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FERNANDA DE OLIVEIRA PEREIRA

Associação entre Avaliação Subjetiva Global Produzida pelo Próprio Paciente e musculatura esquelética determinada pela tomografia computadorizada em pacientes com câncer do colo do útero.

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ASSOCIAÇÃO ENTRE AVALIAÇÃO SUBJETIVA GLOBAL PRODUZIDA PELO PRÓPRIO PACIENTE E MUSCULATURA ESQUELÉTICA DETERMINADA PELA TOMOGRAFIA COMPUTADORIZADA EM PACIENTES COM CÂNCER DO COLO DO ÚTERO.

Trabalho de conclusão de curso apresentado ao Instituto Nacional de Câncer José Alencar Gomes da Silva como requisito parcial para a conclusão do Programa de Residência Multiprofissional em Oncologia.

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Resumo

Introdução: A miopenia é um problema significativo em pacientes oncológicos e a utilização de instrumentos fidedignos para sua identificação faz-se necessária. **Objetivo**: Avaliar a associação entre a Avaliação Subjetiva Global Produzida Pelo Próprio Paciente (ASG-PPP) com a musculatura esquelética avaliada pela tomografia computadorizada (TC) em pacientes com câncer do colo do útero. **Métodos**: Trata-se de um estudo observacional, transversal, com mulheres com câncer do colo do útero, maiores de 18 anos e que iniciaram o tratamento entre janeiro de 2015 e setembro de 2018. Foram incluídas as que apresentaram a ASG-PPP e imagens de TC, com intervalo máximo entre eles de 45 dias. O índice de musculatura esquelética (IME) foi utilizado para classificação da miopenia e um nível de significância de 5% foi adotado. **Resultados**: Pela ASG-PPP, a desnutrição esteve em 56% das pacientes e 23% foram classificadas com miopenia pela TC. Os parâmetros da ASG-PPP apresentaram associação significativa com o IME e os pontos de corte para o escore total da ASG-PPP $\geq$ 10, depleção muscular $\geq$ 2.0 e pontuação do exame físico $\geq$ 2.0, foram os que melhor descriminaram a miopenia. **Conclusão**: A ASG-PPP mostrou ser um método útil e viável que apresenta boa associação e correlação com o IME.

Palavras-chave: câncer do colo do útero, ASG-PPP, músculo esquelético, tomografia computadorizada.

Abstract

Introduction: Myopenia is a significant problem in oncology patients and the use of reliable instruments for its identification in clinical practice is necessary. **Objective**: To evaluate the association between the Scored Patient-Generated Subjective Global Assessment (PG-SGA) and skeletal muscle measured by computed tomography (CT) in patients with cervical cancer. **Methods**: This is an observational, cross-sectional study which enrolled women with cervical cancer, over 20 years, who started treatment between January 2015 and September 2018. The ones who presented PG-SGA and imaging of CT with a maximum interval of 45 days between them were included. The skeletal muscle index (SMI) was used to classify myopenia and a significance level of 5% was adopted. **Results**: According to the PG-SGA, malnutrition was found in 56% patients and 23% were classified with myopenia by CT. The PG-SGA parameters were significantly associated with the SMI. The cut-off points that best discriminated myopenia were the PG-SGA total score ≥ 10, muscle depletion ≥ 2.0 and physical examination score ≥ 2.0. **Conclusion**: The PG-SGA showed to be a useful and viable method that shows good association and correlation with the SMI.

Keywords: cervical cancer, PG-SGA, skeletal muscle, computed tomography.

Introduction

The cervical cancer is the fourth most common type of cancer among women worldwide (1). In Brazil, it occupies the third place and 16,370 new cases are expected for each year of the biennium 2018/2019 (2). Most of the new cases occur in developing countries and roughly 70% are diagnosed in advanced stage (3).

Sarcopenia, characterized by skeletal muscle (SM) loss - myopenia - and reduced muscle function, can occur in cancer patients due to a variety of mechanisms involving the tumour, such as host responses, and anticancer therapies (4). The SM depletion leads to a decreased respiratory capacity, changes in intra and extracellular electrolyte regulations, reduction of the amino acid pool for gluconeogenesis, reduction of the metabolically active tissue and an increase on the resistance to insulin (5). Infectious and non-infectious surgical complications, toxicity during clinical treatment, prolonged hospitalization and reduced survival may, therefore, be the consequences of such depletion (6-8). Thus, the detection of muscle loss and early nutritional intervention can minimize plenty of complications and improve the quality of life of cancer patients (9).

Regarding the nutritional diagnosis and body composition constitution analysis, there are a variety of methods that can be used for this purpose. Computed tomography (CT) is currently considered a reference method for the SM quantification, due to its high accuracy (10). Among its limitations, there is the exposure to radiation and the high cost, whereas it is usually used as part of the cancer treatment for staging and disease control (11). On the other hand, the Scored Patient-Generated Subjective Global Assessment (PG-SGA) is a subjective instrument for assessing nutritional status, which is easy to apply, inexpensive and non-invasive, validated for the oncology community (12) and presents high precision for early detection of changes in nutritional status (13).

The PG-SGA has been recently compared with direct and indirect nutritional diagnosis instruments, including BMI, NRS-2002, MNA and other screening tools. Its association with clinical outcomes has also been widely explored. However, until now, no studies have been conducted to evaluate its ability to identify individuals with or without myopenia. Considering that it is of great relevance to evaluate the reliability of the nutritional diagnosis obtained from a subjective evaluation, such as the PG-SGA, compared with a reference method, the present study aimed to evaluate the association between the parameters of PG-SGA and the SM assessed by CT in patients with cervical cancer, as well as to define the cut-off points of PG-SGA parameters which best discriminate patients with myopenia.

Materials and methods

This is an observational cross-sectional study which enrolled cervical cancer patients, over 20 years old, refereed to the Cancer Hospital II (HC II/INCA), in Brazil, who started cancer treatment between January 2015 to September 2018. The database was composed by cervical patients enrolled in several studies conducted by the Research Group on Nutrition and Cancer (HCII/INCA) who had PG-SGA and CT scans at the third lumbar vertebra (L3) prior to treatment. Also, the interval between the two methods should not be greater than 45 days. Patients with positive serology for Human Immunodeficiency Virus (HIV), with hepatic or renal insufficiency in dialysis treatment, with edema and who had no height data for skeletal muscle index calculus were excluded.

Ethical aspects

The inclusion of each patient in the study was performed through formal authorization, through the signing of the informed consent form, in accordance with Resolution number 196 of 10/10/1996 of the National Health Council. The present study has been approved by INCA's Research Ethics Committee under number: 466.070 / 2013.

Data collection

The weight and height data were collected for the calculation of BMI by the equation *current weight (Kg)/height (m)*^{2}, and subsequent classification according to WHO (14). In the medical record, we collected all the information about the patient’s characteristics, such as: age, ethnicity, marital status, histological type, type of treatment and staging, according to the classification of the International Federation of Gynaecology and Obstetrics (15) and the presence of comorbidities. For the evaluation of the nutritional status, the PG-SGA was applied and for the determination of the SM area, the CT images, available in the hospital system, were used.

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

The PG-SGA is a specific tool for oncology patients, whose translation to Portuguese has been validated by Gonzalez et al. (16). For patients who undergone clinical treatment, the evaluation was made on the day of the first chemotherapy session, just before its beginning. For the patients who undergone surgical treatment, it was carried out on the day of hospital admission for the surgical procedure.

The instrument includes the evaluation of indicators such as weight loss, functional capacity, food intake, symptoms of nutritional impact and metabolic stress (17). It is also composed by physical examination, which allows classification in an increasing degree: no deficit (0), mild deficit (1), moderate deficit (2) and severe deficit (3) in relation to protein and adipose compartments. After the evaluation, the patients were classified as: (A) well nourished; (B) moderately malnourished or suspected of malnutrition; or (C) severely malnourished. In addition to the classification of nutritional status, the tool provides a score, which the greater it is, the worse the nutritional status of the patient. The score is useful to recommend or not the beginning of a nutritional intervention (12).

Computed tomography

In order to determine the SM area by CT, the images of the third lumbar vertebra (L3) were analysed. This procedure was conducted by the same trained observer and checked by a second observer, with the aid of software SliceOmatic version 5.0 (Tomovision, Canada), which allows demarcation specified in Housefield Units (HU).

To identify and quantify the SM, Hounsfield Unit thresholds -29HU to +150HU were used (18). The skeletal muscle index (SMI), which corresponds to the area of muscle tissue obtained at L3 level, corrected for height^2, and expressed in cm^2/m^2, was used to classify myopenia, according to the cut-off point established for females, 38.9 cm^2/m^2 (19).

Statistical analysis

Statistical analysis was performed with the aid of the statistical program Statistical Package for Social Sciences, version 22.0, SPSS (Chicago-USA). Adherence to the normal curve was tested by the Kolmogorov-Smirnov test. A non-normal distribution was identified for all variables, except for SMI. The continuous variables were expressed as mean (± standard deviation) or median (min-max), and proportions for the categorical variables. Associations between the categorical variables were analyzed using the chi-square test ($\chi 2$) or Fisher's exact test. The correlation analysis was performed using the Spearman correlation test. To estimate the predictive values of the domains of the PG-SGA in the discrimination of patients with or without myopenia, the curves Receiver Operating Characteristic (ROC) were generated.

For all statistical tests, the significance level of 5% was adopted.

Results

The study population consisted of 180 women, with at an average age of 44 years (23-77), the majority were brown and single. Most of the patients did not present any type of comorbidity. The most frequent histological type was squamous cell carcinoma - SCC, followed by adenocarcinoma. In addition, there was a high prevalence of women in cancer stages II and III, accounting to about 83% (Table 1).

Table 2 describes the nutritional status parameters stratified by BMI, PG-SGA and CT. According to the BMI, the majority of the patients presented excess of body weight (61%) whereas by the PG-SGA, malnutrition, represented by the B and C classifications, was found in 56% of them, with an average score of 7.5. In addition, 23% of the patients were classified with myopenia.

Table 3 shows that all domains of the PG-SGA and low BMI were significantly associated with the diagnosis of myopenia by CT ($p < 0.05$). In this context, 21.4% of the patients with myopenia presented concomitant excess of body weight and 54.8% were eutrophic. It was also observed that the majority of patients with myopenia were classified as having some degree of muscle depletion, reduced functional capacity, presence of symptoms and reduction in food intake by PG-SGA.

Figure 1 shows the ability of the PG-SGA and BMI in classifying nutritional status in patients who had myopenia according to CT. It can be observed that the PG-SGA identified a greater number of patients with myopenia compared with BMI, since 76.19% were correctly identified by the PG-SGA as malnourished while only 23.8% were classified as low weight by the BMI.

In addition, the PG-SGA variables that directly or indirectly assessed the SM content - functional deficit, muscle depletion and PG-SGA score - presented a significant negative correlation, although moderate, with the SMI (Table 4).

The performance of the PG-SGA parameters in discriminating patients with or without myopenia, with the respective cut-off points, sensitivity and specificity values, are presented in Table 5. For all parameters, the area under the curve (AUC) was greater than 0.6. The muscle depletion and the physical examination score were the parameters that presented the best sensitivities and specificities, with AUC = 0.75. On the other hand, the numeric score provided by the sum of the boxes 1-4 had the worst performance. Regarding the total PG-SGA score, the cut-off point that best discriminated was ≥ 10 (AUC = 0.69, 61.9% sensitivity and 63% specificity).

Discussion

Oncology patients are at a higher risk of worsening their nutritional status and changing their body composition. Thus, the use of reliable tools to identify these patients is necessary (20). However, studies comparing PG-SGA with CT, a reference method of SM assessment, are scarce. This study was the pioneer in the comparison between the PG-SGA and CT in women diagnosed with cervical cancer. We observed that more than half of the patients (56%) were malnourished according to the PG-SGA, and that this tool was superior in identifying patients with myopenia when compared to BMI.

Myopenia implies functional impairment, increased toxicity to treatment, and is associated with worse prognosis and increased mortality (21). The proportion of patients with myopenia found in our study (23%) is in agreement with other studies that assessed endometrial cancer patients (22% to 26%) (22, 23). Aredes et al. (24) in their study with patients with cervical cancer, found 10% of patients with myopenia. However, the small sample size may have influenced this lower prevalence.

Chantragawee and Achariyapota (25) found a 54% prevalence of PG-SGA malnutrition in patients with endometrial, ovary and cervical cancer. Rodrigues et al. (9) found nutritional risk or malnutrition in 62% of women with gynaecological cancer. A study carried out in India, also in women with gynaecological cancer, showed that 88% had some degree of malnutrition by PG-SGA (20). The higher prevalence of malnutrition by PG-SGA in these studies may be related to the inclusion of a variety of gynaecological tumours and even a more advanced staging.

The higher proportion of patients with myopenia that were correctly diagnosed as at nutritional risk or malnutrition by PG-SGA, when compared to BMI, is possibly due to the subjective feature of this tool, which considers, besides the physical examination, the presence of symptoms with gastrointestinal effects, changes in food intake and functional capacity, and, therefore, allows the earlier identification of those patients at nutritional risk, which may progress to myopenia. In addition, the significant association observed between the presence of symptoms and reduction of food intake with myopenia may be related to the higher number of patients identified in more advanced cancer stage at diagnosis. It is known that, in the process of carcinogenesis, tumour secreted factors favour an anorectic state and a decrease in food intake, contributing to weight loss (26). The metabolism of patients with gynaecological cancer is altered, affecting all metabolic pathways and favouring protein catabolism with the loss of SM induced by the proteolysis inducing factor (PIF) (27).

About 60% of our population presented excess body weight, a characteristic which may be common in patients with cervical cancer (28). Considering that 76.2% of patients with myopenia were eutrophic or overweight by BMI, we emphasize that this condition is often masked. In diseases with a strong inflammatory character, such as cancer, SM may be reduced while adipose tissue may remain preserved or even increased (29). The sarcopenic obesity is exactly this condition of SM reduction in the context of adiposity excess (30). Moreover, Laky et al. (31) showed that BMI, weight and percentage of weight loss were not able to detect malnutrition in patients with gynaecological cancer effectively, because they could be altered by edema, dehydration or large tumour mass (32).

The myopenia correlated significantly negatively with functional capacity and muscle depletion domains scores, in which the greater the functional capacity deficit and muscle compartment examination are, the lower the SMI is. This result corroborates the assumption that the reduction of the SM impairs functional capacity and increases the risk of morbidity or mortality (33).

By analyzing the ROC curve, it was observed that the score ≥ 2 for muscle depletion was the one which best discriminated patients with myopenia. One can note that, for this domain, the specificity was greater than the sensitivity, which may be related to the difficulty in identifying myopenia in eutrophic patients or those who presented excess of body weight. In this sense, the PG-SGA score ≥ 10 was the one which best discriminated the presence of myopenia in the present study. It should be noted that this cut-off point was the same that discriminate 1-year mortality after hospital admission in gynaecological cancer patients (9).

Another relevant finding was that, when the PG-SGA score was limited to the first 4 domains, disregarding the assessment of physical examination, disease and metabolic stress, which corresponds to PG-SGA short form (PG-SGA SF), it was observed an AUC of 0.67, with 61.9% sensitivity and 58.6% specificity. This was slightly lower than the results obtained by PG-SGA complete (AUC = 0.69, 61.9% sensitivity, 63.0% specificity). This result suggests a better performance of the complete PG-SGA form in the classification of the presence or absence of myopenia. Gabrielson et al. (34) also found a better performance of the complete PG-SGA form, when compared to PG-SGA SF and Malnutrition Screening Tool.

The application of PG-SGA by different researchers can be considered as a limitation of the present study. However, this may have been minimized since all dietitians were previously properly trained. Moreover, a greater number of participants in the study would allow a proportional increase in the number of patients with myopenia and would favour the performance of other concordance tests between the two methods.

In conclusion, our study suggests that the PG-SGA may be a useful and feasible method for assessing the nutritional status in patients with cervical cancer, considering its association with SM determined by CT and its ability to identify earlier those patients at nutritional risk, even before developing myopenia. Early diagnosis of both tumour and SM reduction directly influence the patient's prognosis (21,22). Myopenia is currently considered a disease, and great efforts have been provided on the investigation of the best practices for its screening, diagnosis and treatment (35). Nutritional intervention to prevent SM loss and treat myopenia should be implemented preferably prior the cancer treatment (36).

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Declaration of Interest

All authors declare no conflicts of interest.

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Table 1. Sociodemographic, clinical and nutritional characteristics of the study patients (N = 180).

Variables	N (%)
Age	
Adults	170 (94.4)
Elderly	10 (5.6)
Ethnicity	
White	58 (32.2)
Brown (mixed races)	99 (55.0)
Black	14 (7.8)
Indigenous	9 (5.0)
Marital status	
Single	99 (55.0)
Married or stable union	61 (33.9)
Divorced	11 (6.1)
Widow	9 (5.0)
Comorbidities[1]	
None	118 (65.6)
Arterial Hypertension	48 (77.4)
Diabetes Mellitus	12 (19.3)
Others	8 (12.9)
Histological type[2]	
SCC	157 (87.2)
Adenocarcinoma	20 (11.1)
Adenosquamous carcinoma	1 (0.6)
Others	2 (1.1)
Tumor staging[3,4]	
Stage I	23 (12.8)
Stage II	82 (45.6)
Stage III	67 (37.2)
Stage IV	7 (3.9)
Type of treatment[5]	
Clinical	159 (88.3)
Surgical	21 (11.7)

[1]Others = arterial hypertension associated with Diabetes Mellitus, cardiopathy, renal failure, dyslipidemia, hypothyroidism and epilepsy; [2]Others = Cardiopathy, renal insufficiency, dyslipidemia, hypothyroidism and epilepsy; [3]Tumor staging classified by the International Federation of Gynecology and Obstetrics (FIGO); [4]Difference in absolute values corresponding to the missing data; [5]Clinical = chemotherapy and radiation therapy / Surgical = hysterectomy or others; Number of participants (N); SCC = Squamous cell carcinoma

Table 2. Data from the nutritional status of the study patients.

Variables	Results (N=180)
BMI (Kg/m²)[1]	
Low weight	13 (7.2)
Eutrophy	57 (31.7)
Overweight	62 (34.4)
Obesity	48 (26.7)
PG-SGA[1]	
Well nourished (A)	79 (43.9)
Moderately malnourished or suspected of malnutrition (B)	85 (47.2)
Severely malnourished (C)	16 (8.9)
PG-SGA score[2]	7.5 (1-29)
CT[3]	
SMI (*categorized*)[1]	
Eutrophy	138 (76.7)
Myopenia	42 (23.3)

[1]Values expressed as absolute numbers (percentage); [2]Value expressed in median (minimum-maximum); [3]Determined by the cut-off point of 38.9 cm^2/m^2; [4]Value expressed in mean ± standard deviation; Number of participants (N); Body mass index (BMI); Scored Patient-Generated Subjective Global Assessment (PG-SGA); Computed tomography (CT); Skeletal muscle index expressed in cm^2/m^2 (SMI).

Table 3. Association between the parameters obtained by PG-SGA and BMI with the classification of the skeletal muscle index by CT (N = 180).

Variables		N	Without myopenia - SMI[2] N = 138 (%)	With myopenia- SMI[2] N = 42 (%)	p-value[1]
BMI	Low weight	13	3 (2.2)	10 (23.8)	< 0.001
	Eutrophy	57	34 (24.6)	23 (54.8)	
	Overweight + Obesity	110	101 (73.2)	9 (21.4)	
PG-SGA	A	79	69 (50.0)	10 (23.8)	< 0.001
	B	85	63 (45.7)	22 (52.4)	
	C	16	6 (4.3)	10 (23.8)	
Muscle depletion[3]	0	121	108 (78.3)	13 (31.0)	< 0.001
	1	37	21 (15.2)	16 (38.1)	
	2	14	6 (4.3)	8 (19.0)	
	3	8	3 (2.2)	5 (11.9)	
Functional capacity	Without limitation	48	46 (33.3)	2 (4.8)	< 0.001
	Not totally normal	52	42 (30.4)	10 (23.8)	
	Does not feel good	35	25 (18.1)	10 (23.8)	
	Able to do little activity	39	23 (16.7)	16 (38.1)	
	Bedridden	6	2 (1.4)	4 (9.5)	
Presence of symptoms	Yes	100	71 (51.4)	29 (69.0)	0.044
	No	80	67 (48.6)	13 (31.0)	
Food intake	No changes	62	54 (39.1)	8 (19.0)	0.049
	Eating more	21	14 (10.1)	7 (16.7)	
	Eating less	97	70 (50.7)	27 (64.3)	

[1]Pearson's chi-square test, statistical difference ($p < 0.05$); [2]Determined by the cut-off point of 38.9 cm^2/m^2; [3]Classification according to the PG-SGA: without deficit (0), mild deficit (1), moderate deficit (2), severe deficit (3); Number of participants

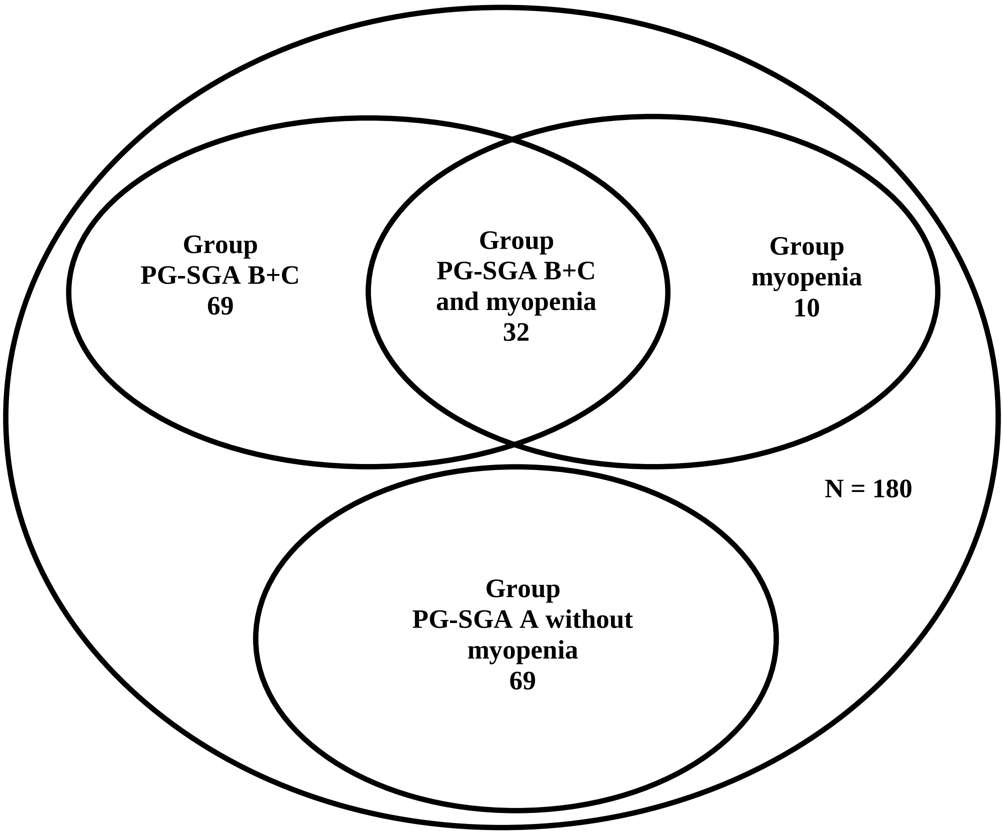
(N); Scored Patient-Generated Subjective Global Assessment (PG-SGA); Skeletal Muscle Index (SMI).

Table 4. Correlation between the PG-SGA domains and skeletal muscle index by CT (N = 180).

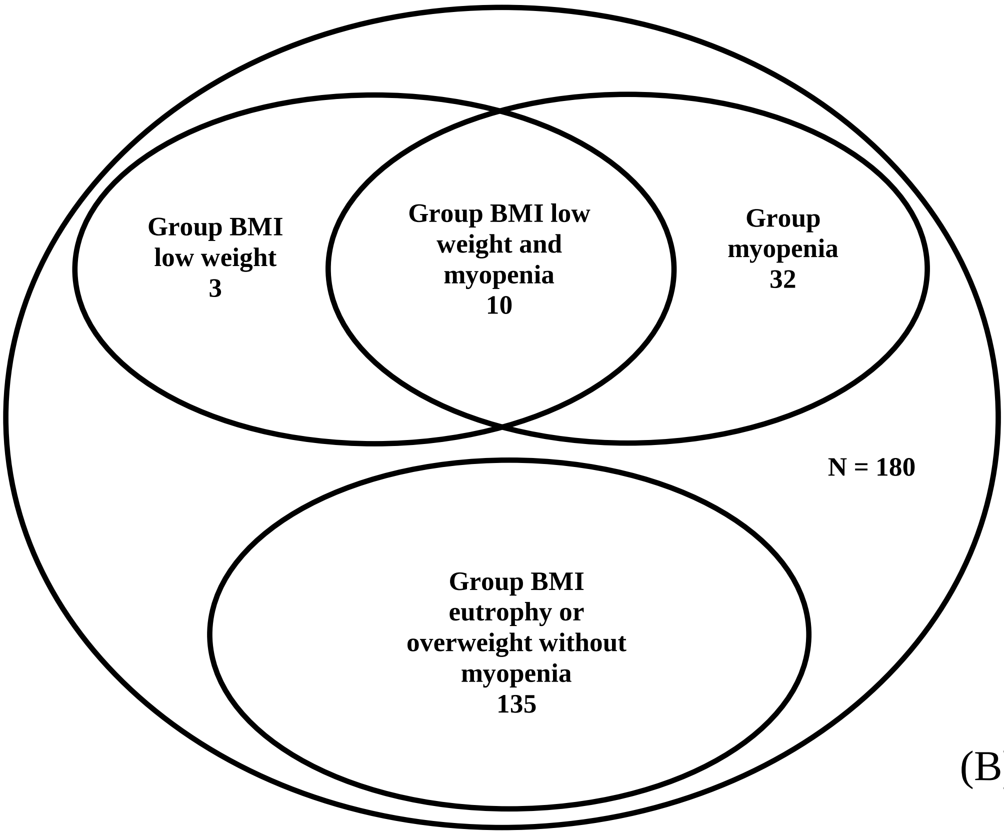
PG-SGA domains	**SMI**[1]	
	R	p-valor
Functional deficit	-0.424	0.000
Muscle depletion	-0.510	0.000
PG-SGA score	-0.334	0.000

[1]Pearson test, statistical difference ($p < 0.05$); Skeletal muscle index (SMI) expressed in cm/m^2.

Figure 1. Ability to classify nutritional status by PG-SGA (A) and BMI (B) in the diagnosis of myopenia by CT.



(A)



(B)

Table 5. Area under the curve, sensitivity, specificity and cut-off points of the PG-SGA domains in the detection of myopenia (N = 180).

PG-SGA domains	Myopenia			
	Cut-off points	**AUC (95% CI)**	**Sen (%)**	**Spec (%)**
PG-SGA score	≥ 10.0	0.69 (0.60-0.78)	61.9	63.0
Muscle depletion	≥ 2.0	0.75 (0.67-0.83)	69.0	78.2
Physical exam score	≥ 2.0	0.75 (0.67-0.84)	71.4	73.9
PG-SGA boxes 1-4 score	≥ 7.0	0.67 (0.56-0.76)	61.9	58.6
Functional capacity	≥ 3.0	0.74 (0.66-0.81)	71.4	63.7

PG-SGA: Scored Patient-Generated Subjective Global Assessment; AUC: area under the curve (CI: confidence interval); Sen: sensitivity; Spec: specificity; $p \leq 0.001$; Cut-off point: values that best discriminate patients with myopia.