Rubber dam isolation increases the costs and does not impact on composite resin restorations' survival in primary teeth. 2-year results from a non-inferiority clinical trial

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Abstract

Background

This non-inferiority randomised trial aimed to evaluate the survival rate, costs and discomfort/behaviour of two operative field isolation methods.

Methods

A total of 93 4–8 years old children (174 molars) with at least one dentine caries lesion were randomly allocated to groups: rubber dam isolation (RDI) and cotton roll isolation (CRI), restored with bulk fill composite resin. Two blinded examiners assessed the restorations up to 24 months. Wong-baker faces, and Frankl's behaviour rating scales were used for accessing child's discomfort and behaviour, respectively. For the statistical analysis, the primary outcome (restoration survival) used two-sample non-inferiority test for survival data using Cox Regression, Bootstrap Linear regression analysis for cost analysis and logistic regression for discomfort and behaviour.

Results

157 restorations were evaluated (drop-out = 9.7%). Survival was RDI = 60.4% and CRI = 54.3. The non-inferiority hypothesis was accepted by the Cox Regression analysis (HR = 1.33; 90% CI 0.88–1.99; $p = 0.036$). RDI was 53% more expensive when compared to the CRI group. No differences were found between the groups in terms of discomfort and behaviour.

Conclusion

Cotton roll isolation proved to be non-inferior when compared to rubber dam for composite restorations longevity in primary molars. Furthermore, the latest presented the disadvantage of higher cost and longer procedure time.

Clinical Significance:

Rubber dam isolation has no impact on the survival of composite restoration in primary molars.

Clinical trial registration:

registered NCT03733522 on 07/11/2018. The present trial was nested within another clinical trial, the CARies DEtection in Children (CARDEC-03 - NCT03520309).

1. Background

The longevity of composite resin as a restorative material has already been demonstrated in the literature through systematic reviews.[1–5] Some authors claim that some factors, such as contamination of the operative field and the number of surfaces involved can influence the bond strength and restoration longevity[6–8], although no study has tested this outcome directly.

The isolation techniques most used in dentistry involve the use of cotton rollers and saliva ejector (cotton roll isolation - CRI) and the use of dental clamps and rubber dam (rubber dam isolation - RDI).[9] Traditionally, the use of RDI is seen as an important step towards clinical excellence in operative dentistry, especially when related to the use of composite materials.[10] In addition to having the potential to improve visibility and access to the operative field and to protect the patient from accidental swallowing or aspiration of dental instruments and materials, the use of a rubber dam aims to decrease the chances of contamination of the operative field.[11]

Laboratory studies show the harmful effects of salivary contamination on the bond strength of composite resin restorations, both to enamel and to dentin.[7,12,13] In these studies, the decrease in bond strength after contamination by saliva or blood is mainly described. This happens because the saliva enzymes, mainly collagenases, are able to degrade exposed collagen fibres after acid etching, interfering in the hybrid layer formation.[9]

To reduce the procedure time, prevent salivary contamination during restorations, and facilitate the restorative technique, universal adhesives and bulkfill composite resins have been used in paediatric dentistry. The use of universal adhesives has already been clinically tested in primary dentition, showing no differences between self-etch and etch-and-rinse techniques.[14] In relation to the use of bulkfill composite in primary molars, there are few clinical trials with promising results on the survival of those restorations.[15,16] However, the current recommendation and protocols used in those clinical trials involve the use of RDI.[6,7]

Despite the advantages presented, rubber dam isolation in restorative procedures is often not used by professionals.[17,18] The most common reasons for not performing this procedure were low patient acceptance, longer consultation time and operator's preference. When analysing the scientific evidence from randomised clinical trials on this subject, it is highly heterogeneous and the studies present high risk of bias[9,19], especially when it comes to primary molars.[4] A systematic review that investigated the survival of adhesive restorations on primary teeth included studies that used rubber dam isolation or not (cotton roll isolation) in their methodology[4], however, there are no studies in the literature that directly compare both techniques.

Both for teaching practices and for clinical decision-making, there is a need to investigate whether the isolation is a factor that compromises the survival of composite resin restorations in primary teeth, using well-designed randomised clinical trials. The aim of the present study was to evaluate the survival of direct bulkfill composite resin restorations in primary molars comparing rubber dam isolation (RDI - local anaesthesia, use of dental clamp and rubber dam) and cotton roll isolation (CRI - cotton roll and saliva ejector).

2. Material And Methods

The report of the present paper followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Trial Design

This is a two-arm parallel single-blind non-inferiority randomised clinical trial. This study was registered at Clinical Trials website under the registration number (NCT03733522) and approved by the local Ethics Committee (#3.065.654).

Eligibility criteria

The inclusion criteria comprehended children aged between 4 to 8 years old, in good general health conditions, with at least one dentine caries lesion without any pulp involvement or failed restoration that required replacement, whose parents sought for treatment at the University of São Paulo (clinics of paediatric dentistry) and consent in participating in this trial. The exclusion criteria were presence of radiographical pulp exposure, confirmed by bitewings radiographs, or clinical signs of pulp necrosis (clinical pulp exposure, pathological mobility, swelling or fistula). The present trial was nested within another clinical trial, the CARies DEtection in Children (CARDEC-03 - wNCT03520309).

Sample description

The sample size estimation was performed based on the primary outcome (restoration survival) based on a previous publication.[20] A survival rate of composite resin restorations after selective caries removal using rubber dam isolation of 66% was found and used as a parameter for the sample estimation. A non-inferiority limit of 15% on the survival rate was considered (alternative hypothesis $HR > 0.85$). The sample size was increased by 40% for the cluster effect (more than one tooth could be included per child) and 10% to compensate for possible losses during the study. This gave a minimal sample size of 170 teeth. The sample unit was the tooth.

Interventions

All restorations and children’s treatment needs were performed by trained dentists, including general practitioners and specialists in paediatric dentistry. All teeth were randomly allocated between the groups: Rubber dam isolation (RDI) and Cotton roll isolation (CRI) and restored with composite resin (Scotchbond Universal Adhesive system and Filtek BulkFill composite resin – 3M ESPE). In the RDI group, all teeth received previous local anaesthesia and the rubber dam was placed aided by dental clamps). In the CRI group, no local anaesthesia was administered, and the isolation was performed only with cotton rolls and saliva ejector.

Selective caries removal was performed in both groups (dentine-enamel junction was cleaned completely while soft dentin layer was left in the cavity to avoid pulpal exposure). In case of surfaces involving proximal surfaces, a matrix and dental wedge were placed for reestablishment of the contact point. Scotchbond Universal Adhesive system (3M ESPE) in a self-etch mode was applied using a microbrush and light cured for 10s (Schuster Emitter B). Bulkfill composite resin (Filtek BulkFill composite resin – 3M ESPE) was inserted using flat plastic composite spatula into the cavity in layers up to 4mm and light cured for 30s. Excess of material was removed using finishing burs after checking contact points with articulation paper.

All information related to the patient (sex, caries experience-DMFT/dmft and child's behaviour during the treatment) along with the clinical characteristics of the cavity (new restoration/replacement, number of surfaces involved: single/multisurface, jaw: upper/lower; molar: 1st or 2nd primary molar) were collected by the operators. An external researcher recorded the time spent in each restoration, together with all materials and instruments used during the procedure. The same researcher evaluated the discomfort reported by the patient at the end of the procedure.

Evaluation of restorations

Two blind calibrated examiners (Kappa > 0.90) carried out the evaluations using Roeleveld et al. criteria[3] up to 24 months. The scores 00 or 10 were considered a success, whilst scores 11, 12, 13, 20, 21, 30, 40 or 50 were considered as failure of the restoration. The remaining scores 60, 70 and 90 were censored in the survival analysis. If a failure of the restoration was recorded, the replacement/repair of the restoration was performed by the dental team.

Randomization and allocation concealment

The children were randomly assigned into two groups: RDI and CRI. The randomization process was generated by an external researcher who was not involved on the clinical procedures, using the website https://www.sealedenvelope.com/, and designed in blocks of different sizes (4, 6 and 8). Sealed, sequentially numbered, opaque envelopes were used and opened at the time of the restoration. A stratification of the randomisation list was performed considering the number of surfaces involved (single/multisurface) and restoration type (new restoration or restoration replacement). It was not possible to blind the operator and patient due to the clear differences in the protocols between study groups. Only the outcome assessor was blinded to groups.

Outcomes

The primary outcome of this trial is the restoration survival. As secondary outcomes, the differences between the baseline and 2-year incremental cost between the groups were evaluated.

Additionally, the discomfort 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 the way that they felt during treatment using the Wong-Baker Faces Pain Scale (WBFPS).[21] The pain score was determined based on the numerical values ranging from 1 to 6.

The behaviour of the child was measured using Frankl's behaviour rating scale (FBRS).[22] It consists of four behaviour categories ranging from definitely positive to definitely negative. The behaviour score was determined based on the numerical values ranging from 1 to 4.

Estimation of costs

Costs for each group were estimated using a micro-costing approach, accounting for professional, instruments, and materials costs (payer's perspective). For this estimation, the time spent, instruments, and materials used at each procedure were registered by the operators using a specific form. To determine the material costs, an average price from three different Brazilian dental material supplies was used and quantities used during each procedure were registered. For the professional costs, we considered the minimal salary of a dentist and dental nurse according to the Brazilian Federal Law with a 40 hours per week working regime (US$22.29/h US$9.00/h, respectively). A life span of 3 years was accounted for instruments with a monthly usage of 160 hours. All costs were calculated per molar in Brazilian Reais (R$) and converted to US Dollars (US$) using Purchasing Power Parities (PPP) currency values from 2020 [23] (1US$ = 2.311 R$).

Statistical analysis

The analysis for the primary outcome (restoration survival) used two-sample non-inferiority test for survival data using Cox Regression (non-inferiority/alternative hypothesis HR > 0.85; CI = 90%). Intention-to-treat analysis was conducted considering the proportion of treatment success at 2 years follow-up (using multiple imputation considering baseline variables) as a sensitivity analysis using non-inferiority test p-value and confidence interval (CI = 95%), derived by from Miettinen and Nurminen's method.[4] These analyses were performed using NCSS Statistical software (NCSS 2021, USA).

As a secondary analysis, a shared frailty (child ID) Cox Regression analysis was performed to investigate the association of other independent variables and restoration failure (two-tailed p values were reported). Treatment survival was evaluated using Kaplan-Meier survival analysis and Log-rank test (α = 5%).

The baseline and 2-year incremental total cost were compared using Linear regression analysis considering child's level and Bootstrap replications were set as 1,000 using Stata 16.0 Software. As cost data presented initially non-parametric distribution, the linear model was built with log-transformed dependent variable and exponentiated coefficient was reported.

For the cost-effectiveness analysis (CEA), we considered the economic impact of using RDI instead of the CRI. The effect was the survival time of the restorations. Therefore, the differences between costs and effects of the strategies were calculated using the following equation: $\frac{\Delta Cost}{\Delta Effect} = \frac{CostCRI - CostRDI}{SurvivalCRI - SurvivalRDI}$

A Bayesian approach was used to explore the uncertainties around the values obtained in the CEA. Firstly, data distribution was checked for cost and effects. Subsequently, a Monte-Carlo simulation (10’000) was conducted using XLSTAT 2020. The values were plotted into a cost-effectiveness plane (scatter plots). The proportion of points in each quadrant was calculated and assessed visually.

For the evaluation of both children’s reported discomfort and children’s behaviour reported by the operator, ordinal logistic regression analysis was used considering the child level (α = 5%).

3. Results

Recruitment and treatment took place between December/2018 and March/2019. The follow-up started on June 5th 2019 and lasted until 20th March/2021. The CONSORT flow diagram for clinical trials is presented in **Fig. 1**. After 2 years, 13 children (17 teeth) were not evaluated (drop-out = 9.77%). As all children were evaluated at least once during the evaluation period, all of them were included in the Cox regression analysis (Cox drop-out = 0).

A total of 93 children were included in this study and received the interventions (n treated teeth = 174). Among the participants, 51 (55%) were male and 42 (45%) were female and the mean DMFT/dmft was 7.52 (± 3.61; min 1 – max 16). A total of 86 teeth were restored under RDI and 88 under CRI. Baseline demographic and clinical characteristics for each group, together with the drop-out distribution are described in Table 1.

Table 1
Baseline characteristics between study groups and restoration drop-out after 24-months.

	RDI	CRI	Stayed in	24-month Drop-out
TOTAL N (%)	86 (49.43)	88 (50.57)	157 (90.23)	17 (9.77)*
Categorical variables - N (%)				
Sex				
Female	33 (49.25)	34 (50.75)	61 (91.04)	6 (8.96)
Male	53 (49.53)	54 (50.47)	96 (89.72)	11 (10.28)
Number of Surfaces				
Single surface (1)	23 (52.27)	21 (47.73)	38 (86.36)	6 (13.64)
Multisurface (> 1)	63 (48.46)	67 (51.54)	119 (91.54)	11 (8.46)
Molar				
First Molar	46 (50.00)	46 (50.00)	82 (89.13)	10 (10.87)
Second Molar	40 (48.78)	42 (51.22)	75 (91.46)	7 (8.54)
Operator				
Specialist	50 (52.63)	45 (47.37)	84 (88.42)	11 (11.58)
GDP	36 (45.57)	43 (54.43)	73 (92.41)	6 (7.59)
Restoration type				
New restoration	56 (50.45)	55 (49.55)	98 (88.29)	13 (11.71)
Restoration replacement	30 (47.62)	33 (52.38)	59 (93.65)	4 (6.35)
Continuous variable - mean (SD)				
DMFT/dmft	6.94 (3.62)	7.98 (3.73)	7.68 (3.42)	5.52 (5.44)
Number of surfaces	2.09 (1.02)	2.22 (1.05)	2.15 (1.01)	2.23 (1.34)

*9 children who dropped-out were from RDI group and 8 were from the CRI group ($p = 0.760$, by chi-square test)

The Kaplan-Meier survival plot is presented in **Fig. 2**. The survival rate after 2 year was RDI = 60.4% and CRI = 54.3% (log-rank p = 0.245). The analysis of the primary outcome using non-inferiority Cox regression and ITT analysis can be found in Table 2. The alternative non-inferiority hypothesis was accepted both by the Cox Regression analysis (HR = 1.33; 90% CI 0.88–1.99; p = 0.036) and Intention-to-treat analysis (success RDI = 62.79%; CRI = 57.95%; p = 0.003). An absolute difference of 5% was found between groups, and the lower confidence limit was − 9%. Since the non-inferiority limited of 15% was considered in this study, the non-inferiority between groups can be claimed. Figure 3 represents the possible results of a non-inferiority clinical trials and a representation of the results found in the present research.

Table 2
Primary outcome analysis (restoration survival) using non-inferiority Cox Regression and Intention-to-treat analyses.

Outcomes	RDI	CRI	p-value
Primary outcome – Non-Inferiority Cox Regression analysis*			
% Survival	60.41%	54.31%	0.036
HR (90% C.L. of HR)	1.33 (0.88–1.99)		
Primary outcome – Intention-to-treat analysis (2 years) **			
N success/N total	54/86	51/88	0.003
% Success	62.79%	57.95%	
Absolute difference (95%CI)	0.05 (-0.09 to 0.19)		
OR (95%CI) **	1.22 (0.67–2.25)		0.201

HR = Hazard Ratio; OR = Odds ratio

Ha = non-inferiority at α = 5%

* 100(1–2α)% Confidence Interval and p-value for non-inferiority survival data (Wald test)

** p-values and 95% CI were derived by Miettinen and Nurminen's method using non-inferiority test for two proportions

The Cox regression analysis of prognostic factors to the failure of the restoration is presented in Table 3. No difference was found between the failure of the restoration and independent variables, both in the univariate and adjusted analysis. The reason of restorations failure according to the Roeleveld criteria[24]were mainly related to the bulk-fracture of the restoration (score 30; 52.24%), followed by secondary caries within dentine (score 21; 25.37%) and defect at the margin > 0.5mm in depth (score 11; 4.48%). Only one 2 restorations presented with inflammation of the pulp where extraction or pulpectomy were required (score 40; 2.99%).

Table 3
Univariate and adjusted two-tailed Cox Regression Analysis between restorative treatment failure and prognostic factors.

Variable	*Survival rate %*	*95% CI*	*HR Univariate†* **95% CI ‡**	*p-value*	*HR Adjusted†* **95% CI ‡**	*Two-tailed p-value*
Group						
RDI (ref)	60.41	48.40-70.47	1.36 (0.82–2.23)	0.222	1.34 (0.81–2.19)	0.244
CRI	54.31	42.52–64.67				
Restoration						
New restoration (ref)	63.16	52.83–71.83	1.54 (0.95–2.52)	0.079	1.53 (0.93–2.52)	0.093
Replacement	46.43	32.60-59.16				
Number of Surfaces						
Single (ref)	62.65	45.69–75.64	1.18 (0.66–2.11)	0.565	1.08 (0.60–1.95)	0.782
Multiple	55.43	45.74–64.08				
Molar						
1st molar (ref)	52.95	41.36–63.25	0.72 (0.44–1.18)	0.203	-	-
2nd molar	62.00	49.79–77.05				
Caries experience (DMFT/dmft)						
Low (1–3) (ref)	52.38	26.54–72.97	1.02 (0.48–2.16)	0.956	-	-
High (> 3)	57.67	48.86–65.51				
Operator						
Specialist (ref)	56.70	45.27–66.61	1.04 (0.63–1.69)	0.872	-	-
GDP	58.20	45.75–68.75				

Variable	*Survival rate %*	*95% CI*	*HR Univariate†* **95% CI ‡**	*p-value*	*HR Adjusted†* **95% CI ‡**	*Two-tailed p-value*
TOTAL	57.30	49.01–64.74				

HR = Hazard ratio ; CI = Confidence Interval; SE=Standard Error * $p < 0.05$ - 95% CI

Adjusted analysis considered only study group, type of restoration and number of surfaces.

The mean (SD) time in minutes spent in RDI and CRI were 30.19 (SD = 12.47) and 17.85 (SD = 10.06), respectively. Regarding restoration costs, the professional component was the most expressive proportion, representing more than 74% of the treatment cost in the baseline **(Fig. 4)**. At baseline, RDI was the most expensive option, requiring an investment of US$ 17.65 per restoration placed (Table 4). When considering the incremental cost (replacement/repairs) after failures during the 2-years follow-up, RDI was 53% more expensive when compared to the CRI group (2-year cost; RDI = US$24.62; CRI = US$16.11). Moreover, multiple surfaces restoration presented higher cost both in baseline and after 2-years ($p < 0.001$).

Table 4. Evaluation of the baseline and 2-year incremental cost between groups and number of surfaces over time using Bootstrap regression analysis (1000 repeats) using Linear Regression considering the child level.

Cost analysis	Mean US$ (SD)	Univariate analysis		Adjusted analysis	
		Coefficient (SE) 95% CI	p-value	Coefficient (SE) 95% CI	p-value
Baseline Total Cost					
Study Groups					
RDI (ref)	17.65 (6.62)	-6.88 (0.89)	< 0.001*	-6.95 (0.93)	< 0.001*
CRI	10.76 (5.09)	-8.64 to -5.12		-8.79 to -5.11	
Number of surfaces					
Single (ref)	12.65 (5.97)	2.01 (1.04)	0.053	2.28 (0.76)	0.003*
Multiple	14.67 (7.03)	-0.02 to 4.06		0.77–3.78	
2 years Total Cost					
Study Groups					
RDI (ref)	24.62 (19.42)	-8.51 (2.44)	< 0.001*	-8.69 (2.45)	< 0.001*
CRI	16.11 (10.64)	-13.30 (-3.72)		-13.49 to -3.88	
Number of surfaces					
Single (ref)	15.95 (7.25)	5.83 (1.89)	0.002*	6.16 (1.94)	0.001*
Multiple	21.79 (17.98)	2.11–9.56		2.36 to 9.97	
CI = Confidence interval; SE = Bootstrap Standard error; SD = standard deviation; *p < 0.05.					
All costs were measured in Brazilian reais (R$) and converted to US Dollars (US$) using purchasing power parities (PPP)– Conversion rate 1US$=2.311R$.					

There is considerable uncertainty surrounding the cost-effectiveness of the interventions. Probabilistic sensitivity analysis indicate there is a 51% probability for the CRI to be less costly than the RDI (South-East and South-West quadrants). When considering the survival of the restorations in months, there is a 30% probability for the CRI to be cost-effective (Northeast and Southeast quadrants) when compared with the RDI, considering a maximum willingness-to-pay of approximately US$120 **(Fig. 5).**

No differences were found between the groups in relation to the discomfort reported by the child using Wong-Baker faces scale using ordinal logistic regression considering the child cluster (OR = 0.58; CI = 0.32–1.05; p = 0.073). Figure 6 shows the distributions of the facial scores between study groups. Similarly, no differences were found between the behaviour of the children during the restorative treatments **(Fig. 7)**, and the majority of children presented ‘definitely positive’ behaviour according to Frankl’s behaviour rating scale (OR = 1.14; 95%CI = 0.43–2.97; p = 0.788).

4. Discussion

A systematic review[25] that investigate the use RDI compared to other forms of tooth isolation for both primary and permanent teeth found no robust evidence to favour rubber dam usage. Two studies were included for primary teeth restorations, but none investigated the use of composite resin. Due to the low-quality of evidence, more randomised controlled trials with longer follow-up were suggested to investigate if the type of isolation could influence the restoration success.

This was the first randomised clinical trial to directly compare the survival between composite restorations in primary molars using two different methods of tooth isolation: RDI and CRI. Our hypothesis was there was the survival rate of composite restorations using cotton roll isolation (CRI) is non-inferior to the use of rubber dam isolation (RDI). The lower confidence interval limit shown by both Cox regression analysis (HR) and for intention-to-treat analysis (OR) were greater than 0.85. As our non-inferiority limit was set as 15%, we can affirm that restorations using CRI is non-inferior to RDI. Also, when looking at the at CI upper bond results, we can also affirm that CRI is not superior to RDI (Fig. 3). Therefore, future recommendations for the use of composite restorations in primary teeth should also consider the use of cotton roll isolation as an alternative to rubber dam.

The survival rate for composite resins in the present study was 60.41% for RDI and 54.31% for CRI after 2 years. This result is close to the estimated survival of 66% used for sample size calculation.[20] If a restoration failure was detected, it was considered as a failure for the primary outcome evaluation, however, all failed restorations receive appropriate treatment depending on the extension of the defect (restoration repair or replacement of the restoration). After 24 months, only 2 restorations presented inflammation into the pulp level, which required endodontic treatment or extraction. Therefore, although this study reported an annual failure rate (AFR) of 21%, the tooth survival (percentage of teeth that remained without pulp inflammation - pain/symptoms free) at the end was 98.8%.

The survival of the restoration did not difference between the operators (specialists in paediatric dentist and general dental practitioners). This could be explained by the fact that all operators received training in how to handle the materials before the start of the trial and were also experienced in treating paediatric patient as part of the CARDEC's clinics. Another factor that has been reported to influence the survival of the restorations is the number of surfaces involved.[26] Occlusal restorations tend to present a higher survival when compared to occlusoproximal restorations in primary teeth.[4,5] In the present trial, no difference was found between single and multiple surface lesions (HR = 1.08; CI = 0.60−1.95). However, single surfaces restorations in the inclusion criteria were not limited to occlusal surfaces, we have also included buccal, palatal and mesial surfaces, which could have contributed to similar failure rate to multisurface restorations.

The present trial also looked at the cost of the restorations as a secondary outcome. As expected, the cost of the use of RDI was higher when compared to CRI in both baseline and after two years considering the incremental cost. The higher cost of the procedure was influenced both by the professional cost (due to the time spend in each restoration) and by the amount of materials needed to perform a rubber dam isolation when compared to CRI.

The CEA demonstrated there is more than 50% probability for the CRI to be less costly than the RDI, considering both more and less effectiveness. However, when considering gains in health effects, the probability for the CRI to be cost-effective is 30%, depending on the willingness-to-pay. Some methodological aspects from our economic evaluation should be highlighted. This analysis was performed based on a Brazilian reality (both in terms of income and material cost) and should be interpreted with caution if extrapolating for other countries.

The time horizon was the study's follow-up, and a wider time frame would allow a better understanding of the long-term effects. Moreover, the cost-effectiveness of the CRI depends on the willingness-to-pay threshold, which depends on the opportunity costs where the strategy will be implemented, and this was not on the scope of the present evaluation. Thus, from our results, it is not possible to make a strong recommendation the implementation of the strategy in a healthcare system, however this is the first study demonstrating that the CRI may be associated not only with better health outcomes, but also with lower costs when compared to the RDI.

As important as looking at the survival and cost of the restoration is to investigate patient reported outcomes (PROs).[28] The present trial investigated the child's discomfort reported by the child immediately after treatment using the Wong Baker faces scale. The use of RDI requires the use of local anaesthesia for the placement of dental clamp. We expected that the fact the children who underwent local anaesthesia for restorative treatment could influence the discomfort values. However, no difference was found between the groups and most of the children reported positive responses (happiest face). Moreover, the analysis of the child behaviour during the treatment reported by the operator (using Frankl's behaviour scale) also did not show a difference between the groups. This could be explained first by the characteristics of the study population. Those children who sought dental treatment in our clinic had overall low socio-economic background and good behaviour and their parents were very pleased to receive the treatment free of cost. Moreover, the operators were experienced in treating children and in applying behaviour management techniques (such as tell-show-do, positive reinforcement)[29] throughout the treatments, which may have helped in providing this positive restorative experience in both groups.

In conclusion, cotton roll isolation proved to be non-inferior when compared to rubber dam isolation for composite restorations in primary molars in terms of restoration survival. No difference was found in relation to the discomfort reported by the child and child's behaviour assessed by the operator. Therefore, for both teaching practices and clinical decision-making, cotton roll isolation can be recommended as well as rubber dam isolation for composite restorations, however, the latest present the disadvantages of higher cost and longer procedure time.

5. Conclusion

- Rubber dam isolation has no impact on the survival of composite restoration in primary molars.
- Rubber dam isolation proved to be more costly and time-consuming than cotton rolls isolation.

List Of Abbreviations

(RDI) rubber dam isolation;

(CRI) cotton roll isolation;

(WBFPS) Wong-Baker Faces Pain Scale;

CONSORT (Consolidated Standards of Reporting Trials);

(FBRS) Frankl's behaviour rating scale;

(R$) Brazilian Reais;

(PPP) Purchasing Power Parities;

(CEA) cost-effectiveness analysis;

(CI) confidence interval;

(AFR) annual failure rate;

(HR) Cox regression analysis;

(PROs) patient reported outcomes.

Declarations

Ethics and consent to participate

All procedures performed in studies involving human participants were approved by the local Ethics Committee at School of Dentistry University of São Paulo (FOUSP) under number (#3.065.654).

The study was conducted in accordance with Helsinki Declaration as revised in 2013.

A written informed consent was obtained from the participants' parents/legal guardians before enrolment, and we have also obtained the child's assent. The relevant document(s) will be provided upon request.

Consent for Publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article and its supplementary information files (Survival analysis isolation methods).

Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

1. Opdam NJ, van de Sande FH, Bronkhorst E, et al. Longevity of posterior composite restorations: a systematic review and meta-analysis. J Dent Res. 2014;93(10):943–949. doi:10.1177/0022034514544217.
2. Ástvaldsdóttir Á, Dagerhamn J, van Dijken JW, et al. Longevity of posterior resin composite restorations in adults – A systematic review. J Dent. 2015;43(8):934–954. doi:10.1016/j.jdent.2015.05.001.
3. Worthington HV, Khangura S, Seal K, et al. Direct composite resin fillings versus amalgam fillings for permanent posterior teeth. Cochrane Database Syst Rev. 2021;8(8):CD005620. Published 2021 Aug 13. doi:10.1002/14651858.CD005620.pub3.
4. Santos AP, Moreira IK, Scarpelli AC, Pordeus IA, Paiva SM, Martins CC. Survival of Adhesive Restorations for Primary Molars: A Systematic Review and Metaanalysis of Clinical Trials. Pediatr Dent. 2016;38(5):370–378.
5. Chisini LA, Collares K, Cademartori MG, et al. Restorations in primary teeth: a systematic review on survival and reasons for failures. Int J Paediatr Dent. 2018;28(2):123–139. doi:10.1111/ipd.12346.
6. Koppolu M, Gogala D, Mathew VB, Thangala V, Deepthi M, Sasidhar N. Effect of saliva and blood contamination on the bond strength of self-etching adhesive system- An in vitro study. J Conserv Dent. 2012;15(3):270–273. doi:10.4103/0972-0707.97956.
7. Aboushelib MN. Clinical performance of self-etching adhesives with saliva contamination. J Adhes Dent. 2011;13(5):489–493. doi:10.3290/j.jad.a19648.
8. Chang SW, Cho BH, Lim RY, et al. Effects of blood contamination on microtensile bond strength to dentin of three self-etch adhesives. Oper Dent. 2010;35(3):330–336. doi:10.2341/09-244-L.
9. Cajazeira MR, De Sabóia TM, Maia LC. Influence of the operatory field isolation technique on tooth-colored direct dental restorations. Am J Dent. 2014;27(3):155–159.
10. H.E. Strassler, Isolation of the field more important than ever., MSDA J. 39 (1996) 119–21. http://www.ncbi.nlm.nih.gov/pubmed/9552635 (accessed February 27, 2018).
11. Kemoli AM, van Amerongen WE, Opinya GN. Short communication: Influence of different isolation methods on the survival of proximal ART restorations in primary molars after two years. Eur Arch Paediatr Dent. 2010;11(3):136–139. doi:10.1007/BF03262729.
12. Ozer L, Ozalp N, Okte Z, Oztas D. Effects of saliva contamination on shear bond strength of compomer to dentin in primary teeth. Am J Dent. 2006;19(1):28–30.

13. Fritz UB, Finger WJ, Stean H. Salivary contamination during bonding procedures with a one-bottle adhesive system. Quintessence Int. 1998;29(9):567–572.
14. Lenzi TL, Pires CW, Soares FZM, Raggio DP, Ardenghi TM, de Oliveira Rocha R. Performance of Universal Adhesive in Primary Molars After Selective Removal of Carious Tissue: An 18-Month Randomized Clinical Trial. Pediatr Dent. 2017;39(5):371–376.
15. Oter B, Deniz K, Cehreli SB. Preliminary data on clinical performance of bulk-fill restorations in primary molars. Niger J Clin Pract. 2018;21(11):1484–1491. doi:10.4103/njcp.njcp_151_18.
16. Akman H, Tosun G. Clinical evaluation of bulk-fill resins and glass ionomer restorative materials: A 1-year follow-up randomized clinical trial in children. Niger J Clin Pract. 2020;23(4):489–497. doi:10.4103/njcp.njcp_519_19.
17. Mala S, Lynch CD, Burke FM, Dummer PM. Attitudes of final year dental students to the use of rubber dam. Int Endod J. 2009;42(7):632–638. doi:10.1111/j.1365-2591.2009.01569.x.
18. Lynch CD, McConnell RJ. Attitudes and use of rubber dam by Irish general dental practitioners. Int Endod J. 2007;40(6):427–432. doi:10.1111/j.1365-2591.2007.01212.x.
19. Daudt E, Lopes GC, Vieira LC. Does operatory field isolation influence the performance of direct adhesive restorations?. J Adhes Dent. 2013;15(1):27–32. doi:10.3290/j.jad.a28194.
20. Franzon R, Opdam NJ, Guimarães LF, et al. Randomized controlled clinical trial of the 24-months survival of composite resin restorations after one-step incomplete and complete excavation on primary teeth. J Dent. 2015;43(10):1235–1241. doi:10.1016/j.jdent.2015.07.011.
21. D.L. Wong, C.M. Baker, Pain in children: comparison of assessment scales., Pediatr. Nurs. 14 (1988) 9–17. http://www.ncbi.nlm.nih.gov/pubmed/3344163 (accessed June 27, 2017).
22. S. Frankl, F. Shiere, H. Fogels, Should the parent remain with the child in the dental operatory?, J. Dent. Child. 29 (1962) 150–163.
23. OECD, Eurostat-OECD Methodological Manual on Purchasing Power Parities (2012 Edition), OECD Publishing, 2012. https://doi.org/10.1787/9789264189232-en.
24. Roeleveld AC, van Amerongen WE, Mandari GJ. Influence of residual caries and cervical gaps on the survival rate of Class II glass ionomer restorations. Eur Arch Paediatr Dent. 2006;7(2):85–91. doi:10.1007/BF03320820.
25. Wang Y, Li C, Yuan H, et al. Rubber dam isolation for restorative treatment in dental patients. Cochrane Database Syst Rev. 2016;9(9):CD009858. Published 2016 Sep 20. doi:10.1002/14651858.CD009858.pub2.
26. Tedesco TK, Gimenez T, Floriano I, et al. Scientific evidence for the management of dentin caries lesions in pediatric dentistry: A systematic review and network meta-analysis. PLoS One. 2018;13(11):e0206296. Published 2018 Nov 21. doi:10.1371/journal.pone.0206296.
27. Rogers HJ, Freitas RD, Beeson MJ, Vernazza CR. Economic evaluations in paediatric dentistry clinical trials. Int J Paediatr Dent. 2020;31 Suppl 1:56–65. doi:10.1111/ipd.12772.

28. Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. JAMA. 2018;319(5):483–494. doi:10.1001/jama.2017.21903.
29. AAPD, Guideline on behavior guidance for the pediatric dental patient., Pediatr. Dent. 30 (2013) 125–33. http://www.ncbi.nlm.nih.gov/pubmed/19216411 (accessed November 23, 2018).

Figures

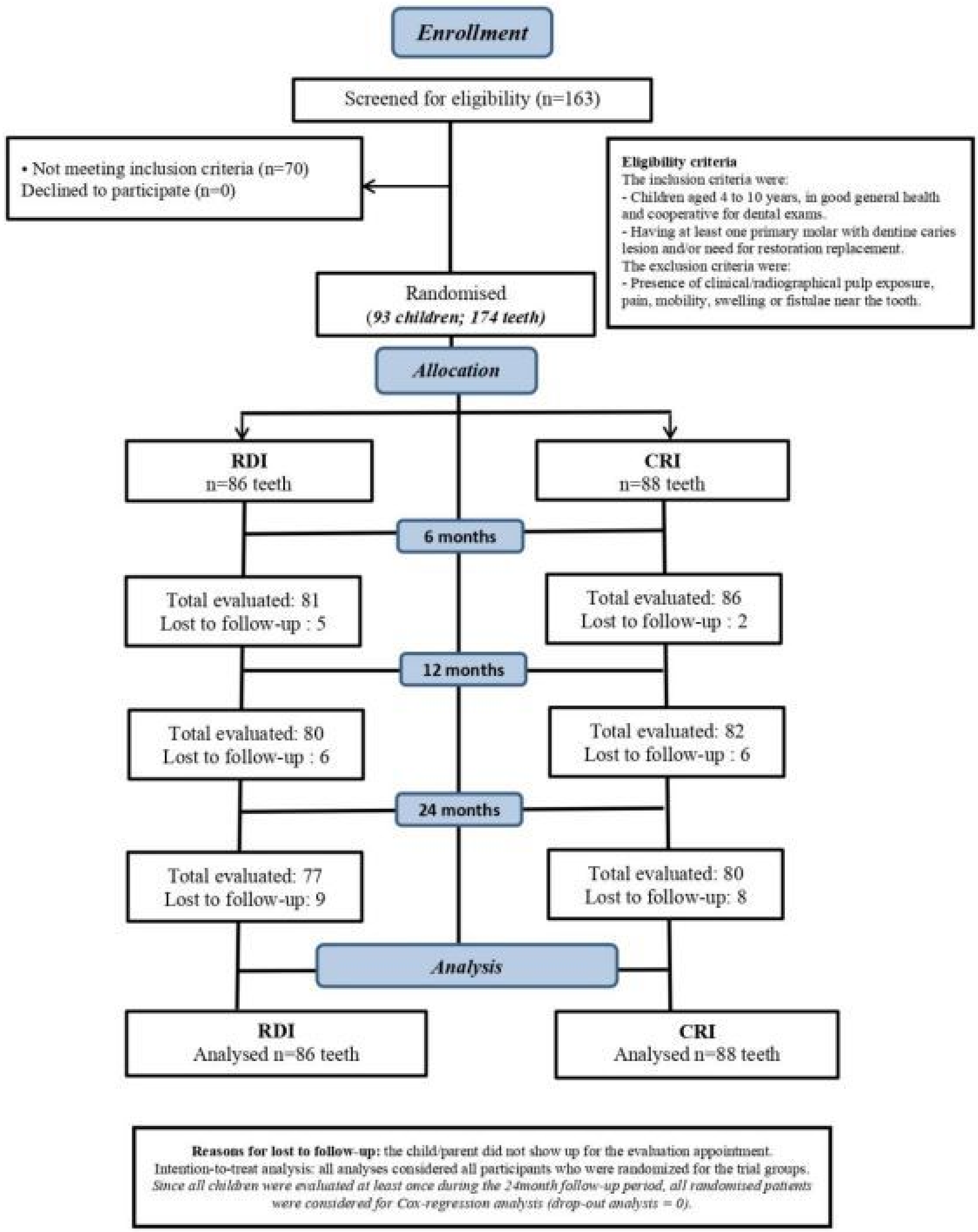

Figure 1

CONSORT Flow Diagram

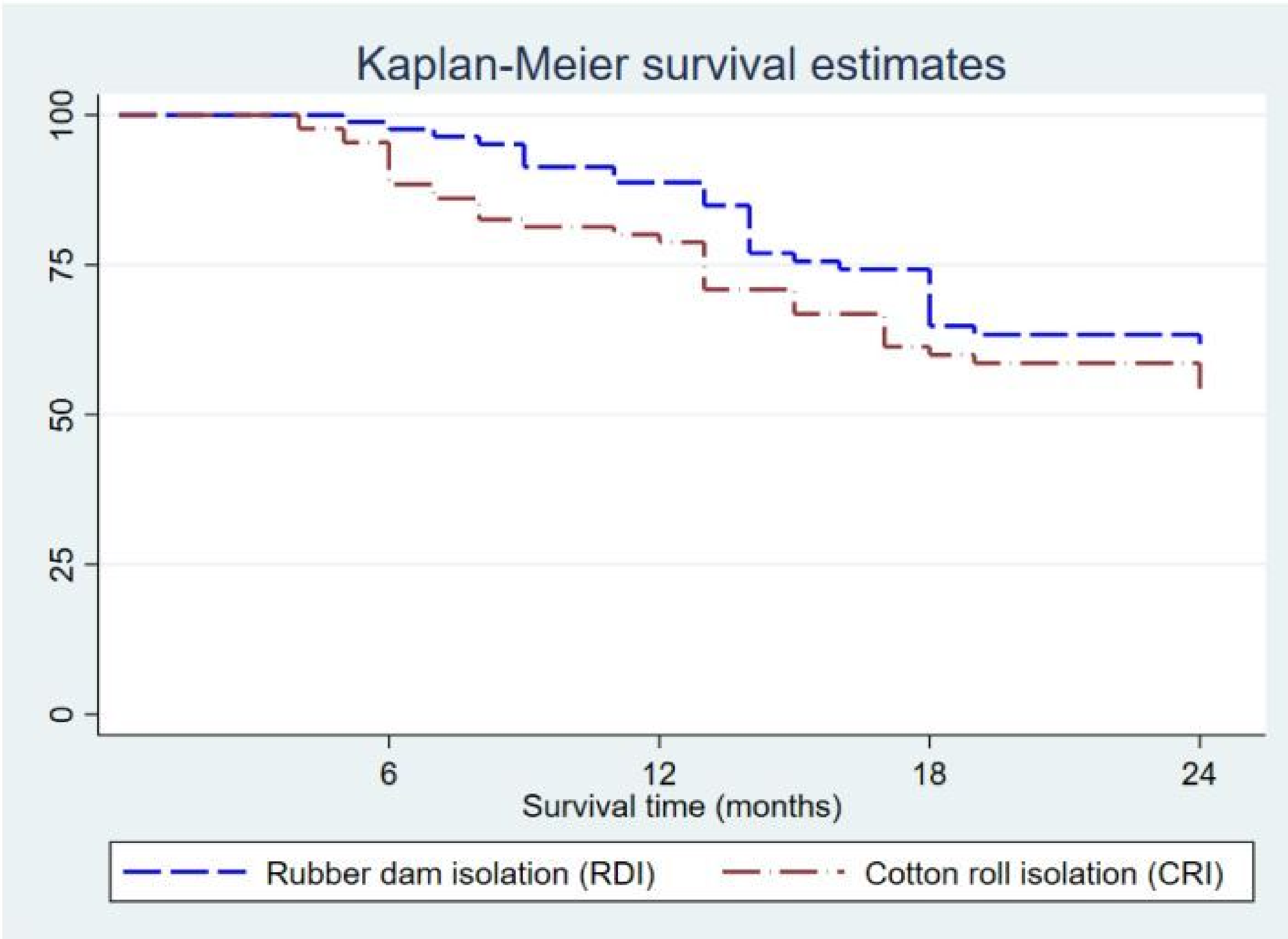

Figure 2

Kaplan-Meier Survival analysis between groups (log rank=0.245).

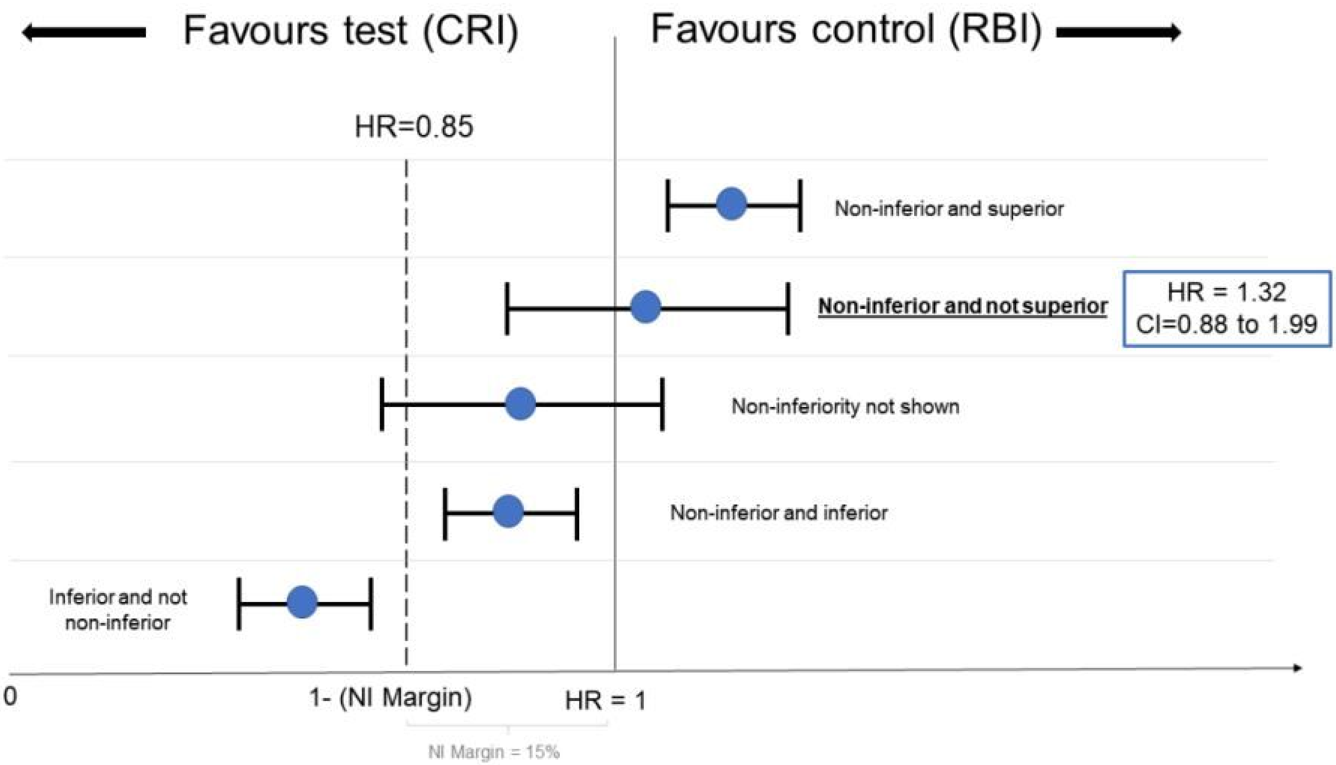

Figure 3

Possible results of a non-inferiority clinical trial considering a non-inferiority limit of 15% between groups using survival results as primary outcome (HR=0.85).

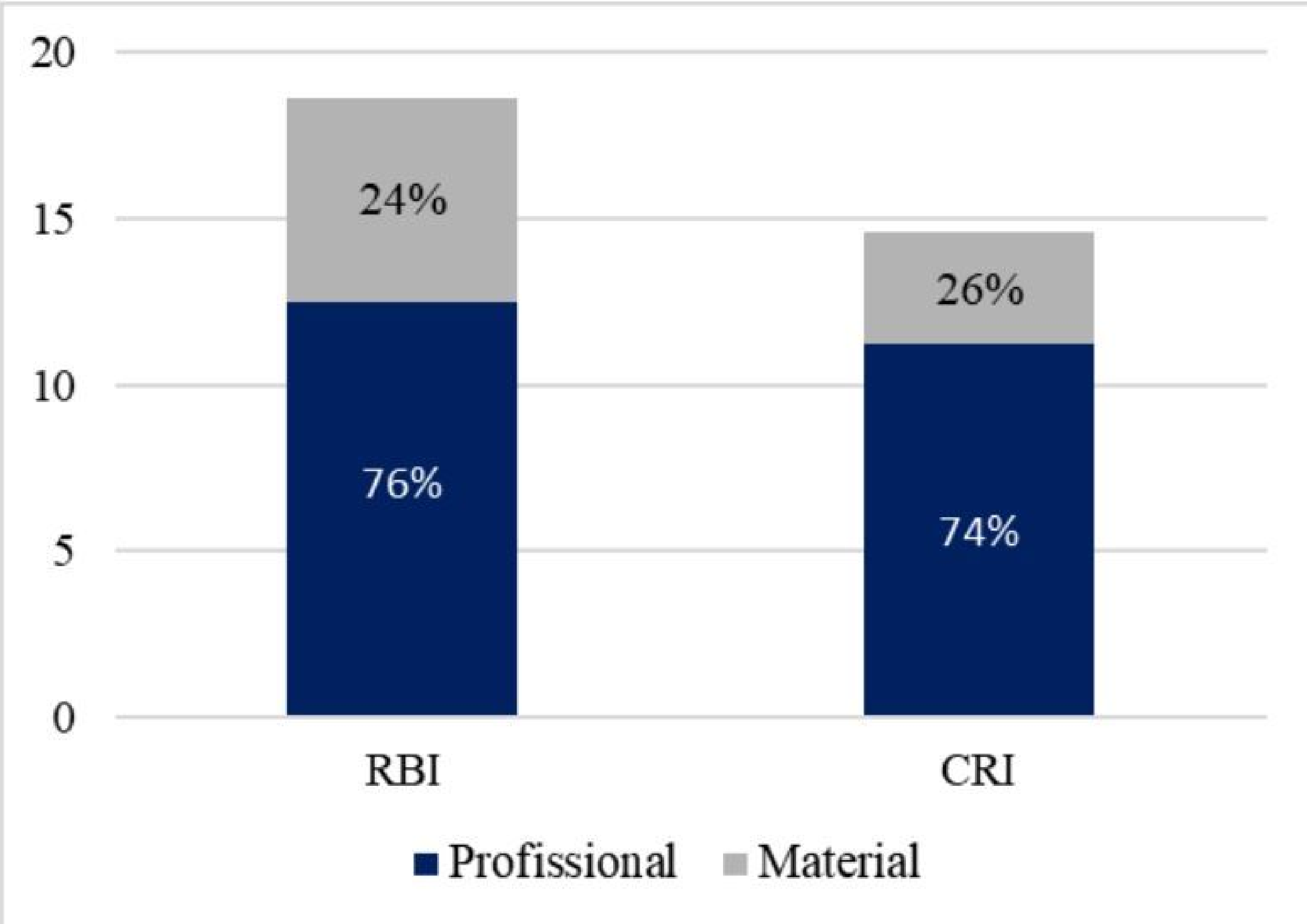

Figure 4

Distribution between mean professional and material baseline cost between study groups in US$.

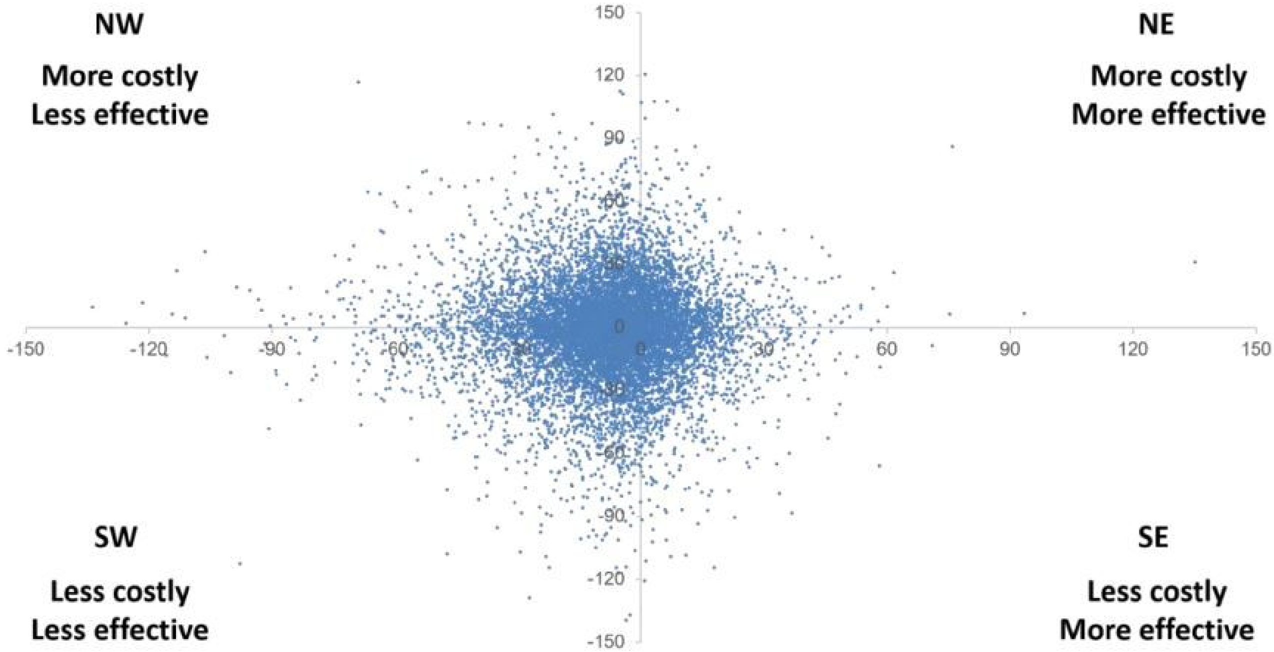

Figure 5

Cost-effectiveness of using CRI versus RDI considering costs (US$) and effectiveness (survival in months)

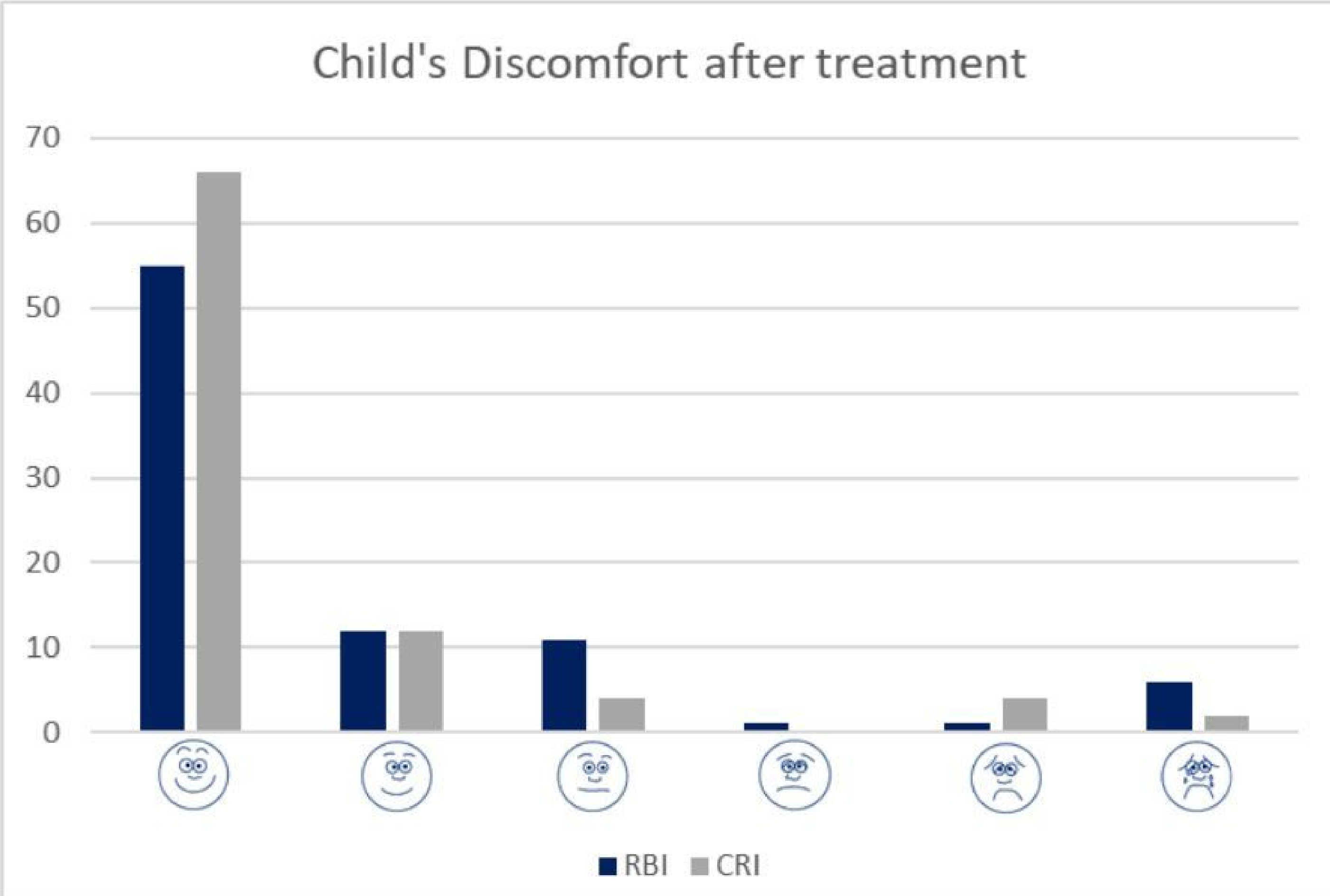

Figure 6

Distribution between discomfort reported by the child after treatment between groups.

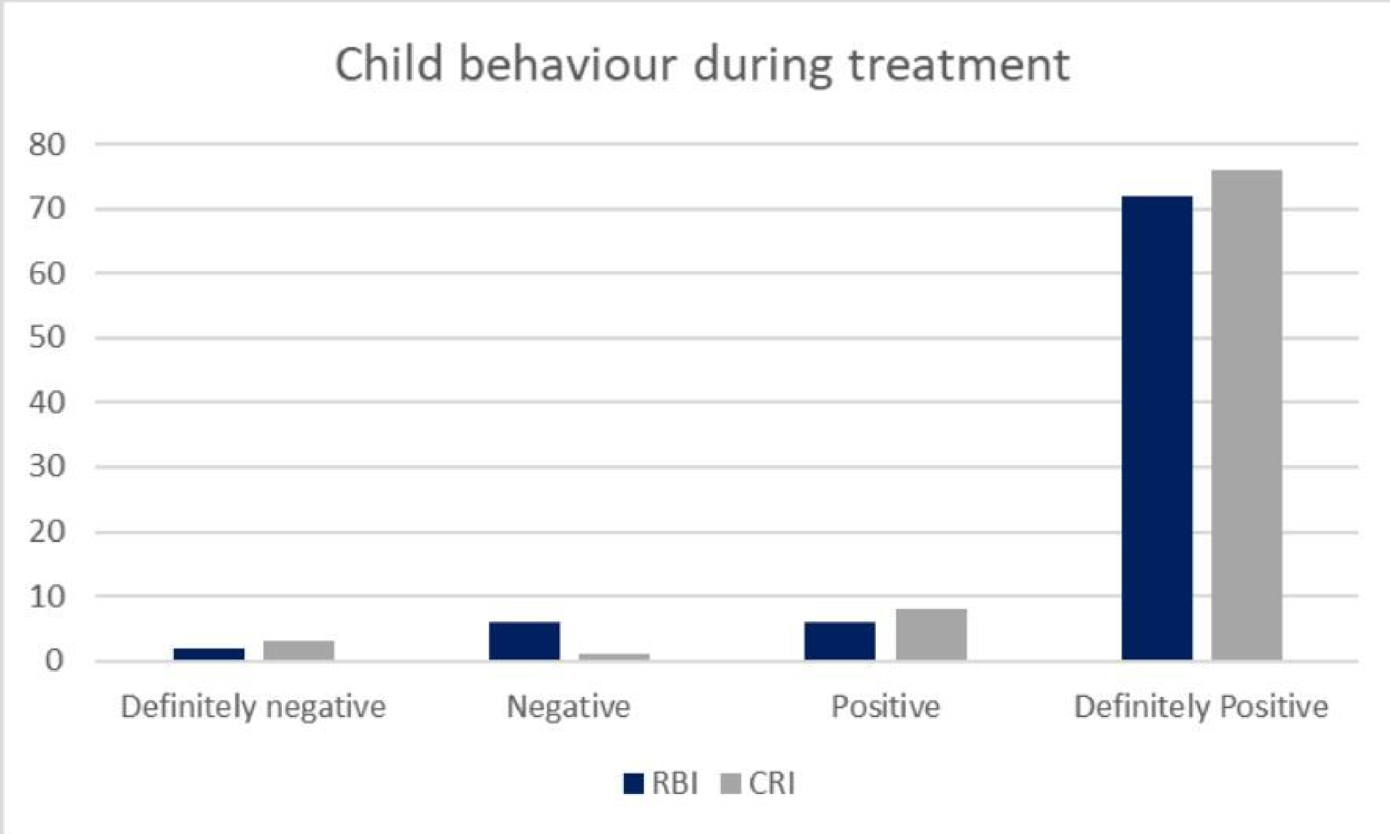

Figure 7

Distribution between child behaviour (Frankl's behaviour rating scale - FBRS) reported by the operator after treatment between groups.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Survivalanalysisisolationmethods.xlsx