

# Evaluation of a generic quality of life instrument for early childhood caries-related pain

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Abstract - Objective: This prospective study evaluated the reliability and validity of the Infant and Toddler Child Quality of Life Questionnaire (ITOOL) by comparing quality of life (QOL) of two groups of children afflicted with early childhood dental caries with a caries-free group. Methods: A convenience sample of 150 children divided into three groups (mean age [months]  $51 \pm 15$ ) was studied. Group I (OR) had extensive dental caries and were waiting for several months for treatment under general anesthesia. Group II were children who sought emergency services for acute odontogenic pain/abscess, and group III were children who were caries-free new patients. Parents/caretakers were administered the ITQOL, which assesses a child's physical, emotional and social well being from the parent/guardian's perspective. Results: The ITQOL had high success in item validity with good reliability. Significant differences in QOL were noted for scales of pain and discomfort, behavior and moods, global behavior, and impact on parental time ( $P \le 0.05$ ) among the three groups. No significant differences were noted for scales of growth and development, general health and impact on parents' emotional and mental health. Conclusions: The ITQOL proved to be a useful instrument for characterizing QOL in this dental caries-afflicted sample. Overall, children with chronic and acute dental caries had a poorer QOL than caries-free children in areas of behavior, mood, pain and parental impact.

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## Introduction

The 2000 United States Surgeon General's report identified limited access to care as a major barrier to oral health (1). Underserved, preschool-age children may experience pain from carious or abscessed teeth often requiring urgent treatment. Lewis and Nowak surveyed pediatric dental programs and found emergency patients increased over 5 years by 76% with an increase in pre-school children (2).

Many with dental pain do not receive care because of cultural issues, lack of dental coverage, or unwillingness of providers (3, 4). Research on how dental pain affects daily family, social and psychological functioning in children is limited. Frequent school absences, inability to concentrate in school, reduced self-esteem, poor social relationships, failure to thrive, impaired speech development, and inadequate diet result from dental caries or related pain (4).

The effect of pain from chronic medical conditions on quality of life (QOL) has been studied extensively (5–7) Children with headaches are more sensitive to pain, cry more during routine medical visits, avoid play and games because of fear of self-injury, and have more frequent abdominal pain and growing pains than other children (6). Children with cerebral palsy, and chronic tonsil and adenoid disease suffer poorer QOL than healthy children (5, 7).

Self-report of pain is always preferred, but not always achievable in preschool children because of

limited communication. Postoperative pain studies show a parent's perception of a child's pain varies from that of a medical professional (8–10).

Few studies of pediatric dental pain and its effects on QOL, development, and family function have used a standardized instrument applied to other health conditions (11, 12). Without a reference measure, dental pain, and suffering are difficult to frame against other forms of acute and chronic childhood illness for issues, such as allocation of resources, pharmacologic management, and health policy. This study tried to ascertain reliability and validity of the ITQOL, a validated instrument for evaluating the effect of disease on pediatric QOL (13–15), in assessing caries-related dental pain, by comparing preschool-age children afflicted with acute and chronic dental pain with caries-free children.

#### Methods

Subjects enrolled in this study constituted a convenience sample of patients attending Columbus Children's Hospital Dental Clinic (CCHDC), and Ohio State University College of Dentistry (OSUCD). The sample size was designed to detect a 1.2 standard deviation difference between groups with a Tukey adjusted alpha = 0.05. Families were approached by the principal investigator (JE) for participation at examination or treatment visits and provided informed consent. The study was approved by the Human Subjects Committee of Columbus Children's Hospital.

Children were classified by principal investigator or trained assistants into three naturally emerging groups, based on duration, type or absence of dental pain. Group I, operating room group (OR), comprised children with extensive dental caries waiting for treatment under general anesthesia (usually greater than 6 months). These children were hypothesized to have chronic dental pain, based on extent of dental caries and delay in treatment. Group II, emergency group (ER), were children attending CCHDC for emergency dental services. These children had acute pain from dental caries and received emergency care at their visit. Group III, cariesfree group (CF), comprised children attending CCHDC hygiene department as new patients with no previous dental experience, and upon clinical and radiographic examination by a dentist, were deemed caries-free.

Children in all three groups were 2–6 years or age, of either gender, healthy (ASA1), taking no long-term medications, and had Englishspeaking primary caregivers. Subjects were continuously enrolled, with a goal of 50 children in each group. No attempt was made to quantify dental caries in OR and ER groups as a variable in this study because of difficulty in obtaining diagnostic radiographs and a detailed examination.

The Infant/Toddler Quality of Life Questionnaire (ITQOL) is a parent-self-completed generic 'profile measure' (i.e., with 10 multi-item and 2 single-item scales) to assess health-related QOL of children 2 months-5-years old (15). The ITQOL adopts the World Health Organization's definition of health as a state of complete physical, mental and social well-being and not merely absence of disease (16), and incorporates results of a review of child health literature and developmental guidelines used by pediatricians (17). Using Likert-type format (18) and graduated response continuum, the ITQOL measures physical function, growth and development, bodily pain, temperament and moods, behavior and general health perceptions. The ITQOL also includes scales to measure parental impact (time and emotions). Lower scores on a scale indicate higher severity. Table 1 provides a brief summary of the scales and their general content.

#### Method of administration

Once eligible, the primary caretaker received a limited explanation about questionnaire completion, as described in the ITQOL User's Manual, from the principal investigator (JE) or one of two trained dental assistants. For all groups, parents completed the questionnaire before their child received any treatment, to avoid bias.

#### Analytic methods

Data were entered into an Excel spreadsheet for analysis. The psychometric underpinnings of the developmental pre-release 103-item Infant Toddler Quality of Life Questionnaire (ITQOL) was evaluated using MAP-R, a confirmatory factor analytic program (19). In addition to examining the internal consistency or correlation of items, the multi-trait method extends exploratory factor analysis by examining the discriminant validity of items. Given that items are expected to be related, for the purposes of scoring and interpretation, it is important to quantify the degree to which items correlate

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	No. of items	General content
	nemo	
Infant concepts		
Physical abilities	10	Amount of limitation in physical activities, such as eating, sleeping, grasping, and playing due to health problems
Growth and development	10	Satisfaction with development (physical growth, motor, language, cognitive), habits (eating, feeding, sleeping) and overall temperament
Bodily pain/discomfort	3	Amount, frequency of bodily pain/discomfort and the extent to which pain/discomfort interferes with normal activities
Temperament and moods	18	Frequency of certain moods and temperaments, such as sleeping/eating difficulties, crankiness, fussiness, unresponsiveness, playfulness and alertness
General behavior perceptions	13	Perceptions of current, past and future behavior
Getting along with others	15	Frequency of behavior problems, such as following directions, hitting, biting others, throwing tantrums, and easily distracted. Frequency of positive behaviors, such as ability to cooperate, appears to be sorry, and adjusts to new situations
General Health Perceptions	12	Perceptions of current, past and future health
Change in health	1	Perceptions of changes in health over the past year
Parent concepts		
Impact-emotional	7	Amount of worry experienced by parent due to child's eating/sleeping habits, physical and emotional well-being, learning abilities, temperament, behavior and ability to interact with others in an age-appropriate manner
Impact-time	7	Amount of time limitations experienced by parent (time for his/her own needs) due to child's eating/sleeping habits, physical and emotional well-being, learning abilities, temperament, behavior and ability to interact with others in an age-appropriate manner
Mental health	5	Parent's general mental health, including depression, anxiety, behavioral-emotional control, and general positive affect
General health	1	Rating of parent's overall health
Family cohesion	1	Rating of family's ability to get along with one another

Table 1. Infant toddler q	uality of life	questionnaire –	general content
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with other items in their assigned set or scale relative to other items in the module. All computations were performed using the Revised Multitrait Analysis Program (MAP-R) for DOS (19).

Specifically, MAP-R performs tests of scaling assumptions using the following criteria. First, each item in a hypothesized scale must be substantially linearly related to the underlying concept being measured (tests of item internal consistency). An item-scale correlation, corrected for overlap, of 0.40 or above has been recommended (20).

Second, each item should correlate significantly higher with its hypothesized scale than with other scales in the same matrix (tests of item discriminant validity). To satisfy the item discriminant validity criterion, the correlation between an item and its hypothesized scale must be significant. The convention, based on a standard error of 0.04, is a magnitude of two standard errors higher than its correlation with other scales (21). For new scales, however, it is acceptable to extend the criteria for tests of discriminant validity such that a 'success' is counted if the correlation of an item to its hypothesized scale was at least one standard error higher than correlations with other scales (22).

Finally, floor and ceiling effects – the percentage of children achieving the lowest and the highest possible scores, respectively – were assessed.

Reliability is a function of the average correlation among items. Since it is possible for a measure to appear quite stable over time, but not be internally consistent, test–retest is not recommended as a method of choice to estimate reliability (23). Thus, the internal consistency and reliability for the ITQOL scales were estimated using the Cronbach Alpha coefficient (24).

Scales with reliabilities of at least 0.70 and greater are sufficiently reliable for use with group comparisons (23, 25). The Alpha coefficient represents the average of all possible split-half reliability estimates adjusting for scale length and has been shown to approximate test–retest estimates when scaling assumptions are met.

## Results

#### Sample characteristics

Characteristics of parents and children are shown in Table 2. The mean age of all children (months) was 51 (±15), with the OR group 48 ± 11, ER group 56 ± 16, and the CF group 49 ± 17. The ER group was about 9 months older than the OR group, (P < 0.01). Forty-eight percent were female. Parents' mean ages (years) in the OR, ER, and CF groups were 30 ± 7, 29 ± 6, and 34 ± 8, respectively. Difference in parental age of approximately 6 years between CF and ER groups only, was statistically significant (P < 0.01). Parent gender was overwhelmingly (89%) female.

A statistically significant difference was noted in level of parental education attained between OR and CF groups, and between ER and the CF groups, respectively (P < 0.01). Only 1 of 50 parents in the CF group had not finished high school compared to about 10 times that many in OR and ER groups (22%, 20%, respectively). In the OR group, only three out of 50 (6.5%) parents had a college degree compared with 1 out of 50 (2%) in the ER group, and 7 out of 50 (14%) in the CF group. Parents of children in the CF group had a higher level of education than parents in the OR then ER groups, respectively.

#### Multi-trait item scaling findings

It has been recommended that item-scaling analysis is not appropriate for single items. Therefore, item-scaling tests were performed for the 10 multiitem scales that constitute the ITQOL. Subjects scoring 'not yet doing' on the physical activities scale were omitted for consistency in sample size across all scales for the multi-trait analysis. A further stringent criterion was used such that respondents had to have at least half the items for each of the scales in order to be in the analysis. Thus, of the 130 remaining eligible respondents, 15 subjects (12%) were omitted. Thus, scaling analysis was performed for 115 subjects. The standard error for the study sample, which is based on sample size, was 0.09.

## *Item convergent validity/item discriminant validity*

Findings for these two criteria are presented in Table 3, Columns 2 and 3. Column 4 presents the number of 'successful' correlations over the number of tests performed. The percentage of scaling success observed using tests of item discriminant validity are summarized in column 5.

Success rates were very high. Perfect or near perfect (≥98%) rates of success were observed for seven scales. Lower, but satisfactory percentages were observed for the remaining three scales – General Health, Getting Along and Temperament and Moods (89%, 93%, 93%, respectively).

*Reliability*: Reliability estimates are presented in Table 4. The median observed alpha coefficient was 0.84 and all coefficients exceeded the minimum criterion for group level analysis (range 0.77–0.98).

*Floor/ceiling effects*: Findings for these two criteria are presented in Table 5. Minimal floor effects were observed for a single scale (physical abilities 1.7%). However, substantial ceiling effects were also observed for this scale (71%). Moderate effects were observed for Impact on Parent Time (36%), Growth and Development (35%). Overall, these findings suggest that ITQOL scales performed well in the dental sample.

To further assess the ITQOL, analysis of variance (ANOVA) was performed using SPSS V10. Specifically, we examined differences in scales scores for children according to three 'severity' classifications, described earlier. We predicted that scale scores for the three groups would be relatively equal for QOL concepts, such as overall health,

Table 2. Parent education and child and parent age for three groups

Table 2. Parent education and child	and parent age for t	three groups		
Characteristic	Group I (OR) n = 50	Group II (ER) n = 50	Group III (CF) n = 50	Significance
Parent age (years) Mean ± SD	$30 \pm 7$	29 ± 6	34 ± 8	0.002
Patient age (months) mean $\pm$ SD	Mean 48 ± 11	$56 \pm 16$	$49 \pm 17$	0.012
Parent education (highest				
achieved) (%)				
< High school	22	20	2	OR versus CF*
High school	47	44	44	
Vocational	22	30	30	
College	6.5	2	14	ER versus CF*
Graduate	2.2	4	10	

\*Significant at 0.01.

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Table 3. Results of the item-scaling tests for the infant/toddler QOL scales

	Item internal consistency <sup>a</sup> $(n = 133)^*$	Item discriminant validity <sup>b</sup> $(n = 133)^*$	Success/total <sup>c</sup> $(n = 133)^*$	% Scaling success <sup>d</sup> $(n = 133)^*$
Infant/toddler scales				
Physical abilities $(k = 10)e$	0.7-1.0	-0.2-0.3	90/90	100
Growth and development ( $k = 10$ )	0.3–0.7	-0.1-0.4	89/90	99
Discomfort and pain $(k = 3)$	0.6–0.7	-0.05-0.6	27/27	100
Temperament and moods $(k = 18)$	0.2–0.7	-0.1-0.6	151/162	93
Global behavior ( $k = 12$ )	0.4–0.7	-0.1-0.6	107/108	99
Getting along with others $(k = 15)$	0.2-0.67	-0.3-0.1	126/135	93
General health ( $k = 11$ )	-0.2-0.7	-0.2-0.5	88/99	89
Parent mental health $(k = 5)$	0.5–0.6	-0.2-0.5	45/45	100
Parent impact-emotional $(k = 7)$	0.3–0.7	-0.1-0.5	62/63	98
Parent impact-time ( $k = 7$ )	0.4–0.8	-0.2-0.5	62/63	98

<sup>a</sup>Range of correlations between items within a hypothesized scale, rounded to nearest tenth.

<sup>b</sup>Range of correlations between items and other scales, rounded to nearest tenth.

<sup>c</sup>Success (numerator) refers to items that correlate > 1 SE higher with their hypothesized scale than with other scales. Total (denominator) refers to the number of items in a scale multiplied by the number of other scales in the matrix <sup>d</sup>Percentage of items correlating higher with their hypothesized scale than with other scales.

 $e_k$  = number of items in that scale.

\*Those scored as 'not yet doing = 9' in PA scale (n = 3) not included in MAPR analysis. Remaining subjects (n = 130) had to have at least 50% of items for each scale to be included in analysis (missing n = 15 (11.5%).

Table 4. The reliability<sup>a</sup> estimates for the infant/toddler QOL scales  $n = 133^*$ 

Infant/toddler scales	Coefficient alpha ( $n = 136$ )
Physical abilities $(k = 10)^{b}$	1.0
Growth and development ( $k = 10$ )	0.8
Discomfort and pain $(k = 3)$	0.8
Temperament and moods $(k = 18)$	0.9
Global behavior ( $k = 12$ )	0.9
Getting along with others $(k = 15)$	0.8
General health ( $k = 11$ )	0.8
Parent mental health $(k = 5)$	0.8
Parent impact-emotional $(k = 7)$	0.8
Parent impact-time ( $k = 7$ )	0.8

<sup>a</sup>Internal consistency reliability (Cronbach's alpha), rounded to nearest tenth.

 ${}^{\mathrm{b}}k$ , number of items in the scale.

\*Those scored as 'not yet doing = 9' in PA scale (n = 3) not included in MAPR analysis. Remaining subjects (n = 130) had to have at least 50% of items for each scale to be included in analysis (missing n = 15 (11.5%).

overall growth and development, physical abilities and the child's ability to get along with others. For other key concepts such as pain, temperament and behavior, we anticipated that the caries-free group would report the highest scores and families of children with chronic decay would have learned to cope with ongoing pain and experience less impact in the three key dimensions relative to the final group. Thus, the lowest scores were expected for pain, temperament and overall behavior for children whose pain was so severe and acute that they sought emergency treatment. We also anticipated

Table 5. Summary of the floor and ceiling effects for the infant/toddler QOL scales ( $n = 133^*$ )

Infant/toddler scales	% Floor	% Ceiling
Physical abilities ( $k = 10$ )	1.7	71
Growth and development ( $k = 10$ )	0	35
Discomfort and pain $(k = 3)$	0	22
Temperament and moods $(k = 18)$	0	3
Global behavior ( $k = 12$ )	0	1
Getting along with others ( $k = 15$ )	0	0
General health ( $k = 11$ )	0	3
Parent mental health $(k = 5)$	0	3
Parent impact-emotional $(k = 7)$	0	17
Parent impact-time $(k = 7)$	0	36

\*Those scored as 'not yet doing = 9' in PA scale (n = 3) not included in MAPR analysis. Remaining subjects (n = 130) had to have at least 50% of items for each scale to be included in analysis (missing n = 15 (11.5%). % ceiling rounded to nearest whole number.

that the impact on parental time and overall cohesion in the family might be more adverse for the latter classification due to upheaval in routine and difficulty in obtaining care.

As anticipated, scale scores for general concepts such as general health, physical ability and growth and development were comparable across all three dental severity classifications. Conversely, statistically significant differences were observed for three ITQOL scales – Discomfort and Pain, Temperament and Moods, and Overall Behavior. As expected, lowest scores for these concepts were reported for the emergency room children. Table 6 provides mean scale scores for the three groups.

Table 6. Infant/toddler QOL scale score means (and SD) based on dental severity classifications\*

Infant/toddler scales	Caries-free $(n = 33)$	Chronic decay $(n = 42)$	Acute ER visit $(n = 50)$	<i>P</i> -value
Physical abilities	96.2 (16.7)	87.5 (28.4)	89.4 (25.8)	0.31
Growth and development	94.2 (6.2)	91.6(12.0)	92.6 (10.3)	0.56
Discomfort and pain	84.6 (14.5)	79.3 (19.7)	55.8 (26.0)	0.00**
Temperament and moods	81.0 (12.5)	76.1 (11.2)	66.2 (17.4)	0.00**
Global behavior	71.9 (18.8)	61.2 (18.8)	66.1 (17.1)	0.04**
Getting along with others	70.0 (16.8)	65.9(14.6)	65.5 (14.8)	0.38
General health	71.1 (20.9)	72.1 (16.0)	64.6 (18.8)	0.12
Parent mental health	63.3 (22.3)	63.9 (17.8)	65.7 (20.4)	0.86
Parent impact-emotional	84.9 (14.3)	78.0 (20.3)	75.6 (20.2)	0.13
Parent impact-time	86.0 (18.4)	90.5 (12.6)	80.8 (22.9)	0.05

\*Subjects had to have at least 50% of items for each scale to be included in analysis.

\*\*Significant difference observed between groups.

#### Discussion

The aim of the study was to evaluate suitability of the ITQOL to measure QOL in children affected by pain of dental caries. Other specific oral health measurement tools may detail the unique impact of dental caries on QOL, but not offer a useful relative scale against other childhood conditions. The utility of a measure that can be weighted for purposes of policy making, resource allocation, and research purposes prompted us to test the ITQOL.

The study had limitations of a cross-sectional study using a convenience sample. While all children were selected from the same pool seen initially at Children's Hospital and Ohio State University, no attempt was made to quantify socioeconomic status because those data were not readily available. We also relied on parents to interpret questions. The ITQOL does not allow explanation bias by an interviewer, and we complied with the instructions.

We found the ITQOL to be a good tool for measuring caries pain-related QOL. Scaling success was perfect or near perfect for 7 of 10 scales, reliability as measure by alpha exceeded the minimum criterion for group level analysis, and floor/ceiling effects were good. In future studies of pediatric dental caries pain or treatment outcomes, the ITQOL should be considered. In addition, future studies should look at QOL pre- and posttreatment to determine its sensitivity.

Children can suffer from either acute or chronic dental caries-related pain, so we anticipated that a different QOL would be experienced by those with either acute or chronic dental caries compared to those caries-free. Further, we felt that children with acute dental pain (i.e., ER group), would have the poorest QOL because their pain is active. Children believed to have chronic pain (i.e., OR group), may have transitioned through an earlier period of acute discomfort but learned to cope to some degree with antibiotics or periodic emergency care. Because of the visit required for placement on a general anesthesia waiting list, these families would have been counseled to manage pain, keeping it under a threshold that affected certain parameters on the ITQOL. A third group (i.e., CF) had no caries-related pain, no previous dental disease or treatment, and should have had no diminished QOL due to dental disease. Thus, by attempting to choose subjects of similar age, good general health and a similar socioeconomic range, we felt differences in QOL indices could be reliably attributed to dental pain. The findings presented in Table 6 support this hierarchy of pain effect among the three groups. However, it should be noted that there may have been other contributing factors to the scores, such as differences in development of the children — at this young age a year's variation can affect behavior. We also did not assess in any detail the living situations which may have affected scores.

Our results suggest that acute pain should not be overlooked when evaluating the impact of early childhood caries. The most impressive effects were on pain, behavior, moods and parental time, while other parameters were not affected, even in the chronic disease state. The ITQOL has profiled the pattern of effect on QOL of other childhood illnesses, each with its own complexion (5–7). A useful outcome of this study may be to characterize the unique footprint of acute caries-related dental pain against other common childhood conditions. Reliance on long-term measures or measures that speak only to oral health-related QOL, may understate the impact of this condition because of adaptation we found in our OR group. Future studies of oral disease's impact on quality of life perhaps should include both oral-directed and general health-directed quality of life measures. This would begin to place the public health impact of dental caries pain in some larger perspective.

Another important clinical corollary of our findings is that a dental home, even defined as a place to seek emergency and episodic care, is better than none at all. Our OR group had dental caries levels equal to or exceeding those of the ER group, based on our institutional criteria for assignment to operating room care. However, because these families had been instructed how to obtain emergency care, pain medication and antibiotics to manage subsequent pain, they appeared to have mediated the effect of caries on their QOL.

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