Importance of sensitivity to change as a criterion for selecting health status measures

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Abstract

***Objective* — To assess the sensitivity to change over time of four health status instruments in relation to patients with rheumatoid arthritis.**

***Design* — Observational three month study of four self assessed instruments (arthritis impact measurement scales (AIMS), health assessment questionnaire (HAQ), Nottingham health profile (NHP), functional limitations profile (FLP)).**

***Setting* — One rheumatology unit.**

***Patients* — 101 patients with definite or classic rheumatoid arthritis.**

***Main measures* — Change scores for dimensions of instruments, as determined by effect size (mean change in score/baseline standard deviation of variable) and conventional rheumatological measures, at baseline and after three months.**

***Results* — Change scores for comparable dimensions (mobility, activities of daily living, household, pain, mood or emotion, and social scales) of the instruments were compared among 30 patients who considered their health status to have improved over three months. For all dimensions of health status the magnitude of change varied considerably according to the instrument. Maximum range in effect size was for social scales (AIMS 0·06, NHP 0·24, FLP 0·60). No single instrument seemed consistently to show the most change over all dimensions.**

***Conclusion* — Selection of health status instruments for audit or evaluation may have a considerable impact on the pattern of results obtained, and the "responsiveness" of such scales should be as carefully examined as their reliability and acceptability when selecting outcome measures.**

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Introduction

In recent years efforts to evaluate the quality and effectiveness of health services have increased appreciably.[1 2] For this purpose a range of outcome measures have been developed, variously termed health status, subjective health status, functional status, or quality of life measures.[3 4] They are considered particularly important because they assess dimensions of health of particular relevance to patients.[5] Measurement properties of such instruments, particularly reliability and construct validity, tend to have been quite extensively examined whereas the ability of the instruments to detect significant change in health status over time, sometimes referred to as "responsiveness" tends to be less well understood.[6] This is somewhat paradoxical given that sensitivity to important changes is the most essential requirement of an outcome measure.[7]

Sensitivity to change over time is a particularly important issue to examine in outcome measures for rheumatology because therapeutic effects tend to be modest and undramatic. There is no consensus regarding the merits of different conventional rheumatological data (clinical, laboratory, and radiological) as measures of outcome.[8 9] Several different health status measures have been developed specifically to address outcomes from patients' perspectives for rheumatoid arthritis (RA).[10] More recently, so called "generic" health status instruments, developed to be applicable to a wide range of health problems, have been suggested as appropriate measures of outcome in RA.[11] It is argued that results obtained with generic instruments can be more readily compared with those obtained for other health problems for purposes such as comparative cost-benefit analyses.[12] There is therefore an extensive range of different health status measures from which to choose, and advantages of generic over disease specific instruments remain unclear.[13]

This paper examines the responsiveness of four widely used health status questionnaires to changes of health status of patients over three months. There are several alternative ways of comparing the sensitivity to change of different health status measures.[14 15] We used "effect size"[16–18] as a simple way of expressing in a standardised way the measures of change in a sample recorded by different instruments. Comparable subscales for each of the four health status instruments were examined in terms of effect sizes, among a subsample of patients considered to have experienced substantial improvement in their health status.

There were several reasons for looking at these four instruments rather than older instruments such as the index of activities of daily living (ADL)[19] or the Barthel index.[20] Firstly, these earlier assessments require judgements by an observer whereas all of the current instruments are completed by patients. Secondly, three of the four instruments

considered here are intended to provide assessments on a wide range of aspects of patients' current health status whereas instruments of the ADL type focus almost entirely on basic self care activities. Finally, ADL and Barthel indices are more appropriate to more severe disability found in rehabilitation and care of the elderly and therefore less relevant to outpatient rheumatology clinics.

Patients and methods

PATIENTS

We selected a sample of 101 patients with a diagnosis of classic or definite rheumatoid arthritis from attenders at the rheumatology unit, Nuffield Orthopaedic Centre, Oxford. Twenty three of the sample were men and the mean age was 56(SD 12·1). The mean duration of disease was 12·9(8·9) years. Seventy one patients described their housing tenure as owner occupier and 60 were coded as social class 1, 2, or 3 (registrar general's classification); seventy five were married or cohabiting and fifteen lived on their own.

Patients were invited to take part in two assessments three months apart; sixty four were recruited at an outpatient clinic and 36 were hospital inpatients at the time of the first assessment and attended the outpatient clinic at the second assessment. No patient refused to take part, although one dropped out before the second stage because of work commitments.

RHEUMATOLOGICAL MEASURES

Within 24 hours of patients completing the health status instruments (see below) a set of standard rheumatological measures were used to assess disease severity. Erythrocyte sedimentation rate, a test that reflects severity of inflammation, was measured by the Westergren method. Haemoglobin concentration was measured with a Coulter counter. The Ritchie articular index was used as a clinical assessment of joint tenderness. Grip strength was measured according to the average of three attempts with each hand at squeezing a bag inflated to 30 mmHg pressure. The duration of morning stiffness was coded on a four point scale. With the exception of grip strength and haemoglobin concentration, a higher score on all these measures represents more severe disease.

HEALTH STATUS MEASURES

At both assessments four health status instruments were completed, two of which are specific for arthritis – the arthritis impact measurement scales (AIMS) and the health assessment questionnaire (HAQ) – and two of which are generic – the Nottingham health profile (NHP) and the functional limitations profile (FLP). The order of administration was systematically varied but presented to each respondent in the same order at subsequent interviews.

The AIMS consist of 45 items over nine separate dimensions of mobility, physical activity, activities of daily living, dexterity, household activities, pain, depression, anxiety, and social activities.[21] The HAQ is a measure of functional limitations wherein patients rate, on a four point scale, the degree of difficulty they have experienced during the past week with eight aspects of life (such as dressing, walking, and eating). Scores are then adjusted to take account of any help or aids that the patient might have and finally summed to produce a score between 0 and 3. In addition the HAQ includes a 10 cm visual analogue scale to represent pain experienced during the past week.[22] The NHP is a questionnaire containing two sections, of which the first is intended to measure perceptions of ill health through 38 items, each with a weighted score, which the respondent either affirms or not. The dimensions of this instrument are physical mobility, pain, emotional reactions, energy, sleep disturbance, and social isolation.[23] The FLP is derived from the sickness impact profile, modified for British use. In its full version of 136 statements the questionnaire features 12 domains, but for this study we used only the nine which constitute the physical and psychosocial dimensions (mobility, body care, ambulation, housework, rest, pastimes, emotions, alertness, and social interactions). As with the NHP the instrument is intended to be generic; items are either affirmed or not and weights, provided by the developers, are assigned before summing the items into the domains. Each domain has a maximum potential score of 100 with higher scores representing poorer health status.[24]

The scores of two of the health status questionnaires (AIMS, HAQ) were transformed to percentage scores, with higher values representing poorer health status in all cases. This transformation made the scores of the AIMS and HAQ directly comparable with the other two instruments (NHP, FLP), which are already expressed as percentage scores.[16]

At the second assessment all patients were asked to complete a global question: "Thinking of any overall effects your arthritis may have on you, how would you describe yourself compared to the last time I interviewed you in (month)? Do you feel that you are much better, slightly better, the same, slightly worse, or much worse." Questions of this form have been shown to be useful bench marks against which to compare change scores on health status instruments.[25]

EFFECT SIZE

The basic principle of an effect size is to take the mean change in a variable, (here, scales of health status instruments) and divide it by the baseline standard deviation of that variable.[16] It is similar to an expression of responsiveness by Guyatt *et al*,[7] which relates clinically meaningful change scores in a health status instrument to the variability of scores in stable subjects. Thus an instrument that has a high variability within stable subjects in relation to typical change scores would be considered to have a poor responsiveness. Effect size is therefore calculated as the difference between the mean score at time 1 and the mean score

at time 2 for each subscale, divided by the standard deviation at time 1. The result may be taken as expressing in a standardised way the magnitude and meaning of an instrument's change scores. Meenan *et al* consider that an effect size of around 0·20 is generally considered to be small, one of 0·50 indicates moderate differences, and those of 0·80 or above, large differences.[18]

Results

Effect sizes of different instruments were examined for those patients who at time 2 reported that they had improved ("much better" or "slightly better") on the single global question. The validity of taking this question as our bench mark or standard was examined by comparing other differences between patients who improved (n = 30) and those who described themselves as stable (n = 34). As table 1 shows, patients who considered themselves improved over three months were more likely to have experienced significant improvements on several other rheumatological measures compared with patients who viewed their health status as unchanged.

In order to compare the four instruments in terms of the magnitude of change they detected in a sample of subjects who considered their health status to have improved, patients' change scores were examined for subscales considered most appropriate for comparison (table 2). The

Table 1 Mean scores (standard deviations) for rheumatological measures at first and second assessements for patients whose health status was self assessed as either stable or improved

	Stable (n = 34)		*Improved (n = 30)*	
	Time 1	*Time 2*	*Time 1*	*Time 2*
Ritchie index	10·88(6·55)	10·94(6·51)	12·03(7·46)**	8·97(6·44)**
Erythrocyte sedimentation index (mm in first h)	36·35(30·21)	28·00(22·75)	56·21(28·55)***	40·34(26·70)***
Haemoglobin (g/l)	125·5(14·1)	126·6(14·1)	113·8(15·1)	116·9(14·4)
Pain (10 cm visual analogue scale)	3·63(1·95)	3·79(2·08)	3·84(1·78)*	2·89(2·14)*
Grip strength	116·25(56·59)	116·19(63·24)	107·03(57·93)***	128·55(62·95)***
Morning stiffness	2·29(1·06)	2·18(1·09)	2·20(1·27)****	1·77(1·14)****

Difference between time 1 and time 2 scores: *p < 0.05, **p < 0.01, ***p<0.001, *t* test; ****p < 0.05, Wilcoxon's signed ranks test.

Table 2 Combinations of scales used for analysis. Term(s) in each cell indicate scale(s) used

	Health status questionnaire			
Dimension	*AIMS*	*HAQ*	*NHP*	*FLP*
Mobility	Mobility and physical activity	Walking and reaching	Physical mobility	Mobility and ambulation
Activities of daily living	Activities of daily living	Dressing, hygiene, and rising	NA	Body care
Household	Household activities	Activities	NA	Activities
Pain	Pain	10 cm Visual analogue scale	Pain	NA
Mood or emotion	Depression and anxiety	NA	Emotional reactions	Emotions
Social	Social activities	NA	Social interaction	Social interaction

NA = not applicable.

Table 3 Mean scores (standard deviations) at times 1 and 2, mean change scores (95% confidence intervals), and effect sizes over selected subscales for patients with improved health by self assessment

	Mean scores on standardised scales (0-100)			
Instrument	*Time 1*	*Time 2*	*Mean change score*	*Effect size*
			Mobility	
AIMS	46·0(21·7)	36·8(19·6)	−9·2(−16·6 to −1·8)	0·43
HAQ	58·8(25·0)	49·4(28·8)	−9·4(−20·1) to 1·2)	0·38
NHP	32·4(22·9)	26·2(18·8)	−6·2(−13·2 to 0·8)	0·27
FLP	29·7(17·8)	17·4(11·2)	−12·0(−17·4 to −6·6)	0·69
			Activities of daily living	
AIMS	5·0(11·2)	2·1(7·4)	−2·9(−6·1 to 0·3)	0·26
HAQ	52·5(25·4)	45·4(28·5)	−7·0(−13·9 to −0·2)	0·28
FLP	18·7(13·3)	12·5(11·2)	−6·2(−10·1 to−2·3)	0·46
			Household	
AIMS	10·5(10·2)	6·7(7·2)	−3·9(−7·1 to −0·6)	0·38
HAQ	61·1(33·8)	35·6(35·1)	−25.6(−42·1 to −9·0)	0·74
FLP	32·9(30·2)	25·0(18·5)	−7·8(−20.2 to 4.6)	0.26
			Pain	
AIMS	60·3(22·7)	43·8(18·5)	−16·5(−24·2 to −8·8)	0·73
HAQ	38·4(17·8)	28·9(21·4)	−9·5(−17.0 to −1·9)	0·53
NHP	35·4(27·4)	24·9(29·7)	−10.6(−22·0 to 0·9)	0·38
			Mood/emotions	
AIMS	29·7(18·4)	14·5(12·0)	−15·2(−22·1 to −8·3)	0·83
NHP	21·9(24·5)	7·3(12·8)	−14·6(−23·1 to −6·1)	0·59
FLP	26·5(19·4)	14·6(16·5)	−11·9(−19·1 to −4·6)	0·61
			Social	
AIMS	39·8(17·9)	38·8(18·2)	−1.0(−7·0 to 5·0)	0·06
NHP	15·0(27·4)	8·3(18·4)	−6·7(−16.7 to 3·3)	0·24
FLP	20·9(14·8)	12·0(11·1)	−8·9(−13·3 to −4·4)	0·60

range of subscales selected was very similar to that of Liang *et al* in a study of responsiveness of health status measures after orthopaedic surgery.[15]

The effect sizes varied considerably between the four health status instruments on any particular dimension (table 3). Thus for mobility the HAQ and NHP scales produced very modest change scores, as expressed in effect sizes, whereas the FLP showed a substantial effect size. Similar variability between the instruments was recorded for other dimensions of physical function such as activities of daily living and housework. When the dimension of pain was examined the rank order of effect sizes for different health status instruments changed, with the AIMS pain scale producing the greatest magnitude of change.

The variability of effect sizes was less when the emotional dimensions of the instruments were compared. One of the most extreme ranges in effect size, however, was observed with social scales. According to the AIMS hardly any change in effect size occurred whereas for the FLP it was substantial. Above all, it was clear that no single instrument consistently produced either the most or least change in this group of patients.

The data were re-examined to see to what extent the variability in effect sizes was a result of the particular group selected for substantial improvement based on other evidence. A second subgroup was formed by considering a quarter of the sample who had experienced the most favourable improvements in erythrocyte sedimentation rate. Their scores had improved by 18 or more units over three months, a degree of change comparable with benefits of effective drug treatments obtained in clinical trials.[26] When the effect sizes for the four health status instruments were calculated for this somewhat different group, the same pattern emerged as in table 3, with each instrument showing the same performance relative to other instruments on all dimensions.

Discussion

Measures of health status have an important potential role in the evaluation of health care, providing a patient based perspective to supplement conventional measures of outcome.[27] Though substantial effort has been made in establishing basic requirements for instruments of acceptability, reliability, and construct validity, what has been termed their "evaluative validity"[7] – that is, the ability to detect clinically significant changes over time within patients – has been less extensively examined. A few studies in the United Kingdom have examined change over time of older instruments such as the index of activities of daily living.[28] In relation to more recent patient completed instruments some studies have appeared using, for example, the AIMS[29] or sickness impact profile (a precursor of the FLP)[30] to evaluate treatments in RA, but the relative sensitivity of different instruments has rarely been examined. An exception is the work of Liang *et al*,[15 31] who compared the relative sensitivity of five different health status instruments to assess change after total hip replacement. However, RA is, like many other medical conditions, more commonly treated by interventions with more subtle effects than surgery so that the current study represents a more reasonable test of the value of different health status instruments. This study is also based on a sample in which the degree of clinical change is closer to that observed when health status instruments are used for medical audit.[30 32]

The importance of considering the comparative sensitivity to change of different instruments is clearly shown by this study. Mobility is an important dimension of quality of life in RA and may be improved by some current treatments even over three months.[17] However, in this particular sample of patients, for whom there is good indication that some substantial improvements did occur over three months, the level of improvement in mobility seemed small according to one instrument (NHP) and moderate to large according to another (FLP). Similarly, pain, which is known to respond to treatments over short periods, seemed substantially improved according to the AIMS but only moderately improved according to the NHP. At the most extreme, no improvement in the social scale of the AIMS contrasted with quite substantial improvement with the FLP.

Looked at in another way, no instrument clearly outperformed the others in terms of effect sizes across a range of dimensions. We examined the same data by using a different expression of the relative sensitivity to change of different instruments, a method known as "relative efficiency."[15 33] Instruments were found to have the same rankings relative to each other for all dimensions as were found with effect sizes, although the degrees of difference were even greater. Thus our results are not a product of using this particular method of expressing sensitivity to change. They are also very similar to those obtained by Liang *et al*, who could find no single instrument that was consistently more sensitive to change in the range of health status instruments examined for hip replacement surgery.[15] Our paper focused on the assessment of improvement. An analysis of deterioration as assessed by the four instruments resulted in a similar pattern in which no instrument seemed consistently more sensitive.

It is rarely the case that those concerned with evaluation, audit, and quality assurance will use more than one instrument to assess the patient's perspective, and that selection needs careful considersation. The conclusion of this paper is therefore clear. Responsiveness is a dimension of health status instruments that requires just as much careful attention as other issues such as reliability and acceptability, because results are sensitive to the selection of the health status instrument. Investigators have always been recommended to look carefully at the content of instruments

to judge their relevance to the particular health problem and intervention under examination. One of the explanations for the differences between instruments obtained here for apparently similar dimensions must be subtle but significant differences in content that also influence responsiveness. This will arise because dimensions of instruments inevitably have to be created by sampling from the universe of items that constitute the dimension.

It is now clear that health status measures can provide results in terms of outcomes that are as informative as traditional measures, but with considerable economy.[34] Clinicians may nevertheless feel uncertain about the intuitive meaning of scores.[35] Effect sizes used in this comparative fashion should help to make results from such instruments more accessible.

In case the message of this paper seems too critical of the value of health status measures in clinical practice, it should be reiterated that the HAQ has several important features that commend it for regular use. It is short and easy to process, reliable, validated against several other variables, and relatively uninfluenced by extraneous factors such as patient's mood[36 37]; it also predicts decline in function and mortality in RA.[38 39] It is therefore an invaluable screening instrument for present and potential future health problems in RA and is widely regarded as informative by clinicians when used in this way.[40] Our reservations are about incautious interpretation of change scores for instruments without consideration of their measurement properties.

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Notes