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Digital Artery Volume Index (Davix©) Predicts Onset of Future Digital Ulcers in Patients with Systemic Sclerosis Klodian Gjeloshi1 , Giovanni Lettieri2 , Fiammetta Danzo1 , Giuseppina Abignano3 , Mark Hinton4 , Anne-Maree Dean5 , Giovanna Cuomo6 , Olga Kubassova7 and Francesco Del Galdo5 , 1 Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK and Internal Medicine Department, University of Campania Luigi Vanvitelli, Naples, Italy, Leeds, United Kingdom, 2 Radiology Department, San Carlo Hospital, Potenza, Italy, Potenza, Italy, 3 Rheumatology Institute of Lucania (IReL), Rheumatology Department of Lucania, San Carlo Hospital, Potenza, Italy; Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds and NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust, Leeds, UK, Leeds, England, United Kingdom, 4 IAG CEO, London, United Kingdom, London, United Kingdom, 5 Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds and NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust, Leeds, UK, Leeds, United Kingdom, 6 Internal Medicine Department, University of Campania Luigi Vanvitelli, Naples, Italy, Naples, Italy, 7 Image Analysis Group, London, United Kingdom SESSION INFORMATION Session Date: Sunday, November 8, 2020 Session Title: Systemic Sclerosis & Related Disorders – Clinical Poster III Session Type: Poster Session C Session Time: 9:00AM–11:00AM Table 1. Comparison of Obstetric outcomes before and after onset of Systemic sclerosis Background/Purpose: Neointima proliferation is a key pathologic feature of Systemic Sclerosis (SSc), causing arterial vessel narrowing. It is a recognised culprit pathological lesion in Digital Ulcers (DUs), pulmonary artery hypertension and renal crisis. Nevertheless, there are no validated imaging techniques to assess the severity of vascular involvement in SSc. This study presents Digital Artery Volume index (DAVIX ©), a novel quantitative MRI based scoring for the assessment of the blood flow in the arteries and its validation in predicting the onset of DUs in SSc patients. Methods: This study enrolled 91 (78 female) consecutive patients with Raynaud's phenomenon, with median disease duration of 4 years (IQR=1.91-9). Complete historical and prospective follow-up data were available for 68 patients. 63 patients fulfilled the 2013 ACR/EULAR classification criteria for SSc; 28 had score < 9. The data collected included: pulmonary function tests (PFTs), nailfold capillaroscopy, modified Rodnan Skin Score (mRSS), and Scleroderma Health Assessment Questionnaire Disability Index (sHAQ-DI). DAVIX of the dominant hand was calculated as % mean of the 4 fingers, employing proprietary algorithm by IAG. The distribution was analysed with D'Agostino-Pearson normality test. The median scores were compared by Mann-Whitney-Wilcoxon test; correlation with clinical parameters was performed using Spearman's or Pearson test, as appropriate (Prism 7). Results: DAVIX correlated with mRSS (r=-0.258, p=0.017), DLCO% (r=0.338, p=0.008) and capillaroscopy pattern (r=-0.388, p=0.001). In patients with DUs, DAVIX showed a stronger correlation with DLCO% (r=0.786, p=0.048). DAVIX predicted the worsening of HAQ-DI (r=-0.295, p=0.029), sHAQ (r =-0.333, p=0.029) and VAS pain (r=-0.269, p=0.038) independently of the presence of DUs. In the context of DU, 7 patients had DUs at baseline (5 with a positive history for DUs). 12 patients developed DUs within 12 months, 3 of them had DUs at baseline. 38 patients did not have either previous or current DUs, neither did they develop new DUs within 12 months. DAVIX of patients with current DUs was lower than DAVIX of patients without DUs (0.18 vs 0.63 p=0.0093). DAVIX of patients with positive history of DUs was lower than

in patient with a negative history (median 0.34 vs 0.64, p=0.0052). In patients without current DUs, DAVIX of patients who developed new DUs within 12 months of follow-up was 3-fold lower than in patients who did not develop DUs (0.21 vs 0.65, p=0.0156). ROC curve analysis indicated that DAVIX threshold < 0.49 conferred a 4 times higher risk of developing new DUs (67%) compared to overall risk of our population 17.6%. Conclusion: The study demonstrates that DAVIX© is a feasible surrogate outcome measure of neointima proliferation in SSc and a useful imaging biomarker of vascular disease activity. Its predictive value of the future onset of DU could be used to stratify patients in clinical trials. The value of DAVIX in predicting the worsening of PROs and clinical parameters in overall patients, may offer insights on the role of vascular disease activity in the overall progression of SSc. Disclosure: K. Gjeloshi, None; G. Lettieri, None; F. Danzo, None; G. Abignano, None; M. Hinton, IAG, Image Analysis Group, 3; A. Dean, None; G. Cuomo, None; O. Kubassova, IAG, Image Analysis Group, 3; F. Del Galdo, None.