

The economic impact of two diagnostic strategies in the management of restorations in primary teeth: a health economic analysis plan for a trial-based economic evaluation

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Abstract

Background

Different approaches have been used in the clinical routine to assess restorations and determine the need for further reinterventions. In general, dentists based their decision in different parameters, including aesthetical ones, leading to a more interventionist approach. Indeed, using a more interventionist strategy (the World Dental Federation - FDI), more replacements tend to be indicated than using a minimally invasive one (based on the Caries Around Restorations and Sealants -CARS). Since the resources related to the long-term health effects of these strategies have not been explored, the economic impact of using the less invasive strategy is still uncertain. Thus, this health economic analysis plan aims to describe methodologic strategies for conducting a trial-based economic evaluation that aims to assess whether a minimally invasive strategy is more efficient in allocating resources than the conventional strategy for managing restorations in primary teeth.

Methods

A trial-based economic evaluation will be conducted, including three cost-effectiveness analysis (CEA) and one cost-utility analysis (CUA). These analyses will be based on the main trial (CARDEC-03/NCT03520309), in which children aged 3 to 10 were included and randomized to one of the diagnostic strategies (based on FDI or CARS). An examiner will assess children's restorations using the randomized strategy, and treatment will be recommended according to the same criteria. The time horizon for this study is two years, and we will adopt the societal perspective. The average costs per child for 24 months will be calculated. Three different cost-effectiveness analysis (CEA) will be performed. For CEAs, the effects will be the number of operative interventions, the percentage of patients who did not need new interventions in the follow-up, and the scores obtained with a questionnaire to assess children's oral health-related quality of life. For CUA, the effect will be quality-adjusted life-years (QALYs). Intention-to-treat analyses will be conducted. Finally, we will assess the difference when using the minimally invasive strategy for each health effect (Δ effect) compared to the conventional strategy (based on FDI) as the reference strategy. The same will be calculated for related costs (Δ cost). The discount rate of 5% will be applied for costs and effects. We will perform deterministic one-way and probabilistic sensitivity analyses to handle uncertainties. The net benefit will be calculated, and acceptability curves plotted using different willingness-to-pay thresholds. A longer-term economic evaluation will be carried out with trial results extrapolated over a primary tooth lifetime horizon using Markov modelling methods.

Discussion

The main trial is ongoing, and data collection is still not finished. Therefore, economic evaluation has not commenced. We hypothesize that conventional strategy will be associated with more need for replacements of restorations in primary molars. These replacements may lead to more reinterventions,

leading to higher costs after two years. The health effects will be a crucial aspect to take into account when deciding whether the minimally invasive strategy will be more efficient in allocating resources than the conventional strategy when considering the management of restorations in primary teeth. Finally, patients/parents preferences and consequent utility values may also influence this final conclusion about the economic aspects of implementing the minimally invasive approach for managing restorations in clinical practice. Therefore, this trial-based economic evaluations may bring actual evidence of the economic impact of such these interventions.

Trial registration:

NCT03520309. Registered May 9th, 2018. Economic evaluations (the focus of this plan) are not initiated at the moment.

Background

Reinterventions in restored teeth are common procedures in Dentistry. Caries lesions around restorations, frequently denominated as "secondary caries", have been identified as the main reason for repair or replacement of the restorations in primary teeth [1]. The detection of these lesions and other aspects related to defective restorations in primary teeth is challenging as it involves a clinical inspection of the dental surface and the restorative material as well as their interface. The visual-tactile method is commonly used for this purpose. Some clinical strategies based on this method have been proposed to standardize the clinical assessment of restorations and support treatment decisions [2].

In general, dentists base their decision on different parameters, including aesthetical ones. This option tends to result in a more interventionist approach. In 2007, the World Dental Federation (FDI) proposed a strategy to evaluate restorations, comprising aesthetic, functional, and biological parameters, including the presence of caries and related aspects [3]. The FDI criteria were proposed for research and clinical practice and used to decide the need for reintervention in restored teeth [4]. Due to the several aesthetic parameters evaluated, the diagnostic strategy based on FDI embraces a cosmetic dentistry perspective, relating to a more interventionist approach for the clinical practice.

On the other hand, the Caries Associated with Restorations and Sealants (CARS) strategy is a more recently minimally invasive strategy proposed as part of the International Caries Classification and Management System (ICCMS) [5] and exclusively focused on detecting caries lesions around the restorations [6]. The CARS strategy is based on the International Caries Detection and Assessment System (ICDAS) scores. It is more consistent with a Cariology background, leaning on a less interventionist approach, based solely on the presence and the characteristics of the caries lesion.

To date, there is no consensus on the best strategy to adopt in clinical practice, and most studies do not explore the clinical relevance of the accuracy tests nor patient-centered outcomes [2]. An ongoing clinical trial (CARies DEtection in Children - CARDEC-03) aims to assess the impact of using the FDI and CARS

criteria in the assessment of restorations in primary teeth [7]. At first glance, when using a more interventionist strategy (using the FDI criteria), the indication of replacements of restorations in the baseline was more frequent than using the strategy based on CARS [8]. Nevertheless, the resources related to the long-term health effects have not been explored yet.

Therefore, when defective restorations need to be assessed to guide their management in primary teeth, it is not known if this minimally invasive strategy is efficient for allocating resources compared to the conventional strategy, based on FDI criteria. Even if the diagnostic method benefits patients, this subsequent financial impact assessment should be performed, featuring phase 5 studies for diagnostic methods [9]. Although many economic evaluations assessing treatment and preventive strategies have been conducted in Dentistry [10], those relating to diagnostic strategies are scarce and, in several cases, are not standardized and present low quality [11].

As dental expenditure was \$298 billion in 2010, representing 4.6% of global healthcare costs [12], economic evaluations to direct resources to the best diagnostic strategies are critical for clinical practice to be financially viable. We are presenting a health economic analysis plan to guide a trial-based economic evaluation assessing whether a minimally invasive strategy is more efficient in allocating resources than the conventional strategy for assessing and managing restorations in primary teeth.

The development of a systematic and transparent analysis plan when conducting an economic evaluation based on a Randomized Controlled Trial (RCT) may increase the transparency and reproducibility of the analyses [13].

Methods

This manuscript is a health economic analysis plan following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Good Research Practices Task Force Report recommendations [14] and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [15] checklist.

Study Design

A trial-based economic evaluation will be conducted (piggyback approach), including three cost-effectiveness analyses (CEA) - different health effects- and a cost-utility analysis (CUA). The clinical trial investigating the diagnostic strategy for restorations assessment is the third diagnostic study conducted by the CARDEC collaborative group at the School of Dentistry of the University of São Paulo (São Paulo, Brazil). The CARDEC-03 trial is a two-arm, parallel-group, patient-randomized controlled trial aiming to assess which of the two diagnostic strategies (based on FDI criteria or CARS) leads to less new interventions in restored primary teeth during two years of follow-up. Further details regarding the trial have been published in the study protocol [7].

The strategy based on the FDI criteria will be acknowledged as the reference strategy for assessing the restorations. However, recognize there is no robust evidence supporting this assumption. Despite this, a reference strategy for economic evaluation must be assumed. Considering that the CARS strategy is associated with a less interventionist approach, we will consider it as the new strategy. Moreover, FDI criteria were first proposed and appointed by experts as the standard criteria for restorations' assessment [16, 17].

Target population and Eligibility Criteria

Children's participation was voluntary. Our sample includes 3-to-10-year-old children seeking dental care at the Pediatric Dentistry clinic from our school, with at least one dental restoration in a primary tooth. The exclusion criteria were children whose parents did not consent to their participation; children who did not assent in participating in this study; and children with limited ability to co-operate even when behavior management was used [18].

Comparators - Interventions and Follow-up

Aiming to compare a more interventionist strategy to a supposedly less interventionist approach when assessing dental restorations and guiding clinical decision-making, children were allocated to one of the two diagnostic strategies for the assessment of restorations. To simplify, we will refer to them, from that point, as FDI and CARS strategies. A trained and calibrated examiner (BLPM) performed the assessments, and treatment decisions were based on the criteria. The FDI criteria [16] can be adapted depending on the purpose of the study. Therefore, since dental caries is the most common reported reason for reinterventions in primary teeth, we chose to evaluate related parameters as marginal staining and adaptation, besides the recurrence of caries. The CARS strategy will be used as originally proposed [5] (Table 1). Details regarding clinical criteria, sample size, randomization, allocation, blinding, and treatment of the restorations have been previously described in a clinical trial protocol [7].

Children will be followed for 24 months after the baseline interventions. Clinical assessments are being scheduled at 6-month intervals. In the baseline and at each follow-up visit, children are being instructed about diet and oral hygiene. The same examiner responsible for baseline evaluation will reassess the restorations at each appointment and propose a new treatment plan for each child, based on the respective randomized strategy.

Time horizon, study perspective and discount rate

The time horizon for the main evaluations was set as 24 months (time of study enrollment). Secondary longer-term economic evaluation with trial results will be performed to extrapolate the results over a primary tooth lifetime horizon. We will adopt the societal perspective, accounting for direct and indirect costs. A discount rate of 5% will be applied for costs and effects as the trial is being conducted in Brazil, a lower-middle-income country [19]. Further sensitivity analyses will test the influence of this assumption by considering different discount rates (0–10%).

Costs and resources

The costs of each strategy will be estimated using a micro-costing approach. The direct and indirect costs per tooth and child will be calculated over 24 months (Supplemental Material 1). Direct costs will comprise the costs related to the dental office accommodation, dental instruments and equipment and their respective maintenance, materials used to implement the strategies and staff expenses (based on working hours and time spent on patient's care). Firstly, direct costs will be estimated per tooth included in the trial. Then, we will sum up all child's included teeth for calculating direct costs with each child.

We will calculate the accommodation costs using rental costs and municipal taxes per m² of the area used by each dental unit. Subsequently, the accommodation costs per hour will be calculated. The same calculation will be used for dental instruments and equipment, estimating a life span of 3 years for instruments [20] and 5 years for equipment [21], with a monthly usage of 160 hours. The staff salary (dentists and dental auxiliaries) will be calculated based on the Brazilian Federal Law's monthly wage, allowing 40 hours per week (8 hours/day) for each dentist and dental nurse. For dental material, we will calculate the mean value of each item in three different dental stores and quantities used during clinical appointments.

Indirect costs will include the out-of-pocket expenditures, such as transportation (public or private), any opportunity costs of accompanying a person's absence from the workplace, and the patient's time accessing care. These costs will be estimated per child, considering the time spent during appointments and waiting or travelling to/from the dental clinic. For indirect costs per tooth, time spent when performing procedures related to each specific tooth will be first considered. For child's general appointments (e.g. instructions, fluoride applications) and child's and accompanying person's waiting/travelling, the time spent will be fully considered for each tooth, as if only one tooth had been included per child.

Possible dental interventions received externally to the research, but related to the included teeth, will also be considered indirect costs. Transportation will be calculated using the municipality's fares for public transportation. For private transportation, we will consider the distance from the family's house to the University and an average price for fuel obtained from the Brazilian National Agency, considering an 8 km per litre efficiency. The patient's and accompanying person's time will be valued, respectively, based on the Brazilian minimum wage and mean Brazilian salary. If the accompanying person reports any earning loss due to being present at child's appointments, an additional cost of a working day will be added for each received appointment.

The accompanying person's working absence time will also be calculated based on the mean Brazilian salary. In this case, the working days and hours will be considered to calculate this person's value per working hour. When treatments have been performed externally to the research, the same strategy used for missing data will be used for cost estimation. To estimate the costs, we have registered in a specific form the number of appointments, the time spent at each one and materials used during patient care (Supplemental Material 2). This form has also been used to collect information about transportation and

absence from work. Details about the cost estimation of each of the resources mentioned above can be found in Supplemental Material 1.

Costs will be calculated in Brazilian Real (BRL) considering the base year for the analysis and converted to international dollars using Purchasing Power Parities (PPP) measured for the same period (or the most recent indicator available at the time of the analyzes).

Health Outcomes

Three health effects will be considered for different CEAs. They are the percentage of children who did not need new operative interventions, the number of new operative interventions after the baseline assessment using FDI or CARS on the baseline, and the Oral Health-Related Quality of Life (OHRQoL) scores (Table 2).

For the two first health outcomes (related to new operative interventions), we will assess the included restored teeth with a 6-month interval, and the cumulative result will be accumulated for 24 months. The restorations will be evaluated by another examiner (TKT), blinded to the diagnostic strategy. At this assessment, surfaces were scored according to the restoration integrity and occurrence of caries, determining the need (or not) of repair, replacement or other possible new interventions [22–23] (Table 2). At this stage, the idea was using an external assessor using a different approach (from those under comparison) not to bias the outcome assessment. Based on this assessment, new interventions will be considered when any need for restoration repair or replacement is identified, any presence of secondary caries lesion exposing dentin is detected, any need for extension of the existing restoration or endodontic treatment is required (due to caries or tooth fracture) and/or any episode of pain is reported (Table 2).

The OHRQoL will be assessed using the Brazilian version of the Early Childhood Health Impact Scale (B-ECOHIS) [24]. This questionnaire is answered by parents as a proxy of the child's OHRQoL and is a valid measure for children [25]. Although the ECOHIS has been proposed for pre-school children [26], it was chosen to measure effectiveness in the entire sample, comprising children from 3-to-9 years-old. The questionnaire was answered in the baseline and will be answered at 24-month follow-up completion. The difference between the ECOHIS final and baseline scores will be calculated.

For CUA, the effect will be the gain in Quality Adjusted Life Years (QALYs). To estimate QALYs, we will use the Standard Gamble (SG) approach to calculate weights (utility scores) based on patients' parent's preferences regarding health states related to dental caries. The parent preference will be used as a proxy measure for the child's preference regarding different health status. More details about the Standard Gamble experiment may be found in the next section.

Standard Gamble

We will conduct an SG experiment to measure different oral health states' preferences related to dental caries in primary teeth. As parents' answers will be considered a proxy measurement, a representative sample of those parents seeking dental treatment in a reference center will be selected. A minimum

sample size of 50 parents was calculated to permit an absolute difference of 0.05 units and to guarantee the power of 80% and a significance level of 5%. To compensate for possible non-normal distribution and possible non-response or lost participants, we added up, respectively, 10% and 20% to this calculated sample, totalizing 63 participants to be recruited.

To also guarantee the representativeness, the recruited sample will be stratified by the child's caries experience and opportunity for dental treatment (children firstly seeking the treatment vs those already enrolled in treatment). Part of this sample will be selected among children's parents from the main clinical trial (CARDEC-3). The other will be recruited among parents from a sample of children seeking treatment in the school's dental clinics. Adults will be asked about their preference between two courses of action resulting in different outcomes regarding his/her child's oral condition.

The health states will be illustrated on cards, and the SG will be conducted using a chance board. The health states considered are: 1) a primary molar with dentin caries lesion; 2) a restored primary molar; 3) a restored primary molar needing repair/replacement. Children's parents will choose between alternatives A and B. Alternative A offers a probability "p" of achieving the best possible health state, which is a sound tooth that will last like that until it exfoliates. Then, a probability "1 - p" of having the worst possible condition assumed (early tooth loss) (Fig. 1). Alternative B will be a certain health state of a restored primary molar. The probability "p" will be changed in the chance board until the parent is indifferent to the two options [27]. This probability will be considered the parent's weight given for his/her child's health state (utility value). We will then calculate the QALYs, also considering the time for which the child presented such a state. The same experiment with the other health states will be conducted, as demonstrated in Fig. 1.

Analytical methods

The economic evaluations will be considered intention-to-treat analyses using data collected after two years, as previously described. In the case of missing data, we will investigate their nature and choose the most appropriate method to handle the missing data, e.g. multiple imputations. Imputations will consider health and economic outcomes and the possible relationship between them and other pertinent covariates.

Cox regression model with shared frailty will be used to compare the need for a new intervention. Some of the health effects listed above (number of new interventions and will be compared between groups using the most appropriate statistical test (McNemar or Student's test) depending on data distribution. Given the usual right-skewed distribution of cost data, we will use the bootstrapping quantile regression to compare the total costs of the diagnostic strategies [28]. Bootstrapping replications will be set at 1,000, and a fixed seed will be determined. To compare the effects, we will choose an appropriate statistical strategy according to data distribution. We will use the software Stata13 (StataCorp LP, Texas, USA) and set a 5% significance level for these analyses.

We will work with the difference between the strategies both regarding the inputs (Δ costs: $CARScosts - FDIcosts$) and outputs (Δ effects: $CARSeffects - FDIeffects$) since the focus of this series of economic evaluations is the economic impact of using the minimally invasive strategy (based on CARS) instead of the conventional strategy (based on FDI criteria) for managing dental restorations. Bootstrap confidence intervals will be calculated for each parameter considering the costs, effects, incremental costs and incremental effects[29].

Deterministic one-way sensitivity analysis will be conducted for CEAs and CUA to assess the quantitative relationship among estimates in parameters that could perform differently in a distinct scenario, such as costs, discount rate, and effects. In these analyses, we will also test the influence of different baseline conditions as covariates associated with the effects and costs [30], checking the possibility of extrapolating data from this single trial to a broader population. The results will be demonstrated in a tornado diagram.

Additionally, a Bayesian approach will be used to explore uncertainties on the same parameters. By adopting this approach, we will describe the probabilities around the actual values obtained in this study [31–33]. The data distribution of costs and effects will be checked using XLSTAT 2017 (Addinsoft, Paris, France), and, based on that distribution, Monte-Carlo simulations (10,000) will be generated to be plotted in a cost-effectiveness plane (CE plane). The proportion of points in each quadrant of the CE plane will be calculated, and the location of points will also be assessed visually. We will calculate the incremental net benefit using the following equation:

$IncrementalNetBenefit = IncrementalEffect \times CeilingRatio - IncrementalCost$,
being value 1 for a positive coefficient and 0 for a negative coefficient value. Thus, for the interpretation, if the difference is higher than zero (the value 1), it means that for one additional unit of effectiveness, the incremental cost is below the Ceiling Ratio (the maximum value that decision-makers are willing to pay). If the difference is less than zero (the value 0), then, for one additional unit of effectiveness the incremental cost is above the Ceiling Ratio [34]. Finally, acceptability curves will be plotted for each effect using incremental net benefit framework and assuming different ceiling ratios to check the uncertainties around threshold points.

Subgroup analyses considering age (3 to 6 vs 7 to 10 years) and patients' caries experience (≤ 3 vs > 3 restorations) will also be conducted.

Modelling for primary tooth lifetime horizon

As a secondary aim, we will construct a decision analytic modelling framework to extrapolate the results for a primary molar lifetime horizon. As the base case, we will consider a child as those enrolled in the trial. Then, based on the mean age of children enrolled on the main trial, we will establish the number of cycles of the Markov model.

Probabilities and costs will be extracted from the main trial. If necessary, any additional reference value will be identified from the literature. The SG experiment will generate utility values. We will assume that probabilities will maintain the same at each cycle until such horizon. The half-cycle correction will be used to account for the fact that events and transitions can occur at any point during the cycle, not necessarily at the start or end of each cycle.

The same strategies of the 2-year time analyses will be used for deterministic and probabilistic analyses using the model framework. The final interpretation of uncertainties will be considered for this longer time horizon. Data will be modelled and analyzed using a Markov simulation model. Tree Age Pro 2017 (TreeAge Software, Williamstown, MA, USA).

Discussion

The results from this study will provide necessary evidence regarding the economic impact of the possible implementation of potentially less interventionist diagnostic strategies, such as that based on CARS, when managing restorations in primary teeth. Owing to the lack of high-quality economic evaluation studies in the pediatric dentistry field [11], our study will strengthen the evidence and guide an evidence-informed decision-making process concerning the diagnosis of dental caries adjacent to restorations in primary teeth. To the best of our knowledge, no study has evaluated the economic impact of diagnostic strategies focused on such a clinical condition.

The strategy based on FDI may lead to a greater number of operative interventions [8], probably due to comprising not only the presence of recurrent caries but also the restoration staining and adaptation. At first glance, the need for more interventions in the first treatment plan may lead to additional costs since the baseline. However, in a full economic evaluation, not only costs are considered, and the health outcomes are also important in determining the cost-effectiveness of a strategy [35]. Considering a longer time horizon, we can expect the more interventionist; more re-interventions may be needed, as demonstrated in a previous clinical trial from our group [36]. Then, much higher expenses could have resulted. On the other hand, eventually, depending on how the non-intervened restorations behave during the follow-up, a different scenario may be observed, impacting on effects or not. Since it is an ongoing trial, the long-term health effects (at two years) will be crucial to decide, for assessment and management of restorations in primary teeth, whether a minimally invasive strategy (as that based on CARS) will be more efficient in allocating resources than the conventional one (based on FDI criteria).

CEA is one of the most widely used economic evaluation in healthcare, as the effects are clinical measures [35, 37]. At this protocol, a series of CEAs considering different health effects was chosen to permit a broader comprehension of potential benefits that the implementation of the proposed caries detection strategy could result. One of these health effects is the clinical trial's primary endpoint (the frequency and the time to the new intervention). However, to distinguish the strategies and measure the impact of the implementation, we also considered it important to assess this possible event

quantitatively and from the patient's point of view. That is why secondary endpoints in the trial were added to be analyzed.

On the other hand, patients/parents preferences and consequent utility values may also influence the final impression about the economic aspects of implementing the minimally invasive strategy, like CARS, in clinical practice. In this sense, CUA would be a useful tool since it integrates patient-centred care philosophy and should be used when the quality of life is an important outcome [27]. CUA evaluates the effects on qualitative and quantitative health gains, often measured through QALYs. These are the product of time and utility obtained through the patient's preferences for different health states [27]. As dental caries in children has a relevant impact on quality of life [38], studies involving the economic impact of caries diagnosis and management would benefit from CUA.

Utilities related to health states related to dental caries in primary teeth have been assessed through pre-scored multi-attribute health status classification systems, such as the CHU-9D, or through the Visual Analogue Scale (VAS) [39, 40]. One of the main concerns about pre-scored measures is that they may not identify the impact of oral diseases, such as dental caries [41]. Besides, the scaling methods will not necessarily express participant's sacrifice is willing to take in order to achieve the health states, and they are more prone to contextual bias [42]. Conversely, the SG is a choice-based method of obtaining 'patients' preferences for health states under uncertainty. Although it is time-consuming, the SG is conceptually based on the expected utility theory [43], and it involves the highest sacrifice the participants are willing to take.

Given the SG experiment inherent complexity, we decided to adopt the parents' valuation of utility as a proxy measurement from the child's preferences related to his/her oral health statuses. This approach has been widely used in studies of children's preference [44]. Although these proxy answers have some limitations, it would be a reasonable and feasible approach to a first attempt in determining utility scores related to dental caries, independently of the child's age. Due to the broader age range in the base clinical trial, we opted for this approach.

Therefore, the results of these trial-based economic evaluations may bring actual evidence about the economic impact of such implementation and contribute to the decision-making process pertaining to the assessment and management of restorations in children. Analytical strategies adopted (e.g. probabilistic sensitivity analyses (scenario) and modelling for primary molars lifespan) may be alternatives to minimize possible limitations in results extrapolation derived from single-studies economic evaluations [45]. In this sense, they may permit that the results are broadly generalized to children seeking dental treatment, who will demand decision and management of their previously placed restorations.

Trial Status

CARDEC-03 trial recruitment took place on November 2017 to November 2018. Each patient will be followed for 24 months. Due to the COVID-19 pandemic situation, our goal is to complete the follow-up by May 2021.

Abbreviations

FDI: World Dental Federation; CARS: Caries Around Restorations and Sealants; CEA: Cost-effectiveness analysis; ECOHIS: Early Childhood Oral Health Impact Scale; CUA: Cost-utility analysis; QALYs: quality-adjusted life years; ICER: Incremental Cost-Effectiveness Ratio; ICCMS: International Caries Classification and Management System; ICDAS: International Caries Detection and Assessment System; HEAP: Health Economic Analysis Plan; RCT: Randomized Controlled Trial; ISPOR: International Society for Pharmacoeconomics and Outcomes Research; CARDEC: Caries Detection in Children; OHRQoL: Oral Health-Related Quality of Life; SG: Standard Gamble.

Declarations

Ethics approval and consent to participate

The clinical trial was approved by the Ethical Committee of the School of Dentistry (registration n° 2.291.642), University of São Paulo (São Paulo, Brazil), on 22nd September 2017, and was registered on Clinicaltrials.gov (registration NCT03520309). All parents or guardians will sign a written informed consent form before the child's participation in the study and literate children will sign an assent form. Parents and guardians are free to withdraw their children from the clinical trial at any time, without losing any rights regard treatments they would receive during the trial.

Consent for publication

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Competing interests

The authors declare they have no competing interests.

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they have no intellectual role or responsibility in/for study protocol design or execution. DPR, FMM, MSC and MMB are granted for research productivity with scholarship awards by CNPq.

Author's contributions

MMB, FMM, DPR, and MSC contributed to the conception of the clinical trial. MMB and RDF were responsible for the idealization of the economic evaluation and drafted the manuscript. BLPM and LRAP are in charge of patients' recruitment and treatment plans. HCMM, ALP, RCO, and JRG are responsible for treating patients and collecting costs data. TKT and DPR will be responsible for the follow-up assessments. MEFV and RDF will develop and execute the SG. MMB and FMM will perform statistical analyses. CD contributed to the methodology, writing, reviewing, and editing. The CARDEC collaborative group staff members are responsible for the study's organization and conduction; performing treatments, and oral hygiene orientation for the participants. All authors critically reviewed and approved the final manuscript as submitted.

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Author's information

The CARDEC collaborative group investigates caries diagnosis in primary teeth. This group involves researchers, dentists, technicians, graduate, and undergraduate students. The list of the participants can be found at the following link (https://sites.usp.br/cardec/grupo_de_pesquisa/cardec-03/grupo-de-colaboradores-2/).

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Tables

Due to technical limitations, Tables 1 and 2 are only available as a download in the supplemental files section

Figures

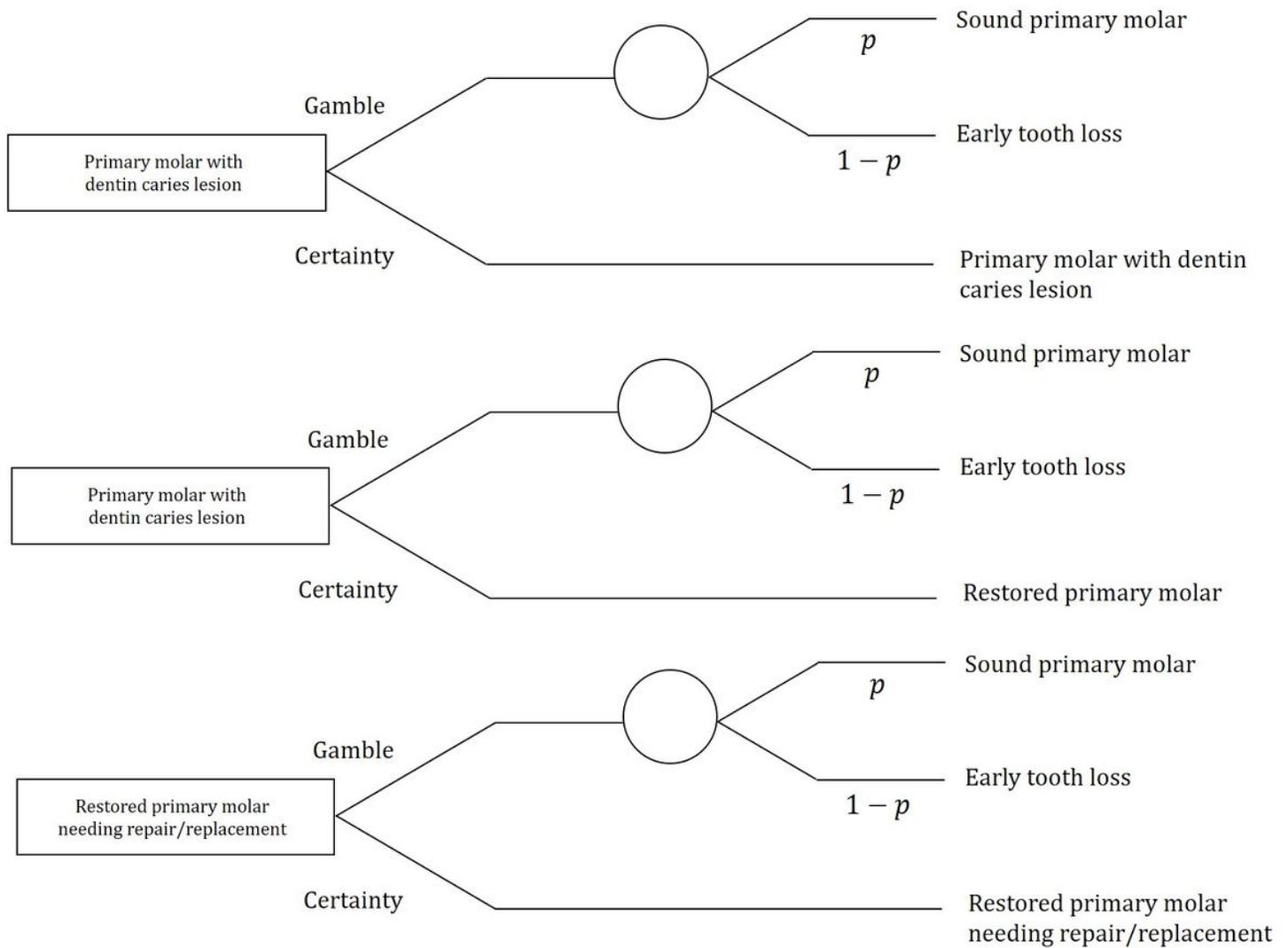


Figure 1

The Standard Gamble experiment performed with parents assessing three health states related to dental caries in their child’s primary molars.

Supplementary Files

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