# Assessing Health-Related Quality of Life in Patients with Migraine

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**ABSTRACT:** ***Background:*** The place of health-related quality of life (HRQoL) instruments in clinical research trials and clinical practice as compared to more traditional clinical outcome measures such as headache intensity and frequency is unclear. ***Objectives:*** To review the current status of HRQoL measurement in migraine. ***Methods:*** A literature search was done for HRQoL *and* migraine. Selected articles dealing with migraine and commonly used HRQoL instruments and HRQoL measures used in recent clinical trials were reviewed. ***Results:*** Several general and migraine specific HRQoLinstruments can detect changes over time in response to at least major changes in migraine therapy. Both also show a correlation with clinical headache features. However, their sensitivity to detect clinically significant changes over time is not clear. ***Conclusion:*** The SF-36, a general HRQoLmeasure and several migraine-specific HRQoL instruments are useful endpoints for migraine clinical trials. Their role in clinical practice is yet to be established.

**RÉSUMÉ: L'évaluation de la qualité de vie reliée à la santé chez les patients migraineux.** ***Introduction:*** La place des instruments pour mesurer la qualité de vie reliée à la santé (HRQoL) dans les essais cliniques et en pratique, par rapport aux mesures de résultats cliniques plus traditionnels tels l'intensité et la fréquence de la céphalée, n'est pas claire. ***Objectifs:*** Revoir le statut actuel de la mesure de la HRQoLdans la migraine. ***Méthodes:*** Une revue de la littérature sur la HRQoL et la migraine a été effectuée. Les articles sélectionnés traitant de la migraine et des instruments d'évaluation de la HRQoL utilisés couramment pour la migraine et des mesures de la HRQoL utilisées dans les essais cliniques récents ont été révisés. ***Résultats:*** Plusieurs instruments généraux et spécifiques de l'évaluation de la HRQoLdans la migraine peuvent détecter des changements dans le temps, du moins quant à la réponse à des changements majeurs dans le traitement de la migraine. Les deux types d'instruments démontrent une corrélation avec les caractéristiques cliniques de la céphalée. Cependant, leur sensibilité pour détecter des changements cliniquement significatifs dans le temps n'est pas claire. ***Conclusion:*** Le SF-36, un instrument de mesure général de la HRQoL, et plusieurs instruments de mesure spécifiques de la HRQoL dans la migraine sont utiles dans l'évaluation des résultats au cours des essais cliniques sur la migraine. Leur rôle en pratique clinique n'est pas encore établi.

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It is unclear which treatment endpoints or outcome measures best reflect success or failure in treatment of the patient with migraine.[1,2] Most clinicians and clinical trials use symptoms directly related to the disease, such as the relief of head pain or the frequency of headache, as an outcome measure. However, it has been suggested that ultimately it is the patient's perception of treatment success or failure that is important and that health-related quality of life (HRQoL) measures might best fulfill this role.[3,4]

In this review, we will address HRQoL in patients with migraine from five perspectives: what it is, how is it measured, how does migraine affect HRQoL, can HRQoL measures help monitor effectiveness of treatment, and what significance do HRQoL measurements have for the clinician.

This review is directed primarily at clinicians who see patients with migraine, and who may not be familiar with the growing literature on HRQoL in migraine. It is intended to provide a broad overview of the topic, with specific examples of questions from the various HRQoLinstruments to give clinicians an appreciation of what is being asked of the patient so that the significance of the patient's answers can be considered. This review is not a meta analysis of the literature, nor does it attempt to specifically compare one HRQoL instrument with another, except in broad terms. It does attempt to provide for the clinician

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a perspective as to the status of assessment of HRQoL in migraine at this time.

A literature search was done in PubMed using "health-related quality of life" *and* "migraine". Reference lists of the manuscripts found were also searched. However, this review focuses on HRQoL instruments, which are either widely used (such as the Short Form-36 or SF-36) or which have been used recently in multi-centre migraine clinical trials [the Migraine Specific Quality of Life Instrument {MSQoLI},[4,5] the Migraine Specific Quality of Life Questionnaire {MSQoLQ},[6-8] and the 24 hour Migraine Quality of Life Questionnaire {24hMQoLQ}[9,10]].

## What is HRQoL?

It is important to understand that the term "Quality of Life" as it is used in this context does not refer to some absolute standard of what might represent quality of life, such as level of income, freedom from disease, or the possession of assets or property. We are dealing with perceived quality of life from the individual person's point of view, and this has been defined as representing peoples'perception of their position in life, in the context of their culture and value system, and in relation to their personal goals, expectations, standards and concerns.[11] It has been stated that determinants of quality of life include a host of factors including financial status, relationships, housing, recreation, health status, and others.[12] HRQoL has been defined as representing the net effect of an illness and its therapy on a patient's perception of his or her ability to live a useful and fulfilling life.[13]

## Why Measure HRQoL?

There is concern that physical measures of clinical efficacy such as headache frequency, headache relief within a certain time period, and others do not reflect the patient's subjective perspective of migraine. They may not reflect the impact of the patient's symptoms on the psychosocial aspects of the patient's life, or the individual patient's perception of this impact. For example, it is unclear what the relative impacts of headache duration, severity and frequency are on a patient's HRQoL and, in fact, the relative importance of each of these might vary from patient to patient. Therefore HRQoL may be an important dimension in the assessment of treatment response.[4] Although, in theory, this assessment of the potential value of HRQoL in measuring treatment outcomes is logical, there are important unresolved issues which include how HRQoL is best measured, and how sensitive the various instruments are to changes in the patient's HRQoL. These changes could occur either because of treatment or because of changes in the underlying headache disorder. As a result, while some open label longitudinal clinical trials have used HRQoL measurements as a primary outcome measure,[14] blinded clinical drug comparison trials generally use more traditional outcomes related to relief of head pain for the primary outcome measure.[15]

## How is HRQoL Best Measured?

How to best measure HRQoL in migraine has not been established and, therefore, a number of different instruments are currently in use. Some of these are labelled as HRQoLmeasures, and others as disability measures. The concept of disability has not yet been clearly separated from HRQoL and, at this time, both HRQoL measurements and disability scales are used to determine the nonmedical impact of disease on a patient.[13]

For patients with migraine, both disease-specific measures and general HRQoL measures are used. Disease-specific measures focus on the symptoms and/or disabilities caused by a specific medical disorder, which may be very different in a patient with migraine as compared for example to a patient with congestive heart failure. Disease-specific measures may, therefore, be more sensitive to changes in a patient's HRQoL over time.

General HRQoL measures are designed so that they inquire about a wide variety of symptoms, and as a result there is concern that they may be less sensitive to changes in specific medical disorders over time. However, they have the advantage that they allow comparison of HRQoL between groups of patients with different disorders.

## Migraine-Specific HRQoL Measuring Tools

A number of HRQoL measures have been devised over the past decade which attempt to focus specifically on HRQoLin the patient with migraine. Some of these are shown in Table 1.

These migraine-specific HRQoL measures come in several types. There are those which are designed to be administered between headache attacks when the patient is otherwise well (MSQoLI and MSQoLQ). One of the HRQoLinstruments listed in Table 1, the 24-hMQoLQ, is meant to be administered 24 hours after the administration of treatment for an acute migraine attack. Migraine is an episodic event, and the concept is that during a migraine attack an individual generally has more impaired HRQoL than between attacks, and it may be best to focus on this time period. This concept has been challenged.[16]

Methods have been developed to measure disability specifically in patients with headache, (Headache Disability Inventory),[17] but the design of these has many similarities to HRQoL measures. Finally, one quality of life measure, the Cavallini quality of life questionnaire, is designed to be administered between headache attacks but has separate sections, one focusing on quality of life between attacks and one focusing on quality of life during a typical headache attack.[18]

The MSQoLI[4,5] attempts to measure HRQoL in migraine by focusing on three domains; avoidance, social relationships, and feelings. The questions have been refined and reduced to a 20-item version, with an international version and an American (US)

**Table 1:** Migraine Specific Health-Related Quality of Life Measures

| |
|---|
| Migraine-Specific Quality of Life Instrument (MSQoLI) |
| Migraine-Specific Quality of Life Questionnaire (MSQoLQ) |
| 24-hr Migraine Quality of Life Questionnaire (24-hMQoLQ) |
| Headache Disability Inventory |
| Cavallini Quality of Life Questionnaire |



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version available.[4] In general, questions seem logical and relevant to migraine. For example, a typical question in the "avoidance" domain is "I try to avoid pushing myself too hard because of my migraine". An example of a question in the "social relationships" domain is "My migraines put a strain on my close relationships". One of the questions in the "feelings" domain is "I feel helpless when a migraine starts". For most questions, patients can indicate one of four answers, and the available options for the "feelings" question listed above are: Yes very much, Yes quite a lot, Yes a little, No not at all.

The questions on the MSQoLI were developed by focus groups of migraine sufferers. It has been tested on a diverse migraine patient population including both patients of neurologists and patients from the general population. It has a high test-retest reliability with an intraclass correlation coefficient of 0.90.[5] Internal consistency was also found to be high, with Crohnbach's Alpha of 0.92.[5] It appears to be valid in that scores correlate with a variety of measurements of migraine clinical severity, e.g. migraine frequency.[4] It has been tested primarily in adult females between the ages of 30 and 40.[4,5]

The MSQoLQ[6-8] consists of 16 items and is also meant to be administered between attacks. It asks specifically about the previous four weeks of the patient's life. It has three dimensions. One is the "role function-restrictive" dimension, and an example of a question in this dimension is one related to difficulty in performing work. A typical question in the next dimension, "role function-preventative" asks about having to cancel work or daily activities. A third dimension deals with "emotional function" and an example of a question in this domain is "In the past four weeks how often have you felt fed up or frustrated because of your migraines?" There are six available answers for the patient to choose from and these range from "none of the time" to "all of the time". It is clear that the MSQoLQ has a significant assessment of disability component built into it.

The MSQoLQ has been tested primarily in females and patient groups have had an average age of approximately 40. It is designed for adults over 18 years of age, and experience with its use in males is limited. It does appear to have good test-retest reliability, good internal consistency[8] and there is evidence for criterion and construct validity.[6,7] Scores on the MSQoLQ showed at least a modest correlation with headache frequency, severity, and with duration of headache, and other migraine symptoms.[6,8] The questions in the MSQoLQ reflect the perspectives of both patients and caregivers, in that questions were not included unless both patients and clinicians thought they were meaningful. It has been tested primarily on patients with relatively severe migraine, as patient populations have been drawn from clinical trials populations and headache referral centres.[6,8] Its sensitivity to change in an individual patient over time is not clear.

The 24-hMQoLQ[9,10] has fifteen items and these focus on five domains: work functioning, social functioning, energy/vitality, migraine headache symptoms, and feelings and concerns. All questions are prefaced by the phrase "in the past 24 hours after you took your first dose of medication for your migraine headache". As can be seen from the domains of this measurement, some of the questions focus directly upon the patient's migraine symptoms, as for example, "How much of the time did you have nausea?" and "How much of the time did you have throbbing head pain?" A typical question in the social functioning domain would be "How much did your migraine headache and accompanying symptoms negatively affect your interactions with people who are close to you?" Finally, some questions are of a more general nature, as for example "How much of the time did your migraine headache and accompanying symptoms limit your ability to enjoy life?" The patient answers the question by selecting one of seven options. For example in the question regarding "enjoying life" the options range from "all the time" to "none of the time".

As can be seen, the MSQoLmeasures have some differences, but also have much in common. The same is true for the Headache Disability Inventory and for the Cavallini Quality of Life Questionnaire, which will not be discussed in more detail here, but more details are available from the references.[17,18]

There is little information available on how well scores using the various migraine specific quality of life measures correlate with each other in the same patient group. Therefore, it would be difficult to compare studies which used different instruments. A meta analysis of studies which all used one instrument should be possible. The MSQoLI scores had only a modest correlation (0.51) with scores on a disability measure, the MIDAS test, in a group of 90 migraine patients who did both measures.[19]

## General HRQoL Measuring Tools and Migraine

The SF-36[20] and the closely related RAND-36 (a questionnaire developed from the Medical Outcomes Study General Health Survey Instrument and basically a Dutch translation of the SF-36) are the most widely used general quality of life tools in migraine. An example of a question from the SF-36 is "During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?" The patient has the option of choosing one of five answers ranging from "not at all" to "extremely". As can be seen, general HRQoL measures have the potential to be less specific, i.e. should a patient have low back pain as well as headache, the patient's answer might well reflect the low back pain more than the headache. The SF-36 also asks questions with regard to the effect of the patient's physical health on various activities, so the effects of any other illness the patient might have in addition to migraine would be captured. Nevertheless, as will be discussed below, such general HRQoL measures have made important contributions to the migraine literature.

## How Does Migraine Affect HRQoL?

As measured by general HRQoL tools, migraine can have a major impact on an individual's HRQoL. In a population-based study, migraineurs had lower scores on all eight domains of the RAND-36 as compared to individuals who did not have migraine.[21] These results are all the more impressive, as population-based studies include all patients with migraine, and not just those patients with more severe migraine who might have a greater tendency to be referred to specialized headache centres. A second population-based study[22] also found that individuals with migraine had a lower HRQoLthan nonmigraine controls, using the Short Form-12, which uses a subset of questions from the SF-36. As migraine has a number of comorbidities, including a higher prevalence of depression than



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the general population, this study[22] also assessed the effects of depression on HRQoL in patients with migraine. The study concluded that HRQoL was still reduced in patients with migraine who did not have depression relative to population controls, but also that in the migraine group, patients who had both migraine and depression had a lower HRQoL as compared to migraine patients who were not depressed.

As measured by the RAND-36, HRQoL could be shown to decrease significantly with increasing frequency of migraine attacks.[21] It is, however, important to note that in this population-based study, patients in the different attack frequency categories had a huge range of attack frequencies. The least affected category of patients had an attack frequency ranging from one to six attacks per year, and the most affected category had more than 24 attacks per year

In population-based studies, migraine has been shown to affect HRQoL more than asthma, but in general somewhat less than does chronic musculoskeletal pain.[21] Compared to patients with asthma, migraine patients scored significantly lower on several domains of the SF-36, including social functioning, emotional role limitations, mental heath, pain, and vitality. Patients with chronic musculoskeletal pain scored significantly lower than migraine patients on physical functioning, physical role limitations, pain, vitality and general health perception. For patients who have two conditions, e.g. migraine and asthma, the HRQoL as measured by the RAND-36 is worse than in patients who have one condition only. The combination of both migraine and chronic musculoskeletal pain has a particularly striking effect upon HRQoL,[21] with significantly lower scores on all eight domains of the RAND-36 as compared to patients with migraine alone or musculoskeletal pain alone.

In summary, migraine has a significant negative impact on HRQoL. It is of interest that as a group, patients experiencing only one to six headaches per year also show a reduction in HRQoL scores on the RAND-36.[21] While it might seem surprising that patients with so few headache days a year still show a reduced HRQoL, it might well be that the unpredictability of the attacks that do occur amplify the effects of a relatively few headache days per year on HRQoL in a very significant way.

For migraine patients, scores have been shown to be lower on all eight domains of the SF-36 as compared to healthy controls,[23] similar to the findings with the closely related RAND-36.[21] Of interest, the domains most affected in migraine sufferers are role physical, bodily pain and vitality.[23]

## Can HRQoL Measures Help Monitor Effectiveness of Treatment?

It seems clear that HRQoL measures can show statistically significant changes when major changes in symptomatic therapies are made. In a large international study, it was found that patients showed a statistically significant improvement in most dimensions of the SF-36 when HRQoL after 12 and 24 weeks of subcutaneous sumatriptan therapy was compared to HRQoL during “customary” migraine therapy for the same patient group before sumatriptan was started.[24] However, it is important to note that significant numbers of patients dropped out after sumatriptan therapy was started. Four hundred and eighty-two patients completed all 36 weeks of the study, while over 200 patients dropped out for a variety of reasons, including lack of efficacy (53 patients) and sumatriptan adverse events (33 patients). It is likely that sumatriptan nonresponders preferentially dropped out of the study and, therefore, were not included in the HRQoL measurements made after sumatriptan therapy was started. Other studies have shown that patients who do not respond to the triptans tend to have lower HRQoL as measured by the SF-36, when compared to patients who respond well to the triptans, even when measured at baseline when patients are taking their usual migraine therapy.[4] Selective drop out of triptan nonresponders would then be expected to increase the mean HRQoL as measured by the SF-36 over time in a large patient group.

In the same study, Dahlof[24] was also able to demonstrate a significant improvement in HRQoL in all dimensions as measured by the MSQoLQ when HRQoLwas measured after the onset of subcutaneous sumatriptan therapy and compared to baseline measurements while patients were using their customary therapy. Once again, some bias may have been introduced into these results, because a number of patients dropped out of the study between baseline evaluations and the evaluations done while on sumatriptan therapy. One of the reasons for patient drop out was lack of efficacy, and it has been shown that baseline scores on some MSQoL measures (the MSQoLI)[4,10] are significantly lower in patients who respond poorly to triptans, as compared to those who respond well.[4]

Others have shown statistically significant improvements in HRQoL as measured by the SF-36 when subcutaneous sumatriptan was introduced into migraine treatment regimens. Solomon[25] was able to show a statistically significant improvement in HRQoL on three of the eight SF-36 domains (role physical, bodily pain and social functioning) after subcutaneous sumatriptan was prescribed.

Other studies have been less successful in showing measurable treatment effects using HRQoL measures over time when oral triptans were added to a patient’s treatment regimen. Patrick et al[4] assessed HRQoL in a large cohort of patients at baseline, and after 180 days of oral (5 mg) zolmitriptan therapy. The MSQoLI was used, and the scores were transformed so that possible patient scores ranged from 0 to 100. Using this scale, the mean HRQoL increased from a baseline score of 57.5 by only 4.1 units after 180 days of zolmitriptan therapy. Unfortunately, the study report does not indicate the proportion of patients who improved, worsened, or remained unchanged on the MSQoLI, although we do know for example that 495 patients out of the total sample of 1,383 had a headache response over 90% of the time when they used zolmitriptan during the study period. This study is difficult to interpret, in that no information is given regarding the medications used by these patients prior to entry into the study. If, for example, most patients were taking the older drug, sumatriptan, prior to study entry, one could hardly expect a major change in their HRQoLwhen they were switched to zolmitriptan. This may, therefore, be one reason why this study showed such a minimal response in HRQoL as measured by the MSQoLI after the initiation of zolmitriptan therapy, and illustrates that many articles published with regard to HRQoLin migraine do not provide all the information needed to interpret the results. It is, however, of interest that this study[4] showed no



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**Table 2:** Average Monthly Migraine Frequency and MSQoLI* Scores

| Average No. of Migraines/Month | No of Patients | Mean MSQoLI Score (with SD) |
|---|---|---|
| 1 | 215 | 63.8 (17.74) |
| 2 | 448 | 59.1 (20.04) |
| 3 | 254 | 56.3 (21.22) |
| 4 | 236 | 53.7 (19.88) |
| 5 | 106 | 56.1 (21.69) |
| 6 | 108 | 52.2 (20.24) |

* Migraine-specific quality of life instrument scores. Information in the table has been extracted from Patrick DL, et al.[4]

improvement in HRQoL during the six month period in patients who responded poorly to zolmitriptan, whereas some improvement (score went from 60 to 65) occurred in patients who responded well to zolmitriptan. In the same patient population, however, the SF-36 was unable to show any change in HRQoL scores either in zolmitriptan responders or non-responders. These data would suggest that in migraine patients, the migraine specific quality of life scales can be more sensitive to treatment effects than a general HRQoL test.

It is surprising, however, how insensitive the MSQoLI is to changes in patients headache frequency. Although there was a trend for higher HRQoL in patients who had fewer headaches (see Table 2), the differences in the MSQoLI scores between patients with one headache per month and six headaches per month were surprisingly small.[4] While these small differences may still indicate clinically significant differences, on face value they do not bode well for the MSQoLI instrument's ability to detect patient improvement during prophylactic migraine therapy. It remains possible, however, that it would be more sensitive to reductions in headache frequency in individual patients over time, despite the relatively small mean differences in patient groups with different headache frequencies (Table 2).

The ability of the 24-hMQoLQ to detect changes in HRQoL during a migraine attack has been studied during a large rizatriptan clinical trial.[26] The results of this trial are shown in the Figure. As can be seen, rizatriptan 10 mg showed a statistically significant improvement in 24-hour HRQoL over placebo in three of the five domains of the 24-hMQoLQ. The O'Brien's Rank Sum Test indicated that patients receiving rizatriptan 10 mg experienced significantly better overall MSQoLcompared to those on placebo (p=0.005). These results are all the more noteworthy because patients who received placebo in this study could take rizatriptan 10 mg at two hours. Therefore, the 24-hMQoLQ was able to detect differences in a 24-hour HRQoL produced by a delay of two hours in taking active medication (rizatriptan 10 mg).

Although not statistically significant, all five domains of the 24-hMQoL showed a trend for lower scores in the 2.5 mg rizatriptan group as compared to the placebo group. This likely can be explained in that the 2.5 rizatriptan dose is a largely ineffective dose and if these patients took a second dose of study medication at two hours, they received a placebo. In contrast, the "placebo group" received rizatriptan 10 mg if they took a second dose of study medication at two hours.

In summary, it would appear that HRQoL measures can, in patient groups, detect the effects of changes in migraine therapy, at least if these changes are relatively major (like going from a nontriptan therapeutic regiment to a triptan regimen). More well-designed studies are needed in this area. Such studies should clearly outline what the patient's customary or baseline migraine therapy was, and what changes in therapy were made. Patient dropouts are a significant problem in such studies. There is some evidence that migraine-specific HRQoLmeasurements are more sensitive than generic HRQoL measurements in assessing the effects of therapy. The 24-hMQoLQ which focuses on the 24 hours after medication is taken for an acute migraine attack appears quite sensitive to the effectiveness of acute symptomatic migraine therapies.

The MSQoLI and the MSQoLQ are meant to reflect the patient's HRQoL over the previous month. With regard to whether HRQoL scores are influenced by whether or not the migraine patient completes the test during a migraine attack or between migraine attacks, there is evidence at least for the MSQoLI that test scores are not influenced by this potential variable.[19]

The relationship of HRQoL scores to individual patient variables like headache frequency, severity, and duration is unclear, although in general these variables do correlate with HRQoL scores on the MSQoLI and MSQoLQ.[6,8] This is similar

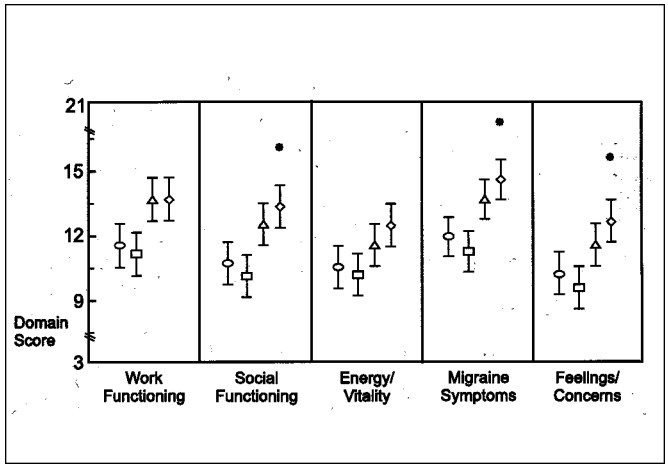


*Figure: Mean (±s.e) scores on the various subscales of the 24-hour Migraine Quality of Life Questionnaire (score range 3-21) are shown for the various treatment groups in a placebo-controlled dose ranging study for rizatriptan.[29] From left to right, in each panel, scores are shown for the placebo group (o), the 2.5 mg rizatriptan group (□), the 5 mg rizatriptan group (Δ), and the 10 mg rizatriptan group (◊).Note that the placebo group could take blinded rizatriptan 10 mg at two hours and 76% did so. Mean scores were significantly higher, indicating better HRQoL on three of the five subscales (*) for rizatriptan 10 mg as compared to placebo (p values ranged from 0.005 to 0.015 for the three subscales). (From Santanello NC, Polis AB, Hartmaier SL, et al. Improvement in migraine-specific quality of life in a clinical trial of rizatriptan. Cephalalgia 1997;17:867-872 with permission.)*



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to other neurological conditions with intermittent but unpredictable attacks of symptoms like epilepsy. For example, in one study, associations between a seizure severity scale and a comprehensive epilepsy HRQoL measure were moderate, although relationships between seizure frequency and HRQoL were nonsignificant.[27] There is also evidence that epilepsy specific HRQoLmeasures tend to be more responsive to changes in a patient's epilepsy than generic measures.[28]

### Health-Related Quality of Life Measures and the Clinician

Although HRQoL instruments would appear to be useful outcome measures for migraine clinical trials and other research studies, their clinical utility for individual patient care has yet to be established. Because HRQoL measurements are based solely on patient perceptions, it is likely that they may be influenced by other factors which influence quality of life, and these other factors might change over time. It must also be kept in mind that HRQoL measurements as currently made are not very specific, and represent a mixture of symptoms, patient feelings and emotional reactions and disability, depending on which HRQoL test is used. The MSQoL instruments which are meant for administration between migraine attacks, and which are designed to reflect the patient's HRQoL over a significant period of time (i.e. four weeks) (MSQoLI and MSQoLQ) could potentially serve as useful audit tools over time if physicians wish to assess the effectiveness of their migraine treatment regimens for migraine patients in their practice. However, there is no published data on the use of these instruments in this context.

Scores on the MSQoLI for example are quite stable in individual patients over short periods of time. Using a Dutch translation of the MSQoLI, test-retest reliability was 0.90 when the test was administered twice to a group of patients approximately two weeks apart.[19] This, combined with score relationships to headache clinical features including frequency[4] suggests that it has the potential to assess changes in the severity of a patient's migraine condition over time.

The 24-hMQoLQ has the potential to be a useful tool for directly assessing the success of symptomatic migraine therapy in clinical practice. It is short (15 items), easily scored, and has the potential to be a useful supplement to headache diaries. It could be expected to reflect both drug effectiveness in relieving migraine symptoms and also drug side effects in this treatment context. Further exploration of this HRQoL instrument in this role is warranted.

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