Original Research
Community Dental Health

Responsiveness of the B-ECOHIS to detect changes in OHRQoL following dental treatment of children with autism spectrum disorder

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Declaration of Interests: The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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https://doi.org/10.1590/1807-3107bor-2022.vol36.0079

Submitted: June 8, 2021
Accepted for publication: January 12, 2022
Last revision: February 8, 2022

Abstract: The Brazilian Early Childhood Oral Health Impact Scale (B-ECOHIS) is an oral health-related quality of life (OHRQoL) questionnaire. This paper aims to investigate the responsiveness of the B-ECOHIS to dental treatment in individuals diagnosed with autism spectrum disorder (ASD) and determine if dental treatment has an impact on OHRQoL. The survey targeted 27 ASD individuals aged 4 to 14 years attending the Acolher Project of the University Federal Fluminense. This project provides children and adolescents with disabilities with oral health services. A group of randomly selected caregivers self-completed the B-ECOHIS before and 14 days after their children's dental treatment. The dental treatment included meticulous screening, preventive treatment, and restorative treatment. Responsiveness was assessed by investigating the effect size (ES) and standardized response mean (SRM). Wilcoxon test was used to evaluate internal responsiveness (distribution-based approach). The B-ECOHIS showed significant changes in the total score (p<0.001) and in all domains. The ES of the total B-ECOHIS after treatment was 1.28 and ranged between 0.70 and 1.14 for the domains. The SRM for each of the domains was large, except for the symptom domain. The B-ECOHIS is sensitive and responsive to ASD individuals undergoing dental treatment. Individuals with ASD showed improvement in their OHRQoL score after dental treatment.

Keywords: Autism Spectrum Disorder; Quality of Life; Dental Caries; Surveys and Questionnaires.

Introduction

Autism spectrum disorder (ASD) is a neurodevelopmental disorder that is characterized by social communication and social interaction in the presence of restricted and repetitive behaviors or interests. It is recognized as a single diagnostic category with an ICD-11-CM code and DSM-5.[1] A diagnosis of ASD now includes several conditions that used to be diagnosed separately: autistic disorder (classic autism), pervasive developmental disorder not otherwise specified (PDD-NOS), and Asperger syndrome.[1-3] In Brazil, there is no official epidemiological

estimate. Current prevalence is estimated to be at least 1.5% in developed countries, with recent increases primarily among those without comorbid intellectual disability.[4] Individuals with ASD often have problems with social, emotional, and communicative competence.[3] Families are usually the major source of support for people with ASD throughout much of their lives and need to be considered, along with the perspectives of individuals with ASD, in both research and practice.[2] Individuals with ASD often have repetitive behaviors and they generally do not like any changes in their daily routines. They have different ways of learning and, in some situations, have difficulty paying attention, as well as different ways of reacting to situations. These behavioral changes start in early childhood and can last a lifetime.[1-3] There are some aspects of oral health that only patients themselves can manage, such as their oral health-related quality of life (OHRQoL). Thus, it is important to consider the patients' views of their symptoms, functional restrictions, and social/emotional well-being, in order to enhance their clinical management.[5] However, symptoms can differ from child to child, and their severity can be sometimes difficult to determine.[5] Severity is usually based on the level of impairments and how they affect the ability to function. Patient-reported outcome measures (PROMs) could be generic or disease-specific instruments used to indicate the extent to which oral health conditions affect OHRQoL. Assessing OHRQoL in children with ASD is, however, complicated because of their difficulty in understanding what is being evaluated.

Several studies have evaluated the impact of dental caries on children's OHRQoL.[6-23] Yet studies on the relationship between ASD and OHRQoL of children and parents of children with autism are still lacking.[24-26] PROMs could be generic or disease-specific instruments used to indicate the extent to which oral health conditions affect OHRQoL. To overcome the limitations of a young child's ability to express thoughts and respond to questions, the Early Childhood Oral Health Impact Scale (ECOHIS) focuses on the perception of parents or main caregivers.[5] ECOHIS is a PROM and it was designed to measure OHRQoL of preschool children. In general, the caregivers of these children fill in such questionnaires because children lack the cognitive skills to assess their own OHRQoL.[6-9] Thus, the ECOHIS has been used to evaluate OHRQoL in children and adolescents with intellectual disability.[24-27] The ECOHIS is a 13-item parent-report questionnaire that evaluates six domains: symptoms; psychology; function; parental distress; self-image/social interaction; and family function.[5,7,15] The ECOHIS has proven to be a reliable and valid instrument for measuring OHRQoL in Brazilian preschool children (B-ECOHIS).[6-8,17] The ECOHIS has been validated for children in other countries[9-14] and for patients with special healthcare needs.[17,18]

Authors[24,28] have emphasized the need for longitudinal studies when investigating OHRQoL in ASD patients in order to evaluate the impact of different variables. Although there is no longitudinal study that has assessed OHRQoL in Brazilian children with ASD, a recent study for patients with special needs has included 48.9% of patients with ASD.[24] Measurement tools with relevant psychometric properties are essential in order to guarantee good-quality and significant OHRQoL data. Although some studies have shown the ECOHIS is sensitive and responsive to dental treatment in children with caries,[17,19,21] other studies have shown modest[22] or poor[18] results. Moreover, there are few OHRQoL studies on children with ASD.[24-27] In addition, there is a lack of information about the effect of dental treatment on OHRQoL in patients with autism. In our study, we hypothesized that the B-ECOHIS can measure improvement in quality of life after dental treatment in patients with ASD. Better understanding of the responsiveness of the B-ECOHIS in children with ASD would improve the use of these measures in both clinical and research settings. In clinical trials, the outcome measures must be reliable, valid, and responsive in order to have a beneficial effect.[17,25] This investigation aimed to evaluate the responsiveness of the B-ECOHIS to dental treatment of Brazilian children diagnosed with ASD and determine its effect size (ES), standardized response mean (SRM), and minimal important difference (MID).

Methodology

Participants

Patients with ASD who were recruited from the Acolher Project of the Fluminense Federal University in the city of Niterói were selected by a random draw from a list of registered children referred for treatment from August to December 2019 at the Fluminense Federal University Dental School. The Acolher Project provides children and adolescents with disabilities with oral health services. All patients are in possession of a medical report when they are referred to the Acolher Project. Eligibility criteria were as follows: a) individuals aged 4 to 14 years, b) informed consent form for participation in the study signed by parent or legal guardian, and c) individuals diagnosed with ASD. Exclusion criteria were caregivers who refused to participate in the study, children with behavioral problems during the appointments, and incomplete questionnaires (two or more unanswered items in the Child section or one unanswered item in the Family section of the B-ECOHIS).[26] No individual was excluded for this reason. Two children were not included in the study because they were indicated for treatment under general anesthesia.

Information was given to all caregivers about the objectives of the study and informed consent forms were signed by them before data collection. All study procedures were approved by the Human Research Ethics Committee of the Fluminense Federal University (process no.: 439.086).

An 80% power was used for sample size calculation, with a nonparametric test for paired samples, a significance of 0.05, and sample size effect of 0.80.[28] A final sample size of 24 was necessary for the purpose of our study. An additional 10% was added to the sample size to compensate for losses due to uncooperative children and missing answers.

Instruments and data collection

This study employed the B-ECOHIS to assess the negative impact of dental caries on the OHRQoL of children with ASD. This questionnaire contains 13 items divided into two sections: the Child Impact Section (CIS - function; symptoms; psychology; and self-image/social interaction) and the Family Impact Section (FIS - parental distress and family function). The scale has five response options ("never"=0, "hardly ever"=1, "occasionally"=2,"often"=3, "very often"=4, "don't know"=5). The "Don't know" answers were not included in the final sum. The scores of each section are the sum of the scores of all items in each section, with the scores for the CIS ranging from 0 to 36 and for the FIS ranging from 0 to 16; and the final score is the sum of the two sections, ranging from 0 to 52. Higher scores denote greater negative oral health impact and poorer OHRQoL.

The B-ECOHIS was applied twice: 1) At the initial dental appointment, prior to clinical examinations, when the caregiver completed the B-ECOHIS during an individual interview (pretreatment), 2) Fourteen days after the completion of treatment;[8,13] the same interviewer applied the B-ECOHIS again (posttreatment) to the same caregiver who answered the first interview.

The caregivers also answered a socioeconomic questionnaire. It included the child's sex (male or female), the child's age (mean and SD), the caregiver's schooling in years (≤8 years, >8 years),[24,28] and the gross household income based on the Brazilian minimum wage – BMW (US$ 284.80), divided into <2 BMW and ≥2 BMW). [24,28]

Oral examination and dental treatment

The oral clinical examinations were performed by two examiners (KF and VC), who had undergone a calibration exercise. The calibration process was described in a previous study.[24] The examiners participated in the calibration exercise (CV — examiner 1 and KF — examiner 2). These steps were reviewed and discussed by the examiners and by an experienced dentist who was considered gold standard. The clinical step was conducted with patients (aged 8/9 years) involved in the Acolher Project on two occasions with a two-week interval between examinations. The intra-examiner and inter- examiner Kappa coefficients were 0.87 to 0.96 (examiner 1) and 0.89 to 0.92 (examiner 2). Examiner 1 assigned the participants to their clinical status. Examiner 2 who was blinded to the assignment of participants recorded all primary and secondary outcome measures.

The World Health Organization (WHO) criteria were used to confirm decayed-missing-filled (DMFT and dmft) index.[29] A mouth mirror (PRISMA; São Paulo, Brazil) and probe (Golgran, São Paulo, SP, Brazil) were used for visual examination with the patient in a dental chair under the light of a reflector. Caries were considered when cavitated lesions were found in the enamel or dentin, as well as restorations performed with provisional filling materials and fillings with leakage or with signs of recurrent caries. Caries experience was calculated: dmft (primary dentition caries index: the number of decayed, missing (decayed), and filled teeth), DMFT (permanent dentition caries index: the number of decayed, missing, and filled teeth). The child was the unit of analysis. The individuals were divided into two groups: without caries experience (dmft/DMFT = 0) and with caries experience (dmft/DMFT ≥ 1).[24,26,28]

The dental treatment was carried out by an experienced professional specialized in the care of patients with disabilities. The procedure included meticulous screening (oral examination, photos, and image exams), preventive treatment (prophylaxis, topical application of fluoride, and fissure sealants), and restorative treatment (composite resin and resin-modified glass ionomer restorations). No patients needed pulp therapy, stainless steel crowns, or extractions. All dental treatments were performed at appointments following the initial oral examination, according to the needs of each patient.

Statistical analysis

The SPSS 20.0 statistical package (SPSS for Windows, IBM Inc, Armonk, USA) was used for the data analyses. Descriptive analyses (including frequency distribution, mean, and standard deviation) were also performed. The Kolmogorov-Smirnov test verified that the data followed a non-normal distribution. The nonparametric Mann-Whitney test was used. The internal consistency of the B-ECOHIS was tested with Cronbach's alpha statistic using the baseline information.

ES, which was calculated in this study, is the variation between the mean baseline scores and the follow-up scores of the measure, divided by the standard deviation of the baseline score. ES varied between small (0.20), moderate (0.50), and large (0.80).[18] The SRM is the ratio of the mean change score divided by the standard deviation of the change score. The standard error of measurement (SEM) can be calculated by the product of the baseline standard deviation with the square root of (1-r), where r is the reliability coefficient (Cronbach's alpha) or intraclass correlation coefficient. The MID was estimated as the mean change in scores (preoperatively and postoperatively), for each of the domains.[23]

Wilcoxon test was used to evaluate internal responsiveness (distribution-based approach). The total B-ECOHIS scores at baseline and 14 days after treatment were compared. External responsiveness (anchor-based approach) was assessed by comparing ECOHIS scores obtained at baseline and after treatment.[22]

Results

The study population consisted of 27 individuals with ASD. All caregivers returned for the second interview. The sociodemographic and clinical data of the sample are shown in Table 1. The mean age (±SD) of the participating children was 8.44 ± 3.17 years (range: 4 to 14 years), with a very balanced sample between boys (n = 15) and girls (n = 12). Only eight patients (30.0%) required restorative treatment and no patients required pulp therapy and/or tooth extractions. Five patients had caries experience in the primary dentition, eight in the mixed dentition, and two in both dentitions. The mean (SD) dmft was 0.72 (1.32) and DMFT was 2.00 (2.52) (Table 1).

There was a 44.16% decrease in total B-ECOHIS scores between pretreatment and posttreatment ($p < 0.001$). There was a 42.12% reduction in the CIS and 46.35% in the FIS scores ($p < 0.001$). A statistically significant reduction ($p \leq 0.001$) was also found for all domains after treatment. Cronbach's alpha statistic showed internal consistency for the B-ECOHIS with CIS (0.87), FIS (0.91), and overall scale (0.97).

The effect sizes of the 'psychology' (ES = 0.51) domains were moderate; while the 'family function' (ES = 1.05) and the 'self-image and social interaction' (ES = 1.14) domains showed a large magnitude of change. The ES of the residual domains for total

Table 1. Sociodemographic and clinical data of the sample (n = 27).

Variable	n	%
Child's sex	27	100
Male	15	55.6
Female	12	44.4
Caregiver's years of schooling	24	88.9
≤ 8	1	3.7
> 8	23	85.2
Household income (BMW)	25	92.6
< 2	5	18.5
≥ 2	20	74.1
Caregivers	27	100
Mother	24	88.9
Father	2	7.4
Grandparent	1	3.7

*Missing data; BMW: Brazilian minimum wage; dmft: primary dentition caries; DMFT: permanent dentition caries.

B-ECOHIS, CIS, and FIS scores had a large magnitude of change (≥ 0.86). Table 2 shows the effect sizes of the domains for the B-ECOHIS scores. The SRM for each of the domains was large, except for the symptom domain. Participants whose change in score was < 1.0 posttreatment were classified as scoring the MID of the B-ECOHIS. Our data show that all children scored at least the MID. The MID is presented in Table 2.

A *priori power* analysis was conducted prior to the research study and is typically used in estimating sufficient sample sizes to achieve adequate power. The power analysis of the data is shown in Table 2. In this study, we focus on estimating sample size. In general, post-hoc power analysis does not provide sensible results. However, in this study, the *post-hoc* power analysis shows the CIS (0.96) and FIS (0.85), respectively.

Discussion

The B-ECOHIS has been validated and has evidenced discriminant validity, convergent validity, test-retest reliability, and internal consistency.[23,] It is an instrument that has been used in many previous studies[5,6-23,25-27] to assess the OHRQoL of Brazilian children aged between 0 and 5 years and the impact on their families. In patients with special health care needs, these questionnaires have been used and have presented positive results in relation to their respective objectives.[24,26]

This is, however, the first time the B-ECOHIS has been applied to a group of children diagnosed with ASD and further investigated for its responsiveness by evaluating its capacity to find changes after dental treatment in this same group. There are no studies in the literature on the responsiveness of OHRQoL instruments for ASD children. Knowledge of OHRQoL can contribute to good oral hygiene and better OHRQoL of children with autism, giving them a better quality of life. The results of the B-ECOHIS, which demonstrated responsiveness, can be used in clinical studies to define the impact of different interventions on OHRQoL, including psychological outcomes. Responsiveness is the gold standard for measuring the impact of health problems on patient's OHRQoL.[19]

Table 2. Mean change in scores for total scores and individual domains of the B-ECOHIS scores before and after treatment (n = 27).

Variable	Baseline range	Baseline mean (SD)	Follow-up mean (SD)	p-value*	ES	SRM	SEM	MID
Children impact score (CIS)	5–20	11.30 (7.20)	4.76 (4.71)	< 0.001	1.07	1.31	0.44	0.87
Symptom domain	0 –4	1.52 (1.12)	0.81 (0.89)	< 0.001	0.70	0.13	0.07	0.14
Function domain	0 –9	5.59 (4.27)	2.19 (2.89)	0.001	0.93	1.01	0.26	0.51
Psychological domain	0 –6	2.22 (1.82)	1.35 (1.57)	< 0.001	0.51	0.81	0.11	0.22
Self-image/social domain	0 –6	1.96 (1.89)	0.35 (0.62)	< 0.001	1.14	5.03	0.12	0.23
Family impact score (FIS)	3 –22	5.07 (2.99)	2.35 (2.19)	< 0.001	0.86	3.40	0.18	0.36
Parent distress domain	0–7	2.74 (1.95)	1.50 (1.81)	< 0.001	0.65	0.93	0.12	0.24
Family function domain	0–6	2.33 (1.77)	0.85 (0.88)	< 0.0010	1.05	37.00	0.11	0.21

*p-value derived from paired t-test; MID: minimal important difference; ES: effect size; SRM: standardized response mean; SEM: standard error of measurement.

OHRQoL instruments that have shown responsiveness to dental interventions in clinical studies can be used to provide treatment options that ensure not only clinical, but also psychosocial outcomes. An important aspect of this study is the nature of the sample in which we tested the instrument responsiveness. The sample consisted of caregivers of 4- to 14-year-old individuals with ASD treated in a dental clinic linked to the Acolher Project. The majority of the caregivers reported high levels of impact on their children before treatment in the function domain, independently of DMFT and dmft means. According to Du et al.,[25] children with ASD have significantly higher scores in general for the CIS and FIS subdomains, and this may have contributed to the results herein. Our hypothesis that parents with children who need special care generally feel more concerned about their children's oral health problems was confirmed.[24,26] Together, these aspects can explain our ES and SRM findings in the function and self-image/social domains. In addition, caregivers responsible for children with serious oral health problems will, in general, be more satisfied with the dental treatment received than caregivers of children with simple dental needs.

The MDI was based on the distribution database that acts on the accuracy of the instrument under evaluation, exclusively using statistical criteria, allowing the MDI to be determined without the influence of measurement errors. Other studies have found higher values.[18,19] The score of the symptom domain showed relatively poor improvement when compared to the other domains. On the other hand, the greatest improvement occurred in the function domain.

Some authors showed the OHRQoL of children and adolescents improved following caries intervention procedures, but the quality of evidence was very low. [13] Other authors[21,22] had good results using the ECOHIS and obtained a large magnitude of change. These studies, however, were conducted with healthy patients with multiple caries, patients under general anesthesia,[26] or individuals who had severe oral health problems.[8,19,21,23] Although in the present study there were no serious dental problems in the sample (extractions, for example), there were positive differences in the results with the use of the ECOHIS. This can be explained by the fact that our work has a sample of children who sought dental care (with treatment needs) and, therefore, the caregivers may have been more sensitive to the associated changes. Our results demonstrate the ES and SRM were large, except for the psychological and symptom domains. In light of these results, we can assume that the B-ECOHIS was responsive to the dental treatment, but we cannot say whether it was due to the treatment of carious lesions, which were small in the studied sample.

Caries experience was low in the sample in this work in comparison to other studies on healthy children.[26,29,30,31] Thus, further studies are needed in samples of autistic patients with more severe dental needs. This low severity of dental problems was also observed in the previous studies conducted by our team.[16,17] However, the change in quality of life can be perceived by families and children because when they have access to dental care, they feel included.[16,17] These families always report that it is very difficult to gain access to healthcare facilities, in general, for special patients. This may be a hypothesis for changes in quality of life, even for groups of children without caries experience.

The changes in the social interaction, psychology, family function, and family distress domains were all statistically significant. The B-ECOHIS demonstrated good external and internal responsiveness for total scores and for individual domains. The total B-ECOHIS scores and scores for the domains indicated significant decreases after treatment, indicating improvement in the children's OHRQoL. Other studies[26,30] have also shown changes in the domains, however, those studies used typically developing patients.

Results were much stronger, as the magnitude of change among most of the domains was large, and total B-ECOHIS scores support the sensitivity for ASD group. Our results are difficult to compare with those of other papers because these works had a general anesthesia[16,17,23] with focus or preschool children extensive dental treatment,[8,18] all with a healthy population. However, these results were good for the international community in that they show the importance of dental treatment in the ASD group.

Our findings demonstrate a high rate of satisfaction with the treatment outcomes. Although most of the caregivers regarded the experience as positive after treatment, only a few children had carious lesions. Therefore, these children were not exposed to very invasive treatments such as extraction. Perhaps another study with a group of children with autism and high caries severity and tooth extractions should be implemented so that these results can be reinforced. Notwithstanding the great change in OHRQoL, these families should be followed up in the long run, given that this change could be temporary. Access to dental care can also be an issue, since it is quite difficult for these patients to obtain dental care.[16,17] More studies need to be carried out with this group in order for these gaps to be filled.

The ECOHIS is the most widely used questionnaire to evaluate OHRQoL in children,[5-6,13,14] and it has demonstrated responsiveness to dental treatment.[19-22,26,27,30] It can be speculated that the differences in these results between studies were related to the dental treatment received by the patients. This is the first study to associate the responsiveness of the B-ECOHIS with ASD children, and since this instrument has proven effective with young healthy children, it seems reasonable that it is also a good instrument for patients with ASD. This is a preliminary study and further studies should be carried out with a sample stratified by degrees of autism. A wider range of dental treatments are also needed to elucidate some questions that could not be answered in the present research.

There are several limitations to the current study. The sample in this study was a clinically referred sample of children and adolescents who had been diagnosed with ASD based on the patients' medical data. In addition, most of the sampled children had mild to moderate autism. Severe cases were excluded from the sample because clinical care was not possible, which limits the generalization of these findings to samples with severe autism. Other limitations in our study were that there was no control group and the sample size was small. Nevertheless, it was able to show statistical difference in the treatment outcome. For example, sex was balanced in this work, despite the prevalence of males described in the literature. Perhaps, this result might have been obtained due to the great demand at a reference clinic. Extrapolation of results must be done carefully.

Furthermore, based on our findings, the B-ECOHIS is an appropriate instrument to test clinical interventions, enabling clinicians to observe changes in the ASD children's OHRQoL caused by their treatments, which are comparable to those reported for typically developing children. Although some research on the OHRQoL of ASD patients has been published recently,[16-18] a lot still has to be elucidated in this area. Based on these findings, a broader policy could be devised and government resources should be directed towards interventions that result in health improvements and provide better OHRQoL for the autistic population in Brazil.

Conclusions

Individuals with ASD showed improvement in their OHRQoL after dental treatment. The results of this work suggest that the B-ECOHIS is responsive to changes in OHRQoL and also indicated its good longitudinal construct validity, making it suitable as an outcome measure in clinical trials.

Acknowledgements

This study was supported by the Fluminense Federal University.

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