

Validation of a new objective index to measure spinal mobility: the University of Cordoba Ankylosing Spondylitis Metrology Index (UCOASMI)

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Abstract Spinal mobility measures are subject to high variability and subjectivity. Automated motion capture allows an objective and quantitative measure of mobility with high levels of precision. To validate the University of Cordoba Ankylosing Spondylitis Metrology Index (UCOASMI), an index measure of spinal mobility, based on automated motion capture, validation studies included the following: (1) validity, tested by correlation—Pearson's r —between the UCOASMI and the mobility index Bath Ankylosing Spondylitis Metrology Index (BASMI), and a measure of structural damage, the modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS); (2) reliability, with internal consistency tested by Cronbach's alpha, test–retest by intraclass correlation coefficient (ICC) after 2 weeks, and error measurement, by variation coefficient (VC) and smallest detectable difference (SDD); and (3) responsiveness, by effect size (ES) in a clinical trial of anti-TNF. Patients for the different studies all had ankylosing spondylitis. Validity studies show correlation between the BASMI ($r = 0.881$) and the mSASSS ($r = 0.780$). Reliability studies show an internal consistency of Cronbach's $\alpha = 0.894$, intra-observer ICC = 0.996, test–retest ICC = 0.996, and a measurement error of VC = 2.80 % and SDD = 0.25 points. Responsiveness showed an ES after

24 weeks of treatment of 0.48. In all studies, the UCOASMI's performance was better than that of the BASMI. The UCOASMI is a validated index to measure spinal mobility with better metric properties than previous indices.

Keywords Validation studies · Spinal mobility · Responsiveness · Reliability · Ankylosing spondylitis

Introduction

Ankylosing spondylitis (AS) is a chronic inflammatory disease that mainly affects spinal mobility, which in return determines disease severity. Measurement of disease in AS is a difficult task despite the use of universally accepted measures, such as the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [1], the Bath Ankylosing Spondylitis Functional Index (BASFI) [2], and the Bath Ankylosing Spondylitis Metrology Index (BASMI) [3], a combined index that measures mobility. All these indices present a varying degree of subjectivity and measurement bias [4, 5]; the first two indices are patient-related outcomes obtained from scale-based questionnaires; the latter is based on measures made on the patient, following specific instructions, with instruments such as a goniometer, or metric tape. The BASMI is thus affected by the experience of the explorer and by musculoskeletal comorbidity, and it has only a moderate reliability in expert hands [6].

There might be ways to increase objectivity in the measurement of spinal mobility. The advantages would be to avoid measurement noise from metric instruments and explorer expertise and to facilitate centralized assessment, guarantee blinding, and subsequently reduce variability. Automated motion capture allows an objective quantitative measure of movement with high levels of precision [7].

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Our group used a motion capture system, the UCOTrack™, to obtain mobility measures in AS patients following a kinematic data collection protocol. We herein present the studies that lead to validate an index that was created based on the experience with this technique.

Methods

The UCOASMI (University of Córdoba Ankylosing Spondylitis Metrology Index) is a composite index that produces a score of cervical and spinal mobility based on serial kinematic measures [7, 8]. The score ranges from 0 to 10 (from best to worst mobility). Similar to the BASMI and the EDASMI (Edmonton Ankylosing Spondylitis Metrology Index) [9], the UCOASMI is derived from a selection of individual measures—based on metric properties—and then calculated as a weighted average.

The validation of the UCOASMI implied the conduct of several studies: (1) its validity was tested in a cross sectional study of 40 patients; (2) its reliability was tested in a test–retest study with the patients included in the cross sectional re-evaluated after two weeks without treatment change; and (3) its responsiveness was tested in two intervention trials, previously presented at rheumatology congresses, one of which was an open clinical trial of anti-TNF therapy for 24 weeks in 15 patients [10], and the other was a randomized controlled trial of patient education versus no education in 30 patients for 6 months [11]. These two latter trials had as response variables all previously commented measures (the BASDAI, the BASFI, the BASMI, and the ASQoL), plus the UCOASMI; effect size (see statistical issues, later) was measured at week 24 and 6 month, respectively. In the anti-TNF trial, all patients were administered an anti-TNF; in the education trial, the sample was part of a larger national study [12]; the two groups' comparison had been randomized and non-significant differences were apparent between them.

Patients for the different validation studies were recruited from the Department of Rheumatology Reina Sofía Hospital among attending patients with a confirmed diagnosis of AS by the modified New York criteria [13], and less than 5 years since diagnosis. Patients for the open trial were selected consecutively from those at need of anti-TNF therapy. Patients for the education trial were selected from consecutive patients being diagnosed at the clinic. They were all informed and consented to participate in the different studies, which were approved by the Reina Sofia Hospital Research Ethics Committee.

Measures were carried out in a motion laboratory at the University of Cordoba by a licensed nurse (CGN). The kinetic measures used to calculate the UCOASMI were obtained from a functional analysis of movement

previously detailed [8]. The system comprises 33 reflective markers placed on anatomical places in the subject, four cameras, and a motion capture system, the UCOTrack™. The patient is required to perform specific movements, such as flexion, extension, and rotation. The software interprets the images and produces 12 summary measures. All measures were performed between 17:00 and 19:00 to avoid morning stiffness.

In addition to the motion analysis, the following measures were also recorded: weight and height, the individual measures to calculate the BASMI (chest expansion, Schöber test, occipital-wall distance, tragus-wall distance, finger-floor distance, lateral flexion, and intermaleolar distance), the BASDAI, the AS Quality of Life (ASQoL), and the BASFI. Spinal radiographs were evaluated by an experienced radiologist in *Hospital de Alta Resolución de Puente Genil*, who calculated the modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS), blinded to the results of the other measures.

Sample size for the cross sectional and test–retest studies was predetermined in 26 subjects to obtain an intraclass correlation coefficient (ICC) greater than 0.8, assuming a real value of 0.9, an alpha error of 5 %, and a beta error of 20 %. Statistical analysis was carried out in Microsoft Excel™ and SPSS™ 14.0 for Windows.

Validity

Face validity

From the 12 measures initially produced by the motion analysis (See Table 2), the UCOASMI should be finally formed by those measures with: (1) lowest variability, as measured by the variation coefficient (VC), (2) highest reliability, measured by the ICC from a test–retest study, and (3) strongest correlation with the BASMI, the mSASSS, and the BASFI.

Construct validity

The hypotheses to be tested were a positive and strong correlation of the UCOASMI with the BASMI, the mSASSS, and the BASFI, as they all reflect similar constructs—mobility, structural damage, and function, respectively. Correlations with constructs other than damage or function were expected to be weak.

Criterion validity

We tested the capacity of the UCOASMI to discriminate patients with worse and best functional state by dividing the sample into the extreme tertiles with respect to the BASFI scores and disregarding the second tertile. The statistic used to test criterion validity was the area under the ROC curve (AUC).

Table 1 Characteristics of the patients included in the validation studies

Study	Validity and reliability	Responsiveness	
		I (anti-TNF trial)	II (educational trial)
<i>N</i>	40	15	30
Women, <i>n</i> (%)	4 (10)	3 (20)	5 (16)
Age in years, <i>m</i> (SD)	38.0 (12.5)	43.1 (10.9)	44.8 (8.5)
Weight in kg, <i>m</i> (SD)	75.8 (11.2)	82.9 (6.5)	82.1 (6.8)
Height in cm, <i>m</i> (SD)	172.6 (7.9)	174.5 (9.6)	169.7 (2.6)
BMI, <i>m</i> (SD)	24.4 (3.6)	27.4 (3.6)	28.5 (1.8)
Age at diagnosis in years, <i>m</i> (SD)	25.8 (7.9)	29.7 (6.8)	30.0 (9.1)
Disease duration in years, <i>m</i> (SD)	14.5 (10.84)	13.1 (6.10)	14.9 (10.8)
BASMI, <i>m</i> (SD)	3.4 (2.5)	1.9 (0.6)	3.0 (1.7)
mSASSS, <i>m</i> (SD)	31.4 (24.1)	21.4 (22.0)	23.1 (18.7)
HLA B27+, <i>n</i> (%)	33 (82)	12 (80)	25 (83)

m (SD) mean (standard deviation), *BMI* body mass index, *BASMI* Bath Ankylosing Spondylitis Metrology Index, and *mSASSS* modified Stoke Ankylosing Spondylitis Spinal Score

Table 2 Full list of measurements available with the analysis of movement system showing face and construct validity of the UCOASMI

Measure	<i>m</i> (SD) ^c	VC	ICC	Pearson's <i>r</i> with the UCOASMI [£]				
				BASMI	mSASSS	BASFI	ASQoL	BASDAI
<i>Cervical movements</i>								
Frontal flexion ^a	96.3 (36.6)	3.81	0.995 (>0.989)	-0.89	-0.86	-0.57	-0.36	-0.19
Rotation ^a	123.3 (40.2)	3.60	0.992 (>0.983)	-0.92	-0.92	-0.66	-0.42	-0.19
Lateral flexion	69.7 (33.0)	12.05	0.992 (>0.981)	-0.89	-0.92	-0.60	-0.39	-0.12
<i>Lumbar frontal flexion</i>								
Finger-floor distance (cm)	11.8 (9.7)	15.18	0.985 (>0.962)	0.74	0.84	0.62	0.72	0.29
Frontal flexion	57.2 (28.4)	9.51	0.929 (>0.804)	-0.75	-0.74	0.01	0.03	0.06
Modified Schöber test (cm)	7.36 (3.2)	6.78	0.909 (>0.775)	-0.81	-0.82	-0.16	-0.29	-0.27
Schöber flexion (cm)	5.7 (2.6)	7.43	0.945 (>0.865)	-0.73	-0.80	-0.27	-0.18	-0.36
Frontal spinal bending ^a	127.1 (25.1)	2.68	0.988 (>0.969)	-0.80	-0.80	-0.69	-0.78	-0.49
Frontal bending flexion	94.4 (17.1)	4.44	0.963 (>0.908)	-0.72	-0.78	-0.73	-0.75	-0.46
<i>Lumbar lateral flexion</i>								
Right lateral flexion	20.8 (8.4)	15.94	0.929 (>0.824)	-0.83	-0.83	-0.33	-0.18	-0.31
Left lateral flexion	20.1 (7.6)	14.53	0.965 (>0.913)	-0.84	-0.83	-0.34	-0.19	-0.30
Lateral flexion range	65.4 (33.6)	22.54	0.934 (>0.837)	-0.79	-0.83	-0.47	-0.42	-0.35
Lateral angle shoulder-hip ^a	78.2 (29.2)	12.67	0.987 (>0.969)	-0.88	-0.81	-0.46	-0.43	-0.43
Lateral bending	67.2 (24.3)	15.87	0.966 (>0.915)	-0.86	-0.87	-0.53	-0.39	-0.39
<i>Trunk rotation</i>								
Trunk rotation ^a	97.1 (32.9)	1.97	0.996 (>0.989)	-0.86	-0.88	-0.70	-0.55	-0.36
UCOASMI ^b	4.54 (1.44)	2.80	0.996 (>0.990)	0.88	0.78	0.69	0.54	0.33

m (SD) mean (standard deviation), *VC* variation coefficient, *ICC* intraclass correlation index, *BASMI* Bath Ankylosing Metrology Index, *mSASSS* modified Stoke Ankylosing Spondylitis Spine Score, *BASFI* Bath Ankylosing Spondylitis Functional Index, *ASQoL* Ankylosing Spondylitis Quality of Life, *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, and the *UCOASMI* University of Cordoba Ankylosing Spondylitis Metrology Index

^a Measurements that are used to calculate the UCOASMI. They were selected based on their validity (see methods > validity)

^b The UCOASMI is the average of the five selected measures; each of one is standardized to a value between 0 and 10, based on reference values

^c Values in this column represent degrees unless otherwise indicated

[£] All correlations showed a *p* value <0.01

Reliability

Internal consistency was tested with Cronbach's α , which was calculated from the intercorrelation of the measures included in the index in the baseline visit.

For the intra-observer reliability (test–retest), measures were repeated after 2 weeks without treatment changes. Reliability was measured as ICC obtained from an ANOVA for repeated measures with the patient as class variable.

Inter-observer reliability was not formally tested as the explorer was the automatic system. In return, error was measured by the VC and the smallest detectable difference (SDD).

Responsiveness

Responsiveness was studied in the open anti-TNF trial using the Cohen's d effect size statistic [14] given by difference in scores—24 weeks minus baseline—divided by the pooled standard deviation of the original time 1 and time 2 scores. In addition, we tested the responsiveness of the UCOASMI in an education trial of 6 month duration, by calculating the mean difference between groups in all indices plus the VC.

Results

Table 1 shows the characteristics of the patients included in the different studies.

Validity

Table 2 shows the results on the 12 measures produced by the motion analysis in 40 patients: mean and standard deviation, VC and ICC from the test–retest study, and correlation with the BASMI, the mSASSS, and the BASFI. The measures chosen for the UCOASMI are highlighted (*face validity*) and these are the following: (1) frontal neck flexion, (2) neck rotation, (3) frontal spinal bending, (4) lateral angle shoulder-hip, and (5) trunk and lumbar rotation (TR). Choosing only five measures reduces computation times.

In addition, Table 2 shows the Pearson's r of the UCOASMI with the BASMI, the mSASSS, and the BASFI (*construct validity*). Correlation of other measures with the mSASSS was slightly weaker than with the UCOASMI: the BASMI $r = 0.621$, the BASDAI $r = 0.092$, the BASFI $r = 0.581$, and the ASQoL $r = 0.408$.

Figure 1 shows the ROC curve for comparing the UCOASMI scores with the referent variable worse/best BASFI. The AUC was 0.74 (95 % CI 0.63–0.86) (*criterion validity*).

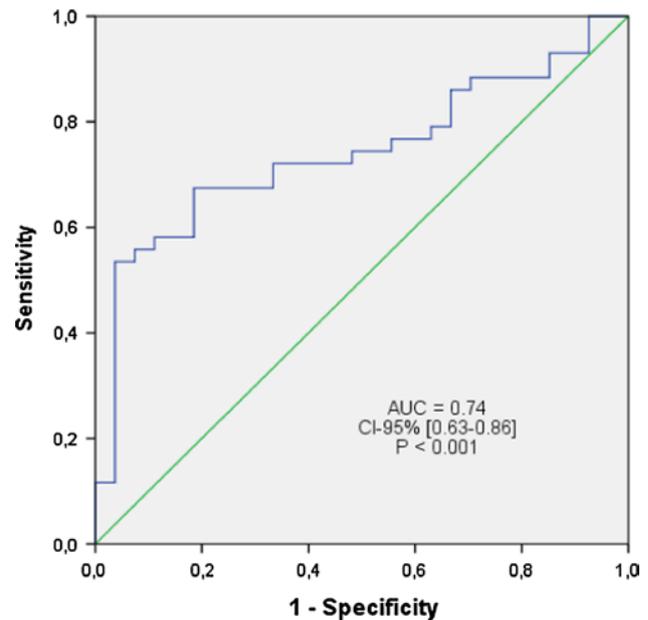


Fig. 1 Receiver operator curve for comparing the UCOASMI scores with the referent variable worse/best BASFI (*criterion validity*)

Table 3 Changes in the different indices during an open uncontrolled anti-TNF trial in 15 AS patients

Index	Baseline	24 weeks	Effect size
BASMI	1.91 (0.6)	1.77 (0.61)	0.23
BASDAI	4.28 (1.12)	3.33 (1.16)	0.32
BASFI	4.40 (0.94)	3.40 (1.13)	0.41
ASQoL	5.23 (1.05)	4.05 (1.08)	0.43
UCOASMI	4.70 (0.63)	4.40 (0.69)	0.48

Results are expressed as mean (standard deviation)

BASMI Bath Ankylosing Metrology Index, *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, *BASFI* Bath Ankylosing Spondylitis Functional Index, *ASQoL* Ankylosing Spondylitis Quality of Life, and the *UCOASMI* University of Cordoba Ankylosing Spondylitis Metrology Index

Reliability

Internal consistency measured by Cronbach's α was 0.894. Intra-observer reliability measured by ICC was 0.996 (the BASMI's ICC = 0.956). The UCOASMI's error as measured by the VC was 2.80 % (the BASMI's VC = 13.71 %). The SDD was 0.25 points (1.27 in the BASMI).

Responsiveness

Tables 3 and 4 show the sensitivity to change of the UCOASMI, as well as the compared responsiveness with other indices.

Table 4 Mean difference and variation coefficient of different indices during an intervention trial of patient education in 30 AS patients

Index	Baseline, m (SD)		Mean difference at 6 months (VC)	
	Education	Control	Education	Control
BASMI	2.85 (0.85)	3.16 (1.84)	−0.07 (2.48 %)	0.10 (−3.05 %)
BASDAI	2.78 (2.06)	4.26 (1.10)	−0.58 (17.30 %)	0.30 (7.63 %)
BASFI	3.06 (2.52)	4.69 (1.56)	−0.61 (16.51 %)	0.07 (1.54 %)
ASQoL	3.54 (2.44)	4.79 (2.72)	−0.56 (13.58 %)	−0.42 (8.09 %)
UCOASMI	4.41 (1.58)	4.68 (2.46)	−0.15 (3.33 %)	0.26 (5.61 %)

Results are expressed as mean (standard deviation)

SD standard deviation, VC variation coefficient, *BASMI* Bath Ankylosing Metrology Index, *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, *BASFI* Bath Ankylosing Spondylitis Functional Index, *ASQoL* Ankylosing Spondylitis Quality of Life, and the *UCOASMI* University of Cordoba Ankylosing Spondylitis Metrology Index

Discussion

We herein present the full validation of a new index for spinal mobility in AS obtained from an automated measure. This outcome tool meets the standards for truth, discrimination, and feasibility from the OMERACT filter [15], and we have demonstrated that it correlates well with the BASMI—they both measure the same construct—but with lower variability.

The strength of the UCOASMI is its low variability and robustness. Compared to commonly used spinal mobility indices, such as the BASMI, the UCOASMI shows a good performance with little noise and adequate sensitivity to change. This is plausibly due to the fact that we are avoiding two sources of error measurement. For any measure, variability reflects true changes in state, variability in the observer's expertise, and variability from the instrument itself. Measuring tape and goniometers, the typical instruments used for spinal mobility measurements are indeed simple to use but prone to a high variability [16]. With the UCOTrack™, the only salient source of variability is the patient status, as the rest is automated. Any technician can follow the instructions simply by placing the markers in the pre-specified points and asking the patient to perform standard movements. Of course, UCOTrack™ is not the only automated motion capture system. There are other devices available (Cybex™ for the neck, Spinal Mouse™ for the spine, Fastrak™) that may produce similar measures [17–19], but in a more complex way, and at a higher cost.

An additional strength of the UCOASMI is its good construct validity, better than the one exhibited by the BASMI. The correlation of this new index with a measure of structural damage, such as the mSASS, supports its use as a measure of limited mobility in relation to damage.

We have been using this system in the clinic already for a year. In our experience, the system has a series of advantages: (1) it saves time to the doctor, as these analyses are

performed in a different room; (2) it shows a much clearer picture of mobility, as it measures rotations and extensions, not measured by the BASMI; (3) the patient can see a report showing the differences in movement with previous visits. Interestingly, we noted that the patients prefer the individual measures shown in graphs in the report, while the rheumatologists prefer a simple index to facilitate the therapeutic decisions. Our studies show good validation of the full system in individual components as well as an aggregated index.

We would recommend the UCOASMI for the daily clinical practice, but especially for research, as it has very appropriate metric properties. Notably, the UCOASMI can be centralized, avoiding interpretation bias by site investigators, and has an excellent SDD compared with other indices. For instance, the BASMI has a larger SDD than our index [4], what may result in a larger sample size to detect between-groups differences.

We acknowledge the limitations and cautions of our index. The BASMI is faster and cheaper than the UCOASMI and, until we produce an automated programme, the production of reports and scoring is tedious. In addition, we have not studied its reproducibility in other scenarios. We are using the same software to study joint instability in OA with good results (data not shown), but the system has not been used by other teams. We are planning to use it in a multicentre intervention trial with centralized reading. Also, feasibility may be an issue at the time of implementing the technique. The average times for the UCOASMI are the following: preparing the patients 5 min, taking the measures 10 min, and producing a report 120 min. The total investment costs include the software (2,000€) + 4 cams (450€*4) + computer (800€) + a 35 m² space. Staff costs will depend on utilization (hours per week), but it should be taken into account that it is nurse or similar grade-time costs, non-doctors. If the interpretation of the analysis was centralized, each analysis would cost an additional 120€.

Finally, we are planning to test our system by functional anatomy, comparing the true movement measured by functional radiology and by surface markers, such as in our system. If our hypothesis is not rejected, the study will increase the face validity of the system.

In conclusion, we have validated a mobility index for AS based on automated measures with better metric properties than commonly used indices that will need reproduction in other settings.

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Conflict of interest None.

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