A pilot quality-of-life instrument for pruritus

Nisha S. Desai, MD,[a] Gabriele B. Poindexter, MD,[b] Yvette Miller Monthrope, MD,[c] Sandra E. Bendeck, MD,[d] Robert A. Swerlick, MD,[e,f] and Suephy C. Chen, MD, MS[e,f,g]
Saint Louis, Missouri; Chapel Hill, North Carolina; Toronto, Ontario, Canada; Dallas, Texas; and Atlanta, Georgia

Objective: We sought to develop a validated, reliable pruritus-specific quality-of-life (QOL) instrument, ItchyQoL.

Methods: From 21 in-depth interviews with patients with pruritus, we developed 22 pruritus-specific items, and hypothesized 3 major constructs that explain the way pruritus affects patients' QOL: symptoms, functional limitations, and emotions. We developed two versions of the pruritus QOL instrument, which assess for level of bother or frequency using items from the interviews and from generic skin QOL instruments, Skindex-16 (bother) and Skindex-29 (frequency). The instrument was tested for validity, reliability, and responsiveness. The frequency version was subsequently applied clinically to further evaluate its face validity.

Results: A total of 89 patients with dermatologic conditions participated in the validation phase and 101 patients participated in the clinical application phase of the study. Construct validity was demonstrated by principal axes factor analyses and by demonstrating that differences in symptoms, functioning, and emotion differed among the varying levels of self-reported pruritus severity more than would be expected by chance ($P < .05$ by analysis of variance). The instrument demonstrated reliability with internal consistency (Cronbach α: frequency 0.72-0.93 and bother 0.78-0.81) and reproducibility (intraclass correlation coefficient: frequency 0.91 and bother 0.84-0.87). The instrument suggested preliminary responsiveness for patients with improved disease for both frequency and bother items with both overall scores and the majority of the subscales scored demonstrating significant changes. Discriminant validity was shown by comparing differences in and the number of insensitive items between the pruritus-specific QOL instrument and the generic Skindex instruments.

Limitations: Lack of generalizability and potential selection bias are limitations.

Conclusions: This study represents, to our knowledge, the first attempt at a pruritus-specific QOL instrument that is reliable, valid, and responsive. (J Am Acad Dermatol 2008;59:234-44.)

Pruritus is the chief symptom in numerous dermatologic conditions,[1-4] and a common symptom in systemic disorders,[5-7] infectious diseases,[8,9] and neoplastic diseases.[9,10] The prevalence of pruritus in the general population is not well documented but has been reported to be around 10%.[11,12] It is the most common dermatologic problem in nursing homes along with xerosis.[13] Not only is pruritus a widespread phenomenon, it also can have a significant quality-of-life (QOL) impact in

From Washington University, Saint Louis[a]; University of North Carolina[b]; University of Toronto[c]; University of Texas Southwestern[d]; Department of Dermatology, Emory University School of Medicine, Atlanta[e]; and Division of Dermatology[f] and Department of Health Services Research and Development,[g] Atlanta Veterans Administration Medical Center.

Supported in part from an American Skin Association (ASA) Health Services Research Grant, the ASA David Martin Carter Research Scholar Award, and an Emory Skin Disease Research Center Pilot and Feasibility grant (No. P30AR42687) from the National Institute on Arthritis and Musculoskeletal and Skin Disease (NIAMS), National Institutes of Health (NIH). Dr Chen was supported in part by a Mentored Patient Oriented Career Development Award (No. K23AR02185-01A1) from NIAMS, NIH.

Conflicts of interest: None declared.

Presented as abstracts at the 66th Annual Meeting of the Society for Investigative Dermatology, Miami, Florida, May 2005, and the 63rd Annual Meeting of the American Academy of Dermatology Annual Meeting, New Orleans, Louisiana, February 2005.

Accepted for publication April 4, 2008.

Reprint requests: Suephy C. Chen, MD, MS, Department of Dermatology, Emory University School of Medicine, 101 Woodruff Circle; Atlanta, GA 30322. E-mail: schen2@emory.edu.

Published online June 12, 2008.
0190-9622/$34.00

doi:10.1016/j.jaad.2008.04.006

Abbreviations used:

ANOVA: analysis of variance
ICC: intraclass correlation coefficient
QOL: quality of life

patients' lives. In a recent French study, more than 40% of patients with chronic pruritus described their disease as burdensome.[12]

Current treatments for pruritus are sparse, mostly consisting of antihistamines, antileukotrienes, and immunosuppressives, which are of varying efficacy. Researchers are challenged to develop better therapies, but pruritus, like pain, is a stimulus that cannot be measured directly. Rather, pruritus is measured either by observing the amount of scratching by the patient or by asking the patient to rate pruritus on some sort of severity scale, such as the visual analog scale or a numeric scale. However, neither the amount of scratching nor the visual analog/numeric scale measures the impact of pruritus on patients' QOL. The extent to which a disease impacts patients' QOL can be quantified by health status instruments. Health status instruments can either be generic or condition specific. Generic instruments capture broad-based QOL issues and, therefore, may be used to directly compare QOL across disparate disease states. However, generic instruments generally exclude QOL aspects that may be significant for a specific condition. Condition-specific instruments, by contrast, focus on QOL aspects pertinent to a particular condition. As a result, they have the advantage of being shorter, more appropriate, and more sensitive to subtle, specific QOL issues related to the disease in question. Currently there are no validated pruritus-specific QOL instruments. Although generic and skin-specific QOL instruments are available, they do not directly assess the issues specific to pruritus and, thus, will not adequately capture itch-specific QOL impact.

In this study, we developed a pruritus-specific QOL instrument, called ItchyQoL, based on concerns and issues pertinent to patients with pruritus. We tested the instrument for validity, reliability, and responsiveness and we report preliminary results. In addition, we tested the instrument in a second sample of patients with pruritus to determine its measurement properties in the clinical setting.

METHODS

All patients were consented and recruited from Emory University Dermatology Clinics, Atlanta, Ga; Grady Memorial Hospital, Atlanta, Ga; or the Veterans Affairs Medical Center of Atlanta, Ga. We obtained approval for the protocol and consent process from the respective institution's research committee and by the university institutional review board.

Item development

We conducted in-depth interviews with adult patients with pruritus of any cause to elicit any and all ways that pruritus affected their lives. Interviews were conducted until no new items were obtained. Based on all patient responses and their frequency, we composed pruritus-specific items. Items were developed into questions that addressed frequency, level of bother, or both. We conceptualized 3 major constructs from these items that explain the way pruritus affects patients' QOL: symptoms, functioning limitations, and emotions. We administered the pruritus-specific items in addition to the 29-item version of Skindex[14] and Skindex-16[15] to comprehensively assess the constructs patients found relevant. Skindex-29 addresses QOL from a frequency perspective whereas Skindex-16 addresses level of bother. For all items, we used the same format as for the Skindex instruments, but changing the wording "skin condition" to "itchy skin condition." All items inquired about the last 7 days. The responses for frequency type questions were ranked on a 5-point scale with designations of: never, rarely, sometimes, often, and all the time. A similar scale was developed for bother type questions: not bothered, little bothered, somewhat bothered, very bothered, and severely bothered. The final survey also contained demographic, pruritus severity, cause, and medication use questions.

After the development of the initial instrument, it was administered to 5 adults with no medical training recruited from the general population for pilot testing, to test for clarity and comprehension. Based on the responses, we made the appropriate modifications to the instrument.

Sample population, measures, and data collection

All adult patients with active pruritus in any area of the body within the past 7 days were eligible to participate. Patients were recruited from our university dermatology clinic by referral from their dermatologist, or by telephone by contacting patients in our pruritus database. The database consists of patients seen at the university dermatology clinic identified by *International Classification of Diseases, Ninth Revision* code for pruritus. Interviewers administered either the bother or frequency version of the instrument to patients in a pseudorandom fashion. For each interviewer, the first patient was