



Applied nutritional investigation

Relationship of nutritional status and inflammation with survival in patients with advanced cancer in palliative care



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ABSTRACT

Objective: This study aimed to evaluate the prognostic value of nutritional and inflammatory status in patients with advanced cancer receiving palliative care.

Methods: The systemic inflammatory response was assessed using the modified Glasgow Prognostic Score (mGPS), and nutritional status was evaluated according to the Patient-Generated Subjective Global Assessment (PG-SGA) in 172 patients evaluated on their first visit in the Palliative Care Unit at the National Cancer Institute in Brazil. The receiver operating characteristic (ROC) curve was used to define the best cutoff point for the death-related PG-SGA score in 90 d. Kaplan-Meier curves were conducted for survival analyses, and logistic regression analyses were performed using the Cox proportional hazards model.

Results: According to the PG-SGA, 83.6% of the patients ($n = 143$) were malnourished (B + C) and 34.8% ($n = 53$) had mGPS ≥ 1 . The best cutoff of the PG-SGA score for death was ≥ 19 points (area under the curve, 0.69; $P = 0.041$). Patients with scores ≥ 19 , mGPS ≥ 1 , albumin < 3.5 g/dL, and C-reactive protein ≥ 10 mg/L had a significantly lower overall survival. According to the multivariate analysis, albumin < 3.5 g/dL (hazard ratio [HR], 2.04; 95% confidence interval [CI], 1.16–3.58), mGPS ≥ 1 (HR, 1.46; 95% CI, 1.09–2.22), and PG-SGA score ≥ 19 (HR, 1.66; 95% CI, 1.08–2.55) were independent prognostic factors for overall survival.

Conclusion: The severity of the systemic inflammation and the poor nutritional status predict survival and were considered independent prognostic factors. Thus they can be useful tools for nutritional evaluation in palliative care.

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Introduction

Cancer represents the second largest cause of death as a result of disease in Brazil [1], and according to the World Health Organization, in developing countries, most individuals at the time of diagnosis present with the disease at an advanced stage [2]. Each year, around 20 million people, of whom 6.5 million represent cancer patients, need some kind of end-of-life palliative care [2]. In this context, prognostic factors have a guiding role in the treatment, because they help avoid futile and disproportionate therapies in cancer progression, when the greatest benefit is found in an exclusively palliative approach [3–5].

Nutritional status has long been recognized as an indicator of poorer prognosis in patients with advanced cancer [3,6,7], being associated with reduced physical function, quality of life, and survival [8–10]. Because of the negative impact of cancer cachexia

on clinical outcomes, knowledge about specific criteria for its identification should be expanded, allowing a better standardization of the recommendations for nutritional intervention in this population [8,11]. In that regard, the scored Patient-Generated Subjective Global Assessment (PG-SGA) is a subjective method that has been developed and validated in cancer populations and provides a standardized approach to nutrition assessment in this patient group [12–14]. The PG-SGA is a modification of the original SGA [15,16] and is the reference method for the assessment of nutrition status of cancer patients. It evaluates several relevant prognostic aspects for advanced cancer patients simultaneously, such as changes in body weight, food intake, nutritional impact symptoms, performance status, and physical examination.

On the other hand, biomarkers of systemic inflammatory response also have prognostic value in advanced cancer [17–21]. In particular the systemic inflammatory response, as evidenced by serum C-reactive protein (CRP), has an important role in the progression of a variety of common tumors and is the most widely accepted index of systemic inflammation [22,23].

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The modified Glasgow Prognostic Score (mGPS) is a simple and objective inflammation-based tool that considers albumin and CRP levels to segregate patients in one of three ordinal categories. The prognostic role of mGPS has been defined in oncology [23,24], and in 2014, Douglas and McMillan [25] proposed its use for the assessment and treatment of cancer cachexia.

The development of suitable clinical identifiers or biomarkers to map out prognosis in advanced cancer is of intense interest; therefore, it would be extremely important to focus on potentially modifiable markers, thereby allowing early therapeutic intervention.

The present study's purpose is to investigate the prognostic value of nutritional status and inflammatory activity in patients with advanced cancer in palliative care.

Methods

Patients

This study presents preliminary results from a prospective observational study conducted in the Palliative Care Unit at the National Cancer Institute José Alencar Gomes da Silva (INCA), Rio de Janeiro, Brazil. The study cohort included 172 eligible patients who were recruited from March to November 2016. Outpatients were evaluated at the first care and inpatients within the first 48 h of the first hospitalization. This evaluation was conducted by three different trained nutritionists, who obtained the following information: age, sex, years of formal education, cancer type, extent of disease, height, weight, comorbidities, and previous and current anticancer treatments. The date of death was obtained from patient medical records.

Eligibility criteria were age ≥ 20 y, ability to answer the necessary information to complete the PG-SGA and/or accompanied by someone capable of completing it, and Karnofsky Performance Status (KPS) $\geq 30\%$. This study received ethical approval from the Research Ethics Committees of INCA (Protocol Number 1.407.458 of 2.016) and all patients signed an informed consent before joining the study.

Questionnaire tools

PG-SGA

Nutritional status was assessed by the Portuguese version of the PG-SGA, made available by Ottery in pt-global.org, upon permission for its use. The scored PG-SGA consists of a questionnaire divided into two sections. In the first section, patients filled out the questionnaire identifying issues regarding weight change, food intake, symptoms, and functional capacity that were measured by the following four boxes scores: Box 1 focuses on weight changes with a maximum score of 5; box 2 on food intake with a maximum score of 4; box 3 on symptom profiling with a maximum score of 24; and box 4 on functional status with a maximum score of 3. The second section was completed by a trained and expert nutritionist. It focused on patient history such as diagnosis, age, metabolic demand, use of corticosteroids, and physical examination, including loss of subcutaneous fat, muscle wasting, and edema or ascites [13].

At the end of the questionnaire, the patient was subjectively categorized into three distinct classes of nutritional status: A) well nourished, B) moderately malnourished or suspected of being malnourished, and C) severely malnourished. Numerical scores were also recorded; the higher PG-SGA score, the greater the risk of malnutrition [12,13].

Anthropometry

Measurements of height and weight were made, on the same day as all the other tests, with participants wearing light clothes and barefoot or with socks. Weight was measured using a calibrated portable Wiso Digital scale (150 kg capacity). A Stryker Go Bed II "weight bed" was used for those patients who were unable to stand. Height was measured using a measuring tape on the wall. If height measurement could not be obtained, it had to be estimated using knee height, which was measured with the knee and ankle joints flexed at 90° , using a measuring tape or an anthropometer. The estimated height was calculated using the formulas of Chumlea et al. [26]. Body mass index was calculated as body weight (in kilograms) divided by height (in meters squared).

Analytical assessments

Laboratory profile included serum levels of erythrocytes, hemoglobin, hematocrit, leukocytes, total lymphocyte count, albumin, and CRP. The mGPS score

was classified as 2 if both albumin and CRP concentration were, respectively, <3.5 mg/dL and >10 mg/L; it was classified as 1 for albumin levels ≥ 3.5 mg/dL and CRP >10 mg/L; and mGPS was defined as 0 if CRP was ≤ 10 mg/L. Thus, the higher the mGPS score, the greater the inflammatory response.

Survival

Patient overall survival (OS) was defined as the time interval, in days, between the nutritional assessment baseline date and the date of death (any cause). All patients who remained alive after the end of the period of study (90 d) were censored, according to statistical analyses.

Statistical analysis

We processed statistical analyses using the Stata Data Analysis and Statistical Software Version 12.0. Kolmogorov-Smirnov's test was performed to assess distribution symmetry. Descriptive statistics are presented in percentages for the categorical variables and as mean with standard deviation (SD) or median with interquartile range (IQR) for the continuous variables. The κ coefficient was used to analyze the reliability of PG-SGA application among researchers ($\kappa = 0.89$). For statistical analyses, mGPSs of 1 and 2 were grouped.

ROC curve analysis was performed to determine optimal cutoff value for predicting mortality in 90 d according to scored PG-SGA global rating. Kaplan-Meier's method was used to estimate the probability of OS, and log-rank tests were used to compare OS according to different variables. The Cox proportional hazard model was used to assess hazard ratios (HRs) of prognostic factors. All factors with a P value ≤ 0.20 in the bivariate analysis were included in the multivariate analysis. The final model was obtained through the stepwise backward procedure, and it included all variables with the level $P < 0.05$.

Results

A total of 172 patients with advanced cancer were included in this study. The median age was 61 y old (IQR: 54.0–69.5), and 60.5% of the patients were female. Patient characteristics are summarized in Table 1. In the group, there is a predominance of a low level of education, because most of the participants attended only elementary school. The most common tumor types were as follows: female tumors (breast, cervix, endometrium, ovarian, and vulva); and tumors located in the gastrointestinal tract, such as stomach, intestine, pancreas, gallbladder, and liver. Almost half of patients (49.7%) had a KPS $<50\%$ at the time of evaluation and 34.8% had mGPS ≥ 1 . In addition, anemia, low serum albumin, reduced lymphocyte count, and elevated CRP level were verified among patients. According to the PG-SGA, 83.6% of the patients were moderately or severely malnourished (B and C), and the mean score was 14 (± 6.4) points.

At the end of the follow-up period of 90 d, 63 patients (36.6%) were alive and 109 (63.4%) had died. The median OS duration was 31 (IQR: 9.0–67.0) d for the entire group.

The PG-SGA score ≥ 19 was the best cutoff value using 90-d mortality as an endpoint in the ROC curve. The area under the curve was 0.69 (95% CI: 0.61–0.77; $P = 0.041$) with a sensitivity of 63.2% and specificity of 61.5%, as seen in Figure 1. Additionally, according to the Kaplan-Meier curves (Fig. 2), patients who had a PG-SGA score ≥ 19 points (22 versus 50 d; 95% CI: 9–56; $P < 0.001$), mGPS ≥ 1 (17 versus 44 d; 95% CI: 9–38; $P = 0.002$), albumin <3.5 g/dL (18 versus 66 d; 95% CI: 9–46; $P < 0.001$), and CRP ≥ 10 mg/L (16 versus 43 d; 95% CI: 7–38; $P = 0.002$) had a significantly lower OS.

Cox modeling was performed to evaluate the influence of the variables analyzed and OS in 90 d (Table 2). In the univariate analysis, significant predictors of shorter survival were gastrointestinal tract tumors, KPS 30% to 50%, CRP level ≥ 10 mg/L, serum albumin <3.5 g/dL, mGPS ≥ 1 , PG-SGA score ≥ 19 , and the presence of at least two of the following components: PG-SGA score ≥ 19 with mGPS ≥ 1 and PG-SGA B or C with mGPS ≥ 1 . In multivariate analysis, serum albumin <3.5 g/dL, mGPS ≥ 1 , and PG-SGA score ≥ 19

Table 1
Characteristics of the patients with cancer treated at a palliative care unit in Rio de Janeiro

Variables	n (%)	
Age (y)	172	61.0 (54.0–69.5)*
Sex		
Female	104 (60.5)	
Male	68 (39.5)	
Education		
Elementary school	125 (73.5)	
High school or higher	45 (26.5)	
Types of tumor		
Female tumors	47 (27.3)	
GI tract	39 (22.7)	
Head and neck	37 (21.5)	
Others	31 (18.0)	
Lung	18 (10.5)	
Metastatic disease		
Local	129 (75.0)	
Liver and peritoneum	95 (55.0)	
Bones	31 (18.0)	
Central nervous system	16 (9.3)	
Others	107 (62.0)	
KPS (%)		
30–50	85 (49.7)	
≥50	86 (50.3)	
Laboratory tests		
Red blood cells (millions/UL)		3.6 (3.1–4.1)*
Hemoglobin (g/dL)		9.8 (8.8–11.6)*
Hematocrit (%)		30.6 (27.5–35.4)*
Lymphocytes (/μL)		1150.0 (745.0–1594.0)*
Leukocytes (/μL)		9100.0 (6400.0–12100.0)*
Albumin (g/dL)		3.2 (2.7–3.7)*
CRP (mg/L)		6.6 (2.5–16.4)*
mGPS		
0	99 (65.1)	
1	7 (4.6)	
2	46 (30.2)	
Survival time (d)		31.0 (9.0–67.0)*
Death at 90 d		
Yes	109 (63.4)	
No	63 (36.6)	
Anthropometry		
Weight (kg)		58.1 (49.0–71.5)*
BMI (kg/m ²)		22.8 (19.6–26.1)*
Classification of PG-SGA		
A (well nourished)	28 (16.4)	
B (moderately malnourished)	86 (50.3)	
C (severely malnourished)	57 (33.3)	
Variables	n(%)	
PG-SGA		
Total score		14.0 (±6.4)†
Domains of PG-SGA		
Weight history		2.5 (±1.8)†
Food intake		1.4 (±1.5)†
Symptoms		7.8 (±4.7)†
Activity		2.5 (±0.9)†

BMI, body mass index; CRP, C-reactive protein; GI, gastrointestinal; GPS, modified Glasgow Prognostic Score; KPS, Karnofsky Performance Status; PG-SGA, Patient-Generated Subjective Global Assessment.

* Median (interquartile range).

† Mean (standard deviation).

remained significantly associated with OS in patients with advanced cancer.

Discussion

The present study evaluated patients with advanced cancer in exclusive palliative care at a national referral center in Brazil. Furthermore, it is a pioneering work in the country, with the purpose of verifying the relationship between the poor nutri-

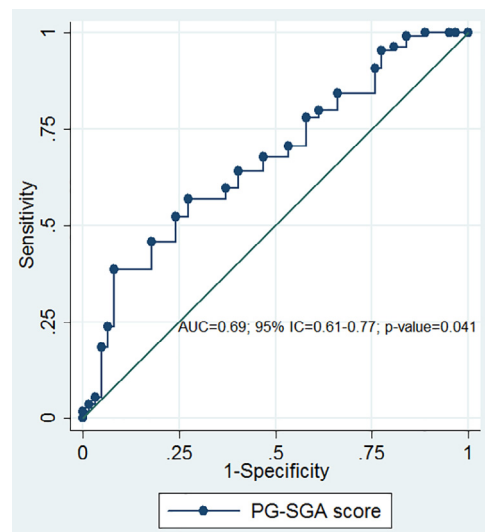


Fig. 1. ROC curve of the PG-SGA score as a predictor of death in 90 d in patients with advanced cancer treated at a palliative care unit. AUC, area under the curve; CI, confidence interval; PG-SGA, Patient-Generated Subjective Global Assessment; ROC, receiver operating characteristic.

tional status and the severity of the systemic inflammation, as well as the association of these factors with OS.

As expected, our results indicated a high prevalence of malnutrition in this population, which is similar to what has been reported in previous studies in palliative care patients [27–29]. Regarding the global score obtained in the PG-SGA evaluation, our results indicated that the optimal cutoff point for PG-SGA, considered predictive of death within 90 d, was a score ≥19 points. According to the method, PG-SGA scores ≥9 points indicate a critical need for improved symptoms control and/or specialized nutritional intervention options. However, one of the challenges of using PG-SGA score ≥9 as a prognostic measure is that the majority of patients in palliative care present with even higher scores [27,28]. In our study, 70.7% of the sample had a score ≥9, and in the study of Andrew et al. [7], total PG-SGA score was >9 for all patients.

In the present study, we found that patients with poor nutritional status (PG-SGA ≥19 points), hypoalbuminemia, or systemic inflammation (CPR >10 mg/L or mGPS ≥1) had significantly lower survival. Other studies in patients with advanced cancer describe the relationship of systemic inflammation and nutritional status with survival [8,15,19]. Read et al. [19] identified that PG-SGA score ≥9 and mGPS = 1 and 2, but not elevated CRP (>10 mg/L), were associated with a significantly poorer survival in patients with advanced colorectal cancer. More recently a study in Brazil by Pantano et al. [30] reported that patients with mGPS ≥1 receiving palliative care had a significantly lower survival rate than those who had mGPS = 0.

Although admittedly patients with advanced cancer are at risk of protein energy wasting (PEW), our results indicate that 65.1% of the sample ($n = 99$) had mGPS = 0 and 16.4% ($n = 28$) were considered well-nourished according to PG-SGA. In this context, we highlight the need for prevention or early management of reversible nutritional elements in cancer patients.

A study by Prado et al. [31] found that patients with advanced cancer may have a potential for muscle anabolism under specific conditions, notably in the early phases of the disease trajectory (>90-d OS). This could be an opportunity for nutritional

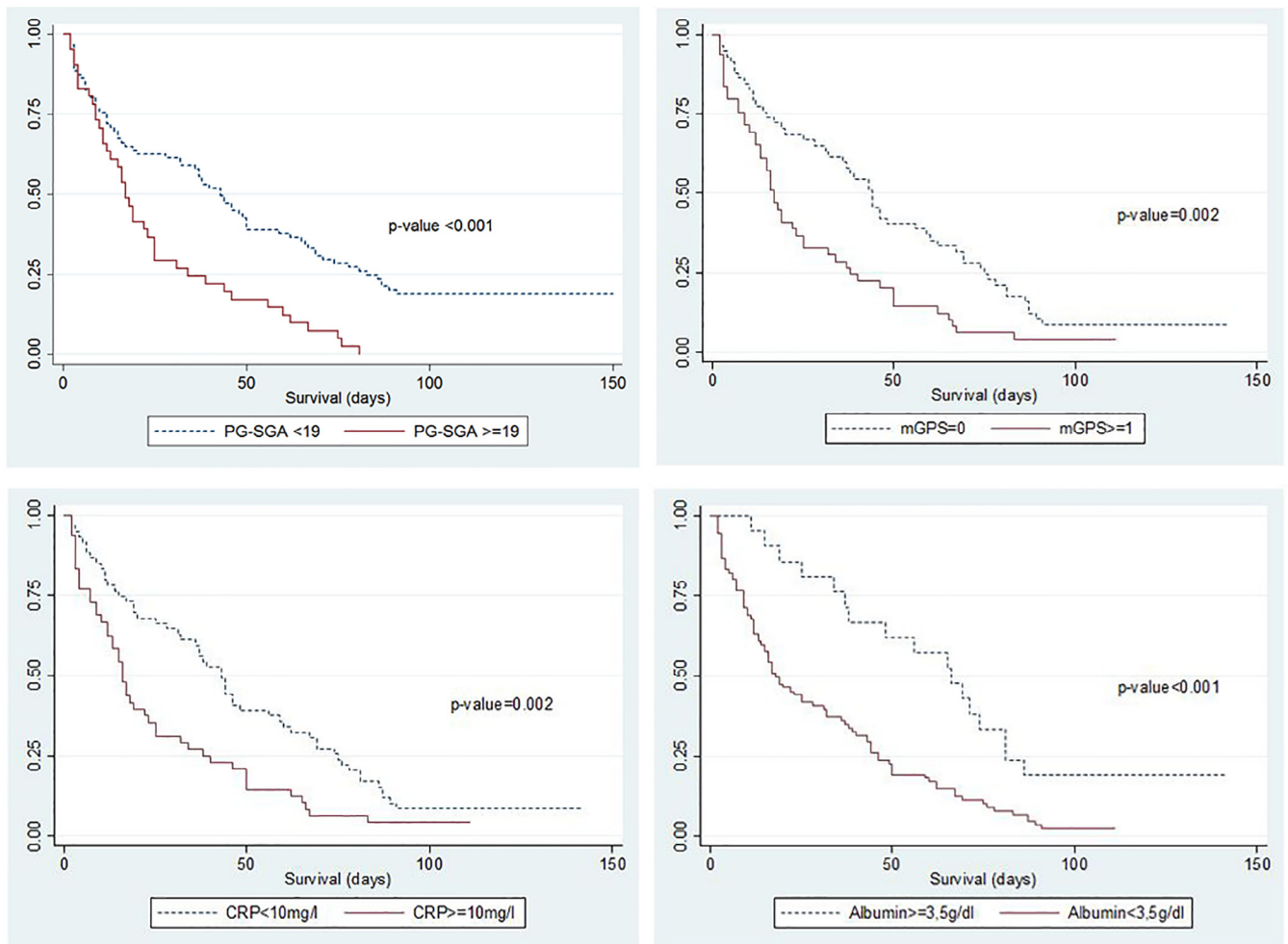


Fig. 2. Kaplan-Meier survival curves stratified by PG-SGA score, mGPS, CRP, and albumin in patients with advanced cancer treated at a palliative care unit. *P* value refers to the log-rank test. CRP, C-reactive protein; mGPS, modified Glasgow Prognostic Score; PG-SGA, abridged Patient-Generated Subjective Global Assessment.

intervention to stop or reverse PEW and consequently improve outcomes in patients with advanced cancer.

Our results indicate, in the bivariate analysis, that tumors in the gastrointestinal tract were associated with reduced survival. This result is in agreement with Dewys et al. [6], reporting a more expressive weight loss in individuals with gastrointestinal tract tumors probably as a result of difficulties in food intake and greater presence of other symptoms. In the present study, KPS was also associated with death. Several studies have already reported its value as a prognostic indicator in advanced cancer [32–35]; however, it is important to highlight that KPS, despite being a traditional tool, is not an indicator of nutritional status and it is a subjective measure, being susceptible to bias [20,35].

We found, in the multivariate analysis, that high PG-SGA score, hypoalbuminemia, and mGPS ≥ 1 were independent prognostic factors for death in 90 d. The mGPS is a combination of sensitive (CRP) and insensitive (albumin) acute-phase proteins [20]. The results of the present study are consistent with the concept that an ongoing systemic inflammatory response (CRP) leads to increased protein breakdown, progressive nutritional decline (hypoalbuminemia), and poorer survival [36]. An important issue is that serum albumin is affected by both inflammation and PEW. However, prealbumin is not affected by overhydration as a con-

sequence of inadequate nutrition and therefore may be a more reliable marker.

In Goldwasser and Feldman's study [37], hypoalbuminemia was considered an independent prognostic factor, and mGPS has been highlighted as a tool for inflammatory evaluation and as an independent prognostic factor in several stages of cancer treatment. In its turn, the study of Proctor et al. [38], with a large patient cohort, found that low albumin alone was associated with poor survival in some tumors (breast, hematologic, and pulmonary) but not others (bladder, gynecologic, prostate, gastroesophageal, renal, colorectal, head and neck, and hepatopancreatobiliary). In this study, they also indicated that the systemic inflammatory response, as evidenced by the mGPS, is a powerful prognostic factor compared with other biochemical parameters, independent of tumor site, in patients with cancer. Moreover, although mGPS may not capture established survival-related cachexia effects, such as weight loss, food intake, functional status, and associated symptom clusters [25], these domains are comprehensively evaluated by PG-SGA.

It is interesting to emphasize that patients with advanced stages of disease have greater alterations in body composition, notably decreased skeletal muscle and fat mass and metabolic derangements [11,15,19]. Therefore, determining reliable and useful

Table 2
Predictors of survival in patients with cancer treated at a palliative care unit in Rio de Janeiro

Variables	Bivariate		Multivariate	
	HR (95% CI)	P*	HR (95% CI)	P†
Age ≥ 60 y	0.99 (0.98–1.01)	0.765		
Female sex	1.04 (0.71–1.53)	0.827		
Types of tumor				
Female tumors	1.17 (0.78–1.77)	0.448		
GI tract	2.25 (1.44–3.51)	<0.001		
Head and neck	0.70 (0.43–1.15)	0.159		
Others	0.66 (0.39–1.13)	0.133		
Lung	0.68 (0.36–1.27)	0.227		
BMI (kg/m ²)	1.00 (0.97–1.03)	0.931		
BMI <20 kg/m ²	1.02 (0.65–1.61)	0.917		
Weight loss in 1 mo (%)	1.01 (0.98–1.04)	0.312		
Weight loss in 6 mo (%)	1.01 (0.99–1.03)	0.125		
KPS <50%	1.59 (1.06–2.35)	0.022		
CRP ≥10 mg/L	1.85 (1.24–2.77)	0.003		
Albumin <3.5 g/dL	2.46 (1.45–4.16)	0.001	2.04 (1.16–3.58)	0.013
mGPS ≥1	1.87 (1.25–2.80)	0.002	1.46 (1.09–2.22)	0.055
Hemoglobin <120 g/dL	1.42 (0.75–2.65)	0.275		
PG-SGA score ≥19	1.80 (1.20–2.69)	0.004	1.66 (1.08–2.55)	0.020
PG-SGA B and C	1.31 (0.61–2.83)	0.491		
PG-SGA score ≥19 + mGPS ≥1	2.04 (1.22–3.42)	0.006		
PG-SGA B or C + mGPS ≥1	1.92 (1.28–2.88)	0.002		

BMI, body mass index; CI, confidence interval; CRP, C-reactive protein; GI, gastrointestinal; HR, hazard ratio; KPS, Karnofsky Performance Status; mGPS, modified Glasgow Prognostic Score; PG-SGA, Patient-Generated Subjective Global Assessment.

* Cox proportional hazard model.

† Multivariate Cox proportional hazard model.

prognostic factors in clinical practice is important in patients with advanced disease in palliative care [3–5]. In addition, the research to find simple and inexpensive tools that can also be favorably modified by appropriate interventions has been a challenge [39].

Ours findings highlight a potential role for the mGPS (objective measure) in combination with PG-SGA (subjective measure) to predict survival effectively. Further studies are required to improve a consistent basis for establishing the use of mGPS and PG-SGA as prognostic tools in clinical practice and also to develop of specific diagnostic criteria for patients with advanced disease in palliative care.

Conclusion

In conclusion, this study found that the presence of systemic inflammation based on mGPS score, hypoalbuminemia, and malnutrition as determined by PG-SGA score were significant independent predictors of survival in patients with advanced cancer in palliative care. Thus, they can be useful tools for nutritional and prognostic evaluation in palliative care.

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