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Clinical science

Responsiveness of spondyloarthritis-specific health utilities based on the ASAS Health Index (U-ASAS-HI): an ancillary analysis from the ASAS-HI validation study

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Abstract

Objectives: To assess responsiveness of the spondyloarthritis (SpA)-specific universal health utility from the ASAS Health Index (U-ASAS-HI) compared with generic health utilities (EQ-5D-5L and SF-6D).

Methods: Data were used from patients with SpA participating in the ASAS-HI international validation study and starting TNF inhibitor (TNFi), conventional synthetic DMARD (csDMARD) or NSAID. *A priori* hypotheses on correlation of change in utility and change in external health anchors between baseline and follow-up were tested. Standardized response mean (SRM) and Cohen's effect size (ES) were calculated in each treatment group. The ability of changes in utilities to discriminate between BASDAI-50% (non)-responders was assessed by standardized estimate of change and receiver operating characteristic (ROC) analyses.

Results: 219 patients were included (110 TNFi, 37 csDMARD, and 72 NSAID). Mean (s.d.) age was 37 (13) years and 63% were male. Hypotheses on correlations of change scores were confirmed for 75% of comparisons for U-ASAS-HI and EQ-5D-5L, but not for SF-6D. As expected, SRM and ES for the U-ASAS-HI were large in the TNFi-treated group, moderate in the csDMARD group and small to moderate in the NSAID group. The hypothesized larger SRM and ES for U-ASAS-HI compared with EQ-5D and SF-6D could not be consistently confirmed across the three treatment groups. Ability to discriminate between BASDAI-50% responders and non-responders did not differ among utility instruments in ROC comparison.

Conclusion: In a context where change is expected, the SpA-specific U-ASAS-HI correlates as expected with changes in other SpA-specific outcomes and shows good responsiveness, which is similar to but not better than for generic utilities.

Keywords: spondyloarthritis, ASAS Health index, responsiveness, health economics, societal utilities

Rheumatology key messages

- In the context of treatment intervention, the changes in utility from the ASAS Health Index (U-ASAS-HI) correlate as hypothesized with changes in other relevant health outcomes.
- The expected large effect size for U-ASAS-HI following TNFi was confirmed.
- The responsiveness of the SpA-specific U-ASASHI does not outperform the responsiveness of the generic health utility instruments.

Introduction

Health utilities are developed to assess the 'preference' or 'value' of the various health states that reflect the impairments and limitations experienced by a person who has a disease or suffers from ill health. These 'health utilities' or 'values for health' are commonly developed from patient-reported

measurement instruments that assesses overall functioning and health or health-related quality of life (HRQoL) and are scaled between 0 and 1 (representing death and perfect health) [1, 2]. Health state values or utilities can be elicited from persons in the general population (societal health utilities) or from

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patients themselves (patient health utilities). Health utilities are essential to decide which health states are preferred in medical decision making. Societal utilities are often the basis to calculate quality adjusted life years, which are used in societal cost-effectiveness analyses [3].

Among the most frequently used generic societal utility measurement instruments are the European Quality of Life five dimensions (EQ-5D-5L) and the Short Form six dimensions (SF-6D). However, it is increasingly accepted that generic health utility instruments might inadequately capture the disease-specific impact on a patient's functioning and HRQoL [4], and may prove insensitive to disease-specific changes, particularly in the case of chronic conditions [5, 6].

The Assessment of SpondyloArthritis international Society Health Index (ASAS-HI) is a disease-specific instrument designed to measure the global functioning and health of patients with axial spondyloarthritis (SpA) [7] and later validated for peripheral SpA [8]. Considering the potential value of SpA-specific health utilities, a universal algorithm has been developed to convert the patient's score of the ASAS-HI into a health utility from the ASAS Health Index (U-ASAS-HI) [9]. Following state of the art methodology, this algorithm was developed in a one-off preference study in which people from the general population were asked to value the health states of people with all possible combinations of limitations and impairment based on the items of the ASAS-HI.

The construct validity of the U-ASAS-HI has been recently shown [10], but data on responsiveness are lacking. The responsiveness refers to the ability of an instrument to detect change over time when a change is expected. Outcome Measures in Rheumatology (OMERACT) [11] distinguishes longitudinal construct validity (where the change score on the scale is compared with the results of other instruments, and the formulated hypotheses), and clinical trial discrimination (where the magnitude of change in a clinical trial setting is evaluated against expected change).

The aim of this study was to determine responsiveness including longitudinal construct validity and trial discrimination of scores from the SpA-specific (U-ASAS-HI) compared with generic (EQ-5D-5L and SF-6D) health utilities in patients with SpA starting or switching treatment.

Methods

Population

A secondary analysis was of data from the ASAS-HI international validation study [12], including 1548 patients from 23 countries. The study population has been described in detail by Kiltz *et al.* [12].

The project was performed in alignment with the principles outlined in the Declaration of Helsinki. Ethical approval from the participating centres had been obtained before the start of the validation study along with informed consent from participating patients. For the current study a subsample of 219 with SpA who required a therapeutic change due to disease activity and who completed ASAS-HI, EQ-5D-5L and SF-36 at baseline and follow-up was used. Patients started either a non-steroidal anti-inflammatory drug (NSAID), a conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) or TNF inhibitor (TNFi). Baseline data were obtained during the visit when the therapeutic change was indicated, prior to the initiation of the new

treatment. Reassessments were performed after 12–24 weeks (2–24 weeks for NSAID group) [12].

Assessments

Data from ASAS-HI validation study used for the current analyses included sociodemographic characteristics (age and gender), disease characteristics (symptom duration, SpA subtype, and HLA-B27 positivity), and several self-reported outcomes measurement instruments (see below).

Health utility measurement instruments

The U-ASAS-HI was developed from the 17-item ASAS-HI (dichotomous response: 'I agree' and 'I do not agree') [8]. Using the best–worst scaling and time trade of experiments in the general population from six countries, algorithms were developed to assess the societal health utilities [9]. One general algorithm was developed with scores ranging from –0.24 (worst health) to 0.88 (best health) [9]. The EQ-5D-5L comprises five questions [13], and the EQ-5D-5L societal health utility was calculated using the UK algorithm ranging from –0.29 to 0.95 [14]. The SF-6D utility derived from the Short Form 36 questionnaire (SF-36) [14] was calculated using the UK algorithm ranging from 0.29 to 1.00 [15].

External health anchors

Outcomes available to evaluate longitudinal construct validity included the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [16], the visual analogue scale (VAS) total back pain (BASDAI-Q2), the VAS peripheral pain (BASDAI-Q3), the VAS fatigue (BASDAI-Q1), and the physical (PCS) and mental component score (MCS) of the SF-36 [17].

Statistical analysis

Descriptive statistics were applied to characterize the population. To assess longitudinal construct validity, Spearman correlation coefficients between changes in utilities and changes in external anchors were calculated in the total sample and interpreted against *a priori* hypotheses. It was expected that all correlations should be moderate ($r \geq 0.4$) or good/very good ($r \geq 0.7$), as (i) all external anchors were considered to represent important aspects of the construct 'health utility' and (ii) disease-specific and generic health utilities have overlapping content. Coefficient interpretations were: very weak ($r = 0–0.19$), weak ($r = 0.20–0.39$), moderate ($r = 0.40–0.69$), strong ($r = 0.70–0.89$), and very strong ($r = 0.90–1.0$) [11, 18]. Per instrument, longitudinal construct was considered appropriate if $\geq 75\%$ of hypotheses were confirmed, acceptable if 50–75% were confirmed and unacceptable if $< 50\%$ were confirmed.

To assess trial discrimination, we calculated within each treatment group (TNFi, csDMARD, and NSAID), standardized response mean (SRM, mean change divided by the standard deviation of the change) and the Cohen's effect size (ES, mean change divided by the s.d. of baseline). Values ≥ 0.80 were considered large, values ≥ 0.50 and < 0.80 moderate, and values < 0.50 small [19]. It was *a priori* hypothesized that the SRM and ES would be large in those starting TNFi, moderate in those starting csDMARD and small to moderate in those starting NSAID. It was also expected that ES for U-ASAS-HI would always be numerically larger than for the generic utilities.

As part of trial discrimination, the ability to discriminate changes between responders and non-responders was

assessed [11]. The SRM was used as a standardized estimate of change, with higher values expected *a priori* for patients achieving BASDAI-50% response [20]. Additionally, receiver operating characteristic (ROC) analyses were performed with BASDAI-50% response as external criterion, ensuring a robust evaluation of their applicability in assessing treatment response in SpA patients [11]. Area under the curve (AUC) was calculated and the DeLong test was performed to evaluate differences between instruments. All analyses were performed using R-Studio statistical software.

Results

Descriptive analysis of baseline and follow-up scores

In total, 219 SpA patients were selected for analysis of whom 110 started TNFi, 37 csDMARDs and 72 NSAIDs. Overall, 63% were male, mean (s.d.) age 37 (13) years, main SpA subtype was radiographic axial SpA in 53% (Supplementary Table S1). The time between baseline and the follow-up was for the TNFi group 16 (4) weeks, for the csDMARD group 15 (2.1) weeks and for the NSAID group 5 (2.0) weeks.

As expected, absolute changes in health utility for each instrument were largest in the TNFi treatment group and lowest for NSAID group. More specifically, change (s.d.) in health utilities was for TNFi: U-ASAS-HI, 0.23 (0.23); EQ-5D-5L, 0.22 (0.24); SF-6D, 0.09 (0.09); for csDMARD: U-ASAS-HI, 0.15 (0.22); EQ-5D-5L, 0.15 (0.21); SF-6D, 0.05 (0.08); and for NSAID: U-ASAS-HI, 0.12 (0.24); EQ-5D-5L, 0.11 (0.22); SF-6D, 0.03 (0.09) (Supplementary Table S2).

Longitudinal construct validity

Across treatment groups, 75% (6 out of 8) of *a priori* hypotheses were confirmed for U-ASAS-HI and EQ-5D-5L, and

Table 1. Correlation matrix of the difference in change utility instruments with external health outcomes in the total population (treatment independent evaluation)

	Δ U-ASAS-HI	Δ EQ-5D-5L	Δ SF-6D
Δ U-ASAS-HI		0.60** ^a	0.42** ^a
Δ EQ-5D-5L	0.60** ^a		0.52** ^a
Δ SF-6D	0.42** ^a	0.52** ^a	
Δ BASDAI	-0.53** ^a	-0.60** ^a	-0.43** ^a
Δ Fatigue (BASDAI Q1)	-0.48** ^a	-0.45** ^a	-0.33** ^b
Δ Pain back (BASDAI Q2)	-0.42** ^a	-0.51** ^a	-0.31** ^b
Δ Pain peripheral joints (BASDAI Q3)	-0.40** ^a	-0.40** ^a	-0.37** ^b
Δ PCS SF-36	0.18** ^b	0.35** ^b	0.39** ^b
Δ MCS SF-36	0.17* ^b	0.18* ^b	0.23** ^b
Overall performance	75% ^c	75% ^c	38%

All coefficients represent Spearman correlations between change scores (Δ: follow-up – baseline).

^a Correlation as hypothesized.

^b Correlation different from hypothesized.

^c ≥75% of hypotheses confirmed.

* $P < 0.050$.

** $P < 0.001$.

^Δ BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; difference between baseline and follow-up; EQ-5D-5L: EuroQoL five dimensions; MCS: mental component score of the SF-36; PCS: physical component score of the SF-36; SF-6D: short form six dimensions; SF-36: short form questionnaire 36; U-ASAS-HI: utility from the ASAS Health Index.

38% (3 out of 8) for SF-6D, indicating that longitudinal construct validity is adequate for U-ASAS-HI and EQ-5D-5L but inadequate for SF-6D (Table 1).

In subgroup analyses by treatment group (Supplementary Table S3), correlations of change scores of U-ASAS-HI with EQ-5D-5L, as well as with SF-6D, were moderate across treatment groups but numerically stronger for correlation of U-ASAS-HI with EQ-5D-5L than with SF-6D.

Trial discrimination

Expected large SRMs and ES were observed in the TNFi treatment group for U-ASAS-HI and SF-6D but not for EQ-5D-5L (Table 2). For both other treatment groups, the SRM and ES were, as expected, moderate and small to moderate for the csDMARD and NSAID group, respectively. Contrary to hypothesized, the ES was not numerically larger for the U-ASAS-HI. Also, there was no instrument that performed consistently better. Regarding discrimination, the SRM for those patients who achieve BASDAI-50% response was higher (U-ASAS-HI, 1.05; EQ-5D-5L, 1.04; and SF-6D, 0.86) compared with those who did not achieve response (U-ASAS-HI, 0.50; EQ-5D-5L, 0.17; and SF-6D, 0.57). Additionally, the AUC for capacity to discriminate between BASDAI-50% (non-)responders of the utility change-values was 0.69 (95% CI: 0.62, 0.76) for U-ASAS-HI, 0.77 (95% CI: 0.71, 0.83) for EQ-5D-5L, and 0.68 (95% CI: 0.60, 0.75) for SF-6D (Supplementary Fig. S1). AUCs were not statistically significantly different between health utility instruments.

Discussion

The results of this study demonstrate that U-ASAS-HI is responsive to detect change in health utility in patients with SpA who start or switch drug treatment. Consistent with our *a priori* hypotheses, the changes in U-ASAS-HI correlate at least moderately with changes in relevant external anchors. Further, ES for U-ASAS-HI following different treatment was largest in the group that received the treatment that was considered most effective (TNFi). Although we expected that ES and discrimination of the disease-specific U-ASAS-HI would

Table 2. Cohen's effect size and standard response mean for utilities score per treatment groups

Group	Measurement	Cohen's ES (95% CI)	SMR (95% CI)
TNFi (n = 110)	U-ASAS-HI	0.91 (0.74, 1.4) ^a	0.99 (0.82, 1.20) ^a
	EQ-5D-5L	0.49 (0.13, 1.21)	0.55 (0.14, 1.04)
	SF-6D	1.06 (0.85, 1.31) ^a	0.95 (0.75, 1.18) ^a
csDMARD (n = 37)	U-ASAS-HI	0.58 (0.31, 0.93) ^a	0.68 (0.43, 0.92) ^a
	EQ-5D-5L	0.72 (0.38, 1.13) ^a	0.73 (0.40, 1.06) ^a
	SF-6D	0.62 (0.33, 0.96) ^a	0.64 (0.34, 0.96) ^a
NSAID (n = 72)	U-ASAS-HI	0.45 (0.25, 0.70) ^a	0.48 (0.28, 0.67) ^a
	EQ-5D-5L	0.52 (0.30, 0.75) ^a	0.52 (0.35, 0.69) ^a
	SF-6D	0.42 (0.17, 0.64) ^a	0.43 (0.19, 0.66) ^a

Large SMR or ES values: ≥0.80; moderate SMR or ES values: ≥0.50 and <0.80; small SMR or ES values: <0.50.

^a Meets hypothesis on trial discrimination (large in TNFi group, moderate in csDMARD group and at least small in NSAID group). csDMARD: conventional synthetic DMARD; EQ-5D-5L: EuroQoL five dimensions; ES: effect size; NSAID: non-steroidal anti-inflammatory drug; SF-6D: short form six dimensions; SMR: standardized response mean; TNFi: TNF inhibitors; U-ASAS-HI: utility from the ASAS Health Index.

be numerically better than the generic EQ-5D-5L and SF-6D, this was not consistently observed.

The U-ASAS-HI is the first SpA-specific utility score, and its advantage over EQ-5D-5L and SF-6D lies in its ability to account for all aspects of health relevant for patients with SpA. U-ASAS-HI not only covers common health utility aspects like pain, function and anxiety, but also areas not addressed by generic instruments, such as fatigue, intimate relationships and financial situation [8]. Notwithstanding, the latter are important aspects of health and, as shown, of preference for health states [21].

Our study confirms that improvements in pain and fatigue correlate as expected with changes in U-ASAS-HI. Surprisingly, improvement in utility correlated poorly with PCS and MCS of the SF-36. Apparently, changes in physical or mental function do not necessarily translate into equivalent changes in health utility, possibly due to the weighting of these aspects in the U-ASAS-HI.

The magnitude of change adjusted for the noise (i.e. ES) of the U-ASAS-HI was large in the treatment group where a large effect was expected (TNFi) and confirms the U-ASAS-HI is adequate to pick changes. Contrary to our hypothesis, U-ASAS-HI ES was not consistently larger compared with either the EQ-5D-5L or the SF-6D. In line with the findings on effect sizes within the treatment arms, the ability of the utility instruments to discriminate between (non-)responders following treatment was adequate, but again not consistently better for the U-ASAS-HI compared with both other instruments. Generic instruments remain essential for comparison of health utilities or QALYs across diseases and in patients with multimorbidity; however, they may underestimate the burden or treatment benefits in SpA when changes occur in domains they do not assess. This broader scope may partly explain the lower absolute utility values observed with U-ASAS-HI compared with generic instruments, as persons need to consider more relevant aspects to health when estimating health utilities [10].

In our observational study, we did not demonstrate superior responsiveness of U-ASAS-HI compared with generic utilities. Nevertheless, the U-ASAS-HI may provide added value in other contexts (such as physiotherapy, telemedicine, or work participation interventions) where capturing disease-specific health domains is essential, and responsiveness may become more apparent. On that line, the sensitivity of the U-ASAS-HI should be evaluated on other trials with different settings (pharmacological and non-pharmacological). Additionally, comparisons to placebo would provide more insight into the trial discrimination.

Our study has several limitations that should be noted. First, when assessing longitudinal construct validity, some degree of conceptual overlap ('circularity') between disease-specific external constructs and the U-ASAS-HI is unavoidable and inherent to validation of a broad construct such as HRQoL, and comparing the observed magnitude of the correlation to the 'desired' correlation (by defining hypothesis) is helpful for complete interpretation of the construct. Second, although longitudinal data were available, the overall sample size was modest, with a particularly small csDMARD subgroup. This limits the precision of our estimates and may have introduced random variation in correlations, as illustrated by the unexpectedly high EQ-5D correlation in the csDMARD group, despite similar baseline values compared with TNFi. Consequently, the stability and interpretability of subgroup comparisons are limited. Third, the

observational design prevented rigorous measurement of treatment response, and the absence of a control/placebo group limits the assessment of the discriminatory capacity of U-ASAS-HI in distinguishing true treatment effects from natural variation. While the absence of some disease-specific outcomes such as the Axial Spondyloarthritis Disease Activity Score (ASDAS) is a limitation, the use of external anchors in the study still provides valuable insights into changes in health utility. While these limitations suggest caution in interpreting our results, this study is the first to evaluate the responsiveness to change of U-ASAS-HI, with the recommended methodology by OMERACT [11]. OMERACT prefers two or three studies to fully endorse instruments, calling for replication of the current findings on responsiveness of the U-ASAS-HI. One of the questions that still needs to be answered is the validity among the SpA phenotypes (radiographic axial SpA *vs* peripheral SpA), as our study sample was not large enough for stratified analyses.

In conclusion, our study demonstrates that the SpA-specific societal U-ASAS-HI is a responsive utility measure for assessing changes in preferences for health state in patients with SpA.

Supplementary material

Supplementary material is available at *Rheumatology* online.

Data availability

Data will be available upon request.

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