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Axial spondyloarthritis

Evaluation of instruments assessing peripheral arthritis in spondyloarthritis: an analysis of the ASAS-PerSpA study

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ARTICLE INFO

ABSTRACT

Objectives: To assess construct validity, including known-group discrimination, of the currently available disease activity instruments assessing peripheral arthritis in spondyloarthritis (SpA).
Methods: In this analysis from the Assessment of SpondyloArthritis International Society (ASAS)-PerSpA study, patients with a diagnosis of axial SpA, peripheral SpA, or psoriatic arthritis (PsA) were included. The disease activity instruments evaluated were the Patient Global Assessment (PGA), Bath Ankylosing Spondylitis Disease Activity Index, Axial Spondyloarthritis Disease Activity Score, Disease Activity Index for PsA (DAPSA), Swollen Joint Count (SJC), Tender Joint Count, Disease Activity Score (DAS) 28, DAS44, and C-reactive protein (CRP). Construct validity was assessed through correlations with external constructs (Bath Ankylosing Spondylitis Functional Index, ASAS Health Index, and Euro Quality of Life 5 Dimensions) and known-group discrimination (active/inactive disease based on a combination of PGA [≥5/<5]), and SJC (≥1/0 and ≥2/<2) was analysed using standardised mean differences (SMDs).
Results: In total, 4121 patients were included (mean age 45 [SD, 14] years, 61% males). When assessing the construct validity through correlations with external constructs, all instruments performed excellently (100% hypotheses confirmed). When assessing known-group discrimination, all disease activity measures, except CRP, presented SMDs ≥ 0.8 (good discrimination), with higher SMDs observed for DAS28 followed by DAPSA. Results were similar across disease phenotypes. Considering all combinations of PGA and SJC to discriminate between active/inactive disease, a better performance was observed for the composite scores, including joint counts.

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Conclusions: In our construct validity analysis, all disease activity instruments assessing peripheral arthritis had a good performance as reflected in the correlations with external constructs and the known-group discrimination. The highest discriminatory capacity to distinguish between 'active/inactive disease' was observed for composite scores, including joint counts, like DAS28 and DAPSA.

What is already known on this topic

- The current instrument endorsed in the Assessment of SpondyloArthritis International Society core outcome set for the assessment of peripheral arthritis in trials is the 44 Swollen Joint Count.
- The performance of other instruments or composite scores in evaluating disease activity related to peripheral arthritis has been scarcely studied.

WHAT THIS STUDY ADDS

- In this study, aiming to identify the optimal instrument to assess peripheral arthritis and related disease activity in spondyloarthritis (SpA), all disease activity instruments had a good construct validity reflected in the correlations with external constructs and known-group discrimination.
- Composite scores, such as Disease Activity Score 28 and Disease Activity Index for Psoriatic Arthritis, which incorporate joint counts, showed the highest capacity to discriminate between active and inactive disease.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- Composite scores seem to be more promising tools for assessing disease activity in peripheral arthritis.
- Future analyses should focus on identifying the most suitable composite scores for assessing peripheral arthritis in SpA.

INTRODUCTION

Spondyloarthritis (SpA) is a heterogeneous disease that can present with several phenotypes or clinical forms, such as axial SpA (axSpA) and peripheral SpA (pSpA). Moreover, peripheral rheumatological manifestations (ie, arthritis, dactylitis, and peripheral enthesitis) can occur either concomitantly with the axial disease, before or independently [1,2].

Recently, the Assessment of SpondyloArthritis International Society (ASAS) core outcome set (COS) for axSpA, which describes the minimum set of outcome measures that should be collected in all studies, has been updated, and for the 'peripheral manifestations domain,' only 2 instruments were assessed for peripheral arthritis, namely the Swollen Joint Count (SJC) with 66 and 44 joints (SJC66 and SJC44, respectively) [3]. Although psychometric properties were comparable for both, with inadequate performance of both for clinical trial discrimination, both were endorsed by ASAS members to facilitate future assessment of their performance by promoting standardised data collection. Finally, the SJC44 was chosen as the preferred instrument for inclusion in the COS [3]. Nevertheless, no composite score was assessed for the peripheral manifestations domain. Although scarce, there is some evidence of the good performance of composite scores when assessing disease activity in the pSpA population [4]. In a previous study from our group [4] addressing the sensitivity to change and discriminatory aspects of different measurement instruments, the Axial Spondyloarthritis Disease Activity Score (ASDAS) [5], Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [6], Patient Global Assessment (PGA), and Physician Global Assessment showed the highest sensitivity to change and the highest level of discriminatory capacity, while the performance of SJC, Tender Joint Count (TJC), and C-reactive protein (CRP) was not good enough. In another study assessing the construct validity of measurement instruments in pSpA in clinical practice, Beckers et al [7] found a good performance of the Disease Activity Index for Psoriatic Arthritis (DAPSA) [8], PsA Disease Activity Score [9], and ASDAS, although agreement among the 3 instruments when classifying disease activity states was not sufficient.

Recently, the ASAS-PerSpA study has focused on the peripheral involvement in patients with SpA, answering some of the previous research questions, such as the prevalence of 'isolated' (ie, without axial disease) pSpA, the clinical presentation of peripheral rheumatological SpA features with regard to the presence or absence of skin psoriasis, and the intercountry variability in the clinical presentation of SpA, among others [10]. One of ASAS-PerSpA's main objectives was to evaluate the validity of existing outcome measures of peripheral rheumatological features and to explore the possibility of improving them. Indeed, the optimal instrument to assess disease activity in patients with peripheral arthritis has not yet been identified. While the SJC is the measurement instrument included in the ASAS COS for axSpA, the use of composite scores validated for other forms of SpA (ie, ASDAS, BASDAI, and DAPSA) or even in other rheumatic and musculoskeletal diseases (RMDs) (eg, Disease Activity Score [DAS]) has also been proposed. Still, little is known regarding the actual performance of these outcome measures in the assessment of peripheral arthritis, as well as their performance across SpA phenotypes.

The objectives of this study were to assess the construct validity, including discriminatory capacity between known groups, of the currently available disease activity measurement instruments in patients with SpA with peripheral arthritis and to investigate whether there are differences across SpA phenotypes.

METHODS

Study design and population

Data from the ASAS-PerSpA study were used. Briefly, the ASAS-PerSpA study is an international, multicentre study with 24 participating countries (23 actively involved), in which data of consecutive patients with SpA (axSpA, pSpA, or PsA based on the physician's diagnosis) were cross-sectionally collected between July 2018 and February 2020. Patients without missing data on all the instruments of interest (described below) were included in the analysis.

Written informed consent was obtained from all patients before enrolment, and ethics committees from the individual participating centres approved the study.

Outcomes measures

The following disease activity measures evaluating peripheral articular involvement (ie, arthritis, not enthesitis or dactylitis) were assessed.

The PGA was adapted from the question of 'Global assessment of well-being: *Considering all the ways your spondyloarthritis has affected you during the last 48 hours, tick the box that best describes how you are doing*' on a numeric rating scale (NRS) (range, 0-10) (10 = worse well-being).

The SJC66 and *68-joint TJC* (TJC68) include the respective number of peripheral joints from the upper and lower limbs, as well as the temporomandibular, sternoclavicular, and acromioclavicular joints.

The BASDAI [6] includes patient-reported levels of fatigue, back pain, peripheral joint pain/swelling, localised tenderness, and severity and duration of morning stiffness. Each question uses an NRS (range, 0-10) (10 = very severe), and the scores are averaged (questions 5 and 6 first and then the remaining 4), giving a final score from 0 to 10 (10 = maximal disease activity).

The ASDAS [5,11] includes patient-reported overall back pain, peripheral pain/swelling, duration of morning stiffness, global assessment of disease activity ranging from 0 to 10 on NRS, and the CRP as a measure of inflammation. All these elements are combined in a weighted equation with higher values indicating higher disease activity.

The DAPSA [7] is calculated by simply summing up the PGA, pain assessment (0-10), SJC66, TJC68, and CRP (mg/dL). As the overall pain assessment was not collected in PerSpA, the third BASDAI question on peripheral pain/swelling was used instead.

The *28-joint and 44-joint DAS* [12,13] are composite scores measuring disease activity in rheumatoid arthritis that combine information on swollen joints, tender joints, acute phase reactants, and PGA. Both scores are calculated using a weighted equation with higher values indicating higher disease activity.

The acute phase reactant CRP (mg/dL) was also assessed as a potential separate outcome measurement instrument for disease activity.

External constructs

The following outcomes were used as external constructs in the construct validity analysis of each instrument: the Bath Ankylosing Spondylitis Functional Index (BASFI) [14], which assesses functional ability (range, 0-10) (10 = worse functional capacity); the rating scale of the Euro Quality of Life 5 Dimensions (EuroQoL) [15] used to measure health-related quality of life (range, 0-100) (0 = worst imaginable health); and the ASAS Health Index (ASAS-HI) [16], assessing the overall functioning and health (range, 0-17) (17 = worse health status).

Statistical analysis

Descriptive statistics were used for the overall population and each of the individual populations of patients with axSpA, pSpA, and PsA.

Following the Outcome Measures in Rheumatology (OMERACT) filter for instrument selection [17], construct validity (as part of the 'Truth pillar') was assessed through 2 different approaches:

Construct validity analysis through correlations of strength

As the first step, hypotheses for the strength of the correlation between the assessed instruments and external constructs were established. Previously, such hypotheses were established by the steering committee for the ASAS COS exercise [3] (when these were available, they were used). However, some of them were missing, namely for the peripheral composite scores and, therefore, a group of 12 rheumatologists, experts in SpA, was consulted to decide on the hypothetical strength of the correlation. Then, we proceeded with the analysis through Spearman correlation, evaluating whether the hypothesis for the strength of each correlation (between the assessed instruments and the external constructs) was accepted/rejected. Construct validity was considered 'good' if ≥75% of the hypotheses were confirmed, 'adequate' if 50% to 75% of the hypotheses were confirmed, or poor if <50% of the hypotheses were confirmed, as per the OMERACT and ASAS COS procedures [3,17]. The correlation cutoffs were weak if <0.30, moderate if 0.30 to 0.69, and strong if ≥0.70 [17,18].

Construct validity through discrimination between known groups

Finally, we measured the discriminatory capacity of these instruments between 2 states of peripheral disease activity. No gold standard is available to define disease activity states concerning peripheral articular involvement; thus, we used 2 disease activity instruments: PGA (as a patient subjective outcome that includes the perception of both axial and peripheral involvement) and SJC (as an objective and exclusive peripheral outcome) to stratify the population. The stratification of PGA was based on the middle of the scale, so it had a value of 5. Due to the high frequency of patients without arthritis, the stratification of SJC was performed in 2 ways: (1) no swollen joints vs any (≥1) swollen joint and (2) SJC below the median SJC vs equal or above the median SJC. Combining both stratifications of PGA and SJC, patients were considered to be in 'low disease activity' in case they had a PGA < 5 and no swollen joints vs in 'high disease activity' in case they had a PGA ≥ 5 and at least 1 swollen joint. Subsequently, comparisons were made across all possible subgroups combining the stratifications based on PGA and SJC: (1) PGA < 5 and SJC < median vs PGA < 5 and SJC ≥ median; (2) PGA < 5 and SJC = 0 vs PGA < 5 and SJC ≥ 1; (3) PGA ≥ 5 and SJC < median vs PGA ≥ 5 and SJC ≥ median; (4) PGA > 5 and SJC = 0 vs PGA > 5 and SJC ≥ 1. Finally, an additional stratification was performed based solely on SJC to minimise the potential influence of axial manifestations on the PGA. Then, the standardised mean difference (SMD) was calculated as the difference between the group means divided by the pooled SD. The SMD has no units, which facilitates comparison across disease measures. An SMD with a higher absolute value indicates better discriminatory ability, and an SMD above 0.8 is considered 'good' [17,19,20].

Sensitivity analysis

Additionally, the same analyses (*correlations of strength* and *discrimination between known groups)* were conducted as sensitivity analyses individually in the different subpopulations (axSpA, pSpA, and PsA) and also in the population of non-PsA SpA, including axSpA and pSpA (so excluding PsA). This last analysis was conducted to ensure that including PsA in the analysis did not drive the results, as PsA is often polyarticular, and the stratifications used in our analyses were often based on SJC.

All the analyses were performed using Stata SE V.17 (StataCorp LLC).

RESULTS

From the 4185 patients included in the ASAS-PerSpA study, 4121 had complete data on all the disease activity measures assessed and were thus included in the analysis. According to the rheumatologist, 2679 (65%) patients had a diagnosis of axSpA, 428 (10%) of pSpA, and 1014 (25%) of PsA. From the entire population, 2291 (56%) patients had a history of peripheral arthritis, mainly with oligo- or polyarticular involvement (43% and 45%, respectively). Across the disease phenotypes, the percentage of patients with a history of peripheral articular involvement was lower in axSpA (36% vs 95% in pSpA and 91% in PsA) with a predominant oligoarticular involvement, while in pSpA and PsA, there was a similar distribution between oligo and polyarticular involvement. The population characteristics and mean values for each disease activity instrument assessed can be found in Table 1.

Construct validity analysis through correlations of strength

When looking at the construct validity through correlations with external constructs (BASFI, ASAS-HI, and EuroQoL), all the assessed disease activity instruments had a good performance, with 100% of the hypotheses confirmed. When stratifying by disease phenotype, all the instruments remained with good performance, except for BASDAI and SJC in pSpA and BASDAI and ASDAS in PsA, where they had only adequate performance (67% of the hypotheses confirmed). Nevertheless, the reason for the 'rejection' of the hypotheses was due to a better correlation than hypothesised (Table 2).

Discrimination between known groups

In the entire population, all disease activity measures, except for CRP (SMD, 0.51), were highly discriminatory as they presented SMDs above 0.8, with the highest SMD being observed for DAS28 (SMD, 3.11), followed by DAPSA (SMD, 2.62), DAS44 (SMD, 2.51), BASDAI (SMD, 2.40), and ASDAS (SMD, 2.40) (Fig).

In the pSpA and PsA subgroups, DAS28 also had the highest SMD, followed by ASDAS and BASDAI, while the highest SMD in the axSpA population was also DAS28, but followed by DAPSA and DAS44 (Table 3).

When stratifying by both PGA and SJC and considering all the possible strata and not only the most extreme ones, a better performance was observed for composite scores that include joint counts, ie, DAS28, DAS44, and DAPSA. With a higher SJC

Table 1
Patient characteristics in the total population and according to spondyloarthritis phenotype

Patients characteristics	Total PerSpA n = 4121, mean (SD) or n (%)	axSpA n = 2679, mean (SD) or n (%)	pSpA n = 428, mean (SD) or n (%)	PsA n = 1014, mean (SD) or n (%)
Age (y)	45 (14.0)	42 (13.0)	44.1 (14.3)	51.8 (12.9)
Male sex	2521 (61)	1829 (68)	203 (47)	489 (48)
Symptom duration (y)	20.9 (18.3)	20.1 (16.6)	14.2 (14.6)	26.0 (22.3)
Disease duration (y)	14.5 (11.4)	14.3 (11.0)	10.0 (9.4)	16.8 (12.3)
Diagnosis delay (y)	6.4 (8.7)	5.8 (7.6)	4.2 (6.6)	9.2 (11.2)
BMI (kg/m^2)	26.4 (5.4)	25.9 (5.1)	26.4 (5.4)	28.0 (5.9)
Axial involvement[a]	3215 (78)	2614 (98)	238 (56)	363 (36)
Peripheral arthritis[a]	2291 (56)	965 (36)	405 (95)	921 (91)
Dactylitis[a]	632 (15)	161 (6)	98 (23)	373 (37)
Enthesitis[a]	1812 (44)	1099 (41)	246 (57)	467 (46)
History of				
Monoarticular[b] involvement	275 (12)	192 (20)	44 (11)	39 (4)
Oligoarticular[b] involvement	979 (43)	472 (49)	180 (44)	327 (36)
Polyarticular[b] involvement	1037 (45)	301 (31)	181 (45)	555 (40)
CRP (mg/L)	11.9 (27.1)	11.7 (26.6)	14.1 (25.5)	11.5 (28.8)
BASFI (0-10)	3.0 (2.7)	3.0 (2.6)	2.80 (2.6)	3.1 (2.7)
ASAS-HI (0-17)	6.6 (4.6)	6.3 (4.5)	6.63 (4.4)	7.3 (4.7)
EuroQoL (0-100)	65 (20)	67 (20)	63 (20)	63 (25)
PGA (0-10)	4.4 (2.7)	4.3 (2.7)	4.6 (2.7)	4.6 (2.7)
BASDAI (0-10)	3.9 (2.4)	3.7 (2.4)	4.0 (2.4)	4.3 (2.5)
ASDAS	2.5 (1.1)	2.5 (1.1)	2.6 (1.2)	2.6 (1.1)
DAPSA	12.3 (11.6)	10.2 (9.5)	14.6 (11.8)	16.8 (14.7)
SJC (0-66)	0.8 (3.1)	0.3 (2.0)	1.2 (2.9)	1.9 (4.8)
TJC (0-68)	2.5 (6.1)	1.5 (4.4)	3.4 (6.2)	4.8 (8.7)
DAS28	2.6 (1.1)	2.4 (0.9)	2.9 (1.2)	3.0 (1.2)
DAS44	1.2 (0.8)	1.1 (0.6)	1.5 (0.8)	1.6 (1.0)
NSAIDs (last month)	2817 (68)	1903 (71)	307 (72)	607 (60)
Current steroids	486 (12)	199 (7)	88 (21)	199 (20)
cDMARDs (since diagnosis)	1452 (35)	616 (23)	229 (54)	607 (60)
b/tsDMARDs (since diagnosis)	1945 (47)	1275 (48)	156 (36)	514 (51)

ASAS, Assessment of SpondyloArthritis International Society; ASAS-HI, ASAS Health Index; ASDAS, Axial Spondyloarthritis Disease Activity Score; axSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; BASFI, Bath Ankylosing Spondylitis Functional Index; BMI, body mass index; c/b/tsDMARDs, conventional/biologic/targeted synthetic disease-modifying antirheumatic drug; CRP, C-reactive protein; DAPSA, Disease Activity in Psoriatic Arthritis; DAS, Disease Activity Score; EuroQoL, Euro Quality of Life 5 Dimensions; NSAID, nonsteroidal anti-inflammatory drug; PGA, Patient Global Assessment; PsA, psoriatic arthritis; pSpA, peripheral spondyloarthritis; SJC, Swollen Joint Count; TJC, Tender Joint Count.
Disease phenotype was defined by the physician. Data were incomplete for BMI (n = 15), ASAS-HI (n = 2), and EuroQoL (n = 14).
[a] Manifestation ever-present.
[b] History of type of involvement: monoarticular, 1 swollen joint; oligoarticular, 2 to 4 swollen joints; polyarticular, 5 or more swollen joints.

Table 2
Correlation between disease activity measures and external comparators

External comparators		Spearman correlations (Weak – Moderate – Strong)§								
Entire ASAS-perSpA population (n=4121)										
		PGA	BASDAI	ASDAS	DAPSA	SJC	TJC	DAS28	DAS44	CRP
BASFI (0-10)	**Hypothesis±**	**Moderate**	**Strong**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.653	0.733	0.697	0.637	0.199	0.367	0.566	0.412	0.273
ASAS-HI	**Hypothesis±**	**Moderate**	**Moderate**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.601	0.682	0.619	0.600	0.208	0.364	0.527	0.399	0.208
EuroQoL	**Hypothesis±**	**Moderate**	**Moderate**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	-0.632	-0.680	-0.652	-0.622	-0.250	-0.377	-0.561	-0.419	-0.261
Construct validity*		100%	100%	100%	100%	100%	100%	100%	100%	100%
axSpA (n=2679)										
BASFI (0-10)	**Hypothesis±**	**Moderate**	**Strong**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.665	0.727	0.691	0.678	0.215	0.372	0.594	0.421	0.284
ASAS-HI	**Hypothesis±**	**Moderate**	**Moderate**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.602	0.663	0.612	0.608	0.192	0.328	0.531	0.377	0.221
EuroQoL	**Hypothesis±**	**Moderate**	**Moderate**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	-0.633	-0.672	-0.649	-0.632	-0.225	-0.342	-0.569	-0.402	-0.264
Construct validity*		100%	100%	100%	100%	100%	100%	100%	100%	100%
pSpA (n=428)										
BASFI (0-10)	**Hypothesis±**	**Moderate**	**Strong**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.614	0.716	0.651	0.600	0.229	0.381	0.492	0.380	0.242
ASAS-HI	**Hypothesis±**	**Moderate**	Moderate	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.610	0.711	0.609	0.591	0.251	0.375	0.469	0.373	0.171
EuroQoL	**Hypothesis±**	**Moderate**	**Moderate**	**Moderate**	**Moderate**	Weak	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	-0.631	-0.676	-0.654	-0.637	-0.345	-0.428	-0.559	-0.444	-0.296
Construct validity*		100%	67%	100%	100%	67%	100%	100%	100%	100%
PsA (n=1014)										
BASFI (0-10)	**Hypothesis±**	**Moderate**	**Strong**	Moderate	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.669	0.767	0.734	0.622	0.216	0.412	0.568	0.456	0.265
ASAS-HI	**Hypothesis±**	**Moderate**	Moderate	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	0.592	0.714	0.641	0.588	0.200	0.422	0.526	0.447	0.203
EuroQoL	**Hypothesis±**	**Moderate**	**Moderate**	**Moderate**	**Moderate**	**Weak**	**Moderate**	**Moderate**	**Moderate**	**Weak**
	Correlation coefficient	-0.627	-0.697	-0.658	-0.604	-0.246	-0.430	-0.551	-0.452	-0.244
Construct validity*		100%	67%	67%	100%	100%	100%	100%	100%	100%

ASAS, Assessment of SpondyloArthritis International Society; ASAS-HI, ASAS Health Index; ASDAS, Axial Spondyloarthritis Disease Activity Score; axSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; BASFI, Bath Ankylosing Spondylitis Functional Index; CRP, C-reactive protein; DAPSA, Disease Activity in Psoriatic Arthritis; DAS, Disease Activity Score; EuroQoL, Euro Quality of Life 5 Dimensions; PGA, Patient Global Assessment; PsA, psoriatic arthritis; pSpA, peripheral spondyloarthritis; SJC, Swollen Joint Count; TCJ, Tender Joint Count.
Hypotheses are in bold when they were met.
[a]Weak < 0.30; moderate, 0.30 to 0.69; strong ≥ 0.70.
[b]Hypothesis for the strength of correlation.
[c]Construct validity: ≥75% of the hypotheses confirmed: good (green); 50%-75% of the hypotheses confirmed: adequate (orange); <50% of the hypotheses confirmed: poor (red).

cutoff (median SJC vs presence of arthritis [≥1]), the performance of the composite scores, including joint counts, was better. ASDAS showed worse performance than the composite scores with joint counts across all groups (Tables 4 and 5). Lastly, the results from the analysis stratified solely by SJC were consistent with the main findings (Supplementary Table S1).

Sensitivity analysis

In the sensitivity analysis, after excluding PsA patients, similarly to the main analysis, all disease activity measures met 100% of the hypotheses (good performance) (Supplementary Table S2). Similar to the main analysis, all the measures except for CRP presented SMDs above 0.8, but in this case, ASDAS discriminated slightly better than BASDAI between active/inactive disease (Supplementary Table S3). When stratifying by the different combinations of PGA and SJC, better performance of composite scores with joint counts was also observed, except for PGA < 5 dichotomising by the SJC median, where BASDAI and ASDAS performed well, though still worse than the composite scores with joint counts. With a higher SJC cutoff, the performance of the composite scores, including joint count, was better or worse than that of a lower cutoff of SJC (Supplementary Table S4).

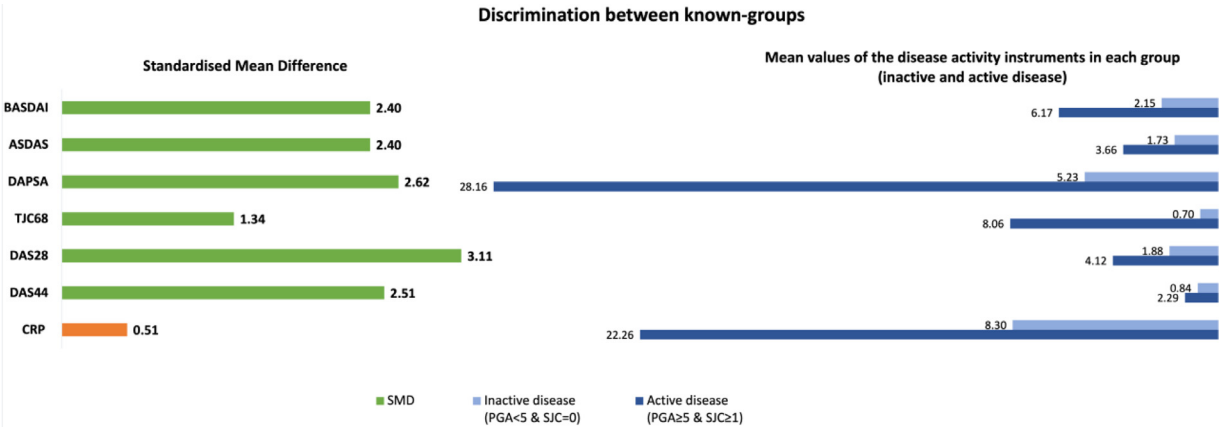

Figure. Discriminatory capacity of the disease activity measurement instruments. Analyses are stratified by extreme groups of inactive and active disease according to the Patient Global Assessment (PGA) and Swollen Joint Count (SJC) in the entire ASAS-PerSpA population, ie, inactive disease (PGA < 5 and SJC $= 0$) vs active disease (PGA ≥ 5 and SJC $= 1$). Bars are coloured in green when the standardised mean difference (SMD) ≥ 0.8 and in orange when SMD ≥ 0.5 but <0.8. ASAS, Assessment of SpondyloArthritis International Society; ASDAS, Axial Spondyloarthritis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; DAPSA, Disease Activity in Psoriatic Arthritis; DAS, Disease Activity Score; TCJ, Tender Joint Count.

DISCUSSION

To our knowledge, the present study is the first to analyse and compare the construct validity between different instruments, particularly the discrimination between known groups, when assessing the impact of peripheral arthritis on disease activity in SpA patients and across the whole spectrum of SpA. In this comprehensive analysis of the ASAS-PerSpA study, all assessed disease activity instruments showed good construct validity reflected in the strength of the correlations with external constructs. Furthermore, when discriminating between known groups, all of them had good performance, and the highest discriminatory capacity to discriminate between 'active and inactive disease' was observed for the composite scores with joint counts, like DAS28 and DAPSA, with consistent results across all disease phenotypes.

Recently, the core set for axSpA was updated, and the SJC44 was selected for the peripheral domain assessment. However, no composite score was assessed. Currently, in almost all RMDs, the use of composite DAS is recommended over separate instruments in both clinical trials and clinical practice. Unlike individual outcomes, composite scores can capture the multiple facets of disease, resulting in more reliability and responsiveness to change instruments [21–23].

The correlation of strength with external constructs is the most commonly used construct validity analysis. With this first approach, when assessing the entire population, all the instruments met 100% of the hypotheses, and that was also true for the axSpA subgroup, which represented more than 60% of the entire population. In pSpA, however, BASDAI and SJC only achieved 'adequate' performance, while in PsA, the 2 specific axSpA scores, BASDAI and ASDAS, had lower performance ('adequate'). As the reason for the 'rejection' of the hypotheses was, in all the cases, a higher correlation than hypothesised, it could be argued that a better correlation than expected should also meet the hypothesis. However, for the time being, there is no agreement on how to handle these cases of better correlations than the ones hypothesised.

By performing discrimination between known-group analyses, we could additionally assess and compare the performance of each instrument when discriminating between 'active and

Table 3
Discriminatory capacity of the disease activity measurement instruments. Analyses are stratified by extreme groups according to PGA and SJC in the entire ASAS-PerSpA population, and the different phenotypes

	Entire population (axSpA, pSpA and PsA)			axSpA			pSpA			PsA		
Assessment measure	PGA<5 & SJC=0 (n=1823)	PGA≥5 & SJC ≥1 (n=577)	SMD	PGA<5 & SJC=0 (n=1335)	PGA≥5 & SJC ≥1 (n=197)	SMD	PGA<5 & SJC=0 (n=144)	PGA≥5 & SJC ≥1 (n=120)	SMD	PGA<5 & SJC=0 (n=344)	PGA≥5 & SJC ≥1 (n=260)	SMD
BASDAI (0-10)	2.15 (1.57)	6.17 (1.95)	2.40	2.12 (1.51)	6.44 (1.96)	2.73	2.05 (1.8)	5.65 (1.88)	1.96	2.32 (1.68)	6.21 (1.94)	2.17
ASDAS	1.73 (0.75)	3.66 (0.96)	2.40	1.74 (0.74)	3.95 (1.01)	2.83	1.65 (0.74)	3.51 (0.95)	2.20	1.72 (0.77)	3.52 (0.89)	2.18
DAPSA	5.23 (4.85)	28.16 (15.67)	2.62	4.83 (4.34)	26.33 (14.11)	3.32	6.02 (5.69)	25.52 (13.5)	1.94	6.44 (5.97)	30.76 (17.30)	1.99
TJC (0-68)	0.70 (2.34)	8.06 (10.40)	1.34	0.48 (1.68)	6.32 (8.48)	1.71	1.35 (3.4)	6.66 (8.68)	0.83	1.26 (3.53)	10.01 (12.01)	1.05
DAS28	1.88 (0.57)	4.12 (1.07)	3.11	1.86 (0.54)	4.03 (0.98)	3.54	1.92 (0.63)	4 (1.06)	2.43	1.94 (0.64)	4.24 (1.12)	2.61
DAS44	0.84 (0.40)	2.29 (0.93)	2.51	0.81 (0.35)	2.17 (0.86)	3.03	0.96 (0.52)	2.2 (0.89)	1.75	0.92 (0.50)	2.42 (0.99)	1.98
CRP (mg/L)	8.30 (22.59)	22.26 (38.67)	0.51	8.09 (20.54)	28.38 (45.17)	0.81	7.46 (16.98)	24.97 (36.94)	0.63	9.48 (30.81)	16.38 (32.99)	0.22

ASDAS, Axial Spondyloarthritis Disease Activity Score; axSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; DAPSA, Disease Activity in Psoriatic Arthritis; DAS, Disease Activity Score; PGA, Patient Global Assessment; PsA, psoriatic arthritis; pSpA, peripheral spondyloarthritis; SJC, Swollen Joint Count; SMD, standardised mean difference; TCJ, Tender Joint Count.
Values are shown as mean (SD).
Cells are coloured according to the following system: SMD ≥ 0.8 (green); ≥0.5 (orange); <0.5 (red).

Table 4

Discriminatory capacity of the disease activity measurement instruments. Analyses are stratified by both PGA and SJC[a] in the entire ASAS-PerSpA population (n = 4121)

	Patient global assessment <5 (n=2100)						Patient global assessment ≥5 (n=2021)					
Assessment measure	SJC<2 (n=1947)	SJC≥2 (n=153)	SMD	SJC=0 (n=1823)	SJC≥1 (n=277)	SMD	SJC<2 (n=1624)	SJC≥2 (n=397)	SMD	SJC=0 (n=1444)	SJC≥1 (n=577)	SMD
BASDAI (0-10)	2.2 (1.6)	3.18 (1.87)	0.60	2.15 (1.57)	3.03 (1.86)	0.54	5.37 (1.96)	6.21 (1.91)	0.43	5.28 (1.93)	6.17 (1.95)	0.46
ASDAS	1.75 (0.76)	2.29 (0.89)	0.70	1.73 (0.75)	2.16 (0.89)	0.56	3.22 (0.86)	3.71 (0.99)	0.55	3.18 (0.84)	3.67 (0.96)	0.55
DAPSA	5.5 (4.98)	19.51 (15.93)	2.18	5.23 (4.85)	15.02 (13.3)	1.48	14.99 (7.84)	31.45 (16.96)	1.60	14.25 (7.39)	28.16 (15.67)	1.33
TJC (0-68)	0.78 (2.4)	6.74 (10.46)	1.64	0.7 (2.34)	4.62 (8.34)	1.05	2.53 (5.42)	9.54 (11.26)	1.01	2.25 (5.09)	8.06 (10.4)	0.83
DAS28	1.92 (0.59)	3.34 (0.97)	2.26	1.88 (0.57)	2.97 (0.94)	1.73	2.95 (0.79)	4.32 (1.13)	1.58	2.86 (0.75)	4.12 (1.07)	1.48
DAS44	0.88 (0.43)	2.02 (0.88)	2.41	0.84 (0.4)	1.72 (0.8)	1.86	1.25 (0.67)	2.5 (0.97)	1.70	1.18 (0.64)	2.29 (0.93)	1.50
CRP (mg/L)	8.4 (22.25)	14.48 (20.28)	0.28	8.3 (22.59)	12.43 (18.72)	0.19	12.83 (26.69)	24.53 (43.5)	0.38	12.28 (26.94)	22.26 (38.67)	0.32

ASDAS, Axial Spondyloarthritis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; DAPSA, Disease Activity in Psoriatic Arthritis; DAS, Disease Activity Score; PGA, Patient Global Assessment; SJC, Swollen Joint Count; SMD, standardised mean difference.
Values are shown as mean (SD).
Cells are coloured according to the following system: SMD ≥ 0.8 (green); ≥0.5 (orange); <0.5 (red).
[a] The population was stratified by PGA and SJC in different ways, showing all the groups of such stratification, allowing us to evaluate the performance of the indices in the complete population and according to the different levels of disease activity (including 2 different cutoffs of SJC).

Table 5

Discriminatory capacity of the disease activity measurement instruments. Analyses are stratified by both PGA and SJC[a] for each disease phenotype

axSpA population (n=2679)												
	Patient global assessment <5 (n=1414)						Patient global assessment ≥5 (n=1265)					
Assessment measure	SJC<2 (n=1377)	SJC≥2 (n=37)	SMD	SJC=0 (n=1335)	SJC≥1 (n=79)	SMD	SJC<2 (n=1139)	SJC≥2 (n=126)	SMD	SJC=0 (n=1068)	SJC≥1 (n=197)	SMD
BASDAI (0-10)	2.14 (1.54)	3.65 (2.41)	0.96	2.12 (1.51)	3.17 (2.29)	0.67	5.25 (1.93)	6.54 (1.9)	0.67	5.19 (1.9)	6.44 (1.96)	0.65
ASDAS	1.75 (0.75)	2.57 (1)	1.08	1.74 (0.74)	2.33 (0.97)	0.78	3.25 (0.86)	4.04 (1.05)	0.91	3.21 (0.84)	3.95 (1.01)	0.86
DAPSA	4.99 (4.47)	21.96 (24.1)	2.90	4.83 (4.34)	15.56 (17.92)	1.80	13.83 (6.94)	30.03 (15.68)	1.97	13.44 (6.75)	26.33 (14.11)	1.55
TJC (0-68)	0.53 (1.75)	8.49 (15.43)	2.64	0.48 (1.68)	5.11 (11.16)	1.50	1.83 (4.27)	7.91 (9.33)	1.22	1.72 (4.13)	6.32 (8.48)	0.91
DAS28	1.88 (0.55)	3.54 (0.99)	2.92	1.86 (0.54)	2.97 (0.99)	1.95	2.86 (0.75)	4.23 (1.09)	1.72	2.81 (0.72)	4.03 (0.98)	1.58
DAS44	0.83 (0.37)	2.26 (1.06)	3.55	0.81 (0.35)	1.82 (0.91)	2.52	1.14 (0.6)	2.42 (0.91)	2.00	1.1 (0.59)	2.17 (0.86)	1.68
CRP (mg/L)	8.23 (20.49)	17.97 (23.96)	0.47	8.09 (20.54)	15.19 (21.24)	0.34	13.31 (27.52)	33.96 (53.5)	0.66	12.96 (27.87)	28.38 (45.17)	0.49
pSpA population (n=428)												
	Patient global assessment <5 (n=201)						Patient global assessment ≥5 (n=227)					
Assessment measure	SJC<2 (n=179)	SJC≥2 (n=22)	SMD	SJC=0 (n=144)	SJC≥1 (n=57)	SMD	SJC<2 (n=150)	SJC≥2 (n=77)	SMD	SJC=0 (n=107)	SJC≥1 (n=120)	SMD
BASDAI (0-10)	2.29 (1.88)	3.26 (1.68)	0.52	2.05 (1.8)	3.27 (1.79)	0.68	5.37 (1.91)	5.58 (1.88)	0.11	5.21 (1.9)	5.65 (1.88)	0.23
ASDAS	1.76 (0.83)	2.48 (0.95)	0.86	1.65 (0.74)	2.31 (0.99)	0.80	3.19 (0.83)	3.51 (1.05)	0.36	3.06 (0.83)	3.51 (0.95)	0.50
DAPSA	7 (6.07)	14.8 (6.56)	1.27	6.02 (5.69)	12.49 (6.43)	1.10	16.49 (7.55)	28.36 (15.38)	1.09	14.89 (7.24)	25.52 (13.5)	0.97
TJC (0-68)	1.55 (3.46)	3.73 (3.01)	0.64	1.35 (3.4)	2.89 (3.43)	0.45	3.11 (5.54)	8.1 (9.72)	0.69	2.72 (5.47)	6.66 (8.68)	0.54
DAS28	2.07 (0.72)	3.32 (0.88)	1.69	1.92 (0.63)	2.93 (0.85)	1.44	3.08 (0.8)	4.19 (1.17)	1.18	2.85 (0.72)	4 (1.06)	1.26
DAS44	1.04 (0.55)	1.93 (0.63)	1.59	0.96 (0.52)	1.6 (0.61)	1.18	1.44 (0.7)	2.42 (0.96)	1.22	1.3 (0.7)	2.2 (0.89)	1.12
CRP (mg/L)	8.54 (17.87)	19.41 (22.9)	0.59	7.46 (16.98)	15.46 (21.69)	0.43	13.92 (22.1)	25.77 (39.76)	0.40	10.06 (15.39)	24.97 (36.94)	0.52
PsA population (n=1014)												
	Patient global assessment <5 (n=485)						Patient global assessment ≥5 (n=529)					
Assessment measure	SJC<2 (n=391)	SJC≥2 (n=94)	SMD	SJC=0 (n=344)	SJC≥1 (n=141)	SMD	SJC<2 (n=335)	SJC≥2 (n=194)	SMD	SJC=0 (n=269)	SJC≥1 (n=260)	SMD
BASDAI (0-10)	2.36 (1.66)	2.97 (1.64)	0.37	2.32 (1.68)	2.86 (1.6)	0.32	5.75 (2.05)	6.24 (1.88)	0.25	5.66 (2.03)	6.21 (1.94)	0.28
ASDAS	1.73 (0.76)	2.13 (0.81)	0.53	1.72 (0.77)	2.01 (0.78)	0.37	3.17 (0.88)	3.58 (0.87)	0.47	3.12 (0.86)	3.52 (0.89)	0.46
DAPSA	6.62 (5.78)	19.65 (13.13)	1.68	6.45 (5.97)	15.75 (12.25)	1.12	18.27 (9.64)	33.6 (18.12)	1.14	17.25 (8.97)	30.76 (17.3)	0.98
TJC (0-68)	1.31 (3.4)	6.76 (9.01)	1.09	1.26 (3.54)	5.05 (7.84)	0.73	4.62 (7.8)	11.16 (12.71)	0.66	4.13 (7.44)	10.01 (12.01)	0.59
DAS28	2 (0.65)	3.27 (0.98)	1.74	1.94 (0.64)	2.98 (0.95)	1.39	3.17 (0.88)	4.44 (1.14)	1.29	3.05 (0.85)	4.24 (1.12)	1.20
DAS44	0.96 (0.51)	1.94 (0.85)	1.67	0.92 (0.5)	1.72 (0.8)	1.31	1.53 (0.77)	2.6 (1.01)	1.23	1.44 (0.75)	2.42 (0.99)	1.11
CRP (mg/L)	8.95 (29.03)	11.96 (17.73)	0.11	9.48 (30.81)	9.65 (15.36)	0.01	10.72 (25.66)	17.92 (36.1)	0.24	10.44 (26.71)	16.38 (32.99)	0.20

ASDAS, Axial Spondyloarthritis Disease Activity Score; axSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; DAPSA, Disease Activity in Psoriatic Arthritis; DAS, Disease Activity Score; PGA, Patient Global Assessment; PsA, psoriatic arthritis; pSpA, peripheral spondyloarthritis; SJC, Swollen Joint Count; SMD, standardised mean difference; TCJ, Tender Joint Count.
Values are shown as mean (SD).
Cells are coloured according to the following system: SMD ≥ 0.8 (green); ≥0.5 (orange); <0.5 (red).
[a] The population was stratified by PGA and SJC in different ways, showing all the groups of such stratification, allowing us to evaluate the performance of the indices in the complete population and according to the different levels of disease activity (including 2 different cutoffs of SJC).

inactive' disease constructs. Starting with the most extreme groups, ie, comparing patients with low PGA and no SJC with patients with high PGA and arthritis, allows us to identify the performance of the instruments in these most extreme situations with more certainty about peripheral disease activity. However, when making decisions about the performance of an instrument, it is important also to consider its performance and discriminatory capacity in less contrasting situations like the discrimination between patients with and without peripheral arthritis when the PGA is low. Therefore, both analyses were conducted so that they could inform on the overall performance of the instruments together.

According to the OMERACT handbook for instrument selection [24], before moving forward with the OMERACT filter, the instruments of interest should pass through a 'Domain match and feasibility' assessment. In this regard, some concerns may be raised about the different joint counts used in the different instruments assessed. For example, the 28-joint count does not include the joints of the feet, which are frequently affected in SpA, and it has, therefore, been considered to not meet the domain match in PsA [25]. For the same reason, the 28-joint count may be problematic in axSpA. This raises concerns about the validity of the DAS28 in SpA.

Continuing with the OMERACT filter, the last pillar, 'Discrimination' (including test–retest reliability, longitudinal construct validity, and ability to discriminate in randomized controlled trials (RCTs), should also be compared across the composite scores. Unfortunately, composite scores nonspecific to axSpA, like the DAS and DAPSA, have not been assessed in trials of axSpA or pSpA so far. Given the positive results obtained in our study for the discriminatory capacity of composite scores, post hoc analyses of RCTs calculating these composite scores and their psychometric properties could provide further valuable insights.

The lower performance of measurement instruments without joint counts, like BASDAI and ASDAS, could be explained by an incomplete appraisal of peripheral arthritis. A previous analysis identified both peripheral arthritis and ASDAS as factors independently contributing to explaining physical function, as measured by BASFI, also confirming that the assessment of peripheral arthritis is not fully captured by ASDAS [26]. A physician's examination reflected on joint count seems to be more accurate and additionally informative.

A key finding of our study is that in the sensitivity analysis, in which patients with PsA were excluded, disease activity measures, including joint counts, performed persistently better, independent of the type of peripheral articular involvement, ie, there were no differences regardless of patients presenting with oligo- or polyarthritis. Similar performance of disease activity measurements, reflecting peripheral arthritis across the SpA phenotypes, reinforces the idea of the spectrum of SpA as a whole.

It is important to emphasise that this study was not intended to provide recommendations on the use of any specific instrument, as proper validation would be required for that. Rather, our aim was to assess all available instruments for measuring disease activity in peripheral arthritis, regardless of whether they had been previously validated for the diseases of interest. The findings of this study underscored the need for a more formal evaluation process, which led to the initiation of the ASAS-SPARADISE (Spondyloarthritis and Peripheral Arthritis Disease Activity Instrument Selection and Evaluation) project. This new initiative aims to systematically evaluate and compare the psychometric properties of different measurement instruments, with the ultimate goal of identifying the most suitable and best-performing instrument to be recommended for evaluating disease activity due to peripheral arthritis in clinical trials involving patients with axSpA or pSpA.

One of the limitations of the discrimination analysis based on the SMD is that it assumes normally distributed data. The lack of normal distribution, as in the case of DAPSA, makes methods like the SMD less suitable to assess discrimination. However, in the absence of a better methodology, the SMD is often used despite this limitation, as there is no consensus on how to analyse discrimination in a different way [3,17]. Notwithstanding, we still believe that this analysis has some strengths worth mentioning. First of all, it is more informative and more robust than the sole comparison of the mean scores between the 2 groups (active/inactive patients) through a simple t-test or analysis of variance. Second and more importantly, the SMD allows a fair comparison across the instruments and their performance. On the other hand, besides the above-mentioned linear score limitation, the same simplicity of DAPSA also becomes a significant advantage over the other more complex instruments that require the calculation of complex formulas or the use of an online tool. Finally, the similarity in SMD values between instruments with normally distributed (DAS28 and DAS44) and nonnormally distributed values (DAPSA) suggests that the nonnormality of DAPSA did not introduce meaningful bias or impact the conclusions.

Another point to consider is the use of external constructs primarily oriented towards axSpA rather than those specifically tailored for pSpA or PsA. This was due to data availability in the ASAS-PerSpA study, where only these instruments were collected. However, given the known overlap between these diseases [27] and the absence of alternative instruments in the study, applying the same constructs was a necessary approach.

To summarise, the present construct validity analysis showed that all disease activity measurement instruments assessing peripheral arthritis have a good performance, reflected in the correlations of strength with external constructs. Furthermore, when discriminating between known groups, all of them have a good performance, with composite scores with joint counts, particularly DAS28 and DAPSA, standing out as having the best discriminatory capacity. Future analyses comparing psychometric properties across composite scores, mainly discrimination in clinical trials, should be performed to identify the most adequate and best-performing measurement instrument to assess peripheral arthritis in SpA (including axSpA and pSpA).

Competing interests

DC declares no conflict of interest. CL-M received consultant fees/speaker from UCB Novartis Janssen Lilly MSD AbbVie. DvH received consultant fees from AbbVie, Argenx, BMS, Galapagos, Glaxo-Smith-Kline, Janssen, Lilly, Novartis, Pfizer, Takeda, and UCB Pharma. RL received consultant fees from AbbVie, BMS, Galapagos, Eli Lilly, Novartis, Jansen, Pfizer, and UCB. MD received grants or consultant fees from UCB, Novartis, Eli Lilly, Pfizer, and AbbVie. JS received consulting fees or honoraria from UCB, AbbVie, MSD, Novartis, and UCB. AM received grants from Biogen, Pfizer, and UCB and honoraria from AbbVie, UCB, Viatris, Amgen, BMS, Biogen, Galapagos, Janssen, Lilly, and Novartis. SR received research grants from AbbVie, Galapagos, MSD, Novartis, Pfizer, and UCB and honoraria or consultancy/speaker fees from AbbVie, Eli Lilly, Galapagos, Janssen, MSD, Novartis, Pfizer, UCB, and Sanofi.

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DC, CL-M, SR, AM, DvH, RL, MD, and JS designed the study. DC and CL-M collected and/or prepared the data. DC analysed the data. DC, CL-M, SR, AM, DvH, RL, MD, and JS critically interpreted the results. DC, CL-M, SR, and AM were involved in drafting the manuscript. All authors revised the manuscript critically for important intellectual content and approved the final manuscript.

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