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Testing responsiveness to change for the early childhood oral health impact scale (ECOHIS)

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Abstract – *Objectives:* The Early Childhood Oral Health Impact Scale (ECOHIS) is a recently developed oral health-related quality of life instrument designed to assess the impact of oral health problems in 0–5-year-old children. It has previously been validated as discriminative instrument. The goal of this study was to investigate the responsiveness to change of the ECOHIS. *Methods:* Data were collected from a convenience sample of 101 parents of 0–5-year-old children attending a hospital dental clinic for dental treatment. The ECOHIS was completed by parents prior to dental treatment and 2 weeks later. Subjects were also asked a global transition judgement concerning change between the second and first completion of the ECOHIS instrument. Responsiveness to change of the ECOHIS was analysed through: (i) a comparison of ECOHIS change scores with a global transition judgment by study subjects; (ii) an assessment of the statistical significance of within-group change in scores over time for groups reporting improvement, stability and deterioration; (iii) an estimation of the ECOHIS's sensitivity; and (iv) an investigation the effect size of the ECOHIS. *Results:* Of the 101 subjects recruited, 94 had full datasets. Their data were used for the analyses reported in this paper. Pre- and post-treatment distributions of ECOHIS scores were strongly distributed towards no oral health impacts. Among the 94 subjects, 51.1% reported improvement, 42.6% reported no change and 6.4% reported deterioration following treatment, using the global transition judgement. The mean ECOHIS change scores for these three groups were −0⁄9, +0.7 and +6.5 respectively, although none of the within-group changes were statistically significant. The effect size for those reporting improvement was small (0.15) but for those reporting deterioration was moderate-to-large (0.69). Sensitivity ranged from 0.61–0.79 depending on the size of the cut-off point, with a change of 3 points demonstrating the best sensitivity to false positive ratio (0.79 versus 0.41 respectively). *Conclusion:* In this sample with low levels of problems, the ECOHIS has demonstrated some limited ability to respond to change. Further work in a larger sample with higher levels of problems is needed to investigate the instrument's ability to respond to change when it has occurred.

Key words: infants; instrument validation; oral health; quality of life; responsiveness to change

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In recent years, the growth in measures of oral health-related quality of life (OHRQoL) has been added to by the development and validation of instruments designed to assess this construct in children and adolescents (1–5). Most recently an OHRQoL questionnaire designed for 0–5-year-old infants, the Early Childhood Oral Health Impact Scale (ECOHIS), has been developed and validated first in English in the USA (6) and then validated in French in Quebec (7), Canada. Because of the target age group for this instrument, it is completed by parent proxy rather than directly by the person concerned, as is the case for the large majority of OHRQoL instruments. In the first instance, as with

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the majority of OHRQoL questionnaires for children and adults alike, the ECOHIS was designed and validated to be able to describe oral health problems experienced by infants in the general population and to be able to discriminate between those with different levels of problems (6). Nevertheless, an important additional possible role for such a questionnaire is to be able to evaluate and demonstrate change in OHRQoL within individuals and groups when it occurs. This is particularly pertinent to be able to understand the deterioration and/or improvement in oral health status of infants in a clinical setting when our goal is to measure the outcomes of treatments.

This ability of a measure to validly demonstrate change is known as 'responsiveness' and it is essential to demonstrate an instrument's responsiveness to change prior to using it in a context where change is expected, desired or possible. If the responsiveness to change of an instrument is not demonstrated prior to its application, instrument users cannot be sure whether any change (or lack thereof) apparently demonstrated by the instrument is genuine change (or lack thereof) or measurement error. The goal of the work reported in this paper therefore, was to investigate the responsiveness to change of the ECOHIS. We wanted to investigate responsiveness to change for this instrument rather than other child OHRQoL instruments because we wanted to use it as a secondary outcome indicator in a randomized controlled trial investigating the effects of an intervention designed to prevent dental caries in 6–30-month-old infants. Of the previously validated OHRQoL instruments for children, the ECOHIS is the only one that is appropriate for such young children.

Methodology

Theoretical approach

A number of methodological and analytical approaches to evaluating responsiveness to change have been advocated: (i) comparison of test instrument scores before and after a treatment of known efficacy (8–11); (ii) correlation of test instrument scores in a longitudinal study with those of a similar instrument known to be responsive (12); (iii) comparison of test instrument change scores with a global transition judgment by study subjects in a longitudinal study (8); (iv) an estimation of the sensitivity and specificity of scales (13–15); and (v) assessment of the statistical significance of the within-group change in scores over time for groups that report change and those who report stability (16). An additional element to assessing the responsiveness to change of an instrument is investigating the effect size, wherein widely accepted standards are 0.2 for a small, 0.5 for a medium and 0.8 for a large effect size (17). We adopted approaches (iii), (iv) and (v), in addition to investigating the effect size.

The instrument

This ECOHIS questionnaire (6) consists of 13 questions and has two main parts: part one is the child impact section and part two is the family impact section. In the child impact section, there are four domains: child symptom, child function, child psychology, child self-image and social interaction. In the family impact section, there are two domains: parental distress and family function. The questionnaire is scored using a simple five-point Likert frequency type scale, with responses ranging from 'Never' to 'Very often' (equivalent to scores of 0–4). Item scores are simply added to create a total questionnaire score. This system creates a questionnaire score range of 0–52, with higher scores indicating greater impacts and/or more problems. The domain ranges are: child symptom, one item, range 0–4; child function four items, range 0–16; child psychology, two items, range 0–8; and child self-image and social interaction, 2 items, range 0–8. In our study, the referral time for the questions was the previous 2 weeks.

Study sample

The sample comprised a convenience group of 101 parents of 0–5-year-old children attending a hospital clinic for dental treatment. They were approached and recruited in the waiting area. To be included, caregivers had to live with the child concerned 50% or more of the time and have a 0–5-year-old child with a dental problem. 'Dental problem' was defined through caregivers response to the question 'Does your child have a dental problem that requires treatment?'. The possible responses were 'yes' or 'no' and those responding 'yes' were eligible for recruitment. The assumption was that these parents had already identified a dental problem in their child, for which they had demonstrated an expressed need by attending a dental clinic for treatment. Furthermore, their child was about to receive a dental treatment aimed at addressing the problem, so it was reasonable to

Table 1. Sample sociodemographic and clinical data (mean age = 54.3 months; total n = 94)

Variables	Category	*N*	%
Age groups	6–12 months	1	1.1
	13–24 months	3	3.2
	25–36 months	6	6.4
	>36 months	84	89.4
Gender	Boy	58	61.7
	Girl	36	38.3
Relationship of caregiver to child	Mother	74	78.7
	Father	20	21.3
Child's family yearly income	<$15 000	13	13.8
	$15 000–29 000	27	28.7
	$30 000–49 000	40	42.5
	>$49 000	14	14.9
Last time mother saw dentist	<1 year ago	47	50.0
	1–2 years ago	26	27.7
	2–5 years ago	15	16.0
	>5 years ago	6	6.4
Treatment received	Restoration	81	86.2
	Pulpectomy/ pulpotomy	3	3.2
	Tooth extraction	5	5.3
	Other	5	5.3
Global transition judgement	No change	40	42.6
	Better	48	51.1
	Worse	6	6.4

expect that a significant proportion of this group so recruited would subsequently report a change in the status of that dental problem.

With respect to estimating the sample size required, although there are no guidelines concerning the sample required for assessing responsiveness (18), a sample size requirement of 100 subjects was set based on the need to have complete datasets (baseline and follow-up data) for 70 subjects following loss to follow-up. The sample estimate of 70 was based on seeking an effect size of 0.5 and using the data from the validation study (7) to provide variance information. Socio-demographic data concerning the children and their caregivers are reported in Table 1.

Data collection procedure

Parents agreeing to participate and signing a consent form were asked to complete the 13-item ECOHIS immediately, prior to their child's dental treatment. They were also provided background sociodemographic and clinical information. The parents were then mailed the ECOHIS to complete it a second time, 2 weeks following treatment. They were provided with a stamped, addressed envelope to return the questionnaire and were telephoned to remind them to complete this procedure. Accompanying the mailed ECOHIS was the question 'How has your child's condition changed since before dental treatment?'. The categorical response options were: 'no change', 'got better' and 'got worse'.

Statistical analyses

All analyses were performed on the total ECOHIS scores generated from subject data. Change scores were generated by subtracting the post-treatment score from the pre-treatment score. Subjects could have positive change (i.e. the post-treatment score was lower than the pre-treatment score), indicating an improvement in level of impacts; they could have zero change; or they could have a negative change (i.e. the post-treatment score was higher than the pre-treatment score) indicating a deterioration in the level of impacts.

In order to compare ECOHIS change scores with the global transition judgment by study subjects, we grouped subjects according to how they responded to the question 'How has your child's condition changed since before dental treatment?' ('no change', 'got better' and 'got worse') and compared mean change scores among these groups. Because of the non-normal distribution of the ECOHIS responses, which were skewed towards the no impact end of the scale, we used a Kruskal–Wallis test as well as an ANOVA to compare means. We also assessed the statistical significance of the within-group change in scores for the 'no change', 'got better' and 'got worse' groups using a Wilcoxon signed rank test. In addition, to estimate the effect size, we used the standard formula (mean pre-treatment score – mean post-treatment score/standard deviation of pre-treatment score) suggested by Cohen[17].

Finally, using ECOHIS change scores, we calculated the sensitivity (number of true positives/number of true positives + number of false negatives) and the proportion of false positives (number of false positives/number of false positives + number of true negatives) for the ECOHIS in the study sample.

Results

Analyses were performed using data from 94/101 (93.1%) of the original sample, representing those who had complete (pre- and post-treatment) datasets. Descriptive sociodemographic and clinical statistics for the sample are shown in Table 1. The mean age of the 94 child subjects was 54.3 months,

with a range of 6–60 months. Of particular note is the observation that 51.1% of parents reported an improvement in the condition of their child following treatment, 42.6% reported no change and 6.4% reported deterioration. Also, it is important to note that the large majority were being treated with a restoration for caries. Mean ECOHIS scores in the whole sample for each domain and for the whole scale prior to and following treatment are shown in Table 2. This clearly demonstrates how the data were skewed towards the no impact end of the scale.

Table 3 shows the between-group comparison of pre-treatment, post-treatment and change scores in the 'no change', 'got better' and 'got worse' groups. The table demonstrates that pre-treatment and post-treatment total ECOHIS scores were significantly different in the three groups and that the change scores were different although the statistical significance of the difference varied according to the results of the parametric and nonparametric tests. Looking at the within-group comparisons, Table 4 demonstrates that within the three 'no change', 'got better' and 'got worse' groups, none of the changes were statistically significant. Table 4 also shows the effect sizes, which for the 'no change' and 'got better' groups were small (0.17 and 0.15 respectively), while for the 'got worse' group the effect size (0.69) was moderate to large.

Finally, Table 5 shows the results of the analyses of the sensitivity and proportion of false positives for the ECOHIS when different change scores (from 1–10) are used as cut-offs to indicate a change. The sensitivity ranges from 0.61 when 1 is used to indicate change to 0.79 when 3 is used. The proportion of false positives remained fairly stable for all cut-off points, ranging from 0.44–0.50. Related to this, Table 6 demonstrates the proportion of subjects in the improved, stable and deteriorating categories with different change scores and illustrates that although significant proportions of subjects in each category have appropriate change scores, significant proportions do not. For instance, 41.7% of the group reporting improvement had reduced scores (i.e. reduced impacts) as expected but 25% had no change and 33.4% actually increased their impact level. Similar

Table 2. Mean ECOHIS domain and total scores in the whole sample, pre- and post-treatment

ECOHIS domains (number of items and possible score range)	Pre-treatment mean (±STD)	Post-treatment mean (±STD)
Child symptoms (1 item; range 0–4)	0.7 (±0.1)	0.6 (±0.1)
Child function (4 items; range 0–16)	1.3 (±0.3)	1.4 (±0.3)
Child psychology (2 items; range 0–8)	0.8 (±0.7)	0.7 (±0.5)
Self-image and social interaction (2 items; range 0–8)	0.3 (±0.1)	0.3 (±0.1)
Parental distress (2 items; range 0–8)	1.3 (±0.1)	1.5 (±0.2)
Family function (2 items; range 0–8)	0.5 (±0.2)	0.6 (±0.1)
Total ECOHIS Score (13 items; range 0–52)	4.9 (±0.6)	5.1 (±0.7)

Table 3. Between-group comparisons of mean pre-treatment, post-treatment and change scores in subjects reporting their child's health improved, remained the same or deteriorated

	Better (n = 48) mean (±STD)	Stable (n = 40) mean (±STD)	Worse (n = 6) mean (±STD)	Kruskal–Wallis test (P-value)	ANOVA (p-value)
Pre-treatment	6.1 (±2.3)	2.9 (±1.4)	8.5 (±4.3)	0.022	0.012
Post-treatment	5.2 (±2.1)	3.5 (±2.3)	15.0 (±7.3)	0.025	<0.001
Change scores	−0.9 (±2.1)	0.7 (±1.3)	6.5 (±9.8)	0.129	0.011

Table 4. Within-group comparisons of total scores before and after treatment for subjects reporting their child's health improved, remained the same or deteriorated

Change group category	Mean total score in pre-treatment group (±STD)	Mean total score in post-treatment group (±STD)	Mean change score (±STD)	P value for within-group test	Effect size
Better (n = 48)	6.1 (±2.3)	5.2 (±2.1)	−0.9 (±2.1)	0.37	0.15
Stable (n = 40)	2.9 (±1.4)	3.5 (±2.3)	0.7 (±1.3)	0.39	0.17
Worse (n = 6)	8.5 (±4.3)	15.0 (±7.3)	6.5 (±9.8)	0.19	0.69

Table 5. Sensitivity and proportions of false positives with different cut-off points used as indicators of change for those who improved versus those who did not improve

Change score cut off point	True E[a] change and True TJ[b] change (a)	False E[a] change and True TJ[b] change (b)	True E[a] change and False TJ[b] change (c)	False E[a] change and False TJ[b] change (d)	Sensitivity $a/(a + c)$	% False positives $b/(b + d)$
1	20	28	13	33	0.61	0.46
2	17	31	8	38	0.68	0.45
3	15	33	4	42	0.79	0.44
4	12	36	4	42	0.75	0.46
5	9	39	3	43	0.75	0.48
6	8	40	3	43	0.73	0.48
7	7	41	2	44	0.78	0.48
8	6	42	2	44	0.75	0.49
9	4	44	2	44	0.67	0.50
10	3	45	1	45	0.75	0.50

[a]E = ECOHIS.
[b]TJ = parent's global transition judgement.

Table 6. Distribution of change scores for those who improved, remained stable and deteriorated

Change score	Better (n = 48)	Stable (n = 40)	Worse (n = 6)
>−3	12 (25%)	3 (7.5%)	1 (16.7%)
−1 to −3	8 (16.7%)	9 (22.5%)	0
0	12 (25%)	14 (35%)	1 (16.7%)
+1 to +3	7 (14.6%)	8 (20%)	1 (16.7%)
>+3	9 (18.8%)	6 (15%)	3 (50%)

apparent discordances are evident for the other groups as well.

Discussion

The aim of this study was to investigate the responsiveness to change of the ECOHIS. This instrument has been validated in English (6) and in French (7) as a descriptive measure able to discriminate between groups with different levels of oral health problems. The study we have performed adds to the aforementioned work by providing some evidence to support the responsiveness to change of the ECOHIS. In summary, the change scores did broadly correlate with the global transition judgement of the subjects, although the within-group changes were not statistically significant. Also, the instrument's sensitivity was fairly good, although the effect size estimate for the improving group was small and for the deteriorating group was moderate to large. Furthermore, the number of false positives was high. Together, these findings suggest that the ECOHIS may not be very responsive to within-group changes.

However, when considering the results of this study it is important to discuss the nature of the sample in which we tested the instrument's responsiveness. The sample consisted of parents of 0–5-year-old children, with the large majority being 4–5-years old, attending a hospital dental clinic with a problem requiring dental treatment. The large majority of parents reported low levels of impacts in their children pre-treatment, despite the fact that they reported that their child had a dental problem requiring treatment. There are several possible explanations for this observation: (i) the ECOHIS has been designed to describe oral health in young children in the general population and to discriminate between groups based on their oral health and so may have items less appropriate to a clinical setting, thereby reducing its validity in this setting; (ii) the parents may have reported a problem because they had already been told by a dentist that their child had caries, for instance, although the parent was completely unaware of this as the child was showing no impacts (i.e. the child had clinical disease but no psychosocial impacts); and/or (iii) the parent did perceive psychosocial impacts but these were low level impacts (i.e. the data presented in this study are a genuine representation of an observation that oral health impacts in young children are generally uncommon and not severe). With respect to the second and third possible explanations, it is important to recognize that the vast majority of the sample had carious lesions requiring a restoration and that this problem commonly has no or very low levels of impacts. Also, it is important to consider the exact nature of the question we posed to parents when recruiting them. We asked them

'Does your child have a dental problem that requires treatment?' and left the parents to decide how they wanted to define 'problem'. An alternative approach to ensure all included subjects had a high level of problems could have been to only analyse data from parent/child dyads who reported relatively frequent impacts, e.g. only those with at least one item reported to be occurring 'often' or 'very often'. This would have necessitated recruiting a larger sample but may have provided a better sample to test responsiveness to change.

Whatever the reasons, it is important to note the low level of problems in our sample because a group with low levels of problems pre-treatment cannot be expected to change very much if they improve following treatment. The only way there can be significant change is with significant deterioration in their condition, which should be a relatively rare event in a context in which subjects are receiving dental treatments. Furthermore, it is interesting to note that the group reporting no change had the lowest mean pre-treatment score (2.9 – see Table 3) suggesting that indeed a substantial proportion of the sample in this study had virtually no impacts and so were unlikely to show any change. Thus, as a sample in which we are attempting to demonstrate the responsiveness to change of the ECOHIS, the sample we recruited was perhaps not ideal. Having said that, the sample was of similar type to the age-relevant, clinic-based, convenience sample recruited by others assessing the responsiveness of different OHRQoL instruments (8, 19).

Having acknowledged this potential limitation of the sample, despite the clearly skewed data distribution towards the low impact end of the scale, the instrument did fulfill some of the criteria of being responsive to change. First, it has already been demonstrated that the instrument has good reliability (6, 7). Second, among those parents reporting an improvement with the global transition judgement, the mean change score was −0.9, indicating a small (statistically insignificant) reduction in impacts. As previously alluded to, given the already low level of impacts, a more impressive reduction would have been difficult, although the effect size was small. However, for the group that reported getting worse following treatment, there was a large mean change score of +6.5 and a moderate-to-large effect size. This remained statistically insignificant, although this is not surprising given this group numbered only six subjects. This suggests that a much larger sample is required to be able to generate improving, stable and deteriorating subgroups, within two of whom we wish to see statistically significant changes in the hypothesised directions. This need for a larger sample size is compounded by the skewed distribution of the data, which we have observed in our study and was observed in the development of the original ECOHIS instrument (6, 7). This is important to note for those considering the possibility of using the ECOHIS as a primary outcome measure to generate a sample size requirement in a clinical trial.

Beyond these results, the sensitivity of the ECOHIS was fairly good. The data in Table 5 suggest that the best balance between high sensitivity and low rates of false positive evaluations is with a cut-off of 3 points when the sensitivity was 0.79 and the rate of false positives was 0.44. This indicates good sensitivity but a relatively high rate of false positive findings. These indicators compare positively with findings for the OHIP-14 and OHIP-49 (8, 19), two of the most widely used OHRQoL instruments. The data in Table 6 illustrate well how, although the ECOHIS has demonstrated some ability to be responsive to change on a group level, at an individual level, the instrument is rather imprecise. Thus, while the ECOHIS may be sufficiently responsive to have a role in research comparing OHRQoL in different infant groups, based on the evidence of our study it does not appear to be sufficiently precise to be used in a clinic setting. This is not surprising, as this purpose is far from the original one for which the ECOHIS was designed.

In conclusion, we have performed a study to investigate the responsiveness to change of the ECOHIS and found that despite the low level of impacts reported by the sample prior to dental treatment (and hence the low level of need for change), the instrument has shown some attributes as a responsive instrument, although other indicators raised questions concerning responsiveness. In other words, the findings from this work are somewhat equivocal and more research in a larger sample with higher levels of impacts would be helpful in further investigating the responsiveness of the ECOHIS.

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