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Short communication

Further psychometric validation of the GAH scale: Responsiveness and effect size

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ABSTRACT

Objectives: The purpose of this study was to assess the responsiveness of the newly developed Geriatric Assessment in Hematology (GAH) scale to clinical change in older patients diagnosed with hematologic malignancies. **Methods:** A prospective observational study conducted in 164 patients aged ≥ 65 years and diagnosed with myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML), multiple myeloma (MM), or chronic lymphocytic leukemia (CLL). Responsiveness of the GAH scales was studied by means of the Eastern Cooperative Oncology Group (ECOG) score, the Karnofsky performance status (KPS) score, the visual analog scale (VAS), and the physician's subjective assessment, used as clinical anchors to identify whether patients had changed clinically (either improved or worsened) or not since the baseline visit. Responsiveness was evaluated on the basis of effect size (ES).

Results: 164 patients (men, 63.7%; median age, 77.0 (72.8–81.4) participated. Statistically significant correlations were obtained between the investigator's qualitative assessment and changes in ECOG, KPS, and VAS scores. Likewise, a statistically significant correlation was obtained between the investigator's qualitative assessment and changes in the GAH scale score. Responsiveness of the GAH scale to detect clinical change was satisfactory (ES 0.34).

Conclusion: Findings confirm that the GAH scale is responsive to clinical changes in patients' health status. Additionally, the GAH scale is a promising tool to improve clinical decision-making in older patients with hematological malignancies.

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1. Introduction

Cancer incidences and mortality rise significantly with advancing age, occurring mostly in persons aged older than 65 years [1]. Since individuals of the same chronological age may show vast differences in functional limitations and physical reserves, physicians usually face a huge challenge in how to determine the optimal care for their older patients with cancer. In this context, it seems vital to perform a comprehensive geriatric assessment (CGA). This is a multidisciplinary framework to evaluate the impact of age-associated physiologic factors, in order to guide clinical decisions in this group of patients [2]. However, most of the available instruments for CGA in cancer patients are considered complex, time-consuming, and difficult to incorporate in routine clinical practice [3].

In an attempt to identify new tools for CGA in the geriatric population with hematologic malignancies, Bonanad et al. [4] designed and developed the Geriatric Assessment in Hematology (GAH) scale. This is a 30-item tool grouped into eight relevant dimensions of geriatric assessment that is intended to be an ancillary questionnaire to better categorize patients into fit or vulnerable for standard treatment based on their clinical, functional and mental status. The GAH scale is therefore intended to help physicians to better define the most appropriate therapeutic approach for older patients (aged ≥ 65 years) diagnosed with hematological malignancies, such as myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML), multiple myeloma (MM), and chronic lymphocytic leukemia (CLL), in routine clinical practice.

Findings from previous studies showed that the GAH scale is a promising newly developed instrument, which demonstrated high convergent validity with performance status indices and physician's clinical examination to assess health status in older patients with different hematological malignancies [4]. The next step in the process of development of a new tool is to assess whether the scale is responsive to clinical change over a period of time. Therefore, the objective of the present study was to assess the responsiveness of the GAH scale to a clinical intervention or the natural course of the disease in older patients with hematological malignancies.

2. Materials and Methods

2.1. Study Design

This study was conducted as part of the previously published prospective observational study carried out to validate the GAH scale's psychometric properties [4], and was approved by the Independent Research Ethics Committee of Hospital Universitario de La Ribera, Alzira (Valencia, Spain). Patients included in the GAH study who were alive at the time of study inclusion and accepted to participate had to provide written informed consent prior to participation. Briefly, eligible patients were male and female, aged 65 years or older and diagnosed with any of the following malignancies: MDS or AML, MM, and CLL.

2.2. Responsiveness

Responsiveness reflects the ability of an instrument to change, given a change in the underlying construct [5]. To assess responsiveness, some sort of criterion was needed to identify whether patients had changed (either improved or worsened) or not over a period of time [5]. Since there is no 'gold standard' to measure clinical change, we used the physician's subjective assessment, the visual analog scale (VAS), the Eastern Cooperative Oncology Group (ECOG) score, and the Karnofsky performance status (KPS) score as clinical standards of change. Relevant change was defined as one-point change from the baseline visit (V0) to the responsiveness visit (V1) in a mean time of 1.37 ± 0.42 years. Responsiveness was calculated in paired-samples. Missing data in at least one of dimensions of the GAH scale in one of the visits were discarded from the analyses.

2.3. Measurements

Study doctors were asked to document the patient's clinical status change over time (from V0 to V1) based on the doctor's judgment, which was recorded as "Improvement", "No change" or "Worsening". This evaluation was made merely according to the investigator's perception on a clinical basis, and took into account several unquantified variables, such as transfusion requirements, infections, hospital admissions, clinical and laboratory results or even patient observations. Nevertheless, this study was not designed to collect and quantify these variables, but only to identify clinical changes in patients' health status.

Additionally, we used the ECOG score, the KPS score and the VAS as external quantitative instruments. Both the ECOG and KPS scores are two oncology evaluation instruments for assessing the performance status in cancer patients in everyday practice. The ECOG scale is a 6-point scale ranging from 0 (normal or fully active) to 5 (dead), where higher scores reflect worse function [6]. The KPS is an 11-point scale ranging from 100% (normal or no complaints) to 0% (dead), where higher scores reflect better function [7]. The VAS is a brief measure widely used to subjectively analyze the patient's overall health. This is a 10-cm line, oriented either vertically or horizontally, where 0 represents the worst imaginable health state and 10 the best imaginable health state.

The GAH scale is a 30-item tool which assesses eight relevant dimensions of geriatric assessment, including number of medications, gait speed, mood, activities of daily living (ADL), subjective health status, nutrition, mental status, and comorbidities [4]. As the final score for the GAH scale has not yet been weighted based on clinical experience, scores for each dimension have been provisionally dichotomized into 0 or 1 for exploratory purposes (Table 1). The scores of all dimensions generate a single summary score for the GAH scale, ranging from 0 (best state) to 8 (worst state).

2.4. Statistical Analyses

Correlations between the changes in measure scores were examined using the Spearman's correlation coefficient.

Table 1
Description of the provisional score for the GAH scale dimensions.

Dimension	Score	Dichotomization
Number of drugs	Continuous item.	0 point for <5 prescribed medications; 1 point for ≥ 5 prescribed medications.
Gait speed	Continuous item.	0 point for >0.8 m/s; 1 point for ≤ 0.8 m/s.
Mood	Never, rarely, occasionally, moderate amount of time, frequently, or all time.	0 point for never, rarely, or occasionally; 1 point for moderate amount of time, frequently, and all the time.
Activities of daily living	Yes or No	0 points for no need of help at all; 1 point for needs help in at least one area.
Subjective health status	Poor, fair, good, very good, or excellent.	0 point for good, very good, and excellent, 1 point for poor and fair.
Nutrition	0–10	0 points for >8 points; 1 point for ≤ 8 points.
Mental status	Right or Wrong	0 points for <3 errors; 1 point for ≥ 3 errors.
Comorbidities	0, for absence; 1 point for DM or BMI < 25 kg/m ² ; 2 points for cancer, lung disease, heart failure, or smoking habit.	0 points for those who scored 0–2 points; 1 point for those who scored ≥ 3 points.

Abbreviations: BMI, body mass index; DM, diabetes mellitus.

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