Comparison of CIPA with the GLIM criteria of malnutrition and prevalence of sarcopenia in inpatients

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Abstract

Background: malnutrition is a poor prognostic factor in inpatients. Its early detection, together to nutritional intervention, can improve clinical evolution. It is important to carry out nutritional screening, however, there is no gold standard, and CIPA (Control of Intakes, Proteins and Anthropometry) has been implemented in our setting. The GLIM criteria (Global Leadership Initiative on Malnutrition) aim to provide a global consensus that allows common criteria for malnutrition diagnosis. The objective of this study is to evaluate the diagnostic quality of the CIPA screening vs the GLIM criteria for malnutrition as well as to establish the prevalence of sarcopenia.

Methods: cross-sectional single-center study comparing the diagnostic quality of CIPA in the diagnosis of malnutrition or risk of presenting it in inpatients vs GLIM. Adults of both sexes with a hospital stay of more than three days and attached to one of the following departments will be included: general surgery, internal medicine, vascular surgery, digestive system, hematology, nephrology, pulmonology, oncology, neurology, traumatology. The diagnostic evaluation of malnutrition and functionality will be carried out after three days of hospital stay, once the CIPA screening has been carried out. The participation of the patients in the study will consist of performing the CIPA malnutrition screening to which the GLIM test will be added. For the CIPA test, the BMI (body mass index), albumin levels and percentage of decreased intake will be taken. For the GLIM test, phenotypic criteria such as non-voluntary weight loss and reduction in muscle mass will also be studied together with etiological criteria to which, in addition to those referred to for the CIPA test, the presence of inflammation will be added. The study consists of a first cross-sectional part that will be completed once the data of the 490 subjects selected through probabilistic sampling has been collected. The second part of the study will consist of the prospective follow-up of the patients and the variables will be analyzed with prognostic criteria.

Discussion: this study will evaluate the diagnostic quality of CIPA vs the GLIM criteria for malnutrition and will establish the prevalence of sarcopenia in inpatients.

Trial registration:

Keywords: nutrition assessment, inpatient, sarcopenia, GLIM, CIPA, screening, body composition, phase angle, hospital stay, mortality.

Background

Malnutrition is a poor prognostic factor for the inpatient. It can contribute to increase the number and severity of the complications of the disease itself, to weaken the response capacity to treatment, increase its morbidity and mortality and the healthcare cost. Numerous research papers corroborate that nutritional intervention can improve the clinical evolution of hospitalized malnourished patients, making early diagnosis of hospital malnutrition (HM) of vital importance [1].

HM is a frequent problem in patients admitted to a hospital. Prevalences ranging between 10% and 50% have been observed, depending on the type of patients analyzed, the category of hospital where they are admitted, and the nutritional assessment markers used for their evaluation. In Spain, the multicenter PREDYCES study conducted in more than 1700 patients, found that 23.7% of hospitalized patients are malnourished or at nutritional risk [2], while the recent seDREno study used to the nutritional evaluation of the GLIM malnutrition criteria, and observed that 29.7% of hospitalized patients are malnourished [3].

There are many nutritional screening methods validated in the hospitalized population, but none meet all the suitability criteria, so there is no gold-standard that favors their widespread implementation in the different hospital centers. At Hospital Universitario Nuestra Señora de la Candelaria (HUNSC) in Tenerife, a nutritional screening method called CIPA (Control of Intakes, Proteins and Anthropometry) was designed, which has covered several phases in its development and validation. In this, different items are evaluated: a) decrease in

intake <50% in 72h; b) plasma albumin <3 g/dl; and c) BMI < 18.5 kg/m^2, mid-upper arm circumference (MUAC) ≤22,5 cm (if the BMI cannot be determined). Positivity of at least one of these items would result in a positive CIPA nutritional screening and would identify the patient with malnutrition or at risk of suffering from it. Since 2015 it has been implemented in the HUNSC, carrying out different validation, optimization and cost effectiveness studies [4–11].

The GLIM criteria (Global Leadership Initiative on Malnutrition) aim to provide a consensus at a global level that allows for common criteria for the diagnosis of malnutrition and, in this way, the results obtained through their application can be compared. It is a two-step strategy: first, a validated screening test would be applied to identify malnourished patients or patients at risk of malnutrition and, later, the second step would be carried out, which consists of the diagnostic evaluation of malnutrition and graduation of malnutrition. To evaluate the diagnosis and degree of malnutrition, phenotypic criteria (unintentional weight loss, BMI and reduction in muscle mass) and etiological criteria (decrease in intake and presence of inflammation) are used. A patient would be identified as malnourished when he presents at least 1 phenotypic criterion and 1 etiological criterion. The severity of malnutrition would be assessed using phenotypic criteria [12].

As a result of the publication of these criteria, different studies have been developed that evaluate the sensitivity and specificity of different nutritional screening tools and/or nutritional evolution with respect to GLIM [13]. However, most are not comparable because they are heterogeneous samples and in different areas of medical care.

Another aspect of great interest at the present time is the evaluation of cellular and muscular functionality and its prognostic implications. For the evaluation of cell function, the phase angle has been developed in recent years. It is obtained through the realization of bioimpedance, being the result of the ratio between reactance and resistance. It has been postulated as an indicator of cell integrity and an early marker of malnutrition [14]. On the other hand, muscle functionality can be assessed using dynamometry. It is a simple and accessible technique that

quickly assesses muscle function. In addition, the determination of these parameters (including muscle mass, also given by bioimpedanciometry), would allow us to know the prevalence of sarcopenia that is associated with the appearance of adverse events such as falls, fractures, physical disability and mortality [15].

This study will provide us with information about the diagnostic quality of the nutritional screening carried out in our environment compared with the GLIM criteria for malnutrition. In addition, by comparing the prevalence of sarcopenia and the phase angle in patients with positive or negative screening, we will be able to estimate the risk of muscle and cellular dysfunction in patients with the worst clinical prognosis.

Methods

Trial design:

Cross-sectional single-center study comparing the diagnostic quality of the CIPA instrument in the diagnosis of malnutrition or risk of presenting it in hospitalized patients vs GLIM and subsequent prospective follow-up of patients for up to six months.

The aims:

Primary endpoint:

- Determine the diagnostic quality of the CIPA tool, in inpatients with stays longer than three days, in the observation of risk of malnutrition compared to the gold standard GLIM as a diagnosis of malnutrition.

Secondary endpoints:

- Determine the positive and negative predictive values in comparison to the selected gold standard.
- Determine the degree of reliability, likelihood ratio and diagnostic odds ratio of the tool compared to the gold standard.

- Determine the point of greatest balance between sensitivity and specificity for each of the three variables that make up the diagnostic instrument for malnutrition.
- Determine the degree of Kappa concordance between both diagnostic criteria (CIPA vs. GLIM).
- Establish the cut-off point for the phase angle of the population studied by bioimpedanciometry for men and women, and determine prognostic values according to the optimal cut-off point.
- Evaluate prognostic variables (mortality, average stay, readmission rate) according to the two tools under study (CIPA vs. GLIM) at discharge, together with early readmissions, and mortality at six months of prospective follow-up.
- Evaluate whether CIPA positive subjects obtain worse muscle functionality results according to dynamometry than CIPA negative subjects.
- Determine if there is a relationship between positive CIPA and sarcopenia according to established EWGSOP2 diagnostic criteria.
- Determine if there is a relationship between positive subjects with sarcopenia vs negatives in relation to the six-month prognosis.

Inclusion criteria:

Adult subjects of both sexes with a hospital stay of more than three days and attached to one of the following departments: general surgery, internal medicine, vascular surgery, digestive system, hematology, nephrology, pulmonology, oncology, neurology, traumatology. The diagnostic evaluation of malnutrition and functionality will be carried out after three days of hospital stay, once the CIPA screening has been carried out.

Exclusion criteria:

Subjects who are not candidates for CIPA nutritional screening at the HUNSC are excluded: with a prognosis of hospital stay of less than or equal to three days; admission to services with a low incidence of malnutrition (ophthalmology, dermatology, obstetrics...); pediatric patient or critical care unit and palliative

care; patients already receiving artificial nutritional treatment. Patients with edemo-ascitic overload will also be excluded.
Written informed consent will be requested from patients who meet all the inclusion criteria and none of the exclusion criteria, and in the case of minors or handicapped, that of their parents or legal guardians will be collected.

Expected criteria for withdrawal of study subjects:

Of all the personal data that is registered, each participant in the study will have access rights for their knowledge, rectification of inaccurate or incomplete data and cancellation (ARCO Rights). Any participant who wishes to exercise their ARCO rights must contact the doctor/investigator responsible at the Study Hospital where said data was collected and submit the corresponding form.

Study variables (primary and secondary):

Variable	**Data collection**
Sex	Basal
Age	Basal
Weight	Basal
Height	Basal
BMI	Basal
Cause of admission	Basal
Type of admission (urgent)	Basal
Days of hospital stay	Follow-up
Comorbiity	Basal
Diabetes mellitus	Basal
Dinamometry	Basal

Grip strength	Basal
CIPA (variables associated with the performance of the test)	Basal
GLIM (variables associated with the performance of the test)	Basal
Bioimpedanciometry (phase angle)	Basal
Fat Free Mass Index	Basal
Appendiceal skeletal muscle mass index	Basal
Sarcopenia	Basal
Patients with nutritional treatment	Follow-up
Mortality (to six months)	Follow-up
Readmissions (to six months)	Follow-up

Data Collect

The participation of the patients in the study will consist of performing the screening for malnutrition that is usually used in the hospital (CIPA) to which the GLIM test will be added, considered as the gold standard for this work. The scores of both tests will be recorded together with the data collection through the clinical history or with direct questions to the patient.

For the CIPA test, the BMI, albumin levels and percentage of decreased intake will be taken. For the GLIM test, phenotypic criteria such as non-voluntary weight loss and reduction in muscle mass will also be studied together with etiological criteria to which, in addition to those mentioned for the CIPA test, the presence of inflammation will be added.

Together with the usual work protocols and data depending on the pathology under treatment, the variables collected will be: age, sex, cause of admission, comorbidity, functionality, interventions or treatments per admission, bioimpedance testing, dynamometry, presence of sarcopenia.

Subsequently, the sample of patients with a positive CIPA (as it is currently considered the screening test used in the hospital) will be implemented the therapeutic measures according to the usual protocol, while the subjects with a negative CIPA test but a positive GLIM will be studied. and constant monitoring taking the appropriate measures according to optional criteria. The patients will be followed up for the study of prognostic factors based on the variables obtained.

Statistical analysis of the data:

The data will be recorded in the data recording notebook and imported once the study is closed to specific software for statistical treatment (STATA SE 14; SPSS, V21). The descriptive analysis of the data will divide the variables into qualitative and quantitative. Obtaining means and standard deviations for the quantitative variables and frequencies and proportions for the qualitative data. Graphs will be obtained for a better understanding of the results.

For the cross-sectional study of the quality of diagnostic criteria between the CIPA instrument and the current gold standard GLIM, a study of sensitivity, specificity, positive and negative predictive values, as well as the likelihood and an estimator of a single value such as the diagnostic odds ratio. In addition, they will determine the best equilibrium points for the three items of the CIPA instrument according to the Youden model, determining in each case the area under the curve (AUC). Likewise, the concordance between both CIPA tests and the GLIM gold standard will be determined by the Kappa coefficient according to Cohen's model. All point estimates will be accompanied by 95% confidence intervals.

For the follow-up study with CIPA positive patients, an initial univariate study of the factors that could determine prognostic levels in the patients will be carried out. These analyzes will be parametric/non-parametric according to the homoscedasticity and normality of the data in each distribution, analyzed by the Kolmogorov-Smirnov test. Subsequently, for the variables with statistical significance or clinical relevance found in the univariate analysis, multivariate models will be carried out with the aim of knowing the one that best fits the data and determining the prognostic factors in the patients studied. The selection of the final model will be guided by the principle of parsimony. Collinearity will be evaluated by the main regression component of the explanatory variables. While

the different models will be compared by the likelihood ratio and the Wald test. The existence of confusion will be evaluated by clinical criteria with a significant change of 10% over the coefficient obtained according to the variables included in the model. The model will be validated by the Hosmer-Lemeshow calibration test and by the area under the curve (AUC) as a measure of discrimination.

Workplan:

This study will select patients with an expected hospital stay of more than three days, through probabilistic sampling to control possible biases in the selection of subjects. The selection will be made in the departments specified by physicians or personnel trained for this purpose, establishing whether they meet all the established inclusion criteria and none of the exclusion criteria, according to the study protocol. Each patient will receive a full explanation of the study objectives and an informed consent form will be signed.

Once the patient is selected and coded to ensure data protection, after three days of stay, according to the usual protocol, the risk of malnutrition will be studied with CIPA and, later, GLIM will be performed on these patients.

For the evaluation of cell function, the phase angle obtained by bioimpedanciometry (Aker BIA 101 Anniversary) will be used and observing the ratio between reactance/resistance between body cell mass and fat-free mass. Likewise, muscular functionality will be evaluated by dynamometry (using a Jamar dynamometer), taking the maximum value of between two measurements in the dominant arm with an interval of at least one minute between one and the other. In turn, the values under study will be collected and the the data collection notebook according to coding. The risk of sarcopenia will be determined according to values observed in dynamometry and bioimpedance measurement established in the 2019 European consensus on Sarcopenia according to the EWGSOP2 criteria: grip strength determined by dynamometry, positive in males if < 27 kg and in women if <16 kg, muscle volume, determined by bioimpedance analysis, positive if appendicular skeletal muscle mass <20 kg in men and <15 kg in women.

All subjects with a positive test according to the CIPA instrument will be treated according to the usual protocol to correct possible malnutrition or risk thereof,

while subjects with a negative CIPA test but a positive GLIM will be studied and constantly monitored, taking the appropriate measures according to criteria. optional. Patients will be followed up during their hospital stay and 6 months after discharge, prospectively collecting variables for the study of prognostic factors (hospital stay, early readmission rate, mortality).
The study consists of a first cross-sectional part that will be completed once the data of the 490 subjects selected through probabilistic sampling has been collected. The second part of the study will consist of the prospective follow-up of the patients and the variables will be analyzed with prognostic criteria. In these cases, follow-up will end 6 months after discharge. Thus, the total estimated months to complete the study is estimated at 15 months. The study will be conducted entirely at HUNSC.

Difficulties and limitations of the study:

The possible difficulties of the study will focus on the time of inclusion of subjects due to the large number of sample used. Likewise, special attention will be paid to the follow-up of subjects during their hospital stay, not assuming a number of patients with simultaneous stays greater than what the components of the research project can manage.

Ethical aspects and confidentiality:

The study will be carried out in accordance with the requirements expressed in the Declaration of Helsinki [revision of Fortaleza (Brazil), October 2013] and the Laws and Regulations in force in Europe and Spain.

The information sheet will be delivered to the participating subjects. The investigator will explain to the patient the objectives and procedures of the study, and will request the signing of the informed consent form. Once the consent is signed, the researcher will begin the explorations and data collection necessary for the study. The investigator will not initiate any investigation corresponding to the study until the consent of the patient has been obtained.

The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of Organic Law 3/2018, of December 5, Protection of Personal Data and guarantee of digital rights, and the application of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD).

To maintain patient confidentiality, no demographic data that could identify the subject will be collected (e.g. initials, date of birth). To protect the identity of the patient, a unique number will be assigned to each subject and their related records.

In order to guarantee the confidentiality of the data of the patients participating in the study, only the researcher and his team of collaborators, the representative of the promoter who will carry out the monitoring tasks, the auditor in the event that the study was submitted to an audit, the CEIm and the Health Authorities.

Discussion:

This study evaluates the diagnostic quality of the CIPA nutritional screening with respect to the GLIM criteria for malnutrition and its prognostic implications, as well as the functionality and cellular vitality by bioimpedance analysis and the presence of sarcopenia. For this, the CIPA nutritional screening will be carried out and the phenotypic and etiological variables will be evaluated to apply the GLIM criteria.

The study of HM is an important objective since it has a high prevalence and is associated with a worse clinical prognosis, as well as higher healthcare costs. In addition, it has been shown that early treatment can mitigate these deleterious effects on the patient's health.

However, in clinical practice, the establishment of a hospital nutritional screening is complex. The lack of care time and the complexity of the same associated with nutritional therapy make its implementation very difficult, so carrying out a subsequent nutritional assessment is even more complicated unless there is enough specialized personnel.

The low cost of oral nutritional support in hospitalized patients and the scarcity of adverse effects if it is prescribed and taken properly, causes that in most hospitals a nutritional therapeutic tool is prescribed directly when the screening is positive without further evaluation. to confirm malnutrition.

The creation of the GLIM consensus [12] as a new definition of malnutrition has stimulated the comparison of previous screening or nutritional assessment methods (such as the VGS, MST, MUST or NRS-2002). Therefore, the objective of this work is to carry out this analysis with the CIPA nutritional screening, designed, validated and implemented in our environment. CIPA screening meets criteria that have made it the choice for its implementation, such as: it uses tools that are commonly used in clinical practice, it does not require specialized personnel, it is performed quickly and at low cost, being useful for detection of malnourished patients or at risk of malnutrition, predicting their prognostic evolution.

In previous studies, a slight-moderate correlation has been observed between nutritional screening methods and the GLIM criteria. Boulhosa et al studied patients with advanced chronic liver disease comparing NRS-2002 with GLIM. They obtained a Kappa index of 0.43 and an AUC of 0.731 [16]. Clark et al compared MST vs. GLIM, sensitivity was 56.7%, specificity 69.0%, AUC 0.63, and kappa index 0.26 [17]. For their part, Bellanti et al. compared GLIM with MUST, VGS and NRS-2002 in a sample of 152 hospitalized geriatric patients, obtaining a sensitivity of 64%, 96% and 47%, and a specificity of 82%, 15% and 76%, AUC of 0.80, 0.77 and 0.69, respectively. In turn, the agreement with GLIM was 89%, 53% and 62% for the MUST, VGS and NRS-2002 [18]. The good correlation of MUST with GLIM can be explained by the degree of similarity between the two tests, since the MUST determines the BMI, percentage of weight loss, presence or absence of inflammation or acute diseases, and these parameters are included. inside the lim. Likewise, the high sensitivity of the VGS is due to the fact that it is not a screening method, but a more specific nutritional assessment, such as the GLIM, and where criteria are similar to the phenotypic and etiological ones. In any case, as can be seen, they are different populations in which it is not convenient to compare or combine the findings.

As for sarcopenia, it is also a pathology with a high prevalence. Ballesteros et al. [19] studied hospitalized patients from the Spanish population, determining a

probable prevalence of sarcopenia of 33%, confirmed by determining muscle mass in 22.5%. Lengelé et al [20] observed a higher risk of sarcopenia in patients diagnosed with malnutrition using the GLIM criteria (HR 3.19 (95% CI 1.56 – 6.5) [20] and Bellanti et al [18] observed that patients with a high risk of malnutrition determined by MUST are also more likely to present sarcopenia (OR 2.5, CI 1.3-3.6).

As for the limitations, we find ourselves with an ambitious study in which a large sample is to be recruited, and it may be assumed that the time necessary for the inclusion of the subjects in the study and data collection is delayed. On the other hand, perhaps the representation of patients admitted to surgical areas may be limited since the need for artificial nutrition prior to performing nutritional screening has been included as an exclusion criterion, the need for this being greater in complex surgical patients.

However, we believe that this study will provide us with interesting data on the diagnostic quality of the CIPA nutritional screening tool, similar to those used in other hospitals regarding the GLIM nutritional assessment, and thus elucidate in which cases it will be necessary to use the latter, taking into account that it is a more complex process that requires trained personnel and higher costs. Previous studies have shown a worse clinical course in patients with positive CIPA screening, both surgical and non-surgical. In this study we go further, and we can also see if they also have a higher prevalence of sarcopenia and a worse phase angle, thus also suggesting a worse clinical prognosis and quality of life.

Abbreviations

BMI: Body mass index; CIPA: Control of food intake, protein and anthropometry; HM: Hospital malnutrition; HUNSC: Hospital Universitario Nuestra Señora de Candelaria; GLIM: Global Leadership Initiative on Malnutrition; MUAC: Mid-upper arm circumference; NRS2002: Nutritional risk screening 2002; SGA: Subjective global assessment; MUST: Malnutrition Universal Screening Tool; AUC: area under the curve.

Availability of data and materials

No data have been generated from this study protocol. Data collection tools are available from the authors upon request.

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Authors' contributions

EMM is the principle investigator and conceptualized and designed the CIPA study with the following investigators: JPSL, ILGS. EMM and JPSL were in charge of project management and supervision and coordinated the different investigators. EMM and JPSL wrote the first draft of this publication with contributions from AJGC, DAH, EDGM, DME and ILGS. AJGC, DAH, EDGM, DME took over patient data and informed consent collecting and transferred the data into the data base. EMM and JPSL supervised proper internal functioning of the CIPA nutrition screening. All authors contributed to the revisions and read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The ethics committee of University Hospital Nuestra Señora de Candelaria gave it's approval for the carrying out of this study on the date 17 December 2020 (project code CHUNSC_2020_105).

All patients included in the study have signed informed consent.

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