years, because only two studies included those aged 8-10 years, and none assessed children aged 6-7 years.

Heterogeneity was considerable ($I^2 > 75\%$) in four meta-analyses: one with studies on preschoolers (symptoms domain, $I^2 = 79\%$) and three with schoolchildren. The three latter were those constructed with the total OHRQoL score ($I^2 = 86\%$), the functional domain ($I^2 = 81\%$) and the psychological one ($I^2 = 88\%$). The only study clearly out of the pattern in these three meta-analyses among schoolchildren was the one published by Antunes et al[43] in 2013, which differs from the others in having a case-control design and a

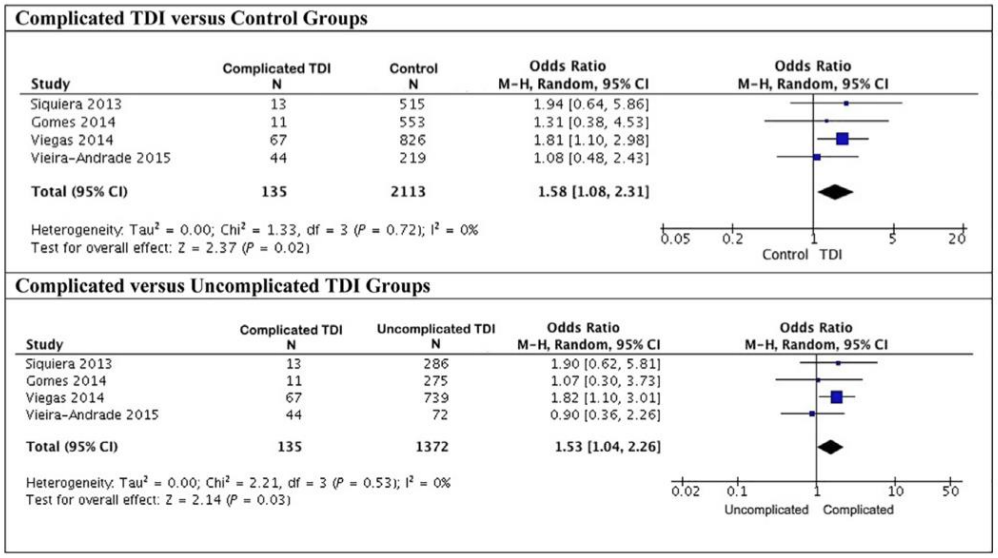

FIGURE 5 Meta-analysis of odds ratios to suffer oral health-related quality of life impact defined as ≥1 endorsed items to assess complicated traumatic dental injuries in preschooler

small sample size (50 subjects). On the other hand, although variety in OHRQoL instruments was anticipated as a relevant source of heterogeneity, it was not a major problem because most of the studies used the same instrument: the ECOHIS in preschoolers and the CPQ11-14 in schoolchildren. Furthermore, no test for subgroup differences was statistically significant ($P = .95$ and $P = .98$), indicating that age-specific instruments could provide comparable measures.

As continuous scores are generally proposed for OHRQoL instruments, two strategies of analysis were applied in these studies: testing between groups' differences in score means, as well as in proportions of patients reporting any impact. In this latter strategy of analysis, the cut-off point selected to dichotomize the continuous variable could affect the prevalence of OHRQoL impacts, which is dependent on the case definition used. Prevalence could be overestimated in the studies included in our review, given the use of the lowest cut-off point (at least one item). Further research is needed to select the most adequate cut-off point to define OHRQoL impact. On the other hand, using different complementary OHRQoL outcomes, such as continuous scores and dichotomized variables, may improve the interpretation of data.[67]

We identified some limitations in our review process that deserve to be commented on. First, there is the possibility that we failed to identify all articles to assess the impact of TDI on children's OHRQoL. However, we believe that this was minimized due to the sensitive search strategy used, the additional search of references by hand and the double independent review process used. Second, three cross-sectional studies could not be included in any of the meta-analyses mainly because of the lack of the specific estimator needed, but their data were consistent with our findings.[34,40,57] Third, the internal validity of the summary provided by a meta-analysis depends on the quality of primary studies. In our systematic review, sensitivity analysis by quality assessment was not performed because the risk of bias was very homogeneous among studies. Quality was considered only moderate for most of them, mainly because the cross-sectional design is considered weak, but all other criteria were principally rated as being of strong quality. Despite the experimental design not being possible in this field, observational prospective studies are needed to evaluate with the best scientific evidence the impact of TDIs on patients' OHRQoL by measuring it before and after trauma. Fourth, caution should be exercised when generalizing the findings, because most of the studies come from Brazilian populations. Finally, because we did not have more than 10 studies to pool in any meta-analysis, funnel plots to explore possible publication biases were not constructed.

5 | CONCLUSIONS

Traumatic dental injuries have a negative impact on OHRQoL in minors, both preschoolers and schoolchildren, and even more if the TDIs involve exposure of the pulp tissue and/or dislocation of the tooth. A standardization of the outcomes to measure TDIs' impact on

children's OHRQoL, such as score mean differences and suitable cut-off points, is needed. Well-designed prospective cohort studies with long-term follow-up are required to confirm the findings reported in this review and to understand how TDIs' impact changes with time.

ACKNOWLEDGEMENTS

Carlos Zaror is a PhD candidate in Methodology of Biomedical Research and Public Health program, Universitat Autònoma de Barcelona, Barcelona, Spain. María José Martínez and Carlos Zaror were awarded CONICYT/MEC grant no 800140042. María José Martínez is funded by a Miguel Servet research contract from the Instituto de Salud Carlos III and European Social Fund (CP15/00116).Montse Ferrer is partially funded by the Departament d'Innovació, Universitats i Empresa, Generalitat de Catalunya (2014 SGR 748). We would like to acknowledge Aurea Martin for her help in the English editing process and figure edition of this manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest.

COMPLIANCE WITH ETHICAL STANDARDS

This article does not contain any studies with human participants or animals performed by any of the authors.

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How to cite this article: Zaror C, Martínez-Zapata MJ, Abarca J, et al. Impact of traumatic dental injuries on quality of life in preschoolers and schoolchildren: A systematic review and meta-analysis. *Community Dent Oral Epidemiol*. 2017;00:1-14. https://doi.org/10.1111/cdoe.12333

Artículo 3: Dorri M, Martinez-Zapata MJ, Walsh T, Marinho VCC, Sheiham A, Zaror C. Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries. Cochrane Database Syst Rev 2017;12:CD008072. (IF:6.264; Q1)

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Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries (Review)

Dorri M, Martinez-Zapata MJ, Walsh T, Marinho VCC, Sheiham (deceased) A, Zaror C

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Cochrane Database of Systematic Reviews 2017, Issue 12. Art. No.: CD008072.
DOI: 10.1002/14651858.CD008072.pub2.

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[Intervention Review]

Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

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Editorial group: Cochrane Oral Health Group.
Publication status and date: New, published in Issue 12, 2017.

Citation: Dorri M, Martinez-Zapata MJ, Walsh T, Marinho VCC, Sheiham (deceased) A, Zaror C. Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries. *Cochrane Database of Systematic Reviews* 2017, Issue 12. Art. No.: CD008072. DOI: 10.1002/14651858.CD008072.pub2.

ABSTRACT

Background

Dental caries is a sugar-dependent disease that damages tooth structure and, due to loss of mineral components, may eventually lead to cavitation. Dental caries is the most prevalent disease worldwide and is considered the most important burden of oral health. Conventional treatment methods (drill and fill) involve the use of rotary burs under local anaesthesia. The need for an electricity supply, expensive handpieces and highly trained dental health personnel may limit access to dental treatment, especially in underdeveloped regions.

To overcome the limitations of conventional restorative treatment, the Atraumatic Restorative Treatment (ART) was developed, mainly for treating caries in children living in under-served areas of the world where resources and facilities such as electricity and trained manpower are limited. ART is a minimally invasive approach which involves removal of decayed tissue using hand instruments alone, usually without use of anaesthesia and electrically driven equipment, and restoration of the dental cavity with an adhesive material (glass ionomer cement (GIC), composite resins, resin-modified glass-ionomer cement (RM-GICs) and compomers).

Objectives

To assess the effects of Atraumatic Restorative Treatment (ART) compared with conventional treatment for managing dental caries lesions in the primary and permanent teeth of children and adults.

Search methods

Cochrane Oral Health's Information Specialist searched the following databases: Cochrane Oral Health's Trials Register (to 22 February 2017), the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, 2017, Issue 1), MEDLINE Ovid (1946 to 22 February 2017), Embase Ovid (1980 to 22 February 2017), LILACS BIREME Virtual Health Library (Latin American and Caribbean Health Science Information database; 1982 to 22 February 2017) and BBO BIREME Virtual Health Library (Bibliografia

Brasileira de Odontologia; 1986 to 22 February 2017). The US National Institutes of Health Trials Registry (ClinicalTrials.gov) and the World Health Organization International Clinical Trials Registry Platform were searched for ongoing trials. No restrictions were placed on the language or date of publication when searching the electronic databases.

Selection criteria

We included randomised controlled trials (RCTs) with at least six months' follow-up that compared the effects of ART with a conventional restorative approach using the same or different restorative dental materials to treat caries lesions.

Data collection and analysis

Two review authors independently screened search results, extracted data from included studies and assessed the risk of bias in those studies. We used standard methodological procedures expected by Cochrane to evaluate risk of bias and synthesise data. Where pooling was appropriate we conducted meta-analyses using the random-effects model. We assessed the quality of the evidence using GRADE criteria.

Main results

We included a total of 15 eligible studies randomising 3760 participants in this review. The age of participants across the studies ranged from 3 to 101 years, with a mean of 25.42 years. 48% of participants were male. All included studies were published between 2002 and 2016. Two of the 15 studies declared that the financial support was from companies that manufacture restorative material. Five studies were individually randomised parallel-group studies; six were cluster-randomised parallel-group studies; and four were randomised studies that used a split-mouth design. Eleven studies evaluated the effects of ART on primary teeth only, and four on permanent teeth. The follow-up period of the included studies ranged from 6 months to 36 months. We judged all studies to be at high risk of bias.

For the main comparison of ART compared to conventional treatment using the same material: all but two studies used high-viscosity glass ionomer (H-GIC) as the restorative material; one study used a composite material; and one study used resin-modified glass ionomer cement (RM-GIC)).

Compared to conventional treatment using H-GIC, ART may increase the risk of restoration failure in the primary dentition, over a follow-up period from 12 to 24 months (OR 1.60, 95% CI 1.13 to 2.27, five studies; 643 participants analysed; low-quality evidence). Our confidence in this effect estimate is limited due to serious concerns over risk of performance and attrition bias. For this comparison, ART may reduce pain during procedure compared with conventional treatment (MD -0.65, 95% CI -1.38 to 0.07; 40 participants analysed; low-quality evidence)

Comparisons of ART to conventional treatment using composite or RM-GIC were downgraded to very low quality due to indirectness, imprecision and high risk of performance and attrition bias. Given the very low quality of the evidence from single studies, we are uncertain about the restoration failure of ART compared with conventional treatment using composite over a 24-month follow-up period (OR 1.11, 95% CI 0.54 to 2.29; one study; 57 participants) and ART using RM-GIC in the permanent teeth of older adults with root caries lesions over a six-month follow-up period (OR 2.71, 95% CI 0.94 to 7.81; one study; 64 participants).

No studies reported on adverse events or costs.

Authors' conclusions

Low-quality evidence suggests that ART using H-GIC may have a higher risk of restoration failure than conventional treatment for caries lesions in primary teeth. The effects of ART using composite and RM-GIC are uncertain due to the very low quality of the evidence and we cannot rely on the findings. Most studies evaluated the effects of ART on the primary dentition.

Well-designed RCTs are required that report on restoration failure at clinically meaningful time points, as well as participant-reported outcomes such as pain and discomfort. Due to the potential confounding effects from the use of different dental materials, a robust body of evidence on the effects of ART compared with conventional treatment using the same restoration material is necessary. We identified four ongoing trials that could provide further insights into this area.

PLAIN LANGUAGE SUMMARY

Atraumatic restorative treatment (hand instruments only) compared with conventional treatment for managing tooth decay

Review question

The aim of this review is to evaluate the effects of a minimally invasive approach, namely Atraumatic Restorative Treatment (ART), for the treatment of tooth decay in children and adults (primary and permanent teeth).

Background

Dental caries (tooth decay) has been considered the most common global disease. Conventional methods (drill and fill) involve the use of electric drills to clear away decayed areas of tooth before filling. Local anaesthetic (painkiller) is normally injected to prevent pain during the procedure. Conventional treatments require highly trained dental health personnel, access to electricity, appropriate tools and are more expensive. These factors may limit access especially in underdeveloped regions of service provision.

Atraumatic Restorative Treatment (ART) is an alternative approach for managing dental decay, which involves removal of decayed tissue using hand instruments alone, usually without the use of anaesthesia (injected painkiller) and electrical equipment.

Study characteristics

This review searched the available evidence that was up to date at 22 February 2017. We found 15 relevant studies including 3760 participants with an average age of 25 years (range 3 to 101) where 48% were male. The follow-up period in the trials ranged from 6 to 36 months. Two of the 15 studies declared financial support from companies that made tooth-filling material. In addition, we found four ongoing studies.

Key results

There is low-quality evidence to suggest that primary teeth treated with the ART approach using high viscosity glass ionomer cement may be more likely than those receiving conventional treatment with the same material to result in restoration failure. In the treatment of primary teeth, ART may reduce pain experience compared with conventional treatment. The evidence available for evaluating the differences between ART and conventional treatments using other restorative materials or in permanent teeth is very low quality so we cannot draw any conclusions. None of the included studies reported on negative side effects or costs.

Quality of the evidence

The available evidence is low- to very low-quality. It is likely that further high-quality research may change our findings. There are four ongoing studies that may provide more information in the future.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Atraumatic restorative treatment (ART) using high-viscosity glass ionomer cement (H-GIC) compared with conventional restorative treatment using H-GIC for dental caries

Patient or population: people with dental caries
Settings: community settings and dental clinics
Intervention: ART using H-GIC
Comparison: conventional treatment using H-GIC

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Conventional treatment with H-GIC	ART with H-GIC			
Restoration failure (primary dentition) at 12 to 24 months	**471 per 1000**	**588 per 1000** (502 to 669)	**OR 1.60** (1.13 to 2.27)	643 participants/846 teeth (5 studies)	⊕⊕○○ **low** [1]
Pain	Mean pain (primary teeth) was 1.38 (SD 1.21)	Mean pain (primary teeth) was 0.73 (SD 1.14)	**MD 0.65 lower** (1.38 lower to 0.07 higher)	40 participants (1 study)	⊕⊕○○ **low** [2]
Adverse events	-	-	-	-	Not measured

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **MD:** mean difference; **OR:** odds ratio

GRADE Working Group grades of evidence
High quality: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Low quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Very low quality: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[1]We downgraded the evidence by two levels because of very serious concerns regarding risk of bias: we judged all five studies as high risk of performance bias, three studies as high risk of attrition bias, and two studies as high risk of reporting bias.
[2]We downgraded the evidence by one level because it is a single study (imprecision) and one level because of serious concern regarding high risk of performance bias.

BACKGROUND

Description of the condition

Dental caries

Dental caries is a sugar-dependent disease that damages tooth structure and may result in cavity formation in the hard tissues of the teeth (enamel, dentine and cementum) (Kidd 2005). Dental plaque is a biofilm formed on the tooth surface soon after tooth cleaning. It frequently contains caries-producing bacteria such as *Streptococcus mutans*. Such micro-organisms metabolise dietary sugars and produce acids on the tooth surfaces. The acid production could lead to the diffusion of calcium and phosphate ions and, consequently, demineralisation of enamel (Fejerskov 2004; Kidd 2004). If this process continues, loss of mineral components will eventually lead to cavitation.

Dental caries is the most prevalent disease worldwide (Marcenes 2013). Dental caries and its consequences are considered the most important burden of oral health. They are especially common in sociodemographically disadvantaged groups (Antoft 1999; Ekstrand 2007; Hannigan 2000; Martignon 2010; Petersen 2005; Schwendicke 2015; Sheiham 2010). It affects 60% to 90% of school-aged children and up to 100% of adults in most countries (Petersen 2005).The resultant pain and discomfort can negatively affect people's quality of life. Furthermore, the management of this condition imposes huge financial burden on society and individuals (Leal 2012).

Description of the intervention

The treatment of dental caries lesions can be either by conventional drill and fill approach, using rotary instruments, or the atraumatic approach, using only hand instruments. Different restorative materials may be used for these two approaches.

Conventional treatments

Conventional methods involve the use of rotary burs, alone or in conjunction with metal hand instruments (Weerheijm 1999). Various dental restorative materials are used, ranging from metal-based materials such as amalgam, the most popular dental restoration material, especially in the posterior teeth, to tooth-coloured materials, such as resin composites.

The pain and discomfort associated with conventional cavity preparation methods have resulted in many patients being reluctant to seek dental treatment (Berggren 1984). Local anaesthesia is frequently needed to control the pain associated with cavity preparation. Factors potentially responsible for the discomfort and pain include: the sensitivity of vital dentine; the pressure on the tooth caused by mechanical stimulation of the tooth by rotary devices; bone-conducted noise and vibration; the high-pitched noise of the rotary device; and development of high temperatures at the cutting surface (thermal stimulation) (Banerjee 2000). In addition, an important limitation of conventional restorative methods is that they require an electricity supply, expensive handpieces and highly trained dental health personnel. This approach has been shown to have an increased risk of pulp exposure, postoperative pulpal symptoms and the weakening of the tooth as result of more invasive caries removal (Ricketts 2013). These factors limit the use of conventional restorative dentistry in many underdeveloped areas, where facilities and trained human resources are scarce.

Atraumatic treatments

To overcome the limitations of conventional restorative treatment, Atraumatic Restorative Treatment (ART) was developed around 1985, mainly for treating caries in children living in under-served areas of the world where resources and facilities such as electricity and trained manpower are limited (Frencken 1996). ART is a minimally invasive approach, which involves removal of decayed tissue using hand instruments alone, usually without use of anaesthesia and electrically-driven equipment, and restoration of the dental cavity with an adhesive material (glass ionomer cement (GIC), composite resins, resin-modified glass-ionomer cement (RM-GICs) and compomers) (Tyas 2000).

Recently, modified ART approaches have been introduced, as opposed to 'true' ART as described above. These modified approaches involve opening the cavity with a drill, cleaning, restoring and finishing with hand instruments, or using alternative restorative materials including amalgam (Monse-Schneider 2003). Also, some studies applied ART-type GICs as pit and fissure sealants using different methods such as the press-finger method (Yip 2002a). These modified ART approaches are not considered to be 'true' ART (Holmgren 2013).

Apart from these modified approaches, the American Academy of Pediatric Dentistry (AAPD) (AAPD 2008-2009) introduced the Interim Therapeutic Restorations (ITR) approach, which uses almost the same technique as ART, although it may have different therapeutic goals. The ITR procedure involves removal of caries using hand or slow-speed rotary instruments, as opposed to ART, which uses only hand instruments, followed by restoration with an adhesive restorative material such as self-setting or resin-modified glass ionomer cement (RM-GIC). While ART is recognised as a permanent treatment, the AAPD regards ITR as a provisional technique. The ITR, according to AAPD, may be used "to restore and to prevent dental caries in young patients, uncooperative patients, patients with special health care needs, and situations in which traditional cavity preparation and/or placement of traditional dental restorations are not feasible; it may be used for caries control in children with multiple carious lesions prior to definitive restoration of the teeth" (AAPD 2008-2009). Based on the AAPD definition, if ITR is applied using hand instruments, and not rotary instruments, it can then be considered as a 'true' ART.

The advantages of ART compared with conventional restorative techniques using dental handpiece and burs include: provision of restorative dental treatment outside the dental surgery setting; a biologically friendly approach; minimal cavity preparations; low costs (Frencken 1999; Mjör 1999; Yip 2001; Yip 2002a); reduced risk for subsequent endodontics and tooth extraction (Anusavice 1999); and lower dental anxiety in children and adults (more 'patient-friendly') (Mickenautsch 2007; Schriks 2003). These advantages are particularly important in low-income countries, where electricity supplies are intermittent and people have difficulties accessing dental care. In addition, people who are elderly, medically-compromised (e.g. HIV infected) or dental phobic can have problems accessing dental care and could benefit from the ART approach (Cole 2000; Honkala 2002; Steele 2007).

Glass-ionomer cements (GICs) are the predominant restorative materials used for ART (Yip 2001). GIC restorative materials have advantages such as the ability to bond chemically to enamel and dentine, biocompatibility with pulpal tissue and less potential to induce recurrent caries, inhibition of enamel demineralisation, good cavity seal, ease of use, and low costs (Frencken 1996; Van 't Hof 2006). As shown by a recent Cochrane Review, the sealing-in effect of GICs apart from replacement of damaged tooth tissue, can help with the management of dental carious lesions (Dorri 2015). Although GICs have been the main material used, other adhesive materials include composite resins, RM-GICs and compomers.

How the intervention might work

As described, ART approach relies on removal of dental caries using hand instruments only, followed by restoration with an adhesive material. The adhesive restorative material prevents diffusion of acids from biofilms into the lesion or mineral out of the lesion, thereby arresting the lesions or reducing their progression. Furthermore, using hand instruments only, minimises iatrogenic damage to the intact tooth substance whilst removing carious tissue.

Why it is important to do this review

Cochrane Oral Health undertook an extensive prioritisation exercise in 2014 to identify a core portfolio of titles that were the most clinically important ones to maintain in the Cochrane Library (Worthington 2015). This review was identified as a priority title by the paediatric dentistry expert panel (Cochrane Oral Health priority review portfolio).

The ART approach seems to be an economic and effective method for improving the oral health not only of people in low-income countries, but also of those in high-income countries (Frencken 2004b). It may be considered as a minimally invasive alternative for conventional restorative dental treatment, particularly for Class I (occlusal) single-surface dental cavities. Because of the advantages claimed for ART, it is important to systematically review the evidence available.

The available systematic reviews on studies comparing the ART approach with conventional approach have limitations including: restricting the search to only one electronic database (MEDLINE) and English language studies (Frencken 2004a; Van 't Hof 2006); not assessing the quality of included studies (Van 't Hof 2006); only including permanent teeth and class I cavities (Frencken 2004a); inconsistency with PRISMA guidelines (Moher 2009) in several areas, such as protocol and registration, risk of bias across studies, reporting of limitations and funding (Frencken 2004a; Mickenautsch 2010; Pettar 2011). We aimed to systematically review randomised controlled trials comparing 'true' ART with conventional restorative approaches.

OBJECTIVES

To assess the effects of true Atraumatic Restorative Treatment (ART) compared with conventional treatments for managing dental caries lesions in the primary and permanent teeth of children and adults.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) with at least six months' follow-up that compared the effects of 'true' ART with a conventional restorative approach using the same or different restorative dental materials. Parallel-group, split-mouth and cluster-study design were eligible for inclusion.

Types of participants

We included dentate participants, regardless of their age and sex, with a history of dental (coronal or root) primary caries lesions extended into enamel and dentine (but not the pulp) and who have undergone restorative treatment using either conventional restorative or true ART approaches. We also considered primary and permanent teeth with single or multiple surface lesions.

Types of interventions

We included adhesive restorative materials, such as GICs with different viscosities or resins, placed with the 'true' ART approach, including ITR with hand instruments, compared with the same or

different restorative materials, such as GIC, placed with conventional cavity preparation methods. Only studies using the same restorative material in both arms were considered as key results and the other studies were included for completeness.
We excluded studies on modified ART techniques.

Types of outcome measures

Primary outcomes

- Restoration failure, that is, a lost or deficient restoration in the 1) primary dentition, 2) permanent immature dentition, 3) permanent mature dentition
- Pain (during and immediately after treatment expressed as intensity of pain or presence or absence of pain)

Secondary outcomes

- Adverse events
- Secondary caries
- Participant experience, for example, satisfaction or quality of life measured by self report, and discomfort, anxiety or stress measured by physiological means or behavioural observation
- Costs (direct) - cost of treatment
- Costs (indirect) - time off school or work to attend dental visits

Search methods for identification of studies

Electronic searches

Cochrane Oral Health's Information Specialist conducted systematic searches in the following databases for RCTs and controlled clinical trials. There were no language, publication year or publication status restrictions:

- Cochrane Oral Health's Trials Register (searched 22 February 2017) (Appendix 1);
- Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 1) in the Cochrane Library (searched 22 February 2017) (Appendix 2);
- MEDLINE Ovid (1946 to 22 February 2017) (Appendix 3);
- Embase Ovid (1980 to 22 February 2017) (Appendix 4);
- LILACS BIREME Virtual Health Library (Latin American and Caribbean Health Science Information database; 1982 to 22 February 2017) (Appendix 5);
- BBO BIREME Virtual Health Library (Bibliografia Brasileira de Odontologia; 1986 to 22 February 2017) (Appendix 6).

Subject strategies were modelled on the search strategy designed for MEDLINE Ovid. Where appropriate, they were combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying RCTs and controlled clinical trials as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Chapter 6 (Lefebvre 2011).

Searching other resources

The following trials registries were searched for ongoing studies:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov; searched 22 February 2017) (Appendix 7);
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; searched 22 February 2017) (Appendix 8).

Reference lists

Two review authors independently examined the reference lists of relevant trials in order to identify studies not identified in the previous searches.

Correspondence

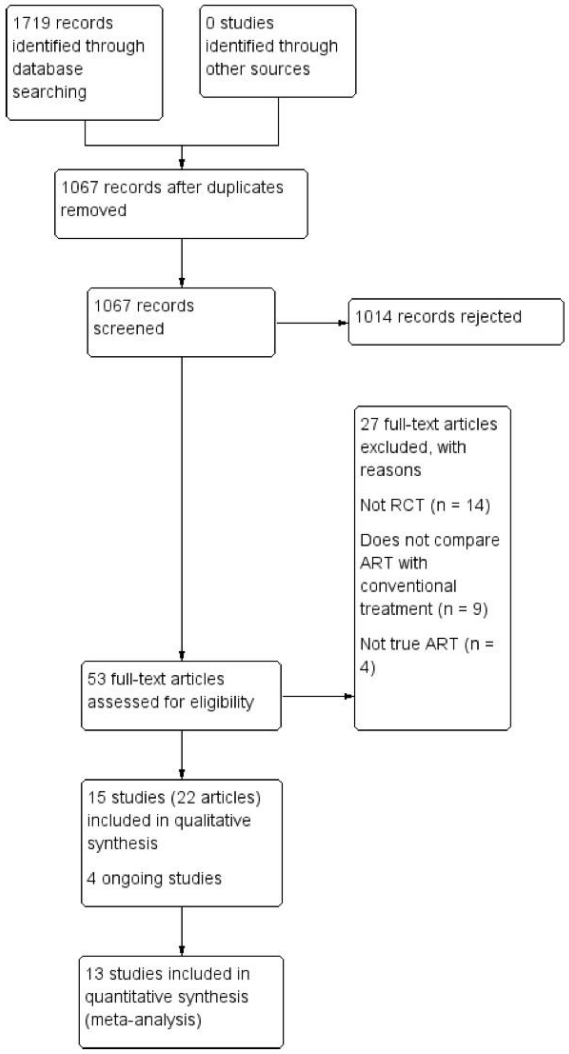
We contacted organisations, researchers and experts known to be involved in the field, either by phone, email or in person during scientific events, in an effort to trace unpublished or ongoing studies. We also contacted dental materials and equipment manufacturers to identify any ongoing or unpublished studies.
We did not perform a separate search for adverse effects of interventions used, we considered adverse effects described in included studies only.

Data collection and analysis

Selection of studies

We imported the downloaded set of records from each database to the bibliographic software package Endnote and merged them into one core database to remove duplicate records and to facilitate retrieval of relevant articles. We also obtained potentially relevant reports identified when searching other sources (reference lists of relevant trials, reviews, articles and textbooks). The records located from searching these (non-electronic) sources were entered manually in Endnote. All records identified by the searches were checked on the basis of title first, then by abstract or keywords or both. Two review authors independently assessed the eligibility of the full text of relevant records (Figure 1).

Figure 1. Study flow diagram



One review author (Mojtaba Dorri (MD)) assessed all the references. Two others researchers (Dominic Hurst (DH) and Carlos Zaror (CZ)) assessed the references to establish whether the studies met the inclusion criteria or not, using an inclusion criteria form, which had been prepared previously and pilot tested. We resolved disagreements by discussion. Had resolution not been possible, we would have consulted a third review author (Valeria Marinho (VM)).

The review authors could read reports in English, Persian, Arabic, Portuguese and Spanish. We identified two papers in Chinese and two papers in Dutch. The papers were translated by two translators who were native speakers and fluent in English. One of the authors (MD) compared two versions. The minor disagreements were resolved by discussion with the translators.

We contacted the authors of any articles we could not classify in order to ascertain if inclusion criteria were met. If we identified more than one publication of a trial, we listed the paper with the primary outcome as the primary reference. Where a trial report thought to be potentially relevant was in a language not known to the review authors, it was translated by a native speaker who was fluent in English.

From all studies meeting the inclusion criteria, we extracted the data and assessed risk of bias. We recorded studies rejected at this or subsequent stages in the 'Characteristics of excluded studies' tables, along with reasons for exclusion.

Data extraction and management

Two review authors (CZ and MD) independently extracted data from the included studies using a pilot-tested data-extraction form. The data were then entered into the Characteristics of excluded studies table in Review Manager 5 (RevMan5) (RevMan 2014) and checked for differences. Any disagreements were resolved through discussion with another review author (Mª José Martínez Zapata (MMZ)) until we reached consensus. We contacted trial authors for clarification or missing information, where there was any uncertainty or data were missing. We treated studies with duplicate publications as a single source of data. Review authors were not blinded to the names of the authors, institutions, journal of publication, or results of the studies.

In the data extraction form, we recorded the following details for each trial: RCT design (e.g. parallel, split-mouth, cluster); country where the trial took place; setting (e.g. primary or secondary care); funding source; inclusion criteria; exclusion criteria; number of participants randomised and evaluated; baseline number of decayed, missing and filled primary teeth (dmfts)/and permanent teeth (DMFTs); test and control interventions; type and number of operators; primary and secondary outcomes; sample size calculation; duration of follow-up; any co-interventions; risk of bias; and any other relevant data. We used the data for each specific time point or time interval separately, as reported in the original studies.

Assessment of risk of bias in included studies

Two review authors (CZ and MD) conducted 'Risk of bias' assessment independently and in duplicate for all the included trials, according to the criteria for assessing risk of bias described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Any disagreements were resolved through discussion with another review author (Mª José Martínez Zapata (MMZ)) until we reached a consensus. We contacted trial authors where necessary.

We assessed the risk of bias to be high, unclear or low for seven domains:

- Sequence generation: was the method used to generate the allocation sequence appropriate to produce comparable groups? We graded this domain as having a low risk of bias if the authors described a random component in the sequence generation process (e.g. random number table, coin tossing, drawing of lots).
- Allocation sequence concealment: was the method used to conceal the allocation sequence appropriate to prevent the allocation being known in advance of, or during, enrolment? We graded this domain as having a low risk of bias if the authors described adequate concealment (e.g. by means of central randomisation, sequentially numbered, opaque envelopes), and graded high risk of bias if inadequate concealment was documented (e.g. alternation, use of case record numbers, dates of birth or day of the week) or if allocation was not concealed.
- Blinding of participants and personnel: was knowledge of the allocated intervention adequately prevented during the study? We graded this domain as having a high risk of bias if the study did not use any blinding of participants or operators.
- Blinding of outcome assessors: was knowledge of the allocated intervention adequately prevented during the study? We graded this domain as having a high risk of bias if the study did not use any blinding of assessors.
- Incomplete outcome data: how complete were the outcome data for the primary outcomes? Did authors report dropout rates and reasons for withdrawals? Did they impute missing data appropriately? We graded this domain as having a low risk of bias if the proportion of the missing outcome data was less than 25% and the groups were balanced in numbers and reasons for dropouts, or if investigators imputed missing data using appropriate methods. If dropout was above 25% and there was no information on reasons for dropouts across groups, but attrition was balanced, we graded the risk of bias as unclear. We graded it as high if the proportion of missing outcome data was over 25% and not balanced between groups.

- Selective outcome reporting: did investigators report appropriate outcomes or were key outcomes missing? We graded this domain as having a low risk of bias if authors reported all pre-specified outcomes. If they did not report prespecified or expected data, we assumed the risk of bias to be high.
- Other sources of bias: was the study apparently free of other problems that could put it at a high risk of bias? These include information on the baseline characteristics of the intervention and control groups and the similarity in using co-interventions between groups. We graded the trials as having a high risk of bias if there were important differences in demographic characteristics or if the groups received different co-interventions during the trial, or if the statistical analysis was inadequate or inappropriate.

We developed a standardised 'Risk of bias' assessment form and entered data in the 'Risk of bias' tables in RevMan 5 (RevMan 2014).

We summarised the potential risk of bias for each study overall:

- low risk of bias: plausible bias not likely to seriously alter the results (if low risk of bias for all items);
- unclear risk of bias: plausible bias that raises some doubt about the results (if unclear risk of bias for one or more key items, but none at high risk of bias);
- high risk of bias: plausible bias that seriously weakens confidence in the results (if high risk of bias for one or more key items), as described in Section 8.7 of the *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0 (updated March 2011) (Higgins 2011).

We completed a 'Risk of bias' table for each included study (see Characteristics of included studies) and presented the results graphically by domain over all studies and by study (Figure 2; Figure 3).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

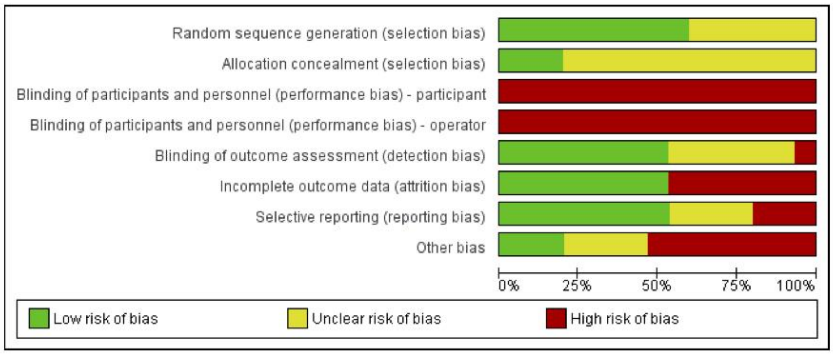
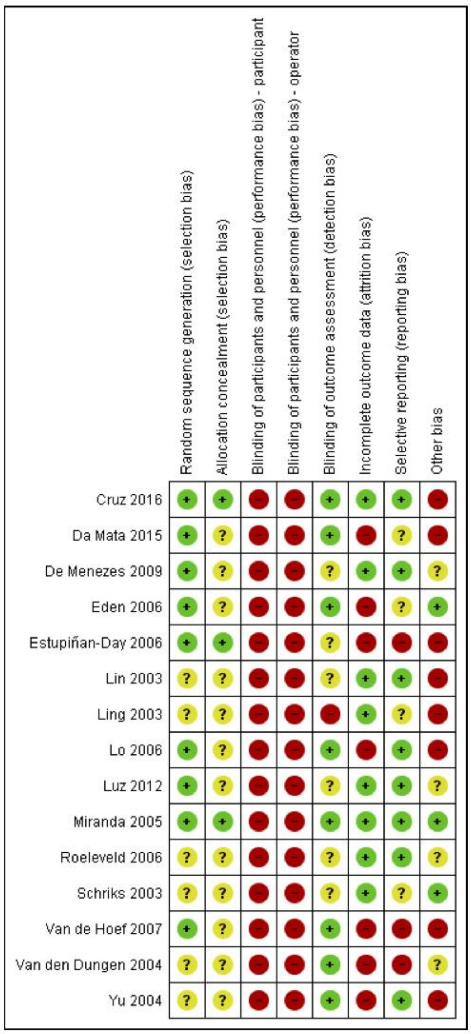


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study



Measures of treatment effect

We planned to convert data obtained from visual analogue scales and any categorical outcomes into dichotomous data prior to analysis. For continuous data, we planned to calculate mean difference with 95% confidence interval (CI). For each trial, we calculated odds ratios (OR) with 95% CIs for all prespecified dichotomous outcomes.

Unit of analysis issues

In parallel-group studies, the unit of analysis was the individual. In studies where the unit of randomisation was the individual, but more than one tooth/surface was treated per individual (cluster-randomised studies), we considered tooth/surface as the unit of analysis and standard errors of the estimates were adjusted taking into account the multiplicity or clustering (Deeks 2011). We considered an intracluster correlation coefficient (ICC) of 0.05, based on published data (Vas 2008).

In split-mouth studies where two tooth/surfaces are randomised per individual, these pairs are not strictly independent (the unit of analysis is the pair) and therefore, were analysed as 'paired data' (Higgins 2003; Deeks 2011). In these cases, we computed design-adjusted ORs and standard errors with the Becker-Balagtas method outlined in Elbourne 2002, assuming a conservative correlation coefficient of 0.05 according to Dorri 2015. We planned to calculate the log odds ratio and standard error separately for each outcome.

In cluster split-mouth studies, where more than two tooth/surfaces are randomised per individual, the unit of analysis is each pair. We considered these trials as split mouth, analysing the pairs independently, ignoring the clustering effect.

Dealing with missing data

We contacted the study authors where data were missing on the trial characteristics, methodology and/or outcomes. We did not consider missing data as a reason to exclude any of the trials from the review. We had planned to impute missing data, if appropriate. However, we did not carry out data imputation as we assumed all missing data to be at random.

Assessment of heterogeneity

We assessed statistical heterogeneity by examining the characteristics of the studies: the similarity between the types of participants, the interventions and the outcomes as described in Section 9.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

For this purpose we used the I^2 statistic (Higgins 2003), which examines the percentage of total variation across studies due to heterogeneity rather than to chance. According to the *Cochrane Handbook for Systematic Reviews of Interventions* the I^2 values are interpreted as follows (Deeks 2011):

- 0% to 40% might not be important;
- 30% to 60% may represent moderate heterogeneity;
- 50% to 90% may represent substantial heterogeneity;
- 75% to 100% represents considerable heterogeneity.

Assessment of reporting biases

We had planned to assess whether the review was subject to publication bias (or small-study effects) by using a funnel plot (plots of the effect estimates versus the inverse of their standard errors) (Egger 1997). Asymmetry of the funnel plot may indicate publication bias or other sources of asymmetry including poor methodological quality leading to spuriously inflated effects in smaller studies, true heterogeneity and chance (Sterne 2011). We did not include more than 10 trials in meta-analysis and therefore, a funnel plot to explore possible publication biases was not indicated. For future updates, if more than 10 trials are included we plan to use a funnel plot to explore publication bias (Egger 1997).

Data synthesis

We pooled only studies that used the same restorative materials in both comparator groups, as different restorative materials require different cavity designs and have different properties that may affect the study outcomes. For example, whilst adhesive restorative materials (e.g. GIC, composite resins) rely on chemical bonding to the tooth for retention, the success of amalgam restoration depends on mechanical retention from the converged cavity walls. This would mean that for an amalgam restoration, following caries removal, the cavity may need to be extended in order to obtain mechanical retention. This may affect the length of procedure, and in turn the patient's experience, and also the restoration survival. In addition GIC releases fluoride that may affect restoration survival.

Our analysis includes data only of those whose results are known, using as a denominator the total number of participants for whom data were recorded for the particular outcome. We expected differences in effect estimates between studies in terms of the number of cavities or surfaces treated per participant and also the duration of follow-up. Therefore, we applied a random-effects model for any meta-analyses (Deeks 2011).

We pooled parallel and split-mouth data using the generic inverse variance (GIV) (Deeks 2011).

We did not pool data if heterogeneity was over 75%. This was mainly because indicating an average value for the intervention

effect when there is a significant inconsistency in the direction of effect may be misleading (Deeks 2011).

We anticipated variation in the timing of endpoints across the studies, both in terms of participant-reported pain and clinical restoration failure. We included in the meta-analysis the longest follow-up reported for each study.

Where studies had multiple intervention or comparator trial arms, we combined summary statistics from all groups where appropriate. We excluded any intervention arms without ART from the meta-analysis.

The data was analysed using RevMan 5 software (RevMan 2014). In the event that there were insufficient clinically homogeneous trials for any specific intervention or insufficient study data that could be pooled, a narrative synthesis was presented.

Subgroup analysis and investigation of heterogeneity

We had planned to perform subgroup analysis for dental caries type, as a source of clinical heterogeneity, if sufficient data were available. Therefore, we stratified the analyses in subgroups according to type of cavity surface:

- studies reporting on single lesion;
- studies reporting on multiple lesions;
- studies reporting on single and multiple lesions;
- studies where lesion type was not reported;
- studies reporting on coronal and root lesion, or on root lesions only.

Sensitivity analysis

We had planned to conduct a sensitivity analysis of the primary outcomes by excluding studies with overall high risk of bias (that is high risk of bias in at least one domain). However, all the included studies were at high risk of bias for at least one domain and therefore, we did not carry out a sensitivity analysis.

Summary of findings

We used GRADEpro GDT software (GRADEpro GDT 2015) to assess the quality of the body of evidence for study outcomes (pain, restoration failure, adverse events) and to develop Summary of findings for the main comparison, Summary of findings 2 and Summary of findings 3. The GRADE approach appraises the quality of a body of evidence based on the extent to which one can be confident that an estimate of effect or association reflects the item being assessed. The approach considers evidence from RCTs that do not have serious limitations as 'high' quality. The following factors can decrease the quality of evidence: within-study limitations (risk of bias), indirectness of the evidence, heterogeneity (inconsistency) in the data, imprecision of effect estimates, and risk of publication bias (Schünemann 2011).

RESULTS

Description of studies

Please see Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

The search strategy retrieved 1719 citations (Figure 1). After deleting duplicates and screening titles and abstracts, we evaluated 53 full texts of potentially eligible studies. We excluded 27 studies (Characteristics of excluded studies), and included 22 articles that corresponded to 15 completed RCTs (Cruz 2016; Da Mata 2015; De Menezes 2009; Eden 2006; Estupiñan-Day 2006; Lin 2003; Ling 2003; Lo 2006; Luz 2012; Miranda 2005; Roeleveld 2006; Schriks 2003; Van de Hoef 2007; Van den Dungen 2004; Yu 2004) (Characteristics of included studies). We also retrieved four ongoing trials (CTRI007332; NCT02562456; NCT02568917; RBR-4nwmk4) (Characteristics of ongoing studies).

Two studies were in Chinese (Lin 2003; Ling 2003) and two articles were in Dutch (Schriks 2003; Van den Dungen 2004). We contacted two authors in an effort to obtain additional information (Estupiñan-Day 2006; Eden 2006). Both trial authors responded and answered our questions.

Included studies

We found 15 completed studies, reported in 22 articles, and 4 ongoing studies. Six studies were reported in multiple articles (Da Mata 2015; Eden 2006; Estupiñan-Day 2006; Schriks 2003; Van de Hoef 2007; Yu 2004). Included studies were published between 2002 and 2016 with a follow-up period that ranged from 6 to 36 months.

Design

Eleven studies used a parallel-group design, with six of these using a parallel-group, cluster-randomised design. Four studies used a split-mouth design (Eden 2006; Ling 2003; Miranda 2005; Yu 2004). Only five studies reported a sample size calculation (Da Mata 2015; Eden 2006; Estupiñan-Day 2006; Lo 2006; Miranda 2005).

Funding for the studies was provided by government (Cruz 2016; Da Mata 2015; Lo 2006), foundations (De Menezes 2009; Eden 2006; Estupiñan-Day 2006; Van de Hoef 2007; Van den Dungen 2004) and pharmaceutical sources or manfacturers(Eden 2006; Roeleveld 2006; Schriks 2003; Yu 2004). Funding was unclear in four studies (Lin 2003; Ling 2003; Luz 2012; Miranda 2005).

Setting

Studies were conducted in China (Lin 2003; Ling 2003; Lo 2006; Yu 2004), Brazil (De Menezes 2009; Luz 2012; Miranda 2005), Indonesia (Schriks 2003; Van den Dungen 2004), and Colombia, Ireland, Turkey, Tanzania and Surinam (Cruz 2016; Da Mata 2015; Eden 2006; Roeleveld 2006; Van de Hoef 2007). There was one international multicentre trial in Ecuador, Panamá and Uruguay (Estupiñan-Day 2006).

The study setting was dental clinics or hospitals for seven studies (Da Mata 2015; De Menezes 2009; Eden 2006; Ling 2003; Luz 2012; Miranda 2005; Yu 2004); schools for two studies (Estupiñan-Day 2006; Van den Dungen 2004), and nursing homes for two studies (Cruz 2016; Lo 2006). Four studies did not report the setting (Lin 2003; Roeleveld 2006; Schriks 2003; Van de Hoef 2007).

Participants

Overall, data on 3760 participants and 9944 teeth were included in the review. The studies examined 6347 teeth that were treated using ART and 3204 that received a conventional treatment. One study did not report the teeth treated by group (Van den Dungen 2004).

The mean age of the participants was 25.42 years (ranging from 3 to 101 years). Forty-eight per cent of participants were male.

Only Eden 2006 reported the baseline dmft index (average number of decayed, missing and filled primary teeth) with a mean dmft of 6.9. Two studies reported a baseline DMFT (average number of decayed, missing and filled permanent teeth) index ranging between 1.0 to 28.54 (Da Mata 2015; Lo 2006).

Eleven trials included only primary teeth, with participants' age ranging from 3 to 13 years (De Menezes 2009; Eden 2006; Lin 2003; Ling 2003; Luz 2012; Miranda 2005; Roeleveld 2006; Schriks 2003; Van de Hoef 2007; Van den Dungen 2004; Yu 2004). Four trials evaluated permanent teeth with participants aged between 7 to 101 years (Cruz 2016; Da Mata 2015; Estupiñan-Day 2006; Lo 2006).

Interventions

The key results of this review are from the nine included studies that evaluated the effects of ART compared to conventional treatment using the same restorative material in both arms:

- seven studies including a total of 1402 participants compared ART using H-GIC (high viscosity glass ionomer cement) with conventional treatment using H-GIC in primary teeth (De Menezes 2009; Lin 2003; Roeleveld 2006; Schriks 2003; Van de Hoef 2007; Van den Dungen 2004; Yu 2004);
- one study with 160 participants compared ART using composite with conventional treatment using composite in primary teeth (Eden 2006);
- one study with 75 participants compared ART using RM-GIC (resin-modified glass ionomer cement) with conventional treatment using RM-GIC in permanent teeth (Cruz 2016).

Five included studies compared ART versus conventional treatment but used different restorative materials in each arm:

- one study with 106 participants compared ART using H-GIC versus conventional treatment using amalgam in primary teeth (Miranda 2005);
- one study with 80 participants compared ART using GIC versus conventional treatment using amalgam in primary teeth (Ling 2003) and one study in permanent teeth (1629 participants) (Estupiñan-Day 2006);
- one study with 30 participants compared ART using H-GIC versus conventional treatment using composite in primary teeth (Luz 2012);
- two studies with 210 participants compared ART using H-GIC versus conventional treatment using RM-GIC in permanent teeth (Da Mata 2015; Lo 2006).

Only one study used local anaesthesia with an ART group (Van de Hoef 2007). This was a four-armed study that used local anaesthesia in two of the four arms (one ART and one conventional treatment). Four other studies reported the use of local anaesthesia with conventional treatment (Da Mata 2015; De Menezes 2009; Lo 2006; Luz 2012); five studies reported that it was not used (Eden 2006; Miranda 2005; Roeleveld 2006; Schriks 2003; Yu 2004); and five studies did not report whether or not local anaesthesia was used (Cruz 2016; Estupiñan-Day 2006; Lin 2003; Ling 2003; Van den Dungen 2004).

Six studies evaluated the effects of ART on multi-surface caries lesions (Eden 2006; Luz 2012; Roeleveld 2006; Schriks 2003; Van de Hoef 2007; Van den Dungen 2004). Four trials evaluated both single and multi-surface lesions (Da Mata 2015; De Menezes 2009; Miranda 2005; Yu 2004). Two trials evaluated root lesions (Cruz 2016; Lo 2006). Three studies did not specify cavity type (Estupiñan-Day 2006; Lin 2003; Ling 2003).

Most studies reported that the interventions were delivered by the dentist or by the dentist and dental students (Schriks 2003; Van de Hoef 2007; Van den Dungen 2004), or by dentists and dental hygienists (Estupiñan-Day 2006).

Outcomes

Four studies measured pain (De Menezes 2009; Estupiñan-Day 2006; Luz 2012; Miranda 2005); one study did not report whether anaesthesia was used (Estupiñan-Day 2006); in two studies, local anaesthesia was given in the conventional treatment arm only (De Menezes 2009; Luz 2012); and the cavity preparation was different in the arms of one study (Miranda 2005).

Restoration failure was assessed in 13 studies (Cruz 2016; Da Mata 2015; Eden 2006; Estupiñan-Day 2006; Lin 2003; Ling 2003; Lo 2006; Luz 2012; Miranda 2005; Roeleveld 2006; Van de Hoef

2007; Van den Dungen 2004; Yu 2004). We pooled the results of the studies only if the same restorative material was used in the intervention and comparison arms.

None of the studies measured adverse effects.

Secondary/recurrent caries were measured in four studies (Cruz 2016; Miranda 2005; Roeleveld 2006; Yu 2004).

Other aspects of participant experience were measured in four studies: discomfort (Schriks 2003; Van de Hoef 2007); anxiety (Eden 2006); acceptability (Luz 2012); co-operation (Estupiñan-Day 2006; Ling 2003).

Two studies assessed cost-effectiveness (Da Mata 2015; Estupiñan-Day 2006).

We did not carry out meta-analysis where different restorative materials were used in trial arms or local anaesthesia was used in only one study arm, as discussed above. In these cases, the data were narratively presented.

Excluded studies

We excluded 27 studies (see Characteristics of excluded studies). The reasons for exclusion were:

- did not compare ART with conventional treatment (nine studies);
- the ART technique was modified (14 studies);
- not randomised (four studies).

Risk of bias in included studies

All studies were judged to be at overall high risk of bias (see Figure 2; Figure 3).

Allocation

Random sequence generation

Of 15 included studies, nine adequately reported the methods used to generate the randomisation sequence, which included computerised sequence generation (Da Mata 2015; De Menezes 2009; Eden 2006; Estupiñan-Day 2006; Lo 2006; Van de Hoef 2007), ballot box (Luz 2012), or table of random numbers (Cruz 2016; Miranda 2005). We classified the other studies as 'unclear' as authors mentioned that the clinical trial was randomised but did not report further details.

Allocation concealment

Only three studies adequately reported allocation concealment using sealed envelopes (Cruz 2016; Miranda 2005) or centralised assignment (Estupiñan-Day 2006). In the remaining studies this was not specified and therefore, we classified them as 'unclear'.

Blinding

Blinding of participants and personnel

Given the nature of the intervention, it is not feasible to blind participants and operators to the type of instruments (i.e. manual or rotary) used for restoration. Therefore, both participants and operators were aware of type of intervention.

Blinding of outcome assessors

It is, however, possible to blind outcome assessors to the type of intervention. The outcome assessors were blind in the eight studies that used the same restorative materials for both the intervention and comparison groups. We considered these studies to be at low risk of bias (Cruz 2016; Da Mata 2015; Eden 2006; Lo 2006; Miranda 2005; Van de Hoef 2007; Van den Dungen 2004; Yu 2004). One study reported that assessors were not blind and therefore we rated it as 'high risk' (Ling 2003). Other studies did not report blinding of outcome assessor and were rated as 'unclear'.

Incomplete outcome data

All trials reported if there were any participants who were lost to follow-up. However, only six studies reported the reasons for dropout (Cruz 2016; Da Mata 2015; Lo 2006; Luz 2012; Miranda 2005; Van de Hoef 2007). We assessed seven studies as 'high risk' of bias because they had losses to follow-up over 20% (Da Mata 2015: Eden 2006; Estupiñan-Day 2006; Lo 2006; Van de Hoef 2007; Van den Dungen 2004; Yu 2004), which was higher than had been estimated in the sample size calculation. We assessed the remaining studies as 'low' risk of attrition bias.

Selective reporting

We judged seven studies to be at 'high' or 'unclear' risk of selective reporting bias (Da Mata 2015; Eden 2006; Estupiñan-Day 2006; Ling 2003; Schriks 2003; Van de Hoef 2007; Van den Dungen 2004). Estupiñan-Day 2006 did not report the results at three years' follow-up and Van den Dungen 2004 did not report results at follow-ups before three years. Other studies reported incomplete data for the follow-ups.

Other potential sources of bias

We assessed three studies as having no other potential sources of bias (Eden 2006; Miranda 2005; Schriks 2003).

We judged four studies to be 'unclear' as they did not provide information about either important baseline characteristics of the included participants or co-interventions, or both (De Menezes 2009; Luz 2012; Roeleveld 2006; Van den Dungen 2004).

We assessed eight studies as 'high risk' of other potential sources of bias. In addition to failing to provide information about baseline

characteristics, Cruz 2016 did not consider the paired data in their analysis. Lin 2003 and Van de Hoef 2007 did not consider the intracluster coefficient. Ling 2003, Lo 2006 and Yu 2004 did not consider the paired data in their analysis. Da Mata 2015 had an imbalance in DMFT score between groups. Estupiñan-Day 2006 did not report DMF scores or information about supply of water fluoridation between countries and their analysis did not consider the intracluster correlation coefficient.

Effects of interventions

See: **Summary of findings for the main comparison** Atraumatic restorative treatment (ART) using high-viscosity glass ionomer cement (H-GIC) compared with conventional restorative treatment using H-GIC for dental caries; **Summary of findings 2** Atraumatic restorative treatment (ART) using composite resins compared with conventional restorative treatment using composite resins for dental caries; **Summary of findings 3** Atraumatic restorative treatment (ART) using resin-modified glass ionomer cement (RM-GIC) compared with conventional restorative treatment using RM-GIC for dental caries

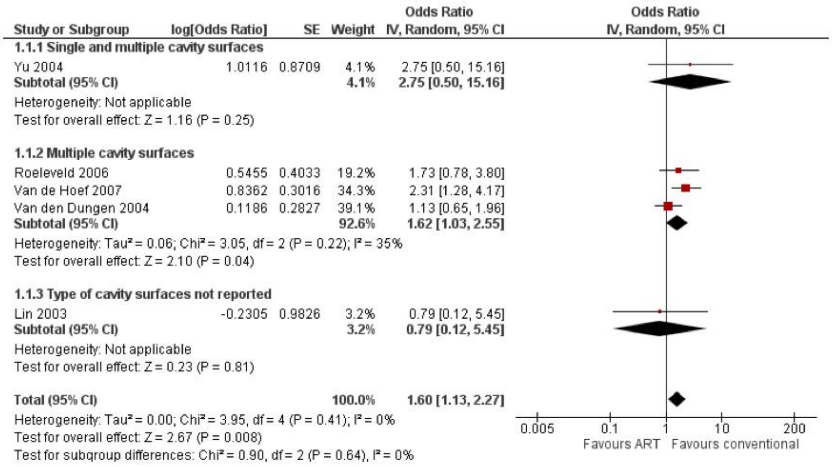
Comparison 1: ART using H-GIC versus conventional treatment using H-GIC

Seven studies reported data for this comparison in primary teeth: De Menezes 2009; Lin 2003; Roeleveld 2006; Schriks 2003; Van de Hoef 2007; Van den Dungen 2004; Yu 2004. Data from Schriks 2003 were not useable.

Restoration failure

Five studies, which randomised 959 participants, reported data for restoration failure in the primary dentition with follow-ups of between 12 and 36 months (Lin 2003; Roeleveld 2006; Van de Hoef 2007; Van den Dungen 2004; Yu 2004). The odd ratios (OR) of restoration failure were 1.60 times higher in the ART arm than in the conventional arm, over a follow-up period of 12 to 24 months (OR 1.60, 95% CI 1.13 to 2.27; I^2 = 0%, 643 participants analysed; Analysis 1.1). The quality of evidence was downgraded by two levels from 'high' to 'low' due to serious concerns regarding risk of performance bias in all five studies, attrition bias in three studies (Yu 2004; Van de Hoef 2007; Van den Dungen 2004), and reporting bias in two studies (Van de Hoef 2007; Van den Dungen 2004) (Analysis 1.1; Figure 4; Summary of findings for the main comparison).

Figure 4. Forest plot of comparison 1. Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC, outcome: 1.1 restoration failure (primary teeth) - longest follow-up



We carried out subgroup analysis to investigate the impact of cavity type on restoration failure. One study with 27 participants included single and multiple surfaces (Yu 2004). Three studies with 558 participants reported on multiple surfaces only (Roeleveld 2006; Van de Hoef 2007; Van den Dungen 2004). One study with 58 participants did not report the type of cavity treated (Lin 2003). The Chi^2 test did not show any evidence of a difference according to cavity type (Chi^2 = 0.90, df = 2, P = 0.64, I^2 = 0%).

Pain

One study, which randomised 40 participants, reported data for pain in the primary dentition for children aged between four and seven years. ART may reduce the pain during procedure compared with control treatment (MD -0.65, 95% CI -1.38 to 0.07; 40 participants analysed; Analysis 1.2) (De Menezes 2009). The evidence was downgraded one level because it is a single study (indirectness) and one level because of serious concern regarding high risk of performance bias (Summary of findings for the main comparison).

Secondary outcomes

Secondary caries

Two studies reported on secondary caries, but this outcome was not reported by trial arm (Yu 2004; Roeleveld 2006).

Participant experience (discomfort)

One study that reported the results of treating multiple lesions in primary dentition, found that the odds of discomfort were reduced with ART in children between six and eight years of age (OR 0.95, 95% CI 0.51 to 1.79; 220 participants analysed; Analysis 1.3) (Van de Hoef 2007). Local anaesthetic was administered in the intervention and comparison groups.

Other outcomes

No studies reported on restoration failure in permanent dentition, adverse events, or costs for this comparison.

Comparison 2: ART using composite versus conventional treatment using composite

Restoration failure

One study, which randomised 160 participants with a mean age of seven years, reported data for restoration failure in multi-surface lesions of primary dentition with follow-up at 24 months (Eden 2006). The odds of restoration failure were slightly greater with ART than conventional treatment, however the 95% CI included the possibility that ART both increased the risk of restoration failure and reduced restoration failure, so this result is inconclusive (OR 1.11, 95% CI 0.54 to 2.29, 57 participants analysed; Analysis 2.1). We downgraded the quality of evidence by three levels: one level because the information was based on a single study comprising participants of a very narrow age range (indirectness) and two levels because of very serious concerns regarding risk of bias (high risk of performance bias and attrition bias (103 children (64%) lost to follow-up at 24 months)) (Summary of findings 2).

Participant experience (dental anxiety)

Eden 2006 was the only study to report on participant experience (dental anxiety). The authors reported no observed difference in mean dental anxiety as measured by the Venham Picture test (MD 0.00, 95% CI -0.52 to 0.52; 57 participants analysed; Analysis 2.2).

Other outcomes

No studies reported on pain, restoration failure in the permanent dentition, adverse events, secondary caries, or costs for this comparison.

Comparison 3: ART using RM-GIC versus conventional treatment using RM-GIC

Restoration failure

One study, which randomised 75 participants with a mean age of 75 years (range 60 to 101 years), reported data for restoration failure in root surfaces of the mature permanent dentition (Cruz 2016). The odds of restoration failure at 24 months' follow-up were not significantly greater with ART than conventional treatment (OR 2.71, 95% CI 0.94 to 7.81; 64 participants analysed; Analysis 3.1). We downgraded the quality of evidence by three levels: one level as the information was based on a single study comprising older adults only (indirectness), one level because of imprecision and one level because of serious concerns regarding risk of bias (high risk of performance bias (11 adults (15%) lost to follow-up at six months)) (Summary of findings 3).

Secondary caries

One study reported data on secondary caries for this comparison (Cruz 2016). The odds of secondary caries at six months were greater with ART than with conventional treatment (Analysis 3.2).

Other outcomes

No studies reported on pain, restoration failure in the primary dentition, adverse events, participant experience, or costs for this comparison.

Comparison 4: ART versus conventional treatment using different restorative materials

Restoration failure

Seven studies used different restorative materials for the intervention and comparator (Da Mata 2015; Estupiñan-Day 2006; Ling 2003; Lo 2006; Luz 2012; Miranda 2005; Yu 2004) (see Table 1).

Studies comparing ART using H-GIC may increase the risk of failure compared with conventional treatment using amalgam in primary teeth (Miranda 2005; Yu 2004).

One study comparing ART using GIC with conventional treatment using amalgam in primary teeth showed that ART may decrease the risk of restoration failure in the primary dentition (Ling 2003). However, in permanent immature teeth, ART resulted in a greater number of failures than conventional treatment (Estupiñan-Day 2006).

When comparing ART using H-GIC with conventional treatment using composite in primary teeth, the latter presented significantly fewer failures (Luz 2012).

In root caries of permanent mature teeth, ART with H-GIC showed greater odds of restoration failure than conventional treatment with RM-GIC (Da Mata 2015; Lo 2006).

Pain

Of the three studies reporting pain, two RCTs showed increased risk of pain during procedures for participants treated with ART compared with conventional treatment for primary dentition (Luz 2012; Miranda 2005).

One study on permanent immature teeth showed that participants treated with the ART approach presented significantly less pain than the control group (Estupiñan-Day 2006).

Other outcomes

Ling 2003 assessed participant co-operation during procedures, showing a co-operation rate in the ART group significantly higher than in the control group.

No studies reported adverse events, secondary caries, or costs for this comparison.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Atraumatic restorative treatment (ART) using composite resins compared with conventional restorative treatment using composite resins for dental caries

Patient or population: people with dental caries
Settings: community settings and dental clinics
Intervention: ART using composite
Comparison: conventional treatment using composite

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Conventional treatment	ART			
Restoration failure (primary dentition)	362 per 1000	387 per 1000 (235 to 565)	OR 1.11 (0.54 to 2.29)	57 participants/100 teeth (1 study)	⊕○○○ very low[1]
Pain	-	-	-	-	Not measured
Adverse events	-	-	-	-	Not measured

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High quality: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Low quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Very low quality: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[1] We downgraded the evidence by three levels: one level because it is a single study (indirectness) and two levels because of very serious concern regarding the risk of bias (high risk of performance bias and high risk of attrition bias). The result was also very imprecise.

Atraumatic restorative treatment (ART) using resin-modified glass ionomer cement (RM-GIC) compared with conventional restorative treatment using RM-GIC for dental caries

Patient or population: people with dental caries
Settings: community settings and dental clinics
Intervention: ART using RM-GIC
Comparison: conventional treatment using RM-GIC

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Conventional treatment	ART			
Restoration failure (primary dentition)	-	-	-	0 studies	No studies included
Restoration failure (permanent teeth)	75 per 1000	180 per 1000 (71 to 388)	OR 2.71 (0.94 to 7.81)	64 participants/ 141 teeth (1 study)	⊕○○○ very low[1]
Pain	-	-	-	-	Not measured
Adverse events	-	-	-	-	Not measured

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **OR:** odds ratio

GRADE Working Group grades of evidence
High quality: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Low quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Very low quality: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[1] We downgraded the evidence by one level because it is a single study (indirectness), one level because of concern regarding high risk of performance bias, and one level because the result was imprecise.

DISCUSSION

Summary of main results

In total, we included 15 eligible published RCTs in this review, with a total of 3760 participants of whom 48% were men. The mean age of the participants was 25.42 years. The median number of participants per RCT was 291 (range 30 to 2298). Eleven of the trials included primary teeth and four were carried out on permanent teeth. Six studies involved multi-surface; four involved single and multiple surfaces; two were on root caries and in three trials cavity type was not specified. Most studies used H-GIC as the restorative material in the ART group; one study used composite resins; and one study used RM-CGIC. In three studies, the conventional group used amalgam; three studies used RM-CGIC; two studies used composite resins; and the remaining studies used H-GIC. We considered the key results to be from the three comparisons that used the same restorative material in both trial arms. The comparison between ART and conventional treatment using different restorative materials was narratively presented.

In primary teeth, there was low-quality evidence that ART using H-GIC may increase the risk of restoration failure compared with conventional treatment using H-GIC. There was low-quality evidence that ART may reduce pain during the procedure compared with control treatment.

Given the very low-quality of the evidence from single studies, we are uncertain about the restoration failure of ART compared with conventional treatment using composite over a 24-month follow-up period and ART using RM-GIC in the permanent teeth of older adults with root caries lesions over a six-month follow-up period.

None of the included studies reported on adverse effects.

Studies that compared ART with conventional treatment, using different restorative materials in trial arms, did not provide consistent results. The results of these studies for pain were also inconclusive.

Overall completeness and applicability of evidence

Although we included 15 studies in this review, there were only a small number of studies eligible for each comparison.

Only a few studies reported on any of the secondary outcomes.

Only one study that reported on pain was included in the analysis for the pain outcome.

Although the evidence showed that conventional treatment may be more effective than ART technique in primary teeth when the teeth are restored with H-GIC, these findings should be considered with caution due to the low quality of the evidence. The findings were inconclusive when composite resins or RM-GIC were used, and applicability to current clinical practice is uncertain due to only one study being included for these comparisons.

There were few available data for secondary caries and participants' experience. No studies reported on adverse events. Only one study reported on the cost of treatment (Da Mata 2015), and concluded that ART was more cost-effective than conventional treatment for treating older adults. However, these results can only be applied to the healthcare system in Ireland.

In general, the findings of the review should be interpreted with caution because of the high risk of bias in the few studies included and low- to very-low quality of evidence. Clinicians should inform patients of potential pros and cons of each treatment option to enable them to make an informed decision.

Quality of the evidence

We graded the evidence taking into account any limitations in the study design, risk of bias, inconsistency of results, indirectness of evidence, imprecision, presence of publication bias and magnitude of effect estimate.

Evidence on restoration failure was mainly assessed as low- to very low-quality due to high risk of bias and imprecision. High risk of bias was due to performance, attrition, and selective reporting bias. Given that participants and personnel could not be blinded, it was not possible to avoid performance bias. Moreover, the low number of events (i.e. single study) led to additional downgrading for imprecision of the effect estimate.

For the pain outcome, the evidence was of very low quality due to high risk of performance bias and small sample size (i.e. single study).

Potential biases in the review process

We carried out this review according to Cochrane guidelines. We searched a wide range of major electronic databases, without any restriction of language or time. Apart from completed RCTs, we also identified ongoing clinical trials. Where there was uncertainty regarding the studies we contacted the study authors for clarification and further information.

It may be argued that the adjustments to the data made by authors to account for unit of analysis issues could have introduced a risk of bias. We endeavoured to minimise the risk of bias by ensuring that the screening of studies and data extraction were carried out by two authors independently. The data analyses were carried out by two authors and all authors examined the analysis and interpretation of results.

Agreements and disagreements with other studies or reviews

The present review included all available randomised trials comparing ART and conventional treatment in primary and permanent teeth of children and adults. We also identified other systematic reviews on the clinical effectiveness of the ART approach, most of which compared ART to conventional treatment using different restorative materials, mainly amalgam.

Frencken 2004a included only single-surface ART restorations restored with GIC compared with conventional restorations with amalgam in permanent dentition. They did not show any differences between the two treatments. Mickenautsch 2012 also compared the failure rate in the ART approach versus amalgam fillings in permanent and primary teeth, leaving aside other filling materials. They found no difference between the approaches in both primary and permanent teeth.

Another important difference with some of the existing reviews, such as Frencken 2004a and Van 't Hof 2006 is that we did not introduce any language restrictions and searched a wide range of databases. In our review, we also assessed the quality of the evidence.

Most previous reviews considered survival rate as their only outcome (De Amorin 2012; Frencken 2004a; Van 't Hof 2006), whilst in our review we included a range of primary and secondary outcomes.

Van 't Hof 2006 and De Amorin 2012 assessed the survival of ART restoration using GIC in primary and permanent teeth. Both studies concluded that single-surface ART restorations using GIC both in primary and permanent dentitions showed higher survival rate compared with multiple-surface ART restorations.

Pettar 2011 carried out a more comprehensive review to assess the effect of ART on decayed primary and permanent teeth in children between four and 16 years old. It concluded that it was not possible to pool the results due to high clinical heterogeneity. Therefore, it was impossible to get a precise conclusion about the effect of treating childhood caries with ART versus a conventional approach.

Finally, a recent systematic review evaluated the effectiveness of ART in reducing dental anxiety in children with caries lesions in primary teeth compared to conventional treatment (Simon 2017). They concluded that ART was not more beneficial in reducing dental anxiety among paediatric dental patients. We reported a similar finding, although we only included one study for this outcome.

AUTHORS' CONCLUSIONS

Implications for practice

The available evidence suggests that atraumatic restorative treatment (ART) using high-viscosity glass ionomer (H-GIC) may have a higher risk of restoration failure than conventional treatment for caries lesions in primary teeth, but the evidence is of low-quality and we cannot rely on the findings. We can draw no conclusions about the effects of ART versus conventional treatment when using resin-modified glass ionomer (RM-GIC) or composite because of the very low quality of the evidence.

The low- to very low-quality of the evidence limits the generalisability of these findings. Practitioners and patients should interpret these results with caution. Although there is some evidence in favour of conventional treatment rather than ART in primary teeth, ART may still be considered as a treatment option where access to resources (e.g. dentists, rotary handpieces and electricity) are limited.

Implications for research

Further well-designed, adequately powered randomised controlled trials are needed to determine whether the ART approach confers any benefit in terms of success rate or patient experience during treatment in primary and permanent teeth. Future trials should aim to reduce risk of bias and consider potential confounding factors (e.g. type of restoration material, age) in their study designs. Pragmatic, multi-centre, practice-based trials, with independent non-industrial funding could help provide evidence with high validity. Trials should report on time- and cost-related outcomes, participant and operator experience using valid indices.

There are currently four ongoing trials assessing the effectiveness and cost-effectiveness of ART and their results could provide further insights into this very important area.

ACKNOWLEDGEMENTS

The review authors would like to thank Cochrane Oral Health and the referees for their comments, support and assistance with conducting this review. We would like to acknowledge Liyuan Ma, Professor Zongdao Shi, Professor Chengge Hua, Dr Fatemeh Mokhtarpour, Professor Bu So and Frans Banki for their help with translating Chinese and Dutch articles. Thanks are also due to Jo Frecken for providing further details of his study; Anne Littlewood (Cochrane Oral Health) for searching different databases; Marta Roqué-Figuls (Iberoamerican Cochrane Center) for their contribution in resolving methodological issues; and Dominic Hurst for his contribution in the early stages of this review. We acknowledge those who provided feedback on the review: Helen Worthington, Jan Clarkson, Liz Bickerdike and Ruth Floate; external referees Ivor G. Chestnutt and Margherita Fontana; and Denise Mitchell for copy editing. Last but not least, we would like to thank Laura MacDonald (Cochrane Oral Health) for her generous and continued support throughout this review and, in particular, for facilitating the communication between the review team and Cochrane Oral Health.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cruz 2016

Methods	**Design:** cluster, parallel RCT (a child is a cluster) **Number of participants:** 75 **Setting:** nursing home **Country:** Colombia **Unit of randomisation:** participant **Unit of analysis:** tooth **Follow-up:** 6 months **Dropout:** 14.9 % after 6 months
Participants	**Number randomised:** 75 participants; 174 teeth (73 ART group and 101 CT group) **Number analysed:** 64 participants/148 teeth **Age mean and SD (range):** 74.9 years (60-101) **Sex:** female 36 (48%), male 39 (52%) **Average DMFT score:** not reported **Dentition:** permanent **Type of caries lesion:** root caries **Inclusion criteria:** root caries defined as the softening of the root dentin to a depth of ≥ 0.5 mm **Exclusion criteria:** teeth with extraction indication, lesion close to the dental pulp or pain symptomatology
Interventions	Two treatment arms: • Gp 1: ART approach + RM-GIC • Gp 2: CT + RM-GIC ART was performed using only manual instrumentation to remove decayed tissue. Cotton rolls and a retraction cord were used to obtain relative isolation of the operative field. 2% chlorhexidine (Clorhexol 0.2 g/100 mL; Farpag®, Bogota, Colombia) was applied for 1 min and the cavity was dried and sealed with a**glass ionomer cement** modified with light-curing composite resin (Vitremer™®, 3M ESPE, Seefeld, Germany). Interproximal metal and paper strips were used Conventional technique was performed using a high-speed handpiece with irrigation and round diamond burs of different diameters. Cavities were restored with RM-GIC Use of anaesthesia was not reported in any group. The interventions were conducted by 2 dentists.
Outcomes	• Success rate and survival rate according to following criteria: 'successful' if the restoration was present and without marginal defects or secondary caries; 'survival' if the restoration was present with a marginal defect of 0.5 mm or less and without secondary caries; and 'failure' if the restoration was absent, if there was a marginal defect greater than 0.5 mm, or if there were secondary caries • Secondary caries defined as softened root dentin with the contact of the periodontal probe on the margin of the restorative material

Notes	Funding: COLCIENCIAS for the Young Researcher Scholarship-Internship Program Trial register number not reported Sample size calculated Intraexaminer and interexaminer reproducibility not assessed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A series of random numbers was used to fabricate sealed envelopes that were only opened for the random allocation of the participants to each working group (ART or conventional technique with rotary instruments)"
Allocation concealment (selection bias)	Low risk	Quote: "A series of random numbers was used to fabricate sealed envelopes that were only opened for the random allocation of the participants to each working group (ART or conventional technique with rotary instruments)"
Blinding of participants and personnel (performance bias) - participant	High risk	Comment: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comment: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "After six months, the condition of the restorations was assessed by two different prosthodontists, without awareness of the technique that was performed in each participant"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "After six months, 64 participants were evaluated (32 men and 32 women) and 26 restorations (14.9%) were lost. Seven participants changed geriatric institutions and were lost to follow-up, two died, and the two remaining participants were unreachable at the institution during the time of revision"
Selective reporting (reporting bias)	Low risk	Comment: all outcomes listed in the methods sections were included

Other bias	High risk	Comment: no information provided about baseline characteristics of included participants. The analysis did not consider the pair data

Da Mata 2015

Methods	**Design:** cluster, parallel RCT (a child is a cluster) **Number of participants:** 107 **Setting:** dental school/hospital **Country:** Ireland **Unit of randomisation:** participant **Unit of analysis:** tooth **Follow-up:** 6, 12 and 24 months **Dropout:** 15.8% and 33.6% after 12 and 24 months, respectively
Participants	**Number randomised:** 107 (53 ART group and 54 CT group); 99 received the intervention/306 teeth (142 ART and 158 CT) **Number analysed:** 71 participants/217 teeth **Age mean and SD (range):** 73 years SD = 6.7 (65-88) **Sex:** female 53 (54%), male 46 (46%) **Average DMFT score:** 25.74 SD = 6.3 ART/28.54 SD = 5.0 CT **Dentition:** permanent **Type of caries lesion:** coronal or root caries **Inclusion criteria:** > 65 years of age, ≥ 1 dentinal carious lesion with no painful symptomatology, ability to perform usual daily dental care activities such as toothbrushing **Exclusion criteria:** people with carious teeth with a history of pain, with cavities resulting from attrition, erosion or abrasion, with no caries, and with teeth that were periodontally involved
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + RM-GIC with anaesthesia The ART approach consisted of opening of the cavity with a dental enamel hatchet when necessary, removal of soft, completely demineralised carious tissue with excavators, conditioning of the cavity with polyacrylic acid for 20 s, washing and drying with cotton pellets and restoration with a high-strength glass ionomer cement (GC Fuji IX) The CT procedure consisted of local anaesthesia, use of rotary instruments for access, rotary and hand instruments for removal of all carious tissue, conditioning of the cavity with a polyacrylic acid for 20 seconds, washing and drying with cotton pellets and a resin-modified glass ionomer (GC Fuji II LC) to restore it The interventions were conducted by 2 dentists
Outcomes	• Restoration survival was evaluated through ART criteria: 0 = present, in good condition, 1 = present, slight marginal defect (0.5 mm), no repair needed, 2 = present, slight wear (0.5 mm), no repair needed, 3 = present, gross marginal defect, repair needed, 4 = present, gross wear, repair needed, 5 = not present, restoration partly or completely missing, 6 = not present, restoration replaced by another restoration, 7 =

	tooth missing, 8 = restoration not assessed, participant not present, C = caries present. Codes 0, 1 and 2 were considered success and 3, 4, 5, 6, and C, failure. Restorations with codes 7 and 8 were excluded from the analysis. • Direct cost of the interventions
Notes	Funding: Irish Health Research Board Trial register number not reported Sample size calculated Interexaminer reproducibility high (kappa = 0.88)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer-generated randomisation list, provided by a statistician involved in the study"
Allocation concealment (selection bias)	Unclear risk	Quote: "The allocation sequence was concealed from the primary researcher treating the participants in sequentially numbered, opaque, sealed envelopes" Comment: unclear if the primary researcher is the same person who performed all restorations
Blinding of participants and personnel (performance bias) - participant	High risk	Comment: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comment: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Restorations were assessed after 6 months and after a year by a calibrated examiner who was not involved in the placement of restorations, and did not know which treatment had been provided for each case"
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: loss to follow-up 33.6% at 24 months
Selective reporting (reporting bias)	Unclear risk	Comment: restorations are not reported individually so we do not know how they compared to the overall average. It may have been space limits rather than deliberate selective reporting that is responsible

Da Mata 2015 (*Continued*)

		for this
Other bias	High risk	Comment: imbalance in DMFT score between groups

De Menezes 2009

Methods	**Design:** parallel RCT **Number of participants:** 40 **Setting:** dental clinic **Country:** Brazil **Unit of randomisation:** child **Unit of analysis:** child **Follow-up:** just after treatment **Dropout:** none
Participants	**Number randomised (participants):** 40 (20 ART group and 20 CT group) **Number analysed:** 40 **Age mean and SD (range):** 5.3 years SD = 1.2 (4-7) **Gender:** female 19 (47.5%) and male 21 (52.5%) **Average DMFT score:** not reported **Dentition:** primary **Type of caries lesion:** occlusal caries **Inclusion criteria:** at least one carious lesion involving the occlusal surface of primary molars without pulp involvement and without pain **Exclusion criteria:** not reported
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + H-GIC with anaesthesia ART group was treated using hand instruments only. The restorative material used was the H-GIC, Fuji IX (GC®, Japan) Conventional restorative treatment was performed under local anaesthesia and rubber dam protection using rotary equipment. Cavity cleaning was restricted to removing all carious tissues in enamel and dentine using the drill. The restorative material used was the H-GIC, Fuji IX (GC®, Japan) The interventions were conducted by 1 dentist
Outcomes	• Pain measurement by Wong-Baker FACES Pain Rating Scale (6 pictures representing feelings ranging from no pain to extreme pain) at the end of the restorative treatment session
Notes	Funding: Brazilian Dental Association Trial register number not reported Sample size not calculated
Risk of bias	

De Menezes 2009 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The children were randomly allocated to a test and control group using a series of computer generated random numbers"
Allocation concealment (selection bias)	Unclear risk	Comment: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comment: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comment: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no dropouts. All participants assessed
Selective reporting (reporting bias)	Low risk	Comment: all outcomes listed in the methods sections included
Other bias	Unclear risk	Comment: no information provided about baseline characteristics of included participants

Eden 2006

Methods	**Design:** cluster, split-mouth RCT **Number of participant:** 160 **Setting:** dental clinic **Country:** Turkey **Unit of randomisation:** tooth **Unit of analysis:** tooth pairs **Follow-up:** 6, 12 and 24 months **Dropout:** 22.5%, 29.4% and 64.4% after 6, 12 and 24 months, respectively
Participants	**Number randomised (participants):** 160 children (96 ART group and 64 CT group)/ 325 teeth (162 ART and 163 conventional) **Number analysed:** 57 children/100 teeth **Age mean and SD (range):** 7.0 SD = 0.3 **Gender:** female 82 (52%), male 75 (48%) **Average DMFT score:** 6.9 SD = 2.5

Eden 2006 (*Continued*)

	Dentition: primary **Type of caries lesion:** multiple surface caries lesion **Inclusion criteria:** ≥ 1 bilaterally matched pair of primary molars with class II cavited dentin lesions in different quadrants or jaws and with cavited dentin lesions presenting with an opening wide enough for the smallest excavator (0.9 mm) to penetrate **Exclusion criteria:** cavities dentin lesions that had pulpal involvement were excluded
Interventions	Two treatment arms: • Group 1: ART approach + composite • Group 2: CT + composite The ART procedure consisted of widening the opening in small cavities and removing thin enamel in larger cavity openings with a dental hatchet, until the enamel was free of visible demineralisation. Soft infected dentin was excavated from the cavity walls and floor with spoon excavators. No local anaesthesia was administered. Cavities were restored with composite (Pertac II) The CT procedure consisted of removing carious tissues using a micromotor and a handpiece with diamond and steel burs. The cavity was prepared following the minimal intervention concept. No local anaesthesia was administered. An omni-matrix and interdental wooden wedges were placed before restoration. The cavities were restored with composite The interventions were conducted by 3 dentists.
Outcomes	• Survival rate measured by modified Ryge criteria (A restoration was considered to have survived if it scored Alpha and Bravo for anatomical form, marginal integrity and marginal discolouration and if recurrent caries was not diagnosed) after 6, 12 and 24 months. • Anxiety assessed by Venham Picture Test (8 pictures representing feelings ranging from anxiety to contentment) at the end of treatment session
Notes	Funding: WHO Collaborating Centre of the Radboud University Medical Centre in Nijmegen, The Netherlands, Hu-Friedy, Germany, and 3M ESPE, Germany Trial register number not reported Sample size not calculated Interexaminer reproducibility moderate (kappa = 0.41)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The cavitied dentin lesions were randomly assigned to the treatment group after stratification for gender, operator, upper/lower jaw, and when needed according to left/right side of the mouth using a validated computer software program (trial Balance)"
Allocation concealment (selection bias)	Unclear risk	Comment: not reported

Eden 2006 (*Continued*)

Blinding of participants and personnel (performance bias) - participant	High risk	Comment: participants aware of different treatments
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comment: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Two calibrated independent examiners who were blinded to the treatment method provided evaluated the occlusal and approximal parts of the restorations after 6 months, 1 year and 2 years..."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Ten children with 33 restorations were not evaluated at any evaluation time" "The total number of children evaluated after 0.5, 1 and 2 years was 124, 113 and 57, respectively" Comment: loss to follow-up high at 2 years (64.4%)
Selective reporting (reporting bias)	Unclear risk	Comment: some results were reported in another study. Maybe there are other results not reported
Other bias	Low risk	Comment: split-mouth design with the same baseline diagnosis of the teeth within a tooth pair

Estupiñan-Day 2006

Methods	**Design:** cluster, parallel RCT **Number of participants:** 1629 children **Setting:** community setting **Country:** Ecuador, Panama and Uruguay **Unit of randomisation:** child **Unit of analysis:** tooth **Follow-up:** 12, 24 and 36 months **Dropout:** 15.6% and 51.47% after 12 and 24 months, respectively
Participants	**Number randomised (participants):** 1629 children (868 ART group and 761 CT group)/ 6773 teeth (4976 ART and 1797 conventional) **Number analysed:** 3287 teeth **Age mean and SD (range):** 7-9 years **Gender:** female 843 (51.38%), male 786 (48.62%) **Average DMFT score:** not reported **Dentition:** permanent **Type of caries lesion:** not reported

Estupiñan-Day 2006 (*Continued*)

	Inclusion criteria • Male and female school children, 7, 8, and 9 years of age in rural and urban schools • Presence of ≥ 1 lesion with one of the following characteristics: 1) initial enamel caries, and 2) teeth with dentinal lesions on a first permanent molar • Parental consent **Exclusion criteria** • Lesions with very large or deep caries that are very close to the pulp • Lesions where caries have compromised the pulp (inflammation or infection of the pulp) • Healthy teeth without an apparent risk of caries as well as overall good health
Interventions	The study has 3 arms: • ART performed by dentist + GIC • ART performed by auxiliary + GIC • CT + amalgam The ART procedure consisted of a manual excavation of dental caries and restoration with **glass ionomer**. CT with **amalgam**. No more details Use of anaesthesia was not reported in any group. The interventions were conducted by dentists and dental hygienists
Outcomes	• Failure rate (USPHS criteria) after 12 and 24 months. It was not reported which codes were considered success or failure. • Pain, co-operation (4 Likert scale questions) during the procedure • Direct cost of the interventions
Notes	Funding: Inter-American Development Bank Trial register number not reported Sample size calculated Results at 3 years not reported Interexaminer reproducibility > 0.75

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "In order to ensure balanced treatment groups within the schools, children were randomised in blocks of 4 or 10 depending on the size of the school. Schools with 15 children or fewer and, whenever possible, within a reasonable distance from one another were collapsed. The randomisation was accomplished using a computer-based (SAS) block randomisation using random number seeds from a random digit table"

Estupiñan-Day 2006 (*Continued*)

Allocation concealment (selection bias)	Low risk	Quote: "Assignment for all three countries was done in Washington, DC to ensure consistency"
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "the PRAT project required its restoration evaluators to be trained and calibrated according to strict standard criteria so that their assessments were reliable and comparable" "At the end of the third year, an external international evaluator will conduct a final evaluation of the condition of restorations performed during the course of the project" Comment: not clear whether the assessments at 1 and 2 years were made by an operator who was not involved in the treatment phase
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: loss to follow-up high at 2 years (51.47%)
Selective reporting (reporting bias)	High risk	Comment: results at 3 years not reported
Other bias	High risk	Comment: DMF scores not reported. Information about supply of water fluoridation between countries not provided. The analysis did not consider the intracluster correlation coefficient

Lin 2003

Methods	**Design:** cluster, parallel RCT (a child is a cluster) **Number of participants:** 58 **Setting:** not reported **Country:** China **Unit of randomisation:** child **Unit of analysis:** tooth **Follow-up:** 6, 12 and 24 months **Dropout:** none
Participants	**Number randomised (participants):** 58 (30 ART group and 28 CT group)/248 teeth (138 ART group and 110 CT group) **Number analysed:** 58 children/248 teeth **Age mean and SD (range):** 3-5 years **Gender:** female 34 (58,6%), male 24 (41.4%) **Average DMFT score:** not reported **Dentition:** primary **Type of caries lesion:** not reported **Inclusion criteria:** primary teeth with carious lesion of enamel or dentin **Exclusion criteria:** not reported
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + H-GIC The ART procedure consisted of opening the cavity using enamel hatchet and sharp excavators to remove the caries. Caries was removed from the dentino-enamel junction using sharp spoon excavators of appropriate size before proceeding on to the floor of the cavity. The glass ionomer silver reinforced restorative was placed in the cavity In CT caries was removed from the dentino-enamel junction using high-speed turbine before proceeding on to the floor of the cavity. The surfaces were then washed with water-moistened cotton pellets and then blotted dry with fresh cotton pellets. The glass ionomer silver reinforced restorative were placed in the cavity Use of anaesthesia was not reported in any group. The interventions were conducted by a dentist.
Outcomes	Success rate was assessed as: • Very good: restoration retention is good, no marginal defect, no secondary carious teeth, the vitality of the pulp is normal; the children have not subjective symptoms • Good: slight marginal defect, slight wear, no secondary carious teeth, the vitality of the pulp is normal and the children have not subjective symptoms after repairing it again. • Failure: tooth is missing, exfoliated or extracted, combine with the symptoms of pulpitis and apical periodontitis.
Notes	Funding not stated Trial register number not reported Sample size not calculated Intraexaminer reproducibility not assessed
Risk of bias	

Lin 2003 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The children were randomly divided into two groups" Comments: method not described.
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comments: not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comments: no dropouts. All participants were assessed.
Selective reporting (reporting bias)	Low risk	Comments: results of all outcomes reported
Other bias	High risk	Comments: baseline characteristics and details about co-interventions were not reported. Analysis did not consider the intracluster correlation coefficient

Ling 2003

Methods	**Design:** split-mouth RCT **Number of participants:** 106 **Setting:** hospital **Country:** China **Unit of randomisation:** tooth **Unit of analysis:** tooth pairs **Follow-up:** 6, 12 and 24 months **Dropout:** none
Participants	**Number randomised (participants):** 106 participants/212 teeth (106 ART group and 106 CT group) **Number analysed:** 106 children/212 teeth **Age mean and SD (range):** (6-8 years) **Gender:** 53 male (50%) and 53 female (50%) **Average DMFT score:** not reported

Ling 2003 (*Continued*)

	Dentition: primary **Type of caries lesion:** not reported **Inclusion criteria:** • 6-8-year-old children in outpatient department in Wuxi Stomatological hospital • Symmetrical primary molars shallow and superficial dentin informed • Consent obtained from parents **Exclusion criteria:** • Symptom of pulpitis and periapical periodontitis • Caries lesion extended to > 2/3 occlusal surface
Interventions	Two treatment arms: • Group 1: ART approach + GIC • Group 2: CT + amalgam For ART group the cavities were filled with FX glass ionomer cement (Japan Co., Ltd), after removing carious tooth tissues and undermined enamel with a sharp excavator In CT the cavities were filled with silver amalgam (China Iron & Steel Research Institute Group), after removing carious tooth tissues and preparation of cavities with high-speed turbine drill Use of anaesthesia was not reported in any group. All interventions were conducted by the same dentist
Outcomes	• Succes rate was evaluated by scoring: 0 = filling was intact; 1 = defect of filling edge was < 0.5 mm. 2 = defect of filling edge was > 0.5 mm. 3 = filling maintained but was broken; 4 = filling maintained but tooth tissue was broken; 5 = partial or completed filling was off; 6 = tooth had been refilled or retreated; 7 = tooth was missing. Level 0-1 were success and level 2-7 were failure. • Children's co-operation was classified as: ○ co-operative: accept treatment initiatively or slightly nervous but is in place. The process of treatment went well. ○ fear: nervous, fearful, crying and only accept treatment under language-induction. It was a little bit difficult to do treatments. ○ compulsive: constant crying and moving the body. Refuse treatment. Coercive method was used to make children accept treatment. It was very difficult.
Notes	Funding not stated Trial register number not reported Samples size not calculated Intraexaminer reproducibility not assessed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Self-control method and randomised method were used to allocate teeth into two groups" Comments: method not described
Allocation concealment (selection bias)	Unclear risk	Comments: not reported

Ling 2003 (*Continued*)

Blinding of participants and personnel (performance bias) - participant	High risk	Comments: participant aware of different treatments
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "all the treatments and clinical examinations were done by the same operator"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comments: all participants were assessed
Selective reporting (reporting bias)	Unclear risk	Comments: some outcomes were not reported in the methods section but were shown in the results
Other bias	High risk	Comments: analysis did not consider the paired data

Lo 2006

Methods	**Design:** cluster, parallel RCT (an individual is a cluster) **Number of participant:** 103 **Setting:** nursing homes **Country:** China **Unit of randomisation:** participant **Unit of analysis:** tooth **Follow-up:** 6 and 12 months **Dropout:** 25.2% after 12 months
Participants	**Number randomised (participants):** 103 participants/162 teeth (78 ART group and 84 CT group) **Number analysed:** 77 participants/122 teeth **Age mean and SD (range):** 78.6 years **Sex:** female 72 (69.9%), male 31 (30.1%) **Average DMFT score:** 1.0 **Dentition:** permanent **Type of caries lesion:** root caries **Inclusion criteria:** > 60 years of age, having basic self-care ability, and with root caries lesions ≥ 1 mm in depth **Exclusion criteria:** lesions involving or judged to be very close to the dental pulp
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + RM-GIC with anaesthesia The ART technique consisted of removing all the soft dentin only with hand instruments.

	Cotton rolls and gingival retraction cord were used when necessary for field isolation and moisture control. Cavity was conditioned for 10-15 s. The prepared cavity was restored with a high-strength chemically cured glass-ionomer material (Ketac Molar, 3M ESPE, Seefeld, Germany). A clear cellulose matrix was used to build up the contour of the root CT used local anaesthesia when required. Cotton rolls and gingival retraction cord were used for field isolation and moisture control. Decayed tooth tissues were removed by means of dental burs until the floor and walls of the cavity were found to be hard. The prepared cavity was conditioned with polyacrylic acid for 10-15 seconds, washed, dried, and restored with a resin modified glass-ionomer material (Fuji II LC, GC Corporation, Tokyo, Japan) The interventions were conducted by 1 dentist.
Outcomes	• Success and survival rate assessed by USPHS criteria and ART criteria. Sound restorations or restorations with marginal defect or wear < 0.5 mm, measured by the ball tip of a CPI periodontal probe, were classified as having survived.
Notes	Funding: Hong Kong Research Grants Council (Ref. HKU 7244/02M) Trial register number: not reported Sample size calculated Intraexaminer reproducibility evaluated but not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We tossed a coin to allocate the selected lesions randomly to receive one of the two study treatments" "For patients who had 2 root-caries lesions, both types of treatment were provided" "The treatment assignment procedure was repeated if there were more than 2 lesions in a subject"
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Restorations was assessed at six-month intervals by a dentist who was not involved in the provision of the treatments, and who did not know which technique had been used in placing the restoration"

Lo 2006 (*Continued*)

		"Blindness was possible because tooth-colored glass-ionomer material was used in both techniques, and the restorations had similar appearances."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The reasons for dropout were that the patients had died, were too ill to be examined, or were not at the home on the examination day" Comments: while the causes of dropout are indicated, the loss was high (25%)
Selective reporting (reporting bias)	Low risk	Comments: all outcomes listed in the methods sections were included
Other bias	High risk	Comments: the analysis did not consider the paired data.

Luz 2012

Methods	**Design:** Parallel RCT **Number of participant:** 30 **Setting:** school of dentistry **Country:** Brazil **Unit of randomisation:** child **Unit of analysis:** child **Follow-up:** 6 month **Dropout:** 23.3% after 6 months
Participants	**Number randomised (participants):** 30 children (16 ART group and 14 CT group) **Number analysed:** 23 children **Age mean and SD (range):** 4-7 years **Gender:** Female 16 (53.3%), male 14 (46.7%) **Average DMFT score:** not reported **Dentition:** primary **Type of caries lesion:** approximal caries lesion **Inclusion criteria:** children who had at least one approximal active caries lesion in a primary molar and that was accessible to hand instruments. **Exclusion criteria:** children with spontaneous pain
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + composite with anaesthesia Children in the ART Group were treated according to ART approach using only hand instruments, no anaesthesia and restorative material was glass ionomer (Ketak-Molar 3-M ESPE, St. Paul, Minnesota). Only the demineralised carious tissue and unsupported enamel were removed. Matrix band and wooden wedges were used Children in CT group were treated with local anaesthesia, rubber dam, rotary instruments

	and the cavity was filled with composite resin (Z 350 3-M ESPE, St. Paul, Minnesota) . Only the demineralised carious tissue and unsupported enamel were removed. Matrix band and wooden wedges were used The interventions were conducted by 1 dentist.
Outcomes	• Acceptability evaluated by Face Image Scale (5 pictures representing feelings ranging from very unhappy to very happy) before and after the procedure • Pain assessed by asking if the child felt any pain during the treatment and were willing to received the same treatment again • Success rate evaluated by USPH modified criteria after 6 months
Notes	Funding not stated Trial register number not reported Sample size not calculated Intraexaminer reproducibility high - kappa > 0.8

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned to one of the treatment group after stratification for tooth in the upper/lower jaw using a ballot box"
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comments: not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comments: for the outcomes evaluated, all participants were assessed
Selective reporting (reporting bias)	Low risk	Comments: all prespecified (primary and secondary) outcomes reported
Other bias	Unclear risk	Comments: baseline characteristics and details about co-interventions not reported

Miranda 2005

Methods	**Design:** split-mouth RCT **Number of participant:** 80 **Setting:** dental clinic **Country:** Brazil **Unit of randomisation:** tooth **Unit of analysis:** tooth pairs **Follow-up:** 6 and 12 months **Dropout:** 3.75% after 6 months and 12.5% after 12 months
Participants	**Number randomised (participants):** 80 children/160 teeth (80 ART group and 80 CT group) **Number analysed:** 70 children/140 teeth **Age mean and SD (range):** 5.71 years (3-9 years) **Gender:** female 33 (41.25%), male 47 (58.75%) **Average DMFT score:** not reported **Dentition:** primary **Type of caries lesion:** single and multiple surface caries lesion **Inclusion criteria** • Child between 3-9 years • ≥ 2 primary molars with similar carious lesions (equal number of surfaces involved, extent and similar depths) • Carious lesions in dentin with access in enamel > 1 mm and that was accessible to hand instruments • Teeth without pulp exposure **Exclusion criteria** • Children without ability to co-operate in treatment
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + amalgam Teeth in the ART group were treated with hand instruments only. The restorative material was glass ionomer (Ketak-Molar 3-M ESPE) In CT group, cavities were filled with silver amalgam (SDI), after removing carious tooth tissues and preparation of cavities with high and low-speed drill Both treatments were started without use of anaesthesia. The interventions were conducted by 1 dentist
Outcomes	• Success rate was assessed by ART criteria after 6 and 12 months (0 = present, in good condition, 1 = present, local marginal defect (0.5 mm), no repair needed, 2 = present, unique defect > 0.5 and < 1 mm, repair needed, 3 = present, gross marginal defect, repair needed, 4 = not present, restoration partly or completely missing, 5 = not present, restoration replaced by another restoration, 6 = tooth missing, 7= present, wear < 0.5 mm, no repair needed, 8 = present, wear > 0.5 mm, repair needed, 9 = restoration not assessed, participant not present. Codes 0, 1 and 7 were considered success and 2, 3, 4 and 8 as failure. Restorations with codes 5, 6 and 9 were excluded from the analysis. • Pain during the treatment was classified as absence of pain, little pain or much pain • Recurrent caries assessed as caries on the margin of the restorative material

Notes	Funding not stated Trial register number no reported Sample size calculated Intraexaminer reproducibility not assessed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We used a simple randomised to two treatment cited by Pocock (1993) and a table of random numbers, randomised formed by digits from 0 to 9 in a sequence from right to left and from top to bottom"
Allocation concealment (selection bias)	Low risk	Quote: "The concealment was performed through sealed envelopes numbered 1-100, containing inside cards with corresponding number and an indication of the first treatment, obtained by the method mentioned, being sequentially archived. The listing and envelopes were made by a professional different to the researcher."
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: participant aware of different treatments
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The restorations were evaluated by paediatric dentist who did not perform any treatment"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comments: low dropout rate (12.5%), reasons for missing outcome data unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Comments: all prespecified (primary and secondary) outcomes reported
Other bias	Low risk	Comments: split-mouth design with the same baseline diagnosis of the teeth within a tooth pair

Roeleveld 2006

Methods	**Design:** parallel RCT **Number of participants:** 217 **Setting:** not reported **Country:** Tanzania **Unit of randomisation:** child **Unit of analysis:** child **Follow-up:** 7 and 12 months **Dropout:** 10.1% and 11.1% after 7 and 12 months, respectively
Participants	**Number randomised (participants):** 217 participants in 3 arms (77 ART group, 72 CT group and 68 Carisolv^{TM} group) **Number analysed:** 109 children (57 ART and 52 conventional) **Age mean and SD (range):** 7.5 years SD = 0.57 (6-7 years) **Gender:** female 123 (56,68%), male 94 (43.32%) **Average DMFT score:** not reported **Dentition:** primary **Type of caries lesion:** multiple-surface caries lesion I**nclusion criteria:** $\geq$ 1 class II cavity in a primary molar, accessible to hand instruments, with an untreated tooth adjacent to cavity, and no pulp exposure **Exclusion criteria:** not reported
Interventions	Three treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + H-GIC • Group 3: chemo-mechanical technique with Carisolv^{TM} + H-GIC With the ART approach, only hatchets and excavators were used The CT group was treated by excavation with a stainless steel bur without water cooling (speed: ± 750 rpm) For Carisolv^{TM} group, excavation was performed with special hand instruments after the application of the gel **In all groups** a matrix band and wooden wedges were inserted after cleaning the cavity. Cotton wool rolls were used to isolate the cavity so as to prevent contamination with saliva and/or blood. The smear layer was removed from the dentine by conditioning for 15 seconds and rinsed and dried with respectively 3 wet and 3 dry cotton pellets. Hand-mix **GIC** (Fuji IX) was placed into the cavity, using the finger press method; Vaseline was applied to the index finger and pressed on for 3 seconds, the finger being removed sideways No local anaesthesia was used in any group. Interventions were conducted by 4 dentists.
Outcomes	• Success rate was evaluated through ART criteria. Codes 00 or 10 = success; codes 11, 12, 13, 20, 21, 30 or 40 = failure • Residual caries and cervical was assessed on bite wing radiographs after the completion of the restorative procedure according to the following scale: 1 = definitely present (failure), 2 = probably present (failure) , 3 = not present (success)
Notes	Funding: GC Europe provided the GIC; Medi Team provided Carisolv and blunt instruments Trial register number not reported

	Sample size not calculated Interexaminer reproducibility ranged between 0.66 and 0.84

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "217 children were randomly divided into three groups for treatment with one of three different methods" Comments: insufficient information about the sequence generation process
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "The restorations were evaluated after 7 months (first evaluation) and one year (second evaluation) by 4 final-year students from The Netherlands" Comments: unclear if different from who was involved in placing them. Blinding would have been possible given that all restorations were GIC
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "There were 193 children present at the second evaluation (t=2), 149 of them could participate in the scoring for success or failure of the restorations." Comments: loss to follow-up was low at 1 year (12%). Reasons for missing outcomes were not reported
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported
Other bias	Unclear risk	Comments: baseline characteristics and details about co-interventions not reported

Schriks 2003

Methods	**Design:** parallel RCT **Number of participants:** 403 **Setting:** not reported **Country:** Indonesia **Unit of randomisation:** child **Unit of analysis:** child **Follow-up:** end of treatment **Dropout:** none
Participants	**Number randomised (participants):** 403 children (202 ART group and 201 CT group) **Number analysed:** 403 children **Age mean and SD (range):** 6.3 years (4.9-7.9) **Gender:** female 208 (51.6%), male 195 (48.39%) **Dentition:** primary **Type of caries lesion:** multiple surface caries lesion **Average DMFT score:** not reported **Inclusion criteria:** ≥ 1 multi-surface cavity in a deciduous molar that was accessible to hand instruments and where no pulp exposure was expected **Exclusion criteria:** not reported
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + H-GIC In ART group, only hand instruments were used, i.e. hatchets and excavators In CT group, excavation of the demineralised tooth material was carried out by means of stainless steel round burs in a handpiece (750 rpm), without water cooling **In both groups**, only the demineralised carious tooth tissue and unsupported enamel were removed. After cleaning the cavity, a matrix band and wooden wedges were applied. Cotton wool rolls were used to isolate the cleaned cavity from contamination with saliva and/or blood. After conditioning the dentin for 15 s, hand-mix H-GIC (Chemflex, Dentsply/deTrey) was placed into the cavity in both groups No local anaesthesia was used in either group. Interventions were conducted by 4 dentists and 1 dental student
Outcomes	• Discomfort was assessed by modified Venham scale and heart rate at six fixed moments during dental treatment: (i) when the child entered the treatment room, (ii) at the start of excavation, (iii) at the moment of deepest excavation, (iv) at the moment of application of the matrix band and wedges, (v) at the moment the restoration was applied, and (vi) after completion of the treatment.
Notes	Funding: this study was supported by Dentsply/deTrey (UK), ESPE, Dental Union and WOTRO (the Netherlands) Trial register number not reported Sample size not calculated Interexaminer reproducibility was good (kappa = 0.87).

Risk of bias

Bias	Authors' judgement	Support for judgement

Schriks 2003 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Quote: "Treatments were allocated randomly" Comments: how this was done not described
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "the Venham score was observed by one of the authors, not participating in the treatments, though aware of the treatment method that was randomly chosen for the child" Comments: this could bias the results, favouring one of the treatment methods
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comments: for the outcomes evaluated all participants were assessed
Selective reporting (reporting bias)	Unclear risk	Comments: all outcomes listed in the methods sections were included, but the results were described incompletely
Other bias	Low risk	Comments: the study appears to be free of other sources of bias. No relations could be found between the treatment and either gender or operator in a number of participants

Van de Hoef 2007

Methods	**Design:** cluster, parallel RCT **Number of participant:** 299 **Setting:** not reported **Country:** Surinam **Unit of randomisation:** child **Unit of analysis:** tooth **Follow-up:** 6 and 30 months **Dropout:** 51.7% after 30 months
Participants	**Number randomised (participants):** 299 children (153 ART group and 146 CT group) /408 teeth (205 ART and 203 CT) **Number analysed:** 211 teeth **Age mean and SD (range):** 7.5 years (6.0-12.9 years) **Gender:** female 155 (51.8%), male 144 (48.2%) **Average dmft score:** not reported **Dentition:** primary **Type of caries lesion:** multiple surface caries lesion **Inclusion criteria:** schoolchildren in good mental and physical health with ≥ 1 small proximally situated cavity in a primary molar that was accessible to hand instruments from the occlusal surface and where no pulp exposure was expected. The measurements of the cavity had to be < 1 mm mesio-distally and 2 mm in bucco-lingual/palatinal direction. The antagonist tooth had to be present. **Exclusion criteria:** pain, swelling or fistula
Interventions	The study had four arms: • Group 1: ART approach + H-GIC • Group 2: ART approach + H-GIC with local anaesthesia • Group 3; CT + H-GIC with local anaesthesia. • Group 4: CT + H-GIC Children in the ART approach were treated using only hand instruments (i.e. hatchets and spoon excavators) to remove the caries lesions Participants in the CT group were treated with rotary instruments, i.e. stainless steel round burs in a slow handpiece without water cooling. After access to the cavity was obtained, at first the enamel-dentine border was cleaned and after that the remaining caries was removed In both treatments after finishing the preparation a piece of metal matrix band (Matrico-dent) was applied and fixed with a wooden wedge. In all cases hand-mixed glass ionomer (Fuji IX, GC Corporation) was used as restoration material The interventions were conducted by one dentist, one dental student and two hygienists
Outcomes	• Success was evaluated through ART criteria after 6 and 30 months • Discomfort assessed by modified Venham scale and heart frequency at seven fixed moments during dental treatment: (i) during entrance in the treatment room, (ii) during local analgesia (in groups 2 and 4), (iii) at the start of preparation, (iv) during deep excavation, (v) during application of the matrix and wedge, (vi) at the start of restoration (when glass ionomer was applied), (vii) at the end of restoration
Notes	Funding: Foundation of Youth Dental Care in Paramaribo, Suriname and GC company provided the GIC

	Trial register number not reported Samples size not calculated Intraexaminer consistency values range from 0.73-0.84 (Cohen's kappa) Interexaminer consistency was calculated: 0.72 for the 6-month evaluation and 0.93 for the evaluation after 30 months Some of the children received a second restoration placed in another molar. In these cases the same treatment protocol for both restorations was used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The children were randomly divided into four treatment groups" "The randomization list was obtained by means of SPSS"
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The restorations were evaluated by two final-year dental students of ACTA (who did not perform any treatment)"
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The majority of the dropouts concerned absent patients and shed teeth" Comments: loss to follow-up close to 50% at 30 months. How many losses due to absence or shedding not reported
Selective reporting (reporting bias)	High risk	Comments: discomfort was not reported at all measured times, only during deep excavation and restoration. Not was included a mean of all measured
Other bias	High risk	Comments: baseline characteristics or details about co-interventions not reported. The analysis did not consider the intracluster correlation coefficient

Van den Dungen 2004

Methods	**Design:** parallel RCT **Number of participants:** 393 **Setting:** school **Country:** Indonesia **Unit of randomisation:** child **Unit of analysis:** child **Follow-up:** 1.5, 6, 12, 24 and 36 months **Dropout:** 41.7% after 36 months
Participants	**Number randomised (participants):** 393 children **Number analysed:** 229 children (116 ART group and 113 CT group) **Age mean and SD (range)**: 6.5 years SD = 0.50 **Gender:** not reported **Average dmft score:** not reported **Dentition:** primary **Type of caries lesion:** multiple surface caries lesion **Inclusion criteria:** • Class II-cavities without occlusal caries in deciduous molars • Accessibility for hand instruments used for the ART method • Access to cavities < 1 mm in mesio-distal direction and 2 mm in buccolingual direction (measured from the occlusal plane with a pocket probe with millimetre scale) • Pulp not infected (no pain, fistulas or swellings) • Teeth had an antagonist **Exclusion criteria:** not reported
Interventions	Two treatment arms: • Group 1: ART approach + H-GIC • Group 2: CT + H-GIC The ART group used hand instruments to remove caries lesion and the cavities were restored with H-GIC (Chem-Flex Dentsply/DeTrey) In the CT group, cavities were excavated using a round, stainless steel drill (750 rpm) and restored with H-GIC (Chem Flex Dentsply/DeTrey) Use of anaesthesia was not reported in any group. Interventions conducted by 2 dentists and 2 dental students
Outcomes	Succes rate assessed by WHO criteria after 1.5, 6, 12 , 24 and 36 months. Success includes the following scores: 00 and 10. Scores of 11, 12, 13, 20, 21, 30 and 40 are regarded as failures. The scores 50, 60, 70 and 90 are not related to success or failure
Notes	Funding: The Foundation Backer Dirks Fund provided a grant and Dentsply/DeTrey suggested the material available Trial register number not reported Sample size not calculated

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Van den Dungen 2004 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Quote: "There were 393 children selected for the study. These were randomly divided into 2 groups and randomly assigned to the four practitioners" Commnents: insufficient information about the sequence generation process
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: no information provided, but the participants could tell whether manual or rotary instruments were used
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The evaluators were blinded of the method of treatment (ART or conventional)"
Incomplete outcome data (attrition bias) All outcomes	High risk	Comments: loss to follow-up was high at 3 years (41.7%). Reasons for missing outcomes were not reported
Selective reporting (reporting bias)	High risk	Comments: all outcomes listed in the methods sections were included, but the results were described incompletely. Results before 3 years were not reported
Other bias	Unclear risk	Comments: baseline characteristics and details of co-interventions not reported

Yu 2004

Methods	**Design:** cluster split-mouth RCT **Number of participants:** 60 **Setting:** school dental clinic **Country:** China **Unit of randomisation:** tooth **Unit of analysis:** tooth pairs **Follow-up:** 6, 12 and 24 months **Dropout:** 33.3% and 55% after 12 and 24 months
Participants	**Number randomised (participants):** 60 children/167 teeth (72 ART group and 95 CT group) **Number analysed:** 27 child/69 teeth **Age mean and SD (range):** 7.4 SD 1.24 (7-9 years)

Yu 2004 (*Continued*)

	Gender: female 33 (55%), male 27 (45%) **Average dmft score:** not reported **Dentition:** primary **Type of caries lesion:** simple and multiple surface caries lesion **Inclusion criteria:** healthy children with ≥ 1 pair of primary molars with caries lesions of similar size and class **Exclusion criteria:** not reported
Interventions	Study has 9 arms: • Group 1: ART approach in class I caries lesion + H-GIC (Fuji IX) • Group 2: ART approach in class I caries lesion + H-GIC (Ketac-Molar) • Group 3: ART approach in class II caries lesion + H-GIC (Fuji IX) • Group 4: ART approach in class II caries lesion + H-GIC (Ketac-Molar) • Group 5: CT in class I caries lesion + H-GIC (Fuji IX) • Group 6: CT in class I caries lesion + H-GIC (Ketac-Molar) • Group 7: CT in class II caries lesion + H-GIC (Fuji IX) • Group 8: CT in class II caries lesion + H-GIC (Ketac-Molar) • Group 9: CT in class I caries lesion + amalgam The ART cavity preparation method followed the directions given in the ART technique manual, ensuring removal of all softened carious dentin at the dentinoenamel junction. Strong, unsupported enamel cusps were left intact where access for caries removal was deemed satisfactory. Bases were not used with any of the restorations The cavities for CT were prepared with conventional rotatory instruments. The cavities were not used with any of the restorations The GICs were coated with a varnish after placement, and the amalgam restorations were left unpolished No local anaesthesia was used in either group. The interventions were conducted by 2 dentists.
Outcomes	• Cumulative success rate assessed by ART criteria at 6, 12 and 24 months. Scores 2, 3, 4 and 5 were considered as failure (2 = restoration present, defect at margin and/or surface wear of 0.5 to 1.0 mm; 3 = present, gross defect at margin and/or surface wear of > 1.0 mm; 4 = not present, restoration has disappeared; 5 = not present, because other treatment has been performed. • Recurrent caries was determined through cavitation and softened dentin at the margin of the restoration.
Notes	Funding: supply of commercial materials and some financial assistance was provided by ESPE Dental Medizin GmbH and by GC International Corp Trial register number not reported Sample size not calculated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Treatments were assigned randomly to one of nine groups" Comments: how this was done is not de-

Yu 2004 (*Continued*)

		scribed.
Allocation concealment (selection bias)	Unclear risk	Comments: not reported
Blinding of participants and personnel (performance bias) - participant	High risk	Comments: participants aware of different treatments
Blinding of participants and personnel (performance bias) - operator All outcomes	High risk	Comments: blinding not possible - operator knew the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The assessment were recorded by a researcher who did not performed any treatment"
Incomplete outcome data (attrition bias) All outcomes	High risk	Comments: loss to follow-up was high at 2 years (55%).
Selective reporting (reporting bias)	Low risk	Comments: all prespecified outcomes reported
Other bias	High risk	Comments: the analysis did not consider the paired data.

ART: atraumatic restorative treatment; **CPI**: Community Periodontal Index; **CT**: conventional treatment; **dmft**: decayed, missing and filled primary teeth); **DMFT:** decayed, missing and filled permanent teeth; **GIC**: glass ionomer cement; **H-GIC**: high-viscosity glass ionomer cement; **RCT**: randomised controlled trial; **RM-GIC**: resin-modified glass-ionomer cement; **USPHS**: US Public Health Service

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Andrade 2010	Compares ART with chemomechanical caries removal (Papacarie)
Barata 2007	Compares ART with chemomechanical caries removal (Carisolv)
Barata 2008	Compares ART with chemomechanical caries removal (Carisolv)
Caro 2012	ART technique was modified with Papacarie
De Amorim 2014	Not an RCT
De Menezes 2011	Not an RCT. Only the schools that received experimental group were randomised. CT group was not randomised

(*Continued*)

Frencken 1994	Not an RCT. One village received ART, a second village was treated with amalgam and a third village was the control
Frencken 2006	Not an RCT. The electricity failed on a number of days and the principal investigator decided that all children, who had been bussed to the WHO Centre for treatment, would be treated using the ART approach
Hilgert 2014	Not RCT
Hu 2005	Not RCT
Hui-min 2005	Compares ART with different GICs
Ibiyemi 2011	Does not compare ART with conventional treatment
ISRCTN76299321	Not an RCT
Kalf-Scholte 2003	No randomisation between CT and ART, only between materials used for ART
Mandari 2001	Modified ART, using hand instruments and a caries-removal solution (Caridex)
McComb 2002	Does not compare ART with CT. Compares different materials
Menezes 2006	Does not compare ART with CT. Compares two types of GICs
Mickenautsch 2007	Not an RCT
Mizuno 2011	Compares ART with chemomechanical caries removal (Papacarie)
NCT02234609	Modified ART. Not an RCT
NCT02274142	Does not compare ART with conventional treatment. Compares different GICs
NTR4400	Not an RCT
Phantumvanit 1996	Not an RCT. One village received ART and those in the other village received CT
Phonghanyudh 2012	Modified ART; this involved accessing caries using high speed to break enamel
Rahimtoola 2002	Not an RCT. Two operators did not strictly follow the randomisation procedure for the selection of the treatment technique
Taifour 2002	Not an RCT. The electricity failed on a number of days and the principal investigator decided that all children, who had been bussed to the WHO Centre for treatment, would be treated using the ART approach
Yip 2002b	Not an RCT

ART: atraumatic restorative treatment; **CT**: conventional treatment; **GIC**: glass ionomer cement; **RCT**: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

CTRI007332

Trial name or title	Comparison of efficacy and acceptability of caries removal methods - a randomized controlled clinical trial
Methods	Design: RCT Country: India
Participants	**Inclusion criteria** • School children aged 5-9 years and who are willing to participate in the study, with consent form signed by parents • Children with ≥ 1 open occlusal carious lesions of primary teeth on different quadrants **Exclusion criteria** • Children who are not co-operative and not willing to participate in the study • Teeth with deep carious lesions involving pulp • Teeth with proximal carious lesions • Teeth with clinical signs and symptoms of pulpal and periapical lesions • Children with presence of any systemic illness
Interventions	The study has three arms • Group 1: ART • Group 2: CT • Group 3: chemomechanical caries removal methods
Outcomes	Primary outcomes • Acceptability • Efficacy Secondary outcomes • Pain • Time taken
Starting date	December 2015
Contact information	DR SS Hiremath, hiremath29@gmail.com
Notes	

NCT02562456

Trial name or title	Cost-efficacy between ART and composite resin restorations in primary molars
Methods	Design: parallel RCT, single-blind Country: Brazil
Participants	**Inclusion criteria** • Children aged 3-6 years • In good health • Whose parents or legal guardians accept and sign the consent form • With ≥ 1 occlusal or occlusal proximal caries lesion in primary molars

NCT02562456 (*Continued*)

	• Only occlusal and/or occlusal-proximal surfaces with caries lesions with dentin involvement **Exclusion criteria** • Severe behavioral issues • Presence of fistula or abscess near the selected tooth • Presence of pulp exposure in the selected tooth • Presence of mobility in the selected tooth
Interventions	Two treatment arms: • Group 1: ART using H-GIC (Fuji IX). No local anaesthesia will be used. Infected carious tissue will be removed with hand instruments. • Group 2: CT using Filtek Z-350 composite resin. Local anaesthesia will be used. Absolute isolation will be performed using rubber dam and clamp. Access to caries lesion will be done using a round bur. Infected carious tissue will be removed with hand instruments.
Outcomes	Primary outcome • Restoration survival Secondary outcome • Child self-reported discomfort • Cost-efficacy assessment
Starting date	October 2015
Contact information	Daniela P Raggio, PhD danielar@usp.br
Notes	

NCT02568917

Trial name or title	Effectiveness of ART and conventional treatment - practice-based clinical trial
Methods	Design: parallel RCT, single blind Country: Brazil
Participants	**Inclusion criteria** • Children aged 6-14 years • In good health • Spontaneous demand for treatment by parents or legal guardians • Whose parents or legal guardians accept and sign the consent form • With ≥ 1 occlusal or occlusal proximal caries lesion in primary or permanent molars • Only occlusal and/or occlusal-proximal surfaces with caries lesions with dentin involvement **Exclusion criteria** • Severe behavioural issues • Presence of fistula or abscess near the selected tooth • Presence of pulp exposure in the selected tooth • Presence of mobility in the selected tooth

NCT02568917 (*Continued*)

Interventions	Two treatment arms: • Group 1: ART using H-GIC (Ketac Molar Easy Mix). No local anaesthesia will be used. Infected carious tissue will be removed with hand instruments. • Group 2: CT using composite Resin (Bulk Fill). Local anaesthesia can be used if necessary. Access to caries lesion will be done using a round bur. Infected carious tissue will be removed with hand instruments.
Outcomes	Primary outcome • Restoration survival Secondary outcome • Longevity of the tooth • Cost-efficacy assessment • Preference of the treatments by dentists
Starting date	January 2016
Contact information	Professor Daniela P Raggio danielar@usp.br
Notes	

RBR-4nwmk4

Trial name or title	Evaluation of atraumatic restorative treatment (ART) in the family health strategy of Teresina, Piauí
Methods	Design: parallel RCT, double blind Country: Brazil
Participants	**Inclusion criteria** • participant with good general health • present dentin caries lesion in vital primary teeth without pain symptoms or signs of pulp envelopment **Exclusion criteria** • deep cavities • presence of fistula, pulp envelopment or mobility of the selected tooth
Interventions	Two treatment arms: Group 1: ART using H-GIC Group 2: CT using H-GIC
Outcomes	Primary outcome • Restoration survival Secondary outcome • Loss of restorations
Starting date	September 2015
Contact information	Marcoeli Silva De Moura. Universidade Federal Do Piauí. marcoeli-moura@uol.com.br

RBR-4nwmk4 (*Continued*)

Notes	Funding: Fundação de Amparo a Pesquisa do Estado do Piauí - FAPEPI

ART: atraumatic restorative treatment; **CT**: conventional treatment; **GIC**: glass ionomer cement; **H-GIC**: high-viscosity glass ionomer cement; **RCT**: randomised controlled trial; **RM-GIC**: resin-modified glass-ionomer cement

DATA AND ANALYSES

Comparison 1. Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Restoration failure - primary teeth - longest follow-up	5		Odds Ratio (Random, 95% CI)	1.60 [1.13, 2.27]
1.1 Single and multiple cavity surfaces	1		Odds Ratio (Random, 95% CI)	2.75 [0.50, 15.16]
1.2 Multiple cavity surfaces	3		Odds Ratio (Random, 95% CI)	1.62 [1.03, 2.55]
1.3 Type of cavity surfaces not reported	1		Odds Ratio (Random, 95% CI)	0.79 [0.12, 5.45]
2 Pain - primary teeth	1	40	Mean Difference (IV, Fixed, 95% CI)	-0.65 [-1.38, 0.07]
3 Participant experience - discomfort	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 2. Atraumatic restorative treatment using composite versus conventional treatment using composite

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Restoration failure - primary teeth - longest follow-up	1		Odds Ratio (Random, 95% CI)	Totals not selected
2 Participant experience - dental anxiety	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Comparison 3. Atraumatic restorative treatment using resin-modified glass ionomer cement (RM-GIC) versus conventional treatment using RM-GIC

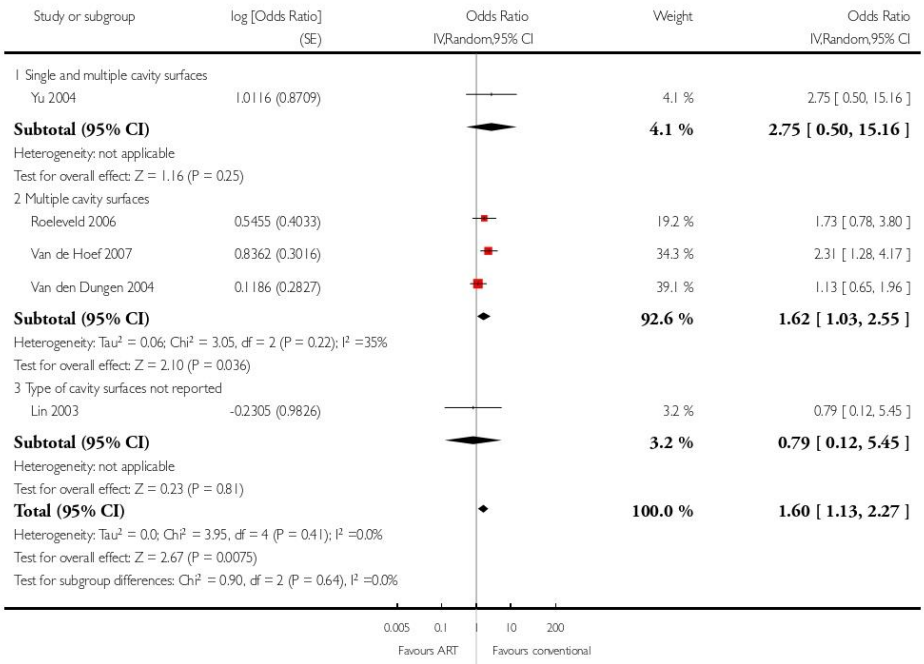
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Restoration failure - permanent teeth - longest follow-up	1		Odds Ratio (M-H, Random, 95% CI)	Totals not selected
2 Secondary caries	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 1.1. Comparison 1 Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC, Outcome 1 Restoration failure - primary teeth - longest follow-up.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 1 Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC

Outcome: 1 Restoration failure - primary teeth - longest follow-up

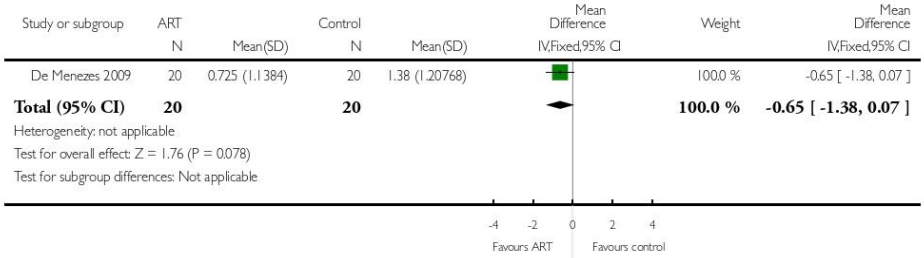


Analysis 1.2. Comparison 1 Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC, Outcome 2 Pain - primary teeth.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 1 Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC

Outcome: 2 Pain - primary teeth

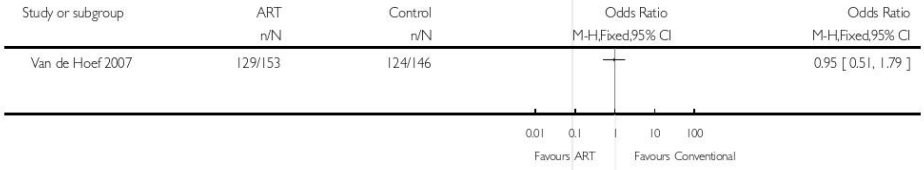


Analysis 1.3. Comparison 1 Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC, Outcome 3 Participant experience - discomfort.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 1 Atraumatic restorative treatment using high-viscosity glass ionomer cement (H-GIC) versus conventional treatment using H-GIC

Outcome: 3 Participant experience - discomfort

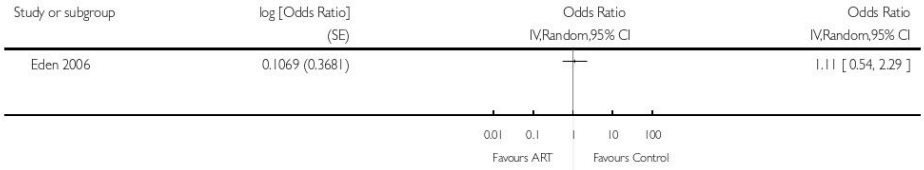


Analysis 2.1. Comparison 2 Atraumatic restorative treatment using composite versus conventional treatment using composite, Outcome 1 Restoration failure - primary teeth - longest follow-up.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 2 Atraumatic restorative treatment using composite versus conventional treatment using composite

Outcome: 1 Restoration failure - primary teeth - longest follow-up

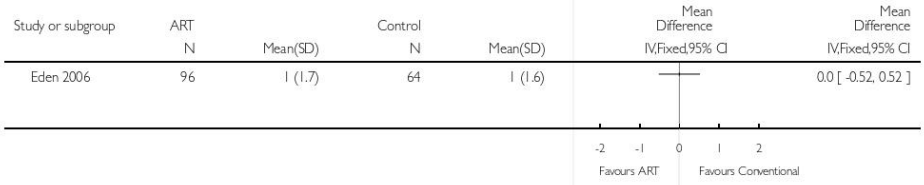


Analysis 2.2. Comparison 2 Atraumatic restorative treatment using composite versus conventional treatment using composite, Outcome 2 Participant experience - dental anxiety.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 2 Atraumatic restorative treatment using composite versus conventional treatment using composite

Outcome: 2 Participant experience - dental anxiety

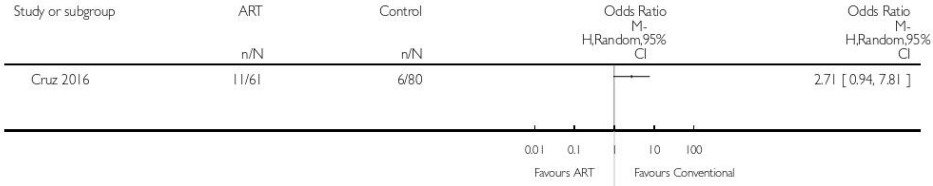


Analysis 3.1. Comparison 3 Atraumatic restorative treatment using resin-modified glass ionomer cement (RM-GIC) versus conventional treatment using RM-GIC, Outcome 1 Restoration failure - permanent teeth - longest follow-up.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 3 Atraumatic restorative treatment using resin-modified glass ionomer cement (RM-GIC) versus conventional treatment using RM-GIC

Outcome: 1 Restoration failure - permanent teeth - longest follow-up

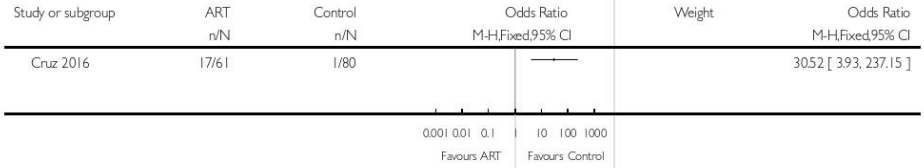


Analysis 3.2. Comparison 3 Atraumatic restorative treatment using resin-modified glass ionomer cement (RM-GIC) versus conventional treatment using RM-GIC, Outcome 2 Secondary caries.

Review: Atraumatic restorative treatment versus conventional restorative treatment for managing dental caries

Comparison: 3 Atraumatic restorative treatment using resin-modified glass ionomer cement (RM-GIC) versus conventional treatment using RM-GIC

Outcome: 2 Secondary caries



ADDITIONAL TABLES

Table 1. ART versus conventional treatment studies using different materials in each arm

ART with one material versus conventional treatment with another material			
ART material	**Conventional treatment material**	**Outcomes**	**Effect estimate** OR (95% CI)
H-GIC	Amalgam	Restoration failure -primary teeth - 2 studies (Miranda 2005; Yu 2004). Studies reporting on single + multiple lesions	2.15 (0.73 to 6.35); I^2 = 0%
		Pain (primary dentition) - 1 study (Miranda 2005). Studies reporting on single + multiple lesions	1.44 (0.45 to 4.60)
GIC	Amalgam	Restoration failure - primary teeth - 1 study (Ling 2003) . Studies reporting on lesion type: not reported	0.78 (0.30 to 2.02)
		Restoration failure - permanent, immature teeth - 1 study (Estupian-Day 2006). Studies reporting on lesion type: not reported	1.71 (1.32 to 2.22)
		Pain - permanent, immature teeth (Estupian-Day 2006)	0.41 (0.35 to 0.47)
H-GIC	Composite and local anaesthetic	Restoration failure - primary teeth - 1 study (Luz 2012). Studies reporting on multiple lesions	8.00 (1.24 to 51.48)
		Pain (primary dentition) - 1 study (Luz 2012)	2.22 (0.51 to 9.61)
H-GIC	RM-GIC and local anaesthetic	Restoration failure - permanent, mature teeth - 2 studies (Da Mata 2015; Lo 2006). Studies reporting on coronal/root caries	1.46 (0.74 to 2.88); I^2 = 0%

CI: confidence interval; **OR**: odds ratio

APPENDICES

Appendix 1. Cochrane Oral Health's Trials Register search strategy

#1 (cavit* or caries or carious or decay* or lesion* or deminerali* or reminerali*:ti,ab) AND (INREGISTER)
#2 (restor* or fill*:ti,ab) AND (INREGISTER)
#3 (ultraconservative or "stepwise excavation" or atraumatic or "minimal invasion" or "minimum invasion" or "minim* invasive" or ART:ti,ab) AND (INREGISTER)
#4 (cement* or resin* or "glass ionomer" or cemet*:ti,ab) AND (INREGISTER)
#5 (seal*:ti,ab) AND (INREGISTER)
#6 (#4 and #5) AND (INREGISTER)
#7 ((fissure and seal*) or (dental and seal*):ti,ab) AND (INREGISTER)
#8 (#3 or #6 or #7) AND (INREGISTER)
#9 (#1 and #2 and #8) AND (INREGISTER)

Appendix 2. Cochrane Central Register of Controlled Clinical Trials (CENTRAL) search strategy

#1 MeSH descriptor: [Dental Caries] explode all trees
#2 ((teeth near/5 cavit*) or (teeth near/5 caries) or (teeth near/5 carious) or (teeth near/5 decay$) or (teeth near/5 lesion$) or (teeth near/5 deminerali*) or (teeth near/5 reminerali*))
#3 ((tooth near/5 cavit*) or (tooth near/5 caries) or (tooth near/5 carious) or (tooth near/5 decay$) or (tooth near/5 lesion$) or (tooth near/5 deminerali*) or (tooth near/5 reminerali*))
#4 ((dental near/5 cavit*) or (dental near/5 caries) or (dental near/5 carious) or (dental near/5 decay$) or (dental near/5 lesion$) or (dental near/5 deminerali*) or (dental near/5 reminerali*))
#5 ((enamel near/5 cavit*) or (enamel near/5 caries) or (enamel near/5 carious) or (enamel near/5 decay$) or (enamel near/5 lesion$) or (enamel near/5 deminerali*) or (enamel near/5 reminerali*))
#6 ((dentin* near/5 cavit*) or (dentin* near/5 caries) or (dentin* near/5 carious) or (dentin* near/5 decay$) or (dentin* near/5 lesion$) or (dentin* near/5 deminerali*) or (dentin* near/5 reminerali*))
#7 ((root* near/5 cavit*) or (root* near/5 caries) or (root* near/5 carious) or (root* near/5 decay$) or (root* near/5 lesion$) or (root* near/5 deminerali*) or (root* near/5 reminerali*))
#8 MeSH descriptor: [Tooth Demineralization] explode all trees
#9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10 [mh ^"Dental restoration, permanent"]
#11 [mh ^"Dental restoration, temporary"]
#12 (restor* or fill*)
#13 (ultraconservative or "stepwise excavation*" or (atraumatic near/6 restor*) or (atraumatic near/6 technique*) or (atraumatic near/6 therap*) or (atraumatic near/6 treat*) or "minimal invasion" or "minimum invasion" or "minim* invasive")
#14 ART:ti,ab
#15 [mh "Pit and fissure sealants"]
#16 ((fissure near/6 seal*) or (dental near/6 seal*))
#17 [mh "Glass ionomer cements"]
#18 [mh "Resin cements"]
#19 (resin near/6 cement*)
#20 (resin near/6 seal*)
#21 ("glass ionomer*" or cemet*)
#22 #17 or #18 or #19 or #20 or #21
#23 ((dental near/6 seal*) or (fissure near/6 seal*) or (teeth near/6 seal*) or (tooth near/6 seal*))
#24 #22 and #23
#25 #10 or #11 or #12
#26 #13 or #14 or #15 or #16 or #24
#27 #9 and #25 and #26

Appendix 3. MEDLINE Ovid search strategy

1. exp DENTAL CARIES/
2. (teeth adj5 (cavit$ or caries or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
3. (tooth adj5 (cavit$ or caries or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
4. (dental adj5 (cavit$ or caries or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
5. (enamel adj5 (cavit$ or caries or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
6. (dentin$ adj5 (cavit$ or caries or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
7. (root$ adj5 (cavit$ or caries or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
8. exp TOOTH DEMINERALIZATION/
9. or/1-8
10. Dental Restoration, Permanent/
11. Dental Restoration, Temporary/
12. (restor$ or fill$).mp.
13. (ultraconservative or "stepwise excavation$" or (atraumatic$ adj6 restor$) or (atraumatic$ adj6 technique$) or (atraumatic$ adj6 therap$) or (atraumatic$ adj6 treat$) or "minimal invasion" or "minimum invasion" or "minim$ invasive").mp.
14. ART.ab,ti.
15. exp "Pit and Fissure Sealants"/
16. ((fissure adj6 seal$) or (dental adj6 seal$)).mp.
17. exp Glass Ionomer Cements/
18. Resin Cements/
19. (resin adj6 cement$).mp.
20. (resin adj6 seal$).mp.
21. ("glass ionomer$" or cemet$).mp.
22. or/17-21
23. ((dental adj6 seal$) or (fissure$ adj6 seal$) or (teeth adj6 seal$) or (tooth adj6 seal$)).mp.
24. 22 and 23
25. 10 or 11 or 12
26. 13 or 14 or 15 or 16 or 24
27. 9 and 25 and 26

This subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity-maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of *The Cochrane Handbook for Systematic Reviews of Interventions,* Version 5.1.0 [updated March 2011](Lefebvre 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 4. Embase Ovid search strategy

1. exp "DENTAL CARIES"/
2. (teeth adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
3. (tooth adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
4. (dental adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
5. (enamel adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
6. (dentin$ adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
7. (root$ adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
8. or/1-7
9. (restor$ or fill$).mp.
10. (ultraconservative or "stepwise excavation$" or (atraumatic$ adj6 restor$) or (atraumatic$ adj6 technique$) or (atraumatic$ adj6 therap$) or (atraumatic$ adj6 treat$) or "minimal invasion" or "minimum invasion" or "minim$ invasive").mp.
11. ART.ab,ti.
12. exp "Fissure sealant"/
13. ((fissure adj6 seal$) or (dental adj6 seal$)).mp.
14. exp "Glass Ionomer"/
15. "Resin Cement"/
16. (resin adj6 cement$).mp.
17. (resin adj6 seal$).mp.
18. ("glass ionomer$" or cemet$).mp.
19. or/14-18
20. ((dental adj6 seal$) or (fissure$ adj6 seal$) or (teeth adj6 seal$) or (tooth adj6 seal$)).mp.
21. 19 and 20
22. 10 or 11 or 12 or 13 or 21
23. 8 and 9 and 22

This subject search was linked to an adapted version of the Cochrane Embase Project filter for identifying RCTs in Embase Ovid (see http://www.cochranelibrary.com/help/central-creation-details.html for information).

1. Randomized controlled trial/
2. Controlled clinical study/
3. Random$.ti,ab.
4. randomization/
5. intermethod comparison/
6. placebo.ti,ab.
7. (compare or compared or comparison).ti.
8. ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.
9. (open adj label).ti,ab.
10. ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.
11. double blind procedure/
12. parallel group$1.ti,ab.
13. (crossover or cross over).ti,ab.
14. ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab.
15. (assigned or allocated).ti,ab.
16. (controlled adj7 (study or design or trial)).ti,ab.
17. (volunteer or volunteers).ti,ab.
18. trial.ti.
19. or/1-18
20. (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.)
21. 19 not 20

Appendix 5. LILACS BIREME Virtual Health Library search strategy

Mh "Dental caries" or carie$ [Words] and (Mh "Dental Atraumatic Restorative Treatment" or Atraumatic or Atraumático or "Restaurador sem Trauma") [Words]
This subject search was linked to the Brazilian Cochrane Center filter for LILACs BIREME:
((Pt randomized controlled trial OR Pt controlled clinical trial OR Mh randomized controlled trials OR Mh random allocation OR Mh double-blind method OR Mh single-blind method) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Pt clinical trial OR Ex E05.318.760.535$ OR (Tw clin$ AND (Tw trial$ OR Tw ensa$ OR Tw estud$ OR Tw experim$ OR Tw investiga$)) OR ((Tw singl$ OR Tw simple$ OR Tw doubl$ OR Tw doble$ OR Tw duplo$ OR Tw trebl$ OR Tw trip$) AND (Tw blind$ OR Tw cego$ OR Tw ciego$ OR Tw mask$ OR Tw mascar$)) OR Mh placebos OR Tw placebo$ OR (Tw random$ OR Tw randon$ OR Tw casual$ OR Tw acaso$ OR Tw azar OR Tw aleator$) OR Mh research design) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Ct comparative study OR Ex E05.337$ OR Mh follow-up studies OR Mh prospective studies OR Tw control$ OR Tw prospectiv$ OR Tw volunt$ OR Tw volunteer$) AND NOT (Ct animal AND NOT (Ct human and Ct animal)))and not (Ct ANIMAL AND NOT (Ct HUMAN and Ct ANIMAL)))

Appendix 6. BBO BIREME Virtual Health Library search strategy

Mh "Dental caries" or carie$ [Words] and (Mh "Dental Atraumatic Restorative Treatment" or Atraumatic or Atraumático or "Restaurador sem Trauma") [Words]
This subject search was linked to the Brazilian Cochrane Center filter for BBO BIREME:
((Pt randomized controlled trial OR Pt controlled clinical trial OR Mh randomized controlled trials OR Mh random allocation OR Mh double-blind method OR Mh single-blind method) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Pt clinical trial OR Ex E05.318.760.535$ OR (Tw clin$ AND (Tw trial$ OR Tw ensa$ OR Tw estud$ OR Tw experim$ OR Tw investiga$)) OR ((Tw singl$ OR Tw simple$ OR Tw doubl$ OR Tw doble$ OR Tw duplo$ OR Tw trebl$ OR Tw trip$) AND (Tw blind$ OR Tw cego$ OR Tw ciego$ OR Tw mask$ OR Tw mascar$)) OR Mh placebos OR Tw placebo$ OR (Tw random$ OR Tw randon$ OR Tw casual$ OR Tw acaso$ OR Tw azar OR Tw aleator$) OR Mh research design) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Ct comparative study OR Ex E05.337$ OR Mh follow-up studies OR Mh prospective studies OR Tw control$ OR Tw prospectiv$ OR Tw volunt$ OR Tw volunteer$) AND NOT (Ct animal AND NOT (Ct human and Ct animal)))and not (Ct ANIMAL AND NOT (Ct HUMAN and Ct ANIMAL)))

Appendix 7. US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov) search strategy

atraumatic AND caries

Appendix 8. World Health Organization International Clinical Trials Registry Platform search strategy

atraumatic AND caries

CONTRIBUTIONS OF AUTHORS

Mojtaba Dorri (MD) - drafting of the protocol, designing a search strategy, screening search results, selection of studies, writing to authors of papers for additional information, quality assessment, data extraction, drafting the final review, updating the review.

María José Martinez-Zapata - selection of studies, quality assessment, data extraction, carrying out the analysis, drafting the final review, updating the review.

Tanya Walsh - data extraction, carrying out the analysis, interpreting the analysis, drafting the final review, updating the review.

Valeria Marinho (VM) - drafting of the protocol, selection of studies, interpreting the analysis, drafting the final review, updating the review.

Aubrey Sheiham (AS) - drafted the protocol, designed a search strategy, and selected studies. Aubrey made a very important contribution to this review. He passed away in 2015.

Carlos Zaror (CZ) - screening search results, selection of studies, writing to authors of papers for additional information, quality assessment, data extraction, carrying out the analysis, drafting the final review, updating the review.

DECLARATIONS OF INTEREST

Mojtaba Dorri: none known.

Maria José Martinez-Zapata: none known.

Tanya Walsh: none known. Dr Walsh is an Editor with Cochrane Oral Health.

Valeria CC Marinho: none known.

Aubrey Sheiham: deceased. Declaration of interest from protocol: 'none known'.

Carlos Zaror: none known.

SOURCES OF SUPPORT

Internal sources

- The University of Manchester, Manchester Academic Health Sciences Centre (MAHSC), UK NIHR Manchester Biomedical Research Centre, UK.

External sources

- CONICYT Higher educational program. Government of Chile, Chile.
Project number 80140042
- Instituto de Salud Carlos III, Spain.
- Dr. Mª José Martinez Zapata is funded by a Miguel Servet research contract from the Instituto de Salud Carlos III and European Social Fund (*Investing in Your Future*) (CP15/00116)

Naitonal Institute for Health Research (NIHR), UK.
This project was supported by the NIHR, via Cochrane Infrastructure funding to Cochrane Oral Health. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health

Cochrane Oral Health Global Alliance, Other.
The production of Cochrane Oral Health reviews has been supported financially by our Global Alliance since 2011 (Cochrane Oral Health Global Alliance partners). Contributors over the past year have been: British Association for the Study of Community Dentistry, UK; British Society of Paediatric Dentistry, UK; the Canadian Dental Hygienists Association, Canada; Centre for Dental Education and Research at All India Institute of Medical Sciences, India; National Center for Dental Hygiene Research & Practice, USA; New York University College of Dentistry, USA; NHS Education for Scotland, UK; Swiss Society for Endondontology, Switzerland

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- The 'Objectives' section was expanded to better describe the objectives of this review for the readers.

- We had planned to include both RCTs and quasi-RCTs in this review. However, we decided to exclude quasi-RCTs to improve the internal validity of findings.

- In the protocol it was not clear whether we would include studies using different restorative materials in study arms. We clarified in the 'Types of interventions section' that studies using the same and different materials in study arms would be included in the review, but only studies using the same restorative material in both arms would be pooled in the meta-analysis.

- We had planned to search IndMED (India), Chinese BiomedicalLiterature Database (CBM) (in Chinese), Grey literature databases such as SIGLE (1980 to present). In the full review, Cochrane Oral Health amended the list of databases and added the following: Meta Register of Controlled Trials (to 6 July 2015), ClinicalTrials.gov (to 22 February 2017), WHO International Clinical Trials Registry Platform (to 22 February 2017).

- Following consultation with Cochrane Oral Health, we decided to reduce the large list of secondary outcomes and to prioritise only the clinically relevant outcomes.

- To pool parallel and split-mouth data, we used the generic inverse variance method (GIV) and therefore, we calculated the OR rather than RR.

Artículo 4: Zaror C, Atala-Acevedo C, Espinoza-Espinoza G, Muñoz-Millán P, Muñoz S, Martínez-Zapata MJ, Ferrer F. Cross-cultural adaptation and psychometric evaluation of the early childhood oral health impact scale (ECOHIS) in Chilean population. Health Qual Life Outcomes 2018;16(1):232. (IF:2.278; Q2)

Zaror et al. Health and Quality of Life Outcomes (2018) 16:232
https://doi.org/10.1186/s12955-018-1057-x

Health and Quality of Life Outcomes

RESEARCH Open Access

Cross-cultural adaptation and psychometric evaluation of the early childhood oral health impact scale (ECOHIS) in chilean population

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Abstract

Background: The Early Childhood Oral Health Impact Scale (ECOHIS) measures the impact of dental diseases on Oral Health-Related Quality of Life both in children and their families. The aim of this study was to develop a Chilean Spanish version of the ECOHIS that is conceptually equivalent to the original and to assess its acceptability, reliability and validity in the preschool population of Chile.

Methods: The Chilean version of the ECOHIS was obtained through a process including forward and back-translation, expert panel, and cognitive debriefing interviews. To assess metric properties, a cross-sectional study was carried out in Carahue, Southern Chile (April–October 2016). Children younger than six years old without systemic diseases, disabilities or chronic medication from eleven public preschools were included. Parents were invited to complete the Chilean version of the ECOHIS, PedsQL™4.0 Generic Core and PedsQL Oral Health scales, and to answer global questions about their children's general and oral health. A subsample was administrated ECOHIS a second time 14–21 days after. A clinical examination was performed to assess dental caries, malocclusion, and traumatic dental injuries. Reliability was evaluated using measures of internal consistency (Cronbach's alpha) and reproducibility (Intraclass correlation coefficient - ICC). Construct validity was assessed by testing hypotheses based on available evidence about known groups and relationships between different instruments.

Results: The content comparison of the back-translation with the original ECOHIS showed that all items except one were conceptually and linguistically equivalent. The cognitive debriefing showed a suitable understanding of the Chilean version by the parents. In the total sample ($n = 302$), the ECOHIS total score median was 1 (IQR 6), floor effect was 41.6%, and ceiling effect 0%. Cronbach's alpha was 0.89 and the ICC was 0.84. The correlation between ECOHIS and PedsQL™4.0 Generic Core was weak ($r = 0.21$), while it was strong-moderate ($r = 0.64$) with the PedsQL Oral Health scale. In the known groups comparison, the ECOHIS total score was statistically higher in children with poor than excellent/very good oral health (median 11.6 vs 0, $p < 0.01$), and in the high severity than in the caries-free group (median 8 vs 0.5, $p < 0.01$). No differences were found according to malocclusion and traumatic dental injuries groups.

Conclusions: These results supported the feasibility, reliability and validity of the Chilean version of ECOHIS questionnaire for preschool children through proxy.

Keywords: Oral health, Quality of life, Questionnaires, Psychometrics, Outcome assessment, Child

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Background

Oral diseases are highly prevalent in children worldwide despite the improvement in oral health indices initiated in the last decades [1–3]. It is well known that their consequences on children are serious and can affect their quality of life [4–8]. Early childhood caries continues to be a serious public health problem in Chile, with a prevalence that can reach 80% at 4 years of age [9–11]. Oral Health-Related Quality of Life (OHRQoL), together with clinical indicators, can jointly provide a more comprehensive assessment of the patient's oral health [12]. The OHRQoL has been defined as a multidimensional concept which includes a subjective evaluation of the individual's oral health, functional well-being, expectations and satisfaction with care, and their sense of self [12].

The knowledge of the OHRQoL might help to improve the development of effective oral health programs and services because it permits the assessment of young children's perceived needs, and treatment strategy effectiveness [13]. This can contribute to the identification of groups with a higher level of need, to prioritize public health programs for care of children and adolescents, and to improve access to care [14]. The use of OHRQoL as an outcome measure is consistent with patient-centered care, being crucial in understanding the effectiveness of treatment from the patients' perspective [12].

Several instruments have been developed to assess the OHRQoL, yet few of them have been specifically designed for preschoolers. The first OHRQoL questionnaire for this age group was the Michigan Oral Health-Related Quality of Life (Michigan OHRQoL) in 2003 [15]. Subsequently, the Early Childhood Oral Health Impact Scale (ECOHIS) was developed in 2007 [16], the Pediatric Oral Health-Related Quality of Life (POQL) in 2011 [17] and the Scale of Oral Health Outcomes for 5-year-olds (SOHO-5) in 2012 [18]. POQL and the ECOHIS measure the OHRQoL impact of dental diseases not only on the children, but also on their families. It is important because oral health conditions have an indirect impact on parents and family members, because they result in lost workdays or in having to spend time and money on dental care [19, 20]. The ECOHIS demonstrated high reliability [21, 22], good validity [23, 24] and responsiveness [25, 26], and it has been adapted into about 10 languages and countries [21–24, 27–31], including Spanish for Argentina [32].

Culture is an important factor that can influence a person's activities, thinking and behavior. As countries differ regarding public health strategies, attitudes, socioeconomic conditions and other factors, the expression of their culture can change between populations [33], and instruments to measure Health Related Quality of life (HRQoL) should go through a cultural adaptation process before being used in a different country. Therefore, even among Spanish speaking countries it is usual to develop country-specific versions of instruments measuring HRQoL [34–36]. Even when the translation is performed with great precision, cultural factors may not be accurately conveyed. In order to study the health care needs of people with diverse cultural backgrounds, research instruments must be reliable and valid in each culture studied [37].

The aim of this study was to develop a Chilean Spanish version of the Early Childhood Oral Health Impact Scale (ECOHIS) that is conceptually equivalent to the original and to assess the acceptability, reliability and validity of this version in the preschool population of Chile.

Methods

The study was performed in two phases. In the first phase, the scale was translated into Spanish and adapted to the Chilean culture. In the second phase, the psychometric properties were tested among a sample of parents of preschool children. The Ethics Committee of the Universidad de La Frontera approved the study protocol (resolution n° 061/2015).

Early childhood Oral Health impact scale (ECOHIS)

The ECOHIS is a proxy-reported questionnaire developed in USA for measuring the OHRQoL of preschool children and their families [16]. It comprises of 13 items, covering six domains in two sections. The child's impacts section contains 4 domains: symptom (1 item), function (4 items), psychology (2 items) and self-image and social interaction (2 items). The family's impacts section contains 2 domains: parental distress (2 items) and family function (2 items). Response categories for each question are rated on a 5-point Likert scale to record how often an event has occurred during the child's life: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = often, 4 = very often, and 5 = don't know. ECOHIS scores are calculated as a simple sum of the response codes for the child and family sections separately and also a total score, after recoding all "Don't know" responses as "missing". In cases with up to 2 missing responses in the child section or 1 missing response in the parent section, they were ascribed the average score of the rest of the items for that section. Parents missing responses to more than two child items and one family item were excluded from the analysis. Thus, the total score ranges between 0 and 52, with higher scores indicating a greater impact of oral problems and therefore worse OHRQoL [16].

Linguistic and cultural adaptation

Standard methods were used to translate and culturally adapt the instrument [38, 39]. The Spanish translation of

the ECOHIS was carried out independently by two professional linguists, both native Chilean Spanish speakers, with a high level of fluency in English. The focus of these forward translations was achieving a conceptual, rather than literal, equivalence. In addition each translator scored the difficulty in finding the conceptual equivalence in translation of each of the items from 1 (least difficulty) to 10 (maximum difficulty). To obtain a first consensual version, a joint revision of the two Chilean Spanish translations was undertaken by a panel composed of two experts in OHRQoL assessment, two pediatric dentists and the two translators. Then this first Chilean version was reviewed by a panel of parents of pre-school children (3 fathers and 4 mothers) to check its understanding and clarity. This pre-final version was translated back into English by two native American-English speakers. The difficulty in finding the linguistic equivalence in back-translation was also evaluated by translators. The equivalence between the original version and back-translation was evaluated by the expert panel who rated the items as: A (conceptually and linguistically equivalent to the original item), B (functionally equivalent, but with grammatical differences), or C (equivalence is not obvious). The report on equivalence between original and back-translated versions was sent to the authors of the original ECOHIS for evaluation.

As a last step, cognitive debriefing interviews were carried out on 15 parents (2 fathers and 13 mothers, aged 24 to 37 years old) of children between 2 and 5 years of age to evaluate the understandability and clarity of this preliminary version. Cognitive debriefing interviews included: first, asking parents to complete the questionnaire independently; and second, performing additional open questions in an effort to assess the content of the adaptation. This technique allowed assessing what the parents understood in the adapted version. For this purpose, we developed a set of questions to be used during the interview to obtain standardized information, such as: "In your own words, what do you think this question is asking? What does this item mean to you?" (Supplementary data). We recorded the conversations and took notes during the cognitive interviews. Then, we transcribed the audiotapes to prepare an item-by-item summary of each section of the questionnaire and modification recommendations if necessary.

Study of the metric properties

A cross-sectional study was carried out in the city of Carahue, Southern Chile, from April 2016 through October 2016 to test the psychometric properties of the Chilean version of ECOHIS. Eleven public preschools were included, which are funded by the Chilean government for children younger than six years old.

Two- to 5-year-old children without any systemic diseases, disabilities or chronic medication were included. A written consent from the parents was obtained and the children gave their verbal consent for considering their participation in the study. The parents were invited to a meeting in the school, during which a dental examination of the participating children was performed and parents were asked to self-complete three questionnaires on their child: one measuring general HRQoL (PedsQL™4.0 Generic Core scale for toddlers), and two on OHRQoL (ECOHIS and PedsQL Oral Health). In addition, the parents completed a structured questionnaire to compile information on the child's age, gender, socioeconomic status, history of oral hygiene habits, as well as their overall and dental health status. We sent by regular mail the questionnaires to parents who did not attend the meeting.

Three experienced researchers performed the dental examinations in the classroom. After cleaning the tooth surfaces with a toothbrush, a visual inspection of the oral cavity was performed under artificial light. The examiners were blinded to the questionnaire responses. The diagnosis of caries was based on the criteria proposed by the World Health Organization in the Oral Health Survey Basic Methods for Epidemiological Studies [40]. The types of traumatic dental injury were classified according to Andreasen & Andreasen [41] and the malocclusion was assessed according to the presence or absence of at least one of the following: anterior open bite, overjet > 4 mm and anterior cross-over bite [4].

Prior to beginning the study, the researchers were trained in dental examination to increase the degree of inter-examiner agreement. The training consisted of a stage in which the examination teams, each composed of an examiner and a recorder, received theoretical training on the study protocol and diagnostic criteria, as well as on how to complete a clinical record and a systematic dental examination. A group of 15 children were then examined to test the inter-examiner agreement on caries and malocclusions traits, with kappa coefficients of 0.83 and 0.70, respectively. A series of 20 pictures were used to assess reliability on traumatic dental injury (kappa = 0.79).

Sample size

According to sample size recommendations to assess construct validity, ceiling/floor effects, internal consistency and factorial analysis, 2 to 20 participants per item are required, with an absolute minimum of 100 to 250 subjects [42–44]. Considering that the highest number of participants recommended per item is 20, and assuming a 15% of potential missing answers, the sample size required was of 300 children.

Statistical analysis

A descriptive analysis of the sociodemographic characteristics and the results of the oral examination was performed. Mean, standard deviations, score range, and percentage of patients with the lowest (floor effect) and highest theoretical scores (ceiling effect) were calculated in order to examine the scores' distribution of the ECOHIS. Reliability was assessed following two approaches: internal consistency was evaluated using Cronbach's alpha; and test-retest reproducibility was assessed using the intraclass correlation coefficient (ICC) calculated by two-way random effects analysis of variance. Test-retest subsample was selected by randomization of 50% of the participants at each school, who received the questionnaires by mail 2–4 weeks after the school meeting. Parents who reported change in their child's oral health status were excluded of this analysis.

Confirmatory Factor Analysis (CFA) was performed to assess the measurement model of the ECOHIS. To test the structure in two sections proposed by developers of ECOHIS (Child and Family impact sections), as well as for the existence of a general factor (the ECOHIS total score), a 2nd order model structure was imposed in the CFA. The CFA was performed using the robust unweighted least squares (ULSMV), and its goodness of fit was assessed using the Confirmatory Fit Index (CFI) and the Tucker-Lewis Index (TLI), which should be above 0.95, and the Root Mean Square Error of Approximation (RMSEA), which indicates an adequate fit below 0.08. The CFA was conducted with MPlus 5 [45].

Construct validity evaluation was based on known groups defined by results of dental examination (caries, traumatic dental injuries and malocclusion) and by responses from the parents about the child's overall and dental health with a 5-Likert scale (Excellent, Very Good, Good, Fair, and Poor). We hypothesized worse child OHRQL (higher scores on the two sections of the ECOHIS) among children with some dental disease identified in the dental examination and among those whose overall and dental health was rated as fair or poor. Given the clearly skewed distribution of the ECOHIS score, we decided to use nonparametric analysis and Kruskal-Wallis or Mann Whitney tests were used to assess ECOHIS differences among these groups. To quantify the magnitude of the difference, effect size was calculated as the difference between means divided by the standard deviation pooled from the two groups. Effect sizes of 0.2, 0.5 and 0.8 were defined as small, moderate and large, respectively [46].

Additionally, to examine convergent and discriminant validity, correlations of ECOHIS scores with the PedsQL™4.0 Generic Core and PedsQL Oral Health scales were calculated using Spearman correlation coefficients, interpreted as follows: negligible relationship when r is < 0.20; weak when 0.20–0.40; moderate when 0.40–0.60; strong-moderate when 0.60–0.80; and strong relationship when > 0.80 [47]. Convergent validity involves demonstrating that different instruments measuring a similar concept inter-correlate at least moderately. We hypothesized moderate to strong correlation coefficients between ECOHIS and PedsQL Oral Health, since both were designed to measure OHRQoL. In contrast, discriminant validity is the extent to which a measure does not correlate too strongly with those measures intended to assess different traits. Therefore, we hypothesized that correlations between ECOHIS and PedsQL™4.0 Generic Core is low, due to differences between OHRQoL and HRQoL. The data analyses were performed using Stata 13 (Stata Corp, College Station, TX, USA).

Results

Cross-cultural adaptation process

The average difficulty for the forward translation of the items into Chilean Spanish was < 2.5. Regarding the back-translation, the average difficulty was of 7.5 for item 13, 6 for item 8, 5.5 for item 12 and below or equal to 4.5 for the rest (Fig. 1). For content comparison between back-translation and the original version, the expert panel rated all items as A (conceptually and linguistically equivalent), except item 13 which was rated as C (equivalence is not obvious). This was due to the replacement of the term "financial impact" by "important economic cost" after members of the panel of pre-school children parents claimed they did not understand the first expression. The author of the original ECOHIS reviewed the Spanish and the English back-translated versions without identifying any lack of equivalence regarding the original.

Finally, the cognitive debriefing showed that the instructions, items and response choice were easy to understand by parents. The parents thought about the whole vital cycle of their child when answering the questions. Some parents had difficulty defining in their own words the terms "frustrated" and "irritable", however they were able to differentiate between them. None of the parents had problems to differentiate among the different response options. All parents agreed that the questions are intended to evaluate OHRQoL. No modification was necessary as a result of the cognitive debriefing interviews.

Psychometric study

The population of Carahue preschools included a total of 435 children, two of them were excluded for presenting special health care needs, twelve because their parents did not sign the informed consent, and 93 children were absent at the time of dental examination. Of the

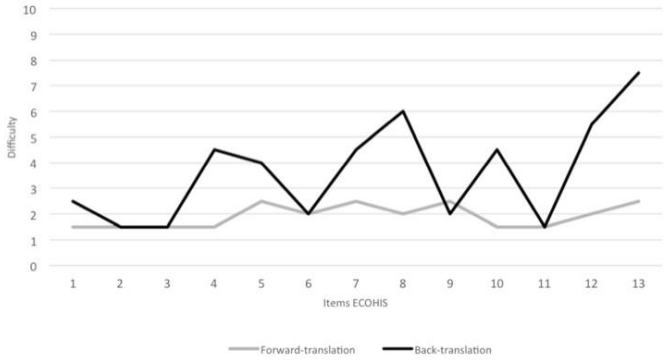

Fig. 1 Average difficulty to find the conceptual equivalence, as reported by translators in the forward and back-translations

328 parents included, 26 did not return the questionnaires (response rate = 92.1%). In total, 302 children were fully evaluated (Table 1), comprising 163 boys and 139 girls, with an average age of 4.0 (SD = 1.1) years. Most were of low socioeconomic status, 40.9% of the parents reported that their children have good general health and 36.5% good oral health. The prevalence of dental caries, malocclusion and traumatic dental injuries was 53.6, 39.4 and 14.5% respectively.

Table 2 shows the children's parents extreme ECOHIS responses and reliability coefficients. All items were rated as "never" by over 60% of parents. The two items most frequently rated as "never" were in the child section: "avoided smiling or laughing" (92.4%) and "avoided talking" (93.7%). The two items most frequently rated as "very often" were in the family section, parents or family members having "been upset" (1.9%) and "feel guilty" (3.6%). The Cronbach's alpha coefficient was 0.89 for the total score showing a good correlation within items. Among the subsample of 84 parents who completed the ECOHIS twice, the Intraclass Correlation Coefficient was 0.84 for the total score. Both reliability coefficients were above the recommended standard of 0.7 in the child and the family sections.

The measurement model consisted of two specific factors and a general factor (Fig. 2). Factor 1 includes the nine items composing the Child Impact Section; factor 2 includes the 4 items composing the Family Impact Section; and the latent construct for the total score includes both factors (Child and Family Impact). This CFA model presented excellent goodness of fit coefficients: CFI = 0.978, TLI = 0.988 and RMSEA = 0.065.

Distributions of the ECOHIS scores are presented in Table 3. The median of the total ECOHIS score was 1 (IQR 6), for child impact it was 1 (IQR 3) and 0 (IQR 2) for the family impact section. In the child impact section, 5.0% of the parents answered "Don't Know" in at least one item and 1.7% in the family impact section. The floor effect was 41.6% and ceiling effect was negligible for the total score.

Table 4 shows the results of the construct validity of ECOHIS based on known groups. As the child's general health and oral health was rated worse by parents, the ECOHIS median total score was higher, but differences among groups were only statistically significant for oral health: from 0 when excellent/very good to 11.6 when poor ($p < 0.01$). Finally, regarding dental diseases, ECOHIS scores presented statistically significant differences among groups defined by dental caries (median 0.5, 2, and 8, $p < 0.01$), but differences between presence or absence of malocclusion or type of traumatic dental injuries were not significant. Effect sizes indicate large differences between groups defined by child's oral health and dental caries.

Table 5 shows that the correlation of the total score of ECOHIS with the PedsQL™4.0 was strong-moderate with the Oral Health scale ($r = 0.64$), weak with the Generic Core scale ($r = 0.21$), and also when both scales were considered ($r = 0.35$). Finally, the correlation between the child and the family impact sections of ECOHIS was moderate ($r = 0.57$; $p \leq 0.001$).

Discussion

We used a standard cross-cultural adaptation process to develop the Chilean version of the ECOHIS, which demonstrated good acceptability by parents; high reliability and good construct validity. The results are consistent with those obtained for the original ECOHIS and suggest that the Chilean version is conceptually and metrically equivalent.

Table 1 Demographic and clinical characteristics of the children assessed in the study

Variables	*n* (%)
Child's age in years (mean ± SD)	4.0 (1.1)
Child's gender	
Male	163 (54.0)
Female	139 (46.0)
Socioeconomic status	
Low	229 (75.8)
Medium-high	73 (24.2)
Child's general health, reported by parents	
Excellent	43 (14.3)
Very good	86 (28.5)
Good	123 (40.9)
Regular	49 (16.3)
Poor	–
Child's oral health, reported by parents	
Excellent	44 (14.6)
Very good	59 (19.6)
Good	110 (36.5)
Regular	70 (23.3)
Poor	18 (6.0)
Tooth brushing	
Once a day or less	51 (16.9)
Twice or more	251 (83.1)
Simplified Oral Hygiene Index	
Good	19 (6.3)
Regular	223 (73.8)
Poor	60 (19.9)
Decayed, missing and filled teeth index (mean ± SD)	2,52 (SD 3.71)
Dental Caries	
Caries free (dmft = 0)	140 (46.3)
Low severity (dmft = 1–5)	108 (35.8)
High severity (dmft > 6)	54 (17.9)
Malocclusion	
Absence	183 (60.6)
Presence	119 (39.4)
Traumatic Dental Injuries	
None	258 (85.4)
Infraction	27 (8.9)
Enamel fracture	4 (1.3)
Avulsion	2 (0.7)
Discoloration	11 (3.6)

"Don't know" and/or missing responses may reflect comprehensibility problems [24]. In our sample, only one parent left some missing items and only 19 (6.3%) responded "Don't know", similarly to the original ECOHIS study (7%) [16]. However, other studies have shown higher "Don't know" percentages [19–22]. The low percentage of "Don't know" supports that the mode of administration (proxy-report) is not a limitation for the ECOHIS Chilean version. According to the ECOHIS proxy-report design [16], in our study most parents completed it during the school meeting, and those who did not attend it completed the questionnaire at home. No interview administration was needed, and no one required assistance to self-complete the questionnaire. Self-administration presents advantages, such as lower cost, preservation of participant's anonymity, and reduction of interviewer bias [48]. Furthermore, studies with other OHRQoL instruments showed that administration mode (interview versus self-administered) does not influence the instruments' scores [48–50]. On the other hand, evidence shows that parents underestimate the impact of children's oral health problems, since they have a different perspective and limited knowledge, particularly related to social and emotional well-being [51]. Indeed, oral health problems directly observable by parents, such as physical complaints and functionality, concur better with children's perceptions [52, 53]. However, in this age group due to their cognitive immaturity, limited social experience and continued dependency, parents are the best source of their child's oral health [54]. As in the original version, we included parents with "Don't know" responses in the analysis because a "Don't know" response reflects an essential characteristic of the phenomenon under evaluation, rather than errors by the respondents [55].

The high floor effect observed in the total score (41.6%) and domain or section scores (ranging 49–92%) is congruent with the clinical characteristics of our participants, since over 40% of the sample was free of oral conditions. Although these results are similar to those obtained in other studies, which have also shown a strong floor effect for ECOHIS total score (ranging 20–54%) [16, 24, 29] they could indicate a limitation of the instrument. The ECOHIS Chilean version needs to be tested in a population with more oral problems to assess adequately the instrument's more severe response levels. The ECOHIS has shown an excellent reliability, both in its internal consistency and its reproducibility, since its coefficient values were over 0.8 allowing to use its scores for the comparison between groups [56]. Our result of internal consistency for the child section (Cronbach's alpha coefficient = 0.88) was similar to the 0.91 reported by the original English questionnaire, but it

Table 2 ECOHIS extreme responses of children's parents and reliability coefficients ($n = 302$)

Impacts	Never		Very often		Cronbach's alpha (ICC)[a]
	n	%	n	%	
CHILD IMPACTS					0.88 (0.81)
How often has your child had pain in the teeth, mouth or jaws	188	62.3	3	0.9	0.86
How often has your child because of dental problems or dental treatments?					
Had difficulty drinking hot or cold beverages	223	73.8	1	0.3	0.85
Had difficulty eating some foods	216	71.5	1	0.3	0.85
Had difficulty pronouncing any words	240	79.5	1	0.3	0.87
Missed preschool, day care or school	252	83.4	–	–	0.86
Had trouble sleeping	263	87.1	–	–	0.86
Been irritable or frustrated	240	79.5	1	0.3	0.86
Avoided smiling or laughing	279	92.4	–	–	0.87
Avoided talking	283	93.7	–	–	0.88
FAMILY IMPACTS					
How often have you or another family memb because of your child's dental problems or treatment?					0.80 (0.75)
Been upset	224	74.2	6	1.9	0.71
Felt guilty	214	70.9	11	3.6	0.74
Taken time off from work	248	82.4	1	0.3	0.76
How often has your child had dental problems or dental treatments that had a financial impact on your family?	252	83.7	3	1.0	0.77

[a]*ICC* Intraclass Correlation Coefficient

was lower for the family impact section (0.80 vs. 0.95). However, with exception of the original version, the family section usually shows a lower internal consistency (Cronbach's alpha ranging 0.59–0.85) than the child impact section (ranging 0.74–0.92) [21, 22, 29], which may be due to the lower number of items rather than a lower consistency. In the test-retest reliability, the ICC for total score was the same as reported in the original version (0.84), but lower than reported in the French (0.95) [24] and Brazilian versions (ranging 0.94–0.99) [22, 57]. Despite this, the ICC value shows that the Chilean version of ECOHIS

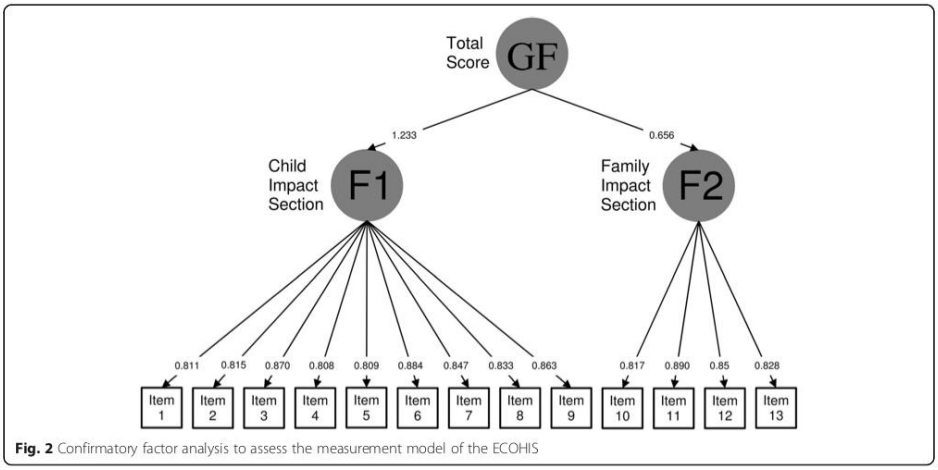

Fig. 2 Confirmatory factor analysis to assess the measurement model of the ECOHIS

Table 3 Descriptive data of the distribution of the ECOHIS scores ($n = 302$)

Section/Scale	Number of items	Observed range	Median (IQR)	Mean (SD)	Percentage (%) of patients with				
					Any missing item	Any 'Don't Know'	Missing score	Floor effect	Ceiling effect
CHILD IMPACT SECTION	9	0–22	1 (3)	2.53 (4.07)	0.0	5.0	0.3	49.3	0.0
Symptom	1	0–4	0 (1)	0.58 (0.89)	0.0	0.7	–	62.9	1.0
Function	4	0–12	0 (2)	1.32 (2.24)	0.0	4.3	–	60.6	0.0
Psychological	2	0–6	0 (0)	0.48 (1.09)	0.0	0.3	–	77.8	0.0
Social	2	0–3	0 (0)	0.15 (0.52)	0.0	1.0	–	91.7	0.0
FAMILY IMPACT SECTION	4	0–14	0 (2)	1.5 (2.65)	0.0	1.7	0.3	61.3	0.0
Parental distress	2	0–8	0 (1)	1.01 (1.80)	0.0	1.7	–	66.2	1.7
Family function	2	0–6	0 (0)	0.51 (1.17)	0.3	1.0	–	78.8	0.0
ECOHIS TOTAL SCORE	13	0–31	1 (6)	4.04 (6.09)	0.3	6.3	0.3	41.6	0.0

Floor effect percentage of patients with score = 0, ***Ceiling effect*** percentage of patients with maximum score (52)

has an excellent test-retest reliability in which it is able to produce reproducible scores when it is administered at two different times [43].

The good results on equivalence with the original ECOHIS shown by its comparison with the back-translation of the Chilean-adapted version support the content validity of this new country version. The higher difficulty of the back-translation compared to the forward one, observed in our adaptation process, has been also described for other adapted instruments [58, 59]. As the first translation seeks conceptual equivalence, and the second one seeks a literal translation of the expressions, this back-translation can often be harder to carry out.

To the best of our knowledge, there is no previous publication describing the factor structure of the ECOHIS. Our results confirm the two- section structure proposed by the developers (child and family impact sections), as well as that correlations between them can be explained by the second order model representing the global OHRQoL. The confirmation of this

Table 4 Construct validity of ECOHIS total score based on known groups ($n = 298$)

Variables	n	Median (IQR)	Mean (SD)	p	Effect size
Child's general health reported by parents					
Excellent/Very good	130	1 (5)	3.84 (6.40)	0.13	
Good	119	2 (6)	3.92 (5.67)		0.01
Regular	49	3 (10)	6.34 (7.74)		0.38
Poor	–	–	–		
Child's oral health reported by parents					
Excellent/Very good	104	0 (3)	1.83 (3.56)	< 0.01	
Good	109	1 (4)	2.70 (3.74)		0.24
Regular	67	6.1 (11)	7.89 (7.73)		1.09
Poor	18	11.6 (18)	14.51 (10.25)		2.50
Dental Caries					
Caries free (dmft = 0)	140	0.5 (3)		< 0.01	
Low severity (dmft = 1–5)	105	2 (5.1)			0.43
High severity (dmft > 6)	53	8 (13)			1.49
Malocclusion					
Absence	180	1 (5)	3.55 (5.48)	0.30	
Presence	118	2 (8)	4.85 (6.97)		0.22
Traumatic Dental Injuries					
Absence	255	1 (5)	3.99 (3.99)	0.11	
Presence	43	3 (7)	4.47 (4.47)		0.48

dmft Decayed, missing, and filled teeth index

Table 5 Correlation of ECOHIS scores with PedsQL™4.0 Generic Core and PedsQL™4.0 Oral Health scales

	Early Childhood Oral Health Impact Scale (ECOHIS)		
PedsQL™	Child Impact Section	Family Impact Section	ECOHIS Total score
PedsQL™4.0 Generic Core scale	0.20*	0.16*	0.21*
PedsQL Oral Health scale	0.65*	0.51*	0.64*
PedsQL ™ 4.0 Generic Core and PedsQL Oral Health scales	0.35*	0.29*	0.35*

*Statistically significant at $p < 0.001$

measurement model in other country versions of the ECOHIS would be recommendable.

For construct validity, the Chilean version of the ECOHIS scale showed significant differences among groups defined by the children's dental health status as reported by parents. These findings were consistent with previous studies where parents who perceived their child's oral health as poor had significantly higher mean ECOHIS scores [16, 21, 24, 27]. Our results showed higher ECOHIS scores among those with more than 6 decayed teeth, compared to those who had 1–5 decayed teeth or to those who were caries-free. The large effect size in children with poor oral health status reported by parents and who have high severity of caries supports the parents' recognition of oral health problems when they become evident, or when it manifests in the form of pain [60]. However, the ECOHIS was not able to discriminate presence or absence of malocclusion or type of traumatic dental injuries. Although the ECOHIS was originally developed to assess the impact of dental caries, it has been widely used to evaluate several oral pathologies [4, 61], but only few studies have validated this application: Peker et al. only found a moderate correlation with gingival index [21], and Scarpelli et al. showed a statistically significant association with discolored upper anterior teeth [22]. This is important because the ECOHIS has been used to measure OHRQoL in patients with traumatic dental injuries or malocclusion, not detecting any impact on the children [4, 62]. Further research is needed to explore whether this absence of impact can be due to the inability of the instrument to discriminate between certain degrees of these pathologies.

The poor correlation between ECOHIS and PedsQL™4.0 Generic Core scale suggests that ECOHIS captures additional information, which is not covered by instruments measuring HRQoL. This is in line with results reported by Lee et al., showing that the ECOHIS is more sensitive than PedsQL™4.0 measuring the impact of oral problems on preschool children [63]. As expected, a high correlation was found with the Oral Health scale of PedsQL™4.0 because it also could be considered specific for measuring OHRQoL [64, 65]. The moderate correlation between the child and the family impact sections of the scale found in our sample ($r = 0.57$) was similar to results reported in previous studies ranging 0.36–0.68 [16, 21, 27]. The correlation in the original English questionnaire between both sections was the lowest (Spearman's $r = 0.36$, $p \leq 0.001$), and the Turkish version the strongest (Spearman's $r = 0.68$, $p \leq 0.001$). Although child and family sections assess different aspects of child's OHRQoL, both sections are related with the underlying construct.

The main limitation of this study was the homogeneity of the sample studied, since only preschoolers from public schools were included. Nonetheless, our sample is representative of children between 2 and 5 years old attending public preschools, and these children are the main target of Oral Health Policies in Chile. Another limitation was that information regarding the parents, such as age, gender, and educational level, was not registered. Finally, the responsiveness was not assessed; therefore, future studies are necessary to evaluate the capacity of the ECOHIS Chilean version to detect changes over time in a clinical or public health intervention.

Conclusions

The Chilean version of the Early Childhood Oral Health Impact Scale was valid and reliable for assessing the OHRQoL in preschool children through proxy. The comparison with the original U.S. version shows similar results in reliability and validity, suggesting that the cross-cultural adaptation method followed has yielded an equivalent Chilean version.

Researchers and clinicians now have at their disposal an OHRQoL instrument for use in Chilean preschool children to assess the impact of oral disorders on them and their families, and also to facilitate the identification of groups at a higher risk of dental health inequity to improve their access to oral health care services.

Abbreviations

dmft: Decayed, missing and filled teeth index; ECOHIS: Early Childhood Oral Health Impact Scale; HRQoL: Health-Related Quality of Life; ICC: Intraclass correlation coefficient; OHRQoL: Oral Health-Related Quality of Life; PedsQL™4.0: Pediatric Quality of life Generic Core scale

Acknowledgements

The authors are especially grateful to Bhavna Pahel for providing the original ECOHIS questionnaire. We also thank the MAPI Research Trust and the author of PedsQL™4.0, Dr. J. W. Varni, for providing us with the copyright permission. Carlos Zaror is a PhD candidate in Methodology of Biomedical Research and Public Health program, Universitat Autònoma de Barcelona, Barcelona, Spain. Mª José Martínez is funded by a Miguel Servet research contract from the Instituto de Salud Carlos III and European Social Fund (CP15/00116).

Montse Ferrer is partially funded by the Departament d'Innovació, Universitats i Empresa, Generalitat de Catalunya (2014 SGR 748).
We would like to acknowledge Aurea Martin for her help in the English proofreading and editing process and in the figures edition of this manuscript.

Funding
This project was funded by a grant from the Convenio de Desempeño Regional, FRO 1301, Universidad de La Frontera N° UNT15–0012, and from DIUE of Generalitat de Catalunya (2017 SGR 452).

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions
All authors have actively participated in the study and have made a substantial contribution to (1) either conception and design, or acquisition of data, or analysis and interpretation of data; as well as (2) the drafting of the article or its critical revision for important intellectual content; and (3) to the final approval of the version to be published. Each author believes that the manuscript represents honest work.

Ethics approval and consent to participate
The study protocol was approved by the Ethics Committee of the Universidad de La Frontera, Temuco, Chile with resolution number 061/2015. Informed consent from all parents and verbal assent from children was obtained to consider their participation in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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Received: 26 April 2018 Accepted: 28 November 2018
Published online: 16 December 2018

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IMPLICACIONES PARA LA PRÁCTICA CLÍNICA Y FUTURAS INVESTIGACIONES

A pesar de que en las últimas dos décadas ha existido un progreso considerable en la medición del impacto de las patologías orales en la calidad de vida en niños y adolescentes, nuestros resultados han permitido identificar brechas en el conocimiento de la calidad de vida relacionada con la salud oral (CVRSO), tanto en el ámbito de la investigación como de la práctica clínica.

Si bien existen numerosos instrumentos diseñados específicamente para una condición patológica o un tratamiento, aún se necesitan nuevas evidencias sobre sus propiedades métricas antes de recomendar su uso. En especial cabe destacar la necesidad de información sobre la sensibilidad al cambio y la interpretabilidad de algunos de los instrumentos disponibles (Artículo 1).

Los déficits en evaluación de la sensibilidad al cambio, vienen determinados por la falta de estudios de diseño prospectivo (Artículo 1). Esto ha sido también lo que ha pasado en la evaluación de la versión Chilena de la ECOHIS (Artículo 4) y por ello su sensibilidad al cambio frente a diferentes tratamientos odontológicos es el siguiente estudio previsto. Por otro lado, tampoco al evaluar el impacto de los traumatismos dentoalveolares en la CVRSO se identificaron estudios prospectivos para comprender cómo el impacto de los traumatismos dentoalveolares evoluciona con el tiempo (Artículo 2). Todo ello refuerza la necesidad de contar con instrumentos que hayan demostrado ser sensibles al cambio.

Un punto crucial para la interpretabilidad es determinar la diferencia mínima importante (MID de sus siglas en inglés) para las diversas escalas puesto que esta ha sido una

de las estrategias más utilizadas para facilitar la interpretación de instrumentos específicos y una de las estrategias de interpretación mejor aceptadas por los clínicos. Sin embargo, la MDI ha sido subutilizada por los instrumentos de CVRSO de niños y adolescentes identificados en nuestra revisión (Articulo 1). Una diferencia mínima importante es la diferencia más pequeña en el puntaje del resultado de interés, reportada por el paciente (o proxy), ya sea beneficioso o perjudicial, y que llevaría al paciente o al clínico a considerar un cambio en el manejo de su tratamiento. Nuestra revisión sobre el impacto de los traumatismos dentoalveolares resalta la necesidad de consenso para seleccionar el punto de corte adecuado (Artículo 2). Si el punto de corte seleccionado para dicotomizar la variable continua es inferior a la MID, se produciría una sobreestimación de la prevalencia del impacto en la CVRSO. Bajo la misma lógica establecer la MID para la versión chilena de la ECOHIS es nuestra investigación futura prioritaria una vez establecida su validez (Artículo 4).

A pesar de que la ECOHIS fue el instrumento mejor evaluado en prescolares y ha sido ampliamente utilizado para evaluar el impacto en la CVRSO de diversas patologías (Artículo1), los resultados de la evaluación psicométrica de la versión chilena muestran que si bien es capaz de discriminar en pacientes con caries, no fue capaz de discriminar entre la presencia y la ausencia de maloclusión o según el tipo de traumatismo dentoalveolar (Artículo 4). Esto deja de manifiesto que, a pesar de ser un instrumento de CVRSO con muy buenas características métricas en pacientes con caries, se debe evaluar su capacidad discriminante en otras patologías frecuentes antes de recomendar su uso de forma generalizada.

Los investigadores están midiendo cada vez más el impacto en la CVRSO de una amplia gama de afecciones orales y orofaciales en los niños con el fin de priorizar grupos de

riesgo para cada condición. Sin embargo, pocas se han centrado en evaluar qué dimensiones se encuentran más afectadas. Nuestra investigación no sólo confirmó el impacto en la CVRSO asociado a haber sufrido un traumatismo dentoalveolar, sino también cómo el aspecto social era el que se encontraba más afectado en la población escolar con esta lesión (Articulo 2). Por otra parte, vale la pena recordar que los determinantes psicológicos, sociales y políticos, entre otros, pueden influir en la percepción de la CVRSO, actuando como confusores o mediadores de la relación entre el estado clínico y la CVRSO. Conocer estos determinantes y su relación con la CVRSO puede ser de utilidad para la práctica clínica porque permitiría diseñar estrategias preventivas más efectivas, orientadas a los grupos de mayor riesgo y hacer una apropiada medición de sus resultados.

Un importante vacío detectado en esta tesis doctoral fue la falta de evidencia de calidad sobre la efectividad de terapias mínimamente invasivas. Su gran relevancia basada en el respeto de estas terapias por el tejido dental, se traduce en tratamientos menos invasivos y más aceptables por los pacientes. Cuando se evaluó el efecto de la técnica restauradora atraumática en el manejo de la caries, pocos ensayos clínicos incluyeron resultados percibidos por los pacientes como medidas de dolor, incomodidad, ansiedad o aceptabilidad y ninguno incluyó CVRSO (Artículo 3). Esto pone de manifiesto que, el uso de medidas percibidas por los pacientes para evaluar la efectividad del tratamiento, es aún emergente en odontología pediátrica. Por un lado, por la falta de instrumentos con sensibilidad al cambio demostrada para diferentes patologías orales (Artículo 1), y por otro lado por la falta de facilidades técnicas (por ejemplo, ordenadores con pantallas táctiles para facilitar la respuesta directa de los niños o programas informáticos que calculen las puntuaciones y muestren la evolución en gráficas) que permita a los clínicos incorporar sistemáticamente la medición

rutinaria de la CVRSO. Actualmente los resultados obtenidos con los cuestionarios de CVRSO muchas veces resultan más difíciles de interpretar que los de otras evaluaciones clínicas. En resumen, los resultados de nuestras revisiones de la literatura destacan la importancia de medir la efectividad de terapias mínimamente invasivas con variables reportadas por los pacientes tales como la CVRSO, además de los resultados clínicos más relevantes en cada caso.

CONCLUSIONES

1. Nuestros resultados respaldan la selección en preescolares de la Early Childhood Oral Health Impact Scale (ECOHIS) o de la Scale of Oral Health Outcomes for 5-year-old (SOHO-5) en el caso de preferir que el reporte sea realizado por los niños. Al evaluar escolares y adolescentes, la edad de la población objetivo es un factor clave al momento de elegir entre los siguientes instrumentos recomendados: Child Perceptions Questionnaires (CPQ11–14) para niños de 11 a 14 años; Child Oral Impact on Daily Performance (Child-OIDP) para niños de 11 a 15 años; Child Oral Health Impact Profile (Child-OHIP) para niños de 8 a 15 años; o CPQ8-10.
2. La administración del CPQ11–14 o el CPQ8–10 junto con el Parental-Caregiver Perceptions Questionnaire (P-CPQ) y la Family Impact Scale (FIS) pueden proporcionar una evaluación completa de la calidad de vida relacionada con la salud oral del paciente, midiendo las percepciones de los padres y los niños, así como también el impacto en la familia. El cuestionario Pediatric Oral Health-Related Quality of Life (POQL) es el recomendado cuando se quiere abarcar un rango más amplio de edades (de 2 a 16 años), tanto su versión para ser administrada a través de un proxy como su versión autoadministrada. Los cuestionarios diseñados más específicamente para evaluar una patología oral, síntoma o tratamiento concreto, así como el único desarrollado para realizar una evaluación económica, requieren de más investigación sobre sus propiedades métricas antes de recomendar su uso. Estos resultados pueden facilitar el proceso de toma de decisiones con respecto a la selección correcta del instrumento de acuerdo al propósito del estudio.

3. La síntesis de la evidencia disponible muestra que los traumatismos dentoalveolares tienen un impacto negativo en la calidad de vida relacionada con la salud oral de preescolares y escolares, más aún si éstos implican la exposición del tejido pulpar y/o la dislocación del diente. Sin embargo los hallazgos de nuestra revisión sistemática sugieren la necesidad de una mayor estandarización de los resultados para medir el impacto de los traumatismos dentoalveolares en la calidad de vida relacionada con la salud oral de los niños, tales como el reporte de las diferencias de medias y consenso en los puntos de corte adecuados. Además, se requieren estudios prospectivos de cohorte bien diseñados con seguimiento a largo plazo para confirmar los hallazgos de nuestra revisión y para comprender cómo el impacto de los traumatismos dentoalveolares evoluciona con el tiempo.
4. En base a una baja calidad de la evidencia el tratamiento restaurador atraumático que usa vidrio ionómero de alta viscosidad puede tener un mayor riesgo de fracaso de la restauración que el tratamiento convencional para las lesiones de caries en los dientes primarios. Los efectos del tratamiento restaurador atraumático usando composite o vidrio ionómero modificado con resina son inciertos debido a la muy baja calidad de la evidencia. La generalización de estos hallazgos esta limitada debido a la baja a muy baja calidad de la evidencia. Por lo tanto, tanto los clínicos como los pacientes deben interpretar estos resultados con precaución. Aunque existe cierta evidencia a favor del tratamiento convencional en lugar del tratamiento restaurador atraumático en los dientes primarios, éste puede considerarse como una opción de tratamiento donde el acceso a los recursos (por ejemplo, dentistas, equipamiento y electricidad) es limitado y no hay otra alternativa.

5. Se requieren ensayos clínicos controlados y aleatorizados adicionales, bien diseñados y con una potencia adecuada para determinar si el enfoque restaurador atraumático presenta algún beneficio en términos de tasa de éxito o experiencia del paciente durante el tratamiento para dientes primarios y permanentes. Los ensayos futuros deben intentar reducir el riesgo de sesgo y considerar posibles factores de confusión (por ejemplo, tipo de material de restauración, edad) en el diseño. Los ensayos pragmáticos, multicéntricos, basados en la práctica, con financiamiento independientes de la industria podrían ayudar a proporcionar evidencia con alta validez. Además, los ensayos clínicos deben aportar información sobre el tiempo y los costos de la técnica, así como resultados reportados por los pacientes (dolor, incomodidad o calidad de vida) y experiencia de los operadores a través de cuestionarios validados.
6. La versión chilena de la Early Childhood Oral Health Impact Scale es válida y fiable para evaluar la calidad de vida relacionada con la salud oral de niños en edad preescolar a través de un proxy. La comparación con la versión original desarrollada en Estados Unidos, muestra resultados similares en fiabilidad y validez, lo que sugiere que el método de adaptación transcultural seguido ha dado como resultado una versión chilena equivalente. Los investigadores y clínicos tienen a su disposición un instrumento de calidad de vida relacionada con la salud oral para su uso en niños preescolares chilenos, para evaluar el impacto de los trastornos orales en ellos y en sus familias, y también para facilitar la identificación de grupos con mayor riesgo de inequidad en salud oral y mejorar su acceso a los servicios de salud bucal.

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