A comparison of the OARSI response criteria with patient's global assessment in patients with osteoarthritis of the hip treated with a non-pharmacological intervention

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SUMMARY

Objective

To compare the Osteoarthritis Research Society International (OARSI) response criteria for clinical trials with patient's global assessment in patients with osteoarthritis (OA) of the hip receiving a non-pharmacological intervention, i.e., manual therapy or exercise therapy.

Methods

Data of a randomized clinical trial on manual therapy and exercise therapy in patients with OA of the hip ($n = 109$) were used. Change scores of measures of hip function, range of joint motion and pain were compared between patients who were differently classified by the OARSI response criteria and the patient's global assessment (using a t test, 95% CI). Furthermore, risk ratios (with 95% CI) were calculated for the contrast between treatment outcome, using the OARSI criteria or patient's global assessment.

Results

Few patients were classified as improved (i.e., responders) with the OARSI response criteria as compared to patient's global assessment. Significantly worse outcome for hip function and pain was observed in patients who were classified as non-responders (OARSI criteria), but who considered themselves as improved (patient's global assessment). Risk ratios for the contrast between the two treatment programs (manual therapy vs exercise therapy) were similar, when using the OARSI criteria or patient's global assessment.

Conclusion

The validity of the OARSI response criteria has been previously demonstrated in OA patients treated with pharmacological interventions. The present study demonstrates the validity of the OARSI response criteria in OA patients treated with a non-pharmacological intervention, i.e., manual therapy and exercise therapy.

INTRODUCTION

The Osteoarthritis Research Society International (OARSI) proposed response criteria to define clinically relevant change in patients participating in osteoarthritis (OA) clinical trials[1]. Criteria include the domains of pain, function and patient's global assessment. These response criteria were validated using data of 14 clinical trials on the effects of pharmacological modalities in patients with complaints due to OA. However, OARSI recommends further validation of these response criteria in additional data sets in other pharmacological and non-pharmacological interventions.

Recently, we compared the efficacy of manual therapy and exercise therapy in patients with OA of the hip in a randomized clinical trial[2]. We chose patient's global assessment on a transition scale as the primary outcome. However, the use of patient's global assessment to determine clinically relevant change has been criticized because it may be affected by other changes in health status and by subjective bias[3, 4 and 5].

The Philadelphia Panel on evidence based practice guidelines on selected rehabilitation interventions, recommended to assess a cut off point of 15% improvement on measures of pain, function and health status when evaluating the efficacy of treatment of physical therapy and other rehabilitation interventions in low back, neck, knee and shoulder pain clinical trials[4]. However, these response criteria were not validated with regard to sensitivity and specificity and it is not clearly described how they should be used. Thus, to our knowledge there are no specific response criteria available to evaluate the efficacy of physical therapy in patients with OA of the hip.

The question arises whether the OARSI response criteria, which were originally validated for pharmacological interventions, are suitable to evaluate the clinical relevance of a non-pharmacological intervention, i.e., manual therapy or exercise therapy in patients with complaints due to OA of the hip. Therefore, the goal of the present study was to compare the OARSI criteria with patient's global assessment using data of a randomized clinical trial on patients with OA of the hip receiving manual therapy or exercise therapy.

METHOD

Patients

Data of 109 patients with OA of the hip, participating in a randomized clinical trial on the effects of manual therapy were used. Results of this study were published elsewhere[2]. Patients included were those suffering from primary OA of the hip according to the clinical criteria of the American College of Rheumatology[6].

Exclusion criteria were (1) symptoms in both hips, (2) age <60 or >85 years, (3) severe complaints of the lower back, and (4) severe cardio-pulmonary disease. All patients completed a written informed consent form. After baseline assessments patients were randomly allocated to exercise therapy or manual therapy by an independent person, using opaque sealed envelopes. A blinded assessor performed all assessments. The study was approved by the medical ethics committee of the Leyenburg Hospital.

Interventions

We made a comparison of two interventions: manual therapy vs exercise therapy. Patients received treatment according to a standardized protocol at the outpatient clinic of physical therapy of our hospital. Manual therapy consisted of stretching of shortened muscles and manipulation of the hip joint [7]. The exercise program was tailored to the individual patient's needs, and consisted of both active and passive exercises and homework exercises. The exercise program was an adaptation of the protocol of Van Baar *et al.*[8].

All patients were treated twice weekly for a period of 5 weeks to a total of nine treatments. The use of NSAIDs (non steroid anti-inflammatory drugs) and pain medication was allowed, under the condition that it was left unchanged during the study period.

Outcome assessment

The primary outcome measure was the patient's global assessment of outcome on a six-point Likert scale (ranging from ‘much worse’ to ‘free of complaints’).

The question that was asked was: what where the effects of treatment on your complaints? Patients who classified themselves as ‘improved’, ‘much improved’, or ‘free of complaints’ were identified as clinically relevant improved. Secondary outcome measures included hip function, range of motion (ROM) and pain. Hip function was evaluated with the Harris Hip Score[9]. The Harris Hip Score has been primarily developed

to evaluate hip function in patients with hip OA. Furthermore, the Harris Hip Score showed to be a reliable and responsive measure[9]. ROM was assessed with a goniometer according to a standardized protocol[10 and 11]. Overall scores (sum score) for ROM were obtained by calculating standardized scores (*Z* scores) of all directions and adding them up . Walking ability was evaluated with an 80 m walking test[12 and 13]. Furthermore, pain during the walking test was assessed using a visual analogue scale (VAS)[13]. A blinded assessor (a physical therapist) evaluated patients at baseline, at 5 weeks (post treatments) and at 3 and 6 months. All assessments followed a standardized procedure. For the present study baseline data and post treatment data (5 weeks) were used.

OARSI response criteria

The OARSI response criteria include two propositions (A and B) (Fig. 1 and Fig. 2). As both response criteria sets gave similar outcome, the authors proposed them both to be used in OA trials (primarily on the efficacy of NSAID), without preferences for either set A or set B[1]. The criteria set A (Fig. 1) firstly emphasizes the domain of pain: a high improvement in pain is sufficient to classify a responder. A high response on pain is defined as an improvement of at least 50% from baseline values, together with an improvement of at least 20 NU (Normalized Units) on a 0–100 scale. Patients can also be classified as responders if a moderate improvement is observed in two out of three domains, and these domains include pain, function and patient's global assessment. A moderate improvement in pain is defined as an improvement of at least 30%, together with an improvement of at least 15 NU.

A moderate improvement for function is defined as an improvement of at least 20%, together with an improvement of 20 NU. When a VAS is applied as a patient's global assessment, an improvement of at least 20% is required.

The second set of criteria (set B) is slightly different with regard to the definition of a high response: with this set a high response in pain or function classifies a responder. However, the criteria for moderate improvement on pain, function and patient's global assessment are similar to the criteria of set A.

[FIGURE 1]

[FIGURE 2]

Statistical analysis

Firstly, OARSI defined responders and patients classified as improved by patient's global assessment were compared using cross tabs on all test data (exercise therapy group and manual therapy group together). Secondly, change scores for hip function (the Harris Hip Score, range of motion (ROM) and pain) were compared for patients who were differently classified by patient's global assessment and by the OARSI response criteria. Differences between change scores were tested using *t* tests (with 95% CI). Thirdly, to test between groups (that is, manual therapy vs exercise therapy) on the primary outcome measure “patient's global assessment” a risk ratio (OR) was calculated with a 95% confidence interval. In addition, a risk ratio (with 95% CI) was calculated using the criteria sets A and B (Fig. 1) to classify patients receiving manual therapy or exercise therapy as responders. A two-sided alpha of 5% was applied for significance[14]. Data were analyzed using SPSS 11.0 software.

RESULTS

Patients

Baseline characteristics of patients are presented in Table I. Mean age was relatively high (72 years). Most patients (80%) had moderate to severe OA on Kellgren and Lawrence radiographic scores.

Furthermore, most patients indicated pain as their main complaint (65%). In total nine patients discontinued the treatment programs. All patients discontinued due to practical problems, such as travel distance or other health problems that cannot be related to treatment with physical therapy or manual therapy.

[TABLE 1]

Outcome of manual therapy and exercise therapy

The results of the randomized clinical trial indicated that manual therapy is superior to exercise therapy in the measures of function and pain. After treatment (5 weeks) the Harris Hip score improved from 54.0 (15) to 69.3 (15) in the manual therapy group, and from 53.1 (14) to 57.2 (11) in the exercise group (mean change score between groups: 11.2, CI: 6.1–16.3). Pain (in mm on VAS) in the manual therapy group decreased from 34.0 (22) to 22.8 (21), while in the exercise group pain during walking remained almost stable (28.9 (22) to 27.1 (21); mean change score between groups −9.6, CI: −17.3 to −1.8). Finally, ROM increased in the manual group from 101.3° (20°) to 115.8° (10°); 16.0° (CI: 8.1–22.6°) degrees more than in the exercise group. These data have been previously reported[2].

OARSI criteria vs patient's global assessment

Table II shows cross tabs of the criteria set A vs patient's global assessment. Results indicate that a large number of patients ($n = 28$) were classified as improved on patient's global assessment, while on the other hand these patients were classified as non-responders by the OARSI criteria. B criteria gave similar results (data not shown). In order to investigate possible differences in characteristics between patients who were classified differentially by patient's global assessment and the OARSI criteria, we compared change scores of hip function (Harris Hip Score), pain (VAS) and ROM (Table III) of these patients with each other. Results show significant lower scores on hip function and lower scores for improvement in pain in patients who were classified as improved on patient's global assessment but as non-responders with the criteria set A vs patients who were classified as improved and as responders with the OARSI criteria A (Table III). Results of the analysis of change scores of hip function, pain and ROM of patient's global assessment vs criteria set B gave similar results (data not presented).

Finally, we investigated the relation between outcome of the classifications (i.e., patient's global assessment and OARSI response criteria) and baseline characteristics (i.e., sex, age, hip function, pain, ROM, duration of complaints). However, no significant differences were found (data not presented).

[TABLE 2]

[TABLE 3]

Manual therapy vs exercise therapy

In Table IV it is shown that 43 (81%) patients receiving manual therapy were classified as ‘improved’ vs 25 (50%) patients receiving exercise therapy (risk ratio 1.62, CI: 1.20–2.20). Results of the analysis with the OARSI A response criteria showed that fewer patients were classified as responders in each treatment group as compared to patient's global assessment.

However, the contrast between the two treatment groups generally remained equal (risk ratio 1.70 CI: 1.03–2.80). Finally, criteria set B gave almost similar results as compared to criteria set A (risk ratio 1.77 CI: 1.11–2.82).

DISCUSSION

This is the first study on the validity of the OARSI response criteria in patients treated with a non-pharmacological intervention, i.e., manual therapy and exercise therapy. The OARSI response criteria were developed to evaluate the efficacy of different classes of interventions: however, the criteria were validated for pharmacological interventions only. We compared two methods to evaluate the success of treatment: (A) patient's global assessment and (B) the OARSI response criteria. Results indicated that in patients treated with a non-pharmacological intervention (i.e., manual therapy and exercise therapy), the OARSI response is more rigorous than the patient's global assessment (fewer patients were denoted as responders as compared to the patient's global assessment).

[TABLE 4]

We examined in the group of patients who considered themselves as improved the differences in the magnitude of changes in measures of pain and function between responders and non-responders according

to the OARSI criteria. In responders a larger increase in hip function and larger decrease in pain were observed than in the non-responders.

Those results suggest that improvement on a single transition measure is not accompanied by improvements in measures of hip and function in all patients. In the OARSI response criteria the outcomes of several measures are combined, thus increasing the likelihood of detecting patients with a clinically relevant improvement.

Response criteria were primarily suggested to be used as evaluation measures in clinical trials[1]. However, response criteria are also valuable in clinical settings. In clinical practice a patient's global assessment or a single clinical test is often used to determine change in clinical status. A patient's global assessment is an easy to use tool, but it has been criticized for its sensitivity to be affected by other changes in health status[10]. Clinical tests give an "objective" (observational) judgment on the clinical status of patients but do not incorporate the patient's perspective. The OARSI criteria incorporate both reported scores and observations by a physician or physical therapist. Furthermore, cut off points for response criteria are constructed by consensus or by validation on data of specified studies, which makes response criteria more widely applicable. Therefore, we recommend assessing response criteria in both research and clinical settings.

A possible limitation of our study could be that we used a transition scale for global assessment. In the OARSI response criteria the use of a VAS is described with a cut off point of 20%, for clinically relevant improvement. Instead, we used a six-point scale ranging from 'much worse' to 'free of complaints'. The fourth step in this scale is defined as 'improved'; therefore we used this as a cut off point for clinically relevant improvement. We believe that these cut off points are comparable, as they both represent moderate improvement in health status.

In conclusion, we found the OARSI response criteria suitable to evaluate the outcome of a non-pharmacological treatment, i.e., manual therapy and exercise therapy, in patients with OA of the hip. Evidence was obtained that the OARSI response criteria gave a more accurate reflection of the actual clinical status of patients than a patient's global assessment of response to treatment alone.

FIGURES AND TABLES

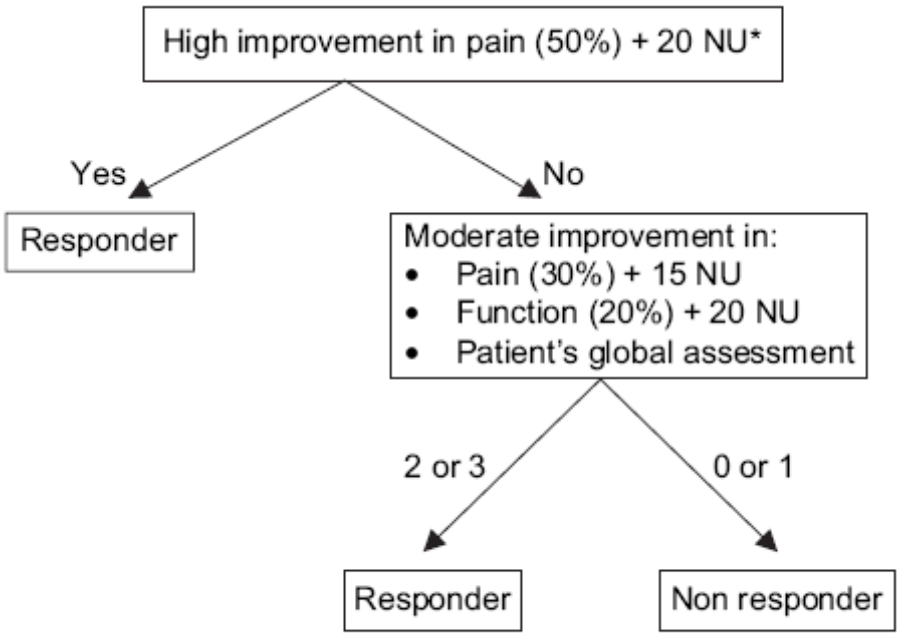

Fig. 1. OARSI response criteria proposition A.

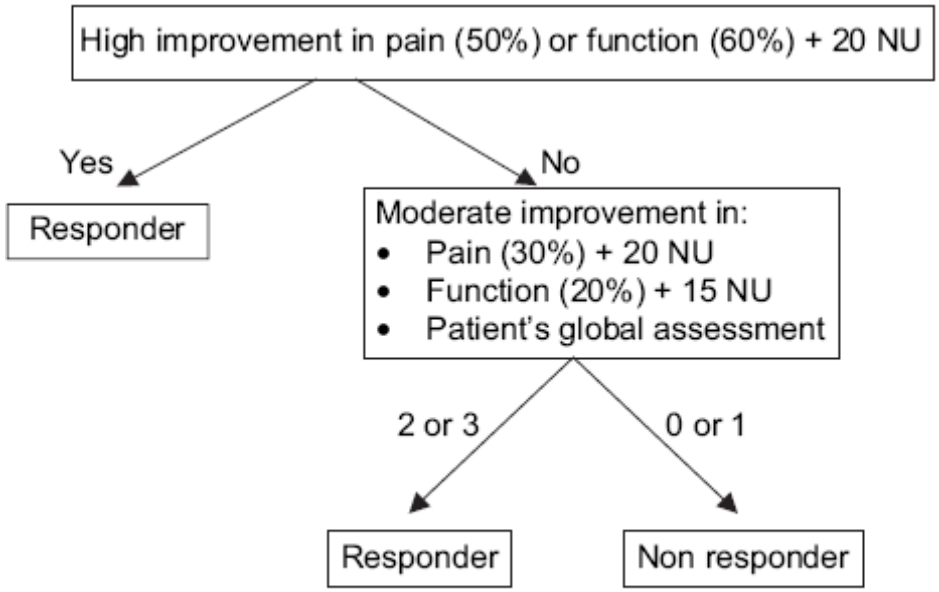

Fig. 2. OARSI response criteria proposition B.

Table I
Baseline characteristics (n = 109)

	Manual therapy	Exercise therapy
Number of patients	56	53
Females/males (*n*)	38/18	38/15
Age in years, mean (sd)	72 (7)	71 (6)
Medication		
No medication (*N*)	41	38
Analgesics or NSAIDs (*N*)	15	15
Radiological degeneration (*N*)*		
0 (No OA)	5	4
1 (Mild OA)	7	6
2 (Moderate OA)	19	23
3 (Severe OA)	25	20
Main complaint (*N*)		
Pain	34	33
Morning stiffness	5	4
Starting stiffness	4	3
Walking disability	13	14
Harris Hip score, mean (SD)	54 (15)	53 (14)
Pain during walking, mm, mean (SD)	34 (22)	29 (22)
Range of motion†	1.6 (4.2)	1.5 (4.4)

*Modified Kellgren and Lawrence.
†*Z* score (sum score of separate directions).

Table II

OARSI criteria set A vs patient's global assessment (patients receiving manual therapy or exercise therapy combined)

Patient's global assessment	OARSI set A	
	Non-responder	Responder
Not improved	33	2
Improved	28	40

Table III

Comparison in mean change scores (standard deviation) of patients differentially classified by the OARSI criteria and global assessment

	Improved (global ass.) and non-responder		Improved (global ass.) and responder		Mean difference	95% CI
	N	(OARSI)	*N*	(OARSI)		
Harris	28	12.7 (9)	40	19.3 (13)	− 6.6	−12.5, −0.7*
Pain	28	−1.7 (20)	40	−32.3 (20)	30.6	20.3, 40.5*
ROM	28	0.9 (3)	40	0.5 (3)	0.4	−1.7, 2.6

*$P < 0.05$. On Harris Hip Score and ROM positive signs indicate improvement. On pain negative signs indicate improvement. N = number of patients.

Table IV

Patient's global assessment vs OARSI criteria: risk ratio for improvement/responder of manual therapy vs exercise therapy

	Manual therapy	Exercise therapy	Risk ratio	95% CI
Patient's global assessment				
Improved	43	25	1.62	1.20–2.20
Not improved	10	25		
Criteria set A				
Responder	27	15	1.70	1.03–2.80
Non-responder	26	35		
Criteria set B				
Responder	30	16	1.77	1.11–2.82
Non-responder	23	34		

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