Atraumatic Restorative Treatment vs. Conventional Treatment for Early Childhood Caries - Randomized Clinical Trial for Survival Analysis and Physiological Discomfort Assessment

Camargo LB¹, Olegário IC², Aldrigui JM², Calvo AFB², Carvalho C³, Mendes FM³ and Raggio DP*¹

Abstract

Objective: The aim of this study was to evaluate patient discomfort during dental treatment and the restoration survival after Atraumatic Restorative Treatment (ART) or Conventional Treatments (CT) for Early Childhood Caries (ECC).

Methods: Seventy three (73) primary teeth with dentin caries lesions were selected from children aged from 12 to 48 months in the ART Clinic of the Faculty of Dentistry, University of São Paulo, Brazil. The patients were randomly allocated in two groups: ART—caries removal with hand instruments followed by restoration with glass ionomer cement and CT-use of local anesthesia, rubber dam, rotary instruments for caries removal and restoration with adhesive system and composite resin. The heart rates were evaluated in different moments during the dental treatment in both groups. The restorations were evaluated after every three months up to 3 years by a single calibrated evaluator. The results were tested by Kaplan Meier survival analysis, log-rank test, Cox regression, ANOVA for Repeated Measures and Student’s t test at 95% confidence level.

Results: The mean values of heart rate were higher in CT and there was a statistically significant difference for the moment of anesthesia and rubber dam application (p<0.001). There was no difference between the restoration survival between ART and CT groups after 3 years follow-up (p>0.05).

Conclusion: ART presented similar restorations survival with lower discomfort levels when compared to CT in young children.

Keywords

Atraumatic restorative treatment; Early childhood caries; Discomfort assessment; Survival

Introduction

Early Childhood Caries (ECC) has implications for the dental and general health of the affected child [1], moreover has a negative impact on the oral health-related quality of life of young children and their parents [2].

The age of those patients involves technical and emotional behaviour complexity. In this way, the Atraumatic Restorative Treatment (ART) has been suggested to be an appropriate approach for managing ECC [3,4]. Following the concepts of Minimum Intervention in Dentistry, ART is a high-quality approach and can be applied to everyone, regardless of their economic or social situation.

Some researchers suggest that dental discomfort is mainly associated with needle visualization or the use of rotatory instruments [5,6]. Since the ART requires no dental anesthesia and only hand instruments are used to caries removal, this approach is shown to be less stressful and present lower discomfort levels [7,8].

Besides the behavioral observations, the most common way to access the discomfort level regarding its physiological aspect is the measuring the heart rate of the children during the dental treatment [8,9]. Some studies already explored those measurements during the ART [7-10], but no study reported its assessment in treating ECC.

Although systematics reviews have shown that ART and conventional treatment using amalgam or composite resin presented similar survival rates in primary and permanent teeth for single and multisurface restorations [11-13], few studies reported the restoration survival for treating ECC [14,15] and all of them had no longer than one year-follow up.

Therefore, the aim of this study was to evaluate patient physiological discomfort during the treatment and restoration survival after Atraumatic Restorative Treatment or Conventional Treatments for ECC after 3 years follow-up.

Material and Methods

Sample size and selection

This is a two-arm parallel randomized clinical trial. To calculate the sample size we used the software Sealed Envelope Ltd. 2012. We took into consideration the primary outcome, restoration survival for the sample calculation, the significance level of 5%, a power of 80% and a limit of non-inferiority between groups of 20% after 3 years and a cluster effect of 40%, reaching a minimum sample size of 28 teeth per group. Adding on 10% to predict possible loss-to-follow-up, we reached the number of 62 teeth.

Inclusion criteria

Children aged between 12-48 months, good behavior, good health conditions, with possibility of following-up for at least three years, whose parents have accepted and signed the consent form and no report of dental pain in the included tooth.

Treatment procedure

This research was approved by the Research Ethics Committee of the Faculty of Dentistry, University of São Paulo.

In deep cavities, a periapical x-ray was performed to evaluate the pulp involvement. In these cases, the teeth were treated but excluded...
from the study. The parents and children received individualized oral health information about diet and hygiene, toothbrush and dentifrice with 1100 ppm to be use during the follow-up.

The patients were randomized by list of random numbers, and allocated at the first intervention in the treatment groups: ART group - caries removal with hand instruments and restoration with Ketac Molar Easy Mix (3M/ESPE) and CT group "Conventional Treatment" - use of local anesthesia, rubber dam, rotary instruments for caries removal and restoration with adhesive system and composite resin (Single Bond and Filtek Z250 - 3M ESPE). A single expert senior lecturer (LBC) held all treatments assisted by two post-graduate students.

During treatment, heart rates were evaluated in six moments: baseline, local anesthesia, rubber dam, caries removal, restoration and at the end of treatment. At every three months, up to 3 years, the children returned to follow-up and the restorations were evaluated by Frencken and Holmgren criteria [4] by a single trained and calibrated evaluator (Kappa=0.86). Failure was characterized by missing restorations, restorations needing repair and presence of active secondary caries lesions.

Data monitoring

There is no external Data Monitoring Committee. The independent oversight of trial data collection, management and analysis were undertaken by LBC. The chief investigator (DPR) has overall responsibility of the study and is custodian of the data.

Analysis

The experimental unit was the tooth, clustered in the individual. For statistical analyses, data were accessed using STATA 11.2 software (StataCorp, College Station, TX, USA). To verify the survival of restorations, Kaplan-Meier survival analysis and log rank test were used. To evaluate the association between the outcome and the variable characteristics of the child, Cox regression test was applied. To compare the heart rate values, ANOVA for Repeated Measures was applied. To compare the baseline frequency between groups, the Student's t test was used.

Results

The intra-examiner reliability was validated in 10% of the sample and was 0.86. There were no dropouts during the study. A total of 73 cavities were treated in 16 children in this study. The mean age was 3.18 (SD=0.33). The overall survival rate of restorations over 3 years was 41% and the restoration survival rate per group was 46% and 34% for CT and ART respectively. The Kaplan-Meier survival analysis between the groups is described in Figure 1 with no difference between the treatments (log-rank p=0.83). Cox regression analysis showed no influence of the variables like gender, anterior or posterior segment, health condition, number of brothers and sisters, jaw, side and caries experience (dmft) on the survival rate of the restorations (Table 1).

In general, the mean values of heart rate were higher in CT group and there was a statistically significant difference for the moment of anesthesia and rubber dam (p<0.001). There was no statistical difference between the initial heart rate of patients from ART and CT groups (p>0.05), suggesting that the initial anxiety level was similar regardless of the type of treatment (Figure 2).

Discussion

This is the first study to compare CT and ART for treating ECC in 12 to 48 months old children. No difference in the restoration survival was found between groups. In the last epidemiological survey in Brazil, it was found that 53% of children under 5 years old had cavitated dentin lesions, and most of this caries index represents untreated cavitated lesions [16]. So, ART could be an option to be performed at dental clinics, reducing caries progression until total tooth destruction and possible pain. Discomfort has been defined as a nonspecific feeling of apprehension towards a concrete situation that does not necessarily involve a previous experience. Dental discomfort can prevent patients from fully cooperating during dental treatment [17]. Given that there is a connection between dental discomfort and uncooperative behavior, it is important for dentists to be able to assess it in their patients, especially in pediatric dentistry. There are many discomfort assessment methods reported in the literature, but depends on age and intellectual development of the child [8]. In this study, as we treated patients between 12 and 48 months, we could not use subjective scales, only physiological aspects as heart rate records were possible to be measured. It is important to state that this is the first RCT evaluating patient-centered outcome that can interfere with choosing the best treatment option for the toddlers. The present findings clearly show a difference between groups regarding the physiological aspects, mainly during anesthesia and rubber dam isolation (Figure 1) in conventional treatment. The conventional treatment is more time-consuming and provokes more discomfort. Besides, the conventional technique using composite resin as restorative material requires rubber dam use and therefore, local anesthesia is needed. This fact was already shown in previously studies with older patients [9,17] showing higher rates of discomfort. No difference between the survival of conventional treatment and ART (Figure 2) restorations was found in this study, which agrees with the previous survivals reports of systematics reviews [11-13]. To ensure this finding, we did a power analysis based on the survival of the treatments, which resulted in 83% of power. As our secondary outcome, the physiological discomfort assessment, showed difference between the treatments, we should take this in to consideration during the decision making for treating cavitated caries lesions in young children. The importance of measuring more than the restoration survival is to analyze how it can rebound to the patient.


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Conflict of Interest

The authors declare no conflicts of interest in the publication of these results.

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References


Variable Success n (%) Fail n (%) Total (n) HR Univaried† 95% IC ‡ P-value HR Adjusted † 95% IC ‡ P-value

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† HR = Hazard ratio ‡ CI = Confidence interval *(p<0.05)


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