Psychosocial Measures in Musculoskeletal Trials

STANTON P. NEWMAN

ABSTRACT. Measurement of psychological and social factors in studies of musculoskeletal disorders has become increasingly important with the need to show an effect of interventions on individuals' lives. Because information of psychological states involves patients reporting their private sensations, specific issues of their assessment need to be considered. Two of these issues are the problem of what constitutes the gold standard and the interpretation of causal direction of effects. The role of psychosocial factors in the assessment of disability is often ignored and frequently the distinction between disability and handicap confused. I describe and discuss the different measures commonly used to assess disability in arthritis. The assessment of symptoms, such as pain, stiffness, and fatigue are considered, as well as the examination of psychological well being. Interactions between these factors are also discussed. A number of other psychological variables have been developed and found to play a mediating role between the illness and its effect. These include coping, social support and other health cognitions, such as perceptions of control. The important role of psychosocial factors and their effect on measures on symptoms and disability suggest the need for more detailed examination of factors associated with outcome, and also the need to consider more complex designs that control for some of these factors at the outset of studies. (*J Rheumatol 1997;***24:979-84**)

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The pressure to confirm not only biological efficacy of drug treatments but also to show a positive effect on patients' lives has led to an increasing focus on psychological and social measures in arthritis. This is a rapidly growing area in the context of rheumatic conditions[1,2], and much progress has been made in our understanding of which psychological factors are important and how they may influence factors commonly measured in trials.

TERMINOLOGY

Terminology continues to cast a cloud over the understanding of this domain of research. The term "quality of life" is perhaps the most widely used and unfortunately has been applied to myriad psychological and social states; in some studies, it serves as a catch-all to "deal" with the psychosocial phenomena. More problematic, quality of life is used with an imprecision that fortunately does not extend to other psychological and social concepts. Its uses include health status, functional status, impairment, disability, handicap, activities of daily living and on occasion a more limited domain such as mood state and psychiatric disturbance. Measures of quality of life often purport to assess all psychosocial domains, often using single item questions that have not been validated against standardized instruments covering the particular domain. What is even more confusing is that in some measures, in an attempt to obtain an index of the global status of patients' psychological and social state, scores are combined from a variety of domains into a single score. This treats all domains of life as equally important both in the study and to the individual. In many ways use of the term quality of life has lessened our understanding of the role and import of specific psychological and social factors in musculoskeletal conditions. To make progress in this area researchers must be more specific about what psychological and social phenomena are important and apply appropriate measures. A focus on specific areas of psychological and social functioning will enable the effect of the illness on different areas of life to be examined.

ISSUES WHEN CONSIDERING PSYCHOLOGICAL AND SOCIAL MEASURES

Gold standard. In many areas of medicine it is possible to define a gold standard for which a measure acts as a proxy. The most obvious gold standard involves postmortem examinations soon after any measure has been performed. MRI scans and x-rays are obvious proxy measures of structure. In some situations the assumption that a measurement taken from one site on the body, such as bone density, reflects other areas of the body or can be generalized to the whole body has been brought into question (bone density).

When one considers symptoms that patients experience and report verbally, the issue of a gold standard becomes even more problematic. For example, the experience and reporting of pain is an important widely measured symptom in musculoskeletal conditions. It is one of the important symptoms that guide treatment. Pain is only known and experienced by the individual and documented by the health

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From the Unit of Health Psychology, Department of Psychiatry and Behavioural Sciences, University College London Medical School, London, UK.

S.P. Newman, DPhil.

Address reprint requests to Prof. S. Newman, Unit of Health Psychology, Department of Psychiatry and Behavioural Sciences, UCLMS, 2nd Floor, Wolfson Building, 48 Riding House Street, London W1N 8AA, UK.

care professional via verbal reports, questionnaires, or behavioral observation. The patient retains the authority over their own private symptoms. This issue extends beyond symptoms of the disease but also to the assessment of mood, satisfaction, and cognitions of health and illness. This difficulty of a gold standard should not deter incorporating psychosocial variables within a study as important relationships between psychosocial variables and their predictive value have been established.

Causal direction and interaction. It is common when working with a particular disease to see it as the wellspring of all symptoms. Causal relations are seen as moving from the disease through its primary symptoms to its psychological and finally social consequences. This view would assume that the condition leads to pain, which in turn leads to depression. It is questionable whether this causal direction should be assumed to be more salient than one that suggests increased levels of depression lead to reports of greater pain. The difficulty involves deciding which of the psychological variables influences/causes which others.

MEASURES OF FUNCTIONAL STATUS — DISABILITY AND HANDICAP

Estimates of the level of disability from musculoskeletal disorders in population studies range from 5 to 8% of individuals reporting substantial disability[3]. It is not surprising that arthritis is the commonest cause of disability[4] and that levels of disability have been found to increase with age[5].

A number of issues regarding the measurement of disability need to be considered. The first involves whether paper and pencil measures of disability reflect disability per se or whether they also examine handicap. In considering this point it is valuable to revisit the World Health Organization (WHO) distinction between disease, impairment, disability, and handicap (see Figure 1). it is often assumed that any measure of disability will be independent of psychological and social factors. To the extent that measures of health status or disability actually assess handicap they will require careful consideration of the effect of the social environment on the ability to perform roles and tasks.

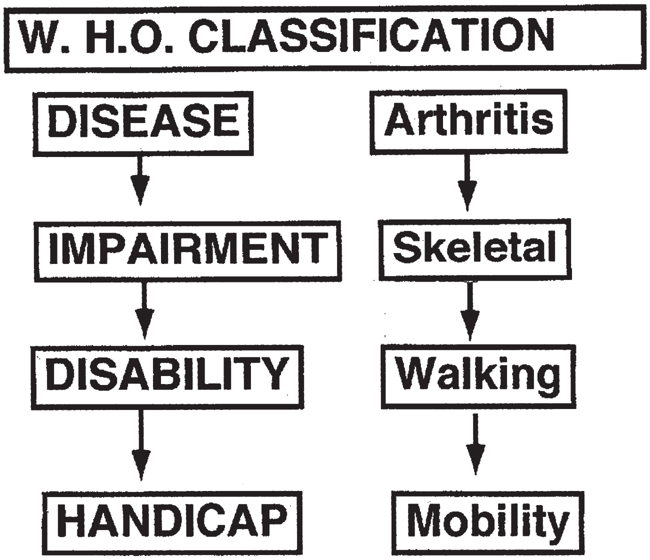

Figure 1. WHO distinction between disease, impairment, disability, and handicap.

A second issue is whether the reports on paper and pencil tests reflect what individuals are actually capable of doing or choose to do. Studies have shown that self-reports of functional performance are related to other factors such as mental health and health. Self-perceptions of health appear in turn to be related to demographic factors such as education, as well as physical activity and depression[6,7].

Few studies have specifically compared both behavioral and self-reports of disability. Studies that have used questionnaires that have a yes/no response format have generally found a high concordance. Jacobs, *et al*[8] used a Dutch version of the Arthritis Impact Measurement Scale (AIMS) and found similar responses for patients and observers. In contrast van den Ende, *et al*[9] examined responses by 51 patients with rheumatoid arthritis (RA) on the Health Assessment Questionnaire (HAQ), which has a graded Likert-type response format. Although the correlation between patients and observers was relatively high, male patients were found to report higher levels of ability than the observers, while female patients' reports were generally much closer to those of the observer. What was also important in this study, and in line with other research, both observer and patient reported HAQ scores were associated with psychological variables such as anxiety and depression. This suggests that psychological variables may have an effect on both self-reports and behavior. That individuals adapt over time to their disease and disability was suggested by the fact that patients who had RA for a longer period tended to overestimate what they could do, while those whose disease had recently been diagnosed tended to underestimate their abilities.

When looking at predictors of disability over time the role and importance of psychosocial measures is clearly apparent. Studies that have used both clinical and psychosocial variables have been able to achieve much greater levels of prediction of functional status than disease measures alone. Lorish, *et al*[10] found that combining psychosocial with physical variables accounted for 54% of the variance of disability at baseline and 35% at 12 month followup. Other factors such as sex[11] and marital status[12] have been found to be significant predictors of disability. The latter finding has been related to the role and importance of social supports as a protective mechanism in relation to disability (see below).

A large number of measures of functional ability or disability have been developed. Of those specifically developed for musculoskeletal disorders, the most widely used is the HAQ[13]. The disability section has 20 items that assess ability to perform activities in 8 different areas such as eating and walking on a scale from “no difficulty” to “unable to do.” With a modification of the HAQ[14], amendments have been found to increase the sensitivity to change[15]. The AIMS has also been developed specifically for musculoskeletal disorders[16]. This scale contains a number of dimensions, but factor analysis suggests it independently assesses lower and upper extremity functions, among other factors[17]. The AIMS has also been modified with the development of the AIMS2[18].

Generic measures to assess disability and handicap have also been developed and applied to individuals with arthritic conditions[19,20]. Perhaps the most widely applied measure is the Sickness Impact Profile (SIP)[21]. This is a 136 item yes/no questionnaire that provides a number of subscales. One measures physical disability, which in turn consists of walking, bodycare movement, and mobility. Some studies have compared the SIP to illness specific measures such as the AIMS, and the HAQ reported similar findings on both generic and illness specific measures[20-22].

Other scales include aspects of disability and handicap that are often combined with other phenomena to provide a comprehensive score of health status. Many combine psychological and social roles in a single score and provide a score of physical functioning. Most commonly used as generic health status measures are the SF36[23] and the Nottingham Health Profile[24]. The SF36 and SF36D (contains an item on depression) have 10 items that reflect physical functioning. The Nottingham Health Profile is widely used in the UK, but the SF-36 is becoming the generic measure of choice in many clinical trials. Bowling[25], however, argues that the SF-36 is not sufficient to assess disability and will need to be supplemented by a specific disability scale.

MEASURES OF SYMPTOMS

Pain is the primary symptom in many arthritic conditions and it has been ranked as the most important symptom for adults with RA[26]. A number of different dimensions of pain may be assessed. The intensity or extent of pain, the quality of pain, restrictions in activities (disability and handicap) caused by pain, and finally the manner of coping with pain. The most widely used measure of the experience of pain is the visual analog scale, often included in studies. In addition many generic questionnaires such as the AIMS include a brief assessment of pain. The McGill Pain Questionnaire assesses 78 qualities of pain[27]. Individuals with arthritis tend to refer to their pain as aching, exhausting, and rhythmic. Some also describe their pain as gnawing, annoying, and constant.

The 2 other symptoms most frequently studied in arthritic conditions are stiffness and fatigue. Stiffness has not been well studied and it is unclear how well individuals can distinguish it from pain. In contrast, fatigue has been reported as the most severe symptom in some arthritic conditions[28].

Fatigue has been found to be associated with sleep difficulties and depression[28-30]. Determining the causal direction of these influences is difficult, but McKinley, *et al*[30] provide data to suggest that the experience of fatigue in systemic lupus erythematosus is best understood by the effect of the disease mediated through sleep and emotional difficulties.

In measuring fatigue it is important to distinguish between the experience of fatigue and its effect on activities. It cannot be assumed that high levels of reported fatigue necessarily correlate with reductions in activity.

ASSESSING PSYCHOLOGICAL WELL BEING

The assessment of psychological well being presents a number of methodological questions to any researcher. Notable among these is what areas are to be researched. The focus has tended to be on measures of depression or depressed mood. This has tended to ignore the relatively high levels of anxiety reported by some patients with musculoskeletal disorders, and in addition fails to take account of other aspects of distress such as feelings of helplessness, uncertainty, loss of control, reduced self-esteem, and impaired body image that may occur in RA[31]. Such forms of distress do not fit neatly into conventional psychiatric categories.

In research on psychological well being it is often assumed that positive well being can be equated with a low score on measures of depression. This assumes that well being and depression are at opposite poles and avoids the difficulty of defining positive well being. Some researchers have begun adding measures of positive well being to studies of musculoskeletal disorders. These include self-esteem[32] and positive moods[33].

Clinical depression in RA has been found to range between 8 and 22%[34]. These numbers are higher than in the general population, but importantly, no different to individuals with other chronic illnesses[35]. In most studies the preferred method of assessment has been self-administered questionnaires. These have included the Beck Depression Inventory, the Zung Depression Scale, the Hospital Anxiety and Depression Scale, The General Health Questionnaire, CES-D 90, and the Middlesex Hospital Questionnaire. These questionnaires provide cutoff points for clinical depression, but in many cases these have not been standardized on the appropriate medical samples[35]. In addition to these scales some of the generic quality of life instruments in musculoskeletal conditions such as the AIMS include depression subscales.

One difficulty with scales measuring depression in musculoskeletal disorders is that they frequently include items susceptible to being positively scored as the result of physical illness rather than mood change. These include items on fatigue and sleep disturbance, both of which are common in musculoskeletal disorders. One technique is to remove these items, although this removes the possibility of applying a cutoff to assess clinical depression[36].

The alternative to questionnaire based assessments of depression is a formal interview. A number of standardized psychiatric interviews have been developed and the evidence suggests that, in contrast to questionnaire assessments, interviews lead to a higher incidence of clinical depression[34].

The assessment of depression in studies of musculoskeletal disorders further emphasizes that views of simple relationships between the extent of disease and levels of depressed mood are not tenable. More severe disease and a higher incidence of clinical depression or depressed mood have generally not been found[34,36-38].

Pain has often been associated with depression and/or distress[39]. Although it is common to believe that increased levels of pain lead to higher levels of depression, the relationship could well be in the opposite direction[40].

In any study it is also important to consider how high levels of depressed mood or clinical depression may affect other aspects of functioning. High levels of depressed mood have been found to be associated with significantly reduced perceptions of quality of life[41]. High levels of depression may also influence perceptions of functioning and lead to self-reports of functional status that are lower than in nondepressed individuals[6,7]. High levels of depression may also lead to restriction on social activities and social isolation. These interactions between mood and other measures underlie the importance of longitudinal studies to enable an examination of the causal direction between variables.

PSYCHOSOCIAL VARIABLES THAT MEDIATE BETWEEN THE ILLNESS AND ITS CONSEQUENCES

Because there is no simple way to interpret the relationship between the extent of musculoskeletal disorders and the physical and psychological consequences, a number of psychological concepts that mediate between disease and its consequences have been proposed.

Coping. The term coping is used to refer to individuals' attempts to limit the effect of a stressor such as arthritis. Coping thus occupies a position between the physical aspects of the disease and its consequences. Coping can involve behavior, such as seeking information, expressing emotions, such as showing anger, or thoughts, such as reinterpreting one's condition. A number of studies have examined the way individuals cope with arthritis[42].

A number of scales have been developed to assess coping in arthritis. The most popular generic inventory (often revised) to assess coping has been the Ways of Coping Scales[43] and the revised Ways of Coping Scale[40]. Disease specific questionnaires have also been developed. These include the London Coping with RA Questionnaire[45]. A number of methodological questions arise out of attempts to study coping in musculoskeletal disorders. These include how stable coping is over time and the effect of low mood on coping skills.

Despite methodological questions regarding assessment of coping studies, both generic and illness specific questionnaires have shown that how you cope with arthritic conditions influences the effects of arthritis. Individuals who are active and combative in regard to their arthritis have been found to report fewer symptoms, be less disabled and have lower levels of depression. The specific coping strategy of cognitive restructuring ("attempts to seek new meaning in their situation") and, in one study, seeking information about the illness, have been found to be associated with improved psychological well being[42]. In contrast, those individuals who adopted the strategy of wishful thinking (e.g., "Wish that the situation would go away or somehow be over with") tended to have lower psychological well being[42].

Social support. "Social support" refers to the process by which interpersonal relationships promote well being and protect people from declining health. In healthy individuals social support has been shown to reduce morbidity and mortality[46], particularly at times when they are facing stressful life circumstances[47].

A large number of studies have been conducted showing the importance of social support on the psychological well being of individuals with RA. Studies have shown that individuals with RA who have or perceive greater social support exhibit greater self-esteem[48] and life satisfaction[49], are better adjusted[50], show less depression[51,52] and cope better with their RA[53], and have slower progression in their disability[54]. In addition, it is important that social support has not always been found to be beneficial[55,56].

The term social support has been defined and measured in a number of different ways. The number of contacts has been taken to provide a structural measure of support and is to be contrasted with an evaluation of the adequacy or satisfaction with support. The latter has been found to be more predictive of psychological well being. The importance of the individual's judgment of their social support parallels findings in both epidemiological studies and studies in other illnesses, and further emphasizes the mediating role of psychological factors. In addition, who provides the support, when it is provided, and the nature of support are all important issues in its measurement[2]. Because of the numerous ways support is used, there are a plethora of instruments to assess social support.

Health cognitions. Individuals hold general beliefs about their health and what they are able to do about the course of their arthritis. These cognitions may also have an effect on outcome of clinical trials. Beliefs regarding who may be able to and whether it is possible to influence the course of health and illness in the future have been widely studied in arthritis. This concept, health locus of control, has a specific instrument that assesses 3 dimensions[57]. Internal health locus of control (IHLC) is an individual's belief he or she can influence future health and illness; chance (CHLC) is the belief that fate and chance will determine future health and illness; and powerful others (POHLC) is the belief that others such as health care professionals will wield an important influence on one's future health and illness. Cross sectional research showed that high internal health locus of control score led to higher levels of psychological well being in both RA and OA[58]. Later studies distinguished between control over treatment and control over symptoms. These have presented a more complex picture. Tennen, *et al*[59] showed that when patients with strong beliefs that they could control their pain (internal health locus of control) had higher levels of pain than expected. they became distressed. In this case, when beliefs about control were contradicted by reality individuals became depressed.

Perceived competence and self-efficacy describe individual's beliefs they have the skills to be able to deal effectively with issues in their environment. This concept has been found to be an important predictor of outcome in psychoeducational interventions[60]. In addition, Smith, *et al*[49] found that levels of competence had an effect on life satisfaction and depression.

CONCLUSION

The assessment of outcome in arthritis clinical trials is surprisingly complex. The important role of psychosocial factors and their impact on measures of symptoms and disability suggests the need for more detailed examination of factors associated with outcome, and also the need to consider more complex designs that control for some of these factors at the outset of studies.

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