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

P. Klemm¹, J. Bär¹, I. Aykara¹, K. Frommer¹, E. Neumann¹, U. Müller-Ladner¹, U. Lange¹. ¹Justus Liebig University Giessen, Campus Kerckhoff, Rheumatology, Clinical Immunology, Osteology and Physical Medicine, Bad Nauheim, Germany

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 30min per day for 8 days) plus the standard of care (Iloprost treatment over 8 days plus daily carbon dioxide hand baths of 20min) 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

S. Parisi¹, M. C. Ditto¹, C. L. Peroni¹, A. Laganà¹, E. Fusaro¹. ¹AOU Città della Salute e della Scienza di Torino, Rheumatology Unit, Turin, Italy

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

The tool we propose could be a valid support in accurately assessing the joint and indirectly skin involvement of sclerodactyly in this type of patient, especially in the context of a clinical trial to evaluate the efficacy of a treatment.

Further studies are needed to compare with other methods to assess hand disability in SSc such as the use of HAMIS (Hand Mobility in Scleroderma) test.

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Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1826

POS0846

SEXUAL FUNCTION IS IMPAIRED IN WOMEN WITH SYSTEMIC SCLEROSIS COMPARED TO HEALTHY CONTROLS

B. Heřmáňková^{1,2}, M. Špiritović^{1,2}, S. Oreska^{2,3}, H. Štorkánová^{2,3}, H. Smucrova², K. Pavělka^{2,3}, J. Vencovsky^{2,3}, L. Šenolt^{2,3}, R. Bečvář^{2,3}, M. Tomčík^{2,3}.

¹Faculty of Physical Education and Sport, Charles University, Department of Physiotherapy, Prague, Czech Republic; ²Institute of Rheumatology, Department of Rheumatology, Prague, Czech Republic; ³First Faculty of Medicine, Charles University, Department of Rheumatology, Prague, Czech Republic

Background: Systemic sclerosis (SSc) is a multisystem, connective tissue disorder characterized by fibrosis of the skin and internal organ involvement, which can influence all aspects of life, including sexual life.

Objectives: This study aimed to compare sexual function in patients with SSc to age-/sex-matched healthy controls (HC) and determine the potential impact of clinical features on sexual function.

Methods: In total, 90 women with SSc (mean age: 49.1, disease duration: 6.1 years, lcSSc/dcSSc: 62/28, mRSS: 9.3, ESSG activity index: 2.1), who fulfilled the ACR/EULAR 2013 criteria, and 90 healthy controls (mean age: 49.1) without rheumatic diseases filled in 12 well-established and validated questionnaires assessing sexual function (FSFI, BISF-W, SFQ-28, SQoL-F), pelvic floor function (PISQ-12, PFIQ-7), fatigue (FIS, Fatigue Impact Scale), physical activity (HAP, Human Activity Profile), disability (HAQ, Health Assessment Questionnaire), depression (BDI-II, Beck's Depression Inventory-II) and quality of life (SF-36, Medical Outcomes Study Short Form 36 – PCS, Physical Component Summary; MCS, Mental Component Summary). A routine laboratory testing was performed. Data are presented as median (IQR).

Results: Patients with SSc reported significantly greater prevalence and severity of sexual dysfunction (FSFI, BISF-W, SFQ28 – in all subscales as well as total scores), worse sexual quality of life (SQoL-F) and pelvic floor dysfunction (PISQ-12, PFIQ-7) compared to HC (table 1). The prevalence of sexual dysfunction in patients with SSc according to the FSFI cut-off score was 77%. Worse scores in SSc patients were associated with longer disease duration [BISF-W-total ($r=-0.243, p=0.026$), FSFI-lubrication ($r=-0.229, p=0.035$)], higher disease activity [ESSG activity index: BISF-W-total ($r=-0.291, p=0.010$), FSFI-arousal ($r=-0.299, p=0.007$)], increased inflammation [CRP: BISF-W-receptivity/initiation ($r=-0.301, p=0.007$)], more pronounced fatigue [FIS-total: BISF-W-total ($r=-0.412, p<0.0001$)], more severe depression [BDI-II: FSFI-total ($r=-0.506, p<0.0001$), SQoL-F ($r=-0.369, p<0.0001$)], worse functional disability [HAQ: FSFI-total ($r=-0.394, p<0.0001$)], reduced physical activity [HAP: FSFI-total ($r=0.535, p<0.0001$)], and decreased overall quality of life [SF-36 PCS: FSFI-total ($r=0.428, p<0.0001$), SF-36 MCS: SQoL-F ($r=0.472, p<0.0001$)].

Table 1. Sexual function and pelvic floor function in women with SSc and healthy controls

Questionnaire: score range (meaning)	SSc (n=90)	HC (n=90)	p-value
FSFI: Female sexual function index: 2 (worst) - 36 (best)	19.4 (3.9-26.8)	30.1 (23.1-32.9)	p<0.0001
BISF-W: Brief Index of Sexual Function for Women: -16 (worst) - 75 (best)	14.3 (2.1-35.1)	38.2 (19.3-46.2)	p<0.0001
SQoL-F: Sexual Quality of Life Questionnaire-61.1 (34.4-81.1)	91.1 (70.0-96.7)	91.1 (70.0-96.7)	p<0.0001
PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form: 0 (best) - 48 (worst)	13.0 (9.0-17.0)	7.0 (5.0-12.0)	p<0.0001
PFIQ-7: Pelvic Floor Distress Inventory Questionnaire: 0 (best) - 300 (worst)	9.5 (0.0-48.8)	0.0 (0.0-8.3)	p<0.0001
SFQ-28: Sexual Functioning Questionnaire-28 desire: 5 (worst) - 31 (best)	17.0 (12.0-20.0)	21.0 (17.0-23.0)	p<0.0001
SFQ-28 arousal sensation: 4 (worst) - 20 (best)	10.0 (8.0-13.0)	12.0 (9.0-15.0)	p=0.0031
SFQ-28 arousal lubrication: 2 (worst) - 10 (best)	5.0 (4.0-7.0)	8.0 (5.2-9.0)	p<0.0001
SFQ-28 arousal cognitive: 2 (worst) - 10 (best)	5.0 (4.0-6.0)	7.0 (5.0-8.0)	p<0.0001
SFQ-28 orgasm: 1 (worst) - 15 (best)	10.0 (6.5-12.0)	12.0 (10.0-13.0)	p<0.0001
SFQ-28 pain: 2 (worst) - 15 (best)	12.0 (9.5-15.0)	15.0 (13.0-15.0)	p<0.0001
SFQ-28 enjoyment: 6 (worst) - 30 (best)	19.0 (12.5-24.0)	24.0 (20.0-25.8)	p<0.0001
SFQ-28 partner: 2 (worst) - 10 (best)	9.0 (8.0-10.0)	10.0 (9.0-10.0)	p=0.0182

Conclusion: Women with SSc reported significantly impaired sexual function and pelvic floor function compared to age-/sex-matched healthy controls. Worse scores in SSc were associated with disease-related features.

Acknowledgements: Supported by MHCR 023728, GA UK 1578119, and SVV 260373.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1829

POS0847

IDENTIFICATION OF MOLECULAR PHENOTYPES IN SYSTEMIC SCLEROSIS BY INTEGRATIVE SYSTEMS ANALYSIS

M. J. Chang^{1,2,3}, S. X. Zhang^{1,2,3}, Q. Wang^{4,5}, J. Qiao^{1,2,3}, R. Zhao^{1,2,3}, S. Song^{1,2,3}, Y. Zhang^{1,2,3}, Q. Yu⁶, P. F. He⁵, X. Li^{1,2,3}. ¹The Second Hospital of Shanxi Medical University, Department of Rheumatology, Taiyuan, China; ²Shanxi Li Xiaofeng Medical Groups, Department of Rheumatology, Taiyuan, China; ³Ministry of Education, Key Laboratory of Cellular Physiology at Shanxi Medical University, Taiyuan, China; ⁴Shanxi Medical University, Basic Medical College, Taiyuan, China; ⁵Shanxi Medical University, Medical Data Sciences, Taiyuan, China; ⁶Shanxi Medical University, Medical Data Sciences/School of Management, Taiyuan, China

Background: Systemic sclerosis (scleroderma, SSc) is a systemic autoimmune disease characterized by inflammation, fibrosis and vasculopathy and associated with high mortality and high morbidity¹. Stratification based on whole-genome gene expression data could provide a new basis for clinical diagnosis from a micro perspective².

Objectives: The objective of this study is to stratify patients with SSc, combine with clinical skin scores and clinical features, and provide a preliminary assessment and novel insights for assessing disease severity, and treatment design.

Methods: The original data mRNA expression profiles of GSE95065 (including 18 SSc patients and 4 healthy controls) and GSE130955 (including 58 SSc patients and 33 healthy controls) were downloaded from the public Gene Expression Omnibus (GEO) database. After batch correction, background adjustment, and other pre-processing, a large gene matrix was obtained to identify the differentially expressed genes (DEGs) of SSc compared with healthy controls. Then the gene expression matrix decomposition was used to identify SSc subtypes by NMF algorithm. The cluster-based signature genes were applied to pathway enrichment analysis by Metascape³. Immune infiltrating cells and clinical skin scores were evaluated in all SSc subtypes.

Results: Total 325 DEGs were imputed to NMF unsupervised machine learning algorithm. Patients were divided into 2 subtypes (Figure 1A), one of which (sub1) was mostly enriched in the defense response to bacterium and cellular response to lipopolysaccharide pathway and another subtype (sub2) was enriched in the PPAR signaling and alcohol metabolic process pathway (Figure 1B-C). According to immune infiltration, sub1 had higher level of immune cells such as B cells, CD4+T cells, DC cells, Th2 cells and Tregs compared with sub2 ($P < 0.01$). Sub2 had more skin-related cells, including Epithelial cells, Fibroblasts and Sebocytes ($P < 0.05$). Interestingly, combined with clinical information, sub1 showed a severe clinical skin score over those of Sub2 patients ($P < 0.05$) (Figure 1D-E).

Conclusion: Our findings indicated that SSc patients could be stratified into 2 subtypes which had different molecular profiles of disease progression and

Figure 1 NMF clustering function enrichment, immune cells infiltration and clinical skin scores in SSc patients. (A) The relationship between cophenetic with respect to number of clusters. (B-C) Genetic functional enrichment for sub1 and sub2. (D) The box plot shows the difference in the clinical skin scores between the two subtypes. (E) Violin plot visualizing the differently infiltrated immune cells and skin cells (red represents sub1 and blue represents sub2). (ns, no significant; * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.)