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Responsiveness and minimal important change of the Oxford Shoulder Score, EQ-5D, and the Fear-Avoidance Belief Questionnaire Physical Activity subscale in patients undergoing arthroscopic subacromial decompression

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Introduction: Adequate responsiveness and knowledge of the minimal important change (MIC) is essential when using patient-reported outcome measures to assess treatment efficacy.

Objective: The objective of this study was to evaluate the responsiveness and MIC of common outcomes in patients with subacromial impingement syndrome undergoing arthroscopic subacromial decompression.

Methods: At baseline and 6 months after surgery, patients completed the Oxford Shoulder Score (OSS), EQ-5D 5-level utility index, EQ visual analogue scale, Fear-Avoidance Belief Questionnaire Physical Activity subscale (FABQ-PA), assessed pain (pain visual analogue scale), and Subjective Shoulder Value. Furthermore, at the 6-month follow-up, patients assessed the overall change with a Global Rating of Change Scale. Responsiveness was examined by analyzing the area under the receiver operating characteristics curve and correlations between the change scores. MIC was assessed using the optimal cutoff point at the receiver operating characteristics curve.

Results: Area under the receiver operating characteristics curve estimates were 0.96 (95% confidence interval [CI] 0.91,1.00) for OSS, 0.82 (95% CI 0.66,0.99) for EQ-5D 5-level utility index, 0.73 (95% CI 0.58,0.87) for EQ visual analogue scale, and 0.74 (95% CI 0.58,0.90) for FABQ-PA. MIC were 6.0 points for OSS, 0.024 points for EQ-5D 5-level utility index, 10.0 points for EQ visual analogue scale, and -5.0 points for FABQ-PA.

Conclusion: Responsiveness of the OSS, EQ-5D, and FABQ-PA was sufficient to measure improvement after arthroscopic decompression surgery.

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Subacromial impingement syndrome accounts for 44% to 65% of shoulder disorders⁷ and is associated with pain and significant impairments in function and health-related quality of life.^{3,28} First-line treatment is conservative and surgical treatment with

arthroscopic subacromial decompression can be considered for those who fail to respond to nonsurgical treatment.³

Patient-reported outcome measures (PROMs) are frequently incorporated in clinical practice and research for evaluating the effectiveness of treatment and change in disease severity.³⁰ PROMs can be divided into disease-specific and generic instruments. The Oxford Shoulder Score (OSS) is a disease-specific PROM and is commonly used for assessing pain and shoulder function after both surgical and nonsurgical treatments.^{1,2,5,11,34,37,38} The OSS has been found valid and reliable in patients with shoulder disorders,^{1,34} and

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specifically, the OSS has been found responsive in patients with rotator cuff disease receiving corticosteroid injection¹¹ and in patients with difficulty returning to usual activities after arthroscopic subacromial decompression receiving physical therapy or occupational medical assistance.²

Genetic health-related quality of life instruments assess how shoulder disorders affect patients' life as a whole and allow comparisons across a wide range of diseases.²⁰ The EQ-5D is the most widely used and is available in 170 languages.³² Investigations indicate good validity and reliability and at least moderate responsiveness of the EQ-5D in patients with upper extremity orthopedic disorders.^{12,15,27,33}

For patients with musculoskeletal pain, behavior that is guided by fear has the potential to impact outcomes negatively.^{13,25} The Fear-Avoidance Belief Questionnaire (FABQ) was originally developed for patients with low-back pain³⁹ but has been adapted to shoulder disorders.^{13,19,26,31,36} The FABQ has two subscales; physical activity (FABQ-PA) and work (FABQ-W).³⁹ Evaluation of the responsiveness of FABQ-PA in patients with subacromial impingement syndrome receiving physiotherapy treatment has shown limited ability to detect changes over time.³⁶

Adequate responsiveness of a PROM is essential in the evaluation of treatment efficacy.³⁰ Responsiveness is an aspect of construct validity and is defined as the ability of an outcome measure to detect changes over time in the construct to be measured.³⁰ Minimal important change (MIC) represents the smallest change in a PROM that patients perceive as important.^{6,30} Responsiveness and MIC for a given PROM may vary across patient groups and contexts and consequently should be assessed in different settings and populations.³⁰

Responsiveness of the OSS, EQ-5D, and FABQ-PA has been partly evaluated in patients with shoulder disorders.^{2,11,12,27,33,36} However, assessment of the responsiveness of the three questionnaires including the MIC in patients with subacromial impingement syndrome treated with decompression surgery has yet to be established. Therefore, the aim of this study was to evaluate the responsiveness and MIC of the OSS, FABQ-PA, and EQ-5D in patients with subacromial impingement syndrome undergoing arthroscopic subacromial decompression.

Materials and methods

Design and study population

A longitudinal study with six-month follow-up was conducted. Responsiveness and MIC were evaluated using a method integrating anchor- and distribution-based approaches.^{5,6}

The included patients were diagnosed with subacromial impingement syndrome and undergoing arthroscopic subacromial decompression at the Department of Orthopaedic Surgery, Aarhus University Hospital, Denmark or Private Hospital Molholm, Denmark between December 2018 and July 2020. Exclusion criteria were age less than 18 years, frozen shoulder, full-thickness tear, osteoarthritis, trauma, cancer, neurologic disorders, previous surgical treatment in the affected shoulder, or inability to communicate in Danish or complete the questionnaires.

Procedure

Patients were recruited at the consultation with the orthopedic surgeon when arthroscopic subacromial decompression was scheduled. Patients from Aarhus University Hospital, after giving informed consent, completed the baseline assessment immediately after the consultation. The questionnaires were completed on tablet with the possibility to use a paper form for those who had

difficulties using the tablet. Patients from Private Hospital Molholm who had given informed consent received an email one or two days after the consultation with a link to the baseline questionnaires. Two reminders were sent out to those who did not respond. The study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tool hosted at Aarhus University. REDCap is a secure web-based software platform for building and managing online databases and surveys.^{16,17}

Six months after surgery, an email (and two reminders, if necessary) with a link to the follow-up questionnaires was sent out. Patients from Aarhus University Hospital were scheduled to a physical examination, and patients who did not complete the questionnaires in advance had the opportunity to complete them at the outpatient visit.

Measurements

Information on baseline characteristics such as age, sex, body mass index, comorbidity, duration of symptoms, working status, educational level, and smoking status was collected. At baseline and follow-up, patients completed the questionnaires OSS, EQ-5D, and FABQ-PA, assessed pain at activity (pain VAS) and rated their Subjective Shoulder Value (SSV). Furthermore, at the 6-month follow-up, patients assessed the overall change of symptoms with a Global Rating of Change Scale (GRCS). The GRCS was treated as primary anchor and change in pain VAS and SSV as secondary anchors for evaluation of responsiveness. The secondary anchors were considered to measure constructs more similar to the OSS than to the EQ-5D and FABQ-PA as the OSS measures shoulder-specific pain and function, while EQ-5D and FABQ-PA are more complex measures of quality of life and fear avoidance behavior.

Oxford Shoulder Score

The OSS contains 12 items, 4 related to pain and 8 related to function. Each item is scored on a 5-point Likert scale corresponding to a score rating from 0 (worst) to 4 (best).⁴ Scores of the 12 items are summarized into a total score ranging from 0 to 48. At least 10 items have to be completed to calculate the total score.⁴

EQ-5D

The 5 level EQ-5D was used in this study. The EQ-5D questionnaire consists of two parts. The descriptive system assesses five different aspects of health: mobility, self-care, usual activities, pain/discomfort, and depression/anxiety on a 5-point Likert scale.^{9,15} A key feature of the EQ-5D is the availability of "value sets" to weight the health states reported by patients into utility indexes (EQ-5D_{index}). We used the UK value set in this study because a Danish value set is not yet available. These values range from -0.285 to 1.0, a value of 1.0 corresponds to full health, 0 corresponds to death and negative values correspond to health status considered to be worse than death.¹⁰ In addition, the EQ-5D contains a visual analogue scale (EQ_{VAS}) that records self-rated health in a single score ranging from 0 to 100.^{8,9}

Fear-Avoidance Believe Questionnaire Physical Activity subscale

The FABQ-PA has five items and responses range from 0 (strongly disagree) to 6 (completely agree) on a 7-point scale. Four of the items are summed into a score rating from 0 to 24, higher scores represent worse outcome (more fear avoidance beliefs).³⁹

Global Rating of Change Scale

Patients were asked to rate the overall change of their shoulder symptoms from before surgery until the day of completing the scale. The scale was a 5-point Likert scale with the following

response options: much better, better, unchanged, worse or much worse.²¹ The question patients were asked was, “How would you describe your shoulder symptoms at present compared to immediately before surgery?”

Pain measured with visual analogue scale

The amount of pain in the affected shoulder that patients experienced during activity was rated on a visual analogue scale (pain VAS). The scale ranged from 0 to 100 with 0 representing no pain and 100 representing the worst possible pain.²²

Subjective Shoulder Value

SSV is defined as the patients' subjective shoulder assessment expressed as a percentage of an entirely normal shoulder, which would score 100%.¹⁴ The question patients were asked was, “What is the overall percent value of your shoulder if a completely normal shoulder represents 100%?”

Statistical analysis

Descriptive statistics were used to describe the demographic and clinical variables; these are presented as mean \pm standard deviation with 95% confidence interval (CI) or number and percentage. If a patient had missing values in one outcome, the patient was still included in the analyses of the completed outcomes. Absolute change scores for the OSS, EQ-5D_{index}, EQ_{VAS}, FABQ-PA, pain VAS, and SSV were calculated by subtracting the baseline scores from the follow-up scores. Floor and ceiling effect defined as >15% archiving the highest or lowest possible score was checked at the baseline and follow-up.⁶

First, a receiver operating characteristics (ROC) curve was made using the change scores of the OSS, EQ-5D_{index}, EQ_{VAS} and FABQ-PA. This is a plot of the sensitivity against 1-specificity for different cutoff values.²⁴ The area under the curve (AUC) was analyzed to assess the ability of the OSS, EQ-5D, and FABQ-PA to correctly classify patients as improved (much better or better) or unimproved (unchanged, worse, or much worse) as per the GRCS.^{5,35} An estimate of ≥ 0.70 was considered acceptable.^{29,35} Owing to the low number of patients reporting worse or much worse outcomes, analysis of responsiveness of deterioration was not included.

Second, predefined hypotheses about the correlations between the change scores of the OSS, EQ-5D_{index}, EQ_{VAS}, and FABQ-PA and the secondary anchors (change scores of pain VAS and SSV) were tested. Higher correlations were expected between OSS vs. pain VAS and SSV because they were considered to measure similar constructs. Lower correlations were expected between EQ-5D_{index}, EQ_{VAS}, and FABQ-PA vs. pain VAS and SSV because they were considered to measure overlapping but not similar constructs. Correlations between the OSS, EQ-5D_{index}, EQ_{VAS}, and FABQ-PA and the anchors were evaluated using Spearman rank correlation coefficients.

The following hypotheses were tested:

- The change score of the OSS has a positive correlation ≥ 0.5 when compared with SSV and a negative correlation ≥ 0.5 when compared with pain VAS
- The change scores of the EQ-5D_{index} and EQ_{VAS} have a positive correlation ≥ 0.3 and < 0.5 when compared with SSV and a negative correlation ≥ 0.3 and < 0.5 when compared with pain VAS
- The change score of the FABQ-PA has a negative correlation ≥ 0.3 and < 0.5 when compared with SSV and a positive correlation ≥ 0.3 and < 0.5 when compared with pain VAS

Table 1

Baseline characteristic of the study population (n = 52)

Sex, n (%)	
Male	26 (50.0)
Female	26 (50.0)
Age, yr, mean (SD)	57.4 (10.1)
BMI, kg/m ² , mean (SD)	26.7 (4.3)
Number of comorbidities, n (%) [*]	
0	21 (40.4)
1	17 (32.7)
2	7 (13.5)
>2	6 (11.5)
Time with symptoms, n (%) [*]	
0-6 mo	5 (9.6)
6-12 mo	11 (21.2)
12-24 mo	12 (23.1)
>24 mo	24 (46.2)
Working status, n (%)	
No	13 (25.0)
Yes	39 (75.0)
Educational level, n (%) [*]	
Compulsory school	8 (15.7)
Skilled worker	23 (45.1)
Bachelor	14 (27.5)
Master degree	6 (11.8)
Smoking status, n (%)	
No	38 (73.1)
Yes	14 (26.9)
OSS, mean (SD) [*]	29.4 (6.6)
EQ-5D _{index} , mean (SD)	0.71 (0.17)
EQ _{VAS} , mean (SD)	68.7 (19.5)
FABQ-PA, mean (SD) [*]	15.5 (5.9)
Pain VAS, mean (SD)	61.8 (23.3)
SSV, mean (SD) [*]	55.5 (18.4)

BMI, body mass index; OSS, Oxford Shoulder Score; EQ-5D_{index}, EQ-5D utility index; EQ_{VAS}, EQ visual analogue scale; FABQ-PA, Fear-Avoidance Belief Questionnaire for physical activity; VAS, visual analogue scale; SSV, Subjective Shoulder Value.

^{*}Data missing for one patient.

Third, the MIC defined as the change score in the OSS, EQ-5D_{index}, EQ_{VAS}, and FABQ-PA that best discriminated between the improved and not improved group of patients was assessed using the optimal cutoff point on the ROC curve. The optimal ROC cutoff point is the value for which the sum of proportions of false-positive and false-negative classifications ((1-sensitivity) + (1-specificity)) is lowest.⁵

We aimed at including a minimum sample size of 50 subjects, as this size is recommended as being adequate for responsiveness studies.^{29,35}

STATA 16.1 (StataCorp LLC, College Station, TX, USA) was used for analyses. The statistical significance level was determined as $P < .05$.

Ethical approval

The study was approved by Danish Data Protection Agency (1-16-02-534-18). The study was requested for notification at the Regional Committee on Biomedical Research Ethics, but further approval was not necessary (185/2018). Participants received oral and written information about the study, and written informed consent was received from all participants.

Results

In total, 58 patients participated in the study; 45 from Aarhus University Hospital and 13 from Private Hospital Molholm. Of these, 52 patients (90%) were included in the analysis; three patients withdrew from the study and three patients did not respond to the follow-up questionnaires. The SSV and pain VAS had missing data

Table II

Mean change scores of the Oxford Shoulder Score (OSS), EQ-5D utility index (EQ-5D_{index}), EQ visual analogue scale (EQ_{vas}), Fear-Avoidance Belief Questionnaire for physical activity (FABQ-PA), Subjective Shoulder Value (SSV) and shoulder pain on VAS for the total group and for the improved and unimproved group as per the Global Rating of Change Scale

	OSS (0-48)	EQ-5D _{index} (-0.205-1.0)	EQ-5D _{vas} (0-100)	FABQ-PA (0-24)	SSV (0-100)	Pain VAS (0-100)
Total group (n = 52) mean (95% CI)	9.5 (6.9,12.1) [†]	0.10 (0.06,0.14)	1.3 (-3.4,5.9)	-4.1 (-6.0, -2.2) [‡]	19.1 (12.6,25.7) [*]	-38.0 (-46.5, -29.5) [*]
Improved group (n = 40) mean (95% CI)	12.7 (10.3,15.0) [*]	0.13 (0.10,0.17)	3.9 (-1.6,9.3)	-5.3 (-7.5, -3.1)	25.5 (18.8,32.3) [*]	-43.2 (-52.6, -33.7) [*]
Unimproved group (n = 12) mean (95% CI)	-1.7 (-4.8,1.4) [‡]	-0.03 (-0.13,0.07)	-7.3 (-15.5,1.0)	-0.3 (-3.9,3.2)	-1.7 (-13.1,9.8)	-21.3 (-39.2, -3.3)
Difference between groups mean (95% CI)	14.4 (9.7,19.1) [§]	0.16 (0.08,0.25) [§]	11.1 (0.4,21.8) [§]	-4.9 (-9.2, -0.7) [§]	27.2 (13.7,40.7) [§]	-21.9 (-41.0,-2.8) [§]

VAS, visual analogue scale.

[†]Data missing for one patient.

[‡]Data missing for two patients.

[§]Data missing for three patients.

[§]Significant at *P* < .05.

for one patient, the OSS for two patients, and the FABQ-PA for three patients. Baseline characteristics are shown in Table I. The average time from baseline measurement to surgery was 49.4 (SD 38.4) days. As per the GRCS, 25 patients responded much better, 15 patients better, 5 patients unchanged, 7 patients worse, and no patients reported much worse at the 6-month follow-up. In total, 40 patients (77%) were categorized as improved and 12 patients (23%) as unimproved. No floor or ceiling effect was observed at the baseline or follow-up.

Table II shows the mean change scores of the OSS, EQ-5D_{index}, EQ_{vas}, FABQ-PA, SSV, and pain VAS between the baseline and follow-up. The differences between the improved and unimproved group of patients were statistically significant for all outcomes.

The ROC AUC estimates were 0.96 (95% CI 0.91, 1.00) for OSS, 0.82 (95% CI 0.66, 0.99) for EQ-5D_{index}, 0.73 (95% CI 0.58, 0.87) for EQ_{vas}, and 0.74 (95% CI 0.58, 0.90) for FABQ-PA (Table III).

The correlations between the change scores of the OSS and EQ-5D_{index} and the change scores of SSV and pain VAS and between FABQ-PA and pain VAS were in accordance with the hypotheses (Table III). The correlations between the change scores of the EQ_{vas} and the change scores of SSV and pain VAS and between FABQ-PA and SSV were lower than expected.

The MIC ROC cutoff points were 6.0 points for the OSS, 0.024 for the EQ-5D_{index}, 10.0 for the EQ_{vas}, and -5.0 for the FABQ-PA.

Discussion

This study examined the responsiveness and MIC of the OSS, EQ-5D_{index}, EQ_{vas}, and FABQ-PA in a sample of 52 patients with subacromial impingement syndrome undergoing arthroscopic subacromial decompression. The change scores of all outcomes were significantly different for patients who were categorized as improved compared to those who were categorized as unimproved according to the GRCS. The responsiveness of the OSS, EQ-5D_{index}, EQ_{vas}, and FABQ-PA was sufficient with ROC AUC values ≥ 0.70, highest for the OSS. Our hypotheses regarding correlations between change scores were confirmed for the OSS, EQ-5D_{index}, and partly for FABQ-PA, but correlations were lower than those hypothesized for EQ_{vas} and partly for FABQ-PA. A possible explanation for this finding could be that the underlying constructs are more different than expected. As expected, higher correlations were found between the OSS compared with SSV and pain VAS than between the EQ-5D_{index}, EQ_{vas}, and FABQ-PA compared with SSV and pain VAS.

The responsiveness results found in this study are essentially comparable with others. Similar ROC AUC estimates for the OSS were found in patients with rotator cuff disease 6 weeks after glucocorticoid injections (0.87, 95% CI 0.80, 0.94)¹¹ and patients with difficulties returning to usual activities after arthroscopic subacromial decompression treated with physiotherapy or

occupational medical assistance (0.81, 95% CI 0.72, 0.90).² For the EQ-5D, ROC AUC estimates ranged between 0.49 and 0.79 in patients who underwent elective surgery¹² and between 0.79 and 0.81 in patients with superior labral anterior and posterior lesions treated with surgery or physical therapy.³³ In contrast to the finding in our study, the responsiveness of the FABQ-PA was found to be limited in patients with subacromial impingement syndrome receiving physiotherapy.³⁶ However, in this study, a different approach was used by calculating Pearson’s correlations coefficient between the change scores of FABQ-PA and OSS which could be a possible explanation for the different finding.

Our findings for MIC values for the OSS were similar to others studies; MIC ROC cutoff points ranged from 4.0 to 7.0.^{2,11} MIC 95% limit cutoff points showed higher scores (8.1 to 12.2).^{2,11} If a questionnaire should be able to detect the MIC from measurement error at the individual level, it is important that the minimal detectable change is smaller than the MIC.⁶ In a population of patients with shoulder problems the minimal detectable change of the OSS was estimated to be 6.0 points, similar to the MIC found in our study.³⁷ We did not find studies evaluating the MIC of the FABQ or EQ-5D 5-level version, only the 3-level version. Because the two versions have different value ranges, the MIC values are not comparable between versions.

Among the included population, 77% of the patients were improved after decompression surgery, which is in line with other studies.^{18,23} A follow-up at 6 months seemed appropriate to achieve that improvement. However, the choice of anchor is essential when using an anchor-based approach to determine responsiveness and MIC. We used an anchor that considered improvement from the patient’s perspective, assessing improvement in a very general way. Furthermore, we chose two more anchors assessing other aspects of improvement, namely shoulder pain at activity and an overall measure of the value of the affected shoulder. Other anchors might have generated different results.

Strengths of the study are that we used several anchors and predefined hypotheses to investigate the responsiveness. Furthermore, the MIC was assessed using a method integrating anchor- and distribution-based approaches. Overall, we succeeded in having high data quality with few patients dropping out or being lost to follow-up and few missings. In addition, no floor or ceiling effect was observed. Limitations are that slightly different techniques for completing the questionnaires were used: tablet, an email with a link and, for few patients, paper forms. Furthermore, we were only able to assess the responsiveness and MIC of the FABQ-PA, not the work scale of the questionnaire. A quarter of the population did not have a job or were retired and the remaining sample was considered too small for an adequate evaluation of the responsiveness and MIC of the FABQ work scale. In addition, we planned to assess the MIC with two cutoff points; ROC cutoff point and 95% limit cutoff point. However, the 95% limit cutoff point is based on the

Table III

Spearman correlation coefficients, ROC curve statistics and MIC estimates for the Oxford Shoulder Score (OSS), EQ-5D utility index (EQ-5D_{index}), EQ visual analogue scale (EQ_{vas}), and Fear-Avoidance Belief Questionnaire for physical activity (FABQ-PA) in relation to change scores of the Subjective Shoulder Value (SSV), shoulder pain on VAS, and the Global Rating of Change Scale

	OSS (0-48) [†]	EQ-5D _{index} (-0.205-1.0)	EQ-5D _{vas} (0-100)	FABQ-PA (0-24) [‡]
SSV*	0.67	0.50	0.28	-0.28
Pain VAS*	-0.58	-0.47	-0.23	0.39
ROC AUC	0.96 (0.91,1.00)	0.82 (0.66,0.99)	0.73 (0.58,0.87)	0.74 (0.58,0.90)
MIC ROC cut-off	6.0	0.024	10.0	-5.0

AUC, area under curve; MIC, minimal important change; MIC ROC, cut-off; MIC, based on optimal cut-off of the ROC curve; ROC, receiver operating characteristic; VAS, visual analogue scale.

*Data missing for one patient.

†Data missing for two patients.

‡Data missing for three patients.

distribution of the patients who are not importantly changed as per the anchor.⁵ In our sample, this group only consisted of five patients which was considered too small a sample to make a meaningful calculation of the MIC based on this method.

Conclusion

The responsiveness of the OSS, EQ-5D, and FABQ-PA was sufficient to measure improvement in patients with impingement syndrome undergoing arthroscopic subacromial decompression. The MIC ROC cutoff points were 6.0 points for the OSS, 0.024 points for the EQ-5D_{index}, 10.0 points for the EQ_{vas}, and -5.0 points for the FABQ-PA. The established MIC values can be used in clinical practice and future research.

Disclaimers:

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