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Can routine use of patient reported outcomes help guide systemic sclerosis chronic disease care?

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Abstract

Background—The implementation of patient reported outcome measures (PROMs) is increasingly recognized as a critical aspect of clinical practice. The use of PROMs is particularly important in patients with complex, chronic medical disease that have heterogeneous, subjective symptoms. In this report, we examine the association of traditional markers of disease severity in the systemic sclerosis (SSc) patient population with PROMs that focus on mental health and physical function.

Methods—SSc patients seen in the University of Utah Chronic Disease Clinic were offered a personal health assessment that included a current health visual analog scale (VAS), PROMs that assessed mental health [Patient-Reported Outcomes Measurement Information System (PROMIS) Bank v1.0 depression], and physical function (PROMIS Bank v1.2 physical function). All PROMIS instruments are normed such that an average person has a score of 50. The assessment was administered on a tablet while patients waited to see the physician(s) for SSc care visits and uploaded in real-time to the electronic medical record for physician review.

Results—During a six-month period, 137 unique SSc patients began a PROM assessment. All 137 patients completed the VAS and PROMIS physical function; 133 completed the PROMIS

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depression scales. Overall, scores were 53.1 and 43.2 for depression and physical function, respectively. Relatively mild patients without end-organ damage or disease activity due to SSc did not have significant differences in perceived reduction in general health, physical function, or depression when compared to SSc patients with digital ulcerations, interstitial lung disease, pulmonary arterial hypertension, inflammatory arthritis, inflammatory myositis, or joint contractures.

Conclusions—Patients with chronic disease report depression and physical health scores that are independent of traditional physician-perceived disease activity or damage. Disease burden associates with the presence of a chronic disease, but is independent of severity. Assessment of PROMs provides an additional perspective on health status for chronic disease care.

Introduction

Chronic and complex disease care is increasingly recognized to benefit from a diverse health care team with an improved capacity for engagement (1). An important aspect of patient engagement is determining whether improvement in health outcomes occurs when patients with chronic disease are targeted for risk factors such as depression or specific functional difficulties (2). Specifically, physician strategies to improve care delivery and outcomes in complex patients is needed. The use of Patient Reported Outcomes Measures (PROMs)—outcomes assessed directly from the patient without interpretation from the physician—to assess these targeted factors provides vital information to patient care. The National Institute of Health (NIH) - Patient Reported Outcomes Measurement Information System (PROMIS) has developed psychometrically advanced generic health measures that span the range of symptoms (3). The PROMIS is a freely available, non-copyrighted, health related quality of life (HRQOL) instrument with US-based norms across 11 domains and are sensitive to change after an intervention(4). While comprehensive organ specific assessments are completed by the health care providers in the chronic disease clinic, PROMIS instruments can supplement care by specifically assessing depression and physical function. Thus we specifically assess these two domains in our patients with complex diseases to allow improved understanding of the variable impact of depression and physical function limitations for those suffering with these diseases.

Systemic sclerosis (SSc, scleroderma) is a multi-organ system disease characterized by progressive vasculopathy, fibrosis, and immune dysfunction (5). This disease has no cure and is marked by considerable variability in both disease course and organ severity. Prognosis is difficult to predict and patients with the same diagnosis have considerable range of symptomatology (6). In particular, gastrointestinal complaints can be challenging to interpret in SSc patients since testing is invasive and may not assist diagnosis (7). Physical exam, pulmonary screening tools, and laboratory assessment are the classic measures of disease severity and constitute the primary data used to guide discussion of disease management and prognosis (8). This objective testing can be extensive, expensive and burdensome. Further, it is likely that these measures alone miss components of a patient's global health. Ideally PROMs can supplement these traditional clinical measures to ensure that care is patient-centered (9). At the University of Utah, SSc is a disease seen in the Chronic Disease Clinic. This specialized clinic offers coordinated care between a

rheumatologist, pulmonologist, and/orgastroenterologist and is supported by a team that includes advanced care practitioners, a pharmacist, a nurse specialist, a medical assistant, and a social worker. The team is organized to implement a subspecialist care plan that is both immediate and multi-organ system-based and is designed to be patient centered to reduce the burden of multiple visits and testing. Patients are offered the opportunity to meet with all providers or a limited number based on their questions and needs, and all care is coordinated with necessary studies for the same day.

As part of our goal to serve patients in ways that are most advantageous to them, we implemented an optional personal health assessment. This tool is called My Evaluation (mEVAL) and included a current health visual analog scale (VAS), PROMIS Bank v1.0 depression, and PROMIS bank v1.2 physical function. The PROMIS item bank PROMIS items have been reported to function similarly whether administered via paper or tablet, with similar user satisfaction(10)We sought to understand if depression and physical function PROMs correlate with more disease-severity measures used in routine clinical practice in order to determine whether this tool could improve provider identification of care needs.. Both mEVAL PROM results and SSc disease severity measures were examined in order to inform the optimal use resources for SSc patient engagement. In particular, the administration of mEVAL in this chronic disease clinic was used to identify which patients would benefit from additional mental health services. We hypothesized that patients that were considered by the health care system to have highest end-stage disease burden would have the highest depression and lowest physical function scores.

Methods

Patient population

Systemic sclerosis patients that were seen in the University Chronic Disease Clinic were offered a mEVAL assessment while they were waiting to see the physician(s) for SSc care visits. The mEVAL is administered on a tablet computer and takes approximately 15 minutes for SSc patients to complete. Patients with hand contractures were provided a stylus to use. Each patient was assessed by one or more physicians for skin, musculoskeletal and cardiopulmonary disease severity at the time of evaluation. Skin severity was determined by digital ulceration or diffuse skin distribution of skin thickening; musculoskeletal severity was presence or absence of arthritis, joint contracture, or myositis; and cardiopulmonary severity was determined by presence or absence of pulmonary arterial hypertension or interstitial lung disease and by pulmonary function testing.

PROMIS Instruments

We use the computer adaptive tests (or CAT) versions of PROMIS to assess depression (v1.0) and physical function (v1.2) (3). Each PROMIS question has five response options. Since the instrument is computer adaptive, subsequent questions are decided by a computer algorithm based on the previous response of the patient. This eliminates irrelevant questions and allows for a more precise score in a shorter amount of time. Typically, patients receive between 4 and 8 questions. PROMIS raw scores are transformed into T-scores with an average score of 50 and a standard deviation (SD) of 10. In all PROMIS domains, a higher

T-score represents more of the concept being measured. For negatively-worded concepts like depression, a T-score of 60 is one SD worse than average; for positively-worded concepts like physical function, a T-score of 60 is one SD better than average.

The depression item bank measures symptoms over the past seven days and assesses self-reported negative mood (guilt and/or sadness), views of self (worthlessness and/or self-criticism), and social cognition (loneliness and/or interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose). Important to the SSc patients, somatic symptoms (such as, changes in appetite and sleeping patterns) are not included, which eliminates consideration of these items' confounding effects when assessing patients with comorbid physical conditions.

The physical function item bank measures self-assessed capability rather than actual performance of physical activities. This includes the functioning of one's upper extremities (dexterity), lower extremities (mobility or walking), and central regions (neck or back), as well as instrumental activities of daily living, such as running errands.

VAS

When responding to the VAS item, respondents specify their level of agreement to a statement of general health by indicating a position along a continuous line between two end-points from 0 to 1.

Results

During the first six-month period of implementation period of mEVAL into the Chronic Disease Clinic, 491 unique SSc patients were seen at the University of Utah and 234 received routine care in Chronic Disease Clinic. Of these 234 patients, 137 patients completed the VAS and PROMIS physical function; 133 completed the PROMIS depression scales. Reasons for not completing the assessment in its entirety were not captured, however there were no significant differences seen in age, sex, or presence of SSc-related symptoms in these non-completers. The age range of these SSc patients completing the assessment are shown in Figure 1. This population was mostly female and had limited skin involvement. Other clinical features of these 137 patients are reported in Table 1. Of these 137, 43 patients would be considered by physical exam and ancillary pulmonary studies to have no evidence of end-organ damage or disease activity, and 19 patients had insufficient ancillary study information to determine disease presence. The mEVAL results are reported in Table 2. No patient considered themselves completely healthy on the VAS, with a mean on 0.51 reported. In the SSc population overall, the mean physical function of 41.26, about one SD below the U.S. general population mean, and the mean depression score was 53.06, approximately in line with the U.S. general population mean. In the SSc patient population neither the physical function nor depression PROM was significantly elevated compared to the U.S. population. For the patients that had no physical exam damage or activity indices, the mean physical function was 43.2 and mean depression 50.9, which was not significantly different than the SSc patients with symptoms (52.9 and 51.7 respectively, $p=0.79$ for both). There was no collinearity of physical function and depression in the patients that completed both assessments (Figure 2).

Conclusions

The implementation of PRO in routine SSc care highlights that self-report of general health, physical function, and depression provides an understanding of health that is distinct from the traditional measures of disease activity and damage for SSc and may be discordant. In this study, SSc patients with disease measured by traditional damage or activity indices had similar levels of perceived decrease physical function and depression to those SSc patients with no disease related complications. This highlights that there is a perceived burden simply associated with a diagnosis of a chronic disease regardless of severity. Knowledge of this decrease in quality of life may suggest targets for interventions earlier in a disease course. This may ultimately impact disease course as disease progresses or patient's sense of well-being while managing a chronic disease. Additionally, bringing mental health and social work resources may restore function in patients who might otherwise be overwhelmed by the prospect of a lifelong chronic disease.

Limitations of this report include the relatively low rate of completion of the mEVAL measures and the single site, specialty nature of the practice. While all patients are enrolled in an institutional review board (IRB) approved registry due to the coordination of clinical care patients may have not have seen the rheumatologist at the care visit when the PRO were administered, thus items such as Medsger severity index or modified Rodnan skin scores were not available at the time of care. Future work should focus on barriers and facilitators to questionnaire completion and on the value of the questionnaires to the patient's overall care. Additionally, the lack of difference in mean physical function and mean depression between patients with and without damage should be furthered explored after educational interventions. We did not adequately capture if a patient understood their prognosis. Of note, 46 patients opted out of completing the PROMIS depression bank, indicating that while mental health needs may be underestimated, this assessment was generally acceptable to patients in this practice. Additionally, patients were provided the mEVAL while waiting for the physician, thus time constraints may have influenced completion rate. Nonetheless, mEVAL was effective in identifying patients with depression (with a score above 60) who would benefit from social work intervention to explore the etiology of these perceived reductions in general health and physical function and provide additional treatment of depression.

Overall, the assessment of depression and physical function was feasible in this specialty population. The use of PROMs resulted in additional intervention directed towards reducing perceived disease burden. Future work should follow patients longitudinally to identify impact of disease course and intervention over time, and determine the optimum time to provide the instrument to the patient. Continued study is necessary to understand the overall benefit to using PROM in the clinical setting to improve health outcomes.

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Figure 1.

Figure 2.
Physical function and depression scores in chronic

Table 1

Characteristics of Systemic Sclerosis Patients Completing the mEVAL Patient Reported Outcome

Variable	Values n=137 (%)
Female	115 (84)
SSc type	
• Limited cutaneous	124 (90)
• Diffuse cutaneous	15 (10)
Disease Severity Measures:	
• Digital ulcer (traumatic or ischemic)	27 (20)
• Pulmonary arterial hypertension	27 (20)
• Interstitial Lung Disease	34 (25)
• Inflammatory Arthritis	17 (12)
• Myositis	4 (3)
• Hand contractures	11 (8)

Table 2

mEVAL results for all systemic sclerosis patients

Instrument	MIN	MAX	MEAN	SD
PROMIS Bank v1.0 - Depression	34.17	73.25	53.06	7.21
PROMIS Bank v1.2 - Physical Function	24.07	59.75	41.26	6.98
Current Health VAS	0.07	1.00	0.57	0.18