Objectives: We aim in our 3 years observational study to evaluate the predictive role of ILC2 in SSc patients.

Methods: We conducted an observational retrospective study on 52 patients with SSc fulfilling the 2013 ACR/EULAR classification criteria. Yearly clinical, laboratory and investigational data according to EUSTAR recommendations were collected. Blood samples collected between 15.09.2014 and 15.01.2015 were analyzed by flow cytometry and ILC2 counts were measured. The predictive value of ILC2 during a 3-year follow-up was analyzed using SPSS 21.0.

Results: 52 patients were included in the study, 78% female, 63% limited cutaneous SSc with a mean follow-up time of 2.85 ± 1.28 years. At baseline we have shown that circulating ILC2s are significantly increased compared to gender and age-matched healthy controls. Increased numbers of ILC2s significantly correlated with worsening of mRSS calculated by five point increase in mRSS or 25% increase from baseline ($p < 0.001$; 95% CI 1.39 – 3.26). ILC2 counts also correlated with 5% decrease of diffusion capacity of carbon monoxide (DLCO) during the follow-up time ($p < 0.0001$; 95% CI 1.83 – 3.49). Worsening of forced vital capacity (FVC) assessed as 5% decrease over 2 years was also significantly correlated with an increased number of ILC2s ($p < 0.0001$; 95% CI 1.27 – 3.04). In contrast, we did not find any correlation regarding increase in pulmonary arterial pressure assessed by echocardiography. Although new appearance of digital ulcers could not be predicted by ILC2 counts, increased numbers of ILC2s were correlated with digital ulcers at follow-up.

Conclusion: Here, we provide first evidence for a role of ILC2s as potential prognostic marker of disease progression in SSc.

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SAT0343

NUTRITIONAL STATUS OF SYSTEMIC SCLEROSIS PATIENTS: A PILOT STUDY

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Background: Gastrointestinal involvement (GI) in systemic sclerosis (SSc) is one of the major disease burdens. Its consequences on the nutritional status of SSc patients and their quality of life is poorly evaluated during routine check-ups. Since malnutrition is an important cause of morbidity and mortality, addressing this issue seems necessary.

Objectives: The aim of this study was to evaluate the risk of malnutrition in SSc patients and to identify potential associations between the risk of malnutrition and clinical features or laboratory parameters.

Methods: All patients aged >18 years old with a definite diagnosis of SSc according to the 2013 ACR/EULAR classification criteria from the EUSTAR Center 16 and ERN ReCONNET cohort of the County Emergency Clinical Hospital Cluj-Napoca were included in the study. Patients with localized scleroderma, scleroderma sine scleroderma, overlap syndromes and mixed connective tissue disease were excluded. Clinical and laboratory data was collected from the EUSTAR database and medical charts. A telephone survey was conducted and patients were interviewed using the Malnutrition Universal Screening Tool (MUST) questionnaire.

Results: 75 patients were eligible for the study. Female to male ratio was 10:1 with an almost equal distribution among limited (57%) and diffuse (43%) SSc subtypes. The most prevalent autoantibodies were anti-TOPO-I and anti-centromere. GI symptoms were reported in 48.6% patients out of which 86% SSc patients underwent further evaluation by upper GI endoscopy. Abnormal endoscopic findings, such as esophagitis, Barrett esophagus and gastritis were identified in 80% patients. Most patients had a low risk of malnutrition (93%) with only a minority carrying a medium (6%) or high (1%) risk. No significant association was demonstrated between MUST score and the extent of cutaneous involvement (limited SSc versus diffuse SSc; $p=0.39$), presence of GI symptoms ($p=0.35$), presence of abnormal endoscopic findings ($p=0.45$) or presence of anemia ($p=0.83$).

Conclusion: The majority of SSc patients from this cohort exhibited a low risk of malnutrition. These results are contradictory to previous literature reports. A possible explanation is that the MUST score is a dynamic screening tool and therefore interviewing patients with a stable disease (outpatient care) versus patients with active disease (inpatient care) might lead to different results. Another limitation of this study is the small number of patients included. This is a pilot study. We aim to further extend the study population to the other EUSTAR cohorts and to prospectively evaluate these patients in an inpatient care setting.

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SAT0344

LIMITED JOINT MOBILITY OF HAND IN SYSTEMIC SCLEROSIS PATIENTS BY USING "PRAYER" AND "TABLE TOP" SIGNS

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Background: Limited joint mobility (LJM) is a musculoskeletal disorder caused by flexion contractures of hand is a common complication in systemic sclerosis (SSc) patients. The distal parts of the upper limb (hands and fingers) is the most involved site in SSc.

Objectives: In this study, we aimed to evaluate LJM in SSc patients and to determine the relationship between the clinical features of the disease.

Methods: A total of 113 patients (>18 years old) diagnosed with diffuse cutaneous systemic sclerosis (DcSSc) and limited cutaneous systemic sclerosis (LcSSc) and 104 healthy controls were included in this study. LJM was evaluated with "prayer sign" and "table top sign" tests. LJM staging was done by Rosenbloom classification method(1, 2). LJM (+) and LJM (-) patients were compared in terms of demographic findings (gender, age and duration of disease), laboratory results (ESR, CRP, ANA, anti-topoisomerase I and anti-centromere) and modified Rodnan Skin Score (mRSS) results.

Results: In our study, a total of 113 patients diagnosed with SSc and 104 healthy controls with similar age and gender distribution were included. While LJM (+) was detected in 75 (66.4%) (LcSSc = 38, DcSSc = 37) of the patients diagnosed with SSc, LJM (mild) (+) was detected in 3 (2.8%) of the control group. One of these people had right 2nd DIF joint contracture due to osteoarthritis, and 1 patient was found to have simple contractures due to minor hand injury previously (Table 1). A statistically significant difference was observed in between LcSSc and DcSSc patients according to the presence of LJM ($p<0.001$) (Table 2). There was a moderate positivity relationship between LJM and mRSS (LcSSc: $r=0.449$ ve $p<0.001$, DcSSc: $r= 0.565$ ve $p<0.001$) (Figure 1).

Table 1. Comparison of demographic findings between SSc and Control group

	SSc Group (n=113)	Control Group (n=104)	p value
Age, year	57.02 ± 11.58	58.47 ± 11.26	0.061
Gender (F / M)	98 (86.7) / 15 (13.3)	65 (62.5) / 39 (37.5)	0.064
CRP (mg/L)	5.45 ± 5.39	2.14 ± 1.12	<0.001
ESR (mm/hr)	25.19 ± 18.9	14.46 ± 10.09	0.024
Smoking, n (%)			
Smoker	89 (78.8)	70 (67.3)	0.464
Non-Smoker	24 (21.2)	34 (32.7)	
LJM (Absent / Present)			
Present	75 (66.4)	3 (2.8)	<0.001
Absent	38 (33.6)	101 (97.2)	
Rosenbloom classification	LcSSc (n=71) (%)	DcSSc (n=42) (%)	Total (n=113) (%)
Normal	46.5	11.9	33.6
Mild	22.5	14.3	19.5
Moderate	23.9	33.3	27.4
Severe	7.1	40.5	19.5

Table 2. Comparison of demographic and clinical findings LJM(-) and LJM(+) in SSC

	LJM (-) (n=38)	LJM (+) (n=75)	p value
Age, year	54.16 ± 11.82	58.47 ± 11.26	0.061
SSc Type	n (%)	n (%)	
LcSSc, n (%)	33 (56.8)	38 (50.7)	<0.001
DcSSc, n (%)	5 (13.2)	37 (49.3)	
Gender, F/M (%)	37 (97.3) / 1 (2.7)	61 (81.3) / 14 (18.7)	0.018
Raynaud's (symptom duration), month	148 (44-456)	150 (35-588)	0.990
Non-Raynaud (symptom duration), month	108 (28-458)	138 (38-447)	0.132
mRSS, median	2 (0-14)	8 (0-36)	<0.001
CRP (mg/L)	4.21 ± 4.48	6.08 ± 5.71	0.069
ESR (mm/hr)	19.74 ± 10	27.95 ± 21.6	0.270
Renal crisis, n (%)	1 (2.6)	4 (5.3)	0.662
PAH, n (%)	8 (21.1)	14 (18.7)	0.762
ANA positivity, n (%)	36 (94.7)	70 (93.3)	1
Anti-centromere positivity, n (%)	18 (47.4)	19 (25.3)	0.01
Anti-topoisomerase-1, n (%)	8 (21)	34 (45.3)	0.01
Smoking, n (%)	n (%)	n (%)	
Non-smoker	30 (78.9)	59 (78.7)	0.970
Smoker	8 (21.1)	16 (21.3)

Figure 1.

Conclusion: In our study, it was found that LJM staging positively correlated with mRSS and DcSSc patients had more severe LJM findings than LcSSc. We conclude that "prayer sign" and "table top sign" tests used in hand evaluation in SSc patients have similar clinical results with mRSS and can be easily performed in daily practice in about 3 minutes.

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SAT0345

IS THERE A DIFFERENCE BETWEEN THE SEXES IN THE RATE OF PROGRESSION OF SYSTEMIC SCLEROSIS-ASSOCIATED ILD (SSC-ILD)? DATA FROM THE SENSICIS TRIAL

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Background: Previous studies suggested that male sex may be associated with a greater rate of decline in FVC in patients with SSC-ILD. In the SENSICIS trial, nintedanib reduced the rate of FVC decline over 52 weeks vs placebo.

Objectives: Analyse the rate of decline in FVC and the efficacy and safety of nintedanib in the SENSICIS trial in subgroups by sex.

Methods: Patients with SSC-ILD with first non-Raynaud symptom <7 years before screening and ≥10% fibrosis of the lungs on HRCT were randomised to nintedanib or placebo. We analysed the rate of decline in FVC (mL/year) and adverse events over 52 weeks in male and female patients.

Results: Of 576 patients, 433 (75.2%) were female. Compared with males, the female subgroup included a smaller proportion of White patients (64.7% vs 74.8%), a smaller proportion on mycophenolate at baseline (46.9% vs 53.1%), a greater proportion of ATA positive patients (63.3% vs 53.1%), and had a lower mean weight at baseline (66.6 vs 79.1 kg). FVC % predicted (72.8% vs 71.7%) and mRSS (11.2 vs 10.8) were similar in females and males. The adjusted annual rate of decline in FVC in the placebo group was numerically greater in male than female patients (-126.8 [SE 29.0] vs -82.0 [16.2] mL/year). The estimated effect of nintedanib vs placebo on reducing the rate of decline in FVC was numerically more pronounced in males than females (difference: 58.6 [95% CI -18.0, 135.1] vs 34.6 [-9.3, 78.4] mL/year), but the interaction p-value did not indicate heterogeneity in the treatment effect between subgroups (p=0.59). Among nintedanib-treated patients, diarrhoea was reported in similar proportions of females and males (74.7% vs 79.1%); nausea, vomiting and liver test abnormalities were reported in greater proportions of females vs males (35.3% vs 19.4%, 28.1% vs 13.4%, and 15.4% vs 9.0%), while serious adverse events were more frequent in males (32.8% vs 21.3%). In the nintedanib and placebo groups, respectively, adverse events leading to treatment discontinuation were reported in 16.7% and 8.5% of females and 13.4% and 9.2% of males.

Conclusion: In the SENSICIS trial in patients with SSC-ILD, the annual rate of decline in FVC in the placebo group was numerically greater in male than female patients. The rate of FVC decline was lower with nintedanib than placebo both in males and females. The safety profile of nintedanib was similar between males and females.

Figure. Rate of decline in FVC (mL/year) over 52 weeks in subgroups by sex in the SENSICIS trial

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