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Responsiveness of the shoulder function assessment scale in patients with rheumatoid arthritis

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Abbreviations: DAS28, 28 joint count Disease Activity Score; ES, effect size; HAQ, Health Assessment Questionnaire; RA, rheumatoid arthritis; RR, responsiveness ratio; ROM, range of motion; SFA, Shoulder Function Assessment scale; SRM, standardised response mean; VAS, visual analogue scale

ABSTRACT

Objectives: To investigate the responsiveness of the Shoulder Function Assessment scale (SFA) in patients with rheumatoid arthritis (RA).

Methods: In 35 patients with RA receiving a (peri-)articular injection because of local shoulder complaints the SFA, impact of shoulder function on activities of daily living, active shoulder range of motion (ROM), the 28 joint count Disease Activity Score (DAS28), and the Health Assessment Questionnaire (HAQ) were measured before and 4–6 weeks after treatment. Responsiveness was determined using the standardised response mean (SRM), effect size (ES), and responsiveness ratio (RR).

Results: Overall, significant improvement was seen according to the SFA (mean change 10.9 (95% confidence interval 6.5 to 15.3)), active shoulder ROM (except external rotation), and the impact of shoulder function on daily activities. In addition, the DAS28 and HAQ scores improved significantly. The responsiveness of the SFA was excellent, with the SRM, ES, and RR being –0.86, –1.16, and 1.28, respectively.

Conclusions: In addition to its good validity and reliability, the SFA proved to have a high sensitivity to clinical changes in patients with RA who received local treatment for shoulder complaints.

The Shoulder Function Assessment scale (SFA) has been developed as a simple outcome measure of shoulder function in patients with rheumatoid arthritis (RA).[1] It is a combined index of shoulder function and activities and can be completed within 3 minutes. The SFA has shown high intra- and interobserver reliability, correlated well with other measures of shoulder function, and shown better discrimination between various levels of shoulder function in patients with RA than other instruments.[1] So far, the responsiveness[2] of the SFA has not been investigated. In this study the responsiveness of the SFA in patients with RA with shoulder complaints receiving an injection with corticosteroids was examined.

PATIENTS AND METHODS

Study design and patients

This prospective study concerned consecutive patients with RA3 attending the rheumatology clinic of the Leiden University Medical Centre who had subacromial bursitis, tendonitis, or capsulitis of the glenohumeral joint, and were treated with a corticosteroid injection in one shoulder. Assessments were done before the injection and 4–6 weeks thereafter. The local medical ethics committee approved the protocol and all patients gave written informed consent.

Assessment methods

Demographic data, disease duration, the Westergren erythrocyte sedimentation rate (mm/1st h), and data on drug treatment were derived from the medical records. All clinical assessments were made by the same physical therapist (HMV) and the scoring of the radiographs by a rheumatologist (AC).

Clinical assessments included SFA, range of motion (ROM), subjective opinion about shoulder function, radiographic score, overall disease activity, and daily functioning.

SFA

The SFA consists of two visual analogue scales (VAS; pain at rest and during movement), four multiple choice questions about activities of daily living (dressing, combing hair, washing opposite axilla, and using the toilet), and three measures for ROM (total active abduction and two combined movements asking the patient to place the hand on the head with the elbow forward and backward). The overall score ranges from 0 (worst shoulder function) to 70 (best shoulder function).1

Range of motion

Active and passive ROM in the directions abduction, forward flexion, and external rotation was measured in both shoulders in a seated position with a goniometer.4 Values were rounded off to 5 degrees.

Subjective opinion about shoulder function

Patients rated the impact of their overall shoulder function on daily activities on a 100 mm VAS, with 0 = no impact and 100 = severe impact. At follow up, they evaluated their shoulder function in relation to baseline on a five point Likert scale (1 = much worse, 5 = much improved).[5]

Radiographic score

Recent radiographs (≤6 months before baseline) of the glenohumeral joint of the affected shoulder were assessed by the Larsen erosion score (grade 0 = no abnormalities, grade 5 = joint space narrowing with bone deformation).[6]

Overall disease activity and daily functioning

Disease activity was measured with the 28 joint count Disease Activity Score (DAS28)[7] and functional ability with the Health Assessment Questionnaire (HAQ), with the mean of the maximum scores of its eight subscales providing a total score ranging from 0 = no disability to 3 = severe disability.[8]

Statistical analysis

In a previous cross sectional study in patients with RA the mean SFA score was 43.0 and the standard deviation (SD) 13 points.[1] If it is assumed that the change score of the SFA should exceed these 13 points, corresponding with an effect size (ES = pretreatment mean minus post-treatment mean divided by the SD of the pretreatment mean) of ≥1.0, in order to measure an improvement in shoulder function, then 35 patients would be needed to detect a significant difference, with α being 0.05 and a power of 0.90. With a dropout rate of 10%, 38 patients in total would be needed.

For all clinical measures mean differences between baseline and follow up with the 95% confidence intervals were calculated. The active and passive mobility of the affected and unaffected side at baseline were compared by paired *t* tests. Unpaired *t* tests were used to compare the mean change score of the SFA of patients who regarded themselves as "improved" or "much improved" with that of patients who considered themselves "stable", "worse", or "much worse". The magnitude of all changes was described by the standardised response mean (SRM; pretreatment mean minus the post-treatment mean divided by the standard deviation of the change score),[2] ES, and responsiveness ratio (RR; the mean change score of "improved" patients divided by the standard deviation of the change score in "stable" patients[9]). The interpretation of the magnitude of the ES (0.2 is small, 0.5 is moderate, and 0.8 is large, the same when values are negative) can also be applied to the SRM,[10] whereas an RR>1.0 is considered necessary to detect a clinical difference.

RESULTS

Between July 2000 and May 2002 38 patients (10 men, 28 women) with a mean (SD) age of 60.5 (13.0) years were included. The median disease duration was 6 years (range 0–47) and the median duration of the shoulder complaints was 7 months (range 1–180). Active and passive ROM of the affected side was significantly impaired in comparison with the unaffected side (all $p<0.05$), except for active external rotation ($p = 0.79$). The median Larsen erosion score of the affected shoulder was 0 (0 in 24 patients and range 1–5 in nine patients); in five patients recent radiographs were not available. Twenty eight patients received an intra-articular injection, seven were injected in the subacromial space, and in three cases the localisation of the injection was not recorded. In 3/32 patients who were receiving a disease modifying antirheumatic drug at baseline, the drug was changed during the follow up period, whereas in seven patients the dose was increased.

Three patients were not able to attend the follow up assessment. Table 1↓ shows that the total SFA score and the subscores improved significantly, with the values of the SRM, ES, and RR for the total SFA score being –0.86, –1.16, and 1.28, respectively. In addition, active and passive ROM increased significantly, except for external rotation ($p = 0.46$ and 0.12, respectively), with moderate results according to measures of responsiveness. The impact of shoulder function on daily activities decreased with the matching measures of responsiveness, showing excellent sensitivity to the clinical improvement.

[TABLE 1]

Nine of the 35 (26%) patients considered their shoulder function stable while 26 (74%) patients reported an improvement, with the mean (SD) change scores of the SFA being 0.58 (11.3) and 14.5 (11.5) in the group of stable and improved patients, respectively ($p<0.01$). Of the stable patients, five showed a decreased and four patients an increased SFA score, whereas in the 26 patients who considered themselves improved, 23 patients had an increased and three patients a decreased SFA score.

The overall functional ability and disease activity of the patients improved significantly according to both the HAQ and the DAS28, with good to moderate sensitivity to clinical change according to measures of responsiveness. Of the HAQ dimensions related to upper extremity function, the largest improvement was seen within the dimension "reaching".

DISCUSSION

In this study evaluating the responsiveness of the SFA in patients with RA who received an injection in the shoulder, it was shown that its ability to detect clinical changes was excellent. After 4–6 weeks significant improvements in the total SFA score as well as its subscores were seen, with high values according to various measures of responsiveness.

Within the SFA, the responsiveness of the pain and disability subscores was greater than that of the ROM subscale. This might be related to the nature of the symptoms of patients with RA with an episode of shoulder inflammation and the resulting local treatment. Injections with corticosteroids are meant to relieve local inflammation and pain, and are not primarily targeted at increasing the ROM.

Of all outcome measures, the VAS for impact of shoulder function on daily activities showed the greatest responsiveness. These results suggest that the four SFA items concerning those activities of daily living that are likely to be limited in the case of shoulder disorders may not be equally relevant to all patients with RA. Therefore, to enhance the responsiveness of the SFA, the substitution of the four predetermined activities by a VAS for impact of shoulder function on daily activities could be considered. Despite the excellent responsiveness of a single VAS, a composite index such as the SFA provides insight into other relevant aspects of shoulder function—namely, ROM and pain.

Both the HAQ and DAS28 improved significantly over time in this study. Conceivably, part of this general improvement might be attributed to the systemic effects of the corticosteroids or the changes in the concurrent drug treatment, or both.

Because neither the patients nor the observer were blinded in this study a bias towards improvement might have been introduced. Thus the inclusion of a control group without treatment might have enhanced the contrast between patients who were stable or who deteriorated and those who improved. In conclusion, the responsiveness of the SFA to clinical changes was found to be excellent in patients with RA who received a local injection with corticosteroids. Future studies should investigate whether the SFA is an appropriate instrument for the evaluation of other treatments in patients with RA, such as a shoulder prostheses.

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TABLES

Table 1 Baseline (n = 38) and follow up (n = 35) scores of patients with RA receiving an injection in the shoulder

	Unaffected shoulder	Affected shoulder						
		Baseline	Follow up	Change (95% CI)	p value*	SRM	ES	RR
SFA								
Total score		34.8 (9.5)	45.9 (15.3)	10.9 (6.5 to 15.3)	<0.01	−0.86	−1.16	1.28
Subscales:								
Pain at rest		4.9 (2.6)	7.1 (2.7)	2.1 (1.2 to 3.1)	<0.01	−0.81	−0.84	1.04
Pain at movement		2.8 (1.8)	5.1 (3.3)	2.3 (1.4 to 3.3)	<0.01	−0.85	−1.27	1.76
Activities of daily living		11.4 (3.3)	14.2 (4.4)	2.8 (1.3 to 4.3)	<0.01	−1.00	−0.84	1.68
Range of motion		15.9 (7.7)	19.5 (7.7)	3.6 (1.0 to 6.2)	<0.01	−0.49	−0.46	0.52
Range of motion in degrees								
Active shoulder abduction	120.9 (41.3)	86.7 (37.9)	109.1 (45.5)	23.3 (10.1 to 36.5)	<0.01	−0.58	−0.59	1.00
Active shoulder forward flexion	132.9 (28.9)	105.4 (35.3)	120.8 (33.3)	15.6 (5.6 to 25.5)	<0.01	−0.53	−0.43	1.18
Active shoulder external rotation	43.8 (15.5)	38.4 (16.0)	41.4 (14.9)	1.4 (2.5 to 5.3)	0.46	−0.26	−0.18	0.29
Passive shoulder abduction	137.8 (33.8)	109.6 (33.2)	125.7 (40.2)	−16.1 (−27.4 to −4.9)	<0.01	−0.49	−0.58	0.68
Passive shoulder forward flexion	145.8 (20.7)	121.8 (30.2)	135.1 (29.0)	−14.5 (−23.2 to −5.9)	<0.01	−0.58	−0.46	1.27
Passive shoulder external rotation	49.6 (14.9)	42.6 (17.2)	47.0 (15.0)	−3.4 (−7.8 to 1.0)	0.12	−0.26	−0.20	0.44
Impact of shoulder function on daily activities on VAS (mm)		66.1 (18.8)	40.7 (28.9)	−26.5 (−34.5 to −18.4)	<0.01	1.09	1.40	2.67
HAQ								
Total score		1.75 (0.5)	1.50 (0.7)	−0.24 (−0.42 to −0.06)	0.01	0.46	0.48	1.10
Subscales								
Dressing		1.81 (0.7)	1.40 (0.7)	−0.34 (−0.06 to −0.08)	0.01	0.45	0.51	0.70
Eating		1.86 (0.6)	1.60 (0.8)	−0.26 (−0.56 to 0.05)	0.09	0.29	0.41	0.49
Hygiene		1.88 (0.7)	1.59 (0.8)	−0.21 (−0.49 to 0.06)	0.13	0.27	0.32	0.55
Reaching		2.00 (0.8)	1.51 (0.8)	−0.43 (−0.71 to −0.15)	< 0.01	0.53	0.55	1.61
DAS28		5.28 (0.93)	4.74 (1.04)	−0.54 (−0.84 to −0.23)	<0.01	0.75	0.58	2.22

All results are expressed as mean (SD).
*The level of significance was set at p<0.05.
CI, confidence interval; ES, effect size; SRM, standardised response mean; RR, responsiveness ratio; VAS, visual analogue scale; SFA, shoulder function assessment scale; DAS28, 28 joint count Disease Activity Score; HAQ, Health Assessment Questionnaire.

REFERENCES

Ende van den CHM, Rozing PM, Dijkmans BAC, Verhoef JAC, Voogt- van der Harst EM, Hazes JMW. Assessment of shoulder functions in rheumatoid arthritis. J Rheumatol 1996;23:2043–8.

Liang MH, Lew RA, Stucki G, Fortin PR, Daltroy L. Measuring clinically important changes with patient-oriented questionnaires. Med Care 2002;40 (suppl) :II45–51.

Arnett FC, Edworthy SM, Bloch DA, McShane DJ, Fries JF, Cooper NS, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988;31:315–24.

AAOS. Joint motion. Method of measuring and recording. Chicago: AAOS, 1965.

Wright JG. Evaluating the outcome of treatment: shouldn't we be asking patients if they are better? J Clin Epidemiol 2000;53:549–53.

Larsen A, Dale K, Eek M. Radiographic evaluation of rheumatoid arthritis and related conditions by standard reference films. Acta Radiol 1977;18:481–91.

Prevoo ML, van't Hof MA, Kuper HH, van Leeuwen MM, van de Putte LB. Modified disease activity scores that include twenty-eight-joint counts: development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Ann Rheum Dis 1995;64:52–5.

Siegert CEH, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984;3:305–9.

Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. J Chron Dis 1987;40:171–8.

Liang MH, Fossel AH, Larson MG. Comparison of five health status instruments for orthopedic evaluation. Med Care 1990;28:632–42.