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8

RESPONSIVENESS OF THE SHOULDER FUNCTION ASSESSMENT SCALE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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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, the Disease Activity Score (DAS28) and the Health Assessment Questionnaire (HAQ) were measured before and 4–6 weeks after treatment. Responsiveness was determined using Standardized Response Mean (SRM), Effect Size (ES) and Responsiveness Ratio (RR).

Results: Overall, significant improvement was seen according to the SFA (mean change 10.9 (6.5–15.3)), active shoulder range of motion (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 the good measurement properties regarding 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.

Introduction

The Shoulder Function Assessment scale 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 showed high intra- and interobserver reliability, correlated well with other measures of shoulder function and proved to discriminate better between various levels of shoulder function in RA patients than other instruments.¹ So far, the responsiveness² 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.

Methods

Study design and patients

This prospective study concerned consecutive RA patients³ visiting the rheumatology clinic of the Leiden University Medical Center who were suffering from subacromial bursitis, tendinitis 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 (ESR, mm/hr) and data on medication were derived from the medical record. All clinical assessments were done by the same physical therapist (HMY) and the scoring of the radiographs by a rheumatologist (AC).

Clinical assessments included

a. 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 range of motion (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

b. Range of motion

Active and passive range of motion (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.

c. 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 the baseline on a five point Likert scale (1 = 'much worse', 5 = 'much improved').⁵

d. Radiographic score

Recent radiographs (6 months or less 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

e. Overall disease activity and daily functioning

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

Statistical analysis

In a previous cross-sectional study in RA patients the mean SFA score was 43.0 and the standard deviation (sd) 13 points.¹ Assuming that the change score of the SFA should exceed these 13 points, corresponding with an Effect Size (ES = pre-treatment mean minus post-treatment mean divided by the sd of the pre-treatment mean) of ≥ 1.0 , in order to measure an improvement in shoulder function, 35 patients would be needed to detect a significant difference, with alpha being 0.05 and a power of 0.90. Considering 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. Active and passive mobility of affected and unaffected side at baseline were compared by means of 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 in terms of the Standardised Response Mean (SRM = pre-treatment mean minus the post-treatment mean divided by the standard deviation of the change score)², Effect Size 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, idem when values are negative) can also be applied to the SRM¹⁰, whereas a responsiveness ratio larger than 1.0 is considered necessary to detect a clinical difference.

Table 8.1. Baseline (n=38) and follow-up (n=35) scores of patients with rheumatoid arthritis 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 (6.5–15.3)	< 0.01	-0.86	-1.16	1.28
subscales:								
- Pain at rest		4.9 (2.6)	7.1 (2.7)	2.1 (1.2–3.1)	< 0.01	-0.81	-0.84	1.04
- Pain at movement		2.8 (1.8)	5.1 (3.3)	2.3 (1.4–3.3)	< 0.01	-0.85	-1.27	1.76
- Activities of daily living		11.4 (3.3)	14.2 (4.4)	2.8 (1.3–4.3)	< 0.01	-1.00	-0.84	1.68
- Range of Motion		15.9 (7.7)	19.5 (7.7)	3.6 (1.0–6.2)	< 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 (10.1–36.5)	< 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 (5.6–25.5)	< 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 (2.5–5.3)	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– -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– -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 (-7.8–1.0)	0.12	-0.26	-0.20	0.44
Impact of shoulder function on daily activities on VAS in mm		66.1 (18.8)	40.7 (28.9)	-26.5 (-34.5– -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– -0.06)	0.01	0.46	0.48	1.10
subscales								
- dressing		1.81 (0.7)	1.40 (0.7)	-0.34 (-0.06– -0.08)	0.01	0.45	0.51	0.70
- eating		1.86 (0.6)	1.60 (0.8)	-0.26 (-0.56–0.05)	0.09	0.29	0.41	0.49
- hygiene		1.88 (0.7)	1.59 (0.8)	-0.21 (-0.49–0.06)	0.13	0.27	0.32	0.55
- reaching		2.00 (0.8)	1.51 (0.8)	-0.43 (-0.71– -0.15)	< 0.01	0.53	0.55	1.61
DAS28		5.28 (0.93)	4.74 (1.04)	-0.54 (-0.84– -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= Standardized Response Mean, RR= Responsiveness Ratio, VAS= Visual Analogue Scale, SFA= Shoulder Function Assessment scale, DAS28= Disease Activity Score-28, HAQ= Health Assessment Questionnaire.

Results

Between July 2000 and May 2002 thirty-eight patients were included, ten males and twenty-eight females, with a mean age of 60.5 (sd 13.0) years. 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 when compared to 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 9 patients); in 5 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 of the 32 patients who were on a DMARD at baseline, the DMARD was changed during the follow-up period, whereas in 7 patients the dose was increased.

Three patients were not able to attend the follow-up assessment. Table 8.1 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.

Nine of the 35 patients (26%) considered their shoulder function stable while 26 patients (74%) reported an improvement, with the average change scores of the SFA being 0.58 (sd 11.3) and 14.5 (sd 11.5) in the group of stable and improved patients, respectively ($p < 0.01$). Of the stable patients, 5 showed a decreased and 4 patients an increased SFA score, whereas in the 26 patients who considered themselves improved, 23 patients had an increased and 3 patients a decreased SFA score.

With respect to overall functional ability and disease activity, 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 could be related to the nature of the symptoms of RA patients suffering from 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 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 RA patients. 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. In spite of the excellent responsiveness of a single VAS, a composite index such as the SFA provides insight into other relevant aspects of shoulder function, i.e. ROM and pain.

Both the HAQ and DAS28 showed significant improvements over time in this study. It is conceivable that part of this general improvement could be attributed to the systemic effects of the corticosteroids and/or the changes in the concurrent medication.

The fact that in this study neither the patients nor the observer were blinded could have introduced bias towards improvement. In that respect, the inclusion of a control group without treatment could have enhanced the contrast between stable or deteriorated versus improved patients.

In conclusion, the responsiveness of the SFA to clinical changes was found to be excellent in RA patients 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 RA patients, such as a shoulder prostheses.

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