KEY NOTE LECTURE

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Migraine and quality of life: psychological considerations

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Abstract In the past decade researchers have become increasingly interested in quality of life as it pertains to headache, in particular migraine. A number of general health or well-being measures and migraine-specific measures have been investigated thus far. This paper briefly reviews investigations conducted to date, argues that measurement consolidation is needed for certain extant approaches, discusses potential uses and interpretations of derived measures, and points out alternative models and approaches that merit further exploration.

Key words Migraine · Quality of Life

Introduction

The World Health Organization [1] long ago defined health as "a state of complete physical, mental and social well-being, and not merely the absence of disease," thus laying the groundwork for a focus on quality of life (QoL). In the 50+ years that have passed, however, QoL has remained an ill-defined term with a loose definition. In the absence of an agreed upon formal definition, researchers typically describe what QoL means to them; definitions must be inferred back from the item content. Item contents are typically drawn from the following categories: general or overall health, physical functioning, physical symptoms and toxicity, emotional functioning, cognitive functioning, role functioning, social well-being and functioning, sexual functioning, and existential issues [2].
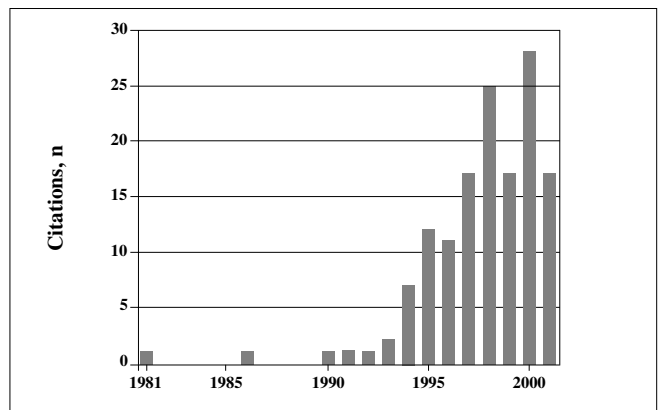
Migraine and quality of life

The history of QoL and migraine and other headache has proceeded much as it has for other medical conditions – a beginning awareness that aspects beyond physical symptoms are important, a focus that first concerns general health measures, which is then followed by exploration of specific or

tailored measures [3]. Both approaches are of value. General assessments provide overviews of health status, they permit comparisons across diverse patient groups, and they may identify unexpected findings worthy of subsequent pursuit. Condition-specific measures have the obvious advantage of being customized, and they may, as a result, be more sestive to detecting small but important differences [4].

Within the area of migraine headache, the interest in QoL is a relatively recent phenomenon. A Medline search, employing the terms "migraine" and "quality of life," revealed minimal, sporadic interest in this topic until 1994, at which point interest greatly increased (Fig. 1). Total citations at the time this article was prepared exceeded 140 (with just a partial tally for 2001). Tables 1 and 2 list the measures investigated to date, in chronological order. Table 1 provides the names for and brief descriptions of general

Fig. 1 Citations of "quality of life" in the migraine literature indexed in Medline, in the period 1981-2001. The value for 2001 corresponds to the period January-July

Table 1 General measures of well being utilized in investigations of migraine and headache

Measure	Brief description
Nottingham health profile (Jenkinson [5])	6 Dimensions: energy, pain, emotional reactions, sleep, social isolation, and physical mobility
Minor symptom evaluation profile (Dahlöf and Dimenäs [6])	3 Dimensions: contentment, vitality, and sleep
Medical outcomes study short form health survey (SF20) (Solomon et al. [7])	6 Dimensions: physical functioning, role functioning, social functioning, mental health, health perceptions, and pain
Medical outcomes study short form health survey (SF-36) (Osterhaus et al. [8])	9 Dimensions: physical functioning, role functioning-physical, role functioning-emotional, social functioning, bodily pain, mental health, vitality, general health, and change in health
Subjective symptom assessment profile (Dahlöf and Dimenäs [6])	6 Dimensions: emotional distress, gastrointestinal symptoms, peripheral vascular symptoms, cardiac symptoms, sex life, and dizziness1
Psychological general well-being (Dahlöf and Dimenäs [6])	6 Dimensions: anxiety, depressed mood, positive well-being, self-control, general health, and vitality
Cantril's ladder (Jelicic et al. [9])	1 Dimension: present life satisfaction
Sickness impact profile (Prudenzano et al. [10])	14 Dimensions: sleep and rest, emotional behaviour, body care and movement, home management, mobility, social interaction, ambulation, alertness behaviour, communication, work recreational pastime, eating, physical distress, psychosocial distress, and overall distress
Illness behaviour questionnaire (Prudenzano et al. [10])	8 Dimensions: general hypochondriasis, disease conviction, psychological vs. somatic perception of illness, affective inhibition, affective disturbance, denial, irritability, and index of hypochondriasis
Quality of well-being scale (Sieber et al. [11])	4 Dimensions: symptom scale, mobility function, physical activity function, and social activity function

1Includes a subset of questions designed to be migraine-specific

Table 2 Migraine- or headache-specific measures of quality of life

Measure	Brief Description
Recurrent illness impairment profile (Wittrock et al. [12])	2 Dimensions: general functional impairment and employment-specific functional impairment
Headache disability inventory (Jacobson et al. [13])	2 Dimensions: emotional disabling effects and functional disabling effects
Migraine quality of life questionnaire (Hartmaier et al. [14])	5 Domains: work, social, energy/vitality, feelings/concerns, and symptoms
Quality of life questionnaire (Cavallini et al. [15])	6 Dimensions: physical functioning, role functioning, social functioning, mental health symptoms, health perception
Migraine-specific quality of life measure (Wagner et al. [4])	1 Dimension: general quality of life
Quality of life headache in youth (Langeveld et al. [16])	5 Dimensions: psychological functioning, functional status, physical status, social functioning, and satisfaction with life in general
Migraine-specific quality of life questionnaire (Jhingran et al. [17])	3 Dimensions: role function-restriction, role function-preventive, and emotional function
Health impact questionnaire (Stewart et al. [18])	1 Dimension: impact (pain and disability)
Migraine disability assessment (Stewart et al. [19])	1 Dimension: disability
Migraine work and productivity loss questionnaire (Davies et al. [20])	7 Dimensions: time management, work quality, work quantity, bodily effort, interpersonal demands, mental effort, and environmental factors
Quality of life pain in youth (Hunfeld et al. [21])	6 Dimensions: psychological functioning, social functioning, functional status, physical status, satisfaction with life, and satisfaction with health
Quality of life headache in youth questionnaire (Hartmaier et al [22])	5 Dimensions: activities, social functioning, cognitive functioning, migraine headache symptoms, and emotional functioning
Headache needs assessment survey (Cramer et al. [23])	2 Dimensions: migraine frequency and migraine bothersomeness

measures of well-being, along with the citation for when the measure was first applied to a headache sample. Table 2 provides a chronology of the development of migraine- and headache-specific measures, along with brief descriptions of the domains or aspects addressed.

Taking stock of current approaches

Tables 1 and 2 reveal that a virtual explosion of research investigations of QoL has occurred since the mid-1990s. As an aid to digesting the extant literature, I began to itemize each and every subscale that has been addressed in order to see which particular aspects have appeared most frequently (studies were selected at random). After cataloguing 9 published reports, a total of 63 subscales had been identified, with no overlap among them (scales being identical in content). Continuation of this cataloguing exercise did not seem wise or likely to be productive in making sense of the burgeoning database on migraine and QoL. Perhaps it is time to slow the proliferation of current measures (with the exception of measures deriving from alternative models that will be discussed in a later section) and to attempt some type of consolidation. Perhaps it is advisable to take stock and ask "which of the various measures are closely related to one another or are overlapping," "which of the various measures provide unique contributions to understanding the pain and suffering of headache," and "what is the minimum number of measures that are necessary for providing the most complete picture?"

A recent investigation by Holroyd and colleagues [24] may well serve as a model for how to approach this needed consolidation and begin to provide answers to the previously mentioned questions. It has long been recognized that pain, disability, and affective distress are the main distinguishing features of chronic pain [25, 26]. Holroyd et al., therefore, compiled a rather large battery of measures that were selected in order to provide a good sampling of scales from the 3 major domains that serve as hallmarks of chronic pain (pain, disability, and affective distress) and then administered the resultant scales to a large number of headache patients. Table 3 lists the 22 "headache-impact" measures they selected for investigation (note, some are single items or questions, some are single-focused measures, and some are subscales from multi-component measures). Various statistical approaches were pursued in order to reduce the data array to the fewest number of separable constructs that accounted for a maximum amount of the explainable variance. The suspected 3-factor solution emerged as the most viable. Five variables loaded most highly on the affective distress dimension: STAI trait anxiety, MOS mental health subscale, BDI depression, Prime MD mood diagnosis, and Headache disability inventory. Five variables loaded most highly on the pain density dimension: headache index by diary, headache days with at least moderate pain by diary, number of headache days by diary, headache frequency by interview, and headache duration by interview. Finally, 6 variables loaded significantly on the disability dimension: interference with daily activities, interference with work, interference with social activities, headache intensity by interview, average pain, and worst pain intensity.

Affective distress emerged as a significant construct to consider, which is consistent with findings from various psychological investigations of headache, one of which found affective responses to be a better predictor of disability than headache pain itself [32]. This point merits further elaboration. For certain individuals, headaches elicit a host of affective distress: depressed mood that leads to discouragement, helplessness, and resignation; fears that promote avoidance and withdrawal; anticipato-

Table 3 Headache-impact measures selected for investigation

Pain density
> Headache frequency by interview
> Headache intensity by interview
> Headache duration by interview
> Headache index by diary
> Number of headache days by diary
> Number of days with at least moderate pain by diary
> Pain subscale, from MOS-SF20 (Stewart et al. [27])

Affective distress
> Beck depression inventory (Beck et al. [28])
> State-trait anxiety inventory, trait scale, form x-1 (Spielberger et al. [29])
> Anxiety disorder, from PRIME MD (Spitzer et al. [30])
> Mood disorder, from PRIME MD (Spitzer et al. [30])
> Mental Health Subscale, from MOS-SF20 (Stewart et al. [27])

Disability
> Interference with daily activities (Von Korff et al. [31])
> Interference with work (Von Korff et al. [31])
> Interference with social activities (Von Korff et al. [31])
> Headache-related disability days (Von Korff et al. [31])
> Average pain (Von Korff et al. [31])
> Worst pain intensity (Von Korff et al. [31])
> Headache disability inventory (Jacobson et al. [13])
> Physical functioning, from MOS-SF20 (Stewart et al. [27])
> Role functioning, MOS-SF20 (Stewart et al. [27])
> Social functioning, from MOS-SF20 (Stewart et al. [27])

MOS-SF20, Medical outcomes study short form general health survey; *PRIME MD*, Primary care evaluation of mental disorders

ry anxiety that impairs functioning even during headache-free episodes; etc. Affective distress has not generally been included in QoL research, but it certainly appears to be warranted. Studying affective distress in systematic fashion will entail some difficulty. Affective distress that is observed in headache patients may be due to the headache per se, a co-morbid psychiatric disorder, co-morbid life stress, or combinations of the preceding [24]. Approaches will need to be developed to partial out the varied sources of the affective distress and their relative contributions. Although the study by Holroyd et al. is exemplary, it focused basically on tension-type headache patients who were highly screened and selected (patients were excluded if taking antidepressant, anti-anxiety, or prophylactic medication). Whether their findings will readily extrapolate to migraine is uncertain.

Another approach to consolidation has been attempted, but it is more limited in that it has been conducted within a single domain. In preparing the Headache impact test (HIT) Ware et al. [33] pooled the most salient items from 4 existing scales (Headache disability index, Headache impact questionnaire, Migraine disability assessment score, and Migraine-specific questionnaire) into a single, more streamlined instrument by using item response theory. This approach to consolidation merits further exploration as well.

Interpreting QoL measures

Re-examination of Tables 1 and 2 reveals that although the domains have expanded considerably, nearly all of the measures continue a somewhat singular overall approach – linking QoL to functional capacity [2]. Individuals who are unable to achieve full functioning within the physical, psychological, or social realms are considered to have a poorer QoL. In this situation, functioning is regarded as a key *causal* variable for QoL. However, QoL is influenced by multiple variables, some of which are related to functioning and some of which may not (a similar point was made in the prior section regarding affective distress). Also, there is a tendency to assume an isomorphic relationship exists between pain severity and QoL. Hunfeld et al. [21] report this is not always so. When comparing adolescents who experienced chronic pain in varied locations, they found that although adolescents with headache reported less pain than adolescents with pain at other locations, adolescents with headache reported the poorest QoL and the greatest behavioral disruption. They speculated that headaches likely had a greater impact on cognitive functioning, which led to greater disruption.

This leads to the issue of interpretation and evaluation of score values derived from QoL scales. A major reason for pursuing QoL measures is to identify targets in need of inter-vention and to permit investigation of change over time (which hopefully is in the direction of improvement). In the typical group outcome investigation, mean levels for the various conditions are compared quantitatively to determine whether any differences are *statistically* significant. This approach, although common, is limited in several respects. First, one index, the group mean, is selected to represent the response of all subjects within the same condition. This index completely ignores variability and, as variability increases, the mean becomes less and less representative of the group as a whole. Second, and perhaps more importantly, achieving statistical significance does not assure that the findings have applied or *clinical* significance. With enough replications, even trivial differences can be found to be statistically significant. As an example, suppose that an experimental treatment led to a one-point reduction in LDL ("bad" cholesterol). Assume further that the control group revealed no change over time. With enough subjects and minimal variability, this difference could be found to be statistically significant, yet few (if any) would argue that the difference is of sufficient magnitude to be clinically meaningful. Third, experiments often end up being inconclusive because no statistically significant differences emerge. This is not always undesirable and can even be important from a clinical standpoint in certain situations. For example, if treatment A and treatment B do not differ significantly with respect to improvements in QoL, then the researcher and clinician now have more alternatives from which to choose.

Jacobson and Truax [34] have suggested several criteria for documenting that effects are clinically meaningful and significant. Included among these are: (1) having a high percentage of subjects showing a given level of improvement, (2) obtaining a level of change that significant others or peers recognize as substantial (labeled by Kazdin [35] and Wolf [36] as "social validation" and shown to be of value in headache research by Blanchard et al. [37]), (3) achieving complete elimination of the presenting problem, (4) achieving a level of functioning that now falls within the normative range, (5) achieving high end-state functioning, or (6) obtaining changes that reduce a person's risk for other health-related problems.

Jacobson and Truax [34] prefer the approach that derives from the fourth consideration above because it is thought to have the broadest applicability. This approach assumes that the target of the intervention is a member of a dysfunctional population and that, following intervention, the individual needs to resemble someone from a nondysfunctional population in order for the intervention to have applied or clinical significance. In the present context, the comparison population could be individuals who do not experience migraine, do not have any type of chronic pain condition, or who have migraine or other pain but do not view the pain as troubling or limiting. Knowledge of this type would be helpful in identifying targets for intervention as well. Clinically meaningful

change would be demonstrated when post-intervention functioning results in the subject (1) falling outside the range of the dysfunctional group, defined as being two standard deviations away from the mean, (2) falling within the range of the functional group, defined as being less than two standard deviations away from the mean, or (3) being closer to the mean of the functional group than to the dysfunctional group. The various cutoff points for determining clinical significance for these three different approaches are depicted in Fig. 2. The major difficulty with adopting this approach is obtaining adequate normative data. However, it can be applied to all types of data collected from subjects or informants.

Another outcome evaluation consideration relates to the existence of negative findings. When no differences are found between two or more interventions, can the treatments be considered clinically equivalent? Hatch [38] proposed a way to address this important clinical issue, which he labels equivalence testing. Hatch begins by identifying situations where it is desirous to "prove" the null hypothesis. These are (1) to test whether experimental groups are equivalent or matched prior to intervention, (2) to determine whether dropouts are equivalent to completers as a test for potential biasing effects, or (3) to evaluate whether two different interventions are indeed equivalent. With respect to the last item, it may be important to establish that an experimental treatment is comparable to a standard, accepted treatment, that an abbreviated, reduced cost form of treatment is equivalent to an identical but more intense and costly form of treatment, or that treatments deriving from different approaches have similar effects on QoL (pharmacological versus nonpharmacological intervention, for example). Equivalence testing involves reversing the statement of hypotheses (the null hypothesis asserts inequivalence, while the alternative hypothesis asserts equivalence), defining an "equivalence interval," establishing two one-tailed null

hypotheses, and performing appropriate statistical tests. Readers are referred to Hatch [38] for further details and computational formulas.

Selective expansion of QoL boundaries

A hallmark of QoL investigations is a focus on subjectivity and inclusion of content that is personally relevant. Few of the existing QoL studies have capitalized on these features to the extent possible. Fayers and Machin [2] discuss a number of other theoretical models for QoL assessment that merit consideration by headache researchers and clinicians. These are described in brief in Table 4. What stands out most when considering these alternative approaches is the increased emphasis on subjective standards and personal values of individuals. The QoL scale developed by Wagner et al. [4] and listed in Table 2 derives from one of these alternative models – the needs-based model of Hunt and McKenna [39, 40]. Prior discussion on norm-based evaluation of change is consistent with another of the alternative models mentioned in Table 3 – the reintegration to normal living model.

Our steadfast adherence to pain *intensity* measures in outcome investigations (the measures collected in the standard daily diary [41]) has caused us to miss an opportunity to collect more personally relevant data in daily pain diaries. Although not a measure of QoL per se, the discussion to follow is consistent with the aims of this research and relates as well to the point to be advanced here.

The experience of pain is complex and includes several dimensions or aspects, such as sensory, affective, and evaluative. The sensory or intensity component, for example, includes stimulus attributes such as intensity, location, and

Fig. 2 Pretest and post-test scores for a hypothetical subject (x) with reference to three suggested cutoff points for determing clinically significant change. M_1, mean of the dysfunctionally population; M_0, mean of the well functioning normal population; X_1, pretest score for a hypothetical subject; X_2, post-test score for a hypotetical subject. (Adapted from Jacobson and Truax [34]).
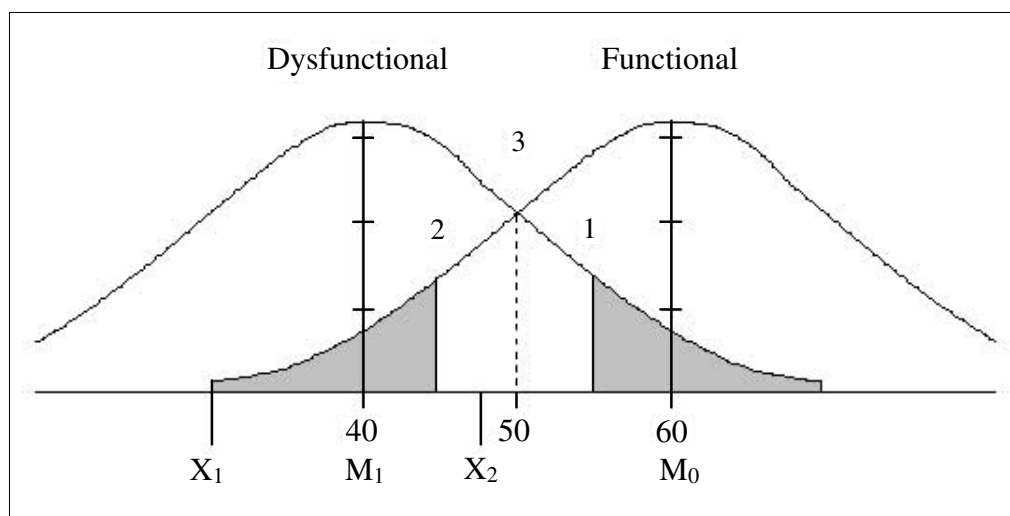
Table 4 Sample alternative models for evaluating quality of life (from Fayers and Machin [2])

Model	underlying assumptions and brief description
Expectations	QoL is the discrepancy between the individual's hopes and expectations and present experience. Present-ideal discrepancy may be narrowed by Improving functioning, modifying expectations, or both. Emphasis placed on incorporation of personal values
Needs	QoL relates to ability and capacity of individuals to satisfy various human needs, ranging from basic (food, sleep, pain avoidance, security, enjoyment, etc.) to more complex (identity, status, self-esteem, affection, love, creativity, etc.)
Reintegration to normal living	QoL relates to "the ability to do what one has to do or wants to do, but it does not mean being free of disease or symptoms"
Existential	QoL results from having a "positive approach to life" and is intimately related with abilities to cope
Patient-preference/utility	QoL needs to consider the relative importance that individuals assign to specific dimensions. Patient-defined "weights" are used to rank dimensions with respect to one another. This approach derives from decision-making theory

quality of the pain, while the *affective* (or reactive) component involves a patient's emotional reaction to the pain, fears about what the pain may signal, and concerns about ability to cope in a socially acceptable manner. Research suggests that the headache diary as typically used is sensitive primarily to the sensory (or intensity) dimension and is not all that effective for tapping into the affective dimension [42]. In a previous work [42], my colleagues and I adapted Tursky's [43] idiographic multidimensional measurement technique for separating the two dimensions of headache pain (sensory and affective). Although effective, Tursky's procedure requires considerable patient time for administration and therapist time for scoring, which restricts its utility for everyday clinical application. Items contained in the McGill pain questionnaire [44] are similarly designed to access varied components of pain, and these items may be more practical for use by therapists.

Price, McGrath, Rafii, and Buckingham [45] successfully piloted a procedure for assessing the sensory and affective aspects of chronic pain by use of visual analog scales (VASs). Their approach could be adapted for use with headache patients and repeated at various times during the day. In their procedure, the VASs were anchored as follows: "no sensation" and "the most intense sensation imaginable" for the sensory dimension, and "not bad at all" and "the most intense bad feeling possible for me" for measuring the affective dimension.

The clinical utility of considering multiple aspects of the pain experience is illustrated by the following. When using standard headache diary measures alone, it is common for a patient to complete treatment with no appreciable change being reflected in numerical pain ratings. Upon interview, such patients often describe marked improvement, most notably in the level of distress now experienced. Although it is possible that such comments result from efforts or perceived demands to please the therapist, it seems more likely that even though the sensory aspects of pain have not changed, significant change has occurred in the affective realm. In support, patients may report: "Even though my head hurts just as much, I don't let it bother me so," and "It still hurts a lot, but I can cope with it better now." Failure to incorporate aspects other than the sensory dimension may have lead to a loss of much clinically important information, information that does have relevance to QoL. The Headache needs assessment survey [23], which incorporates a measure of migraine "bothersomeness", is consistent with this recommendation.

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