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ORIGINAL ARTICLE

Impact of pulpectomy versus tooth extraction in children's oral health-related quality of life: A randomized clinical trial

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Abstract

Aim: The aim of this randomized clinical trial was to compare the impact of two management options for primary molars with pulp necrosis (pulpectomy or extraction) on children's oral health-related quality of life (OHRQoL).

Design: A total of 100 children aged 3–5 years with at least one necrotic primary molar were selected and randomized into the study groups. The Brazilian version of early childhood oral health impact scale (B-ECOHIS) was completed by the parent proxy reports at baseline and after 4, 8 and 12 months. Differences between the trial groups were assessed through bootstrap linear regression for B-ECOHIS scores, logistic regression for dental pain self-reports and anxiety scores ($\alpha = 5\%$).

Results: The mean (SD) B-ECOHIS scores at baseline and after 12 months were 17.7 (6.5) and 3.0 (4.0) in the pulpectomy group and 18.8 (7.7) and 7.9 (7.7) in the extraction group. Both treatments significantly improved OHRQoL, but tooth extraction group showed higher scores in total B-ECOHIS ($p < .001$) and most domains, indicating lower OHRQoL. Furthermore, higher anxiety levels were reported for dental extraction compared to pulpectomy (OR = 2.52; $p = .008$).

Conclusion: Pulpectomy resulted in an improved OHRQoL scores after 12 months when compared to tooth extraction and should be considered as the treatment of choice for necrotic primary molars.

KEYWORDS
anxiety, children, endodontic treatment, pain, patient-reported outcomes, primary teeth, tooth extraction

1 | INTRODUCTION

Early childhood caries (ECC) is a prevalent preventable disease that affects almost half of 0–5 years old children worldwide.[1] Prevalence in Brazil is one of the highest in the world, ranging from 41.6% to 64.8%.[1] Untreated cavitated lesions in primary teeth represent a significant burden[2] and are consistently associated with a negative impact on health-related quality of life (HRQoL)[3] and oral health-related quality of life (OHRQoL) of preschool children and their families.[4]

The prevalence of severe caries lesions with irreversible pulp inflammation or pulp necrosis in the primary dentition remains high among

preschool children in many countries.[5] When a permanent tooth presents with pulpal involvement and subsequent necrosis, the endodontic treatment, whenever possible, is a consensual management option.[6,7] However, such consensus does not exist for primary teeth.[8]

Guidelines from both of the American Academy of Paediatric Dentistry and Brazilian Society of Paediatric Dentistry recommend pulpectomy as the preferred treatment approach with the exception of more advanced cases.[9,10] Preservation of the tooth may be the best treatment for maintenance of overall oral health, space, growth and arch integrity.[9] Furthermore, early loss of primary teeth can negatively affect the child's appearance and oral functioning.[11,12] Alternatively, the United Kingdom national clinical guidelines report extraction as the most commonly adopted treatment strategy for severely carious primary molars.[13] The popularity of this approach may be related to several factors including poor cooperation, sociocultural contexts, type of dental practices (public/private), professionals' preferences and local guidelines.[14,15]

Nonetheless, the current evidence is inconclusive in terms of comparing the different treatment for primary molars with pulpal necrosis.[8] Randomized clinical trials are necessary to compare these two options of management for necrotic primary teeth. One of the difficulties in this particular study type is choosing a comparable outcome for both treatment options. The most utilized outcome for endodontic treatment is the clinical and radiographical success of the treatment,[8] while tooth extraction outcomes are usually related to space loss, orthodontic impact or speech disorders.[11] The different nature of these outcomes makes the comparison between these treatments a challenge. A favourable alternative would be to consider a patient-reported outcome measure (PROM), such as OHRQoL, dental anxiety and pain reports. PROMs are applicable for both these treatments and probably the most important outcomes to be assessed in a clinical trial, as the effects of the treatments are evaluated from patients' perspective. For younger children, those outcomes can be collected throughout parent's proxy reports, which are a valid and reliable source of information.[16]

Thus, the aim of this randomized clinical trial was to compare the OHRQoL impact after 12 months between two treatment alternatives for necrotic primary molars: pulpectomy and tooth extraction. Secondary outcomes included the analysis of each of the OHRQoL domains, child's self-reported dental anxiety and pain scores for each follow-up period.

2 | METHODS/DESIGN

This manuscript was written following the guidelines of CONSORT (Consolidated Standards of Reporting Trials), using its extension for PROMs.[17]

2.1 | Study design and ethical aspects

This study is a two-arm, randomized parallel controlled clinical trial. This study was approved by the Human Research Ethics Committee of the University of São Paulo (CAAE # 18198113.0.0000.0075) and registered in the platform clinicaltrials.gov (NCT01858298), in May 21, 2013.

Informed consent forms were obtained from children's parents or guardians before participation in the study. Changes in the protocol registered are mentioned in the specific sections below.

2.2 | Eligibility criteria

Healthy children from 3 to 5 years old whose parents/caregivers sought dental treatment at the University of São Paulo were screened. Children were not included if they had any systemic, neurological, or other diseases that adversely affected their growth according to the parental report.

A clinical and radiographical examination was conducted by one of the researchers (JA).

Clinical Eligibility criteria:

1. Children from 3 to 5 years old that presented with extensive caries lesions in at least one primary molar;
2. With clinical signs of pulp necrosis, including clinical pulp exposure, presence of pain, fistulae and/or abcess near the selected tooth, furcation;
3. With sufficient coronal structure to allow rubber dam placement and tooth restoration (restorable tooth);
4. Whose parents/guardians agreed to their children's participation in the study;

3 | RADIOGRAPHICAL ELIGIBILITY CRITERIA

Periapical radiographs of the potentially eligible teeth selected by the clinical criteria were taken to determine eligibility. The criteria are described below:

1. Baseline diagnosticable (Grade 1–2) periapical radiographs of the selected tooth/teeth;
2. Primary molars with coronal caries into pulp (without presence of a dentine bridge);
3. Primary molars without any internal resorption or presence of external root resorption of more than one-third of the root or involvement of the permanent successor crypt;

For the included children, demographic and socioeconomic information were collected, such as child's age, sex, household structure (father and mother/only mother) and household income (categorized according to the Brazilian minimum wage—BMW).

3.1 | Sample size

The sample size of the study was calculated based on the primary outcome. The sample size of the study was calculated based on

the primary outcome. The sample size calculation was based on an effect size of 0.62, considering the difference between the change scores obtained with the change scores obtained with the ECOHIS after and before the dental treatment, considering the child section according to the study of Lee et al., 2011. With this effect size, a minimum of 10 children (50 per group) was calculated considering a error of 20%, and adding 20% to compensate possible drop-outs.

3.2 | Randomisation

The randomisation unit was the child; therefore, more than one tooth could be included per child. The randomisation list was computer-generated (Medcalc software version 12.4.0.0, Ostend, Belgium). Simple randomisation procedure with 1:1 allocation rate was used. The generated sequence was closed in opaque, sealed, and sequentially numbered envelopes. The allocated group was disclosed only after the inclusion, immediately before the beginning of the dental procedure.

3.3 | Interventions

The participants of this trial were randomly allocated to two groups according to the management options for necrotic primary molars: pulpectomy or dental extraction.

All treatments were performed by a trained and experienced paediatric dentist (JA) who was assisted by a dental nurse. Both treatments were performed under local anaesthesia without any type of sedation or general anaesthesia. Non-pharmacological behavioural approaches were employed including tell-show-do, positive reinforcement, non-verbal communication and distraction. Voice control was used on very few occasions.

The pulpectomy technique was performed following recommended clinical guidelines.[13] After topical anaesthesic solution application in a dry mucosa for 2 min (Benzotop, DFL, Brazil), local anaesthesia was administered (Alphacaine, DFL, Brazil). All endodontic treatments were performed under rubber dam isolation in a single session. The periapical radiograph was used for work length determination. Carious tissue was removed prior to the endodontic access with spherical drills of adequate size for access to the pulp chamber. Chemo-mechanical root canal preparation was done using a 1% sodium hypochlorite solution for irrigation and manual instrumentation using three Kerr-type files (initial size + two successive sizes). Final irrigation was performed after instrumentation with the third file with 20 mL of 17% EDTA (Formula & Ação®, Brazil) for 3 minutes. The canals were dried using Capillary Tips (Ultradent®, Brazil), followed by absorbent paper points. Root canal obturation was done using Vitapex® (Neo Dental International, Inc.). A thin layer of gutta-percha was applied with the aid of endodontic intracanal condenser with a diameter compatible with the cavity-size for cavity seal. Tooth restoration of the teeth was carried out in the same session using direct composite resin (Filtek Z250 Universal restorative, 3M ESPE, Germany) for single surface restorations. In case of multisurface restoration, the composite resin was inserted using strip crown (TDV, Santa Catarina, Brazil).

In the dental extraction group, the treatments were also conducted with the use of topical and local anaesthesia as described above. The clinician used paediatric forceps and elevators, using recommendations and techniques described a guideline on paediatric oral surgery.[18]

3.4 | Outcomes

The primary outcome was OHRQoL scores, assessed through the Brazilian version[19] of the early childhood oral health impact scale (B-ECOHIS).[20] The questionnaire is a parental proxy reported measure developed to assess the impact of oral condition on the children's quality of life. In this case parents/guardians are the secondary respondents, as it is believed that very young children do not have sufficient cognitive skills to evaluate their own quality of life. This method has been validated in the literature. B-ECOHIS has 13 items, divided into two sections: a child impact section with four domains (child symptoms, function, psychological, and self-image/social interaction domains) and a family impact section with two domains (parental distress and family function), all answered by parents/guardians. Parents responded to each item using a rating scale from 0 to 5. Total scores can range from 0 to 52, with higher scores representing higher negative impact on children's OHRQoL.

The B-ECOHIS was chosen as it has shown good internal consistency, reliability and validity assessed in several Brazilian studies.[4,20] In addition, it has shown to be responsive to dental treatment[21] and sensitive to detect oral health impairment.[22]

The B-ECOHIS was administered at baseline through face-to-face interviews with parents, carried out by a trained researcher who was unaware of children's clinical conditions and before randomisation into the treatment group. It was also administered at 4, 8 and 12 months after the conclusion of dental treatment. The primary outcome was the total B-ECOHIS scores assessed 12 months after treatment completion.

A range of other PROMs were measured as secondary outcomes. These were the scores for each B-ECOHIS domains assessed after 12 months and the intermediate total B-ECOHIS scores (obtained at 4 and 8 months of follow-up). Moreover, child's self-reported dental anxiety was assessed using the facial image scale (FIS).[23] FIS was administered at baseline and after 4, 8 and 12 months of the treatment. A single trained examiner showed the scale to the child in the waiting room. The faces ranged from very happy to very unhappy (scores 1–5, respectively). Children were invited to point to the face that they felt most represented their feelings at that moment.

Dental pain related to the dental treatment was assessed immediately after the treatment. The child was instructed by the interviewer to select the face that best reflected their pain level during treatment using the Wong-Baker Faces Pain Scale

(WBFPS).[24] The pain score was determined based on the numerical values ranging from 0 to 5 (0 = does not hurt; 1 = hurts little bit; 2 = hurts little more; 3 = hurts even more; 4 = hurts whole lot; 5 = hurts the worst). When the children had more than one tooth included, this evaluation was performed only after the treatment of their first tooth.

Other clinical secondary outcomes described in the protocol, such as weight-for-age Z scores, height-for-age Z scores, body mass index-for-age Z scores, and space loss (only in the extraction group) were also evaluated and will be further explored in another manuscript.

3.5 | Blinding

Participants, operators and evaluators could not be blinded as the treatment groups were very different in nature. Only the interviewer who applied the parental PROs questionnaires could be blinded.

3.6 | Statistical analysis

Intention-to-treat analysis following conditional multiple imputation was conducted for missing data. Linear regression was used for quantitative data (B-ECOHIS scores) while ordered logistic regression analysis was used for ordinal data (anxiety scores) imputation. Children's age, sex, caries experience and baseline data were used for data imputation for each specific domain.

For the primary endpoint (total B-ECOHIS score after 12 months), linear regression analysis was performed for comparisons between trial groups. As data did not present normal distribution (Shapiro-Francia normality test), bootstrap linear regression (1000 replications) was conducted. Unadjusted analysis was initially conducted to derive the *p* values, followed by adjusted analysis (children's sex and baseline B-ECOHIS scores), as imbalances were noted in these baseline variables. Also, the effect size (ES) with its respective 95% confidence interval (95% CI) between the groups at 12 months of evaluation were calculated.

The B-ECOHIS scores for the different domains were also compared by bootstrap linear regression. The ES values between the groups were also calculated for each domain and the data related to the change scores (final minus baseline B-ECOHIS scores) is presented. The ES values were derived dividing the mean change scores by the pooled SD.

The evaluation of B-ECOHIS scores in the baseline and intermediate periods of follow-up was assessed by linear regression. To deal with the non-normal distribution of the data, the standard errors were adjusted by robust variance. The multilevel structure considered the scores of B-ECOHIS at different follow-up times (0, 4, 8 and 12 months) as first level, nested for each child (second level) as more than one tooth could be treated per child. Additionally repeated measures ANOVA test was conducted to evaluate the interaction between time and treatment. For this, Box-Cox transformation was performed prior to the analysis.

Throughout the data analysis, FIS scores (1–5) were dichotomised into low (1–3) and high (4, 5) anxiety.[25] The same categorization was performed for pain scores after treatment (1–3: low/moderate pain; 4–5 high pain level). For anxiety scores, multilevel ordered logistic regression analysis[26] was conducted, taking into consideration the anxiety levels throughout the period. For children' self-reported pain after treatment, a logistic regression analysis was conducted. Interaction between time and treatment groups were conducted separated through Kruskal–Wallis test.

MedCalc® software (version 18.6, Ostend, Belgium) was used for the calculation of the B-ECOHIS change score effect sizes (ES) and their respective 95% confidence interval. For all other analysis, Stata® software was used (Stata 16.0, Stata Corp).

4 | RESULTS

Recruitment took place in December 2013 and treatments were performed between January and March 2014. The follow-up started in May 2014 and lasted until March 2015. Overall, 100 children were included in the study and 175 teeth with pulp necrosis were treated. Out of the 100 children treated, 88 children were followed-up until 12 months (follow-up rate of 88.0%). There were no significant differences in the drop-outs between the groups. The study flowchart for clinical trials is presented in Figure 1.

Regarding the baseline sample characteristics, 55 girls and 45 boys were included. Children's age varied from 3 to 5 years, with a mean (SD) of 3.7 (0.7) years. The majority of the children included in the study (57/100) had more than one tooth treated, and all had a dmft>6. Baseline demographic and clinical characteristics for each group are described in Table 1. An imbalance between the groups was noted for sex ($p = .01$, by chi-squared test) and B-ECOHIS baseline scores ($p = .069$, by Mann–Whitney test). All other variables were similarly distributed between the groups. No difference was observed for all variables comparing participants who droped-out and those who stayed-in (Table 1).

Children that underwent pulpectomy presented significantly lower total B-ECOHIS scores than those treated with dental extraction; the effect size (ES) for the difference between the two treatment groups was 0.8; (95% CI = 0.46–1.13; $p < .001$) and this was the case also after adjusting for sex and baseline B-ECOHIS scores. Moreover, change scores and effect size values were larger for the children allocated to the pulpectomy group than the dental extraction group (Table 2).

Considering the different B-ECOHIS domains, a significant lower negative impact on OHRQoL at 12 months post-treatment was observed for children submitted to pulpectomy treatment, compared to extraction, for the 'symptoms' (ES = 0.1), 'function' (ES = 0.5), and 'psychological' (ES = 0.4) domains in the child section, and for the 'parental distress' domain (ES = 1.2) in the family section (Table 2).

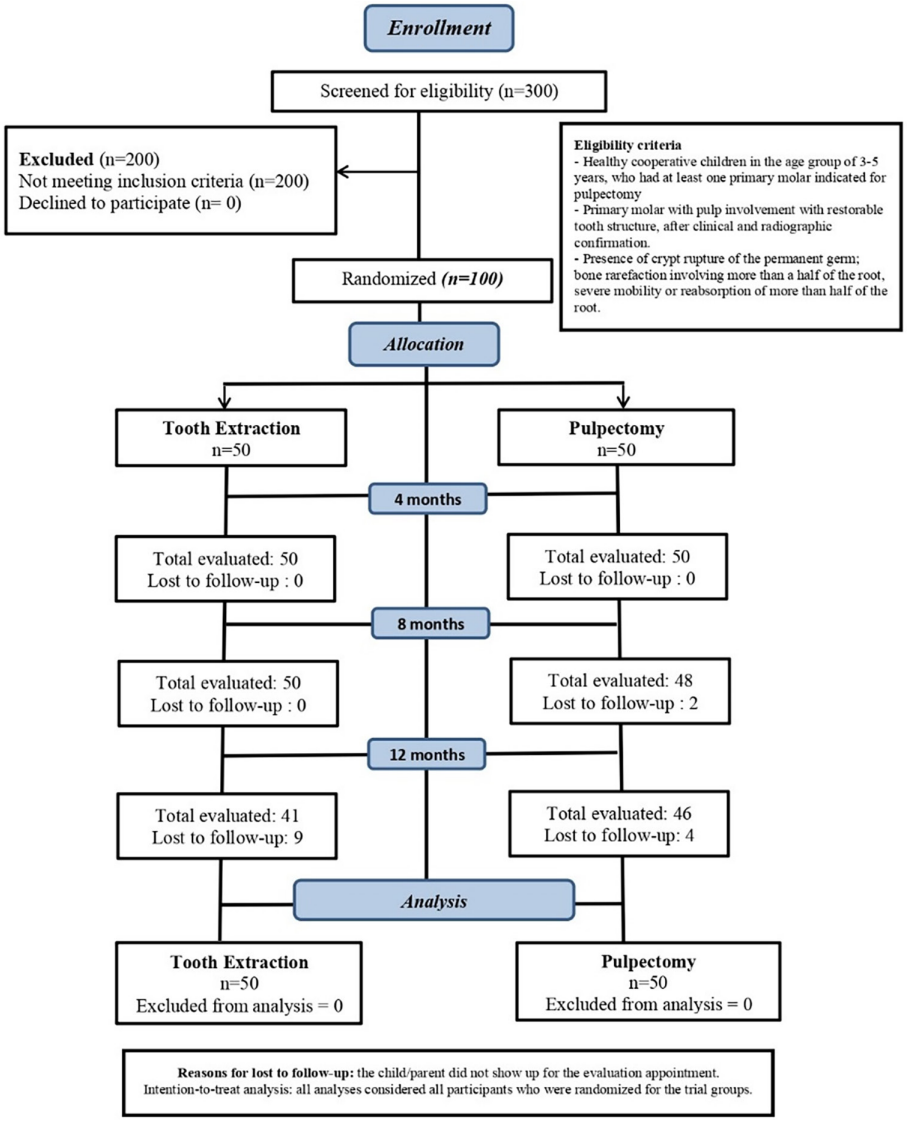

FIGURE 1 CONSORT flow diagram.

The B-ECOHIS scores were relatively steady throughout the follow-up period with a clear improvement in all evaluation periods when compared to the baseline scores (Table 3). Children that were treated with a more invasive approach (tooth extraction) had total B-ECOHIS scores 32% higher when compared to those treated by a more conservative approach (pulpectomy). Furthermore, older children had a lower impact on the OHRQoL when compared to younger ones. Also, the higher the number of treated teeth, the more the negative OHRQoL impact was observed (Table 3). Those results were independent of the treatment groups (adjusted analysis).

With regard to the analysis of the interaction between time and treatment, the *p* value obtained for the between-subjects effects (differences between groups) was .022, while for the within-subjects effects (differences between time periods) was <.001. For the time × treatment effects interaction, the *p* value obtained was .002.

A clear reduction in anxiety scores after 8 and 12 months was evident for each of the treatment groups, when compared to baseline. However, children who had an extraction showed higher levels of anxiety when compared with those in the pulpectomy group at follow-up (OR = 2.52; 95% CI = 1.30–4.89). Children's age, sex and number of treated teeth did not influenced the anxiety results (Table 4). Interaction between time and treatment groups was also tested individually. Differences between the groups was observed after 4 months and after 12 months. In both time periods, anxiety scores were higher for extraction group.

Overall, 50% of the children reported high pain level (WBFPS scores 4–5) immediately after treatment (44.4% in the pulpectomy group and 56.5% in the extraction group); however, no differences was found between the groups and the pain levels (OR = 1.93; 95% CI = 0.83–4.49). Besides the post-operative pain, no other important harms of unintended effects were observed for both groups.

TABLE 1 Distribution of sociodemographic and clinical variables between the groups.

	Pulpectomy	Extraction	Stayed in	Drop-out
Total	50 (50.0)	50 (50.0)	87 (87.0)	13 (13.0) *
N (%)				
Categorical variables, *N* (%)				
Sex				
Female	34 (61.8)	21 (38.2)	49 (89.1)	6 (10.9)
Male	16 (35.6)	29 (64.4)	38 (84.4)	7 (15.6)
Age				
3 years old	22 (47.8)	24 (52.2)	42 (91.3)	4 (8.7)
4 years old	21 (50.0)	21 (50.0)	34 (81.0)	8 (19.1)
5 years old	7 (58.3)	5 (41.7)	11 (91.7)	1 (8.3)
Caries Experience (dmf-t)				
1–5	24 (51.1)	23 (48.9)	41 (87.2)	6 (12.8)
>5	26 (49.1)	27 (50.9)	46 (86.8)	7 (13.2)
Household structure				
Father and mother	43 (48.31)	46 (51.7)	78 (87.6)	11 (12.4)
Only mother	7 (63.6)	4 (36.4)	9 (81.8)	2 (18.3)
Household income				
<1BMW	19 (52.8)	17 (47.2)	32 (88.9)	4 (11.1)
>1BMW	31 (48.4)	33 (51.6)	55 (85.9)	9 (14.1)
Quantitative variables, mean (SD)				
Number of treated teeth	1.7 (0.9)	1.8 (1.1)	1.8 (1.0)	1.4 (0.5)
Anxiety level (FIS 0–5) baseline	1.9 (1.2)	2.28 (1.5)	2.0 (1.3)	2.9 (1.4)
Caries experience (dmft)	6.2 (3.9)	6.8 (2.7)	6.5 (3.5)	6.3 (1.9)
Age (3–5 years old)	3.7 (0.7)	3.6 (0.7)	3.6 (0.7)	3.8 (0.6)
Baseline B-ECOHIS scores, mean (SD)				
Total scores	15.7 (6.5)	18.8 (7.7)	17.2 (7.2)	17.4 (8.1)
Child section				
Symptoms	1.2 (0.9)	2.6 (0.9)	1.9 (1.2)	2.2 (0.9)
Function	3.8 (2.2)	5.2 (2.5)	4.5 (2.5)	4.6 (2.1)
Psychological	2.5 (1.5)	3.1 (1.6)	2.7 (1.6)	3.2 (1.5)
Self-image/social interaction	1.3 (1.8)	1.5 (1.9)	1.4 (1.8)	1.2 (2.2)
Family section				
Parental distress	4.5 (2.0)	3.8 (1.3)	4.3 (2.0)	3.2 (1.6)
Family function	2.2 (1.3)	2.5 (1.8)	2.3 (1.6)	2.8 (1.6)

Abbreviations: B-B-ECOHIS, Early Childhood Oral Health Impact Scale; BMW, Brazilian Minimum Wage (U$195 during the data gathering); dmf-t, number of primary teeth decayed, missed due to caries or filled; SD, standard deviation.

*Four children who dropped-out were from pulpectomy group and nine from the extraction group ($p = .234$, by Fisher's exact test).

5 | DISCUSSION

There is a lack of evidence comparing pulpectomy to extraction in the management of carious primary molars with pulp necrosis. The findings from the clinical trial show that performing pulpectomy in primary molars, in an effort to maintain these teeth until the regular period of exfoliation, results in higher children's OHRQoL compared to simply extracting those teeth. As such, pulpectomy should be considered the best evidence-based choice to treat primary molar teeth with pulp involvement.

Although both treatments improved the children's OHRQoL, the mean B-ECOHIS change score was larger in the pulpectomy group,

TABLE 2 Intention-to treat analysis ($n = 100$) considering the final B-ECOHIS scores between the trial groups (primary outcome, highlighted in the shade cells) and B-ECOHIS scores for different domains, as well as change scores values and effect sizes.

			Between groups (pulpectomy × extraction)				Change scores (baseline–final)	
B-ECOHIS scores	Trial groups	B-ECOHIS final scores mean (SD)	Mean differences (SD)	Effect size (95% CI)	Unadjusted *p* value	Adjusted *p* value *	Mean (SD)	Effect size (95% CI)
Total scores (primary outcome)	Pulpectomy	3.02 (3.98)					12.66 (6.79)	3.2 (2.42–4.20)
	Extraction	7.88 (7.70)	4.86 (6.13)	0.8 (0.46–1.13)	<.001	<.001	10.94 (9.28)	1.4 (0.84–2.11)
Child section								
Symptoms	Pulpectomy	0.44 (0.83)					0.78 (1.28)	0.9 (0.42–1.64)
	Extraction	0.54 (1.09)	0.10 (0.97)	0.1 (−0.24–0.52)	.602	.022	2.10 (1.65)	1.90 (1.10–3.15)
Function	Pulpectomy	0.48 (1.23)					3.34 (1.95)	2.7 (1.90–4.13)
	Extraction	1.12 (1.22)	0.64 (1.23)	0.5 (0.05–0.99)	.007	.028	4.08 (2.60)	3.3 (2.71–4.11)
Psychological	Pulpectomy	0.44 (0.83)					2.06 (1.71)	2.5 (1.71–3.63)
	Extraction	0.88 (1.56)	0.44 (1.25)	0.4 (0.02–0.74)	.072	.034	2.24 (2.29)	1.4 (0.86–2.25)
Self-image/social interaction	Pulpectomy	0 (0)					1.26 (1.81)	**
	Extraction	1.04 (2.27)	1.04 (1.61)	**	.001	.001	0.48 (2.65)	0.2 (−0.13–0.66)
Family section								
Parental distress	Pulpectomy	0.66 (1.36)					3.8 (2.53)	2.8 (1.73–4.35)
	Extraction	3 (2.53)	2.34 (2.03)	1.2 (0.71–1.55)	<.001	<.001	0.8 (1.89)	0.3 (0.11–0.58)
Family function	Pulpectomy	1 (1.35)					1.22 (2.09)	0.9 (0.44–1.52)
	Extraction	1.3 (1.64)	0.30 (1.51)	0.20 (−0.19–0.60)	.319	.319	1.24 (1.87)	0.8 (0.42–1.22)

Abbreviations: 95% CI, 95% confidence interval; B-ECOHIS, Brazilian version of early childhood oral health impact scale; SD, Standard deviation.

*p-values for the comparisons between the treatment groups considering the final B-ECOHIS scores after 12 months calculated using Bootstrap Linear Regression adjusted by sex and baseline score.;
**Value was not calculated because all chidren in the pulpectomy group achieved values equal to 0 at this domain.

TABLE 3 Unadjusted and adjusted multilevel linear regression with robust variance for B-ECOHIS total scores evaluated in all recalls (0, 4, 8 and 12 months) and independent variables.

	B-ECOHIS total scores			
	Unadjusted β(SE)	*p*-value	Adjusted β (SE)	*p*-value
Group				
Pulpectomy	Ref.		Ref.	
Extraction	1.94 (0.80)	.015*	2.05 (0.70)	.004*
Time				
Baseline	Ref.		Ref.	
4 months	−14.75 (0.72)	<.001*	−14.75 (0.72)	<.001*
8 months	−10.64 (0.93)	<.001*	−10.64 (0.93)	<.001*
12 months	−11.80 (0.81)	<.001*	−11.80 (0.81)	<.001*
Sex				
Female	Ref.		Ref.	
Male	−0.46 (0.87)	.596	−1.26 (0.75)	.091
Age				
Quantitative variable	−1.55 (0.51)	.002*	−1.81 (0.50)	<.001*
Number of treated teeth				
Quantitative variable	0.69 (0.34)	.040*	0.89 (0.38)	.020

Abbreviations: B-ECOHIS, Brazilian version of early childhood oral health impact scale; SE, Standard Error; β, Coefficient of linear regression.
*$p < .05$.

TABLE 4 Unadjusted and adjusted logistic regression analysis for anxiety scores.

	Multilevel logistic regression—Anxiety scores			
	Unadjusted		Adjusted	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Group				
Pulpectomy	Ref.		Ref.	
Extraction	2.57 (1.22–5.39)	.013*	2.52 (1.30-4.89)	.008*
Time				
Baseline	Ref.		Ref.	
4 months	0.60 (0.28–1.26)	.183	0.58 (0.26–1.28)	.181
8 months	0.09 (0.02–0.46)	.003*	0.09 (0.02-0.45)	.004*
12 months	0.36 (0.14–0.98)	.047*	0.35 (0.12-1.00)	.05
Sex				
Female	Ref.		Ref.	
Male	1.49 (0.74–2.97)	.255	1.14 (0.57–2.28)	.697
Age				
Quantitative variable	1.17 (0.74–1.86)	.491	1.13 (0.66–1.94)	.649
Number of treated teeth				
Quantitative variable	1.40 (1.12–1.73)	.003*	1.40 (0.99-1.97)	.056

Abbreviations: 95% CI, 95% Confidence Interval; B-ECOHIS, Brazilian version of early childhood oral health impact scale; OR, Odds Ratio.
*$p < .05$.

indicating greater long-term OHRQoL improvement in this group. Children allocated to the extraction group presented B-ECOHIS scores 32% higher, that is, with lower OHRQoL, than children who had their necrotic molars endodontically treated (IRR = 1.32; $p = .018$). Moreover, the effect sizes (ES) for children who underwent pulpectomy was twice as large as the ES obtained for children who had tooth extraction, indicating larger improvement in OHRQoL in favour of pulpectomy, even 12 months after treatment.

Furthermore, differences in scores for the intermediate follow-up assessments as well as for different domains of the B-ECOHIS were found. A larger improvement in total B-ECOHIS scores was observed in the pulpectomy group, with most of the B-ECOHIS domains in the child and family section showing moderate to large improvements. Previous studies have showed that children who require more complex dental treatments, such as endodontic treatment and dental extraction, have presented higher responsiveness to dental treatment than children with simpler dental treatments.[27]

Using OHRQoL assessment as the primary outcome of the present trial reflects a shift from traditional tooth orientated criteria to an evaluation that considers the patient and parent's experience when defining the most appropriate treatment plan.[28] A similar approach considering the OHRQoL as outcome has recently been used in a cohort that evaluated the effect of root canal treatment in permanent teeth compared to patients allocated to dental extraction.[7]

Considering the primary and some of the secondary outcomes, there seems to be a clear advantage in terms of OHRQoL for the endodontic treatment of primary molars with pulp involvement compared to their extraction. Our findings are similar to results observed in the permanent dentition regarding the benefits of endodontic management compared to extraction therapy, although extractions of primary teeth will result in eruption of permanent successors.[29]

It is comprehensible that children with extensively carious teeth, sometimes with dental pain, present an improvement in their quality of life after extraction of the severely carious teeth. Nevertheless, if the maintenance of the involved primary teeth is feasible, the endodontic treatment should be considered as the primary choice. Actually, a recently published study identified that children who had early loss of their primary molars presented a more negative impact on OHRQoL, and this result was independent of the presence of untreated dental caries.[30] Younger children and children with a higher number of teeth with pulp involvement presented a more negative impact on the OHRQoL. After 4 years of age, children tend to present higher cognitive maturity, better anxiety control and better cooperative behaviour during the dental treatment,[31] which may explain the lower anxiety scores in older children. Also, time until tooth exfoliation and permanent successor eruption in younger children is longer, which may affect the parental perception on OHRQoL when there is a pulp involvement in a tooth at such a young age. The number of treated teeth also influenced the B-ECOHIS scores regardless of the treatment group. This can be explained by the fact that children with more than one teeth with pulp necrosis have higher disease severity and therefore, higher impact on their OHRQoL.

Looking at the anxiety results, both treatments were associated with reduced anxiety levels at 12 months post-treatment; however, a higher improvement (lower anxiety levels) were observed in the pulpectomy group in comparison with the extraction group. This could be partly due to the fact that extraction is a more radical treatment option and could increase the children's dental anxiety on a long-term basis.

Another PROM evaluated was the pain reported by the child immediately after treatment; however, no pre-treatment pain assessment was performed. Both pulpectomy and extraction are not minimally invasive procedures and for this reason, a higher level of discomfort is expected. In the present study, no difference was found in the pain reported by the child immediately after tooth extraction or pulpectomy. This could be explained as the children were still anaesthetised when this outcome was measured. The severity of dental caries could also have influenced the pain experience in this age group.[32]

The present study design did not include space maintainers for children in the extraction group. There is insufficient clinical evidence that supports the use of space maintenance in younger children with high caries experience, both in terms of efficacy and children's compliance.[33,34] As this is still a topic of debate, further studies are needed in order to evaluate the impact of the provision of space maintenance (fixed/removable) for this age group following extraction.

This study has some limitations that should be recognized. The lack of evaluation of pretreatment pain levels and the relatively short follow-up time (12 months) must be considered when interpreting the results. However, it was expected that the randomisation procedure would balance any difference among the children concerning the baseline characteristics. Symptomatic children at baseline would have reported greater differences in all PROMs assessment, since both treatments are known to alleviate pain/symptoms. Another point is that older children presented with a lower negative impact on the OHRQoL when compared to younger children. It is important to note that B-ECOHIS is a proxy-reported measure, which reflect parent-perception of the impact of oral conditions on OHRQoL. This could be one reason why negative impact was higher in younger children. Also, as younger children have longer time until exfoliation of the primary teeth and eruption of permanent successor, the tooth absence might be a reason of concern. Although the recommended minimal follow-up for pulp therapy outcome is suggested to be 12 months,[8] long term endodontic treatment failures can occur, and further clinical trials with longer follow-ups are necessary to corroborate this recommendation.

This is the first study to evaluate the treatment effect of pulpectomy and extraction from both patients and parents perspectives. A possible explanation for the paucity of clinical studies comparing pulpectomy and dental extraction for primary molars with pulp involvement is the difficulty to select an adequate outcome. Appropriate and validated PROs (or proxies) can address this difficulty and also bring forward patients' perceptions in terms of the impacts of oral health in their quality of life.

Considering the PROMs (or proxies) evaluated in our clinical trial, almost all comparisons, including the analysis of the primary endpoint, were consistent in favouring pulpectomy instead of dental extraction for necrotic primary molars. PRO variables have been used as the primary outcome in other randomized clinical trials in order to provide a more patient-centered approach and guide the clinical decision-making process.[34]

In conclusion, pulpectomy resulted in an improved OHRQoL and lower anxiety 12 months after treatment when compared to tooth

extraction. Pulpectomy should be considered as a viable option for the management of necrotic primary molars.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request

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