inadequate or limited by side effect. Cannabidiol-CBD, is the major non-psycho-tropic component of the Cannabis sativa, recent studies on its effectiveness as an anxiolytic, anti-inflammatory, and antipsychotic drug showed promising results, in the setting of chronic pain too.

Objectives: We evaluated the efficacy of CBD drop in pain management in a cohort of SSc patients using standard rating scale VAS, PSQI and HAQ. We further assessed the safety profile and the potential use as opioid-sparing.

Methods: From January to November 2019 we consecutively enrolled 31 SSc patients (F/M 26/5, mean age 53.0±14.6SD-years) referred to our Scleroderma Unit. All patients satisfied the EULAR/ACR SSc classification criteria. All cases were complicated by painful DUs resistant to analgesics and pain was classified as severe, according to WHO guidelines. CBD drops consist of cannabis sativa seed in olive oil, 10% CBD, laboratory tested to confirm a tetrahydrocannabinol-THC level<0.3%. The CBD oil was administered sublingually twice-a-day. All patients started with CBD 3 drops twice-a-day, and progressively increased to the maximum dosage of 6 drops twice-a-day (from 27.6 g to 55.2 g dose/day). All patients continued local/systemic treatments for SSc: 24/31 subjects performed calcium-channel blockers, 31/31 prostanoids infusion, 24/31 anti-endothelin drugs. All subjects were provided with a daily diary to record self-evaluation of pain using VAS, PSQI, hours of sleep per night, use of other analgesics, eventual side effects. HAQ-DI was also administered. These indicators were assessed baseline and during follow-up. Safety of CBD was evaluated by patient's records of side effects. All data were analyzed by paired t-test. This investigation was a monocentric, prospective study. Ethical approval was obtained from the Competent Ethics Committee (protocol n. 282/15) and all participants gave written consent.

Results: CBD was administered for a mean period of 5.9±3.2SD-months. After the first month, VAS decreased from 94.80±8.72SD to 54.70±9.40SD ($p<0.0001$), PSQI decreased from 9.27±2.9SD to 4.47±1.06SD ($p<0.001$), total hours of sleep increased from 2.56±1.28 SD to 5.67±0.85SD ($p<0.0001$). The additional analgesic therapy was necessary in 22/31 patients: 6/22 only paracetamol, 12/22 paracetamol+oxycodone reducing the dosage of oxycodone at the minimum, 2/22 oxycodone 20 mg twice-a-day, 2/22 need fentanyl transdermal patch. After 3 months, VAS further reduced to 40.90±12.90, PSQI decreased to 3.1±1.4SD, the mean total hours of sleep per night was 6.10±0.79SD and the HAQ-DI decreased from 2.19±0.67SD (baseline) to 0.79±0.46SD at the last patients' evaluation. At the end of the observation, 18/31 patients (58%) showed DUs healing. We also interestingly reported improvement of dysphagia and appetite in 70%, and an improvement in constipation related to opioids in 48%. No patients experienced severe side effects in particular no psychoactive aspects. Mild side effects, namely dry mouth was referred by 9/31 (29%), mild abdominal pain and changes in appetite by 10/31 (32%). No interaction with other drugs was observed.

Conclusion: Our study suggests that oral CBD is effective and safe in maintaining analgesia in SSc patients with DUs. Furthermore, CBD could be helpful in opioids tapering and to treat dysphagia, even if these observations need focused investigations. In conclusion, CBD might be a useful tool to manage chronic pain in SSc-DUs. These data provide a compelling rationale for further research to clarify the therapeutic potential of CBD in SSc.

Disclosure of Interests: None declared

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POS0838

EPIDEMIOLOGY AND TRENDS IN SURVIVAL OF SYSTEMIC SCLEROSIS IN OLMSTED COUNTY: A POPULATION-BASED STUDY (1980-2018)

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Background: Systemic sclerosis (SSc) is a complex immune-mediated disease with heterogeneous manifestations, which is characterized by vasculopathy and fibrosis of the skin and visceral organs. Mortality associated with SSc exceeds that of other rheumatic diseases, though population-based studies assessing recent trends in survival are lacking.

Objectives: We aimed to determine the incidence and prevalence of physician-diagnosed SSc in a population-based cohort over a 39-year time period, and assess for trends in survival over time.

Methods: Medical records of patients with a diagnosis or suspicion of SSc in a geographically well-defined area from Jan 1, 1980 to Dec 31, 2018 were reviewed to identify incident cases of SSc. Cases were defined by physician diagnosis of SSc, and fulfillment of the 2013 ACR/EULAR classification criteria was ascertained. Prevalent cases of SSc on Jan 1, 2015 were also identified. Incidence and

prevalence rates were age- and sex-adjusted to the 2010 U.S. white population. Survival rates were compared with expected rates in the general population.

Results: 85 incident cases of SSc (91% female, mean age 55.4 ± 16 y) and 49 prevalent cases on Jan 1, 2015 were identified. Patients had a mean 11.7 (SD 9.4) years of follow-up available. The overall age and sex adjusted annual incidence for 1980-2018 was 2.5 (95% CI: 2.0-3.1) per 100,000 population, with no change in incidence over time ($p=0.32$). The age-adjusted incidence was 4.4 (95% CI: 3.4-5.4) for females, and 0.56 (95% CI: 0.16-0.96) for males per 100,000 population. The age- and sex-adjusted prevalence on Jan 1, 2015 was 43.6 (95% CI: 31.3-55.8) per 100,000 population.

77 (91%) patients fulfilled the 2013 classification criteria; 38 (45%) fulfilled 1980 criteria. 70 (82%) had limited cutaneous involvement, 12 (14%) had diffuse cutaneous involvement, and 3 (4%) had sine scleroderma. At SSc diagnosis, 80 (94%) patients had Raynaud's, 43 (51%) had sclerodactyly, 39 (46%) had telangiectasias, 14/48 (29%) had abnormal nailfold capillaries, 16/35 (46%) had digital ulcers or fingertip scarring, 8 (9%) had interstitial lung disease (ILD), and 7 (8%) had pulmonary arterial hypertension (PAH). 77/82 patients (91%) had a positive antinuclear antibody. 44 (52%) had a known SSc-related autoantibody: 32 (73%) with anti-centromere, 9 (20%) with anti-Scl-70, and 4 (9%) with anti-RNA-polymerase III.

Survival was 77% (95% CI: 69-87) at 5 years, 66% (95% CI: 56-78) at 10 years, and 42% (95% CI: 30-57) at 20 years, with no evidence of improved survival over time ($p=0.46$). Age (Hazard ratio [HR]: 1.49 per 10 year increase; 95% CI 1.19-1.88), smoking at time of diagnosis (HR: 2.37; 95% CI: 1.05-5.34), digital ischemia (HR: 2.54; 95% CI: 1.33-4.87), ILD (HR: 4.00; 95% CI: 2.11-7.59), and PAH (HR: 4.30; 95% CI: 2.24-8.25) had significant associations with mortality. Survival of patients with SSc was poorer than the general population (standardized mortality ratio: 2.48; 95% CI: 1.76-3.39).

Conclusion: The average incidence of SSc in this population-based cohort spanning 39 years was 2.5 per 100,000 population, with no change in incidence over time. Age, smoking, digital ischemia, ILD and PAH were risk factors for poorer survival. Overall survival for patients with SSc is worse than that of the general population and shows no improvement over time, suggesting continued need for improved diagnostic and treatment measures.

Figure 1. Survival of 85 Olmsted County residents with SSc compared with expected survival rates from Minnesota lifetables (observed: solid line, expected: dashed line).

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POS0839

BODY COMPOSITION AND FREQUENCY OF SARCOPENIA IN PATIENTS WITH SYSTEMIC SCLEROSIS

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Background: Sarcopenia can be age associated (primary form) or secondary to chronic disorders, including rheumatic inflammatory disorders. Systemic sclerosis (SSc) is a chronic autoimmune rheumatic disease characterized by widespread vasculopathy, progressive fibrosis of the skin and other internal organs, such as lung, kidneys, gastrointestinal tract, cardiovascular system. Different from the other chronic rheumatic inflammatory disorders, sarcopenia has not been well evaluated in SSc patients.

Objectives: To assess the body composition (BC) and to identify the frequency of sarcopenia (SP) in SSc patients.

Methods: A total of 44 women who met the ACR/EULAR 2013 classification criteria were included. Mean age was 53.2±8.8 years. The median disease duration was 7.0 [4.0;12.0] years. 26 (59.1%) patients had limited and 18 (40.9%) - diffuse cutaneous subtype. Body composition was measured using Dual-energy X-ray absorptiometry (DXA) of whole body. The appendicular lean mass index (ALMI) was calculated as the ratio of appendicular lean mass (ALM) to height (kg/m²). Handgrip measurement and chair stand test were performed. Physical function was measured with the Short Physical Performance Battery (SPPB). SP was diagnosed in agreement with the 2019 revised consensus on definition and diagnosis of SP of the European Working Group on Sarcopenia in Older People 2 (EWGSOP2): handgrip <16kg, chair stand test > 15 seconds for 5 rises, ALM <15 kg or ALMI <5.5 kg/m². Severe SP was detected if the patient additionally had gait speed ≤0.8 m/s or SPPB ≤ 8-point score. Overfat was defined as body fat percentage >35%.

Results: The median bone mineral content was 2.0 [1.8; 2.2] kg, total lean mass - 39.5 [35.7; 45.5] kg, ALM - 16.3 [14.5; 19.4] kg, ALMI - 6.5 [5.7; 7.2] kg/m², trunk fat mass - 13.5 [9.1; 16.7] kg and total fat mass - 26.6 [20.1; 34.5] kg. Body fat percentage was 38.8% [34.2; 42.7]. 9 (20.5%) women had low ALM and low ALMI, 6 (13.6%) - only low ALM. Healthy BC was found in 5 (11.3%), low ALM or low ALMI - in 7 (15.9%), overfat - in 24 (54.5%), low ALM + overfat - in 8 (18.2%) patients. We found no differences in BC between SSc patients with limited and diffuse cutaneous subtype. Low muscle strength (SP probable) was found in 21 (47.7%) women, meanwhile confirmed SP (low muscle strength and muscle mass) was diagnosed in 10 (22.7%) patients, among them 5 (11.4%) persons had severe SP. No significant difference in SP frequency among patients with limited and diffuse cutaneous SSc 4 (15.4%) and 6 (33.3%), respectively, (p=0.27). Osteoporosis was found in 6 (60%) patients with SP without differences in SSc subtypes.

Conclusion: Healthy BC was found only in 11.3% cases, while overfat - in 72.7% and low ALM - in 34.1% SSc patients. SP was detected in 22.7% of women, among them in half of cases - severe SP, without any differences between the limited and diffuse subtypes of the disease.

Disclosure of Interests: None declared

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POS0840

RISK OF MALNUTRITION IN PATIENTS WITH SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD): FURTHER ANALYSES OF THE SENSICIS TRIAL

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Background: Gastrointestinal (GI) involvement is common in patients with SSc and may lead to weight loss and malnutrition. In the SENSICIS trial in patients with SSc-ILD, nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) over 52 weeks, with mainly GI adverse events. The Malnutrition Universal Screening Tool (MUST) was developed to identify adults who are at risk of malnutrition and has been used in studies of patients with SSc.

Objectives: To evaluate nutritional status over 52 weeks in the SENSICIS trial based on a modified MUST score.

Methods: The SENSICIS trial enrolled patients with SSc-ILD with first non-Raynaud symptom ≤7 years before screening, extent of fibrotic ILD ≥10% on HRCT and FVC ≥40% predicted. Patients who had taken a stable dose of mycophenolate for ≥6 months were eligible to participate. Patients were randomised to receive nintedanib 150mg bid or placebo. Dose reductions to 100mg bid and treatment interruptions were allowed to manage adverse events and specific recommendations were provided for the management of diarrhoea. We calculated a modified MUST score at baseline and weeks 12, 24, 36 and 52 based on (A) BMI, (B) weight loss (week 12 vs baseline; week 24 vs week 12; week 36 vs week 24; week 52 vs week 36), and (C) a surrogate for acute disease effect (if

the patient had any serious adverse event that led to hospitalisation between weight assessments and received ≥1 medication from the WHO classification code for "solutions for parenteral nutrition" for ≥5 days). MUST score at baseline was based solely on BMI. With scores ranging from 0 to 6, the risk of malnutrition is defined as low (score = 0), medium (score = 1) or high (score ≥2).

Results: Among 576 patients who received nintedanib (n=288) or placebo (n=288), mean (SD) age at baseline was 54.0 (12.2) years, weight was 69.7 (15.9) kg and BMI was 25.9 (5.0) kg/m²; median time since onset of first non-Raynaud symptom was 3.4 years; and 75.2% of patients were female. In the nintedanib and placebo groups, respectively, MUST scores suggested that 74.0% and 78.1% of patients were at low risk of malnutrition at baseline and remained at low risk at their last measurement (Table 1). At weeks 12 and 52, respectively, mean (SD) MUST scores were 0.3 (0.6) and 0.4 (0.7) in the nintedanib group and 0.2 (0.5) and 0.2 (0.6) in the placebo group. At weeks 12, 24, 36 and 52, respectively, the proportions of patients at low risk of malnutrition were 81.8%, 80.9%, 72.9% and 76.5% in the nintedanib group and 86.6%, 86.4%, 88.3% and 80.8% in the placebo group; the proportions at medium risk were 12.1%, 13.1%, 18.0% and 13.5% in the nintedanib group and 8.5%, 8.6%, 5.8% and 13.1% in the placebo group; and the proportions of patients at high risk were 6.1%, 5.6%, 8.3% and 9.6% in the nintedanib group and 4.9%, 4.3%, 4.7% and 5.4% in the placebo group.

Table 1. Risk of malnutrition at baseline and at last assessment over 52 weeks in the SENSICIS trial.

Last assessment of risk	Nintedanib (n=288)				Placebo (n=288)			
	Baseline risk				Baseline risk			
	Low	Medium	High	Total	Low	Medium	High	Total
Low	213 (74.0)	1 (0.3)	0	214 (74.3)	225 (78.1)	7 (2.4)	0	232 (80.6)
Medium	31 (10.8)	8 (2.8)	0	39 (13.5)	20 (6.9)	14 (4.9)	4 (1.4)	38 (13.2)
High	13 (4.5)	8 (2.8)	7 (2.4)	28 (9.7)	3 (1.0)	2 (0.7)	10 (3.5)	15 (5.2)
Missing	7 (2.4)	0	0	7 (2.4)	3 (1.0)	0	0	3 (1.0)
Total	264 (91.7)	17 (5.9)	7 (2.4)	288 (100)	251 (87.2)	23 (8.0)	14 (4.9)	288 (100)

MUST score ranges from 0 to 6. Score of 0 = low risk; score of 1 = medium risk; score of ≥2 = high risk. Baseline MUST score was based solely on BMI.

Conclusion: In the SENSICIS trial, scores based on a modified MUST indicated that most patients treated with nintedanib were at low risk of malnutrition at baseline and remained at low risk over 52 weeks. The proportions of patients at high risk of malnutrition were low but were numerically greater in patients who received nintedanib than placebo. Management of disease manifestations and gastrointestinal adverse events that may be associated with weight loss is important to reduce the risk of malnutrition in patients with SSc-ILD treated with nintedanib.

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POS0841

RISK FACTORS OF LOW BONE MINERAL DENSITY IN WOMEN WITH SYSTEMIC SCLEROSIS

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