

Assessing Health-Related Quality of Life in Children with Recurrent Headache: Reliability and Validity of the PedsQL™ 4.0 in a Pediatric Headache Sample

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Objective To evaluate the reliability and validity of a commonly used measure of health-related quality of life (HRQOL), the Pediatric Quality of Life Inventory (PedsQL™ 4.0), in a sample of children with a recurrent headache syndrome. **Methods** Participants were 40 children aged 7–12 who completed measures of HRQOL, headache-related disability, and headache activity during a baseline period and following a self-directed cognitive-behavioral intervention. **Results** The data are supportive of the reliability (internal consistency and test-retest) and validity (criterion related, convergent, known-groups, and responsiveness to intervention) of the PedsQL™ 4.0 within a pediatric headache sample. **Conclusions** We conclude that the PedsQL™ 4.0 is a reliable and valid measure of HRQOL in children with recurrent headache and captures important information not routinely evaluated in chronic pain populations.

Key words child; headache disorders; migraine; quality of life; tension headache.

Recurrent headache is one of the most common and disabling pain conditions in children and adolescents, often causing marked impairments in physical, academic, and social functioning both between and during headache attacks (Holden, Levy, Deichmann, & Gladstein, 1998). Recent evidence indicates that recurrent headache may produce more pain and have a greater impact on functioning than many chronic diseases in children such as idiopathic arthritis and sickle cell disease (Peterson & Palermo, 2004). Nevertheless, empirical attention to the impact of this pervasive condition lags behind that devoted to other chronic illnesses in children. This gap in knowledge has recently prompted the World Health Organization to announce a global campaign (“Lifting the Burden”) designed to facilitate efforts toward quantifying and reducing the adverse effects of recurrent headache on the lives of individuals affected by this condition (Steiner, 2004). Given that the initiation of recurrent headache syndromes typically begins between the ages of 7 and 12 (Bille, 1981; Stewart, Lipton, Celentano, & Reed, 1992),

it follows that the impact of chronic headaches should be evaluated and treated early on.

The impact of chronic illness on the lives of individuals with these conditions is generally assessed through health-related quality of life (HRQOL). This construct is defined as an individual’s subjective perception of his or her functioning and emotional state vis-a-vis the effects of disease and treatment. A commonly used HRQOL measure in the pediatric literature is the Pediatric Quality of Life Inventory (PedsQL™ 4.0) (Varni, Seid, & Kurtin, 2001), which has been evaluated in several pediatric chronic illness samples (Varni et al., 2001; Varni, Seid, Knight, Burwinkle et al., 2002; Varni, Seid, Knight, Uzark, & Szer, 2002) but has been generally neglected in chronic pain samples. Although the PedsQL™ 4.0 has been evaluated in one study of pediatric headache patients and was found to characterize a significant negative impact of chronic headaches on the quality of life of children (Powers, Patton, Hommel, & Hershey, 2003, 2004), to date no study has evaluated this measure

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prospectively to evaluate reliability over time, validity related to daily reports of the impact of headache, and responsiveness to treatment effects.

The purpose of this study was to determine whether the generic version of the PedsQL™ 4.0 is capable of reliably and validly assessing the construct of HRQOL in a sample of children being evaluated and treated for a recurrent pediatric headache syndrome. Through incorporating a headache-specific comparison measure evaluating the related construct of disability (the Pediatric Migraine Disability Assessment Scale; Hershey et al. 2001) and using daily headache diaries to track the severity of headache at baseline and following a psychosocial intervention, we sought to determine whether the generic PedsQL™ 4.0 could provide accurate, reliable, and clinically important information about the psychosocial burden of headache in children.

Method

Participants

Participants were 40 children (20 M, 20 F) between the ages of 7 and 12 years ($M = 10.00$, $SD = 1.60$) who attended the outpatient neurology clinic at a large children's hospital. This age range captures the typical age of onset of recurrent headache. Most of the children were Caucasian (82.5%) consistent with the general trend in the literature (Stewart, Lipton, & Liberman, 1996). The remainder of the self-identified ethnic breakdown was as follows: 10.0% Hispanic (White), 5.0% African-American, and 2.5% Asian-American.

Most of the participants had recurrent migraine (72.5%), followed by chronic daily headache (22.5%) and episodic tension-type headache (5.0%) as diagnosed by a board-certified neurologist. The median reported symptom duration based on caregiver report was 12.00 months (ranging from 1 month to 60 months; $SD = 27.27$). Headaches had to occur at an average frequency of at least four times monthly per caregiver or child report for participation in the treatment study from which these data are taken. Children were deemed otherwise healthy by means of a medical history and physical examination.

Exclusion criteria were history of significant developmental delay or psychological issues that may have impeded ability to complete study requirements. Children having concurrent chronic or acute illness or taking other medication that might confound responses to assessments were excluded. Children who were non-English speaking were also excluded from participation. Children provided signed assent, and their legal guardians signed a consent form approved by the institutional review boards of the

participating institutions. Of the 70 children approached for recruitment into this study, 15 did not meet headache frequency inclusion criteria for the treatment study, nine refused to participate due to time constraints, three had a history of seizure, and three were non-English speaking.

Measures

HRQOL

The fourth edition of the Pediatric Quality of Life Inventory (PedsQL™ 4.0; Varni et al., 2001) requires children to report on various aspects of physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and school functioning (5 items). Respondents indicate the extent to which they are having problems in each of these areas using a (0, "never a problem" to 4, "almost always a problem") response scale. Items are then reverse scored and linearly transformed to a 0–100 scale such that higher scores indicate better HRQOL. Data from the total scale score as well as the psychosocial and physical health summary scores were used for analyses in this study. Much research evidence supports the reliability, validity, and responsiveness to treatment of the PedsQL™ 4.0 in pediatric chronic illness populations (Varni et al., 2001; Varni, Seid, Knight, Burwinkle et al., 2002; Varni, Seid, Knight, Uzark et al., 2002).

Headache-Related Disability

We included a headache-specific measure of disability in this study to assess convergent validity of the PedsQL™ 4.0 in a headache sample. The PedsMIDAS is a developmentally sensitive six-item questionnaire quantifying the level of headache-related disability in the past month at school, at home, and at sports and social activities. Research has supported the reliability and validity of this measure in pediatric headache patients (Hershey et al., 2001).

Headache Activity

Participants recorded the occurrence, duration (in hours), and severity (impact on functioning using a scale ranging from 0, "no headache," to 5, "I could not do anything") of headache activity at the end of each day. Information from the diaries on average baseline headache severity per episode was used to assess criterion-related validity of the PedsQL™ 4.0.

Procedure

This study was part of another investigation assessing the efficacy of a self-directed pain management program for recurrent pediatric headache. Baseline data from the intervention study were used to evaluate the reliability

and validity of the PedsQL™ 4.0 in the pediatric headache sample, and follow-up data were used to evaluate the responsiveness of the measure. Children were recruited for the study by research staff during their initial appointment at an outpatient neurology clinic. Following a brief screening interview to ensure whether inclusion criteria were met, the study was discussed with the child and caregiver, and consent/assent was obtained from those families interested in participating. Participants completed baseline questionnaires and were given packets to take home containing 14 baseline diaries, additional questionnaires for the end of the baseline period, and postage-paid return envelopes. Families were called each week to see whether they had any questions regarding completing the diaries and to encourage completion. Families were also told that they would be paid \$10 for completing each packet of diaries (for a total of \$50 per family over 5 months).

Children were then randomly assigned to a wait-list control condition or a self-directed computer-based intervention containing cognitive-behavioral treatments (i.e., relaxation training, cognitive coping skills, and behavioral pain management strategies). The child worked through the intervention over the course of 4 weeks. Participants in both groups were contacted weekly by phone to encourage adherence. Follow-up data were collected for 3 months post-intervention. Participants continued to submit daily diaries weekly via prepaid mail during the follow-up period and submitted the questionnaires at the end of each month.

Data Analysis

Missing data on the PedsQL™ 4.0 were limited to occasional skipped questions (3.5% of the PedsQL™ 4.0 data over all administrations) and handled according to the standardized instructions of the authors of the scale (i.e., subscale mean imputation). Within-case mean

imputation was used to complete the missing at random daily headache diary data (2.9% of the total diary data).

Internal consistency estimates of reliability using Cronbach's alpha (Cronbach, 1951) were computed on the PedsQL™ 4.0 total scale and summary scales (psychosocial and physical functioning) data for both caregiver and child versions. Two-week test-retest estimates of total scale score reliability using the Pearson correlation coefficient also were computed at baseline for the collapsed sample. Criterion-related validity (evaluated concurrently) was examined by using baseline headache severity diary data (assessing the degree to which the respondent globally perceives the headache to interfere with daily functioning) as the external criteria and correlating these data with the child PedsQL™ 4.0 summary scales. Convergent validity was assessed by computing validity coefficients between the total scale scores of the PedsMIDAS and the PedsQL™ 4.0 summary scales. Known-groups construct validity was computed via one-sample *t* tests comparing the baseline data from the pediatric headache sample to those of a healthy norm group using normative data from Varni et al. (2001). Finally, we examined the responsiveness of the PedsQL™ 4.0 to changes in HRQOL from baseline through 3-month follow-up resulting from a self-directed cognitive-behavioral pain management program. Responsiveness was calculated by computing dependent *t* tests within the treatment group between baseline and 3-month follow-up evaluations. We used Holm's (1979) sequential Bonferroni method within each validity analysis to maintain family-wise Type I error at $\alpha = .05$.

Results

Table I provides a summary of the reliability and validity analyses of the PedsQL™ 4.0 in the current sample. As summarized in Table I, internal consistency estimates of

Table I. Estimates of Reliability and Validity for the PedsQL™ 4.0

Measure	α	Criterion related (<i>r</i>)	Convergent (<i>r</i>)	Known-groups (<i>t</i>)		Responsiveness (<i>t</i>)	
				Sample <i>M</i> (SD)	Normal <i>M</i> (SD)	Baseline <i>M</i> (SD)	Three-month <i>M</i> (SD)
PedsQL™ 4.0 total scale score	.92	-.54*	-.47*	70.73* (17.13)	83.00 (14.79)	68.26 (15.24)	79.46* (9.61)
PedsQL™ 4.0 physical functioning score	.89	-.38*	-.32*	72.28* (21.23)	84.41 (17.26)	67.81 (16.68)	82.73* (12.43)
PedsQL™ 4.0 psychosocial functioning score	.88	-.57*	-.49*	69.83* (17.78)	82.38 (15.51)	68.49 (16.05)	77.72* (10.60)

Criterion-related and convergent validity were assessed by correlating the Pediatric Quality of Life Inventory (PedsQL™ 4.0) scales with headache severity data and the PedsMIDAS total scale score at baseline, respectively. Known-groups validity was assessed by computing one-sample *t*-statistics evaluating data from the current sample against data from the normative healthy comparison group reported in Varni et al. (2001). Responsiveness to change was assessed within the treatment group only by computing dependent *t*-statistics evaluating changes in the PedsQL™ 4.0 from baseline to 3-month follow-up subsequent to a self-directed cognitive-behavioral treatment. *Significant at the adjusted alpha level using the Holm's sequential Bonferroni method (highest *p*-value tested against .017, next highest *p*-value tested against .025, and the final *p*-value tested against .05).

reliability were found to be very good to excellent (average Cronbach $\alpha = .89$). Test–retest values for the 2 week baseline interval were found to be very good as well ($r = .86, p < .01$).

Results for criterion-related validity showed that each of the summary scales on the PedsQL™ 4.0 was significantly related to average headache severity in the expected direction at the corrected alpha levels (r ranged from $-.38$ to $-.57$), suggesting good concurrent validity. Convergent validity was supported as well through significant correlations between the PedsQL™ 4.0 scales and the PedsMIDAS total scale score in the expected direction (i.e., lower HRQOL was related to higher headache-related disability).

Each of the PedsQL™ 4.0 summary scales was significantly different from the normative population estimate, which supports known-groups validity of the measure. Compared to the normative data, children in our headache sample on average had significantly lower total scale scores, $t(39) = 4.53, p < .01$, physical functioning scores, $t(39) = 3.61, p < .01$, and psychosocial functioning scores, $t(39) = 4.46, p < .01$, indicating that the population values for children with headache significantly differ from those suggested by healthy children. Effect sizes using Cohen's d statistic were found to be large, ranging from .57 for the physical functioning scale to .71 for both the total and psychosocial functioning scales.

Responsiveness to treatment was also supported. By the end of the 3-month follow-up period, participants receiving a self-directed cognitive-behavioral pain management intervention on average demonstrated significant improvements on the PedsQL™ 4.0 total scale, $t(18) = 3.03, p < .01$, physical functioning scale, $t(18) = 3.07, p < .01$, and psychosocial functioning scale, $t(18) = 2.77, p = .01$. Effect sizes computed by Cohen's d statistic were moderate to large, ranging from .63 for the psychosocial functioning scale to .71 for the physical functioning scale.

Discussion

Analyses in the current study indicated that the PedsQL™ 4.0 is a suitable measure of the HRQOL construct in children with headache. Internal consistency estimates of total-scale and subscale reliability were very good to excellent, which is consistent with internal consistency reliability computed on other chronic illness samples (e.g., Varni et al., 2001). Ratings of HRQOL based on the PedsQL™ 4.0 total scale score also were significantly correlated across a 2-week baseline period, further supporting reliability.

We also found evidence for the validity of the PedsQL™ 4.0 in assessing HRQOL within a pediatric headache sample. Criterion-related validity was supported through significant inverse correlations between the baseline PedsQL™ summary scales and headache severity data extracted from daily diaries. Although we found statistical support for criterion-related validity, the associated coefficients were moderate in size ($-.38$ to $-.57$) and suggested that a large proportion of the variance in PedsQL™ 4.0 and headache severity scores is non-shared. This is likely due in part to methodological differences in how the data for these two measures were obtained (i.e., cross-sectional vs. daily diary), differences in content (i.e., multiple domains of functioning versus a single global question on impact of headache), and severity of headache only partly accounting for how pediatric headache impacts HRQOL. Other methods of assessing validity used in this study provided additional support for the validity of the PedsQL™ 4.0 in pediatric headache. Specifically, our data further showed significant inverse correlations between HRQOL (as reflected by PedsQL™ 4.0 scales) and headache-related disability (as reflected by the PedsMIDAS total scale score), significant differences between PedsQL™ 4.0 scores of the headache sample and those of a healthy normative group, and significant improvements in HRQOL from baseline to 3-month follow-up for those receiving a self-directed cognitive-behavioral intervention.

Our findings are consistent with previous research suggesting the marked impact recurrent headache has on multiple domains of functioning in children (Bille, 1981; Holden et al., 1998; Steiner, 2004) and extend the initial research of Powers et al. (2003, 2004) by showing that the PedsQL™ 4.0 is reliable across time, responsive to treatment, and related to headache-related disability and severity. However, the results of this study must be interpreted within the limitations of the study. The sample size for this study was relatively small. Although sample size does not impact validity and reliability coefficients, it reduces the power of statistical tests associated with them. The representativeness of the sample and generalizability of the findings of this study to the pediatric headache population are further issues. Although the demographic characteristics of the sample were comparable to that cited in other studies (e.g., Stewart et al., 1996), participants were recruited from an outpatient neurology clinic for a headache treatment study. Therefore, the generalizability of results to other settings (e.g., primary care) and nontreatment seeking samples cannot be ascertained based on these data.

Notwithstanding these limitations, this study adds to the previous work by Powers et al. (2003, 2004) by supporting the reliability and validity of the PedsQL™ 4.0 for use in prospective studies in pediatric headache. Using this measure in pediatric headache samples appears tenable and warranted, given that both our study and that of Powers et al. found that headaches in children clearly significantly impact components of HRQOL. Furthermore, measuring HRQOL should be a standard part of evaluating treatment outcome in pediatric headache given the current international agenda of reducing the burden of headache worldwide.

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