



**6. Demographic and Disease Correlates of Clinically Significant Fatigue in Systemic Sclerosis: Preliminary Evidence Using Case-Definition Criteria.**

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**Background:** Fatigue is common across rheumatic diseases and is a crucial determinant of quality of life. Most studies use single questions or continuous measurement scales to define fatigue. These methods, however, do not necessarily identify clinically significant fatigue levels that warrant investigation and treatment. Case-definition standards for identifying clinically significant fatigue would facilitate research and clinical management, and contribute to a better understanding of the etiology of fatigue in rheumatic diseases. Case-definition criteria for Cancer-Related Fatigue were proposed for inclusion in ICD, and a recent study has demonstrated that these criteria can be applied more broadly to define Chronic Illness-Related Fatigue in patients with systemic sclerosis (SSc, or scleroderma).

**Objective:** The aim of this study was to evaluate demographic and disease correlates of clinically significant fatigue, as defined by the case-definition criteria, in a large sample of patients with SSc.

**Methods:** Patients with SSc from the Canadian Scleroderma Research Group Registry completed a telephone interview that determined whether patients met fatigue case criteria; 2 weeks of significant fatigue in the preceding month, at least four of seven fatigue-related symptoms, a significant effect of fatigue on work or self care, and not primarily the consequence of a co-morbid psychiatric disorder, primarily depression. Demographic characteristics (age, sex, education level, marital status and current smoking status) were patient-reported, and the Medsger Scleroderma Disease Severity Scale (general system, peripheral vascular, skin system, joint/tendon involvement, muscle strength, gastrointestinal tract, and lung, heart, and kidney system) and medical comorbidities were recorded by a rheumatologist. Patients who met case-definition criteria were compared with non-cases on demographic and disease variables using logistic regression analysis.

**Results:** Among 331 patients with SSc who completed the fatigue interview, 113 (34%) had clinically significant fatigue. Variables independently associated with fatigue case status included current smoking (OR=2.71, 95% CI 1.29 to 5.72, p=0.009), general system involvement (OR=1.41, 95% CI 1.07 to 1.87, p=0.016), lung involvement (OR=1.37, 95% CI 1.06 to 1.76, p=0.015), and medical comorbidities (OR=3.08 95% CI 1.56 to 6.07, p=0.001). Other Medsger items, age, sex, education level, and marital status were not significantly associated with fatigue case status.

**Conclusions:** Clinically significant fatigue in patients with SSc is independently associated with smoking, general system involvement, lung involvement and medical comorbidities. Smoking, a modifiable behaviour was robustly associated with fatigue caseness, even after considering disease-related variables.