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Measuring Health-Related Quality of Life in Leukemia: The Functional Assessment of Cancer Therapy – Leukemia (FACT-Leu) Questionnaire

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ABSTRACT

Objective: Develop and validate a health-related quality-of-life (measure for patients with acute and chronic leukemia). **Methods:** The study consisted of two phases: scale construction and scale validation. For the item-generation phase, a summary of the literature combined with qualitative results from item-generation interviews with 29 acute or chronic leukemia patients and 16 health care providers yielded an initial item pool reflecting leukemia-specific concerns and symptoms. Items underwent iterations of review and reduction according to defined retention criteria to support content validity, as defined by priority concerns of patients. Seventeen final leukemia-specific items were combined with the Functional Assessment of Cancer Therapy–General to create the FACT-Leukemia (FACT-Leu) scale. For the validation phase, 79 individuals with acute or chronic leukemia completed questionnaires at three time points. **Results:** All FACT-Leu subscale and aggregated scores showed high

internal consistency (α s ranging from 0.75 to 0.96). Test-retest reliability was adequate for all subscales (intraclass correlation range 0.765–0.890). The FACT-Leu scale demonstrated good convergent validity, with significant correlations with quality-of-life criteria and performance status, in the expected direction. FACT-Leu subscale scores were significantly different among the three performance status change groups, suggesting good responsiveness to change. **Conclusions:** The FACT-Leu scale is a valid, reliable, and efficient measure of leukemia-specific health-related quality of life for acute and chronic disease.

Keywords: acute leukemia, chronic leukemia, health-related quality of life, patient-reported outcomes.

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Introduction

In 2012, leukemia is estimated to account for 47,150 new cases and 23,540 deaths in the United States [1]. While the clinical management of hematologic malignancies has improved over the past 50 years, cures remain elusive [2–5]. The addition of treatment options and a better understanding of factors predicting treatment response have improved the 1- and 5-year relative survival rates but have also introduced toxicities that can offset clinical benefit [4,6]. In cases where the chance for cure is low (e.g., acute myeloid leukemia) and available treatments have a questionable impact on survival and known toxicity/cost, health-related quality of life (HRQOL) becomes an even more important clinical management concern.

HRQOL concerns in leukemia may vary depending on prognosis (and related therapeutic intent), disease-specific concerns, and treatment-specific concerns [6]. Primary concerns may include disease symptoms, treatment toxicity, increased risk of second malignancy, long-term and late effects of treatment (e.g.,

fatigue), and treatment decision making. Because of the prolonged course and risk of life-threatening or disrupting treatments, patients with leukemia have concerns about their mortality, loss of independence, disfigurement, life disruption, and disability [7–9]. Concerns related to living with uncertainty and the “emotional exhaustion” due to the potentially long-term disease course, financial burden, increased risk for depressive mood and anxiety, sexual functioning, interference, and family disruption are also significant [9–11]. Stem cell transplantation also confers risks for acute and chronic graft-versus-host disease, infection, endocrine disturbances, fatigue, and cognitive dysfunction [12].

Although HRQOL concerns of patients with acute and chronic leukemia have been reported, few validated instruments measure them concisely [13–15]. This has been cited as a factor limiting the use of HRQOL as an end point in leukemia treatment research [16]. Very few clinical trials in leukemia, acute or chronic, have included a study of HRQOL [17]. Those which have tended to use general measures such as the European

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Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Core Questionnaire 30 [18,19] and the Functional Assessment of Cancer Therapy-General (FACT-G [20,21]). Available disease-specific questionnaires include the Life Ingredient Profile for hematologic malignancies [22], and the Medical Research Council/EORTC Quality of Life Questionnaire-Leukaemia Module (MRC/EORTC QLQ-LEU [14]), a measure of HRQOL for individuals with leukemia in long-term remission. Two additional EORTC leukemia-specific modules—the EORTC Quality of Life Module for Chronic Lymphocytic Leukaemia [23] and the EORTC Module for Chronic Myeloid Leukaemia [24]—are currently in development; however, validity data have not been published.

As international collaboration in clinical research has increased, so has the need for cross-culturally relevant patient outcome assessments. International applicability could be enhanced if an HRQOL questionnaire specific to leukemia underwent a parallel cross-cultural development approach to ensure semantic equivalence and cultural relevance [25,26]. The purpose of this study was to develop and examine the preliminary validity of a questionnaire developed with cross-cultural input, to measure the HRQOL of patients with acute and chronic leukemia.

Methods

Study Design

The development and validation of the FACT-Leukemia (FACT-Leu) scale consisted of two stages: 1) scale construction (item generation and scale construction) and 2) scale validation (reliability/validity testing). All patients in both stages provided informed consent for participation. This study was conducted in compliance with all relevant local institutional review boards.

Scale Construction

Participants

A purposive sample of 29 patients (19 acute, 10 chronic) from seven countries (Argentina, Brazil, France, Germany, Poland, Russia, and the United States) and 16 health care providers from nine countries (above plus Greece and Uruguay) participated in item generation and scale construction. This portion of the study was conducted under local institutional review board approval that included a contractual agreement with the international sites that only de-identified data would be transmitted. Therefore, demographic data are not available. The number of patients and providers in the item-generation phase exceeds the number of cases typically required (12–15) for saturation in qualitative research [27–29]. Given the inclusion of acute and chronic leukemia and the possibility that each would manifest with unique sets of symptoms and concerns, we estimated an item-generation sample size of up to 30 patients. Saturation was met prior to this goal as determined by the centralized project manager who noted that no new content was coming in the last several interviews.

Providers (nine physicians and seven nurses) were leukemia specialists with a range of 3 to 45 years of experience in hematology/oncology and hematopoietic cell transplantation. Eligible providers were sufficiently proficient in English for interviews and completion of forms. Providers were recruited at two international leukemia investigator meetings: one sponsored by the US National Cancer Institute and the other sponsored by a pharmaceutical company. Patients were recruited by the investigators at their home institutions and then interviewed by our trained instrument development interviewers and language translation professionals.

Procedures

Experts and patients were interviewed individually by trained researchers by using a semi-structured item-generation interview designed to elicit patient experiences and expert opinions and observations regarding how leukemia may affect physical status, emotional well-being, functional well-being, family/social issues, sexuality/intimacy, work status, and future orientation. According to Functional Assessment of Chronic Illness Therapy item-generation standard practice, each patient interview began with a nondirective, open-ended inquiry as to the most important HRQOL concerns associated with leukemia and its treatment [30]. Experts were also asked to comment on whether acute and chronic disease questionnaires should be separate or combined into one common instrument.

In addition to the above, we conducted a literature search to identify additional HRQOL issues. We performed a MEDLINE search of English language studies from 2000 to 2002 by using the search terms “acute leukemia” and “chronic leukemia.” Articles were retained for review if they addressed physical, functional, social, or emotional aspects of acute or chronic leukemia. A summary of the 24 articles selected, combined with qualitative data collected from patients and experts, was used to generate items reflecting unique symptoms/concerns related to leukemia.

Source data were summarized individually and then collectively by leukemia subtype (chronic vs. acute). Symptoms and concerns were grouped according to preset HRQOL domains and tracked according to the frequency each one was referenced, by source. This created an initial item pool. Items underwent iterations of review and reduction according to defined retention criteria. The selection criteria included all items referenced at a cumulative (patient, expert, literature) frequency of 10% or greater for physical symptoms and 15% or greater for all other problems/issues for both the chronic and acute subtypes. Retained items were then presented to 15 of the 16 international clinical experts who participated in the item-generation phase for more detailed ratings of symptom prevalence and degree of concern by leukemia subtype. Each item was rated for each subtype on two 0 to 3 scales (“0” = not at all common/not at all a concern to “3” = very common/very much of a concern”).

Expert review of these 53 items was summarized by subtype and used in combination with the summarized patient data to derive content for the scale that would go to initial validity testing. Items with a median expert rating of greater than or equal to 2 (either for how common a symptom it is or how much of a concern the symptom is) plus a frequency of more than 15% across both subtypes were retained. During a final review, item wording was refined to produce the test version of the leukemia subscale. Special attention was given to whether a common (acute and chronic) or separate (acute vs. chronic) subscale would be optimal. This was explored during the initial item-generation interviews and addressed in all iterations of review during scale construction. For quality and clarity, an internal team with extensive expertise in self-report scale development (composed of two allied health professionals with clinical mental health experience treating leukemia, one psychometrician, one statistician, one cross-cultural and language translation expert, and a qualitative researcher) navigated the development process and reviewed and edited final subscale items for wording (semantic simplicity), cross-cultural relevance, and translatability.

Scale Validation

Participants

A convenience sample of 79 men and women recruited from oncology clinics at three Chicago-area hospitals participated in the reliability and validity testing. We estimated that a minimum

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