patients with myopathy. The FVC improved or stabilized in 22% and 56% of ILD, respectively, and the DLCO stabilized in 66.70% (not significant). TACAR stabilized in 55.56% of ILD, with some degree of worsening in the rest. Outcomes evolution in the Table:

Functional Parameters	Basal (mean±SD)	6-12 m (mean±SD)	CI 95%	P	Final (mean±SD)	CI 95%	P
FVC (n=9)	63.2±16.8	70.3±18.6	[-13.3–6.1]	0.40	71.9±21.1	[-14.4–5.9]	0.36
DLCO (n=9)	46.3±18.5	46.1±20.3		0.34	45.2±22.03	[-3.9–12.8]	0.24
Clinical Parameters Basal (mean±SD)	Final (mean±SD)	CI 95%	P				
mRSS (n=11)	13.1±7.2				8.8±7.1	[0.9–9.4]	0.02
CK (n=3)	1786.7 ±1483.8				134.7±119	[-2181.9 –5485.9]	0.2

CK: Creatine kinase; SD: Standard deviation; CI: Confidence interval; m: months.

The AE were mostly mild: 13 infusion reactions (6 patients), 1 uncomplicated herpes zoster and 2 serious infections that required admission. There were no exits.

Conclusion: Our results, with a limited sample, suggest that the long-term use of RTX in real world clinical practice may be beneficial for the cutaneous, pulmonary and myopathic manifestations of SSc, with an acceptable security profile.

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FRI0265

IS AN IMPROVEMENT IN SKIN FIBROSIS ASSOCIATED WITH BETTER OUTCOME IN PATIENTS WITH SYSTEMIC SCLEROSIS? A EUSTAR ANALYSIS

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Background: In previous studies, we showed that in patients with diffuse cutaneous systemic sclerosis (dcSSc), worsening of skin fibrosis predicts later decline in lung function and worse survival. However, in many patients, an improvement of skin fibrosis is the natural course of dcSSc, and many current clinical trials are designed to show improvement of skin fibrosis rather than prevention of skin fibrosis progression.

Objectives: To investigate whether an improvement in skin fibrosis is associated with less progression of visceral organ involvement and better overall-survival during follow-up.

Methods: We evaluated patients from the European Scleroderma Trials and Research Group (EUSTAR) database with diffuse cutaneous systemic (dcSSc), baseline modified Rodnan skin score (mRSS) ≥7, valid mRSS at 12±3 months after baseline and ≥1 follow-up visit. Regression of skin fibrosis was defined as a decrease in mRSS >5 and ≥25% and progression as increase by the respective numbers from baseline to 12±3 months. Outcomes were pulmonary progression, cardiac progression, intestinal progression, new onset of scleroderma renal crisis and all-cause death using recently specified definitions (1). Associations between skin changes and outcomes were evaluated by Kaplan-Meier analysis and multi-variable Cox regression.

Results: Of 1257 included patients, 282 (22.4%) showed a regression of skin fibrosis, 883 (70.2%) were categorized as stable patients and 92 (7.3%) showed progression of skin fibrosis at 12±3 months. Median long-term follow-up for organ involvement/death was 4.2 years. Cox regression analyses indicated that skin fibrosis regression had a significantly lower probability of later FVC decline ≥10% than non-regressive (stable and progressive) patients when controlled for baseline mRSS (p=0.013). No significant association of skin fibrosis regression was found with other organ manifestations or all-cause death. Conversely, associations of skin fibrosis progression were found for later FVC decline ≥10% with a more significant p-value (p<0.001, Figure 1), and there was also an association with all cause death (p=0.026).

Conclusion: Progression of skin fibrosis is stronger associated with organ changes and all-cause death at follow up than improvement of skin fibrosis. These data suggest a prevention of progression paradigm for clinical practice. They also suggest that clinical trials designed for prevention of skin fibrosis progression are more meaningful for long-term outcome of SSc patients than trials designed to show improvement of skin fibrosis

References:

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FRI0266

THE REAL-WORLD EFFICACY OF THE 2015 EULAR/ACR RECOMMENDATIONS FOR THE MANAGEMENT OF POLYMYALGIA RHEUMATICA WITH ADDITIONAL TOCILIZUMAB THERAPY

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Background: A Part of patients with polymyalgia rheumatica (PMR) are refractory to the 2015 EULAR/ACR algorithm for the management of PMR. Recent

reports have demonstrated that tocilizumab (TCZ) may be efficacious for refractory and relapsing PMR.

Objectives: To determine the real-world efficacy of the 2015 EULAR/ACR algorithm for the management of PMR plus introduction of TCZ for refractory and relapsing PMR.

Methods: Patients who had been diagnosed with PMR according to the 2012 EULAR/ACR provisional classification criteria for PMR were recruited in the study. Registered variables included demographic data, disease characteristics, prednisolone (PSL) dosage and duration, addition of methotrexate (MTX) and TCZ, adverse effects, and clinical outcomes.

Results: There were 101 patients who had originally diagnosed as PMR (50 males and 65 females) and followed up for at least one year; the mean $\pm$ SD age at onset was 73 ± 11 years at onset, with the mean observational period being 44 ± 26 months. Their treatments were initiated with PSL of 15.5 ± 4.3 mg/day. 41 patients experienced disease recurrence after 9.6 ± 6.7 months (median 9 month) of GC therapy, while receiving PSL at 5 ± 4.5 mg/day (3.7 mg/day). Baseline factors that were associated with relapse in our cohort were higher-grade thrombocytosis and higher-dose of initial GC by multivariate analysis. In 30 of the 41 patients who failed GC monotherapy, MTX was added. Five patients reached GC-free remission, but 25 patients failed GC tapering. In such refractory patients to a combination of GC plus MTX, 8 patients agreed to add TCZ therapy, and 5 of them reached drug-free remission. At present, 67 of the total 101 patients maintained drug-free remission, but most others were still receiving low-dose GC and/or MTX ($n=17$). No significant adverse effects did not occur during therapy, except for GC-related adverse effects such as diabetes, dyslipidemia and osteoporotic fractures.

Conclusion: Our experience indicated that there is notable heterogeneity across PMR patients in terms of drug response, and the patients with severe inflammation, e.g. thrombocytosis, may need higher-dose of initial GC and addition of biologics such as TCZ on the 2015 EULAR/ACR algorithm.

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FRI0267

CLINICAL CORRELATES AND RELEVANCE OF UCLA GIT 2.0 FOR ESOPHAGITIS AND INDICATION FOR ESOPHAGOGASTRODUODENOSCOPY IN REAL-LIFE PATIENTS WITH SYSTEMIC SCLEROSIS

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Background: The gastrointestinal (GI) tract is frequently involved in systemic sclerosis (SSc). The University of California Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument 2.0 (UCLA GIT 2.0) is validated to capture GI morbidity in patients with SSc (1). The routine clinical investigation of GI involvement in these patients is not standardized and there is no consensus about when and how frequently an esophagogastroduodenoscopy (EGD) should be performed.

Objectives: The main aim of this study was to analyze the capacity of UCLA GIT 2.0 to identify patients with erosive esophagitis in an unselected, real-life SSc patients' cohort. Secondary aim was to determine whether the UCLA GIT 2.0 could discriminate SSc patients for whom an expert rheumatologist would recommend an EGD.

Methods: We selected patients fulfilling the ACR/EULAR 2013 criteria for SSc from the Zurich cohort, having completed at least once the UCLA GIT 2.0 questionnaire. We reviewed the medical charts of SSc patients from 2013 to 2019 and recorded data on EGD. We analyzed by univariable logistic regression several parameters, including UCLA GIT 2.0, considered as potentially associated with 1) the referral to EGD and 2) macroscopic esophagitis according to the Los Angeles criteria.

Results: We identified 346 patients (82.7% female, median age 63 years, median disease duration 10 years, 23% with diffuse cutaneous SSc) satisfying the inclusion criteria, who filled in 940 UCLA GIT 2.0 questionnaires.

From 940 visits, 31 were excluded because EGD was done within 3 months before completing the UCLA GIT 2.0. In the 909 remaining visits, EGD was recommended by the expert rheumatologists in 128 cases. In logistic regression, UCLA GIT 2.0 total score and some of its subscales, but also the modified Rodnan skin score (mRSS) and esophageal and stomach symptoms by past medical history, associated with the referral to EGD (Table 1).

Table 1. Logistic regression of factors associated with referral to EGD

	OR (95% CI)	p-value
mRSS	1.04 (1.01 - 1.06)	0.009
Hemoglobin (Hb)	1.00 (0.96 - 1.04)	0.978
Proton pump inhibitor (PPI)	0.37 (0.12 - 1.15)	0.086
Esophageal symptoms	3.37 (2.28 - 4.96)	<0.001
Stomach symptoms	2.93 (2.02 - 4.26)	<0.001
Reflux subscale	2.04 (1.52 - 2.73)	<0.001
Distention/bloating subscale	1.53 (1.24 - 1.89)	<0.001
Social functioning	2.20 (1.57 - 3.07)	<0.001
Emotional wellbeing	1.42 (1.03 - 1.97)	0.034
Total score of UCLA GIT 2.0	2.27 (1.55 - 3.32)	<0.001

We found data on 177 EGD performed in 150 patients, meaning that 49 EGD were performed on indication by another physician. In logistic regression, mRSS and esophageal symptoms correlated with esophagitis, while neither the total UCLA GIT 2.0 score nor the reflux subscale or any of the other subscales showed an association with esophagitis (Table 2).

Table 2. Logistic regression of factors associated with esophagitis

	OR (95% CI)	p-value
mRSS	1.09 (1.03 - 1.15)	0.001
Hb	1.03 (0.99 - 1.06)	0.126
PPI	0.52 (0.27 - 1.03)	0.059
Esophageal symptoms	2.92 (1.29 - 6.61)	0.010
Stomach symptoms	1.60 (0.80 - 3.21)	0.183
Reflux subscale	1.07 (0.60 - 1.93)	0.816
Distention/Bloating subscale	0.63 (0.39 - 1.01)	0.054
Social functioning	0.65 (0.31 - 1.35)	0.245
Emotional wellbeing	0.77 (0.36 - 1.61)	0.483
Total score of UCLA GIT 2.0	0.67 (0.28 - 1.60)	0.367

Conclusion: In a real-life setting, UCLA GIT 2.0 subscales (reflux, distention/bloating, social functioning, emotional wellbeing) and total score strongly associated with expert interpretation of gastroesophageal symptoms and consecutive referral to EGD. However, they showed no correlation with esophagitis on EGD. The main clinical association of esophagitis was the presence of esophageal symptoms.

References:

- [1] Khanna D, et al. Reliability and validity of the University of California, Los Angeles Scleroderma Clinical Trial Consortium Gastrointestinal Tract Instrument. *Arthritis Rheum.* 2009;61(9):1257-63.

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FRIDAY, 05 JUNE 2020

Spondyloarthritis - treatment

FRI0268

REMISSION IN AXIAL SPONDYLOARTHRITIS: IS THERE A DIFFERENCE BETWEEN NSAIDS AND BIOLOGICS IN THE REAL LIFE?

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Background: Randomized-controlled trials (RCTs) done in axial spondyloarthritis (AxSpA) patients have shown that remission in AxSpA and nonradiographic