OP0009

DERIVATION AND VALIDATION OF THE SCLERODERMA LUNG 3-STAGE INDEX (SL3SI), A NEW FUNCTIONAL INDEX FOR INTERSTITIAL LUNG DISEASE WITH PROGNOSTIC IMPLICATIONS

A. Santaniello¹, C. Bellocchi¹, L. Bettolini¹, M. Cassavia¹, G. Montanelli¹, A. Severino¹, M. Caronni¹, C. Campochiaro², E. De Lorenzis^{3,4}, G. Natalello^{3,4}, P. Delvino⁵, C. Tirelli⁵, L. Cavagna⁵, G. De Luca², S. L. Bosello³, L. Beretta¹.

¹Scleroderma Unit, Referral Center for Systemic Autoimmune Diseases, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano, Milan, Italy; ²Unit of Immunology, Rheumatology, Allergy and Rare Diseases IRCCS San Raffaele Hospital, Università Vita-Salute San Raffaele, Milan, Italy; ³Rheumatology Division, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy; ⁴Catholic University of the Sacred Heart, Rome, Italy; ⁵Division of Rheumatology, University and IRCCS Policlinico S. Matteo Foundation, Pavia, Italy

Background: The staging of interstitial lung disease (ILD) is important to monitor disease progression and for prognostication. A disease severity scale of Systemic Sclerosis (SSc)-related lung disease has long been proposed (i.e. Medsger's severity scale). This scale was mostly developed by discussion and consensus and stage thresholds were not computed by a data-driven approach. Hidden Markov models (HMM) are methods to estimate population quantities for chronic diseases with a staged interpretation which are diagnosed by markers measured at irregular intervals.

Objectives: To build a SSc-ILD specific disease severity scale with prognostic relevance via HMM modeling.

Methods: A total of 358 SSc patients at risk for or with ILD were enrolled in a discovery (207 cases, Milan1) and in a validation (151 cases, Milan2, Pavia and Rome) cohort. Patients were included if satisfied the following criteria: 1) Diagnosis of SSc according to the EULAR/ACR 2013 criteria, 2) absence of anticentromere antibodies, 3) dcSSc subset or 4) other subsets with either 4a) ILD-related antibodies (Scl70, PmScl, Ku) or 4b) evidence of ILD on HRCT, 5) disease duration < 5 years at the time of the first pulmonary function test (PFT). Serial PFTs were retrieved and the time up to the last available visit -if the patient alive-, or to death due to pulmonary complications, was recorded. HMM were used to estimate the threshold of a 3-stage model (SL3SI, Scleroderma Lung 3-Stage Index) based on PFT functional values (normal/mild, moderate, severe involvement) in the discovery cohort. Survival estimates of the SL3SI model were compared to Medsger's severity classes estimates and their predictive capability evaluated via the explained residual variation (R^2) of prediction errors (the higher the better). One-hundred random replicates were generated to simulate the prediction effort in patients with different disease duration and lung severity.

Results: Patients characteristics are summarized in the Table. Fifteen-years survival estimates for Medsger's classes in the discovery set were: normal=0.88, mild=0.86, moderate=0.84 and severe=0.71. The SL3SI was defined by the following thresholds: normal/mild, FVC and DLco $\geq 75\%$; moderate FVC or DLco 74-55%; severe, FVC or DLco <55%. SL3SI 15-yr survival estimates were: normal/mild=0.89, moderate=0.82 and severe=0.63. Prediction analysis showed a higher R^2 values at 15 yrs for the SL3SI compared to Medsger's classes, providing evidence for a better predictive capability of the former (discovery: 0.31 vs 0.25; validation: 0.28 vs 0.19).

Conclusion: The SL3SI, a simplified 3-stage functional model of SSc-ILD, yields better survival estimates and long-term prognostic information than Medsger's classes. Its reproducibility and ease of use make it a useful tool for the functional and prognostic evaluation of SSc patients at risk for or with ILD.

Table:

Variables	Discovery (n=207)	Replication (n=151)
DcSSc	62 (30%)	98 (64%)
Age at first PFR	48.6±12	49.1±14.4
Disease duration at first PFR	1.7±1.6	1.3±2.4
FVC	90.5±18.1	91.1±20.2
DLco	70.7±19.8	61.3±20.1
ILD on HRCT	179 (86%)	125 (80%)
Scl70	157 (76%)	153 (78%)
SSA	63 (30%)	32 (21%)
n of visits	3857	1473
Follow-up time, yrs	11±5.6	10.6±5.7
Deaths	27 (13%)	23 (15%)

Disclosure of Interests: Alessandro Santaniello: None declared, Chiara Bellocchi: None declared, Luca Bettolini: None declared, Marcello Cassavia: None declared, Gaia Montanelli: None declared, Adriana Severino: None declared, Monica Caronni: None declared, Corrado Campochiaro Speakers

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Opening Plenary abstract session

OP0010

EFFECTIVENESS OF THE MAKING IT WORK™ PROGRAM AT IMPROVING PRESENTEEISM AND WORK CESSATION IN WORKERS WITH INFLAMMATORY ARTHRITIS – RESULTS OF A RANDOMIZED CONTROLLED TRIAL

A. Luquini^{1,2}, Y. Zheng², H. Xie^{2,3}, C. Backman^{1,2}, P. Rogers², A. Kwok², A. Knight², M. Gignac⁴, D. Mosher⁵, L. Li^{1,2}, J. Esdaile^{1,2}, C. Thorne⁶, D. Lacaille^{1,2}. ¹The University of British Columbia, Vancouver, Canada; ²Arthritis Research Canada, Richmond, Canada; ³Simon Fraser University, Faculty of Health Sciences, Burnaby, Canada; ⁴Institute for Work and Health - University of Toronto, Dalla Lana School of Public Health, Toronto, Canada; ⁵Cumming School of Medicine, University of Calgary, Department of Medicine, Division of Rheumatology, Calgary, Canada; ⁶University of Toronto, Department of Medicine, Division of Rheumatology, Toronto, Canada

Background: Arthritis often leads to presenteeism (decreased at-work productivity), missed days from work and permanent work disability, leading to reduced quality of life and high costs to individuals and society. Yet, health services addressing the employment needs of people with arthritis are lacking.

Objectives: We evaluated the effectiveness of the Making-it-Work™ (MiW) program, an online self-management program developed to help people with inflammatory arthritis (IA) deal with employment issues.

Methods: A multi-center RCT evaluated the effectiveness of MiW at improving presenteeism and preventing work cessation (WC) over two years. Participants were recruited from rheumatologist practices, consumer organizations and arthritis programs, in three Canadian provinces. Eligibility criteria: diagnosis of IA, employed, age 18-59, and concerned about ability to work. Participants were randomized 1:1 to MiW or usual care plus printed material on workplace tips. MiW consists of five online self-learning modules and group meetings, and individual vocational counselling and ergonomic consultations. Questionnaires were administered every 6 months. Outcomes were presenteeism [Rheumatoid Arthritis Work Instability Scale (RA-WIS)], time to WC ≥ 6 months, and time to WC ≥ 2 months (secondary outcome). Baseline characteristics (age, gender, ethnicity, occupation, education, disease duration and self-employment) were collected. Intention-to-treat (ITT) longitudinal analysis of RA-WIS using linear mixed effect regression models with 2-year comparison as primary endpoint and survival analysis for time to WC using Kaplan-Meier and Cox Proportional Hazard models were performed. Robustness analyses were conducted by using various missing values imputation methods like last observation carried forward, imputation using worst possible outcomes and model-based multiple imputations; using square root transformation of RA-WIS outcome; and adjusting for baseline covariates. SAS version 9.4 was used.

Results: A total of 564 participants were recruited, with 478 (84.75%) completing 2-year follow-up. Baseline characteristics were similar between groups. Mean RA-WIS scores were significantly lower in the intervention group from 6 months onwards, with the greatest difference observed at 2 years (-1.78, 95%CI: -2.7, -0.9, $p < .0001$), yielding a standardized effect size of 32%. Satisfactory robustness was observed. Work cessation occurred less often in intervention than control groups, but only reached statistical significance for WC ≥ 2 months (WC ≥ 6 months: 31 versus 44 events, aHR 0.70, 95%CI: 0.44, 1.11, $p = 0.13$; WC ≥ 2 months: 39 versus 61 events, aHR: 0.65, 95%CI: 0.43, 0.98, $p = 0.04$).

Conclusion: Results of the RCT reveal the program was effective at improving presenteeism and preventing short-term WC. Effectiveness at preventing long-term work disability will be assessed at 5 years. This program fills one of the most important and costly unmet needs for people with inflammatory arthritis.

References:

- [1] Carruthers EC, Rogers P, Backman CL, et al. "Employment and arthritis: making it work" a randomized controlled trial evaluating an online program to help people with inflammatory arthritis maintain employment (study protocol). *BMC Med Inform Decis Mak*. 2014;14:59. Published 2014 Jul 21. doi:10.1186/1472-6947-14-59