J. Nicolaes[1,2], E. Tselenti[3], T. Aouad[4], C. López-Medina[5,6,7], A. Feydy[6,8], H. Talbot[4], B. Hoepken[9], N. De Peyrecave[2], M. Dougados[5,6]. [1]*KU Leuven, Department of Electrical Engineering (ESAT), Center for Processing Speech and Images, Leuven, Belgium*; [2]*UCB Pharma, N/A, Brussels, Belgium*; [3]*Veramed, N/A, London, United Kingdom*; [4]*Universite Paris-Saclay, CentraleSup´elec, Inria. Gif-sur-Yvette, France*; [5]*Cochin Hospital, Rheumatology Department, Paris, France*; [6]*University of Paris, INSERM (U1153): Clinical Epidemiology and Biostatistics, Paris, France*; [7]*Reina Sofia Hospital, Cordoba/ IMIBIC/ University of Cordoba, Rheumatology Department, Cordoba, Spain*; [8]*Cochin Hospital, Radiology Department, Paris, France*; [9]*UCB Pharma, N/A, Monheim am Rhein, Germany*

Background: Magnetic resonance imaging (MRI) of the sacroiliac joints (SIJ) is an essential tool in the evaluation of patients with axial spondyloarthritis (axSpA). In-depth knowledge of characteristic MRI lesions and their definitions, as well as reliability of identification and scoring, varies amongst general radiologists and rheumatologists.[1] A deep learning algorithm was developed to detect the presence of inflammation in SIJ MRI (MRI+) scans with promising results.[2]

Objectives: The aim of this diagnostic performance study was to assess the ability of a deep learning algorithm to identify MRI+ scans in a study cohort of axSpA patients.

Methods: 731 baseline SIJ MRI scans were collected from two prospective randomised controlled trial cohorts in patients with non-radiographic (nr-) and radiographic (r-) axSpA (RAPID-axSpA [NCT01087762] and C-OPTIMISE [NCT02505542])[3,4] and were centrally evaluated by two expert readers (and adjudicator in case of disagreement) for the presence of inflammation by the 2009 Assessment in SpondyloArthritis international Society (ASAS) definition.[5] The MRI scans were processed by the previously trained deep learning algorithm,[2] blinded to clinical information and central expert readings.

Performance evaluation included sensitivity, specificity, positive and negative predictive values (PPV and NPV), Cohen's Kappa and the absolute agreement to assess the agreement between the deep learning algorithm and the human readers for the classification of MRI-SIJ scans. Bootstrapping was used to construct the 95% confidence interval (CI).

Results: Pooling the patients from RAPID-axSpA (n=152) and C-OPTIMISE (n=579) yielded a validation set of 731 patients (mean age: 34.2 years, SD: 8.6; 69.1% male) of which 44.6% were patients with nr-axSpA and 59.6% were MRI+ as per central readings.

Comparing the trained algorithm with the human central readings for the classification of MRI+/MRI– on the pooled validation set yielded a sensitivity of 70% (95% CI: 66–73%), specificity of 81% (95% CI: 78–84%), PPV of 84% (95% CI: 82–87%), NPV of 64% (95% CI: 61–68%), Cohen's kappa of 0.49 (95% CI: 0.43–0.55), and absolute agreement of 74% (95% CI: 72–77%; **Table 1**).

Conclusion: A previously trained deep learning algorithm enabled acceptable detection of the presence of inflammation according to the 2009 ASAS MRI definition in axSpA patients from two clinical trials. This suggests that an MRI+ detection algorithm has the potential to support clinicians in identifying axSpA patients.

REFERENCES:

[1] Bennett AN. J Rheumatol 2017;44(6):780–5;
[2] Aouad T. Proc Int Conf Image Proc 2022;3351–5;
[3] van der Heijde. Rheumatology. 2017;56(9):1498–1509;
[4] Landewé RB. Ann Rheum Dis. 2020;79(7):920–28;
[5] Rudwaleit M. Ann Rheum Dis 2009;68(6):777–83.

Table 1. Performance results comparing the algorithm and the human readers for the classification of MRI-SIJ scans. The metric values are point estimate (95% CI).

Metric	All (N=731)	RAPID-axSpA (N=152)	C-OPTIMISE (N=579)
Central reading, MRI+; n(%)	436 (59.6%)	99 (65.1%)	337 (58.2%)
Sensitivity	0.70 (95% CI: 0.66–0.73)	0.66 (95% CI: 0.58–0.73)	0.71 (95% CI: 0.67–0.75)
Specificity	0.81 (95% CI: 0.78–0.84)	0.89 (95% CI: 0.82–0.95)	0.79 (95% CI: 0.75–0.83)
PPV	0.84 (95% CI: 0.82–0.87)	0.92 (95% CI: 0.87–0.96)	0.83 (95% CI: 0.79–0.86)
NPV	0.64 (95% CI: 0.61–0.68)	0.58 (95% CI: 0.50–0.67)	0.66 (95% CI: 0.62–0.70)
Cohen's kappa	0.49 (95% CI: 0.43–0.55)	0.48 (95% CI: 0.36–0.61)	0.49 (95% CI: 0.42–0.56)
Absolute agreement	0.74 (95% CI: 0.72–0.77)	0.74 (95% CI: 0.68–0.79)	0.74 (95% CI: 0.72–0.77)

CI: confidence interval; MRI: magnetic resonance imaging; NPV: negative predictive value; PPV: positive predictive value; SIJ: sacroiliac joints.

Acknowledgements: We thank the patients who participated. Funded by UCB Pharma. Editorial support provided by Costello Medical and funded by UCB Pharma.

Disclosure of Interests: Joeri Nicolaes Shareholder of: UCB Pharma, Employee of: UCB Pharma, Evi Tselenti Employee of: Veramed statistical consultant for UCB Pharma, Theodore Aouad: None declared, Clementina López-Medina Speakers bureau: Eli Lilly, Novartis, UCB Pharma, MSD, Abbvie and Janssen, Consultant of: UCB Pharma, Eli-Lilly, and Novartis, Grant/research support from: Abbvie, UCB Pharma, Eli Lilly, and Novartis, Antoine Feydy Consultant of: Guerbet, Hugues Talbot: None declared, Bengt Hoepken Shareholder of: UCB Pharma, Employee of: UCB Pharma, Natasha de Peyrecave Employee of: UCB Pharma, Maxime Dougados Speakers bureau: UCB Pharma, Grant/research support from: UCB Pharma.

DOI: 10.1136/annrheumdis-2023-eular.2357

POS0342

PERFORMANCE OF THE EULAR SYSTEMIC SCLEROSIS IMPACT OF DISEASE (SCLEROID) QUESTIONNAIRE AS A PATIENT REPORTED OUTCOME MEASURE FOR PATIENTS WITH DIFFUSE SYSTEMIC SCLEROSIS

Keywords: Patient-led research, Patient reported outcomes, Systemic sclerosis

R. Dobrota[1], A. Garaiman[1], K. Fligelstone[2], A. Kennedy[3], A. Roennow[4], Y. Allanore[5], P. Carreira[6], L. Czirják[7], C. P. Denton[8], R. Hesselstrand[9], G. Sandqvist[9], O. Kowal-Bielecka[10], C. Bruni[1,11], M. Matucci Cerinic[11], C. Mihai[1,12], A. M. Gheorghiu[12], U. Müller-Ladner[13], J. Sexton[14], T. K. Kvien[14], T. Heiberg[15], O. Distler[1], M. O. Becker[1]. [1]*University Hospital Zurich, Department of Rheumatology, Zurich, Switzerland*; [2]*Federation of European Scleroderma Associations (FESCA), Federation of European Scleroderma Associations (FESCA), London, United Kingdom*; [3]*Federation of European Scleroderma Associations (FESCA), Federation of European Scleroderma Associations (FESCA), Tournai, Belgium*; [4]*Federation of European Scleroderma Associations (FESCA), Federation of European Scleroderma Associations (FESCA), Saint Maur, Belgium*; [5]*University Paris Descartes and Cochin Hospital, Department of Rheumatology, Paris, France*; [6]*Hospital Universitario 12 de Octubre, Department of Rheumatology, Madrid, Spain*; [7]*Medical School, University of Pécs, Department of Immunology and Rheumatology, Pecs, Hungary*; [8]*University College London, Royal Free Campus, Center for Rheumatology, London, United Kingdom*; [9]*Lund University, Department of Rheumatology, Lund, Sweden*; [10]*Medical University of Bialystok, Department of Rheumatology and Internal Medicine, Bialystok, Poland*; [11]*Careggi University Hospital, University of Florence, Department of Experimental and Clinical Medicine, Division of Rheumatology, Florence, Italy*; [12]*Cantacuzino Hospital, Carol Davila University of Medicine and Pharmacy, Department of Rheumatology and Internal Medicine, Bucharest, Romania*; [13]*Justus-Liebig University Giessen, Campus Kerckhoff, Department of Rheumatology and Clinical Immunology, Bad Neuheim, Germany*; [14]*Diakonhjemmet Hospital, Division of Rheumatology and Research, Oslo, Norway*; [15]*Oslo University Hospital, Regional Research Support, Oslo, Norway*

Background: There is a high unmet need for disease-modifying antifibrotic therapies in diffuse cutaneous systemic sclerosis (dcSSc) which could improve the outcome of this severe disease. Patient reported outcome measures (PROMs) are important and mandatory for randomized clinical trials (RCTs). The EULAR-endorsed ScleroID is the first comprehensive PROM specifically developed by SSc patients and experts to reflect the disease impact of SSc and showed a good performance in the clinical validation study [1]. However, most RCTs focus on dcSSc patients, hence a validated PROM to reflect the disease burden experienced by patients with dcSSc is needed and a detailed analysis of ScleroID in this subset of patients is lacking.

Objectives: To investigate the performance of the EULAR ScleroID in patients with dcSSc as a prerequisite for its use as a PROM in RCTs testing potentially disease-modifying drugs.

Methods: This is a subanalysis of all patients with dcSSc from the large, multicentric, ScleroID validation cohort [1]. As comparators, SSc-HAQ, EQ-5D, SF-36 were included. The study had a longitudinal arm with a reliability visit at 7+/- 3 days and a 12-month follow-up visit [1]. The performance of ScleroID in dcSSc was assessed according to the OMERACT filter [1].

Results: 152 dcSSc patients with a baseline visit were analyzed (44, 28.9% male, median age 54 years, median disease duration 7 years). ScleroID performed well as a PROM reflecting the disease impact of dcSSc: it showed a good construct validity with high Spearman's correlation coefficients with comparators (SSc-HAQ, 0.79, 95%CI [0.69, 0.86]; HAQ-DI, 0.72 95%CI [0.60, 0.80]; SF-36 physical score, -0.69 95%CI [-0.77, -0.60]). Furthermore, the internal consistency was strong: