A Comparative Study of Patient-Reported Functional Outcomes in Acute Rheumatoid Arthritis

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ABSTRACT. ***Objective.*** To assess the performance of the Barthel Index (BI) in patients with rheumatoid arthritis (RA) in the acute care hospital, as compared to the Stanford Health Assessment Questionnaire (HAQ) and the Hannover Functional Questionnaire (Funktionsfragebogen Hannover, FFbH).

Methods. A prospective study of 97 patients with RA admitted to an acute rheumatology hospital with new onset or acute flare of RA. Patients were required to self-complete the BI, the HAQ, and the FFbH. Disease activity was measured using the Disease Activity Score (DAS28).

Results. Seventy-eight percent of patients were female, average age was 61.5 (SD 12.5) years, and 72.2% were rheumatoid factor-positive. The median HAQ was 1.29 (range 0–3), median FFbH was 50% (6–100%), and median BI was 95 (0–100), and distribution was highly skewed. All measures of physical functioning were significantly correlated with each other and with the DAS28; however, the BI discriminated poorly between low and high disease activity.

Conclusion. The BI is not a useful instrument to assess physical functioning in patients with acute symptoms of RA, but may have a role in assessing patients with comorbidities and in assessing nursing care needs in the acute care hospital. (First Release Nov 15 2006; J Rheumatol; 2007:34:64–9)

Key Indexing terms:
RHEUMATOID ARTHRITIS OUTCOME ASSESSMENT
HEALTH ASSESSMENT QUESTIONNAIRE

Rheumatoid arthritis (RA) is an inflammatory joint disease that affects 1% of the population[1]. It is associated with considerable morbidity[2], causing acute symptoms of joint pain and swelling, and subsequent joint destruction and significant loss of function. Alongside pain reduction and the control and prevention of joint damage, prevention of loss of function is one of the primary aims of RA treatment[3], and thus it must be appropriately measured and monitored in daily practice, in the hospital environment, and in clinical trials.

In Germany, 22% of patients with RA require inpatient care in either an acute care hospital or a rehabilitation facility each year[4]. Although there are many disease-specific instruments available to measure physical function in RA, none were developed specifically for patients with acute RA or in the acute care hospital setting, and therefore existing RA-specific instruments need to be validated in the acute care setting. We compared the performance of the Barthel Index (BI)[5], the generic functional tool used in the German hospital system, and of 2 validated RA-specific instruments, the Stanford Health Assessment Questionnaire (HAQ)[6] and the Hannover Functional Questionnaire (Funktionsfragebogen Hannover, FFbH)[7], in a prospective cohort of patients with acute symptoms of RA requiring admission to hospital, based on the OMERACT filter principles of truth, discrimination, and feasibility[8].

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Accepted for publication August 28, 2006.

MATERIALS AND METHODS

Patients were recruited as part of a larger observational study of rheumatology patients in the acute care hospital. Consecutive patients with RA were included over a 6 month period between July 2004 and January 2005. Inclusion criteria were age over 18 years and recent onset (within 2 mo) of acute inflammatory joint symptoms in 2 or more peripheral joints requiring hospital admission for therapy, confirmed by the treating physician. Patients were excluded if they were unable to understand or complete the paper-based questionnaires due to cognitive impairment or poor understanding of the German language. All patients gave written informed consent before participating in the study. The study was approved by the medical ethics committee of Westfalen-Lippe and the University of Munster.

Patients were asked to self-complete a questionnaire including 3 function-based measures of health outcome. They were instructed to complete the questions with regard to current health status. When patients were unable to complete the questionnaires due to difficulties with hand function or writing, trained staff read each question to the patient and recorded the responses, without offering opinion or suggestions regarding the content of responses. Disease activity was assessed using the Disease Activity Score (DAS28)[9], with joint counts carried out by experienced medical staff within 1 week of completion of the questionnaires. Visual analog scales were used to quantify arthritis pain and general health, on a scale of 0–100 mm, where 0 reflected "no pain" or "perfect health" and 100 indicated "unbearable pain" or "worst possible health." Inflammatory markers including the C-reactive protein and erythrocyte sedimentation rate (ESR) and baseline rheumatoid factor were measured.

The instruments used to measure function included the Barthel Index[5], the HAQ[6], and the FFbH[7]. The BI is a generic measure of health status, not specific for rheumatology patients, that is commonly used in a hospital setting. It consists of 10 items with ordinal descriptive responses that are then given numerical value, the scale ranging from 0 to 100, where lower scores indicate worse self-reported function. Each domain gives 3 response alternatives, which are weighted differently according to domain, for example, "eating and drinking" scores 0 = not possible, 5 = with difficulty, and 10 = independently, whereas "bathing/showering" scores 0 = not possible, 0 = with difficulty and 5 = independently. The HAQ is an 8-subscale, 20-item questionnaire that has been extensively validated in RA. Each item has an ordinal response of 0–3, where in contrast to the BI, lower scores represent better function. The worst item score in each subscale is then averaged to obtain the final HAQ summary score between 0 and 3. The FFbH is an 18-item instrument with ordinal response options 1–3, validated against the HAQ in a rheumatology setting, where lower item scores indicate better function. The final score is then expressed as a percentage of normal functioning, using the equation: % functioning = [2 × (number of "1" responses) + number of "2" responses/36] × 100. This gives a final percentage score for which higher scores indicate higher functional ability. Scores ≥ 80% are considered to reflect normal functioning; between 70% and 80% indicates there is some deterioration in functioning, and < 50% indicates extremely severe impairments in physical functioning.

Individual items within each instrument were assessed for distribution and symmetry of item response scores, endorsement frequencies, and item-total correlation. Internal consistency reliability of the instruments was assessed by Cronbach's alpha[10]. Face and content validity were assessed by comparing the conceptual content of the 3 instruments using the International Classification of Functioning, Disability and Health (ICF)[11]. Concepts contained within each instrument have previously been extracted and linked to ICF categories[12], using standard linkage rules[13,14]. Construct validity was assessed by correlating the scores for the separate instruments to assess the convergent validity of related dimensions (Pearson's correlation coefficient). Agreement with the external construct "disease activity" as measured by the DAS28 was also performed (criterion validity).

In order to assess longitudinal construct validity, a random subset of 40 subjects from the original cohort were contacted by mail 12 months after the original study and asked to repeat the BI, HAQ, and FFbH, and to indicate if their arthritis was currently better, worse, or the same as it had been at initial admission to the acute care hospital. Scores were compared for each instrument over time using the nonparametric Wilcoxon signed-rank test.

The distribution of final scores for each of the 3 functional instruments was described using stem-and-leaf plots to assess potential problems with discrimination between high and low functional states.

RESULTS

Ninety-seven patients were included in the study: 76 (78%) were female, the mean age was 61.5 years (SD 12.5 yrs), range 23 to 82 years, and the mean duration of the underlying RA was 6.6 years (SD 9.4, range 0–51 yrs). Mean ESR was 38.1 (SD 25.6) and 72.2% were rheumatoid factor-positive. Disease activity was elevated in all patients, and there was a large range of functional impairment across the study population (Table 1). Only one patient was excluded during the study period due to cognitive or language problems.

The item and scale properties of the 3 instruments measuring physical function are shown in Table 2. For items of the HAQ and the FFbH, lower scores reflect a better health state; for the BI the lower scores reflect a poorer health state. Internal consistency was acceptable (i.e., > 0.8) in all measures, ranging from 0.89 for the BI to 0.94 for the FFbH.

Table 1. Disease activity and functional measures in patients with new onset or acute flare of RA (n = 97).

	Mean	SD	Median	Range
DAS28	5.81	1.15	5.63	3.44–8.00
VAS pain, mm	63.41	25.37	70	0–100
VAS general health, mm	61.48	25.87	65	4–100
HAQ	1.39	0.80	1.29	0–3
FFbH	51.37	2.46	50	6–100
BI	83.14	20.52	95	0–100

DAS: Disease Activity Score, VAS: visual analog scale, HAQ: Health Assessment Questionnaire, FFbH: Hannover Functional Questionnaire, BI: Barthel Index.

The 3 instruments were expressed in terms of ICF categories to enable direct comparison of the concepts each contains (Table 3). All 3 include a high number of self-care concepts; however, compared to the HAQ and the FFbH the BI contains few mobility concepts, and includes the 2 body functions "fecal continence (b5253)" and "urinary continence (b6202)," which detract from the face and content validity of the BI as a measure of the impact of RA on patient functioning.

Construct validity is reflected by the correlation of the BI to other instruments measuring function, in this study the HAQ and the FFbH. A Pearson correlation coefficient of 1 (or –1) indicates perfect positive (or negative) linear correlation of 2 variables; a coefficient of 0 indicates there is no linear relationship between the variables. The 3 instruments were significantly correlated with each other and with the DAS28. As expected[7], the HAQ and the FFbH scores were strongly correlated with each other (r = –0.87), and were moderately correlated with the BI (HAQ r = –0.67, FFbH r = 0.63). The 3 instruments of function were less strongly correlated with the DAS28, a measure of disease activity in RA (r = 0.45 to 0.55).

Twenty-two patients (55%) returned followup questionnaires after 12 months. Of these, 8 patients reported their arthritis was better than 12 months ago, 8 reported their arthritis was worse, and 6 were unchanged. Patients who said that their RA was better had a median score–improvement of 0.72 as measured by the HAQ, 14% by the FFbH, and a median score–improvement of 0 by the BI. The BI was not better able to detect deterioration over 12 months, with a median score–deterioration of –2.5. Changes of the BI over 12 months did not reach statistical significance.

Scale scores for the 3 instruments covered the full range of possible responses. Scores for the HAQ and the FFbH approached normality; however, scores for the BI were highly skewed (Figure 1). Fifty percent of the BI responses scored 95 or 100 (reflecting good physical function), indicating a significant ceiling effect and therefore a poor

Table 2. Instrument item and scale properties (n = 97).

Scale/item	Mean (SD)	Response options		Item-total correlation	Cronbach's alpha
		% floor	% ceiling		
HAQ					0.93
Dressing and grooming	1.25 (0.98)	19.6	18.5	0.85	
1. Dress yourself	1.26 (0.96)	23.7	12.4	0.82	
2. Shampoo your hair	1.23 (1.05)	28.9	16.5	0.81	
Arising	1.03 (0.86)	29.9	6.2	0.81	
3. Stand up from an armless straight chair	1.04 (0.92)	34.0	6.2	0.81	
4. Get in and out of bed	0.98 (0.83)	33.0	2.1	0.77	
Eating	1.53 (1.01)	17.5	22.7	0.86	
5. Cut your meat	1.16 (1.01)	30.9	12.4	0.83	
6. Lift a full cup or glass to your mouth	0.88 (0.85)	39.2	3.1	0.77	
7. Open a new carton of milk	1.54 (0.99)	15.5	20.6	0.85	
Walking	0.98 (0.88)	29.9	7.2	0.73	
8. Walk outdoors on flat ground	0.86 (0.88)	42.3	4.1	0.72	
9. Climb up five steps	1.09 (0.95)	33.0	7.2	0.68	
Hygiene	1.48 (1.15)	24.7	28.8	0.85	
10. Wash and dry your entire body	1.11 (0.99)	30.9	12.4	0.82	
11. Take a bath	1.46 (1.17)	27.8	27.8	0.85	
12. Get on and off the toilet	0.78 (0.79)	43.3	1.0	0.79	
Reach	1.38 (0.99)	12.4	23.7	0.81	
13. Reach and get down a 2kg object from just above your head	1.53 (1.00)	14.4	22.7	0.82	
14. Bend down to pick up clothing from the floor	1.03 (0.62)	35.1	9.3	0,77	
Grip	1.44 (1.03)	20.7	20.6	0.84	
15. Open car doors	1.04 (1.05)	39.2	13.4	0.76	
16. Open jars which have been previously opened	1.29 (0.97)	22.7	13.4	0.79	
17. Turn taps on and off	1.07 (0.90)	30.9	6.2	0.73	
Activity	2.02 (0.97)	6.2	44.3	0.76	
18. Run errands and shop	1.23 (1.08)	32.0	16.5	0.79	
19. Get in and out of a car	2.06 (0.94)	26.8	13.4	0.74	
20. Do housework or gardening	2.02 (0.97)	6.2	41.2	0.77	
FFbH					0.94
1. Spread a slice of bread	1.54 (0.61)	52.6	6.2	0.64	
2. Get out of a bed of normal height	1.63 (0.62)	44.3	7.2	0.69	
3. Writing by hand	1.60 (0.66)	49.5	9.3	0.66	
4. Turn taps on and off	1.77 (0.64)	34.0	11.3	0.68	
5. Stretch (eg. To get a book down from a high shelf)	2.07 (0.71)	21.6	28.9	0.73	
6. Lift and carry an object at least 10 metres	2.53 (0.61)	6.2	58.8	0.73	
7. Wash and dry oneself	1.74 (0.67)	38.1	12.4	0.85	
8. Bend over and pick up a light object	1.79 (0.66)	34.0	13.4	0.73	
9. Wash hair over a handbasin	2.01 (0.80)	30.9	32.0	0.78	
10. Sit on a chair for 1 hour	2.16 (0.73)	19.6	36.1	0.68	
11. Stand for 30 minutes	2.33 (0.67)	11.3	44.3	0.71	
12. Get into bed	1.91 (0.71)	29.9	20.6	0.72	
13. Put on and take off a pair of stockings	1.85 (0.64)	28.9	13.4	0.75	
14. Lift an object from a sitting position	1.97 (0.70)	25.8	22.7	0.71	
15. Lift a heavy object from the floor and place it on a table	2.60 (0.66)	9.3	69.1	0.71	
16. Put on and take off a winter coat	1.84 (0.73)	36.1	19.6	0.73	
17. Walk quickly for 100 metres	2.59 (0.66)	9.3	68.0	0.69	
18. Use public transport	1.59 (0.72)	54.6	13.4	0.68	
Barthel Index *(maximum score)*					0.89
1. Eating and drinking (maximum score 10)	8.56 (2.50)	2.1	73.2	0.62	
2. Get out of a wheelchair into bed (15)	13.30 (3.81)	1.0	82.5	0.73	
3. Self-care (eg. wash face, clean teeth, comb hair) (5)	3.66 (2.23)	26.8	73.2	0.71	
4. Use the toilet (10)	8.66 (2.45)	2.1	75.3	0.76	
5. Bathe/shower (5)	3.09 (2.44)	38.1	61.9	0.71	
6. Walk on level ground (15)	13.04 (3.27)	3.1	67.0	0.61	
7. Climb up/down stairs (5)	6.91 (3.57)	13.4	51.5	0.78	
8. Get dressed/undressed (10)	7.22 (3.14)	7.2	51.5	0.74	
9. Bowel control (10)	9.59 (1.56)	1.0	92.8	0.65	
10. Bladder control (10)	9.59 (1.72)	2.1	93.8	0.55	

Table 3. International Classification of Functioning, Disability and Health (ICF) concepts within the 3 instruments. * Indicates this item has been included in the instrument construct; number of asterisks corresponds to the number of times the item is measured within that instrument.

ICF chapter	HAQ	FFbH	BI
Activities and Participation: Mobility, total no. categories	11	11	4
d410–Changing body position	***	**	
d415–Maintaining body position		**	
d420–Transferring oneself			*
d430–Lifting and carrying objects	*	**	
d440–Fine hand use	*	*	
d445–Hand and arm use	***	**	*
d450–Walking	*	*	*
d455–Moving around	*		*
d470–Using transportation	*	*	
Activities and Participation: Self-care, total no. categories	7	7	7
d510–Washing oneself	***	***	*
d520–Caring for body parts			*
d530–Toileting	*		*
d540–Dressing	*	***	**
d550–Eating	*	*	*
d560–Drinking	*		*
Activities and Participation: Domestic life, total no. categories	3	0	0
d620–Acquisition of goods and services	*		
d640–Doing housework	*		
d650-Caring for household objects	*		
Body Functioning, total no. categories	0	0	2
b525–Defecation functions			*
b620–Urination functions			*

capacity to discriminate between different levels of functional ability, particularly at better levels of functioning.

DISCUSSION

Measurement of physical functioning in RA is an integral part of baseline patient assessment, clinical monitoring in daily practice, and outcome assessment in clinical trials. For a measurement or an instrument purporting to measure an outcome to be valid, it needs to fulfill the OMERACT filter of *truth*, *discrimination*, and *feasibility*[8]. Truth reflects the ability of a test or instrument to measure what it is intended to measure, and includes such statistical concepts as face validity, content validity, and construct and criterion validity. Discrimination is the ability of a test or instrument to detect differences between groups, and includes test reliability, sensitivity, and responsiveness to change. Finally, feasibility is how easy the test or instrument is to perform, given the constraints of time, money, and interpretability.

Both the HAQ and the FFbH have been extensively validated in RA[7,15,16], although they have not been examined previously in the acute care hospital setting. Face validity of both instruments is good, fulfilling *truth* (Table 3), although the HAQ includes elements on domestic life and both instruments include the element "transportation," elements that are not relevant to the acute care hospital. The BI has not been assessed for *truth* in RA; however, item validity in some factors is low, particularly with regard to bladder and bowel function, which are not impaired by RA. The use of the ICF enables a direct comparison of the concepts measured by each of the 3 instruments, and reveals significant differences between the BI and the more established functional measures in RA in the areas of mobility and bowel and bladder functions. RA affects primarily the musculoskeletal system, and thus measures of function should logically concentrate on the functions of the musculoskeletal system, i.e., mobility and independent functioning, if they are to exhibit face validity.

The 3 instruments examined in this study correlated well with each other, although the BI correlated less well with the HAQ and the FFbH than these 2 correlated with each other. Such agreement with other related constructs (construct validity) is a part of the validation of a measure, but depends to some extent on the quality of the comparators; the conclusions are strengthened by the consistently lower correlation of the BI to both of the 2 more established measures, both in a cross-sectional and a longitudinal setting (despite small numbers in the longitudinal study). Assessment of the measures against an external comparator (criterion validity) is more difficult. The DAS28 is a measure of disease activity and inflammation, not of physical function, but it seems logical to suggest that patients with elevated disease activity will have more pain and more swollen and tender joints, and thus have more problems with mobility and functioning. Disease activity can there-

Barthel Index		Total
0	0	1
1		0
2	0	1
3	5	1
4	055	3
5	00055555	8
6	0055	4
7	00000055555555	14
8	000005555	9
9	000000055555555555555555	24
10	00000000000000000000000000000000	32

Health Assessment Questionnaire*		Total
3.	0	1
2.	5555666778	10
2.	00122333334444	14
1.	5555556666777788889	19
1.	000001111122222223344	21
0.	55555666677788889	17
0.	000111223334444	15

Hannover Functional Questionnaire		Total
0	58	2
1	11366699999	11
2	25777	5
3	00003333366668888	17
4	11444447777	11
5	00022222222255555888	20
6	13699999	8
7	225557777	9
8	0066688	7
9	114	3
10	0000	4

Figure 1. Stem-and-leaf plots of the Barthel Index (BI), Health Assessment Questionnaire (HAQ), and Hannover Functional Questionnaire (FFbH) in patients with new onset or acute flare of RA, n = 97. *HAQ scores have been inverted, so that poorer function is seen at the top of the plot (HAQ = 3.0), as in the BI and the FFbH.

fore be considered to be indirectly associated with physical functioning in RA. Correlation of all 3 instruments with the DAS28 was significant but low (r = 0.45 to 0.55), consistent with previous comparisons of the HAQ and DAS in RA patients in remission (r = 0.42)[17]; clearly, physical functioning in RA is not determined solely by disease activity, but will also be influenced by structural joint and organ damage, frailty, and psychosocial and environmental factors. Thus the low correlations with DAS28 cannot be interpreted as poor instrument validity, but are more a reflection of the choice of comparator.

The HAQ and the FFbH have been shown in previous studies to be capable of discriminating between patients with high and low functional states[18], and to be responsive to change over time and with therapy[19,20]. Our study failed to show good *discrimination* between patients with high and low functional health with the BI. It classified over 95% of patients at the top of the scale (good physical functioning), despite the large range of physical functioning seen with the other 2 validated instruments, and a large range of disease activity. This is consistent with results in a population based study of functional impairment in elderly individuals with RA[21], in which 50% scored 100 on the BI, and those who scored poorly had concomitant dementia, suggesting that the BI is sensitive for cognitive impairment rather than for RA. Similar problems with ceiling effects have been observed to a lesser extent with the modified HAQ compared to the standard HAQ in detecting clinical change in ambulatory patients[22]. A good measurement instrument also needs to be responsive to change if it is to do more than document a patient's current status. This study was not specifically designed to look at how the BI performs in response to treatment; however, intuitively, if the great majority of patients are classified as having good physical functioning at the peak of their active disease, then the BI does not have the scope to improve further with therapy. This was supported by the lack of significant improvement of the BI scores over 12 months in patients who reported a clinical improvement in our study. Clearly, the BI is not an ideal instrument for measuring physical functioning in patients with RA in an acute hospital setting, where the assessment of treatment effect and patient improvement is central to patient care.

The BI is most commonly completed by nursing staff in the hospital environment and is quick and easy to use (*feasibility*). The HAQ and FFbH are also easy to perform, both being short questionnaires that can be completed by the patient or a proxy, although they are somewhat longer and both are more complicated to score than the simple tally required for the BI.

Our study shows that the BI is highly *feasible*; however, objectively it does not fulfill the OMERACT filter concept of *truth* and is likely to perform poorly in the area of *discrimination*. Nevertheless the BI was developed as a generic health measure, and not to measure musculoskeletal health specifically. It can identify general health impairments and physical functioning limitations independent of disease state, and thus may be of more value in patients with multiple comorbidities and impairments in other organ systems alongside their arthritis. It is also useful for assessing the level of nursing care a patient may require during admission in an acute care hospital, indicating areas where assistance is required, and so has a place in patient assessment in the acute care hospital.

In contrast, the HAQ and the FFbH perform extremely well for *truth* and *discrimination* in patients with new-onset and acute flare of RA, and despite complicated scoring are practical and easy to complete in daily practice (*feasibility*). On balance, we believe the BI is not an appropriate surrogate for physical functioning in this group of patients with rheumatic disease, and should be reserved for assessing general health and level of care. Disease-specific, validated instruments such as the HAQ or the FFbH should be used

routinely for assessing disease state and progression/treatment response in patients with RA in the hospital setting.

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