during the cooling and recovery procedure (p=0.008, figure 1), and in the fingertips with LASCA (p=0.023). No serious adverse events occurred.

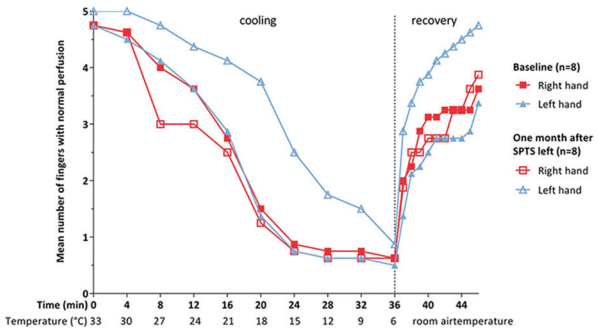


**Figure 1.**. Mean number of fingers per hand with normal perfusion during a cooling and recovery procedure before and after left-sided SPTS

**Conclusion:** SPTS, a minimally invasive technique, appears to be feasible and effective in improving hand perfusion in patients with RP after one month. Although these results are promising, long-term efficacy needs to be established and therefore follow-up is on-going.

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## SAT0303 DESIGN OF PHASE 3 STUDY OF LENABASUM FOR THE TREATMENT OF DERMATOMYOSITIS

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**Background:** To date, there has not been a Phase 3 study evaluating efficacy and safety of a new chemical entity solely in subjects with dermatomyositis (DM). There is no precedence for design of such a pivotal study, including selection of patients or efficacy outcomes.
**Objectives:** Develop a Phase 3 study design for testing efficacy and safety of lenabasum in DM that would be acceptable to experts and for registration purposes.
**Methods:** Lenabasum is a synthetic, non-immunosuppressive, selective cannabinoid receptor type 2 agonist that activates resolution of innate immune responses. Lenabasum had acceptable safety and tolerability and improved multiple physician-reported and patient-reported efficacy outcomes in a 16-week double-blinded, randomized, placebo-controlled Phase 2 trial in DM subjects with refractory, skin-predominant involvement, as well as in the open-label extension of that study. The Phase 3 trial design was based on Phase 2 data, input from a steering committee of experts in DM clinical trials, and recommendations made by regulatory authorities in the US, EU, Sweden, and Japan.
**Results:** A global, double-blind, randomized, interventional design was chosen to provide an unbiased assessment of the efficacy, safety and tolerability of lenabasum 20 mg bid and 5 mg bid compared to placebo in the treatment of DM. A 52-week treatment duration was selected to provide safety and efficacy data adequate to support chronic treatment. Subjects with DM were classified by Peter and Bohan criteria or the 2017 EULAR/ACR classification criteria for DM (both amyopathic DM and classic DM). Subjects will be required to have active disease, as assessed by an expert and based on a range of muscle, skin, and other disease manifestations. Subjects must be on stable doses of current DM treatments with any background immunosuppressive medications allowed except prednisone $\geq$ 20 mg per day or equivalent. This inclusivity allows testing of efficacy and safety of lenabasum in the setting of current treatment practice and reduces risk of disease flare early in the study. The primary efficacy outcome is change from baseline in 2016 ACR/EULAR Total Improvement Score (TIS) for DM and polymyositis. This composite outcome has six domains that broadly capture improvement in disease activity, is relevant to the range of manifestations in DM, and is applicable to the assessment of efficacy in the target patient population. Secondary efficacy outcomes were chosen to assess how the subject functions (Short Form – 36 physical functioning domain), major organ involvement (MMT-8, CDASI activity score, and a new Investigator Global Assessment scale of skin activity designed specifically for this study), and lung function (FVC). Change in oral corticosteroid dose also will be captured.
**Conclusion:** To our knowledge, this is the first Phase 3 study in DM with a new molecular entity. As such, agreement with experts and regulatory authorities on design represents a step forward in the development pathway of new treatments for DM.
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Corbus—design of clinical trial in DM
23 and me—ad hoc consulting
Admiryx—ad hoc consulting
Janssen—SAB for PSOLAR database
Beigene—paid consultant, Caitlin Cornwall Shareholder of: Corbus Pharmaceuticals, Inc., Employee of: Corbus Pharmaceuticals, Inc., Nancy Dgetluck Employee of: Corbus Pharmaceuticals, Inc., Scott Constantine Shareholder of: Corbus Pharmaceuticals, Inc., Employee of: Corbus Pharmaceuticals, Inc., Barbara White Shareholder of: Corbus Pharmaceuticals, Inc., Employee of: Corbus Pharmaceuticals, Inc.
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## SAT0304 RELATIONSHIP BETWEEN INTERLEUKIN-23 AND GASTROINTESTINAL INVOLVEMENT IN PATIENTS WITH SYSTEMIC SCLEROSIS

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**Background:** Growing evidence suggests that T-cell proliferation and cytokine secretion play an important role in the pathogenesis of systemic sclerosis (SSc). Gut involvement is the leading cause of morbidity in patients with SSc. In this study we evaluated interleukin-23 (IL-23) protein expression profiles and investigated its association with gastrointestinal involvement in SSc patients.

**Objectives:** To evaluate IL-23 expression profiles and to explore association between IL-23 and gastrointestinal involvement in SSc patients.
**Methods:** Study included 31 SSc patients. The expression level of IL-23 mRNA was determined by qRT-PCR method and Enzyme-Linked Immunosorbent Assay (ELISA) was used for analysis of IL-23 serum protein level. We used UCLA GIT 2.0 questionnaire to assess gastrointestinal (GIT) involvement in SSc patients.
**Results:** We found a positive correlation between disease duration and expression levels of IL-23mRNA ($r = 0.49$, $p<0.05$). Nine SSc patients with high IL-23 levels (cut off point 6.8 pg/ml) had significantly higher UCLA GIT 2.0 score, compared to 22 SSc patients with normal IL-23 levels ($p<0.05$). Serum level of IL-23 positively correlated with total GIT score ($r = 0.35$, $p<0.05$) and distension scale score ($r= 0.5$, $p<0.05$).
**Conclusion:** High IL-23 serum levels significantly correlated with gastrointestinal involvement (higher UCLA GIT 2.0 score) in patients with SSc.

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## Spondyloarthritis - clinical aspects (other than treatment)

SAT0305

### ASSOCIATION OF SKIN PSORIASIS WITH CLINICAL AND RADIOGRAPHIC CHARACTERISTICS IN AXIAL SPONDYLOARTHRITIS: RESULTS FROM THE GERMAN SPONDYLOARTHRITIS INCEPTION COHORT

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**Background:** Overlap between psoriasis and axial spondyloarthritis (axSpA) is common, as psoriasis occurs in approximately 10% of patients with axSpA. It has been noted that such an association may result in a particular phenotype of the disease, which has not been extensively investigated so far.
**Objectives:** To analyze the association between skin psoriasis and clinical and radiographic characteristics of axSpA.
**Methods:** Altogether 210 patients with definite axSpA (115 with radiographic and 95 with non-radiographic axSpA) from the German Spondyloarthritis Inception Cohort (GESPIC) were included in the current study. Information on the presence of psoriasis, clinical features, parameters of disease activity, and treatment were collected at baseline and every 6 months thereafter. Radiographs of sacroiliac joints and spine were obtained at baseline and after 2 years of follow-up and were scored by two trained readers according to the conventional grading system of the modified New York criteria (grade 0 to 4 per joint) and mSASSS (score 0-72). Group comparison was performed using Mann-Whitney U-Test for continuous variables and Fisher exact test for binary variables. A logistic regression model was constructed to assess the association of the psoriasis with radiographic progression in the sacroiliac joints and in the spine.
**Results:** Overall, 28 patients (13.3%) with axSpA had skin psoriasis. Patients with psoriasis were less frequently HLA-B27 positive in comparison with patients with no skin symptoms (57.1% and 82,9% respectively, p=0.004), had more frequently a history of peripheral arthritis (57.1% and 31.9%, p= 0.01), had higher disease activity (BASDAI baseline 5.0 ± 2.2 and 3.8 ± 2.1, respectively, p=0.01) and worse physical function (BASFI at baseline 3.8 ± 2.3 and 2.8 ± 2.3, respectively, p=0.02) (***Table 1***). They were also more frequently treated with DMARDs (57.1% and 24.7%, respectively, p=0.001). Baseline radiographic characteristics were comparable between the groups. There was no statistically significant difference in rates of radiographic spinal progression and progression of radiographic sacroiliitis in patients with vs. without psoriasis (***Table 2***). In the multivariable logistic regression analysis, adjusted for the smoking status, sex, NSAID intake, presence of syndesmophytes at baseline and time-averaged ASDAS, skin psoriasis showed no significant association with radiographic spinal progression (OR 2.93, 95% CI 0.81 to 10.58) nor with progression of radiographic sacroiliitis by at least 1 grade (OR 1.98, 95% CI 0.72 to 5.43)
**Conclusion:** Presence of skin psoriasis in patients with axSpA was associated with HLA-B27 negativity, peripheral arthritis, higher disease activity and worse functional status, but had no significant impact on radiographic characteristics of the disease.

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none

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**Table 1.** Demographic, clinical and radiographic characteristics of axSpA patients with and without psoriasis.

| Parameter (n (%) or mean±SD) | Psoriasis (n=28) | No psoriasis (n=182) | P* |
|---|---|---|---|
| **Clinical characteristics and demographics** | | | |
| Male sex | 12 (42.9%) | 95 (52.2%) | 0.419 |
| Age, years | 39.1 ± 10.7 | 37.0 ± 10.5 | 0.278 |
| Age at symptom onset, years | 33.9 ± 11.4 | 33.0 ± 10.8 | 0.63 |
| Diagnostic delay, years | 3.2 ± 2.1 | 2.6 ± 2.4 | 0.08 |
| HLA-B27 positivity | 16 (57.1%) | 150 (82.9%) | **0.004** |
| Smoking, BL | 6 (21.4%) | 65 (35.7%) | 0.20 |
| Inflammatory back pain, BL | 25 (89.3%) | 153 (84.1%) | 0.58 |
| Family history of SpA | 15 (53.6%) | 63 (34.6%) | 0.06 |
| Peripheral arthritis at BL | 7 (25%) | 24 (13.2%) | 0.15 |
| Peripheral arthritis ever | 16 (57.1%) | 58 (31.9%) | **0.01** |
| Enthesitis at BL | 8 (28.6%) | 38 (20.9%) | 0.34 |
| Inflammatory bowel disease, ever | 1 (3.6%) | 3 (1.6%) | 0.44 |
| Uveitis, ever | 6 (21.4%) | 36 (19.8%) | 0.80 |
| **Disease activity** | | | |
| BASDAI, BL | 5.0 ± 2.2 | 3.8 ± 2.1 | **0.01** |
| CRP mg/l, BL | 10.1 ± 13.1 | 9.7 ± 15.6 | 0.84 |
| **Functional status** | | | |
| BASFI, BL | 3.8 ± 2.3 | 2.8 ± 2.3 | **0.02** |
| BASMI, BL | 2.1 ± 1.5 | 1.7 ± 1.7 | 0.07 |
| **Radiographic characteristics** | | | |
| Fulfillment of the mNY criteria, BL | 17 (60.7%) | 98 (53.8%) | 0.55 |
| Sacroiliitis sum score, BL | 4.1 ± 2.2 | 4.1 ± 2.0 | 0.95 |
| Asymmetric sacroiliitis, BL (difference in by ≥1 sacroiliitis grade between the sides) | 2 (7.1%) | 17 (9.3%) | 1.00 |
| Mean mSASSS, BL | 7.4 ± 12.1 | 3.8 ± 7.5 | 0.25 |
| At least 1 syndesmophyte, BL | 9 (32.1%) | 55 (30.2%) | 0.84 |
| **Treatment** | | | |
| NSAID intake, BL | 17 (60.7%) | 123 (67.6%) | 0.52 |
| NSAID Index over 2 years of follow-up | 43.6 ± 30.9 | 31.6 ± 27.1 | 0.06 |
| DMARD intake, BL | 16 (57.1%) | 45 (24.7%) | **0.001** |
| TNFi intake over 2 years of follow-up | 6 (21.4%) | 16 (8.8%) | 0.08 |
| CS intake, BL | 3 (10.7%) | 9 (4.9%) | 0.20 |

* Mann-Whitney U-Test for continuous variables, Fisher exact test for binary variables.

BL – baseline; HLA-B27 - Human leukocyte antigen B27; SpA – spondyloarthritis; BASDAI – Bath Ankylosing Spondylitis Disease Activity Index; CRP - C-reactive protein; BASFI – Bath Ankylosing Spondylitis Functional Index; BASMI – Bath Ankylosing Spondylitis Metrology Index; mNY Criteria – modified New York Criteria for Ankylosing Spondylitis, 1984; mSASSS - modified Stoke Ankylosing Spondylitis Spine Score; NSAID – non-steroid anti-inflammatory drugs, DMARD – disease-modifying anti-rheumatic drugs; TNFi – tumour necrosis factor α inhibitors; CS – corticosteroids.

**Table 2.** Association of skin psoriasis with radiographic progression in axial spondyloarthritis after 2 years of follow-up.

| Outcome | Psoriasis (n=28) | No psoriasis (n=185) | p* |
|---|---|---|---|
| **Spine** | | | |
| mSASSS change | 1.52 ± 4.02 | 0.61 ± 1.95 | 0.55 |
| Progression of mSASSS by ≥2 points | 6 (21.4%) | 24 (13.2%) | 0.25 |
| New syndesmophytes or progression of syndesmophytes | 7 (25.0%) | 26 (14.3%) | 0.16 |
| **Sacroiliac joints** | | | |
| Change of the sacroiliitis sum score | 0.18 ± 0.63 | 0.12 ± 0.87 | 0.71 |
| Progression of sacroiliitis by at least 1 grade in opinion of both readers | 3 (10.7%) | 23 (12.6%) | 1.00 |

* Mann-Whitney U-Test for continuous variables, Fisher Exact test for binary variables.

mSASSS - modified Stoke Ankylosing Spondylitis Spine Score.

Rudwaleit Consultant for: AbbVie, BMS, Celgene, Janssen, Eli Lilly, MSD, Novartis, Pfizer, Roche, UCB Pharma, Consultant for: AbbVie, BMS, Celgene, Janssen, Eli Lilly, MSD, Novartis, Pfizer, Roche, UCB Pharma, Denis Poddubnyy Grant/research support from: AbbVie, Merck Sharp & Dohme, Novartis, Consultant for: AbbVie, Bristol-Myers Squibb, Janssen, Merck Sharp & Dohme, Novartis, Pfizer, UCB Pharma, Speakers bureau: AbbVie, Bristol-Myers Squibb, Janssen, Merck Sharp & Dohme, Novartis, Pfizer, Roche, UCB Pharma

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SAT0306

## COMPARISON OF MEN AND WOMEN WITH AXIAL SPONDYLOARTHRITIS IN THE US-BASED CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS (PSA/SPA) REGISTRY

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**Background:** Axial spondyloarthritis (AxSpA) is a chronic inflammatory rheumatic disease that primarily affects the axial skeleton and frequently affects the peripheral joints and entheses. AxSpA encompasses ankylosing spondylitis and nonradiographic AxSpA. Sex differences have been described for patient reported outcomes (PROs) in SpA; however, more research is needed to better understand the overall clinical burden of AxSpA in women, particularly in the United States.

**Objectives:** To compare the patient demographics, clinical characteristics, treatment profiles, disease activity, quality of life, and work productivity between men and women with AxSpA in the US-based Corrona PsA/SpA Registry.

**Methods:** This study included patients aged ≥ 18 years with AxSpA enrolled in the Corrona PsA/SpA Registry between March 2013 and November 2018. Patients who were concurrently diagnosed with PsA were excluded. Patient demographics, clinical characteristics, treatment profiles, disease activity, quality of life, and work productivity were characterized for all patients with AxSpA at enrollment and were compared between men and women using *t* tests or Wilcoxon rank-sum tests for continuous variables and $\chi^2$ or Fisher's exact tests for categorical variables.

**Results:** Of 498 patients with AxSpA who were included in the study, 307 (61.6%) were male and 191 (38.4%) were female. Compared with men, women were less likely to work full time, were more likely to be normal weight/underweight, had a shorter disease duration, and were more likely to have depression, fibromyalgia, and prior csDMARD and prednisone use (**Table 1**; all $P < 0.05$). At enrollment, women with AxSpA had a shorter occiput-to-wall distance, but also had worse disease activity compared with men, as reflected by higher BASDAI and BASFI scores, higher enthesitis and tender/swollen joint counts, worse pain and fatigue, worse physical function (HAQ-S) and health state today (EQ VAS), and more severe work and activity impairment (**Table 2**; all $P < 0.05$).

**Conclusion:** In this US registry of patients with AxSpA, women had an increased overall burden of disease compared with men, including higher patient reported symptoms, higher disease activity, and greater work productivity impairment. Women also had lower scores for spinal mobility with increased signs of peripheral arthritis (eg, higher tender/swollen joint and enthesitis counts), suggesting that conventional definitions of AxSpA centered around axial symptoms may not be representative of the female population with disease. Improved awareness of sex differences in presentation of AxSpA may aid physicians in earlier identification and improved management of the disease.

**Acknowledgement:** This study was sponsored by Corrona, LLC. Corrona is supported through contracted subscriptions with multiple pharmaceutical companies. The abstract was a collaborative effort between Corrona and Novartis, with financial support provided by Novartis.

**Table 1.** Demographic and Clinical Characteristics and Treatment Profiles in Men and Women With AxSpA at Enrollment

| Characteristic | Patients With AxSpA | | *P* Value |
|---|---|---|---|
| | Men (N = 307) | Women (N = 191) | |
| Age, mean (SD) [n], years | 47.3 (13.9) [305] | 47.7 (13.5) [190] | 0.75 |
| Race, n (%) | n = 302 | n = 186 | 0.08 |
| White | 276 (91.4) | 172 (92.5) | |
| Black | 3 (1.0) | 6 (3.2) | |
| Other | 23 (7.6) | 8 (4.3) | |
| Work status, n (%) | n = 306 | n = 190 | < 0.01 |
| Full time | 190 (62.1) | 102 (53.7) | |
| Part time | 11 (3.6) | 20 (10.5) | |
| Disabled | 49 (16.0) | 24 (12.6) | |
| Retired | 38 (12.4) | 22 (11.6) | |
| Other | 18 (5.9) | 22 (11.6) | |
| BMI, mean (SD) [n], kg/m$^2$ | 29.8 (6.0) [297] | 30.0 (8.5) [189] | 0.32 |
| BMI (in kg/m$^2$) categories, n (%) | n = 297 | n = 189 | 0.04 |
| Normal/underweight (< 25) | 64 (21.5) | 60 (31.7) | |
| Overweight (25 to < 30) | 102 (34.3) | 54 (28.6) | |
| Obese (≥ 30) | 131 (44.1) | 75 (39.7) | |
| Symptom duration, mean (SD) [n], years | 17.6 (12.3) [296] | 15.7 (11.6) [184] | 0.09 |
| Disease duration, mean (SD) [n], years | 10.3 (10.8) [301] | 8.2 (9.9) [188] | 0.02 |
| HLA-B27 positive test result, n (%) | 224 (73.0) | 124 (64.9) | 0.06 |
| Select comorbidities, n (%) | | | |
| Depression | 37 (12.1) | 49 (25.7) | < 0.01 |
| Fibromyalgia | 3 (1.0) | 20 (10.5) | < 0.01 |
| Ulcerative colitis | 9 (2.9) | 13 (6.8) | 0.04 |
| Anxiety | 7 (2.3) | 10 (5.2) | 0.08 |
| Prior biologic use, n (%) | 89 (29.0) | 63 (33.0) | 0.35 |
| Number of prior biologics, n (%) | | | 0.62 |
| 0 | 218 (71.0) | 128 (67.0) | |
| 1 | 57 (18.6) | 39 (20.4) | |
| ≥ 2 | 32 (10.4) | 24 (12.6) | |
| Prior csDMARD use, n (%) | 41 (13.4) | 42 (22.0) | 0.01 |
| Prior prednisone use, n (%) | 27 (8.8) | 30 (15.7) | 0.02 |

AxSpA, axial spondyloarthritis; BMI, body mass index; csDMARD, conventional synthetic disease-modifying antirheumatic drug.

**Table 2.** Disease Activity, Quality of Life, and Work Productivity in Men and Women With AxSpA at Enrollment

| Characteristic | Patients With AxSpA | | *P* Value |
|---|---|---|---|
| | Men (N = 307) | Women (N = 191) | |
| ASDAS, mean (SD) [n] | 2.6 (1.2) [179] | 2.8 (0.9) [123] | 0.07 |
| BASDAI (0-10), mean (SD) [n] | 4.2 (2.5) [294] | 4.9 (2.3) [187] | < 0.01 |
| BASFI (0-10), mean (SD) [n] | 3.4 (2.8) [295] | 4.1 (2.7) [185] | < 0.01 |
| Lateral lumbar flexion (average of left and right), mean (SD) [n], cm | 24.1 (20.1) [276] | 23.4 (19.0) [170] | 0.76 |
| Occiput to wall, mean (SD) [n], cm | 5.8 (7.7) [277] | 2.7 (5.0) [172] | < 0.01 |
| Enthesitis, n (%) | 62 (20.2) | 71 (37.2) | < 0.01 |
| SPARCC Enthesitis Index (1-16) | 3.2 (2.4) [62] | 4.8 (3.2) [71] | < 0.01 |
| Dactylitis, n (%) | 9 (2.9) | 3 (1.6) | 0.39 |
| Dactylitis count (1-20) | 3.4 (3.5) [9] | 1.3 (0.6) [3] | 0.37 |
| Tender joint count (0-68), mean (SD) [n] | 1.8 (4.7) [299] | 5.1 (9.6) [190] | < 0.01 |
| Swollen joint count (0-66), mean (SD) [n] | 0.6 (2.5) [299] | 0.9 (2.2) [190] | 0.01 |
| Physician global assessment, mean (SD) [n] | 25.7 (23.4) [295] | 30.8 (22.2) [188] | < 0.01 |
| Patient pain (VAS 0-100), mean (SD) [n] | 45.3 (30.5) [293] | 51.6 (27.8) [172] | 0.03 |
| Patient fatigue (VAS 0-100), mean (SD) [n] | 45.4 (29.1) [306] | 53.9 (27.4) [191] | < 0.01 |
| Morning stiffness, n (%) | n = 299 | n = 190 | 0.10 |
| < 30 minutes | 88 (29.4) | 43 (22.6) | |
| ≥ 30 minutes | 211 (70.6) | 147 (77.4) | |
| Patient global assessment (VAS 0-100), mean (SD) [n] | 52.2 (32.5) [102] | 52.5 (33.1) [41] | 0.82 |
| HAQ-S (0-3), mean (SD) [n] | 0.59 (0.62) [258] | 0.82 (0.65) [131] | < 0.01 |
| EQ VAS (0-100), mean (SD) [n] | 66.2 (22.2) [298] | 61.1 (22.4) [189] | < 0.01 |
| WPAI domains, mean (SD) [n] | | | |
| Current employment, n/m (%) | 206/304 (67.8) | 121/189 (64.0) | 0.39 |
| % Work time missed | 6.7 (18.4) [190] | 7.3 (17.4) [109] | 0.33 |
| % Impairment while working | 24.9 (23.8) [199] | 35.4 (28.5) [113] | < 0.01 |
| % Overall work impairment | 28.4 (27.1) [184] | 36.4 (28.6) [105] | 0.03 |
| % Activity impairment | 36.1 (29.7) [299] | 45.9 (30.0) [188] | < 0.01 |

ASDAS, Ankylosing Spondylitis Disease Activity Score; AxSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Functional Index; EQ VAS, EuroQol visual analogue scale; HAQ-S, Health Assessment Questionnaire for the Spondyloarthropathies; SPARCC, Spondyloarthritis Research Consortium of Canada; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.