How did CariesCare International performed under pandemic conditions in children: 1-year multicenter single-group interventional study

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Abstract

Background: In 2020, CariesCare International (CCI) -derived from ICCMS- was plannedto be tested for caries-control effectiveness in children by means of a multicenter randomized clinical trial (RCT). Nevertheless, due to the pandemic, RCTs proved unfeasible and aerosol-generating procedures (AGP) were associated with a spread of COVID-19. Consequently, the study design required to be modified to a single-interventional study and CCI had to be adapted excluding AGP and reducing on-site consultation (CCI-adapted).

Objective: This 12-month multicenter single-group interventional study aimed at assessing the effect of a pandemic CCI-adapted protocol on caries control in children.

Methods: Twenty-one Latin American and European centers with n³20 3-8-year-old children per center were invited to participate; 17 obtained IRB and signed written informed consents. Trained examiners assessed at baseline (T0) and 1-year follow-up (T1y) (blind to the intervention): CCI-caries risk, oral-health-related practices; dmf/DMFS with ICDAS-merged-Epi visual caries severity and activity criteria; dental sepsis and toothache. Individual- and tooth-surface-level personalized care plan was then performed by dental practitioners previously trained in CCI-adapted. After 5 months, parents' and dentists' dental-care-process acceptance (Treatment Evaluation Inventory) was assessed. The one-year caries-control effect of CCI-adapted was assessed in terms of tooth-surface and individual-level caries-progression control; oral-health behavior improvement, and caries-care system acceptability.

Results: Sixteen centers finished the study (94.1%; Latin America: n=13; Europe: n=3), with 337 children (78.6%;mean age of 5.5±1.6 years). There was a T0 to T1y significant decrease ($p<0.05$) in the mean number of tooth surfaces with caries lesions (7.7±9.1 to 2.8±4.6), with active caries lesions (6.8±8.8 to 0.8±2.2), and a tooth-surface caries-progression control of 99.3%. In the majority of children there was a significant ($p<0.05$) control of: caries progression (79.5%), high-caries risk (86.6%), and non-adequate oral-health behavior (72.7%). There was a very high (parents) and a high-very high (dentists) acceptability of CCI.

Conclusion: Given the challenge of the pandemic, this single-group interventional CCI-adapted study showed one-year control of caries progression, caries risk, and high parents' and dentists' CCI acceptance.

Trial registration: Retrospectively-registered-ClinicalTrials.gov NCT04666597 07/12/2020 (Protocol version 2): https://register.clinicaltrials. gov/prs/app/action/SelectProtocol?sid=S000AGM4&selectaction=Edit&uid=U00019IE&ts=2&cx=uwje3h

Introduction

The caries management system CariesCare International (CCI) was derived from ICDAS (International Caries Detection and Assessment System) and ICCMS (International Caries Classification and Management System) (Pitts & Ekstrand, 2013). CCI was developed to further help bridging ongoing

barriers which prevent the translation of caries management best practices into the dental practice setting (Vernazza et al., 2021a,b; Pitts et al., 2021a; Urquhart et al., 2019).

CariesCare International is a practice-friendly, health outcomes-focused, patient-centered, risk-based approach to caries management designed for the dental practice setting and organized in a CCI 4-D cycle (Martignon et al., 2019; Beltran et al., 2019). It uses and adapts evidence-based tools and resources developed systematically by ICDAS since 2012 and ICCMS since 2013 (Pitts et al., 2021b), sharing same principles. These are being followed globally in many settings, with local adaptations, including a large number of dental schools and cariology-teaching consensus guides for undergraduates in Colombia (Martignon et al., 2014), the USA (Fontana et al., 2016) and Caribbean countries (Abreu-Placeres et al., 2016), as well as in the practice and the academy in Colombia (Abreu-Placeres et al., 2023). In 2019, the FDI called for “a shift in caries management from restorative treatment to measures that arrest and prevent caries development including monitoring, following the concepts of ICCMS” (FDI, 2020).

Cariologists, clinicians, educators and policy makers agree that the CCI consensus guide promotes best practice in the control of caries and in maintaining oral health in patients (Martignon et al., 2019; Beltran et al., 2019). CCI has been included as a core part of a Policy Lab conducted with the Global Collaboratory for Caries Management (GCCM) to raise awareness and to promote a cavity-free future; this involved experts in public health, the industry and the profession (Vernazza et al., 2021b).

To our knowledge there are no studies to date which have reported on the caries-control effect of CCI. In 2020, with ethical approval from the lead center, the so called Caries OUT collaboration (21 centers in 13 countries) attempted to conduct a 12-month multicenter pragmatic RCT in schoolchildren to compare the CCI system versus standard care in the control of individual and tooth-level caries progression. Plans were revised due to the COVID-19 pandemic and the consequent restrictions imposed by universities’ Ethical Boards to conduct randomized controlled trials (RCT). To permit caries care to be offered to children, we modified CCI protocols by avoiding aerosol generating procedures (AGPs) and reducing in-office appointment time (CCI-adapted). Furthermore, we modified the study design from a pragmatic RCT to a single-group interventional study (see study protocol, Martignon et al., 2021). All of the original 21 centers were willing to attempt the revised study and were invited to participate. Seventeen centers agreed to participate with Institutional Review Board approval.

The aim of this 12-month multicenter single-group interventional study was to assess the effect of a pandemic-adapted CCI protocol on caries control in children.

Methods

Design

This was a 12-month multicenter single-group interventional study with approval from the Research Institutional Ethical Committee at Universidad El Bosque (PCI 2019-10718). Written informed consents

were signed by parents/caregivers and written assent forms (needed in some countries) by children; subjects were coded to keep confidentiality.

This report follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines, as they can take the form of a cohort study. The STROBE checklist has been completed and loaded as a supplementary file to this manuscript (Supplementary file 1).

Participants, settings and location

The sample size of this single-group interventional study was determined based on the sample size calculated for the previous randomized clinical trial, which was based on Curtis et al. (2011). The mentioned study deals with caries care using an updated system, similar to CCI, considering both the care of caries lesions according to their severity and activity status, as well as of the individual caries risk. The results show differences in averages of tooth surfaces with caries progression. The Whitehead sample size calculation formula was taken into account, with type-I error: 0.05, type II error: 10%, standard deviation 2.5, expected average of the first group 1.3 and expected average of the second group 2.1 (Curtis et al., 2011). As for the current study there is no control arm, the sample size of the previous RCT sample size was halved. Thus, the sample size calculation of this single-group interventional study to look for a difference between baseline and 1-year follow up corresponded to 206 3-8 years old children, increasing to a total of 258 after including a 25% drop- out. This had been previously described in the study protocol (Martignon et al., 2021).

Three to eight year-old children's parents of 17 centers (dental schools or private clinics) in 10 countries (Argentina, Brazil, Colombia, Dominican Republic, France, Mexico, Peru, Portugal, Russia, and Uruguay) accepted to participate (Institutional Review Board).

The following exclusions applied: children with a major systemic disease, mental/physical disability; with orthodontic appliances, and whose family had plans to move or planning to attend a different dental practice during the study period.

Training of examiners and dental practitioners (DP)

The center leader had previously collaborated over the years with researchers from all centers in projects or continuous education related to ICDAS, ICCMS or CCI. Each center had an examiner that had been previously trained in the ICDAS visual caries criteria by the Local Centers' Leaders leaning on the ICDAS calibration e-learning (ICCMS, 2023) or by the leader center (inter-/intra-examiner Kappa weighted values ³ 0.7). The examiners and 1-2 dental practitioners (DP) per center received online training delivered by the Steering Committee through 4-hour workshops (in English or Spanish) covering the CCI 4-D cycle steps, the non-AGP procedures, online consultation -contributing to the control of the SARS-CoV-2/COVID19 transmission risk in the dental office, the behavior-change tool, and completion of the oral health record (which they had to practice on with a patient). Discussion of clinical cases were included to achieve agreement between DPs and training was conducted until they demonstrated an appropriate

level of understanding and skills to conduct the CCI-adapted care. Additional online meetings took place to audit, to discuss possible protocol modifications and solutions, and as requested with the Coordination Center. All centers received related e-learnings, forms, materials, full oral-health record (Excel) in English or Spanish, and behavior didactic and self-assessment aids (which were translated into country language, printed and provided to all children and parents) (see Martignon et al., 2021).

The study phases were based on the CCI 4D-cycle, previously reported in Martignon et al. (2021). These are displayed in the study flowchart (Figure 1) and included at each center:

1. Baseline examinations

Baseline (T0) assessments corresponded to: CCI 1D - Determine caries risk; CCI 2D - Detect and assess caries lesions severity and activity, and CCI 3D - Diagnosis at the individual- and tooth-surface level and Personalized care plan decisions.

The individual caries-risk determination included assessing oral-health behaviors/practices and risk factors (CCI 1D). The tooth-surface level caries detection (D) with severity and activity assessment (CCI 2D) was conducted by a previously trained examiner without air-drying using ICDAS-merged Epi (Pitts & Ekstrand, 2013). Fillings (F), sealants, missing teeth (M), teeth with untreated-caries consequences (primary / Permanent-teeth pulpal / roots / sepsis -prs/PRS) and toothache were also registered.

In synthesis (diagnosis) (CCI 3D), at the individual level, the CCI caries risk was classified into High or Low. This was based on an algorithm constructed using multiple sources of information. This included data on each child's three caries-protective factors (including receiving community fluoride) and 11 caries-risk factors (including access barriers), 5 of which were clinically assessed (Martignon et al., 2019). Oral-health behavior was classified into Adequate, Inadequate or Very inadequate, based on information about toothbrushing, free sugar intake, visible plaque, and presence of active caries lesions (8 items). At the tooth-surface level, caries lesions were visually classified into Initial (D_I), Moderate (D_M) or Extensive (D_E) and Active or Inactive. Teeth in need of endodontic treatment or extraction at T0, were referred and not considered for the analyses (due to need of AGP).

Care plans were co-created between examiner, child's caregiver and dental practitioner (DP). Each plan considered individual child-level and tooth-level care.

2. Intervention

Caries preventing and tooth-preserving care (CCI 4D)

Interventions were conducted by the DP. A basic individual and tooth-surface levels' patient-centered agreed management approaches/interventions (CCI 4D) included only non-AGP and when possible remote care. Both individual home-care and clinical approaches/interventions, included the application of the short behavior-change tool based on the COM-B behavior model focusing on improving oral hygiene and dietary habits, risk-based care and tooth-surface active monitoring (AM), non-operative care (NOC)

and tooth-preserving operative care (TPOC) interventions for primary and permanent teeth (see Figure 1 and for more details see Martignon et al., 2021).

In line with the CCI 4D-cycle, patients received two risk-based recalls: one at 5 months (after the basic management) and one at 8 months. A shorter risk determination and oral-health behaviors' version (CCI-1D) was applied for patients previously classified as Low-caries risk, reassessing only four oral-health practices/risk items. Conversely, the complete version was used for previously High-caries risk patients. At the tooth-surface level (CCI-2D) in all patients the presence of dental biofilm and of new/progressing caries lesions was assessed (to include objective indicators related to the classification of oral-health behavior). The CCI 3D decision care plan and CCI 4D care followed as appropriate. Recalls are described in detail in Martignon et al. (2021).

3. Follow-up examinations

A final reassessment was conducted after 12 months (T1y) by the examiner blind to the intervention. This was the same as Baseline examinations, including failure of fillings and sealants.

Parents' and Dentists' acceptance of the dental care process

Parents' and dentists' acceptance of the dental care process was assessed by an external researcher at the 5-month recall. This involved an adapted Treatment Evaluation Intervention (TEI) 12- (parents) and 14-item (dentists) self-assessed questionnaire utilizing a 5-point Likert scale where 1 corresponded to the lowest grade and 5 to the highest grade of acceptance (Newton & Sturmey, 2004).

Child dropout criteria from the study included: -patient's/parent's voluntary trial withdrawal; -not attending appointments after three phone/message reminders; -moving from institution/school or city.

Outcomes

Primary health outcome:

Difference in T0-to-T1y mean number of tooth surfaces with caries and T1y percentage of tooth surfaces with control of caries progression at one-year follow-up.

Secondary health outcomes:

-Proportion of children with control of caries progression at one-year follow-up.

-Proportion of children with 1-year avoidance of: being designated as High-caries risk, having Inadequate/Very-inadequate oral-health behavior; with control of: extractions, toothache, and of failure of fillings/sealants.

-Proportion of parents and dentists with reported high-acceptability levels of the dental care process.

Statistical analysis

At T0 and T1y the individual- and tooth-surface level data were digitally registered per patient in each center, as well as parents' and dentists' TEI data. Data were stored and with limited access in a designed Microsoft Excel (2010) database. Each center sent their data to the Data-Management Team at each time point. Data were organized into a dataset with quality assurance and validation. Missing data was identified and collected through a new online/on-site appointment with related center/s.

The number of surfaces with ICDAS caries lesions (d/D) and with ICDAS caries experience (dmf/DMFS) per patient was calculated by summing up the combined primary- with permanent-teeth number of surfaces with caries lesions (d/DS), and the number of surfaces with caries lesions (d/DS), fillings (f/FS) and missing due to caries (m/MS), respectively, at T0 and at T1y. The difference in T0-to-T1y mean number of tooth surfaces with caries lesions ($d_{IME}/D_{IME}S$) was calculated first, both according to severity and to activity.

For T1y caries progression, this was defined as a progression from the tooth-surface T0 3D diagnosis and basic-management care decision (sound; $d/D_I/d/D_M/d/D_E$ Active/Inactive; sealant, restoration -f/F) to new caries lesions, caries-severity increase or an active caries lesion; a new sealant (placed due to caries as opposite to risk management) or restoration (f/F), dental sepsis, toothache or extraction (m/M). Primary missing teeth at T1y due to exfoliation were not considered as caries progression. The percentage of tooth surfaces with control of progression at T1y of these indicators was calculated.

All statistical tests were two-tailed tests (Martignon et al., 2021). Mainly parametric methods were used; non-parametric when data did not meet the former criteria. Participants' demographic and clinical features (center, gender, age, caries risk, toothache, filling/sealant status, pulpal sepsis), oral-health behavior, mean number of tooth surfaces with caries experience (dmfs/DMFS with the d/D component including ICDAS-merged Epi: D_I, D_M, and D_E) and mean number of tooth surfaces with caries (D_I, D_M, and D_E), as well as parents' and dentists' TEI, were described using mean and standard deviation (SD) for quantitative variables and percentages for qualitative variables. Statistical significance level for all two-sided tests were set at 0.05.

Results

Out of the 17 centers which participated, 16 finished the study with T1y at the set deadline (94.1%), corresponding to all seven Colombian centers, the three centers from European countries, and six centers from other Latin American countries (minus Brazil), with a total of 337 children finishing the study out of 429 recruited in T0 (78.6%). Number of centers starting recruitment by year quarter corresponded to: n=3 (2020-4th), n=2 (2021-1st), n=5 (2021-2nd), n=2 (2021-3rd), and n=5 (2021-4th). Table 1 shows the T0 age and sex distribution of the 17-center sample who initiated the study. All countries, apart from Russia, counted with a community water or salt fluoridation program.

Table 1. Baseline distribution of the sample according to center, age and sex.

	Center (C)	Children	Age		Sex			
		n	Mean	SD	Female		Male	
					n	%	n	%
	C1	29	5.5	1.3	24	82.8	5	17.2
	C2	25	5.2	1.7	10	40.0	15	60.0
	C3	30	5.2	1.8	14	46.7	16	53.3
	C4	21	5.3	1.2	14	66.7	7	33.3
	C5	22	5.1	1.5	15	68.2	7	31.8
	C6	30	5.7	1.6	16	53.3	14	46.7
	C7	28	5.5	0.7	16	57.1	12	42.9
	C8	28	6.3	1.5	18	64.3	10	35.7
	C9	30	5.7	1.7	15	50.0	15	50.0
	C10	30	7.1	0.8	15	50.0	15	50.0
	C11	20	5.7	1.7	10	50.0	10	50.0
	C12	20	4.5	1.5	6	30.0	14	70.0
	C13	30	4.6	1.5	14	46.7	16	53.3
	C14	31	4.2	1.0	14	45.2	17	54.8
	C15	22	6.0	1.3	10	45.5	12	54.5
	C16	13	5.9	1.7	7	53.8	6	46.2
	C17	20	5.7	1.5	11	55.0	9	45.0
Total	**17**	**429**	**5.5**	**1.6**	**229**	**53.4**	**200**	**46.6**

At T0 the prevalence of caries experience (ICDAS-merged Epi dmf/DMFS) was 77.2%, with a mean of 8.6±9.8 surfaces (d_I/D_IS: 3.8±5.5; d_M/D_MS: 1.4±2.4; d_E/D_ES: 2.5±5.5; m/MS: 0.2±1.1; f/FS: 0.7±2.0).

At the end of the study (T1y), 92 children (21.4%) had dropped out. Reasons for dropouts included change of school or city; voluntary trial withdrawal, not attending all appointments/meeting the study deadline (Figure 1). Statistical analysis revealed no significant difference between the baseline mean number of ICDAS-merged Epi dmfs/DMFS in children who did not complete the study (9.3±9.1) compared to those who did (8.6±9.8) (p=0.58).

T1y tooth-surface control of caries progression

The mean number of tooth surfaces with caries lesions decreased significantly ($p<0.05$) from T0: 7.7±9.1 to T1y: 2.8±4.6 (d_I/D_IS: 3.8±5.5; d_M/D_MS: 1.4±2.4; d_E/D_ES: 2.5±5.5) (Figure 2A). Furthermore, the mean number of active caries lesions decreased significantly from T0 (6.8±8.8) to T1y (0.8±2.2) ($p<0.05$) (Figure 2B).

There was a T1y tooth-surface control of caries progression of 99.3%, out of a total of 33.012 T0 tooth surfaces included in the study.

T1y individual control of caries progression

The T1y children's control of caries progression corresponded to 79.5% and that of extractions, toothache and failure of fillings/sealants corresponded to 97.9%, 100% and 96.7%, respectively (Figure 3).

At T1y there was a control of High-caries risk in 86.6% of children with a significant T0-to-T1y increase of children with Low caries risk ($p=0.0001$) (Figure 4A), and a control of very inadequate and inadequate oral-health behavior in 72.7% of children, with a T0-to-T1y increase of children with adequate oral-health behavior ($p<0.05$) (Figure 4B).

Parents' and dentists' dental care process acceptability

All children's parents answered the TEI questionnaires (n=337). There was a high-very high acceptability of CCI (Table 2). CCI principles (questions 1-8) showed a change to 'more' to 'a lot more' parents' knowledge / learning / information / understanding. They reported adhering to child's health recommendations 'more' to 'a lot more' by co-creating the child's care plan together with the dentists; likewise, with the change in behaviors regarding toothbrushing and sugar intake control, and in awareness to avoid cavity formation. They reported being 'satisfied' to 'very satisfied' with the use of the non-AGP procedures. No significant differences were found between the 12-question answer scores ($p>0.05$).

Table 2. Parents' dental-care process acceptance was measured via Treatment Evaluation Inventory –TEI with a 5-point Likert scale (n=337).

Parents' dental-care-process acceptance		
Question	Acceptance	
	Mean	SD
How much:		
1. More knowledge about your child's teeth and mouth health do you think you and your child now have?	4.4	1.0
2. Did you learn about your child's risk of getting caries?	4.7	0.8
3. More information about how to look after your child's teeth and mouth health do you think you and your child now have?	4.6	0.9
How much do you think:		
4. Your and your child's understanding of how to look after the teeth and mouth health has improved?	4.5	0.9
5. That discussing and co-creating the child's care plan together with the dentist/s enhances your and your child's understanding and adherence to the plan?	4.7	0.7
6. The dentists' advice and in-office approaches helped you change the child's behavior for controlling/reducing the daily consumption of sugary products?	4.7	0.8
7. These approaches helped you to change your behavior towards ensuring twice-daily child's toothbrushing with fluoridated toothpaste?	4.7	0.8
8. The early caries management helped you to change your awareness of seeking to control the caries situation before it becomes a cavity?	4.8	0.6
How satisfied do you feel with the:		
9. Procedures used by the dentist to restore child's cavities without drilling?	4.8	0.7
10. Personalized assessment to decide when your child should come for recall?	4.8	0.6
How:		
11. Would you rate yours and your child's relationship with the dentist in charge?	4.7	0.7
12. Much you feel you can apply what you learned from the child's dental management?	4.8	0.6

The dentists' acceptability of the dental care process (TEI) questionnaire was answered by the 2-3 dentists involved in each of the 16 centers (n=40). Results were similar to those from parents, showing a high CCI use acceptability. The highest rated question corresponded to 'more' to 'a lot more information' in patients/parents about how to look after the child's teeth and mouth health (Table 3). No significant differences were found between the 14-question answer scores ($p>0.05$).

Table 3. Dentists' dental care process acceptance was measured via the Treatment Evaluation Inventory - TEI with a 5-point Likert scale (n=40).

Dentists' dental-care-process acceptance		
Question	Acceptance	
	Mean	SD
How much more knowledge about their:		
1. Risk of getting caries do you think your patients have now?	4.4	0.9
2. Current teeth health do you think your patients/parents have now?	4.4	0.9
How much:		
3. Relevance does knowledge of caries severity and activity do you think contributes your patients/parents to modifying oral health behaviors now?	4.0	1.0
4. Do you think the co-creation of a care plan together with the parents/patients do you think enhances their understanding and adherence to the plan?	4.3	1.0
5. Information do you think your patients/parents now have about how to look after the child's teeth and mouth health?	4.8	0.7
How much do you think:		
6. Your patients'/parents' perception of the child's low/high susceptibility to caries increased?	4.2	1.0
7. The non-operative care of initial active caries lesions helped your patients' parents to change their awareness of seeking to control the caries process at an early stage?	4.3	1.1
8. The tooth-preserving operative care helped your patients' parents to understand the relevance of avoiding unnecessary tooth structure removal?	4.0	1.1
How much do you think the home-care and in-office individual-level approaches helped your patients' parents to change their behavior towards:		
9. Restricting the child's free-sugar consumption?	4.1	1.0
10. Assuring child's twice-a-day toothbrushing with fluoridated toothpaste?	4.5	0.9
How satisfied do you think your patients' parents felt with the:		
11. Conduction of non-AGP tooth-preserving operative care?	4.6	0.8
12. Child's personalized risk-based recall interval decision?	4.6	0.8
How:		
13. Would you rate in general your relationship with the patients/parents who completed the CCI management?	4.6	0.8
14. Much you feel your patients/parents will be able to use and apply what they learned from CCI.	4.5	0.9

Discussion

This 12-month multicenter single-group interventional study in children found with the use of CariesCare International adapted for the pandemic control of caries progression. In addition to demonstrating high levels of control of caries progression at the tooth-surface according to severity and to activity status, control of caries progression and of caries risk was achieved in around four fifths of the children. CCI was highly accepted by both parents and dentists.

The main weakness of a single-group interventional study is the lack of a control group. Even though the original study design would have been a pragmatic RCT for which all 21 centers signed up in 2019, the pandemic became an opportunity for testing the CCI system in another environment where there was a great need to adapt to new threats, hence the avoidance of aerosols (non-AGP) and reduction of in-person clinical time (Martignon et al., 2021). No control group following standard practice including AGP procedures was ethically possible due to the public health emergency. This single-interventional study type has been used elsewhere (e.g. oncology) as the only -or one of the few options for evaluating therapies for which placebos are not ethical and control groups are limited (Evans, 2010). In addition to the ability to explore the caries-control effect of CCI in the dental practice setting, the CCI-adapted trial offered centers a pandemic-appropriate way to offer dental care to children. Such care was not possible for long periods of time during the pandemic in many countries (Okike et al., 2021; Liu & Wehby, 2022; Beltrán et al., 2022; Stennett & Tsakos, 2022).

Linked to the single group, there is a potential examiner bias in the final assessment as examiners may have had subconscious bias about expecting improvements. The robustness of our results can be supported first, by the fact that examiners were blind to the intervention. Also, the T0-to-T1y decrease in the mean number of caries lesions could be explained in a large part by TPOC and NOC (fillings/sealants used for moderate-extensive caries lesions and sealants used for some initial caries lesions), as well as by other NOC strategies as fluoride topical application and increased frequency and quality of fluoridated-toothpaste toothbrushing (Urquhart et al., 2019). Another potential bias is the inability to compare the acceptability of parents (and dentists) with another intervention. The ICCMS caries-control effectiveness study using a similar caries management system showed (vs. standard care) a significantly higher compliance of parents towards children's twice-a-day fluoridated-toothpaste toothbrushing (Martignon et al., 2022).

There was a reduced number of centers eligible for the study (17 out of 21) due to delayed ethical approval (2 USA centers); no IRB application due to lack of general dental practice for conducting this study (UK), no IRB after several attempts and loss of interest (the Netherlands). In the center that did not finish by the study deadline (Brazil), this was related to ethical-approval delays and local setting difficulties (3-month clinic closure for structural issues after starting). Despite the loss of this center together with the dropout of its children plus other dropouts in the remaining centers, the sample size was achieved, and further these were related to the world-wide health emergency situation, which in fact supports the conduction of this study.

Even though the study duration (one year) could be regarded as a limitation, the use of the ICDAS criteria with severity and activity status assessment favors the assessment of progression of caries lesions and appearance of new lesions within that period of time, as shown by Ferreira-Zandoná et al. (JDR 2002). The findings of this study could be explained by the comprehensiveness of the CCI caries management system through a patient-centered, preventively-based care with an emphasis on caries prevention and control, and minimally invasive caries management where necessary (Martignon et al., 2019; Pitts & Ekstrand, 2013). ICCMS demonstrated in a 3-year multicenter RCT of children in Colombia to be more

effective in controlling caries progression and to offer more improvement in toothbrushing practices than the conventional national caries-management system (Martignon et al., 2022). While in that study the proportion of active caries lesions was of over 49%, this corresponded in to 28% in this study. Current more positive findings could be for several reasons, including a shorter follow-up time, but also the great percentage of children with T1y control of caries progression (79.5%). Instead of three caries-risk classification categories in ICCMS (low, moderate and high), CCI only uses low/high, allowing for clearer management planning (Martignon et al., 2019). Also, in the current study there was emphasis given to improve oral-health practices through the use of a short COM-B behavior-change tool including a goal-setting, planning and self-monitoring intervention (see protocol study) and this technique follows psychological behavior change science (Asimakopoulou & Newton, 2014; Newton & Asimakopoulou, 2016) proven to be effective in e.g., improving periodontal treatment outcomes (Asimakopoulou et al., 2019). In addition, it focused on improving two critically relevant behaviors to prevent caries, namely, twice-a-day fluoridated-toothpaste toothbrushing (Walsh et al., 2019), and reducing daily sugar intake (WHO, 2015). The findings of the TEI questionnaires conducted among parents and dentists suggest a high acceptability of CCI, in particular on the knowledge of how to improve the children's oral health and the parents' participation in the treatment plan. Similar results have been previously reported for the use of the Denplan/Previser patient assessment tool (Newton & Asimakopoulou, 2017).

Besides ICCMS, other caries management systems that support NOC have also shown caries-control effectiveness at longer period times in children (Vermaire et al., 2014) and adults (Curtis et al., 2011) when compared to standard care, while Innes et al. (2020) did not find significant toothache/infection-episode differences of cavity sealing versus conventional operative care or only individual-level care in children. Risk-related personalized care has also been shown to offer caries-control effectiveness; in Russia with Nexö-method principles (Kuzmina et al., 2015) which are similar to those of CCI, and in the US with the CAMBRA system (Featherstone & Chaffee, 2018), which conversely to CCI uses antibacterial therapy. The use of the Hall technique and ART in the CCI-adapted protocols allowed for TPOC without AGPs. Both procedures as well as other non-operative approaches like silver diamine fluoride, fluoride varnish and sealants, have been recommended in recent caries-management guidelines (Slayton et al., 2019).

Finally, the implementation in practice of a caries management system such as CCI that focuses on health outcomes has widespread support from different areas (including the CCI webpage) but the process needs to speed up. The implementation of the cariology teaching consensus for undergraduates that started with the European core curriculum over 10 years ago (Schulte et al., 2011) and which was recommended and/or nationally adapted in many countries, seems to be slower than expected (Santamaría et al., in press). From the policymaker perspective, the support that appeared over 20 years ago from the FDI for 'minimal intervention in the management of caries' has also had a slow uptake in daily clinical practice, which further motivated the FDI in 2019 to promote the principles of ICCMS (Bondioni, 2020). This also led to the International Standards Organisation (ISO) using ICCMS terminology (equal to ICDAS-merged criteria) as the global standard for dental caries (https://www.iso.org/ obp/ui/#iso:std:iso:1942:ed-3:v1:en). The 2021 WHO Resolution on Oral Health

also supports the CCI approach (WHO, 2021). Finally, from the dental practitioners perspective, there has been a world widespread of educational material to translate the current care philosophy to the practice, with a short time to clinically assess caries with the ICDAS-merged criteria (around 4 minutes) (Martignon et al., 2018), the development of standardized software for the caries care oral health record (Pitts et al., 2021), and assessing the implementation of CCI in real clinical scenarios in eight Latin American dental schools within the LAOHA (Latin American Oral Health Organization) call for action initiative (https://laoha.org/newsletters/en/ed10_eng_newsletter_laoha_2023.pdf).

Conclusion

Given the challenge of the pandemic and within the limitations of this study, CariesCare International adapted for the pandemic showed after one year control of caries progression and caries risk in children, as well as a high acceptance by children's parents and dentists.

Abbreviations

AGP: Aerosol-generating procedures

AM: Active monitoring

ART: Atraumatic restorative treatment

CCI: CariesCare International

CCI-adapted: CCI caries management system adapted for the pandemic period (avoiding AGPs and reducing on-site consultation)

CCI 1D: Determine caries risk

CCI 2D: Detect and assess caries lesions severity and activity:
CCI 3D: Diagnosis at the individual- and tooth-surface level and Personalized care plan decisions.

CCI 4D: Basic individual and tooth-surface levels' patient-centered management.

D_I: Initial caries lesion

D_M: Moderate caries lesion

D_E: Extensive caries lesion

DP: Dental practitioner

E: Blinded examiner

HVGI: High viscosity glass ionomer

ICCMS: International Caries Classification and Management System

ICDAS: International Caries Detection and Assessment System

NaF: Sodium fluoride

NOC: Non-operative care

PRS: Pulp involvement / Root / Sepsis with fistula

SDF: Silver diamine fluoride

TEI: Treatment Evaluation Inventory

TPOC: Tooth-preserving operative care

T0: baseline caries assessment and management

T1y: 1-year follow-up

Declarations

• Ethics approval and consent to participate: The study protocol and informed consents obtained approval from the Research Institutional Ethical Committee at Universidad El Bosque (PCI 2019-10718). Written informed consents were obtained from parents/caregivers and written informed assent were obtained from children (in countries and ages that require it).

• Consent for publication: Not applicable

• Data Availability statement: The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

• Competing interests: The authors declare that there are no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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• Author contributions: Stefania Martignon, Edgar O. Beltrán, Andrea Cortes: substantially contributed to the conception and design of the study; contributed to data acquisition, analysis and interpretation; drafted the manuscript and critically revised the manuscript for important intellectual content; gave final approval and agreed to be accountable for all aspects of work ensuring integrity and accuracy.

Gail V. A. Douglas, J. Timothy Newton, Nigel B. Pitts, Christopher Deery: contributed to the design of the study; contributed to interpretation; critically revised the manuscript for important intellectual content; gave final approval and agreed to be accountable for all aspects of work ensuring integrity and accuracy.

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Figures

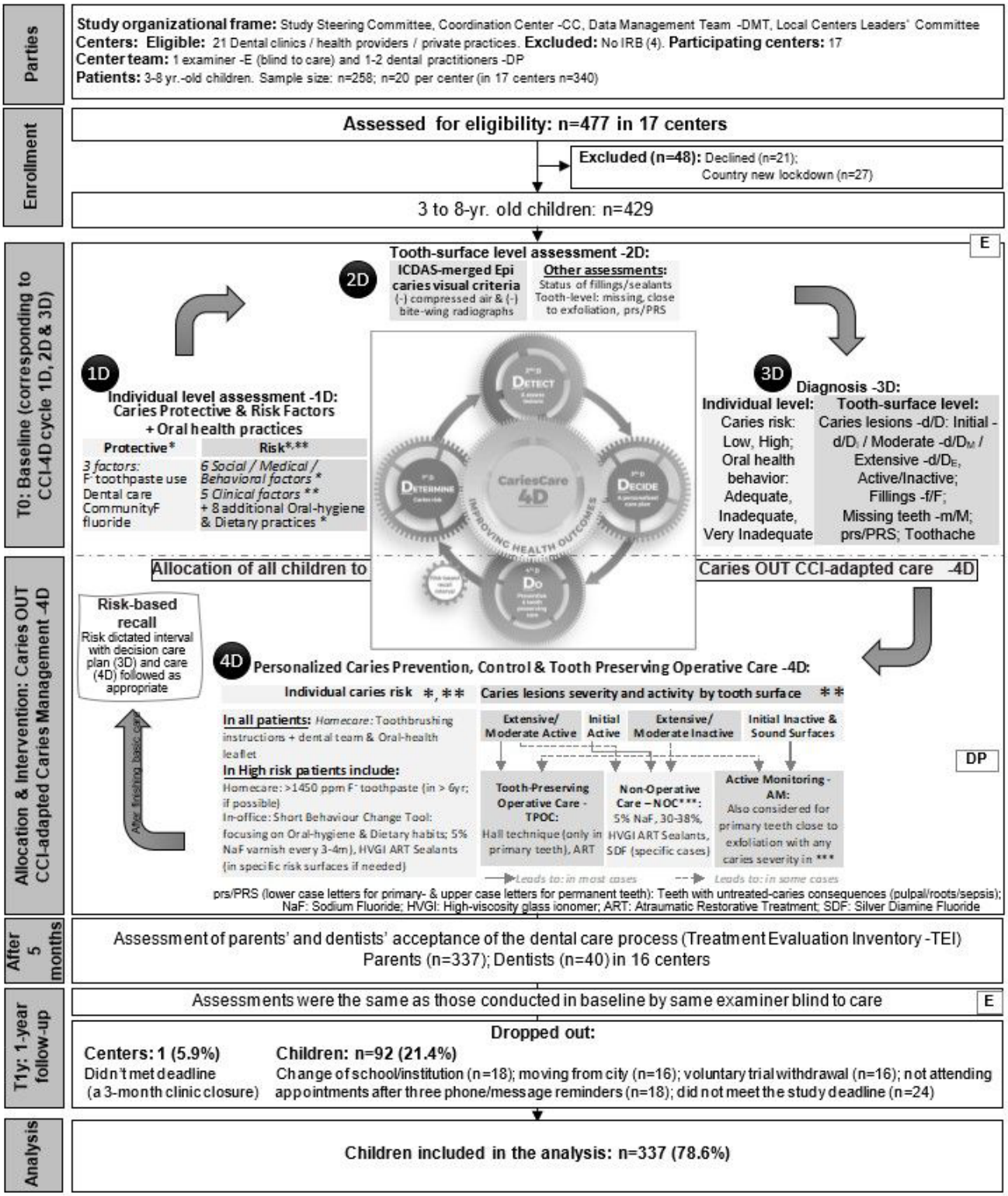

Figure 1

CCI-adapted study flowchart.

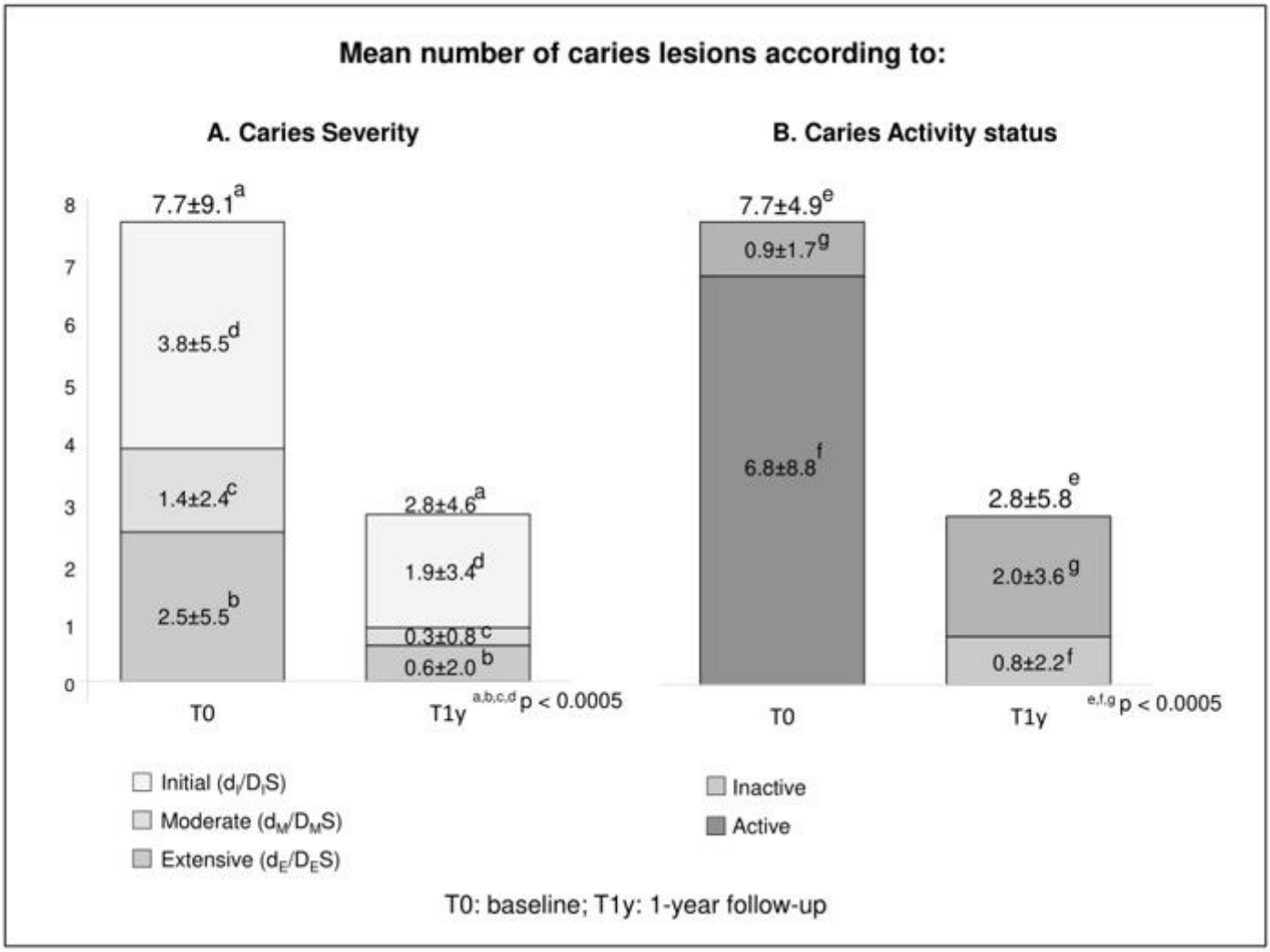

Figure 2

Distribution of mean number of caries lesions at baseline (T0) and 1-year follow-up (T1y).

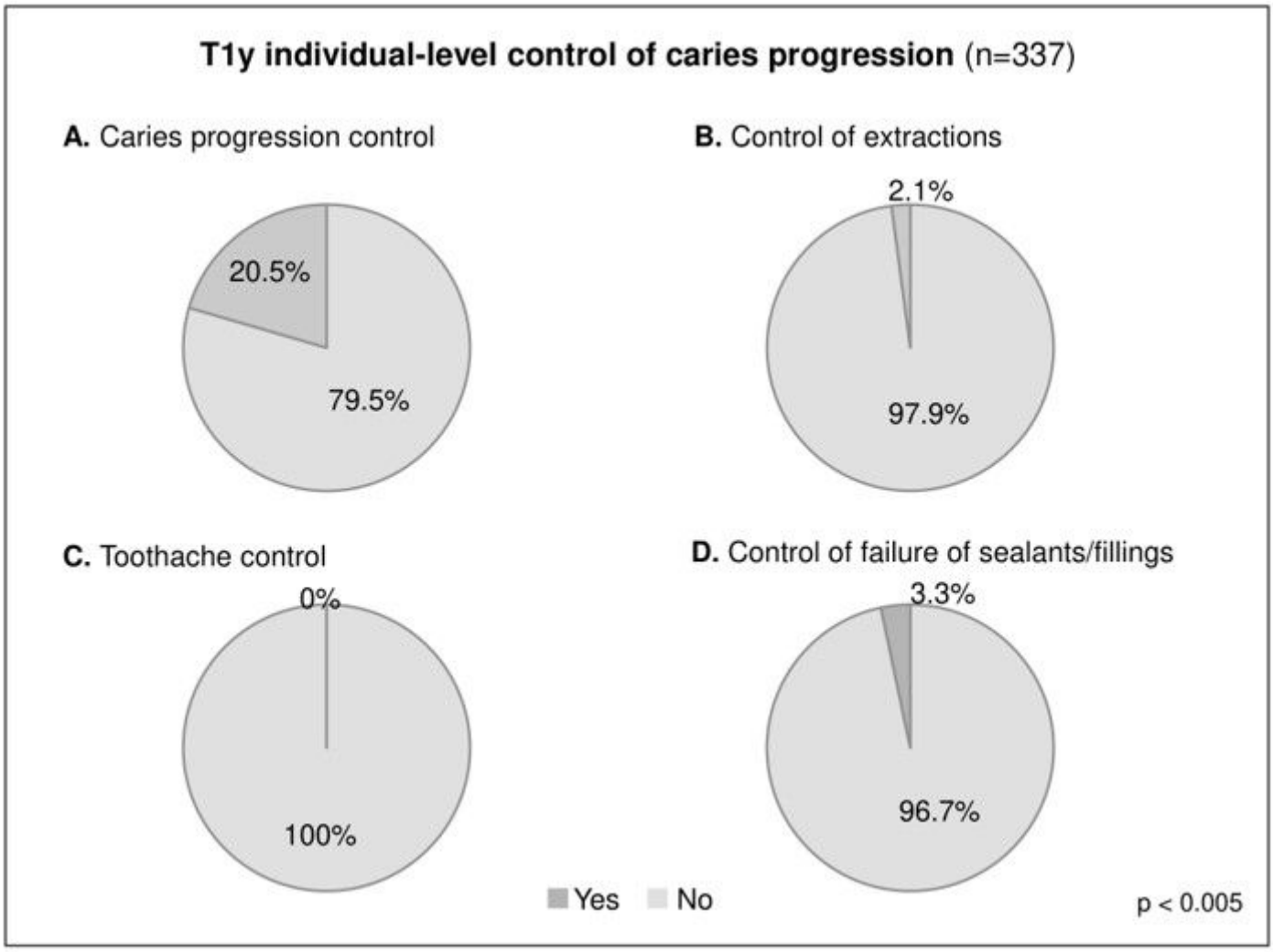

Figure 3

One-year follow-up (T1y) control of caries progression at the individual level.

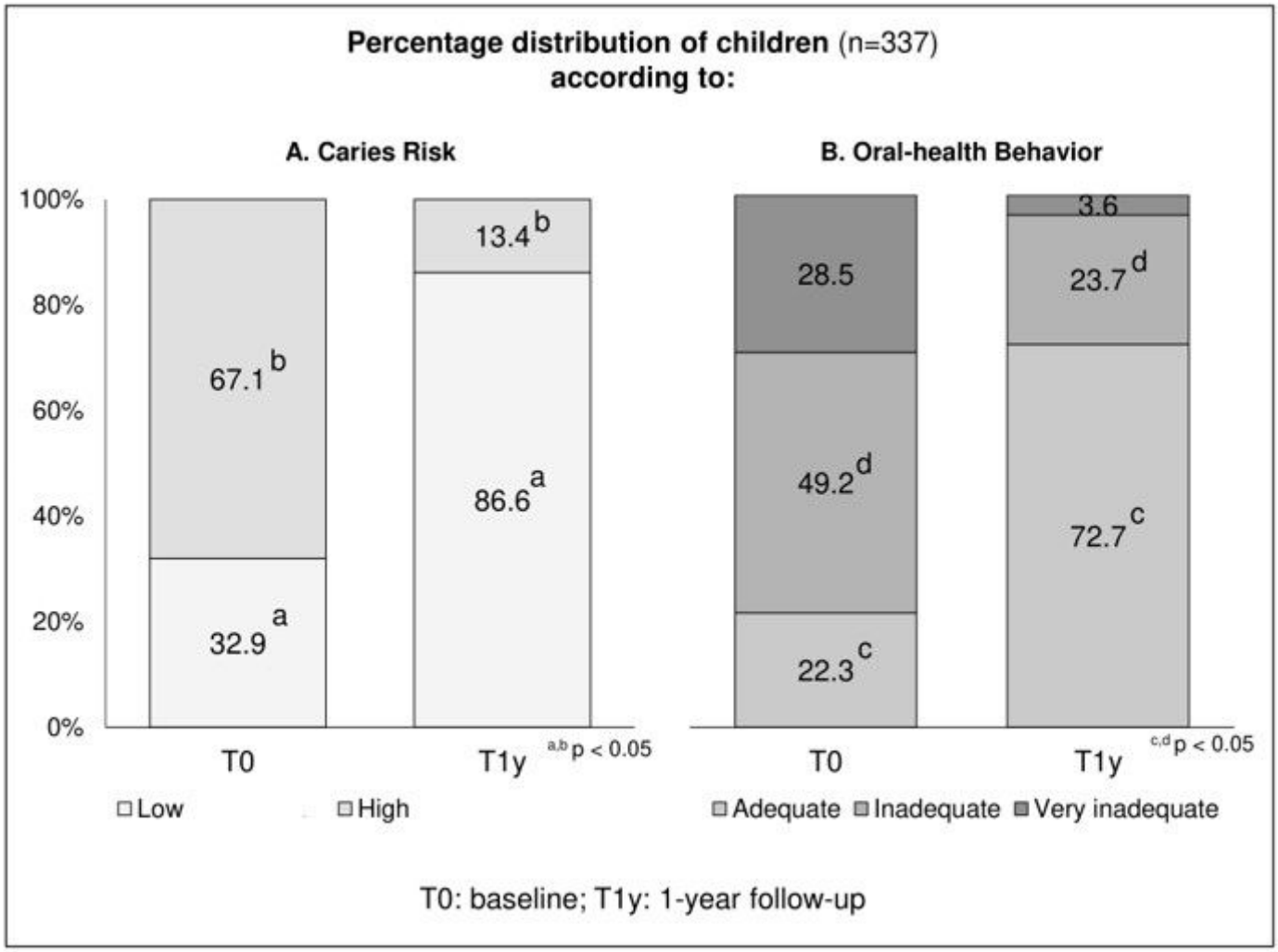

Figure 4

Caries risk (A) and Oral-health related behavior (B) baseline and 1-year follow-up children's percentage distribution.

Supplementary Files

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

- Supplementary1STROBEchecklistCCIadapted29012024.pdf
- Supfile2ClinicalTrialsPRSReceiptCariesOUT2024.pdf