AJKD
Original Investigation

Patient-Reported Outcome Instruments for Physical Symptoms Among Patients Receiving Maintenance Dialysis: A Systematic Review

Jennifer E. Flythe, MD, MPH,[1,2] Jill D. Powell, MPH,[1] Caroline J. Poulton, MSW,[1] Katherine D. Westreich, MD,[1] Lara Handler, MSLS,[3] Bryce B. Reeve, PhD,[2,4] and Timothy S. Carey, MD, MPH[2,5]

Background: Patients with end-stage renal disease (ESRD) receiving dialysis have poor health-related quality of life. Physical symptoms are highly prevalent among dialysis-dependent patients and play important roles in health-related quality of life. A range of symptom assessment tools have been used in dialysis-dependent patients, but there has been no previous systematic assessment of the existing symptom measures' content, validity, and reliability.

Study Design: Systematic review of the literature.

Settings & Population: Patients with ESRD on maintenance dialysis therapy.

Selection Criteria for Studies: Instruments with 3 or more physical symptoms previously used in dialysis-dependent patients and evidence of validity or reliability testing.

Intervention: Patient-reported physical symptom assessment instrument.

Outcomes: Instrument symptom-related content, validity, and reliability.

Results: From 3,148 screened abstracts, 89 full-text articles were eligible for review. After article exclusion and further article identification by reference reviews, 58 articles on 23 symptom assessment instruments with documented reliability or validity testing were identified. Of the assessment instruments, 43.5% were generic and 56.5% were ESRD specific. Symptoms most frequently assessed were fatigue, shortness of breath, insomnia, nausea and vomiting, and appetite. Instruments varied widely in respondent time burden, recall period, and symptom attributes. Few instruments considered recall periods less than 2 weeks and few assessed a range of symptom attributes. Psychometric testing was completed for congruent validity (70%), known-group validity (25%), responsiveness (30%), internal consistency (78%), and test-retest reliability (65%). Content validity was assessed in dialysis populations in 57% of the 23 instruments.

Limitations: Consideration of physical symptoms only and exclusion of single symptom–focused instruments.

Conclusions: The number of available instruments focused exclusively on physical symptoms in dialysis patients is limited. Few symptom-containing instruments have short recall periods, assess diverse symptom attributes, and have undergone comprehensive psychometric testing. Improved symptom-focused assessment tools are needed to improve symptom evaluation and symptom responsiveness to intervention among dialysis-dependent patients.

Am J Kidney Dis. 66(6):1033-1046.

INDEX WORDS: Maintenance dialysis; end-stage renal disease (ESRD); health-related quality of life (HRQoL); physical symptoms; patient-reported symptom tool; patient-reported outcome instrument; patient-centered care; comorbidity burden; fatigue; shortness of breath; insomnia; poor appetite; nausea; systematic review.

Patients with end-stage renal disease (ESRD) on dialysis therapy have poor health-related quality of life (HRQoL) compared with members of the general population.[1-4] A high burden of comorbid illness, impaired physical function, and other factors contribute to this suboptimal HRQoL, and existing data suggest that physical symptoms also play important roles.[5,6]

Dialysis-dependent patients have numerous physical symptoms, with more than half the patients reporting fatigue, pain, cramps, sleep disturbance, and sexual dysfunction.[7-9] Despite the relevance of symptoms to HRQoL, health care providers are not adept at recognizing them. One study found that providers frequently do not identify key symptoms, and when

From the [1]University of North Carolina Kidney Center, Division of Nephrology and Hypertension, Department of Medicine, University of North Carolina School of Medicine; [2]The Cecil G. Sheps Center for Health Services Research and [3]Health Sciences Library, University of North Carolina; [4]Department of Health Policy and Management, University of North Carolina Gillings School of Global Public Health; and [5]Division of General Internal Medicine and Clinical Epidemiology, Department of Medicine, University of North Carolina School of Medicine, Chapel Hill, NC.

Received February 2, 2015. Accepted in revised form May 18, 2015. Originally published online July 23, 2015.

Address correspondence to Jennifer E. Flythe, MD, MPH, University of North Carolina Kidney Center, 7024 Burnett-Womack CB #7155, Chapel Hill, NC 27599-7155. E-mail: jflythe@med.unc.edu

0272-6386
http://dx.doi.org/10.1053/j.ajkd.2015.05.020

symptoms are recognized, providers underestimate their severity.[8] Additionally, evidence-based dialysis treatment interventions and symptom-targeted pharmaceutical therapies are lacking. Erythropoiesis-stimulating agent use is associated with improved HRQoL and reduced fatigue,[10,11] but few other dialysis prescription changes have been shown to modulate HRQoL or symptoms. To inform the development of new symptom interventions, accurate understanding of symptom prevalence, patient prioritization of symptoms, and the pathophysiology underlying common symptoms is needed.

To assess symptoms, clinicians and investigators rely on a range of patient-reported symptom tools, including instruments that measure HRQoL,[12-18] dialysis-specific symptom indexes,[5,19] and symptom questionnaires originally developed for nondialysis patients.[20-23] As a result, the type and quality of data collected are widely varied, thus limiting precise conclusions about patient prioritization of symptoms and symptom responsiveness to mitigation strategies. Understanding symptoms related to dialysis procedures may inform symptom pathophysiology comprehension and may help identify therapeutic treatment modifications.

We undertook this systematic review to identify measures used to assess patient-reported physical symptoms in the dialysis-dependent population and to describe instrument development, symptom-related content, and psychometric properties of the identified measures. We limited our review to physical symptoms to capture symptoms most likely to fluctuate on a treatment-to-treatment basis. To establish a baseline quality threshold for considered instruments, we limited the review to measures with published validity and/or reliability assessments.

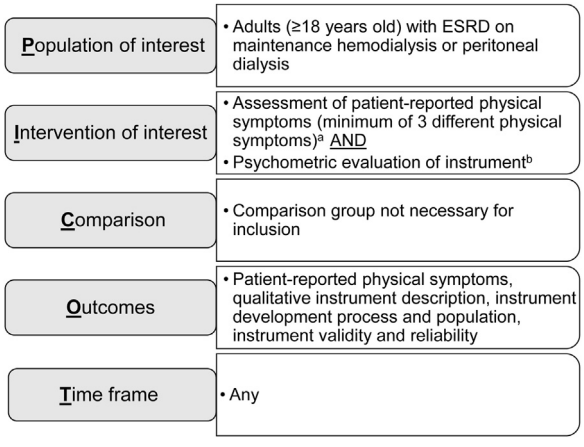

Figure 1. PICOT criteria and search strategy.[27] [a]Instruments focused on a single symptom such as pruritus, thirst, fatigue, sleep, or sexual dysfunction and instruments with mood symptoms only were excluded. Physical function and capacity were not considered symptoms. Instruments focused exclusively on physical function were excluded. [b]Instrument psychometric assessment included content validity, construct validity, responsiveness, internal consistency reliability, and test-retest reliability. Instruments with no retrievable information on validity or reliability were excluded.

METHODS

Study Overview

We conducted a systematic literature review according to guidelines provided by the US Department of Health and Human Services Agency for Healthcare Research and Quality[24,25] and used the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines to guide data collection and reporting of evidence.[26]

Selection Criteria for Articles and Instruments

Eligibility criteria were developed using modified PICOT (population of interest, intervention of interest, comparison, outcomes, and time frame) criteria (Fig 1).[27] Full inclusion and exclusion criteria are reported in Table 1. We began by identifying relevant articles for review, but the unit of analysis was the patient-reported outcome instrument ascertained from identified articles.

Article and Instrument Identification

Articles for review were identified from MEDLINE (by PubMed) and EMBASE (by Elsevier), which were searched from 1946 (MEDLINE) and 1966 (EMBASE) to December 31, 2014, with the assistance of an experienced reference librarian (L.H.). Key words and controlled vocabulary were used for each database, and searches were constructed using a combination of medical subheadings, key words, and text words. Because physical symptom assessments are often embedded in HRQoL assessments, we conducted searches for HRQoL or symptoms. Complete search strings are available in Table S1 (provided as online supplementary material). Reference lists of selected studies were further searched for additional instruments and articles. Individual

Table 1. Article and Instrument Selection Criteria

	Inclusion Criteria	Exclusion Criteria
Article level	• Studies of patients with end-stage renal disease on dialysis therapy who were ≥18 years old • Reported use of a patient-reported outcome instrument that included physical symptoms	• Studies of patients with acute kidney injury or those requiring short-term dialysis • Non-English articles • Letters and case reports
Instrument level	• Instruments with ≥3 unique physical symptoms[a] • Instruments with psychometric evaluation that included reporting of validity and/or reliability testing results	• Instruments focused on a single symptom • Instruments with mood or mental health symptoms only • Instruments with no retrievable data on validity or reliability

[a]Physical function and capacity were not considered symptoms.