ratio correlated significantly with BMI in both cohorts (r^2=0.19 for study cohort, r^2=0.25 for validation cohort; p<0.0001). MUST score had only moderate value in predicting weight loss in the study cohort (AUC 0.7; 95% CI: 0.58–0.82). Specifically, 46.5% of SSc patients lost >10% wt despite having "no" or "mild" MUST scores. Logistic regression analysis identified the combination of BMI and A/L as the best PREdictor of MAlnutrition in Systemic Sclerosis (PREMASS). The formula 12.18-(0.63*BMI)+(1.51*A/L) predicted the end point with AUC=0.91 (95% CI:0.77–0.84). A PREMASS score >0.23 showed 91.3% sensitivity (95% CI:79.79–100) and 80.46% specificity (95% CI:72.13–88.79) for >10% wt loss with an overall 55.26% positive predictive value (PPV) (95% CI:39.45–71.07) and 97.22% negative predictive value (NPV) (95% CI:93.43–100) and a relative risk (RR) of 19.90 (95% CI:4.93–80.37). In the validation cohort, PREMASS showed 76.47% sensitivity (95% CI:56.31–96.63) and 75.47% specificity (95% CI:63.89–87.06) with an overall 50% PPV (95% CI:30.78–69.22) and 90.91% NPV (95% CI:82.41–99.4) and a RR of 5.5 (95% CI: 2–15.10).

Conclusions: PREMASS is the first validated index for weight loss risk stratification in the following 12 months in SSc. Prediction of future weight loss in SSc could aid both in clinical management and stratification/enrichment in clinical trials.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.4102

THU0394 ENTHESITIS IN SYSTEMIC SCLEROSIS (SSC): AN ULTRASOUND (US) PILOT STUDY

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Background: Articular involvement is frequently encountered in SSc and previous US studies suggest that synovitis is the commonest manifestation. Recently, it has been reported that SSc patients may show typical "hall-marks" of spondyloarthritis (SpA). Apart from tendon involvement which is a common event, sacroiliitis has been estimated to have a prevalence of 23%.

Objectives: To estimate the prevalence of entheseal and Synovio-Entheseal Complex (SEC) modifications in SSc

Methods: 30 SSc patients (2013 ACR/EULAR classification criteria) without a history of articular involvement (4 male, 26 female, mean age 53,3±16,6 years) were included in this pilot cross sectional US study. 12 healthy subjects (2 male, 10 female, mean age 46,9±5,8 years) were used as controls. The entheseal sites were the lateral epicondylar common extensor tendons (CET), and sites of the Glasgow Ultrasound Enthesis Scoring System. The GUESS score was also calculated as a soft tissue score (GUESS soft tissue) and as a bone score (GUESS bone). US assessment was performed with a MyLab 70XVG scanner equipped with a 6–18 MHz linear transducer (Esaote). Only the epicondylar region was evaluated with PowerDoppler US (PDUS), using semi-quantitative graded from 0 to 3. Involvement of SEC was evaluated at the epicondylar region in SSc patients who presented a PDUS signals≥1 in the CET closer than 2 mm from the bony surface. SEC involvement was defined as the presence of a PDUS signal ≥2 in the elbow epicondylar synovial fold proximal to the annular ligament (AL), inferior to the bone insertion of CET and to the radial collateral ligament (RCL). Statistical analyses were carried out using Mann-Whitney U, Spearman correlation and Chi-square tests. Results were considered significant if p<0,05

Results: In SSc, the GUESS and GUESS soft tissue scores were significantly higher (5.67±0.87 and 3.43±0.44, respectively) than in controls (1.25±0.41 and 0.92±0.29, respectively) (p<0,0001) as was the GUESS bone score (SSc 2.23 ±0.55 vs controls 0.33±0.22; p<0,05). The CET entheses of SSc patients showed significantly more US B-mode alterations than controls (hypoechogenicity χ^2=5.95, p=0.015, cortical irregularity χ^2=7.90, p=0.005, calcification/enthesophytes χ^2=3.78, p=0.05). A PD signal in the CET enthesis was found in 18/60 sites in SSc and in 1/24 in controls. The PD signal of the CET enthesis was significantly higher in SSc patients than in healthy controls (0.47±0.10 and 0.08±0.08 respectively, p=0.018) as was the presence of SEC inflammation (χ^2=4.54, p=0.033). In SSc, there was a strong correlation between the presence of PD signal at CET entheses and concomitant SEC inflammation (rho=0.655, p<0.0001) but there were no correlations between GUESS score or CET enthesitis and disease subset, disease duration, antibodies, DLCO, FVC, DLCO/VA.

Conclusions: Our data show that SSc patients frequently present the usual US features of enthesitis. Moreover, CET enthesitis were correlated with SEC inflammation suggesting that entheseal inflammation in SSc may share same microanatomical targets as SpA.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.4174

THU0395 INFLUENCE OF SETTING AN UPPER LIMIT OF THE MRSS AS AN INCLUSION CRITERION IN SSC CLINICAL TRIALS ON THE RATIO OF SKIN FIBROSIS PROGRESSION VS. IMPROVEMENT – AN ANALYSIS OF THE GENISOS COHORT

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Background: Skin involvement is a main domain in the assessment of patients with systemic sclerosis (SSc), and the modified Rodnan skin score (mRSS) is a primary outcome measurement in SSc clinical trials. Recent studies on large SSc cohorts have shown that lowering the upper threshold of mRSS as a study inclusion criterion leads to cohort enrichment with patients with progressive skin disease. Limitations of these studies were lack of racial diversity and low proportion of patients with anti-RNA-Polymerase III (Pol3) antibodies.

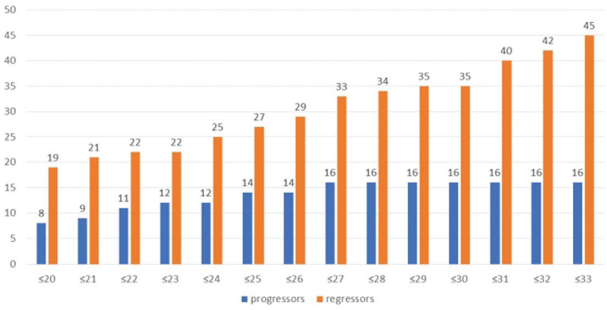
Objectives: As the Texas-based GENISOS is an ethnically diverse cohort and includes a large proportion of Pol3-positive patients, this study aimed to assess the effect of different mRSS cut-off values at baseline on progression of skin fibrosis after one year of follow-up.

Methods: We extracted data from GENISOS for patients fulfilling the 1980 ACR criteria for SSc and the Le Roy criteria for diffuse cutaneous SSc, who had a mRSS ≥7 at inclusion and a follow-up visit with documented mRSS at 12±2 months. Progressors were defined as having an increase in mRSS >5 points and ≥25% from the baseline to 2nd visit, while regressors were defined as having a decrease in mRSS of >5 points and ≥25%. To identify the optimal cut-off of baseline mRSS that yields the highest sensitivity for progressive skin fibrosis, we developed ROC curves and logistic regression models with "progression" as outcome variable and a binary variable of baseline mRSS cut-off point as predictor.

Results: We identified 152 patients (age and disease duration [median, Q1-Q3, years] 49.5, 40.2–57.3 and 2.2, 1.1–3.3 respectively, 22.4% males) who matched the inclusion criteria. The proportion of patients of African American ethnicity was 31/152 and 50/152 were Pol3-positive patients, both substantially higher than in European cohorts.

After one year, 17 patients (11.2%) classified as progressors and 51 (33.6%) as regressors. Progressors were more frequently positive for anti-topoisomerase antibodies (37.5% vs. 15.3%, p=0.028), negative for anti-Pol3 antibodies (93.8% vs. 62.3%, p<0.012), had a shorter disease duration (median, Q1-Q3: 1.3, 0.5–2.2 vs. 2.4, 1.1–3.5 years, p<0.005) and lower mRSS (median, Q1-Q3: 21, 11–25 vs. 24, 16–31, p<0.012) than non-progressors.

Sixteen of 17 progressors, but only 33 of 51 regressors had a baseline mRSS ≤27. The mRSS cut-off of ≤27 had the highest probability of progression (odds ratio 9.1, 95% confidence interval 1.2–70.9, p<0.035, area under the curve 0.652). Using this cut-off as an inclusion criterion (vs. no cut-off) would have included 94% of all progressors, but only 65% of all regressors and 67% of all patients. The figure 1 displays absolute numbers of progressors and regressors at 1 year for each mRSS cut-off.



Conclusions: This analysis reconfirmed, in a population rich in patients of African American origin and with high prevalence of Pol3 antibodies, that setting a lower upper threshold of mRSS at study inclusion increases the proportion of progressors and reduces the absolute number of regressors. This confirms that this recruitment strategy should be used for clinical trial design in early diffuse SSc.

Acknowledgements: The authors wish to thank all GENISOS investigators and patients.

Disclosure of Interest: C. Mihai Grant/research support from: Actelion Pharmaceuticals Ltd, Abbvie, Speakers bureau: Roche, Geneva Romfarm, R. Dobrota Grant/research support from: Actelion Pharmaceuticals Ltd, Pfizer, S. Assassi Grant/research support from: U.S. National Institutes of Health-National Institute of Arthritis and Musculoskeletal and Skin Diseases, U.S. DOD Peer Reviewed

Medical Research Program, Consultant for: Boehringer-Ingelheim, M. Mayes Grant/research support from: U.S. National Institutes of Health-National Institute of Arthritis and Musculoskeletal and Skin Diseases, U.S. DOD Peer Reviewed Medical Research Program, Consultant for: Boehringer-Ingelheim, Genentech, Astellas, Mitsubishi-Tanabe, O. Distler Grant/research support from: Actelion, Bayer, Boehringer Ingelheim, Mitsubishi Tanabe Pharma, Roche, Consultant for: Actelion, Bayer, BiogenIdec, Boehringer Ingelheim, ChemomAb, espeRare foundation, Genentech/Roche, GSK, Inventiva, Italfarmaco, Lilly, medac, MedImmune, Mitsubishi Tanabe Pharma, Pharmacyclics, Novartis, Pfizer, Sanofi, Sinoxa, UCB

DOI: 10.1136/annrheumdis-2018-eular.5077

THU0396 COMBINED POSITRON EMISSION TOMOGRAPHY AND MAGNETIC RESONANCE IMAGING FOR THE ASSESSMENT OF SYSTEMIC SCLEROSIS GASTROINTESTINAL INVOLVEMENT

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Background: The gastrointestinal (GI) tract is affected in 90% of patients with systemic sclerosis (SSc), a disease characterised by excessive fibrosis. Baseline GI involvement is an independent predictor of 2 year mortality in patients with early diffuse cutaneous SSc. There is an urgent need to develop non-invasive methods of assessing SSc GI involvement for early diagnosis and monitoring. Novel non-invasive tools such as fluorodeoxyglucose-positron emission tomography (FDG-PET) and magnetic resonance imaging (MRI) have been used in oncology. Development of a new MRI sequence, T1 MOLLI (modified look-locker inversion recovery) mapping, has been used in cardiac imaging for detection and quantification of diffuse fibrosis.
Objectives: In this pilot study comparing SSc patients with healthy controls, we investigated whether FDG-PET-MRI is able to detect fibrosis and inflammation associated with SSc GI tract involvement.
Methods: We recruited 16 patients fulfilling the 2013 ACR/EULAR criteria for SSc and 15 healthy age-matched (within 5 years) controls. Severity of GI involvement was determined by the total Gastrointestinal Tract score (GIT, from University of California Los Angeles Scleroderma Clinical Trials Consortium).
All subjects fasted 6 hours prior and had non-spicy low-residue diet 3 days prior. Subjects were injected with FDG (6mCi) 1 hour prior and 10 mg hyoscine butylbromide (to reduce peristalsis) immediately before scanning. Breath-hold native T1 MOLLI mapping was acquired. FDG uptake was quantified by specific uptake value (SUV). All SSc patients and 5 controls underwent PET-MRI protocol. The remaining 10 controls only had MRI scanning. Student t-test was performed and statistical significance was taken to be $p<0.05$.
Results: Demographics and clinical features of our study cohort are shown in table 1. Mean T1 values on MRI for the large and small bowels were significantly higher in SSc patients than healthy controls (large bowel: 1113±189 ms vs 856 ±182 ms respectively, p=0.0006; small bowel: 1331±246 ms vs 1169±123 ms respectively, p=0.0296), indicating the presence of GI fibrosis.
Mean PET SUV values for the large bowels were also higher in SSc patients than healthy controls (1.12±0.23 vs 0.82±0.23 respectively, p=0.0217).

Abstract THU0396 – Table 1. Demographics and clinical features

	SSc patients (n=16)	Controls (n=15)
Limited/Diffuse SSc, n	11/5	Not applicable
Female, n (%)	14 (87.5%)	11 (73.3%)
Age, years	49.2±13.9	45.3±14.4
Mean disease duration from Raynaud's phenomenon onset, years	6.1±7.3	Not applicable
Mean disease duration from non-Raynaud's phenomenon onset, years	6.6±7.4	Not applicable
Mean GIT score	0.43±0.31	0

Conclusions: MRI T1-MOLLI mapping demonstrated evidence of bowel fibrosis in SSc patients. FDG-PET showed increased large bowel inflammation in patients. FDG-PET-MRI may potentially be a useful diagnostic and monitoring tool for SSc GIT disease.
Disclosure of Interest: None declared
DOI: 10.1136/annrheumdis-2018-eular.4410

THU0397 THE PROGNOSTIC VALUE OF AUTOANTIBODIES IN SYSTEMIC SCLEROSIS AND A TWO-YEAR FOLLOW-UP OF FORCED VITAL CAPACITY

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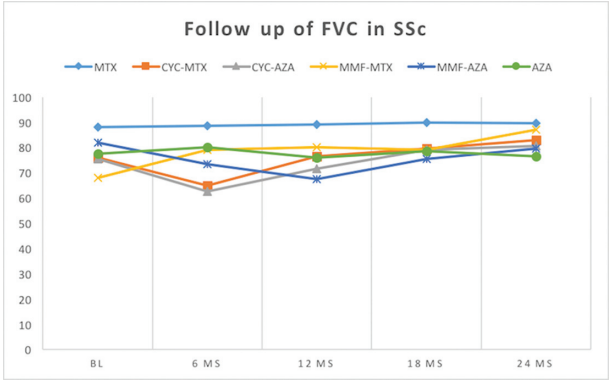
Background: Systemic sclerosis (SSc) is a connective tissue disease involving the skin and internal organs of the body. Affection of the lungs and the vascular system significantly increases the morbidity and mortality. Controlling disease progression represents a challenge in clinical practice.
Objectives: We aimed to address prognostic factors of disease activity and study the progress of interstitial lung disease (ILD) under conventional disease modifying anti-rheumatic drugs (DMARDs) therapy.
Methods: Data of SSc patients (limited or diffuse) followed up in the Rheumatology Department Clinics throughout the past 2 years were collected for a retrospective study. The positivity of Antinuclear (ANA), Anti-centromere (ACA) and Anti-Scl70 antibodies was gathered from patients' data. Disease activity was assessed by the European Scleroderma Study Group (EScSG) activity index. Forced vital capacity (FVC) was used to mark the progress of ILD. Friedman and Wilcoxon signed rank tests were used for comparison of paired data as appropriated. Mann-Whitney U test, Kruskal-Wallis test and Chi-Square test were used to compare between two or more groups.
Results: The data of 42 SSc patients (59.5% limited SSc and 40.5% diffuse SSc) with a mean age 40±12 years were enrolled. 83.3% of the patients showed ANA positivity. ACA was positive in 28.6% of the patients and Anti-Scl70 in 23.8% while 47.6% of the patients were negative for both. DMARDs were indicated according to organ involvement, and changes were made according to breakthrough events. Low scores of EScSG were noticed in the ACA +ve group compared to intermediate scores in the Scl70 +ve group and high scores in the negative group at baseline (p=0.082) and 24 month follow-up (p=0.045). The frequency of pitting digital ulcers at baseline was lowest in the ACA +ve group compared to the highest frequency in the negative group (p=0.026), however, there was no difference between the groups at the 24 month follow-up. ANA did not affect the activity throughout the studied period. Follow up of FVC in the two years with different DMARDs is illustrated in figure 1. Patients followed on methotrexate (MTX) after cyclophosphamide (CYC) or mycofenolate (MMF) had raised FVC (p=0.033 and p=0.054 respectively) comparable to azathioprine (AZA) after CYC or MMF (p=0.031 and p=0.27 respectively).



Conclusions: ACA is proposed to be a marker of low disease activity and good response to therapy. Despite the risk of inducing ILD, MTX maintained a favourable effect on FVC throughout a follow-up period.

Disclosure of Interest: None declared
DOI: 10.1136/annrheumdis-2018-eular.4113

THU0398 UNEXPLAINED IRON DEFICIENCY IS FREQUENT IN SYSTEMIC SCLEROSIS

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Background: Prevalance of iron deficiency (ID) in systemic sclerosis (SSc) is unclear and can occur related to several causes.
Objectives: This cross sectional study aims to analyse association between ID and disease characteristics in SSc patients who does not have an overt cause for ID.
Methods: We identified 227 consecutive SSc patients who had iron laboratory studies (serum iron, total iron binding capacity and ferritin) with concurrent full blood count and serum C-reactive protein (CRP) measurement between May