Development and psychometric validation of a brief comprehensive health status assessment scale in older patients with hematological malignancies: The GAH Scale


On Behalf of GAH Group

Abstract

Objectives: The purpose of this study was to develop a new brief, comprehensive geriatric assessment scale for older patients diagnosed with different hematological malignancies, the Geriatric Assessment in Hematology (GAH scale), and to determine its psychometric properties.
1. Introduction

Older subjects (aged 65 years or older) encompass the most prevalent population in the oncologic setting.\(^1\) A considerably increase is expected in the prevalence of neoplastic diseases in the forthcoming decades, as a result of the increment of life expectancy and the aging of the population.\(^2\)

Older cancer patients, compared with their younger counterparts, commonly have distinct characteristics (multi-morbidity, geriatric conditions, physical and cognitive impairments, social and care problems, need for help or assistance from a third party, and lower physiologic reserves) that complicate the process of decision-making, leaving part of this group of patients under-treated.\(^3\)–\(^5\)

The US National Comprehensive Cancer Network and the International Society of Geriatric Oncology\(^6\)–\(^7\) have recommended that some form of geriatric assessment in the oncology setting are needed to discriminate between older patients who are fit enough for intensive therapy and those who are frail.\(^8\)–\(^9\) However, most of the available instruments for comprehensive geriatric assessment (CGA) in cancer patients are complex and time-consuming, which may hinder its regular use in daily practice as a tool for proper clinical decision.\(^10\)

Despite the fact that several screening tools have been developed for geriatric assessment in the oncology setting,\(^11\)–\(^14\) there is still a need for a short health status assessment scale to identify opportunities for effective interventions in the geriatric population with hematologic diseases.

Current research to improve outcomes in cancer older patients keeps working on the development of new geriatric screening tools. In fact, the recently published validation process of the G8 screening tool in older patients with aggressive hematological malignancies was shown to be valid to identify frail patients that would benefit from a comprehensive assessment, although their comorbidities were not considered.\(^15\) Additionally, the systematic review conducted by Hamaker et al.\(^16\) demonstrated that a geriatric assessment in elderly patients with a hematologic malignancy can detect health issues, even in patients showing a good performance status.

In this context, we aimed to develop and validate the psychometric properties of a new and brief CGA scale of Geriatric Assessment in Hematology (the GAH scale) and to determine its psychometric properties in patients diagnosed with different hematological malignancies.

2. Material and Methods

The GAH scale was designed by a group of hematologists and geriatricians as a thorough evaluation for older subjects with different hematologic malignancies, encompassing 30 items grouped into eight pre-defined dimensions from individually validated and standardized clinical tools (Appendix 1). The development of the GAH scale was conducted through a multi-step process that included: inter-pool generation, stakeholder consultation and content validation. The design of the scale was focused to obtain a short, quick and reliable tool to be employed in the clinical field, where time-consuming procedures are often difficult to implement.

2.1. GAH Scale Dimensions

Table 1 lists the eight dimensions of the GAH scale, their measurement and cut-off points.

1. Number of drugs. Polypharmacy has been associated with medication-related adverse effects for frailty, disability, mortality, and falls in older patients,\(^17\) and may be more prevalent in older cancer patients.\(^18\)

2. Gait speed. There is enough evidence for considering gait speed at usual pace as a strong and consistent predictor of adverse health outcomes, such as disability, cognitive impairment, falls, or mortality in older subjects.\(^19\)–\(^21\)

3. Mood. Depressive symptoms were assessed using a single item from the Depression Scale of the Centre for Epidemiological Studies Depression Scale (CES-D) that has been proved to predict mortality over 5 years in cognitively intact populations.\(^22\)
4. Activities of daily living. The activities of daily living (ADL) are well known, and frequently used, as predictors of hospitalization and mortality among elderly patients, and are followed in current practice elsewhere. In the GAH scale, they were taken from item no. 4 of the 13-item Vulnerable Elders Survey (VES-13) Instrument and two additional questions.

5. Subjective health status. The health status self-assessment has proved to be a consistent predictor of functional impairment or death. Subjective health status was assessed based on a single item from the VES-13 Instrument.

6. Nutrition. Nutritional deficit is a frequent and serious problem in older patients, that contributes significantly to morbidity and mortality in this group of people. For the nutritional dimension, some items from the short version of the complete Mini-Nutritional Assessment questionnaire (MNA-SF) were selected, as this is a valid nutritional screening tool to detect malnourished elderly subjects and those at risk for malnutrition.

7. Mental status. Mental status was evaluated with the Short Portable Mental Status Questionnaire (SPMSQ) that was designed, tested, standardized, and validated to detect the presence of cognitive impairment in community-dwelling older adults. Cognitive impairment is also an independent factor for mortality and chemotherapy completion.

8. Comorbidity. We ascertained from medical records and self-report each patient’s comorbidities at study initiation and used this information to calculate the Prognostic Index for 4-year mortality in Older Adults, including the following six conditions: diabetes mellitus, cancer (other than non-melanoma skin cancer), lung disease, heart failure, BMI < 25/25 kg/m², and smoking habit.

### 2.2. Study Design and Population

This was a multicenter, prospective observational study conducted at 20 hospital-based Hematology clinics across Spain. All participants provided written informed consent and the study was approved by the Independent Research Ethics Committee of Hospital Universitario de La Ribera, Alzira (Valencia, Spain).

Patients aged 65 years or older, newly diagnosed with any of the following malignancies: 1) myelodysplastic syndrome (MDS) or acute myeloblastic leukemia (AML); 2) multiple myeloma (MM); and 3) chronic lymphocytic leukemia (CLL), and treatment-naïve were eligible for the study inclusion. No exclusion criteria were defined for the study as we expected not to restrict the study population in order to obtain representative results for the target population. A sample size of 360 patients was calculated, and recruitment was balanced to achieve a similar number of patients with each diagnosis.

### 2.3. Statistical Analyses

2.3.1. Testing of Feasibility

Feasibility was assessed as the time taken to administer the GAH scale. The frequencies of missing items, and missing items per dimension were investigated.

2.3.2. Floor and Ceiling Effects

Potential floor and ceiling effects (i.e. percentage of patients scoring the highest and the lowest score possible in the scale, 0-10 in this case, were calculated.

### Table 1 - Dimensions used for the development of the GAH scale.

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Measurement</th>
<th>Range of score</th>
<th>Cut-off point (1 point)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of drugs</td>
<td>Medication count of drugs of current use.</td>
<td>Continuous</td>
<td>≥517</td>
</tr>
<tr>
<td>Gait speed</td>
<td>Double determination of gait speed at usual pace over a 4 meter course</td>
<td>Continuous</td>
<td>&lt;0.8 m/s21</td>
</tr>
<tr>
<td>Mood</td>
<td>Single item from the CES-D: In the last week, did you feel depressed?</td>
<td>Never, rarely, or occasionally (no more than 2 days); frequently, most of the time or all time (3-7 days)</td>
<td></td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>• Item no. 4 of the VES-13 Instrument: Do you have any difficulty in ...?</td>
<td>Yes/no</td>
<td>Needs help in at least one area</td>
</tr>
<tr>
<td>Subjective health status</td>
<td>Single item from the VES-13 Instrument: Compared to other people your age, would you say your health is ...?</td>
<td>Poor, fair, good, very good, or excellent</td>
<td>Poor and fair</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Four items from the MNA-SF: BMI, weight loss during the last 3 months, food intake decline over the past 3 months, and psychological stress or acute disease.</td>
<td>0-10</td>
<td>≤8</td>
</tr>
<tr>
<td>Mental status</td>
<td>SPMSQ</td>
<td>Right/wrong</td>
<td>≥3 errors</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Prognostic Index for 4-year Mortality in Older Adults</td>
<td>0, for absence; 1 point for DM or BMI &lt; 25 kg/m²; 2 points for cancer, lung disease, heart failure, or smoking habit.</td>
<td>≥3</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; CES-D, Centre for Epidemiological Studies Depression Scale; DM, diabetes mellitus; MNA-SF, Mini-Nutritional Assessment questionnaire; SPMSQ, Short Portable Mental Status Questionnaire; VES-13, 13-item Vulnerable Elders Survey.
respectively) were measured. Minimal floor and ceiling effects were expected (<15%).

2.3.3. Criterion Validity
Criterion validity is the correlation of a scale with some other measure of the trait or disorder under study, ideally a ‘gold standard’. This property was assessed by correlational analysis using Spearman’s rank correlation with external variables. In the absence of a comparing standard of reference that provides external consistency, developers of the GAH scale decided to use the following instruments as reference values: a visual analogue scale (VAS), widely used by the specialists in their daily practice to subjectively analyze the patient’s overall health, ranging from 0 (worst imaginable health state) to 10 (best imaginable health state). The GAH scale was also correlated with the validated and broadly used instruments for assessing the performance status in cancer patients, the Eastern Cooperative Oncology Group (ECOG) score, and the Karnofsky performance status (KPS) score. The ECOG scale is a clean 6-point scale ranging from 0 (normal or fully active) to 5 (dead), where higher scores reflect worse function. KPS is an 11-point scale ranging from 100% (normal or no complaints) to 0% (dead), where higher scores reflect better function.

2.3.4. Construct Validity
For construct validity (the extent to which an instrument measures the intended dimension or construct), a factor analysis was performed to derive independent dimensions from the 30 items of the scale. Previously, the Kaiser–Meyer–Olkin (KMO) and Barlett tests had been performed to measure sampling adequacy. Criteria used to determine the dimensions were eigenvalues >1, and the scree plot test was also calculated.

2.3.5. Internal Consistency Reliability
Internal consistency assesses the extent to which individual items of the scale are consistent to one another and reflect an underlying construct. Internal consistency of the GAH scale and its dimensions were estimated using the Cronbach’s α coefficient, ranging from 0 (indicating no internal consistency) to 1 (indicating high degree of internal consistency).

2.3.6. Test–Retest Reliability
Test–retest reliability of the GAH scale assessed the extent to which the measure produces the same result in repeated applications in an unchanged population. Approximately 50% of the patients that had been included in the study and who were clinically stable, according to the local investigator criterion, were retested after a period of 5–15 days. Reliability was evaluated from two perspectives, intra-observer (the same investigator administers the scale in the two visits) and inter-observer (different investigators administer the scale in the two visits). The objective was to determine if, in stable patients, the scale was indeed observer-independent. The intraclass correlation coefficient (ICC) with 95% confidence intervals (CI) of the mean values was used as a measurement of test–retest reliability.

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS version 17.0).

3. Results

3.1. Study Participants
Between May 2012 and January 2014, a total of 363 subjects were enrolled in the project. Fourteen were excluded due to not meeting the selection criteria (13 patients) and withdrawal of informed consent (1 patient). Thus, 349 patients were finally evaluable for final analyses. As per protocol, diagnoses were equally distributed: MDS or AML (33.2%), MM (33.8%), and CLL (33.0%). Patients’ demographic and clinical characteristics are presented in Table 2.

3.2. Feasibility
The mean time taken to complete the GAH scale was 11.9 ± 4.7 min. There was evidence for an investigator’s learning curve, among those investigators that had performed the GAH scale to at least 10 patients (mean number of patients, 23.7), a statistically significant improvement was observed of the time spent to complete the GAH scale from the first 25% of patients to the last 25% patients (11.8 ± 6.1 min vs 9.5 ± 3.1 min; p < 0.05). The majority of patients (89.4%) completed all items of the GAH scale. Gait speed was the dimension with more omissions (1.7%).

3.3. Floor and Ceiling Effects
No floor or ceiling effects were identified for the whole scale. Thirty (9.6%) participants scored the lowest score of 0, and only one (0.3%) participant achieved the highest score of 8 points on the GAH scale.

3.4. Criterion Validity
Correlation between the external variables VAS, ECOG, and KPS was statistically significant and overall excellent: ECOG–KPS r: −0.846, p < 0.001; ECOG–VAS r: +0.712, p < 0.001; KPS–VAS r: −0.777, p < 0.001. Table 3 displays the correlations between the eight dimensions of the GAH scale and the three external variables. Low-to-moderate significant positive correlations between number of drugs, mood, activities of daily living, subjective health status, mental status, and comorbidities and the

Table 2 – Demographic and clinical characteristics of the study population (N = 349).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median (range)</td>
<td>76.0 (71.0–81.0)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>180 (51.6)</td>
</tr>
<tr>
<td>Hematological diagnosis, n (%)</td>
<td></td>
</tr>
<tr>
<td>MDS/AML</td>
<td>116 (33.2)</td>
</tr>
<tr>
<td>MM</td>
<td>118 (33.8)</td>
</tr>
<tr>
<td>CLL</td>
<td>115 (33.0)</td>
</tr>
<tr>
<td>BMI (kg/m²), mean ± SD</td>
<td>27.8 ± 5.3</td>
</tr>
</tbody>
</table>

Abbreviations: AML, acute myeloblastic leukemia; BMI, body mass index; CLL, chronic lymphocytic leukemia; MDS, myelodysplastic syndrome; MM, multiple myeloma; SD, standard deviation.
VAS and ECOG were found, suggesting that the concepts are connected but not exactly possesses the same meaning. The respective correlations for gait speed and nutrition were weak and negative, indicating that the concepts are opposed. Correspondingly, statistical significant correlations were found between the eight dimensions of the GAH scale and KPS, showing low-to-moderate negative correlations for number of drugs, mood, activities of daily living, subjective health status, mental status, and comorbidities, and weak positive correlations for gait speed and nutrition.

### 3.5. Construct Validity

The Barlett test generated a statistically significant result (p < 0.05), and a KMO of 0.791, indicating sufficient sample size for factor analysis. The varimax rotation revealed nine factors with eigenvalues > 1, achieving to explain almost 60% of the total variance (Table 4) and the scree plot analysis supported this finding (Fig. 1).

### 3.6. Internal Consistency Reliability

The Cronbach’s α coefficient for the GAH scale was 0.610, indicating moderate internal consistency reliability. Table 5 shows Cronbach’s α values for the GAH scale dimensions that were composed of more than one item, ranging from 0.166 to 0.856.

### 3.7. Test–Retest Reliability

The response to the GAH scale showed excellent temporal stability after 5–15 days. Almost all dimensions surpassed the 0.70 criterion for ICC test–retest reliability (ICC coefficients ranged from 0.695 to 0.928), indicating excellent reliability for the GAH scale (Table 6).

### 4. Discussion

The present study describes the methodological approach to the development and validation of the psychometric properties of "the GAH scale", a new CGA scale for older adults diagnosed with different hematological malignancies (MDS, AML, MM, and CLL). Our study results demonstrate that the GAH scale is psychometrically valid, internally reliable and a consistent tool to assess health status in older patients with hematological malignancies.

Our study clearly shows that the GAH scale is an easy instrument to administer and only requires a relatively short period of time to be administered in routine clinical practice (10–12 min), which is similar to the results obtained with other specific CGA conducted in older cancer patients, other than hematological. Furthermore, a "learning curve" has been observed in the administration of the GAH scale, showing a significant improvement of the time spent. As time constraints are a usual aspect of clinical practice, therefore a short administration time is a key feature for a scale to be acceptable in routine clinical practice.

### Table 4 – Factor loading matrix.

<table>
<thead>
<tr>
<th>Item</th>
<th>Correlation</th>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have any difficulty in bathing or showering?</td>
<td>0.791</td>
<td>1</td>
</tr>
<tr>
<td>Do you have any difficulty in walking? (cane or walker is admitted)</td>
<td>0.785</td>
<td></td>
</tr>
<tr>
<td>Do you need any help in your daily living?</td>
<td>0.759</td>
<td></td>
</tr>
<tr>
<td>Do you have any difficulty in doing light housework (like washing dishes, straightening up or light cleaning)?</td>
<td>0.724</td>
<td></td>
</tr>
<tr>
<td>Do you have any difficulty in shopping for personal items (p.e. toilet items or medicines)?</td>
<td>0.668</td>
<td></td>
</tr>
<tr>
<td>Do you have any difficulty in managing money (p.e. keeping track of expenses or paying bills)?</td>
<td>0.525</td>
<td></td>
</tr>
<tr>
<td>Do you have a caregiver?</td>
<td>0.523</td>
<td></td>
</tr>
<tr>
<td>How old are you?</td>
<td>0.790</td>
<td>2</td>
</tr>
<tr>
<td>What date of the week is it?</td>
<td>0.679</td>
<td></td>
</tr>
<tr>
<td>What is the date of today?</td>
<td>0.522</td>
<td></td>
</tr>
<tr>
<td>When were you born?</td>
<td>0.474</td>
<td></td>
</tr>
<tr>
<td>What is the name of this place?</td>
<td>0.615</td>
<td>3</td>
</tr>
<tr>
<td>What's the name of the current President?</td>
<td>0.458</td>
<td></td>
</tr>
<tr>
<td>What are your mother’s second names?</td>
<td>0.573</td>
<td></td>
</tr>
<tr>
<td>Who was the President just before him?</td>
<td>0.593</td>
<td></td>
</tr>
<tr>
<td>Have you lost any weight within the last 3 months?</td>
<td>0.810</td>
<td>4</td>
</tr>
<tr>
<td>Have you eaten less than usual over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?</td>
<td>0.809</td>
<td></td>
</tr>
<tr>
<td>Number of drugs at baseline</td>
<td>0.714</td>
<td>5</td>
</tr>
<tr>
<td>Heart failure</td>
<td>0.642</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.614</td>
<td></td>
</tr>
<tr>
<td>In the last week, did you feel depressed?</td>
<td>0.746</td>
<td>6</td>
</tr>
<tr>
<td>Have you suffered psychological stress or an acute disease in the past 3 months?</td>
<td>0.742</td>
<td></td>
</tr>
<tr>
<td>In general, compared to other people of your age, would you say that your health is?</td>
<td>0.460</td>
<td></td>
</tr>
<tr>
<td>Baseline BMI!</td>
<td>0.696</td>
<td>7</td>
</tr>
<tr>
<td>Subtract 3 from 20 and keep subtracting 3 from each number, all the way down</td>
<td>0.600</td>
<td></td>
</tr>
<tr>
<td>What is your telephone number?</td>
<td>0.477</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>0.708</td>
<td>8</td>
</tr>
<tr>
<td>Lung disease</td>
<td>0.649</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>0.753</td>
<td>9</td>
</tr>
<tr>
<td>Gait speed</td>
<td>0.324</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3 – Correlation of GAH scale dimensions with external variables.

<table>
<thead>
<tr>
<th>GAH scale dimension</th>
<th>VAS</th>
<th>ECOG</th>
<th>KPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of drugs</td>
<td>0.319*</td>
<td>0.320*</td>
<td>−0.354*</td>
</tr>
<tr>
<td>Gait speed</td>
<td>−0.399*</td>
<td>−0.440*</td>
<td>0.485*</td>
</tr>
<tr>
<td>Mood</td>
<td>0.290*</td>
<td>0.305*</td>
<td>−0.364*</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>0.528*</td>
<td>0.526*</td>
<td>−0.592*</td>
</tr>
<tr>
<td>Subjective health status</td>
<td>0.548*</td>
<td>0.514*</td>
<td>−0.512*</td>
</tr>
<tr>
<td>Nutrition</td>
<td>−0.264*</td>
<td>−0.319*</td>
<td>0.336*</td>
</tr>
<tr>
<td>Mental status</td>
<td>0.312*</td>
<td>0.361*</td>
<td>−0.344*</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>0.120b</td>
<td>0.136b</td>
<td>−0.136b</td>
</tr>
</tbody>
</table>

Abbreviations: ECOG, Eastern Cooperative Oncology Group; KPS, Karnofsky Performance Status; VAS, Visual Analogue Scale.

* p < 0.01 (2-tailed).

b p < 0.05 (2-tailed).
Criterion validity of the GAH scale was evidenced by statistically significant correlations between the scale dimensions and the external variables selected for the validation process (VAS, ECOG and KPS), except for the dimension comorbidities that was found to be poorly correlated with the reference tools. This is not surprising, as in older patients general health status is loosely linked with multiple morbidities.

Despite the lack of a comparing standard of reference, there were significant correlations between the three selected external variables, particularly between ECOG and KPS, which is consistent to the correlation previously described by Suh SY, et al (r = −0.81, p < 0.001), indicating that these scales address factors that matter to a CGA in the oncology setting.

For the 30 items that are part of the GAH scale, factor analysis and scree plots revealed a 9-factor solution with eigenvalues > 1, which are in line with the initial proposed scale. However, it is important to shed light on the fact that the factor analysis showed that two numerical items of the dimension mental status were combined with the BMI. Due to this discrepancy, we further conducted an internal consistency analysis of this factor, confirming that these items measured different aspects and suggesting that the BMI should be separated from these items. Additionally, statistically significant moderate internal consistency was found for the whole GAH scale, and moderate-to-high for the dimensions that were composed of more than one item.

The GAH scale included a retest interval not less than 5 and not longer than 15 days (with no interference in the routine clinical practice) in order to avoid patients remembering their answers and variations in clinical conditions. The selected interval is in line with retest interval of 2–14 days proposed by Streiner and Norman. The test-retest reliability was overall statistically significant and excellent for the scale dimensions, suggesting the internal validity of the scale. Moreover, a further measure to test reliability of the GAH scale is expected to be conducted shortly, in terms of ‘sensitivity to change’ that is the description of an instrument’s ability to detect the overall effect of treatment.

In spite of several screening methods have recently been proposed for CGA in the oncologic setting, there is still a need to identify frail patients for whom the CGA would be beneficial. Most instruments either are exclusively focused on a particular diagnosis, in contrast to the G-8 geriatric screening tool that targets a very heterogeneous cancer population, or have not been psychometrically validated yet. In contrast to all this, the GAH scale appears to address these two issues. This is a potential specific geriatric tool aimed for helping physicians in

![Fig. 1 – Scree plot of the 30 items of the GAH scale.](image-url)
the process of treatment decision-making for older patients suffering from hematological malignancies, and it has been rigorously developed and validated from a methodological point of view.

Conversely to what was found in the study led by Klepin, the GAH scale encompasses multiple domains to perform an integral assessment in geriatric population, including number of drugs and nutritional status, considered to be key factors for effective interventions in the geriatric hematologic assessment. Interestingly, the geriatric evaluation proposed in our investigation is in line with the methodological approach suggested in the systematic review of Ellis et al., in which it was noted that inpatient multidisciplinary programs in older patients improved survival and cognitive function.

The authors recognize that the limitation of the study is that it was conducted in a cohort of patients with selected hematological malignancies (i.e. MDS or AML, MM and CLL), excluding other hematological entities such as lymphoma. The reason behind not including patients with lymphoma is besides this is a quite heterogeneous hematological entity, and the median age of patients diagnosed with lymphoma is lower that the cut-off point set for the study selection criteria, which would had increased the time needed to achieve complete recruitment.

In conclusion, our study suggests that the GAH scale is a valid, internally reliable and consistent tool to assess health status in older patients with different hematological malignancies. We also consider that this scale may be a useful instrument to be used in daily practice as an ancillary tool to better define the most appropriate therapeutic approach to older patients. Nevertheless, these findings need to be confirmed by future studies.

Disclosures and Conflict of Interest Statements

Silvia López is a Medical Affairs Project Manager of Celgene S.L.U. Marta Durán and Marina Marcos are Regional Medical Liaisons of Celgene S.L.U.

Silvia López, Marta Durán and Marina Marcos declare that they have stock ownership from Celgene S.L.U.

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Author Contributions

Study concept: S Bonanad, J De la Rubia, AJ Cruz-Jentoft
Study design: S Bonanad, J De la Rubia, AJ Cruz-Jentoft
Quality control of data and algorithms: A Casado
Data analysis and interpretation: S Bonanad, J De la Rubia, AJ Cruz-Jentoft, A Casado, S López, M Durán, M Marcos

Statistical analysis: A Casado
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Appendix A. Supplementary data

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