Sigma’s 30th International Nursing Research Congress
Exploring Self-Efficacy and Pain Trajectories in Systemic Sclerosis
Robyn Wojeck, MSN, RN, APRN, FNP-C
Susan Silva, PhD
Donald E. Bailey Jr., PhD, RN, FAAN
Mitchell R. Knisely, PhD, RN-BC, ACNS-BC
School of Nursing, Duke University, Durham, NC, USA

Background:

Systemic sclerosis (SSc; scleroderma) is a rare, progressive, multisystem autoimmune disease with significant pain burden. SSc is characterized by immune-mediated attacks on the body’s healthy connective tissues resulting in fibrosis of the skin and tissues surrounding the internal organs (American College of Rheumatology, 2017; B. D. Thombs, Hudson, Taillefer, & Baron, 2008). Pain is a prominent symptom often experienced by individuals with SSc, resulting in decreased physical functioning, social adjustment, and health-related quality of life (Benrud-Larson et al., 2002; Georges et al., 2006; Suarez-Almazor, Kallen, Roundtree, & Mayes, 2007). Previous studies have identified that approximately 60-80% of individuals with SSc experience pain (Bassel et al., 2010; Benrud-Larson et al., 2002; Richards et al., 2003; Schieir et al., 2010), yet few studies have addressed the variations in pain along the disease trajectory (Merz et al., 2017; Sekhon, Pope, & Baron, 2010). Limitations in previous research addressing pain in SSc includes small sample sizes and lack of longitudinal studies (Benrud-Larson et al., 2002; Schieir et al., 2010; Brett D Thombs et al., 2010).

Self-management may improve health-related quality of life in those with SSc, thus understanding one’s self-efficacy, or perceived confidence in performing self-management behaviors associated with his or her health condition, is essential (Buck, Poole, & Mendelson, 2010; Riehm et al., 2016; Brett D Thombs, Kwakkenbos, Riehm, Saadat, & Fedoruk, 2017). Higher levels of pain have been associated with lower levels of self-efficacy (Buck et al., 2010), yet previous studies have not addressed the fluctuations in self-efficacy within and between individuals longitudinally or in relation to variations in pain severity along the disease trajectory.

SSc is a rare disease and little is known about the interrelationship between patient characteristics, self-efficacy in managing pain, and pain outcomes (pain interference, intensity, and severity). Our understanding of the disease and its symptomatology has been primarily based on studies with small sample sizes. Recommendations for future research include using larger sample sizes and longitudinal studies in patients with SSc. Findings from this study will lead to the development of targeted self-management interventions to enhance pain management and improve quality of life in individuals with SSc.

Purpose: The purpose of this study is to describe the methodology that will be used to analyze data from a large international database, the Scleroderma Patient-centered Intervention Network (SPIN) Cohort, to address the following research questions in adults with SSc: (1) What is the relationship between patient characteristics, self-efficacy in managing pain, and pain outcomes? (2) Which patient characteristics influence trajectories of self-efficacy in managing pain and pain outcomes; and (3) How do changes in self-efficacy in managing pain mediate the trajectories of pain outcomes?

Methods:
Design. A 5-year, prospective longitudinal cohort study will be conducted using data collected by the Scleroderma Patient-centered Intervention Network (SPIN) to determine patient characteristics that influence self-efficacy in managing pain, pain outcomes (pain interference, intensity, and severity), and self-efficacy and pain trajectories among individuals with SSc.

Database. SPIN is an international collaboration of patient organizations, clinicians, and researchers from 45 centers in Canada, the United States, France, the United Kingdom, Spain, Mexico, and Australia that can help address important gaps in SSc (Dougherty et al., 2018). The goal of SPIN is to develop, adapt, and test interventions to complement standard care to help patients with SSc cope with their illness and improve their health-related quality of life (Brett D Thombs et al., 2012). A member of the patient’s healthcare team invites eligible patients, obtains informed consent, and completes the medical data form online to initiate the patient’s registration into the cohort (Dougherty et al., 2018). Participants then complete patient-reported outcome measures online at enrollment and every 3 months (Dougherty et al., 2018).

Participants. The expected sample size will be 1,600 adults with limited or diffuse SSc. Eligible participants are those: (1) classified as having SSc according to the 2013 American College of Rheumatology/European League against Rheumatism classification criteria (Van Den Hoogen et al., 2013) by a SPIN physician, (2) at least 18 years old, and (3) able to provide consent and complete questionnaires online in English, French, or Spanish.

Measures. Patient characteristics will include patient-reported demographic characteristics (i.e. age, sex, race/ethnicity, employment status, education level) and clinical characteristics provided by healthcare providers (i.e. disease subtype, age of onset, time since diagnosis, presence of Raynaud’s phenomenon, previous or current use of rehabilitation therapy, presence of ulcers, tendon friction rubs, joint contractures, and presence of an overlapping autoimmune disease). Pain outcomes will include pain interference, intensity, and severity based on PROMIS-29v2 and the Symptom and Transition Questionnaire. Self-efficacy in managing pain will be assessed using the Self-Efficacy for Managing Chronic Disease, and health-related quality of life will be assessed using PROMIS-29v2.

Analysis Plan. Non-directional statistical tests will be performed with significance set at 0.05 for each test. Effect sizes and their 95% confidence intervals (CIs) will be reported to address clinical significance. Sample Characteristics. Descriptive statistics will be used to detail the patient characteristics along with self-efficacy and pain outcome scores at baseline. Patient characteristics will be included as explanatory or predictors variables in the baseline regression models and trajectory analyses. Baseline Analysis. Bivariate regression methods will be used to examine the baseline relationship (a) between patient characteristics and measures of self-efficacy in managing pain, and (b) between self-efficacy in managing pain and pain outcomes. Hierarchical (sequential) forward multivariable regression models using General Linear Model (GLM) will be applied to determine the influence of baseline patient characteristics on self-efficacy and pain. For this hierarchical approach, block 1 will be comprised of individual demographic characteristics and block 2 will include individual clinical characteristics added to the model after the influence of block 1 has been examined. Adjusted R² and partial R² values will be reported as effect size indicators. Trajectory Analysis. Descriptive
statistics will detail the self-efficacy in managing pain, pain interference, pain intensity, and pain severity at baseline and follow-up visits during the observation period. For each of these outcomes, a separate trajectory analysis will be conducted. Hierarchical multi-level mixed-effects models for longitudinal data will be used to examine the pattern and rate of change of each outcome over the period. More specifically, a random coefficients regression models for repeated measures in which the fixed effects will be patient baseline characteristics and time, while the random effects will be participant and participant-by-time. Patient characteristics included in the baseline multivariable regression will be included and will be entered in the trajectory model using the forward (sequential) block approach described earlier. To evaluate self-efficacy as a mediator of pain over time, self-efficacy and its interaction with time will be added as a time-dependent covariate to the trajectory model for the pain outcomes. The effects of significant characteristics and self-efficacy will be further examined to determine the nature of the relationship with the pain outcomes and the magnitude of effect will be reported using intraclass coefficients. Sample size calculation. A sample size of 1,600 will provide at least 80% power for the planned baseline and trajectory analyses, assuming small effects and two-tailed tests with the level of significance set at 0.05 and patient characteristics as predictors. The significance level will not be adjusted for multiple outcomes and multiple tests due to the exploratory nature of the analyses.

Results: A description of methods and decision-rules used to derive the final sample will be presented in the form of a flow diagram. Characteristics of the sample and its representativeness will be described. The results from the planned analyses designed to address the project aims will be presented.

Conclusion: This study will be the first to explore trajectories of self-efficacy in managing pain and pain outcomes in patients with SSc. Findings from this study will help identify those at highest risk for pain symptom burden and lead to targeted self-management interventions to improve SSc patient outcomes.

Title:
Exploring Self-Efficacy and Pain Trajectories in Systemic Sclerosis

Keywords:
Pain, Self-Efficacy and Systemic sclerosis

References:

Bassel, M., Hudson, M., Taillefer, S. S., Schieir, O., Baron, M., & Thombs, B. D. (2010). Frequency and impact of symptoms experienced by patients with systemic sclerosis:


Abstract Summary:

Systemic sclerosis is a rare autoimmune disease associated with significant pain burden. This study will describe the methodology used to extract and utilize data from the Scleroderma Patient-centered Intervention Network (SPIN) Cohort, a large international database, to explore self-efficacy and pain trajectories in adults with systemic sclerosis.

Content Outline:

1. Introduction
   1. Systemic sclerosis (SSc) is a rare autoimmune disease with significant pain burden and reduced health-related quality of life.
   2. Self-efficacy is essential to improving self-management and health-related quality of life in individuals with SSc.

2. Body
   1. Main Point #1: High pain symptom burden
      1. Pain is experienced by up to 80% of individuals with SSc.
      2. Pain results in decreased physical functioning and reduced health-related quality of life.
   2. Main Point #2: Self-efficacy
      1. Need a better understanding of self-efficacy in SSc in relation to pain.
      2. Higher levels of pain have been associated with decreased self-efficacy.
      3. Improving self-efficacy may improve self-management in this population.
   3. Main Point #3: Limitations of previous research
      1. Has not addressed variations in pain and self-efficacy along the disease trajectory.
      2. Small sample sizes and lack of longitudinal studies.
   4. Main Point #4: Methodology of using a large, international database
      1. The Scleroderma Patient-centered Intervention Cohort is a large international database for adults with SSc.
      1. Longitudinal data collection every 3 months using patient-reported outcome measures.
      2. Explore the relationship between patient characteristics, self-efficacy in managing pain, pain outcomes, and the trajectories of self-efficacy and pain outcomes using this database.

3. Conclusion
   1. Help identify those at highest risk for pain symptom burden.
   2. Lead to the development of targeted self-management interventions.
**Primary Presenting Author**

Robyn Wojeck, MSN, RN, APRN, FNP-C  
Duke University  
School of Nursing  
PhD Student  
Durham NC  
USA

**Author Summary:** Robyn Wojeck is currently a PhD student at Duke University School of Nursing. Robyn is actively involved in multiple projects related to chronic illness. Her research interests focus on the symptom experience of living with systemic sclerosis, a rare autoimmune disease, to improve self-management and quality of life.

**Second Author**

Susan Silva, PhD  
Duke University  
School of Nursing  
Associate Research Professor  
Durham NC  
USA

**Author Summary:** Dr. Silva is an Associate Research Professor at the Duke University School of Nursing. She has served as the Statistical PI on an NIMH P30 Treatment for Adolescent with Depression Study, P30 NIMH Child and Adolescent Psychiatry Pragmatic Trials Network, NICHD Reproductive Medicine Network, NIDA Substance Abuse Network, and RO1 Substance Use Outcomes following Treatment for Adolescent Depression, among others.

**Third Author**

Donald E. Bailey, PhD, RN, FAAN Jr.  
Duke University  
School of Nursing  
Associate Professor  
Durham NC  
USA

**Author Summary:** Dr. Donald Bailey is an Associate Professor of Nursing, Co-Director of ADAPT Center for Cognitive/Affective Symptom Science and Director of the Scholarship and Mentoring Core of the Center and Senior Fellow in the Center for the Study of Aging and Human Development. The primary aim of his program of research is to generate new knowledge to improve self-management and life quality among individuals that are watching/monitoring serious chronic illnesses, those that are life threatening.

**Fourth Author**

Mitchell R. Knisely, PhD, RN-BC, ACNS-BC
Dr. Knisely is an Assistant Professor at Duke University School of Nursing. His research interests are in the areas of precision health and pain management. Particularly, his program of research seeks to optimize pain assessment and management through a better understanding of the biopsychosocial determinants of pain, co-occurring psychoneurological symptoms, and associated treatment responses in individuals with chronic conditions.