Background: Chronic inflammatory rheumatic diseases are risk factors of bone loss and fractures. Systemic sclerosis (SSc) has been recognized to be another potential inflammatory joint disease that may affect bone tissue.

Objectives: to evaluate bone mineral density (BMD) and risk factors of low BMD in women with SSc.

Methods: 173 women, among them 110 postmenopausal (median age 60[55,63] years) and 63 premenopausal (median age 35[31,44] years). BMD was measured at lumbar spine (LS), femoral neck (FN) and total hip (TH) by dual energy X-ray absorptiometry (DXA, Hologic 4500A). Low BMD was diagnosed if the T-score was < -1.0 standard deviation (SD) in postmenopausal women and if the Z-score was < -2.0 SD in premenopausal women. The relationship between BMD and SSc patients' characteristics was evaluated using univariate linear regression analysis.

Results: Low BMD was found in 66% patients: 79% - in postmenopausal and 18% - in premenopausal women. Among postmenopausal persons osteoporosis was discovered in 47% and osteopenia - in 32% cases. In postmenopausal woman BMD of LS, FN and TH were associated with body mass index (BMI) ($\beta=0.27$, $p=0.010$; $\beta=0.47$, $p<0.001$ and $\beta=0.45$, $p<0.001$, respectively), duration of glucocorticoids (GCs) using ($\beta=-0.31$, $p=0.008$; $\beta=-0.34$, $p=0.003$ and $\beta=-0.27$, $p=0.022$, respectively); BMD of FN and TH with C-reactive protein ($\beta=-0.32$, $p=0.016$ and $\beta=-0.29$, $p=0.029$, respectively) and LS BMD with current and cumulative GCs dose ($\beta=-0.24$, $p=0.039$ and $\beta=-0.29$, $p=0.014$, respectively). In premenopausal women BMD of LS, FN and TH were associated with BMI ($\beta=0.51$, $p<0.001$; $\beta=0.45$, $p=0.003$ and $\beta=0.47$, $p=0.002$, respectively), duration of GCs using ($\beta=-0.45$, $p=0.004$; $\beta=-0.47$, $p=0.003$ and $\beta=-0.48$, $p=0.002$, respectively) and GCs cumulative dose ($\beta=-0.48$, $p=0.002$; $\beta=-0.51$, $p=0.001$ and $\beta=-0.46$, $p=0.004$, respectively); BMD of FN and TH with 25(OH)D level ($\beta=0.52$, $p=0.008$ and $\beta=0.54$, $p=0.005$, respectively), and LS BMD with SSc duration ($\beta=-0.44$, $p=0.004$).

Conclusion: Low BMD was diagnosed in 66% of women with SSc. Low BMI, GCs cumulative dose and duration of GCs using were independent risk factors for low BMD in both premenopausal and postmenopausal persons. Additional factors as SSc duration and low vitamin D level were found out for premenopausal and current GCs dose and C-reactive protein level for postmenopausal women.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1339

POS0842

LUNG ULTRASOUND TO ASSESS THE SEVERITY OF INTERSTITIAL LUNG DISEASE IN SYSTEMIC SCLEROSIS

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Background: Interstitial lung disease (ILD) is one of the most common complications and one of the main causes of morbidity and mortality in Systemic Sclerosis (SSc). High-resolution computed tomography (HRCT) is the gold standard for the diagnosis of ILD and it allows its quantification. Among semi-quantitative methods, Goh et al proposed a semi-quantitative scoring system to visually quantify ILD extent, with categorical cut-off of 20% to distinguish limited and extensive parenchymal involvement with prognostic implications. More recently, the use of radiomics has allowed the objective quantification of ILD through the use of dedicated software, which calculate different parameters of lung density. Given the exposure to ionizing radiation that the procedure entails, other methods of ILD evaluation are being studied, among which lung ultrasound (LUS) identifies the B-lines as a main feature of ILD. So far, different evidences have proposed the use of LUS for the screening of ILD, even in the early phases of the disease and in subclinical lung involvement.

Objectives: the aim of this study is to test the role of LUS in quantifying the severity of SSc-ILD, evaluated with both semi-quantitative visual radiological and quantitative radiomic scores.

Methods: Adult SSc patients classified according to the ACR/EULAR 2013 criteria patients were assessed with pulmonary function test (PFTs), lung ultrasound and HRCT over 60 days. CT images were analysed qualitatively (by presence/absence of ILD), semi-quantitatively (categorical Goh score $<20\%$ vs $>20\%$ of extent and the continuous extent Goh score made from 5 levels' assessment- 0 to 100%) and quantitatively [with the densitometric radiomic data obtained through the Horos software - Mean lung attenuation (MLA), Standard Deviation (SD), Kurtosis, Skewness and Lung volume (LV)]. LUS was used to quantify the B-lines detected in each patient by scanning a total of 13 intercostal spaces, on both anterior and posterior chest wall.

Results: Among 59 SSc patients (81% women, mean age 48 ± 14 years, 45% anti-Scl70 positive), 23 (39%) presented ILD on HRCT, of which 14 limited and 9 extensive. The mean visual semi-quantitative score was 6%, ranging from 0 to 66%. Our data showed a significantly different number of B-Lines in ILD vs non-ILD patients (median 38 vs 9, $p<0.005$), a result which was further confirmed among non-ILD vs ILD $>20\%$ (median 47 vs 9, $p=.001$) and ILD $<20\%$ (median

36 vs 9, $p=.001$) patients. Conversely, the number of B-lines was not statistically different between patients with ILD $<20\%$ and $>20\%$ (median 47 vs 36, $p=.78$). We observed a significant negative correlation between the number of B-lines and FVC ($r=-.472$, $p<0.05$) TLC ($r=-.436$, $p=.003$), DLco ($r=-.515$, $p<0.001$), DLCO/VA ($r=-.306$, $p=.03$). Finally, the number of B-lines showed a statistically significant correlation with the Goh score on 5 levels ($r=.437$, $p=.001$), MLA ($r=.571$, $p<0.001$), kurtosis ($r=-.285$, $p=.028$), skewness ($r=-.370$, $p=.004$) and LV ($r=-.277$, $p=.033$). All data were confirmed analysing anterior and posterior B-Lines separately.

Conclusion: Our study confirms that LUS represents a useful tool for the identification of SSc-ILD. In addition, we showed that LUS may be useful also for the quantification of the severity of SSc-ILD, by correlating with PFT parameters, radiomics parameters and visual radiological evaluation. Together with the PFTs, LUS could be used to increase the accuracy of the screening and, potentially, of the follow-up of SSc-ILD patients.

Disclosure of Interests: Cosimo Bruni: None declared, Lavinia Mattolini: None declared, Lorenzo Tofani: None declared, Luna Gargani Consultant of: GE Healthcare, Philips Healthcare and Caption Health, Nicholas Landini: None declared, Gemma Lepri: None declared, Martina Orlandi: None declared, Serena Guiducci: None declared, Silvia Bellando Randone: None declared, Marco Matucci-Cerinic: None declared

DOI: 10.1136/annrheumdis-2021-eular.1350

POS0843

A NEW RISK MODEL IS ABLE TO IDENTIFY SYSTEMIC SCLEROSIS PATIENTS WITH A LOW RISK OF DISEASE PROGRESSION

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Background: Disease course in Systemic Sclerosis (SSc) ranges from mild, to severe with progressive organ involvement within months. Guidelines for follow-up are mainly based on expert consensus, and advocate annual assessment. So far, no data driven guidelines exist that describe tailored systematic assessments for individual patients in line with individual disease course.

Objectives: To develop a prediction model to guide annual assessment of SSc patients tailored in accordance to disease activity.

Methods: A machine learning approach was used to develop a model that can identify patients without disease progression. SSc patients included in the prospective Leiden SSc cohort and fulfilling the ACR/EULAR 2013 criteria were included. The primary endpoint in the prediction model was disease progression which was defined as progression in ≥ 1 organ system, and/or start of immunosuppression or death between the two most recent visits. Using elastic-net-regularization, and including 90 independent clinical variables (100% complete), we trained the model on 75% and validated it on 25% of the patients in order to perform internal validation of the final model. We optimized the model on negative predictive value (NPV) to minimize the likelihood of missing progression. By expert assessment of the test characteristics, including swarm plots of the probability scores, cut-offs were identified for low, intermediate and high risk for disease progression.

Results: Of the 492 SSc patients (range of follow-up: 2-10yrs), disease progression during follow-up was observed in 52% (median time 4.9yrs), including myocardial progression in 29%, lung progression in 23%, skin progression in 16%,

Baseline characteristics	Total n=492	Non-Progressors N=235	Progressors N=257
Demographics			
Female, n (%)	389 (79)	193 (82)	196 (76)
Age, mean (SD)	55 (14)	55 (15)	55 (13)
Disease duration nonRP, median (IQR)	3.2 (0.9-10.3)	3.5 (0.8-10.5)	3.6 (1.1-9.3)
Organ involvement			
DcSSc, n (%)	118 (24)	34 (15)	84 (33)
DLCO% of pred, mean (SD)	66 (18)	69 (18)	64 (17)
FVC% of pred, mean (SD)	98 (23)	96 (24)	97 (21)
ILD on HRCT, n (%)	183 (37)	66 (28)	117 (46)
PAH, n (%)	26 (5)	10 (4)	16 (6)
GAVE, n (%)	9 (2)	4 (2)	5 (2)
Cardiac involvement, n (%)	28 (6)	14 (6)	14 (5)
Myositis, n (%)	8 (2)	6 (3)	2 (1)
Renal crisis, n (%)	14 (3)	6 (3)	8 (3)
Autoantibodies			
Anti-centromere, n (%)	194 (39)	118 (50)	76 (30)
Anti-topoisomerase, n (%)	116 (24)	42 (18)	74 (29)

RP=raynaud phenomenon, dcSSc= diffuse cutaneous systemic sclerosis, mRSS=modified rodnan skin score, DU=digital ulcers, DLCO= single-breath diffusing capacity for carbon monoxide, FVC= forced vital capacity, ILD=interstitial lung disease, HRCT= high resolution computed tomography, PAH= pulmonary arterial hypertension, GAVE= gastric antral vascular ectasia.

and death in 12%. Performance of the model in the test set showed an AUC-ROC of 0.66. Probability score cutoffs were defined: low risk for disease progression (<0.197, NPV:1.0; 29% of patients), intermediate risk (0.197-0.223, NPV:0.82; 27%) and high risk (>0.223, NPV:0.78; 44%). The predictive variables included in the model were: previous use of cyclophosphamide or corticosteroids, start with immunosuppressive drugs, previous gastrointestinal progression, previous cardiovascular event, pulmonary arterial hypertension, modified Rodnan Skin Score, creatinine kinase, and diffusing capacity for carbon monoxide.

Conclusion: Our machine-learning-assisted model for disease progression enabled us to classify 29% of SSc patients as 'low risk'. In this group annual assessment programs could be less extensive than indicated by international guidelines.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1418

POS0844

EFFECTS OF SERIAL LOCALLY APPLIED WATER-FILTERED INFRARED A RADIATION IN PATIENTS WITH SYSTEMIC SCLEROSIS WITH SEVERE RAYNAUD'S SYNDROME RECEIVING PROSTAGLANDINE TREATMENT – A RANDOMIZED CONTROLLED TRIAL

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Background: More than 95% of patients with systemic sclerosis (SSc) suffer from Raynaud's syndrome (RS) leading to digital ulcerations (DU). In severe RS, intravenous application of prostaglandins is required. Moreover, these patients profit from an additional non-pharmacological treatment using hyperthermia to increase vasodilatation and perfusion, and to reduce pain.

Serial locally applied water-filtered infrared A radiation (sl-wIRAR) is a hyperthermia treatment modality using infrared heat radiation in the range of 780-1400nm with high tissue penetration and low thermal load on the skin surface [1]. wIRAR has both, temperature-dependent and non-dependent effects, which do not inherit thermal energy transfer and/or relevant temperature changes [1]. It is therefore not only used in acute and chronic wound healing as it promotes perfusion, alleviates pain and has anti-infectious effects [2], but is also used in oncology [3] and rheumatology [4].

Objectives: We conducted a randomized controlled trial with a follow-up visit after 2 weeks to evaluate the value of a high-frequency hyperthermia treatment using sl-wIRAR in comparison to a low-frequency hyperthermia treatment (our standard) in SSc patients with severe RS receiving Iloprost treatment.

Methods: Eligible patients had SSc according to the 2013 ACR/EULAR classification criteria, were 18 to 80 years old and had RS requiring treatment with Iloprost in an in-patient setting. Key exclusion criteria were contraindications to any hyperthermia treatment such as infection or heat insensitivity. The trial was conducted at Campus Kerckhoff of Justus-Liebig University Giessen. Eligible patients were equally randomized to the intervention group (IG) receiving additional sl-wIRAR treatment (2 treatments for 30 min per day for 8 days) plus the standard of care (Iloprost treatment over 8 days plus daily carbon dioxide hand baths of 20 min) and the control group (CG) receiving only the standard of care. Primary outcome was the between-group difference in pain measured on a numeric rating scale (NRS) after intervention. Key secondary outcomes included a change in RS frequency, RS duration, and a change in Interleukin (IL) -6 and VEGF levels.

Results: From 01.03.2020 to 31.12.2020 49 SSc patients met the inclusion criteria. 42 patients were enrolled (IG: 21, CG: 21). 38 patients (IG:19, CG: 19) completed the full trial period and were analyzed. There was no statistically significant between-group difference in pain levels (NRS) ($p=0.284$, $Z = -1.082$ (Mann-Whitney U Test)) and thus the primary outcome was not met. Therefore, all p values for secondary outcomes are nominal. Intensity (Visual analogue scale 0-100mm) and duration (min) of RS were reduced in the IG (mean $\pm$ standard error) -14.579 ± 7.214 mm ($p=0.058$) and -2.917 ± 1.510 min ($p=0.08$), respectively. Intra- and inter-group comparison of IL-6 and VEGF levels showed no relevant change.

Conclusion: The additive and frequent use of sl-wIRAR in the treatment of SSc patients with RS requiring Iloprost treatment does not improve outcomes regarding pain levels, RS intensity or frequency nor IL-6 and VEGF levels when compared to Iloprost treatment and low-frequency hyperthermia application.

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Acknowledgements: We acknowledge the help of Carina Schreyäck.

This study was in part supported by the Dr. med. h.c. Erwin Braun Foundation, Basel, a charitable, nonprofit Swiss scientific foundation approved by the Swiss Federal Administration. The foundation supports clinical investigation of waterfiltered infrared-A. The foundation was not involved in any content- or decision-related aspect of the study.

This study was prospectively registered at www.drks.de (German Registry of Clinical Studies): DRKS00021098

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1735

POS0845

SCLERODERMIC HAND SENSOR: SMART TECHNOLOGY APPLIED TO RHEUMATOLOGY

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Background: Systemic Sclerosis (SSc) is an autoimmune rheumatic disease characterized by excessive production and accumulation of collagen in the skin and internal organs and by injuries to small arteries.

Impairment of the musculoskeletal system is one of the main causes of disability in SSc, indeed, about 90% of these patients have a loss of hand function. To date, the degree of skin involvement is evaluated through a semi-quantitative method called Rodnan Skin Score (RSS) or Modified-RSS (MRSS). However, MRSS is a method that has limitations related to the operator and his experience and does not provide information on joint mobility.

Arduino® is an open source integrated online platform based on easy to use hardware and software. It is a system for creating interactive projects by inserting a special configuration code, using the Arduino® development environment. Through this platform it is possible to create electronic devices with specific purposes to lead the possibility of integrating different kits (eg types of sensors) in relation to the object of study.

Objectives: We have therefore created an electronic instrument (Sclerodermic Hand Sensor - SHS) independent operator and easily reproducible in order to measure the degree of mobility (flexion) of the hand in patients with SSc (Fig.1). The aim was to evaluate whether the SHS was able to highlight significant differences between patients with SSc and healthy patients.

Methods: We recruited 20 female patients with SSc according to ACR criteria with a mean age of 50.8 ± 15.5 years and 20 healthy (HC) patients with a mean age of 44.3 ± 10.8 years (Tab.1), in order to test the effectiveness and sensitivity of the SHS tool.

Results: The results showed a significant difference between the two groups of patients (SSc vs HC) independent of the measurement method used as expected (Goniometer SSc / HC: $\Delta 45.80^\circ$ $p: 0.003$ SHS SSc / HC: $\Delta 65.17^\circ$ $p: 0.002$, Fig.1c), however the device created with Arduino® proved to be more sensitive than the goniometric measurement in detecting the degree of joint flexion ($p: 0.002$). The flexion sensor, indeed, unlike the goniometer, evaluates the simultaneous articular excursion of the entire finger (MCF, IFP and IFD) and not just one segment (Fig.1).

Conclusion: This technology application, thanks to the creation of dedicated electronic devices, allows the physicians to be supported in clinical practice with independent operating tools.

Table 1. SSc Patients Characteristics

Characcteristics	SSc
Patients (n°, subset D=Diffuse; L=Limited)	20 (9D/11L)
Age, mean $\pm$ SD years	50.8 ± 15.5
Duration of Raynaud's Phenomenon (mean $\pm$ SD years)	12.8 ± 4.4
Duration of SSc (mead $\pm$ SD years)	8.4 ± 3.6
MRSS (mean $\pm$ SD years)	15.9 ± 5.3

Fig.1. Comparison between the use of the goniometer and SHS in SSc patients