LONG-TERM OUTCOMES OF AFRICAN AMERICAN PATIENTS WITH SYSTEMIC SCLEROSIS-RELATED INTERSTITIAL LUNG DISEASE

Shervin Assassi1, Michael Roth1, Robert Elashoff1, Donald Tashkin1, Elizabeth Volkmann*, Ling1, Dinesh Khanna2, Philip Clements1, Daniel Furst1, Ning Li: None declared, Dinesh Khanna Shareholder of: Eicos Sciences, Inc, Grant/research support from: Bayer, BMS, Pfizer, Horizon, Genentech/Roche, Cytori, GSK, Genentech/Roche, Galapagos, Employee of: Elcos Sciences, Inc, Philip Clements: None declared, Daniel Furst Grant/research support from: Genentech/Roche, Robert Elashoff: None declared, Donald Tashkin Consultant for: Boehringer Ingelheim, Ning Li: None declared, Dinesh Khanna Shareholder of: Eicos Sciences, Inc, Consultant for: Boehringer Ingelheim, Bayer, BMS, CSL Behring, Corbus, Cytori, GSK, Genentech/Roche, Galapagos, Employee of: Elcos Sciences, Inc, Philip Clements: None declared, Daniel Furst Grant/ research support from: F. Hoffmann-La Roche, Genentech, Shervin Assassi: None declared, Michael Roth Consultant for: Actelion Acceleron, Arena, Bayer, BI, BMS, CSL Behring, Corbus, Cytori, GSK, Genentech/Roche, Galapagos, Employee of: Elcos Sciences, Inc, Philip Clements: None declared, Daniel Furst Consultant for: Boehringer Ingelheim, Employee of: Boehringer Ingelheim, Ning Li: None declared, Dinesh Khanna Shareholder of: Eicos Sciences, Inc, Consultant for: Boehringer Ingelheim, Speakers bureau: Boehringer Ingelheim, Consulting interests: Boehringer Ingelheim, Chugai, Consultant for: Boehringer Ingelheim, Employee of: Boehringer Ingelheim.

Methods: Relevant full-text articles using durometry in SSc patients were identified through a systematic literature search in 3 electronic databases and a hand search of reference lists, according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. All retrieved articles were screened on title, abstract and full-text level. Additionally, a pilot study was conducted in a cohort of non-selected consecutive SSc patients to assess the intra-rater reliability of durometry, by having an anchor rater performing 3 cycles of durometry measurements at 17 skin sites approximating those of the mRSS. Reliability was described by calculating the intraclass correlation coefficient (ICC).

Results: A total of 94 records were identified through the systematic search of which a total of 40 unique titles were screened. After a thorough screening of all titles and abstracts, 7 manuscripts were eligible for full-text review. Finally, of these, only 2 manuscripts fulfilled the predetermined inclusion criteria to be included, as they documented the reliability of durometry as an outcome. Hence, both manuscripts were included in the final analysis for quality appraisal and data extraction. Regarding intra-rater reliability, Kissin et al. reported ICC values ranging from 0.86-0.94 in a small cohort study including 5 diffuse SSc patients (DcSSc) [1]. Regarding inter-rater reliability, ICC values ranged from 0.82-0.96 according to a multicentre randomised clinical trial (n=43 DcSSc) by Merkel et al. and 0.61-0.85 according to Kissin et al. [1,2]. Finally, only 5 fulfilled the predetermined eligibility criteria to be included for quality appraisal and data extraction. Subsequently to this systematic review, an additional pilot study investigating the intra-rater reliability was performed. Seventy-four SSc patients (61 women; 13 LSSc, 53 LcSSc and 8 DcSSc) underwent durometry assessment in this pilot study. The ICC values for intra-rater reliability ranged between 0.93-0.99.

Conclusion: The systematic literature review revealed that reliability, in particular intra-rater reliability, of durometry in SSc is nearly unexplored territory. The findings of our very pilot study, demonstrating as first an excellent intra-rater reliability of durometry measurements in a large unselected cohort of SSc patients, could confirm the explorative findings previously reported in a small cohort study. Hence, our results stepped forward to the need for intra-rater validation of durometry.

REFERENCES

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Background: Observational studies have demonstrated that African American patients with Systemic Sclerosis (SSc) have a more unfavorable prognosis compared with non-African Americans. However, no studies have evaluated racial disparities using data from a randomized controlled trial (RCT) where all patients have equal access to care and standard treatment and follow-up during the trial.

Objectives: To compare morbidity and mortality in African American and non-African American patients who participated in the Scleroderma Lung Study (SLS) I and II.

Methods: SLS I randomized 158 SSc patients with interstitial lung disease (ILD) from 13 US SSc centers to 1 year of oral CYC (cyclophosphamide) versus placebo. SLS II randomized 142 SSc-ILD participants from 14 US SSc centers to 1 year of oral CYC, followed by 1 year of placebo, versus 2 years of mycophenolate (MMF). Up to 12 (SLS I) and 5 (SLS II) years after randomization, we contacted enrolled patients or designated surrogates to assess the following: mortality, cause of mortality, and development of organ failure. We used cox proportional hazard modeling to determine the variables associated with survival.

Results: Baseline characteristics of the SLS I and II cohorts were similar. In SLS I, African American participants (N=26) were younger than non-African American participants (N=132) (43.1 vs. 49.5 years, P=0.015). In SLS II, African American participants (N=33) had slightly increased baseline forced vital capacity (FVC) (69.2 vs 65.6, P=0.038), compared with non-American American participants (N=109). There were no significant baseline differences in the extent of cutaneous sclerosis (Modified Rodnan Skin Score [MRSS]), presence of diffuse cutaneous disease or serological profiles between racial groups. After adjusting for age, MRSS, FVC, there was no difference in long-term mortality outcomes (due to all causes or due to respiratory failure) in African American versus Non-African American SSc-ILD participants in SLS I or II (Figure 1). There was also no difference in time to the development of respiratory failure in African American versus Non-American American SSc-ILD participants in SLS I or II.

Conclusion: Data from two of the largest RCTs in SSc-ILD demonstrated that African American patients with SSc-ILD have similar morbidity and mortality outcomes compared with non-African American SSc-ILD patients, even after adjusting for age and baseline disease severity. These findings contrast with the racial disparities described in previous observational studies and warrant further investigation.

REFERENCES

Figure 1a. Time to death in African American participants of SLS I (red line) and non-African American participants of SLS I (blue line).

Figure 1b. Time to death in African American participants of SLS II (red line) and non-African American participants of SLS II (blue line).

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