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THE EULAR SYSTEMIC SCLEROSIS IMPACT OF DISEASE (SCLEROID) SCORE – A NEW PATIENT-REPORTED OUTCOME MEASURE FOR PATIENTS WITH SYSTEMIC SCLEROSIS

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Background: Patient reported outcome measures (PROs) are increasingly important for clinical practice and research. Given the unmet need for a comprehensive PRO for systemic sclerosis (SSc), the ScleroID questionnaire was developed by a joint team of patients with SSc and medical experts in the field. This approach was designed as a brief, specific, patient-derived, disease impact score for research and clinical use in SSc. A preliminary analysis was previously reported. Here, we present the first computation of the ScleroID score and an extended pre-final analysis from the ongoing ScleroID validation study.

Methods: This EULAR-endorsed project involves 11 European expert SSc centres. Patients fulfilling the ACR/EULAR 2013 criteria were prospectively included since 05/16 in the ongoing observational cohort study. Patients completed the ScleroID questionnaire (figure 1), as well as the selected comparators mSHAQ, EQ5D, and SF36. Additionally, they weighted the 10 dimensions of the ScleroID by distributing 100 points according to the perceived impact on their health. The final score calculation was based on the ranking of the weights. The study included a reliability arm (follow-up questionnaire 7–10 days from baseline), as well as a longitudinal arm, looking at sensitivity to change at follow-up visits after 6 and 12 months from baseline.

How much have the different aspects of systemic sclerosis affected you during the last week? Please mark your responses on the scale by choosing the appropriate number for each of the following dimensions:

Raynaud's phenomenon:
Circle the number that best describes the severity of your Raynaud's phenomenon during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Hand function:
Circle the number that best describes your hand function limitations due to your systemic sclerosis during the last week:
No limitation 0 1 2 3 4 5 6 7 8 9 10 Extreme limitation

Upper gastrointestinal tract symptoms (e.g. swallowing difficulties, reflux, vomiting):
Circle the number that best describes the severity of your upper gastrointestinal tract symptoms due to your systemic sclerosis during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Pain:
Circle the number that best describes the pain you felt due to your systemic sclerosis during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Fatigue:
Circle the number that best describes the impact of overall fatigue due to your systemic sclerosis during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Lower gastrointestinal tract symptoms (e.g. bloating, diarrhea, constipation, anal incontinence):
Circle the number that best describes the severity of lower gastrointestinal tract symptoms during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Limitations of life choices and activities (e.g. social life, personal care, work):
Circle the number that best describes how severe the limitations of life choices and activities due to your systemic sclerosis were during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Body mobility:
Circle the number that best describes how much your body mobility was affected due to your systemic sclerosis during the last week:
Not affected 0 1 2 3 4 5 6 7 8 9 10 Extremely affected

Breathlessness:
Circle the number that best describes how severe your breathlessness due to systemic sclerosis was during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Digital ulcers:
Circle the number that best describes how much your digital ulcers affected you overall during the last week:
None 0 1 2 3 4 5 6 7 8 9 10 Extreme

Abstract AB0787 – Figure 1. The EULAR Scleroderma Impact of Disease Score (ScleroID)

Results: As of January 2018, the study cohort included 417 patients with valid baseline data, 80 patients also had a reliability visit and 42 patients a follow-up

visit. 84% of patients were female, 62% had limited cutaneous SSc, mean age was 56 years, and median disease duration 10 years. 19% of patients were not able to work. The highest weights by the patients were assigned to Raynaud's phenomenon, fatigue, hand function and pain, in accordance with our previous results. The total ScleroID score showed good Spearman correlation coefficients with the comparators (mSHAQ, 0.59; EQ5D –0.62; Patient's global assessment, VAS 0.75; SF36 physical score –0.62; each $p < 0.001$). The internal consistency was good with a high Cronbach's alpha by 0.86.

Conclusions: The EULAR ScleroID score is a promising, novel PRO tool designed for use in clinical practice and clinical trials to display the disease impact of SSc, showing good performance in this pre-final analysis. Importantly, Raynaud's phenomenon, impaired hand function, pain and fatigue were the main patient reported drivers of disease impact. To date the recruitment has reached more than 80% of the targeted number, the study is ongoing.

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OSTEOARTICULAR INVOLVEMENTS IN PATIENTS WITH SYSTEMIC SCLEROSIS

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Background: Osteoarticular involvements are common in systemic sclerosis (SS) and are considered as an important cause of disability.

Objectives: The aim of this study was to assess clinical, radiological and immunological characteristics of patients with systemic sclerosis and who present with osteoarticular involvements at any time of the disease course. Patients with arthralgia and/or arthritis and/or imaging abnormalities were included.

Methods: A retrospective descriptive and comparative study was performed in an internal medicine department. One hundred thirty one patients who fulfilled 2013 ACR/EULAR criteria for SS were studied.

Results: We identified 101 patients with osteoarticular involvements (77.1%); 92 women and 9 men. Mean age at SS diagnosis was 47.6 ± 12.4 years. Disease was revealed by joint manifestations in 10.7% of cases. Arthralgia and arthritis were observed in 61.8% and 21.4% of cases respectively. Flexion deformities with disability were noted in 26 cases. X-Ray investigations revealed distal phalanges resorption ($n=24$), dystrophic calcifications ($n=10$) and joint space narrowing ($n=9$). Tendinitis was observed in one patient. Patients with osteoarticular manifestations developed more frequently digital ulcers (100% vs 78.3%; $p < 0.001$). Osteoarticular involvements was associated to diffuse cutaneous sclerosis (37.7% vs 12.5%; $p=0.002$) and to telangiectasis (91.3% vs 70%; $p=0.027$), gastrointestinal manifestations (90.1% vs 54.5%; $p=0.001$) and interstitial lung disease (92.7% vs 67.9%; $p=0.001$). SS was associated to sjögren syndrome ($n=20$), to systemic lupus erythematosus ($n=15$) and to rheumatoid arthritis ($n=2$). Patients received non-steroidal anti-inflammatory drug ($n=26$), corticosteroids ($n=8$) and methotrexate ($n=8$).

Conclusions: Osteoarticular involvement in systemic sclerosis has heterogeneous aspects. Its frequency ranges from 40% to more than 85% of cases in some studies. Early screening and treatment associated with physiotherapy session are essential to avoid complication and loss of function.

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