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’s score 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 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 through the semi-quantitative and quantitative radiomic data obtained through the Horos software.

Mean lung attenuation (MLA), Standard Deviation (SD), Kurtosis, Skewness and LV (r=-.277 , p=.033) were observed a significant negative correlation between the number of B-lines and MLA. The mean visual semi-quantitative score was 6%, ranging from 0 to 100%, and it was statistically different among non-ILD vs ILD (p=0.010; β=-0.47, p<0.001 and β=0.45, p<0.001, respectively). 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 myocardiopathy in 29%, lung progression in 23%, skin progression in 16%, and systemic arterial disease in 10%. In univariate analysis, the number of B-lines (median 23 vs 9, p=0.001) patients. Conversely, the number of B-lines was not statistically different between patients with ILD <20% and >20% (median 47 vs 36, p=0.78). We observed a significant negative correlation between the number of B-lines and FVC (r=-.47, p<.05) TLO (r=-.436, p<.003), DLco (r=-.515, p<.001), DLCO VA (r=-.306, p=0.03). Finally, the number of B-lines showed a statistically significant correlation with the Goh score on levels 5 (r=.437, p<.001), MRA (r=.571, p<.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: None declared

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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 enables us to classify 29% of SSc patients as 'low risk.' This low group annual assessment programs could be less extensive than indicated by international guidelines.

Disclosure of Interests: None declared

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POS844

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 (si-wiRaR) is a hyperthermia treatment modality that adds 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-inflammatory 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-frequent hyperthermia treatment using si-wiRaR in comparison to a low-frequent 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 si-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 ± standard error) -14.579 ± 7.214 mm (p=0.058) and -2.91 ± 1.510 min (p=0.08), respectively. Intra- and inter-group comparison of IL-6 and VEGF levels showed no relevant change.

Conclusion: The frequent use of si-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-frequent hyperthermia application.

REFERENCES:

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

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POS845

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: d=0.80 * p=0.003 SHS SSc / HC: d=0.17 * 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, IPF 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

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<th>Characteristics</th>
<th>SSc</th>
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<tr>
<td>Patients (n°, subset D=Diffuse; L=Limited)</td>
<td>20 (9D/11L)</td>
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<tr>
<td>Age, mean ± SD years</td>
<td>50.8 ± 15.5</td>
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<tr>
<td>Duration of Raynaud’s Phenomenon (mean ± SD years)</td>
<td>12.8 ± 4.4</td>
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<tr>
<td>Duration of SSc (mean ± SD years)</td>
<td>8.4 ± 3.6</td>
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<td>MRSS (mean ± SD years)</td>
<td>15.9 ± 5.3</td>
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Fig. 1. Comparison between the use of the goniometer and SHS in SSc patients

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