

# Validation of disease activity and functional status questionnaires in spondyloarthritis

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## Abstract

### Objective

Patients naïve to the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and to the Ankylosing Spondylitis Disease Activity Score (ASDAS) have voiced confusion in our clinics over the use of the term “AS” in these instruments. It is unknown whether these tools may be applied to other related forms of spondyloarthritis (SpA). The Bath Ankylosing Spondylitis Functional Index (BASFI) questionnaire also requires more definitive validation. We 1) validated the BASFI against a standard definition of disability; and 2) validated slightly modified versions of the BASDAI and ASDAS questionnaires that replace references to “AS” with the term “inflammatory arthritis” for use in non-AS SpA.

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### Methods

Adult patients with SpA enrolled in the Veterans Affairs Program to Understand the Longterm outcomes in Spondylo-Arthritis (PULSAR) completed the BASFI, BASDAI, ASDAS and altered versions of the BASDAI (PULSAR-modified Bath Disease Activity Index [PuBaDAI]) and ASDAS (PULSAR-modified Ankylosing Spondylitis Disease Activity Score [PuASDAS]). Spearman correlations and logistic regression were used to analyse the scores.

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### Results

The correlation between BASDAI and PuBaDAI and between ASDAS and PuASDAS scores was high (Spearman's  $\rho=0.92$ ,  $p<0.001$  and Spearman's  $\rho=0.85$ ,  $p<0.001$ , respectively). The test-retest correlation of BASFI was also high (Spearman's  $\rho=0.92$ ,  $p<0.001$ ). The BASFI (OR 1.67, 95% C.I. 1.12–2.47), ASDAS (OR 1.34, 95% C.I. 1.02–1.76) and PuASDAS (OR 1.62, 95% C.I. 1.07–2.49) predicted federally-determined disability.

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### Conclusion

Preliminary data suggest that BASDAI and ASDAS scores correlate well with modified forms of these questionnaires and that the ASDAS, PuASDAS and BASFI are associated with disability.

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### Key words

ankylosing spondylitis, questionnaires, health impact assessment

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## Introduction

Trials in ankylosing spondylitis (AS) historically rely upon the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (1), Bath Ankylosing Spondylitis Functional Index (BASFI) (2), and more recently for axial spondyloarthritis, the Ankylosing Spondylitis Disease Activity Score (ASDAS) (3) in order to determine the efficacy of treatment approaches. Despite their long-standing use, the characteristics of the BASDAI and BASFI remain incompletely understood.

For example, Calin *et al.* determined that the BASFI scores demonstrate reproducibility over 24 hours, good inter-observer consistency, and sufficient sensitivity to detect the clinical improvement associated with a three weeks' intensive inpatient treatment of physical therapy in a cohort of patients in the pre-biologic era (2). This instrument, however, has not been formally evaluated in comparison to a *gold standard* – that is, whether patients have been declared disabled by a standardised evaluation – nor has the reproducibility been corroborated in an independent cohort.

In addition, patients with new onset AS and those naïve to these questionnaires, in particular, have voiced confusion in our clinic over the use of the term “AS” in the BASDAI. This terminology persists in the Assessment of SpondyloArthritis international Society (ASAS) questions for spinal pain and nocturnal spinal pain, also leaving the ASAS-endorsed disease activity score (ASDAS) susceptible to misinterpretation (4, 5). Modifying the “AS”-specific terminology from the BASDAI and ASDAS, as well as from the nocturnal pain question item (*i.e.* the question used to assess nocturnal symptoms as part of the ASAS core set for daily practice, improvement criteria, and disease controlling anti-rheumatic treatments) (4) may alleviate some of this confusion and allow their use for other spondyloarthritides (*e.g.* enteropathic arthritis, reactive arthritis).

Questions also surround the wording of the patient's *global assessment*, where the ASDAS (4) only inquiries regard the activity of patients' spondylitis,

rather than attempting to capture a more comprehensive relationship between a patient's illnesses and their well-being. This alternate broader approach, exemplified by the terminology of the Multi-Dimensional Health Assessment Questionnaire (MD-HAQ, “Considering all the ways in which illness and health conditions have affected you...”) (6), may elicit different responses from patients compared to the more narrowly defined ASAS question.

Finally, there is limited information regarding the time required to complete the BASFI and BASDAI, and patients' perception of the difficulty in completing the questionnaires has also not been assessed. These practical questions have implications for the implementation of patient self-assessment instruments in the clinical setting.

In order to assess: 1) the correlation of the generic term “inflammatory arthritis” instead of “AS” in the individual BASDAI/ASDAS questions and the nocturnal pain question; 2) the association of ASDAS, BASDAI and BASFI scores with patients being classified as disabled and 3) the time to complete the individual questionnaires, we performed a cross-sectional pre- and post-visit questionnaire assessment in US veterans in three rheumatology clinics. We hypothesised that: 1) the modified questionnaires would correlate well with the traditional versions of these instruments; 2) BASFI questionnaire scores would be associated with likelihood of being classified as disabled and demonstrate good reproducibility; and 3) the time/difficulty to complete traditional and modified questionnaires would be statistically similar.

## Materials and methods

### Study design

Cross-sectional sub-study by investigators participating in the prospective longitudinal Program to Understand the Longterm Outcomes in SpondyloArthritis (PULSAR) registry. The PULSAR registry is a longitudinal prospective clinical registry and biorepository examining HLA-B27-related disorders in US veterans. Patients completed questionnaires and responses were verified based on medical record review.

### Setting

The study was executed by investigators at the Denver Veterans Affairs Medical Center (VAMC) (Denver, CO), Washington D.C. VAMC, and G. V. (Sonny) Montgomery VAMC (Jackson, MS). These sites are affiliated with the PULSAR study.

### Participants

The recruitment of consecutive patients with HLA-B27 associated conditions (AS according to modified New York Classification Criteria (7), and spondyloarthritides such as enteropathic associated arthritis, psoriatic arthritis (PsA), and reactive arthritis without axial involvement according to the Amor criteria (8)) occurred in an otherwise unselected fashion from the population of subjects attending the rheumatology clinic at each location. A cut-off of 6 points was required to meet the Amor criteria and patients with non-radiographic axial involvement were not excluded. Subjects granted consent and privacy authorisation to allow for the completion of the questionnaires. Subjects at the Denver site were naïve to the use of all questionnaires, while those at the Jackson and Washington D.C. sites had employed

the questionnaires for clinical use for approximately 2 years and 4 years, respectively, at the time of this evaluation. In a single clinic visit, patients underwent consent and then completed the two sets of questionnaires.

### Data sources / instruments

In the modified BASDAI and ASDAS, termed the PULSAR modified Bath Disease Activity Index (PuBaDAI, pronounced “pub-a-day”) and PULSAR-modified Ankylosing Spondylitis Disease Activity Score (PuASDAS), the phrase “AS neck, back or hip pain” from the BASDAI/ASDAS was revised to read “neck, back or hip pain related to your inflammatory arthritis”. A similarly worded modification was made to the nocturnal pain question. In regards of the global assessment, the ASDAS asks “How active was your spondylitis on average during the last week?”; this was substituted in the PuASDAS for a more generally worded global assessment based on the terminology of the MD-HAQ: “Considering all the ways in which your illness and health conditions have affected you during the last week please mark an ‘X’ on the line below to show how you are doing”.

### Procedure

The traditional BASFI (2), patient global assessment (3), BASDAI (1), ASDAS (8, 9) and nocturnal AS pain question (3) were completed at one time either before or after a regular rheumatology clinic appointment. The traditional BASFI, patient global assessment, PULSAR-modified Bath Disease Activity Index (PuBaDAI), PULSAR-modified Ankylosing Spondylitis Disease Activity Score and modified nocturnal pain question were completed at a second time during the same patient encounter (approximately 1.5 hours between recordings). To account for potential bias introduced by the order of questionnaires (*i.e.* more rapid completion of the second set of questionnaires, changes in patient responses recorded before visits *versus* after visits, etc.), we alternated the order of the traditional and modified questionnaires; we randomly assigned whether each patient complete the traditional or modified version prior to their health care provider’s appointment, with the other version completed immediately after their visit.

Using a stopwatch on a smart phone, staff surreptitiously recorded the time required by the study participants to complete the traditional questionnaires

**Table I.** Demographics.

Variable	PULSAR cohort					Nested Study				
	n	Mean or proportion	SD	Min	Max	n	Mean or proportion	SD	Min	Max
Age, years	612	55.46	13.21	24	89	60	54.77	11.76	18	78
Caucasian, %	612	73.0				62	65.0			
African American, %	612	12.4				62	21.0			
Hispanic, %	612	7.0				62	10.0			
Native American, %	612	1.0				62	2.0			
Other race, %	612	6.5				62	3.0			
Male, %	612	98.0				62	94.0			
Hypertension, %						61	62.0			
Diabetes, %						62	19.0			
Cancer, %						62	8.0			
Declared disabled*, %						33	45.0			
CRP mg/L	418	8.8	11.6	0.0	96.0	35	8.8	15.4	0.2	82.4
Instruments										
BASFI	372	5.46	2.35	0.00	9.95	62	5.42	2.47	0.50	9.60
BASDAI						60	5.90	2.29	1.20	10.00
PuBaDAI	399	5.33	1.98	0.20	9.67	62	5.75	2.39	0.60	10.00
ASDAS						35	8.49	3.58	2.07	14.63
PuASDAS						35	8.94	3.37	1.39	13.85

\*Disability status determined by federal institution; For variables denoted with “%”, results are reported as the proportion of the cohort. BASFI: Bath Ankylosing Spondylitis Functional Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; PuBaDAI: PULSAR-modified Bath Disease Activity Index. Data in grey fields were not collected.

**Table II.** Spearman correlation coefficients.

Compared instruments	Question or total score that is compared	Correlation coefficients	p-value	95% CI	
				Lower	Upper
BASDAI vs. PuBaDAI	Nocturnal pain question	0.774	<0.001	0.649	0.859*
BASDAI vs. PuBaDAI	Neck, back, or hip pain question	0.855	<0.001	0.735	0.896*
ASDAS vs. PuASDAS	Overall assessment question, (PG vs. MD-HAQ)	0.766	<0.001	0.608	0.838
ASDAS vs. PuASDAS	Total instrument score, entire cohort	0.845	<0.001	0.760	0.934
ASDAS vs. PuASDAS	Total instrument score, AS patients only	0.763	0.015	0.532	0.944
ASDAS vs. PuASDAS	Total instrument score, non-AS patients only	0.839	<0.001	0.785	0.963
BASDAI vs. PuBaDAI	Total instrument score, entire cohort	0.920	<0.001	0.891	0.960*
BASDAI vs. PuBaDAI	Total instrument score, AS patients only	0.922	<0.001	0.869	0.973*
BASDAI vs. PuBaDAI	Total instrument score, non-AS patients only	0.912	<0.001	0.864	0.965*
BASDAI vs. ASDAS	Total instrument score, entire cohort	0.780	<0.001	0.621	0.889
BASFI test-retest	Total instrument score, entire cohort	0.917	<0.001	0.895	0.961*

BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; PuBaDAI: PULSAR-modified Bath Disease Activity Index; PG: Patient Global assessment from the ASDAS; MD-HAQ: Multi-Dimensional Health Assessment Questionnaire; BASFI: Bath Ankylosing Spondylitis Functional Index; ASDAS: Ankylosing Spondylitis Disease Activity Score; PuASDAS: PULSAR-modified Ankylosing Spondylitis Disease Activity Score; AS: Ankylosing Spondylitis.

**Table III.** Relationship of BASFI, BASDAI, PuBaDAI, ASDAS and PuASDAS with current working status and disability rating.

	Odds ratio	<i>p</i> -value	95% Confidence intervals	
Association with current work status				
BASFI	0.75	0.103	0.52	1.06
BASDAI	0.92	0.600	0.66	1.27
PuBaDAI	0.92	0.597	0.66	1.27
ASDAS	0.96	0.757	0.75	1.21
PuASDAS	0.87	0.285	0.66	1.12
Association with current disability status*				
BASFI	1.67	0.012	1.12	2.48
BASDAI	1.40	0.055	0.99	1.98
PuBaDAI	1.41	0.057	0.99	2.01
ASDAS	1.34	0.034	1.02	1.76
PuASDAS	1.62	0.024	1.07	2.49

\*Disability status determined by federal institution.

and the modified questionnaire versions, in order to assess for differences in questionnaire burden. Subjects rated the difficulty completing each set of questionnaires using a 0–10 Likert scale.

#### Formal determination of functional status

Subjects were classified as disabled if they reported being classified as disabled by one of two agencies:

1. Disability Determination Services (DDS) – federally funded agencies affiliated with the U.S. Social Security Administration responsible for evaluating medical evidence and determining whether or not a claimant is disabled under the law. These determinations apply standardised legal definitions of impairment and are based on patients' medical record data and a consultative examination
2. U.S. Department of Veterans Affairs

(VA) Office of Disability and Medical Assessment. Using a process similar to that of the DDS, certified clinicians employed by the VA perform standardised medical record reviews and exams to determine disability.

#### Statistical methods

First, we examined the correlation between traditionally-worded items and their modified counterparts using Spearman coefficients and scatterplots with trend lines: nocturnal AS pain question vs. nocturnal inflammatory arthritis pain question; Patient Global from ASDAS vs. MD-HAQ global assessment; AS pain question within the BASDAI/ASDAS vs. the neck, back or hip pain question in the PuBaDAI/PuASDAS; overall BASDAI score vs. PuBaDAI score; and overall score comparing ASDAS vs. PuASDAS). Coefficients were determined for the cohort as a whole,

and separately for subjects with AS and subjects without AS. For comparison, correlations were also determined for those questions which did *not* change between questionnaires completed before and after encounters, in order to estimate the baseline degree of variation over 1.5 hours. Similarly, we calculated the correlation of BASFI scores prior to and following the visit with the clinician in order to assess test-retest reproducibility, and correlated BASDAI with ASDAS in our population.

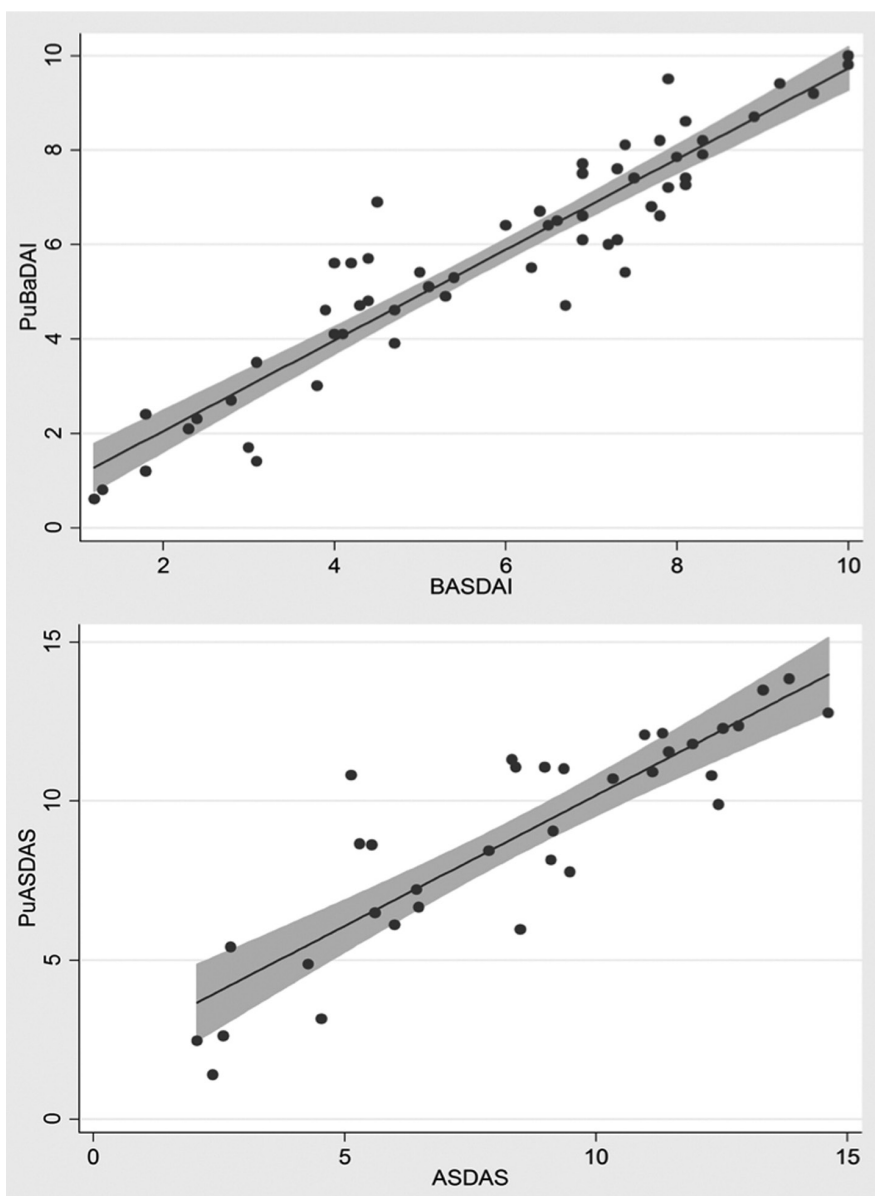
We then employed unconditional multivariate logistic regression to determine whether ASDAS, BASFI, BASDAI and ASDAS scores were associated with patients' likelihood of being classified as "disabled" according to the standards established by U.S. governmental agencies. For the BASDAI and for ASDAS, we used both the traditional and modified (PuBaDAI/PuASDAS) questionnaires.

The mean time required to complete both sets of questionnaires (in minutes) was compared using a Wilcoxon Mann-Whitney two sample test, stratified by site (since patients were naïve to the questionnaire at one site). We also compared the mean self-reported difficulty in completing each set of questionnaires (score 0–10) by way of the Wilcoxon Mann-Whitney statistic.

#### Ethics

Each participating site received Institutional Review Board approval prior to initiation of the study. Patients consented and completed agreements to dis-





**Fig. 1.** Scatterplot of the unmodified versus the PULSAR-modified version of the BASDAI and ASDAS questionnaires. Shaded grey represents 95% Confidence Bands for trend line. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; PuBaDAI: PULSAR-modified Bath Disease Activity Index; ASDAS: Ankylosing Spondylitis Disease Activity Score; PuASDAS: PULSAR-modified Ankylosing Spondylitis Disease Activity Score.

close health information at the time of enrollment. An independent Scientific Ethics Advisory Committee approved this sub-study.

## Results

The PULSAR registry has enrolled 612 patients to date; sixty two subjects were enrolled across all three sites for this nested study. Demographic characteristics for both are described in Table I. The nested study cohort, in general, reflects the characteristics of the

larger PULSAR cohort. In particular, mean BASFI ( $p=0.90$ ) and PuBaDAI ( $p=0.13$ ) did not differ between the larger PULSAR cohort and the nested study. For non-AS SpA, the mean number of points in the Amor criteria were 8.04 (SD 1.62).

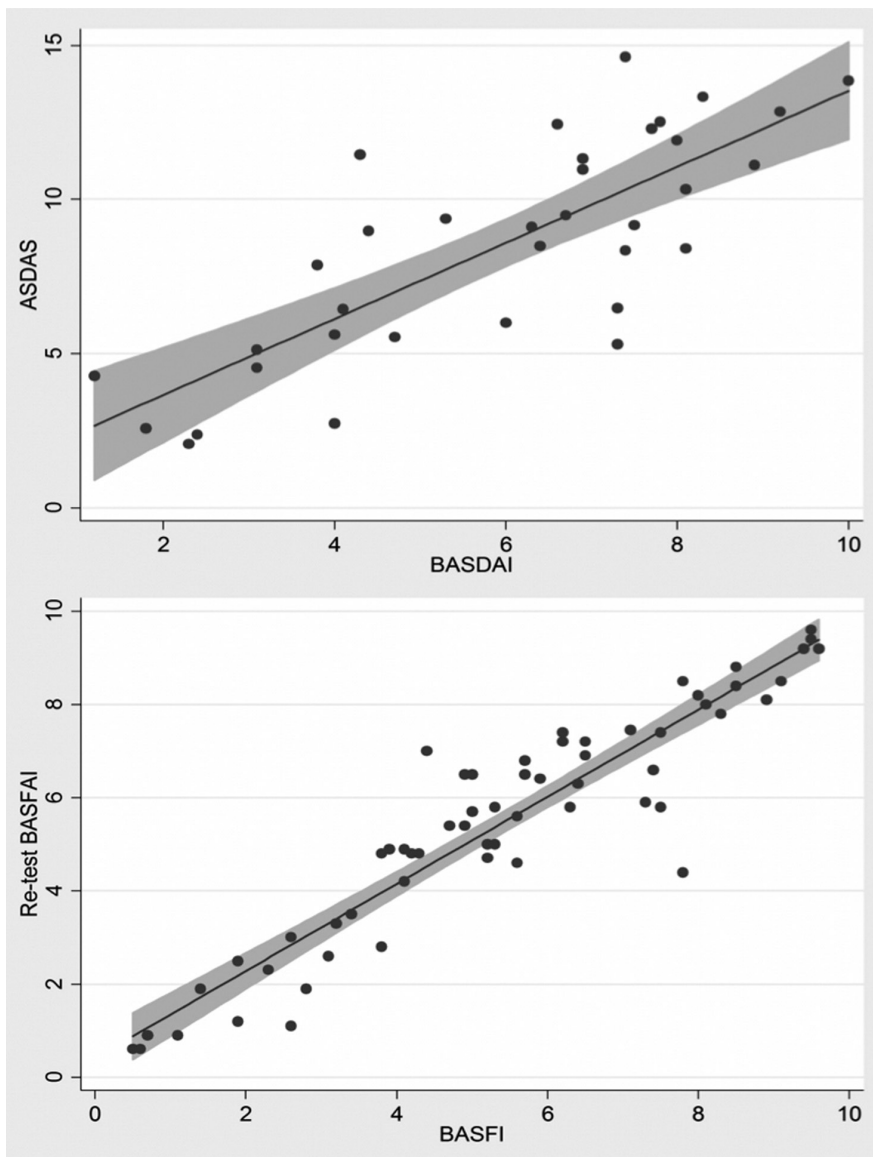
For individual survey questions, correlations of the traditionally-worded and modified questions were calculated (Table II, first three rows) and found to be 0.77, 0.86 and 0.77 – generally regarded as good correlation. By compar-

ison, Spearman coefficients for single BASFI questions that were not changed before and after the visit (*i.e.* test-retest of traditional single BASFI items) ranged from 0.81 to 0.90. Individual BASDAI items performed before and after visits ranged from 0.76 to 0.96, with all correlations found to be significant ( $p<0.001$ , data not shown). Spearman coefficients comparing traditional ASDAS/BASDAI composite scores *versus* their modified counterparts (PuASDAS/PuBaDAI) were excellent (0.85 and 0.92, respectively: Table II); These correlations did not vary when stratifying subjects with AS and subjects without AS (Table II). Scatterplots of the scores appear in Figure 1.

The test-retest correlation for the BASFI was excellent (0.92, Table II) and the correlation of BASDAI and ASDAS was good as well (0.78) (10, 11) Visual representations of these relationships appear in scatter plots (Fig. 2).

After controlling for age, BASFI scores demonstrated a trend towards predicting whether patients were currently working (odds ratio=0.75,  $p=0.10$ ) (Table III). The traditional questionnaire versions of BASDAI and ASDAS, and modified versions (PuBaDAI/ PuASDAS) demonstrated no such relationship. The BASFI, ASDAS and PuASDAS were associated with current disability status: a subject was 1.67 times more likely to have been declared disabled by a federal institution for each additional point in the BASFI, 1.34 times more likely for each point on the ASDAS, and 1.62 times more likely for each point in PuASDAS. BASDAI and PuBaDAI scores both demonstrated similar trends towards association with disability status.

Mean times to complete traditional and modified questionnaires were compared for the overall cohort, as well as those at sites naïve to the questionnaires. In both cases, the mean times to complete questionnaires were not statistically different (3.33 minutes vs. 3.27 minutes,  $p=0.69$  for the overall cohort). The distribution of times required to complete each set of questionnaire appears as Figure 3. In terms of rating the difficulty to complete the questionnaires, subjects scored both the alternate and traditional formats similarly (1.78 vs. 1.95,  $p=0.58$ ).



**Fig. 2.** Scatterplot of the Ankylosing Spondylitis Disease Activity Score and the Bath Ankylosing Spondylitis Disease Activity Index (above); And a scatterplot of Bath Ankylosing Spondylitis Functional Index test retest correlation (below).

Shaded grey represents 95% Confidence Bands for trend line. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; ASDAS: Ankylosing Spondylitis Disease Activity Score; BASFI: Bath Ankylosing Spondylitis Functional Index.

## Discussion

Our study achieves a number of important objectives. First, we demonstrated good correlation of slightly modified BASDAI and ASDAS questions with the traditional BASDAI and ASDAS. The overall questionnaire scores exhibited excellent correlation, and correlations were consistent for both AS and non-AS spondyloarthritis. The similar results (Table II) between AS and non-AS spondyloarthritis provide preliminary support for the use of these questionnaires in non-AS spondyloar-

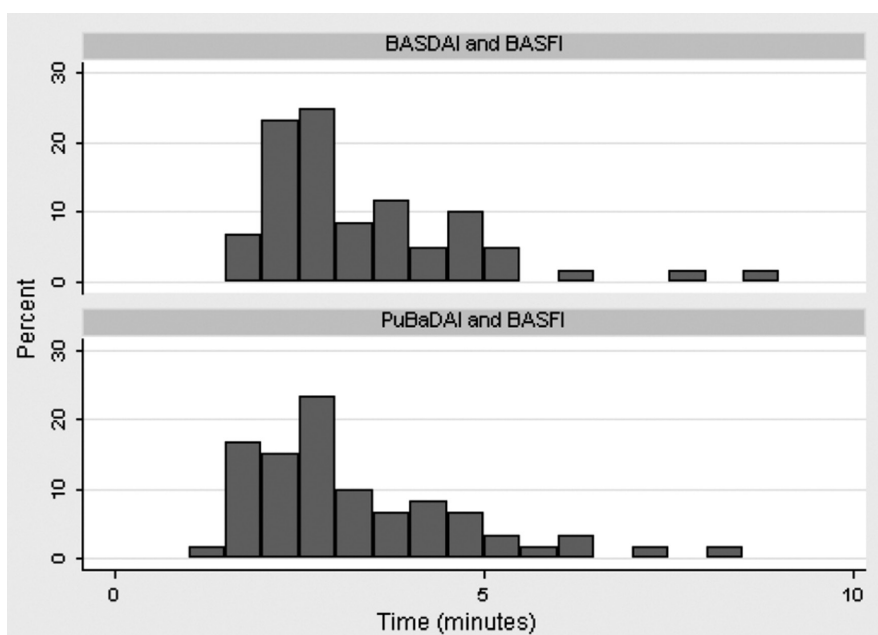
thritis. In addition, the good correlation (Spearman = 0.77) between global assessments based on terminology from ASDAS and MD-HAQ suggest that patients attending a rheumatology clinic do not make substantial distinctions between disease-specific and more generally worded questionnaires.

The use of multiple disease-specific activity and severity measures in the clinical setting complicates patient care, may lead to substantial inefficiencies, and impedes the comparison of cohorts suffering from related, but

different, rheumatic diseases, such as PsA and AS. For spondyloarthritis, clinicians and researchers may choose to use the BASDAI, ASDAS, Composite Psoriatic Disease Activity Index (CPDAI) (12), and Disease Activity index for REactive Arthritis (DAREA) (13), among others. By eliminating the AS-specific verbiage in our questionnaires, we hope to obviate some of the confusion manifest by our clinic patients around terminology. We also hope to adopt use of this questionnaire for patients and research subjects with AS and non-AS spondyloarthritis, in a manner that simplifies care.

Our study examines the test-retest characteristics of the BASFI. While a prior report evaluated the reliability of the BASFI, that cohort differed markedly from our own (Taiwanese, including juvenile onset AS) (14) and employed a non-English version. Despite these differences, results from that report (correlation coefficient 0.92–0.94) were similar to our own. Several studies have compared the BASFI against other questionnaires that measure disability (*i.e.* Leeds Disability Questionnaire and the Dougados Functional Index) (15, 16). However, by establishing a standardised approach to defining disability, we have performed a long-overdue and more rigorous validation of this instrument with a robust outcome. Under these circumstances, the BASFI, ASDAS, and Pu-ASDAS perform comparably well.

A few published reports have attempted to clarify the relationship between disease activity indexes and disability status in spondyloarthritis. These studies have sought correlations between BASDAI and BASFI or Dougados Functional Index (15, 17) and have compared mean BASDAI scores for patients who report current employment *versus* those who report an inability to work due to self-described “ill health” (18). BASDAI scores and current work status were not associated in our study, though a trend was discernible between BASDAI and disability status. Validity for the BASDAI has also been previously assessed by determining the convergence with other disease-specific patient reported measures of health outcome (such as the AS Quality of Life Questionnaire),



**Fig. 3.** Distribution of times required to complete traditional questionnaires and modified questionnaires. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; PuBaDAI: PULSAR-modified Bath Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index.

24-hour reproducibility, inter-observer consistency, and sensitivity to detect improvement during a three-week intensive inpatient course (1).

Finally, the time to complete questionnaires and self-reported difficulty completing questionnaires did not vary between traditional and modified versions of the BASDAI. The short time to complete questionnaires and the low difficulty ratings associated with completion of these instruments reinforce the feasibility their adopting in a clinical setting.

In summary, we have found the traditional and modified versions of spondylitis-oriented questionnaires to be well correlated, valid, and amenable to use in the clinical practice.

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