

Assessing the Impact of Migraine on Health-Related Quality of Life: An Additional Use of the Quality of Well-being Scale—Self-administered

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Objectives.—To compare the interviewer-administered Quality of Well-being Scale (QWB) with a self-administered form (QWB-SA) for patients with migraine, and to compare the health status of migraineurs to other medical populations.

Background.—With the increasing need to document the cost-effectiveness of treatment for migraine, limitations with both the Medical Outcomes Study Short Form-36 items and the QWB have been an impediment to research using cost-effectiveness as an outcome. Demonstrating the sensitivity of an alternative instrument which addresses these limitations would facilitate cost-effectiveness analyses on treatments for migraine.

Methods.—Eighty-nine adults (87% women) known to suffer from migraine were asked to complete both the interviewer-administered QWB and the self-administered version (QWB-SA) on three occasions. The first occasion was on a day when no migraine was experienced in the previous 7 days. The second and third assessments were completed within 48 hours of the onset of a migraine.

Results.—While both the QWB and the QWB-SA successfully distinguished migraine from nonmigraine days, more migraines were reported on the QWB-SA. Overall, both instruments showed similar patterns of patient dysfunction during a migraine attack. Each component of the QWB-SA successfully distinguished migraine from nonmigraine days, and the QWB-SA showed a linear sensitivity to pain intensity and disability during a migraine episode. Both instruments are able to detect a migraine's effect on multiple domains of quality of life. Study participants scored significantly lower on the QWB-SA during a migraine episode than several comparison medical populations.

Conclusions.—The QWB and the QWB-SA appear to have sensitivity to migraine severity, and the ability to quantitate an effect in multiple quality-of-life domains. Both measures can be used to calculate quality-adjusted life-years, thus facilitating cost-effectiveness and health policy work in this important clinical area.

Key words: migraine, health-related quality of life, cost-effectiveness, QWB-SA

Abbreviations: QALY quality-adjusted life-years; QWB Quality of Well-being Scale; HRQOL health-related quality of life; SF-36 Medical Outcomes Study Short Form-36 items; QWB-SA Quality of Well-being Scale, Self-administered; QOL quality of life; UCSD University of California, San Diego

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While the assessment of quality of life in migraine sufferers has received increased attention over the past decade, less focus has been directed at determining the cost-effectiveness of interventions targeting this condition. The acute burden of migraine is determined by the intense pain and associated symptoms, while the consequences of migraine attacks often lead to missed

work and impairment of work activities, reduced social/recreational activities, and poor mental health.¹⁻³ Quantifying this burden of illness can help determine the benefits of treatment at both a clinical and a societal level.^{4,6} A consensus report from US Department of Health and Human Services (DHHS) agencies (including the National Institutes of Health, Agency for Health Care Policy and Research, Health Care Financing Administration, and others) urged the evaluation of cost-effectiveness of health care interventions using a common methodology.⁷ The DHHS report noted that cost-effectiveness analysis (CEA) requires a common metric, such as dollars per quality-adjusted life-year (QALY).⁸ The Canadian guidelines for pharmacoeconomic analyses⁹ also recommend the use of QALYs or instruments able to measure across diseases and programs as the preferred outcome measure in CEA. These metrics are built upon generic, preference-weighted measures of health status. The use of a measure that produces information used in calculating QALYs would help demonstrate the true burden of migraine at a societal level and help in resource allocation decisions.

One measure that can be used to calculate QALYs is the Quality of Well-being Scale (QWB).¹⁰ The QWB is a preference-weighted measure combining three scales of functioning with a measure of symptoms and problems to produce a point-in-time expression

of well-being that ranges from 0 (for death) to 1.0 (for asymptomatic full function). Several studies have compared the QWB to the most common measure of health-related quality of life (HRQOL), the Medical Outcomes Study (MOS) Short Form-36 (SF-36),¹¹ and some conclusions can be drawn.¹² Table 1 summarizes characteristics of the SF-36, the QWB, and the self-administered version of the QWB (QWB-SA).¹³ As can be seen in Table 1, there are a number of drawbacks to both the SF-36 and the QWB. One significant limitation of the QWB has been the relative expense to use an interviewer-administered instrument. An important limitation of the SF-36 is that it does not produce a metric that can be used in cost-effectiveness analyses. We believe the QWB-SA addresses both these limitations.¹⁴

The interviewer-administered version of the QWB has been used in numerous clinical trials and population-monitoring studies.^{5,8,15} Earlier work suggested biases in an early self-administered format,¹⁶⁻¹⁸ yet recent refinements in questionnaire design have helped to circumvent and/or minimize these problems. The QWB-SA appears to have good test-retest reliability,^{14,19,20} adequate discriminant validity in a variety of illness populations,^{21,22} and sensitivity to outcomes of cataract surgery,²³ and to severity of mental illness.^{24,25}

The specific aims of the current study are to assess the sensitivity of the QWB-SA to detect changes in

Table 1.—Characteristics of the Medical Outcomes Study Short Form-36 (SF-36), the Quality of Well-being Scale (QWB), and the Quality of Well-being Scale, Self-administered (QWB-SA)

Feature	SF-36	QWB	QWB-SA
Administration	Self-administered	Interviewer-administered	Self-administered
Cost to administer	\$	\$\$\$	\$
Time frame assessed	1 or 4 weeks	6 days	3 days
Symptom assessment	Minimal	Extensive	Extensive
Emotional assessment	Direct	Indirect	Direct
Pain assessment	More extensive	Less extensive	More extensive
Assessment of death	Not assessed	Assigns values of 0.0	Assigns values of 0.0
Ceiling and floor effects	Greater	Less	Less
Primary output	Health status profile over the length of the recall time frame	Single QOL score for the recall time frame and/or each day of time frame	Single QOL score for the recall time frame and/or each day of time frame
Used to calculate QALYs	No	Yes	Yes

QALYs indicate quality-adjusted life-years; QOL, quality of life.

HRQOL of migraineurs as a function of migraine and to compare the HRQOL of migraineurs to that of medical clinic patient groups.

METHODS

Subjects.—A total of 100 adults living in Canada known to suffer migraine were approached by a market research firm to participate in the study and provided informed consent. All subjects were 18 years of age or older, spoke English as their primary language, were available to complete periodic telephone interviews, and reported a history of two or more migraines per month on average. All subjects were compensated \$30 after agreeing to participate and an additional \$30 upon completion of the study. Only the 89 participants who completed all study assessment instruments during at least one of three assessment periods were included in the analyses reported here. A comparison of the 89 participants with the 11 excluded from analyses found no differences on age, gender, or migraine frequency. Of the 89 participants, 77 (87%) were women, with the mean age of 42.2 ± 9.8 years (range, 36 to 64 years).

Procedure.—Each subject was instructed on the study protocol, signed a consent form (this study was approved by the University of California, San Diego [UCSD] IRB), and was provided with study materials. Each subject was asked to complete three different assessment instruments (described below). For the first assessment, participants were instructed to complete a QWB-SA during a time in which no migraine was experienced in the previous 7 days, mail the questionnaire in the envelope provided to them, and then call the UCSD Health Outcomes Assessment Program's toll-free line to schedule a telephone-administered QWB interview and complete that interview within 2 days. The second and third assessments each were completed within 48 hours of the onset of separate migraines and included completion of all three instruments. The order in which participants completed these instruments, on each of three occasions, was counterbalanced. That is, half the participants completed the QWB-SA first, followed by the QWB; the other half completed the QWB first, followed by the QWB-SA. Since each instrument covers a time period of 3 (QWB-SA) or 6

(QWB) days, there were to be both migraine and nonmigraine days covered in each of the final two assessments.

Instruments.—*Quality of Well-being Scale.*—The QWB¹⁰ is a generic HRQOL instrument that was designed for use in CEA. The output from the QWB is an index score between 0.0 (death) and 1.0 (perfect health). The QWB includes a symptom scale and three scales of function: mobility, physical activity, and social activity. Each symptom and step on these scales has its own associated preference weight. The overall QWB score is based on a preference-weighted average of functioning in the previous 6 days with respect to symptoms and the three function scales. For this study, scores were computed for each day separately to allow aggregation based on migraine status. The QWB has been shown to be reliable, internally consistent, correlate with a wide variety of medical and psychosocial variables, and the preference weights have been shown to be stable across patient groups and over time.^{8,10}

Quality of Well-being Scale, Self-administered.—The QWB-SA¹³ format is similar to the interviewer version, in that it includes a symptom scale and three scales of functioning: mobility, physical activity, and social activity. The primary differences are the mode of administration, respondents are asked to report on only the previous 3 days, and there are an increased number of mental health items in the symptom/problem subscale, resulting in a total of 77 items. It takes an average of 11 minutes to complete the entire questionnaire. Initial studies have demonstrated good psychometric properties of the QWB-SA.^{14,19,20} In ad-

Table 2.—No. of Completed Assessments at Each Time Point for Each Instrument

Time	QWB	QWB-SA
Baseline	95	89
Time 2	85	79
Time 3	72	66

QWB indicates Quality of Well-being Scale; QWB-SA, Quality of Well-being Scale, Self-administered.

Table 3.—“Matching Days” by Presence of Migraine on Each Instrument

	QWB-SA Migraine	QWB-SA No Migraine
QWB migraine	191	44
QWB no migraine	65	321

QWB indicates Quality of Well-being Scale; QWB-SA, Quality of Well-being Scale, Self-administered.

dition, the QWB-SA was found to be sensitive to clinically significant change in patients with depression²⁴ as well as change in patients after cataract surgery.²³

Migraine Intensity Questionnaire.—This questionnaire has been used as a primary endpoint in clinical trials of several pharmaceutical products.²⁶ A copy of the 5-question instrument is in the Appendix.

Analytic Methods.—Within-subject analysis of variance (ANOVA) was performed on all continuous variables when comparing the two instruments used in this study, and between-subject ANOVA when comparing two or more independent groups. Intraclass correlations were used to assess the test-retest reliability comparing the first assessment (nonmigraine days) to the second and third assessments (nonmigraine days); the same was done when deriving this reliability during active migraine. Finally, Bonferroni corrections were used when multiple comparisons were performed.

Table 4.—Means (SD) for Measures by Migraine Status

Instrument	Migraine Days	Nonmigraine Days	Difference Between Migraine and Nonmigraine Days
QWB	.610 (.079)	.730 (.114)	$F_{1,620} = 203; P < .01$
QWB-SA	.492 (.157)	.628 (.149)	$F_{1,620} = 119; P \leq .01$

QWB indicates Quality of Well-being Scale; QWB-SA, Quality of Well-being Scale, Self-administered.

RESULTS

A one-way ANOVA addressing the impact of order of questionnaire completion was not significant ($F_{1,88} = 1.26, NS$).

Table 2 shows the number of completed assessments, by questionnaire version (self-administered and telephone interview) and by assessment time. As can be seen, fewer QWB-SA questionnaires were completed and returned by mail than QWB interviews completed by phone. According to the research design, assessments at time 2 and time 3 were to be completed subsequent to a migraine episode, with baseline assessments to be migraine-free. However, some subjects reported migraine during the baseline period while others reported no migraine during assessments time 2 and time 3. Therefore, all assessment periods were pooled and data for only those days on which health status was reported for both the QWB and the QWB-SA (ie, “matching days”) are reported here. Each assessment could contribute up to 3 matching days, depending on the number of days of overlap between the 3-day QWB-SA assessment and the 6-day QWB assessment. Thus, a total of 621 days serve as the primary dataset. The unit of measurement is subject-day, with each subject contributing 6.98 subject-days/matching days on average.

A comparison between instruments was made to establish the rate of agreement for reporting migraines. Table 3 shows the days on which subjects reported a migraine on the QWB and QWB-SA. The κ between the two instruments was 0.85, reflecting a high rate of agreement above chance. It appears migraines were reported more often on the QWB-SA than on the QWB, but further study would be required to determine which instrument was actually more valid in this respect. That is, the higher frequency of migraines reported on the QWB-SA may reflect better recall of these events given the shorter window of recall or may reflect overreport of morbidity.

Test-retest reliability of the QWB-SA was calculated in the following manner: each subject’s first nonmigraine day was paired with a nonmigraine day approximately 2 months (mean 63 days) after the initial assessment. A similar analysis was conducted across migraine days by constructing a pair of scores for each subject’s migraine days, approximately 2

months apart (mean, 57 days). The resulting intraclass correlation for nonmigraine days was 0.74, while the correlation for migraine days was 0.51 ($P < .01$).

Table 4 shows the means for migraine and nonmigraine days for both the QWB and the QWB-SA. A two-way within-subject ANOVA used four observations on each subject (obtained by crossing QWB and QWB-SA with migraine and nonmigraine days). The analysis showed a significantly lower score for migraine days (as compared to nonmigraine days) for both instruments. The interaction term was nonsignificant, suggesting no significant difference between the instruments in the sensitivity of QOL given migraine status. (There was a main effect due to instrument, but this reflects the different weighting/scoring systems used for the two instruments.)

Additionally, we performed separate between-subjects ANOVA on QWB-SA scores with pain and then disability 2 hours after taking medication as the independent variables in order to assess the sensitivity of the instrument. Table 5 shows mean QWB-SA scores by the reported intensity of the migraine experienced as well as self-reported disability. As can be seen, there is a linear trend for lower scores as reported migraine intensity increases ($F_{1,72} = 5.3$, $P < .05$) and as reported disability increases ($F_{1,72} = 10.1$, $P < .01$).

While overall scores on both measures were found to be lower during migraine days, further examination of which aspects of health status are affected is warranted. Therefore, we used within-subject paired t tests to compare migraine versus nonmigraine days separately on the four dimensions assessed by the QWB-SA: symptoms, mobility, physical activity, and social activity/self-care. Table 6 shows lower QOL and greater dysfunction on all dimensions during migraine days.

Table 5.—Quality of Well-being Scale (QWB) and Quality of Well-being Scale, Self-administered (QWB-SA) Mean Scores (SE) by Category Rating Migraine Pain Intensity 2 Hours After Taking Medication

Rating	QWB-SA
Pain intensity	
Mild	.551 (.060)
Moderate	.505 (.054)
Severe	.394 (.017)
Disability	
Mildly impaired	.565 (.038)
Severely impaired	.426 (.047)
Requires bed rest	.396 (.038)

The QWB-SA has been completed for several specific population samples from various research studies coordinated by the UCSD Health Outcomes Assessment Program. Health status is often found to vary by age and gender. Eighty-seven percent of the sample were women, with an age range of 36 to 64 years, roughly approximating the demographics of this disease.¹ The composition of the comparison groups was adjusted to match this age and gender profile as closely as possible. The characteristics of the resulting comparison groups are shown in Table 7. Family medicine clinic patients were evaluated at least 10 days postclinic visit in order to minimize bias of a sample of adults presenting with somatic complaints. Arthritis clinic patients were approached while waiting for a routine visit to their rheumatologist and completed paperwork within 7 days of their office visit. Ophthalmology clinic patients were all assessed within 3 weeks of a scheduled cataract surgery.

Using QWB-SA scores as comparison, Table 8 shows a relatively clear pattern. Following between-

Table 6.—Quality of Well-being Scale, Self-administered Scores (SE) by Dimension and Migraine Status

	Symptoms	Mobility	Physical Activity	Social/Self-care
Nonmigraine	.337 (.013)	.001 (.005)	.025 (.047)	.009 (.020)
Migraine	.406 (.009)*	.004 (.011)*	.067 (.070)*	.031 (.028)*

Higher dimension scores reflect lower health-related quality of life. * $P < .001$.

Table 7.—Characteristics of Study Sample and Comparison Groups

Sample	No. of Subjects	Mean Age, (SD)	Women, %
Migraine participants	89	42.2 (9.8)	87
Family medicine clinic patients	171	38.2 (11.4)	88
Arthritis clinic patients	139	45.0 (11.2)	84
Ophthalmology clinic patients	19	56.3 (4.7)	79

subject ANOVA showing significant differences between groups overall, Bonferroni-adjusted post hoc comparisons showed that migraineurs on migraine days reported similar scores to patients with arthritis and patients with cataracts (just prior to cataract surgery). The QWB-SA scores for migraine days were significantly lower than those for migraineurs on nonmigraine days and family medicine clinic patients.

Table 9 shows a similar pattern when examining the individual component scores for all groups (in contrast to QWB-SA total scores, lower component scores indicate high QOL). Specifically, scores for symptom distress on migraine days were no different than those reported by patients with arthritis or patients with cataracts, but were significantly greater than nonmigraine days and for family medicine patients. For both physical activity and social activity/self-care component scores, migraineurs reported greater dysfunction and lower QOL on migraine days than all other groups except patients with arthritis. No differences were found between any of the groups in mobility, namely driving an automobile nor being

a patient in a hospital/nursing home; this is not surprising since all study groups were recruited from outpatient settings.

We have previously defined a constellation of mental health items on the QWB-SA.^{24,25} A QWB-SA mental health score is derived from a total of 11 items summed from each participant's QWB-SA responses, reflecting an array of mental health concerns (eg, anxiety, upset, irritability). Post hoc comparisons were then performed for migraine and nonmigraine days (Table 10).

An overall one-way ANOVA showed a significant difference between groups. Multiple group comparisons revealed significant differences between migraine days and all other groups except arthritis clinic patients.

COMMENTS

In helping to understand the humanistic impact of migraine and estimate the effectiveness of various interventions targeted at treating this condition, a general preference-weighted measure of HRQOL was used to quantify the personal burden of this illness. The QWB-SA was recently developed to address limitations in other popular health status instruments. The current study was designed to assess the instrument's sensitivity to change in health status, as well as to compare the impact of migraine relative to other medical conditions.

The findings reported here demonstrate the QWB-SA is sensitive to the presence and severity of migraine and suggests that the QWB-SA may have reasonable convergent validity as an outcome measure for patients with migraine. Similarly, low scores were found on both the QWB and the QWB-SA for migraineurs on migraine days as compared to migraine-free days. Scores on both instruments showed a linear decrease as patient-reported migraine severity increased.

Table 8.—Comparison of Groups on Total Quality of Well-being Scale, Self-administered (QWB-SA) Score

Group	Mean QWB-SA Score
Family medicine clinic patients	.635*
Migraineurs on nonmigraine days	.628*
Ophthalmology clinic patients	.583*†
Arthritis clinic patients	.504†
Migraineurs on migraine days	.492†

Higher score reflects better quality of life. Groups with identical symbols do not differ significantly from each other.

Table 9.—Comparison of Groups on Quality of Well-being Scale, Self-administered (QWB-SA) Component Scores

Group	Symptom	Physical Activity	Social Activity/ Self-care
Family medicine clinic patients	.327*	.023*	.012*
Migraineurs, nonmigraine days	.337*	.025*	.009*
Ophthalmology clinic patients	.377*†	.025*	.007*
Arthritis clinic patients	.398†	.066†	.029†
Migraineurs, migraine days	.406†	.067†	.031†

Higher scores reflect greater negative impact on quality of life. Groups with identical symbols do not differ significantly from each other.

While the QWB-SA, a self-administered questionnaire that often takes less than 12 minutes to complete, may be more readily used in large clinical trials and epidemiologic research, results from this study are consistent with other reports that the rate of mail-back response is lower than investigator-initiated telephone interviews. As always, investigators must weigh methodological convenience with the importance of potential response bias in any particular study. However, the QWB-SA may be especially useful in assessment of migraine status given it demonstrated sensitivity to migraine intensity and the relatively extensive mental health symptomatology included, an aspect often reported to be impacted by migraines.

Results from this study help quantify the impact of migraines relative to other medical conditions. Specifically, patients report low HRQOL for days on which they suffer a migraine similar to patients pre-

sented to an arthritis clinic. In fact, similarity in scores between migraineurs on migraine days and arthritis patients was found in the area of symptoms, physical activity, and social activity. The current findings also suggest that when not suffering a migraine attack, migraineurs report HRQOL scores similar to a cohort of patients presenting to a general medical clinic. While this comparison group completed the QWB-SA at least 1 week after presenting to a clinic, this population is likely to be less healthy than the general population. This pattern of similarity—migraine days similar to arthritis patients, nonmigraine days similar to general medical clinic patients—was also true for a measure of general mental health.

We caution the reader that there are significant limitations to this study. This work was completed on only a small number of patients with migraine. The subjects in this study were recruited from a Canadian metropolitan area and may not represent the general population of migraineurs. Another important limitation is that we do not know the nature of the migraines or the specific diagnosis. The data reported here are based exclusively on self-report. Although these data are preliminary, they do suggest that the generic QWB-SA may have value as an outcome measure for studies of migraineurs. With these limitations in mind, the current study shows promise for the QWB-SA to be used in larger trials of the impact of migraine and possibly help determine the cost-effectiveness of various interventions targeted toward treating this condition.

Several additional studies should be performed to establish the QWB-SA as a primary measure of outcomes in migraine populations. Such studies would help

Table 10.—Group Means on Mental Health Score of Quality of Well-being Scale, Self-administered

Group	Mean
Family medicine clinic patients	1.36*
Migraineurs, nonmigraine day	1.87*
Ophthalmology clinic patients	1.91*
Arthritis clinic patients	2.54†
Migraineurs, migraine day	2.66†

Higher scores reflect poorer mental health. Groups with identical symbols do not differ significantly from each other.

establish the measure's sensitivity to clinical improvement and further specify the areas of greatest impact from this often chronic, painful condition. The current results show the promise of this instrument in helping to document the burden of migraine to consumers in a cost-conscious world.

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Appendix.—Migraine Intensity Questionnaire

Date on which migraine attack began: _____

Immediately before taking medication for your migraine symptoms today, how bad was your migraine?
(check only one)

- _____ no pain
- _____ mild pain
- _____ moderate pain
- _____ severe pain

Immediately before taking medication for your migraine symptoms today, how would you rate your ability to perform normal functions? (check only one)

- _____ ability to work/function normally
- _____ ability to work/function mildly impaired
- _____ ability to work/function severely impaired
- _____ requires bed rest

Two hours after first taking medication for your migraine symptoms today, how bad was your migraine? (check only one)

- _____ no pain
- _____ mild pain
- _____ moderate pain
- _____ severe pain

Two hours after first taking medication for your migraine symptoms today, how would you rate your ability to perform normal functions? (check only one)

- _____ ability to work/function normally
- _____ ability to work/function mildly impaired
- _____ ability to work/function severely impaired
- _____ requires bed rest

If your migraine improved in the first two hours after taking a medication, did it then get worse again in the next 24 hours?

_____ yes _____ no _____ N/A