

The patient-generated subjective global assessment is a promising screening tool for cancer cachexia

Minghua Cong,¹ Chenxin Song,¹ Hongxia Xu,² Chunhua Song,³ Chang Wang,⁴ Zhenming Fu,⁵ Yi Ba,⁶ Jing Wu,⁷ Conghua Xie,⁸ Gongyan Chen,⁹ Zihua Chen,¹⁰ Lan Zhou,¹¹ Tao Li,¹² Li Deng,³ Lin Xin,² Liuqing Yang,¹³ Jiuwei Cui,⁴ Hanping Shi,¹³ The Investigation on Nutrition Status and Clinical Outcome of Common Cancers (INSCOC) Group

For numbered affiliations see end of article.

Correspondence to

Professor Hanping Shi,
Department of Gastrointestinal
Surgery/Clinical Nutrition, Capital
Medical University Affiliated
Beijing Shijitan Hospital, Beijing
100038, China;
shihp@vip.163.com

MC, CS and HX contributed
equally.

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ABSTRACT

Background Cancer cachexia is a complex metabolic syndrome characterised by a loss of muscle with or without loss of fat mass, and is associated with high morbidity and mortality. Despite its clinical importance, there is a lack of simple tools to screen patients for cancer cachexia. The aim of this study was to evaluate and validate the patient-generated subjective global assessment (PG-SGA) as a screening tool for cancer cachexia.

Methods This is a secondary analysis of a multicentre, cross-sectional, observational study. Cancer cachexia was diagnosed when there was weight loss $\geq 5\%$ during the past 12 months and at least three of the five following conditions were present: decreased muscle strength, fatigue, anorexia, low Fat-Free Mass Index (FFMI) and abnormal laboratory findings. A quadratic discriminant analysis was conducted for the ability of PG-SGA to predict cachexia.

Results A total of 4231 patients with cancer were included in this analysis, and 351 patients (8.3%) were diagnosed as having cachexia. The highest incidence of cachexia was found among patients with pancreatic cancer (32.5%), oesophageal cancer (21.5%) and gastric cancer (17.9%). Compared with patients without cachexia, patients with cachexia had a lower body mass index, FFMI, hand grip strength, total protein, prealbumin, albumin, haemoglobin and Karnofsky performance status ($p < 0.05$), while they had a higher C reactive protein level and PG-SGA Score (4.71 ± 3.71 vs 10.87 ± 4.84 , $p < 0.05$). The best cut-off value for PG-SGA was 6.5, with 79.8% of sensitivity and 72.3% specificity for cachexia, and the area under the receiver operating characteristic curve was 0.846 (95% CI 0.826 to 0.866, $p < 0.001$).

Conclusions PG-SGA is a highly specific tool that can be used to screen patients for cancer cachexia.

INTRODUCTION

Malnutrition frequently occurs in patients with cancer, with an estimated prevalence ranging from 40% to 80%.¹ Malnutrition has serious adverse consequences, including decreased muscle mass, immune dysfunction, an increased risk of complications, prolonged length of stay in the hospital, reduced response or tolerance to treatment, and reduced quality of life.²⁻⁷ Malnutrition is associated with excess morbidity and mortality.⁵⁻⁷

Cachexia has long been recognised as an adverse effect of cancer, which is associated with reduced physical function, reduced tolerance to anticancer therapy and reduced survival.⁸⁻¹¹ Cachexia is defined as a complex metabolic syndrome associated with underlying illness and characterised by a loss of muscle with or without loss of fat mass.¹² Anorexia, inflammation, insulin resistance and increased muscle protein breakdown are frequently associated with cachexia.

Cancer-related malnutrition and cancer cachexia are considered to be underdiagnosed and under-resourced aspects of cancer supportive care.^{13 14} In particular, cachexia in patients with cancer is barely recognised, assessed or managed actively, despite the fact that more than 50% of patients with advanced cancer experience cachexia, and more than 10% die with or from it.¹⁴

One of the reasons why cancer cachexia is underdiagnosed and treated is



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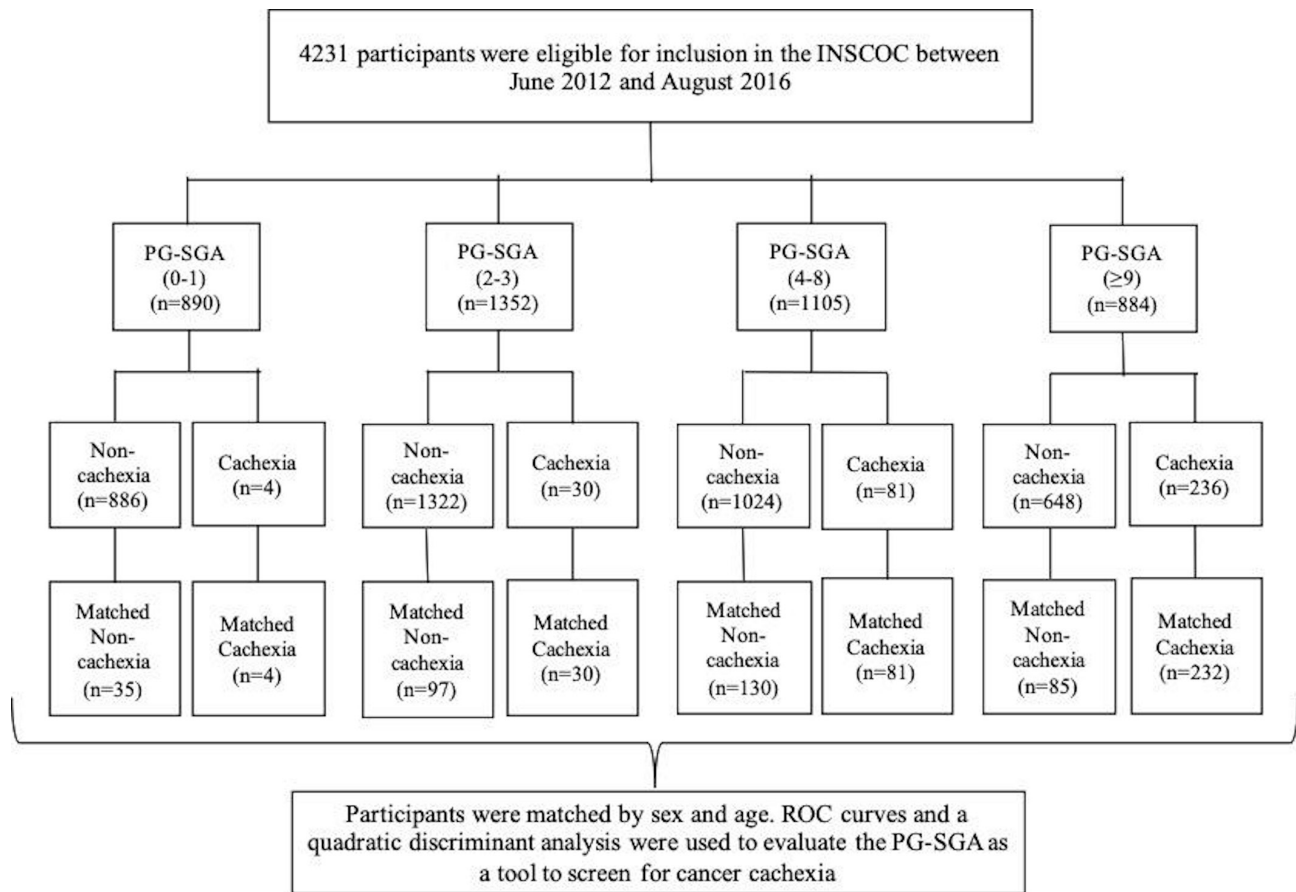


Figure 1 A flow chart showing the analyses performed. INSCOC, Investigation on Nutritional Status and its Clinical Outcomes of Common Cancers; ROC, receiver operating characteristic; PG-SGA, patient-generated subjective global assessment.

that there has not been a simple and accurate diagnostic tool available to screen patients. The patient-generated subjective global assessment (PG-SGA) for oncology patients was developed by Ottery as a general nutritional assessment.¹⁵ This tool has two sections—a medical history section that is completed by the patient, and a physical assessment section that is completed by nursing, medical or dietetic staff. A scored version of the PG-SGA, including a numerical score and the overall global rating, was subsequently developed.¹⁶ The scoring system allows patients at risk for malnutrition to be accurately identified, and the score can be used for guiding nutritional therapy. The scored PG-SGA has been accepted as the standard for nutrition assessment for patients with cancer by the Oncology Nutrition Dietetic Practice Group of the American Dietetic Association (ADA).^{15 16} Studies showed PG-SGA had a sensitivity of higher than 90%, and a specificity of higher than 80% for malnutrition in patients with a variety of cancers.^{16 17}

Early and accurate recognition of cachexia in patients with cancer, followed by rapid therapeutic and nutritional intervention, is the most effective way to prevent muscle mass deterioration. The aim of the current study was to assess the utility of PG-SGA to

screen patients with cancer for cachexia according to an international consensus definition of cachexia.

SUBJECTS AND METHODS

Study design

This is a secondary analysis of a multicentre, cross-sectional, observational study. The study population was a subset of the patients included in the Investigation on Nutritional Status and its Clinical Outcomes of Common Cancers (INSCOC), a nationwide cross-sectional study on the correlation between the nutritional status of patients and the clinical outcomes of common cancers in China.¹⁸

Participants

In the present study, consecutive patients at numerous tertiary hospitals in different regions of China were offered study entry. All patients who were pathologically diagnosed with cancer and were explicitly admitted for cancer treatment (surgery, radiotherapy, chemotherapy or other anticancer therapy) were eligible to be included in the INSCOC cohort between June 2012 and August 2016.

Methods

A flow chart of the study is shown in [figure 1](#). All patients who presented to the oncology centres were

interviewed by trained personnel and asked to answer a formatted questionnaire, including the PG-SGA. During a face-to-face interview, participants were asked questions about their demographics, selected lifestyle factors, medical history, treatment, and were given various questionnaires, including the PG-SGA. A medical history was taken and a physical examination was performed. The anthropometric and biochemical characteristics of subjects were provided by some centres that also obtained the results of a body composition analysis. All of the patients were classified into one of the following groups: PG-SGA Score 0–1, PG-SGA Score 2–3, PG-SGA Score 4–8, PG-SGA Score ≥ 9 .¹⁶

Based on the consensus definition of cachexia,¹² cachexia should only be diagnosed in the presence of weight loss $\geq 5\%$ within the last 12 months if at least three of the following five conditions are identified: decreased muscle strength, fatigue, anorexia, low Fat-Free Mass Index (FFMI) and abnormal laboratory biochemistry findings (increased inflammatory markers, anaemia and low serum albumin).¹² In order to diminish the potential for confounding due to differences in observed personal characteristics, sex-matched and age-matched patients with cancer without cachexia were selected as controls.

Statistical analysis

The quantitative data were presented as the means and SDs, and qualitative data were expressed as percentages. Differences in mean values were tested with a one-way analysis of variance and a paired or independent t-test, depending on the comparison groups. Differences in qualitative data were assessed using a χ^2 test. The graphics were generated with the ggplot2 software package. The PG-SGA Scores were compared with the diagnosis of cancer cachexia. For the discriminant analysis, receiver operating characteristic (ROC) curves were calculated. A quadratic discriminant analysis was conducted among the four groups stratified by PG-SGA to predict cachexia.

All statistical analyses were performed with IBM SPSS Statistics V.19 (SPSS, Chicago, Illinois, USA). Significance was considered to be present for values of $p < 0.05$ for all tests.

RESULTS

Table 1 outlines the number of participants classified by different cancers. A total of 4231 patients with cancer were included in this analysis. The most common cancer diagnosis was lung cancer (1179, 27.9%), followed by breast cancer (942, 22.3%). Using the established definition of cachexia,¹² 351 patients (8.3%) were diagnosed with cancer cachexia, which a high incidence of cachexia observed in patients with pancreatic cancer (32.5%), oesophageal cancer (21.5%) and gastric cancer (17.9%). All but four of the patients with cachexia were able to be matched

Table 1 Numbers of participants with different cancers evaluated in this study

	Total population (n=4231)	Non-cachexia (n=3380, %)	Cachexia (n=351, %)
Lung cancer	1179	1091 (92.5)	88 (7.5)
Breast cancer	942	916 (97.2)	26 (2.8)
Colorectal cancer	507	453 (89.3)	54 (10.7)
Gastric cancer	385	316 (82.1)	69 (17.9)
Cervical cancer	147	143 (97.3)	4 (2.7)
Liver cancer	142	137 (96.5)	5 (3.5)
Oesophageal cancer	121	95 (78.5)	26 (21.5)
Ovarian cancer	115	106 (92.2)	9 (7.8)
Pancreatic cancer	40	27 (67.5)	13 (32.5)
Nasopharyngeal carcinoma	24	21 (87.5)	3 (12.5)
Multiple cancers	42	35 (83.3)	7 (16.7)
Other cancers	587	540 (92.0)	47 (8.0)

to a same-age patient without cachexia, to obtain a matched sample of 794 patients with cancer.

The results of a comparison of the clinical characteristics between the non-cachexia and cachexia groups are shown in table 2. As expected, the patients with cachexia had a significantly lower body mass index (BMI) ($18.90 \pm 2.61 \text{ kg/m}^2$ vs $23.77 \pm 3.38 \text{ kg/m}^2$, $p < 0.05$), FFMI ($41.38 \pm 6.74 \text{ kg}$ vs $46.12 \pm 8.44 \text{ kg}$, $p < 0.05$) and hand grip strength ($18.84 \pm 7.02 \text{ kg}$ vs $24.83 \pm 9.68 \text{ kg}$, $p < 0.05$) than the group of patients without cachexia. Patients with cachexia also had lower total protein ($61.84 \pm 7.85 \text{ g/L}$ vs $66.66 \pm 7.10 \text{ g/L}$, $p < 0.05$), prealbumin ($0.19 \pm 0.19 \text{ g/L}$ vs $0.23 \pm 0.23 \text{ g/L}$, $p < 0.05$), albumin ($35.15 \pm 5.72 \text{ g/L}$ vs $39.28 \pm 5.16 \text{ g/L}$, $p < 0.05$) and haemoglobin ($106.23 \pm 23.86 \text{ g/L}$ vs $121.27 \pm 22.70 \text{ g/L}$, $p < 0.05$) levels, and a poorer Karnofsky performance status (79.23 ± 15.76 vs 88.93 ± 10.11 , $p < 0.05$) when compared with patients with cancer without cachexia. On the other hand, the patients in the non-cachexia group had a significantly lower C reactive protein level and PG-SGA Score than the patients with cancer with cachexia ($16.83 \pm 32.76 \text{ g/L}$ vs $33.63 \pm 43.61 \text{ g/L}$, $p < 0.05$ and 4.71 ± 3.71 vs 10.87 ± 4.84 , $p < 0.05$, respectively). Of note, compared between matched non-cachexia group and matched cachexia group, there was a significant difference in the height between the groups ($162.53 \pm 7.99 \text{ cm}$ vs $164.03 \pm 7.61 \text{ cm}$, $p < 0.05$), while there was no significant difference in FFMI between the patients with cancer with and without cachexia (table 2).

As shown in table 3, we separated all patients into four groups based on the PG-SGA Score and compared the patients with and without cachexia. A total of 236 patients with cancer with cachexia (67.2%) had a PG-SGA Score ≥ 9 , while 317 patients with cancer with cachexia (90.3%) had a PG-SGA Score ≥ 4 , and were classified as having moderate or severe

Table 2 Comparison of the clinical characteristics between patients with and without cachexia, for both the full population and sex-matched and age-matched samples

	Non-cachexia (n=3380)	Cachexia (n=351)	Matched non-cachexia (n=347)	Matched cachexia (n=347)
Height (cm)	163.99±8.04	164.06±7.57	162.53±7.99	164.03±7.61*
Weight (kg)	64.00±10.48	51.01±8.68*	53.13±7.90	51.08±8.68*
BMI (kg/m ²)	23.77±3.38	18.90±2.61*	20.09±2.39	18.93±2.60*
FFMI (kg)	46.12±8.44	41.38±6.74*	41.97±7.30	41.41±6.75
Grip strength (kg)	24.83±9.68	18.84±7.02*	23.90±8.44	18.87±6.98*
TP (g/L)	66.66±7.10	61.84±7.85*	65.39±7.44	61.85±7.84*
PALB (g/L)	0.23±0.23	0.19±0.19*	0.22±0.27	0.19±0.19*
ALB (g/L)	39.28±5.16	35.15±5.72*	38.34±5.24	35.19±5.74*
Transferrin (g/L)	2.46±2.46	2.27±3.15	2.63±3.68	2.28±3.15
CRP (g/L)	16.83±32.76	33.63±43.61*	11.60±23.23	33.72±43.66*
WBC (g/L)	6.84±6.31	7.63±5.98	7.24±5.87	7.61±6.00
HGB (g/L)	121.27±22.70	106.23±23.86*	118.83±21.10	106.25±23.92*
PLT (g/L)	224.27±101.06	235.31±114.63	227.92±106.92	235.40±115.27
KPS	88.93±10.11	79.23±15.76*	87.06±10.31	79.60±15.33*
PG-SGA	4.71±3.71	10.87±4.84*	6.16±3.89	10.84±4.85*

Values are expressed as the means±SD.

*Values of p<0.05 were considered statistically significant.

ALB, albumin; BMI, body mass index; CRP, C reactive protein; FFMI, Fat-Free Mass Index; HGB, haemoglobin; KPS, Karnofsky performance status; PALB, prealbumin; PG-SGA, patient-generated subjective global assessment; PLT, platelets; TP, total protein; WBC, white blood cells.

malnutrition. These values remained consistent in the matched sample after the four non-age-matched patients were removed (66.9% and 90.2%). In the matched patients without cachexia, only 85 patients (24.5%) had PG-SGA Scores ≥9, and only 215 (62%) had scores ≥4.

The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) using different cut-offs for the PG-SGA are shown in table 4. According to the ROC curve, the best cut-off of the PG-SGA was 6.5, which had a sensitivity of 79.8% and a specificity of 72.3%, and the area under the ROC curve was 0.846 (95% CI 0.826 to 0.866, p<0.001) (figure 2). The PPV and NPV were 20.68% and 97.53%, respectively.

DISCUSSION

The present study showed that pancreatic cancer (32.5%), oesophageal cancer (21.5%) and gastric cancer (17.9%) are associated with a high incidence of cachexia. Compared with patients without cachexia,

patients with cancer with cachexia had a lower BMI, FFMI and hand grip strength, and a higher PG-SGA Score (4.71±3.71 vs 10.87±4.84, p<0.05). Importantly, PG-SGA was highly specific for screening patients with cancer for cachexia, because 90.3% patients with cancer with cachexia had a PG-SGA Score ≥4.

Approximately half of the patients with advanced-stage cancer had cachexia, and the incidence in patients with cancers of the upper digestive tract and pancreas was as high as 80%. Vaughan *et al* reported that 86% of their patients with cancer had cachexia in the last 1–2 weeks of life, and 45% of patients lost more than 10% of their body weight throughout the disease process.¹⁹ In addition to increasing morbidity and mortality, aggravating the side effects of chemotherapy, and reducing the quality of life for patients, cachexia is considered to be the immediate cause of death for an estimated 22%–40% of patients.²⁰ A report about the psychosocial impact of cancer cachexia by Hopkinson indicated that cancer cachexia

Table 3 Numbers of participants in the non-cachexia and cachexia groups stratified by PG-SGA Score, for both the full population and sex-matched and age-matched samples

PG-SGA Score	Total population (n=4231)	Non-cachexia (n=3380, %)	Cachexia (n=351, %)	Matched non-cachexia (n=347, %)	Matched cachexia (n=347, %)
0–1	890	886 (22.8)	4 (1.1)	35 (10.0)	4 (1.2)
2–3	1352	1322 (34.1)	30 (8.5)	97 (28.0)	30 (8.6)
4–8	1105	1024 (26.4)	81 (23.1)	130 (37.5)	81 (23.3)
≥9	884	648 (16.7)	236 (67.2)	85 (24.5)	232 (66.9)

PG-SGA, patient-generated subjective global assessment.

Table 4 The sensitivity, specificity, PPV and NPV at different cut-off values

Cut-off	Sensitivity, %	Specificity, %	PPV, %	NPV, %	ROC	95% CI	P value
-1	100.00	0.00	8.30	100.00	0.846	0.826 to 0.866	<0.001
0.5	100.00	0.05	8.30	100.00			
1.5	98.86	22.84	10.39	99.55			
2.5	97.44	39.18	12.66	99.41			
3.5	94.30	48.61	14.24	98.95			
4.5	90.31	56.91	15.94	98.48			
5.5	85.47	64.97	18.09	98.02			
6.5	79.77	72.35	20.70	97.53			
7.5	72.65	78.20	23.17	96.93			
8.5	67.24	83.30	26.71	96.56			
9.5	61.25	87.58	30.86	96.15			
10.5	53.28	91.34	35.77	95.57			
11.5	45.30	94.30	41.86	95.01			
12.5	35.61	96.01	44.66	94.28			
13.5	28.77	97.40	50.01	93.79			
14.5	21.08	98.30	52.87	93.23			
15.5	16.52	98.87	56.88	92.90			
16.5	11.97	99.25	59.17	92.57			
17.5	8.26	99.64	67.45	92.31			
18.5	5.41	99.74	65.53	92.10			
19.5	4.27	99.87	75.01	92.02			
20.5	3.13	99.90	73.34	91.93			
21.5	2.56	99.95	81.83	91.89			
22.5	1.42	99.97	83.34	91.81			
23.5	1.14	100.00	100.00	91.79			
24.5	0.85	100.00	100.00	91.77			
26	0.28	100.00	100.00	91.72			
28	0.00	100.00	100.00	91.70			

NPV, negative predictive value; PPV, positive predictive value; ROC, receiver operating characteristic.

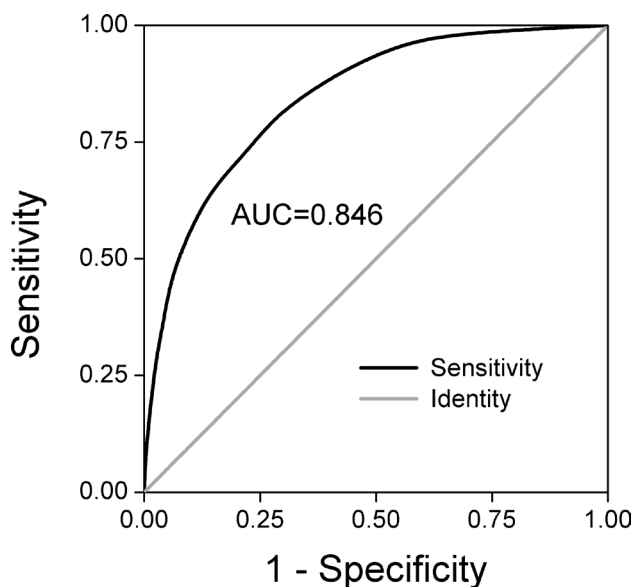


Figure 2 Area under curves in predicting cachexia assessed by the PG-SGA Score. AUC, area under the receiver operating characteristic curve; PG-SGA, patient-generated subjective global assessment.

had a major impact on the patients and their families, including pain, depression, anxiety and so on, and led to emotional conflict.²¹

The exact mechanism(s) by which these diseases cause cachexia is poorly understood, but it is likely that inflammatory cytokines, such as tumour necrosis factor-alpha, interferon-gamma and interleukin 6 (IL-6), as well as the tumour-secreted proteolysis-inducing factor,²² play a role. The treatment or management of cachexia depends on the underlying causes, the general prognosis and other individual factors. Primary disease control, nutritional intervention, inflammation control, immune regulation, metabolic conditioning, physical exercise and/or symptom-related therapy should all be provided if possible and acceptable.²²

Effective treatment of cancer cachexia depends on early detection, with screening being the first step. It is necessary to carefully monitor for any involuntary loss of weight or reduction in food intake in the clinical setting, because they can help with the early detection of cancer cachexia. According to clinical practice guidelines on cancer cachexia by the European Palliative Care Research Collaborative, the assessment of signs and symptoms has to cover different dimensions

of cachexia. A model with four dimensions has been proposed, including Storage, Intake, Potential and Performance.²³ Any cachexia screening tool should include at least subjective symptoms, history, clinical examination, laboratory examination, activity monitoring and body composition analysis.²³

There are two major definitions of cachexia that have been proposed. We chose to use the method described by Evans *et al*¹² in the present study because it includes indicators of the inflammatory and metabolic status, unlike the method described by Fearon *et al*.²⁴ In the present study, 351 patients (8.3% of all patients with cancer evaluated) were diagnosed as having cachexia according to the above definition.¹² The diagnosis of cancer cachexia using simple diagnostic tools is essential, because the detection of lean muscle tissue is often impossible in developing countries. Even in countries where bioelectrical impedance analysis is readily available, performing an initial screen for cachexia and then evaluating the body composition for the high-risk group would provide better resource utilisation. Although calculating the BMI is an easy and low-cost method for providing an initial assessment, it often does not reflect the real nutritional status because it cannot distinguish lean muscle from fat mass. The BMI also does not consider recent weight loss, which is included in the PG-SGA.

The PG-SGA is a non-invasive clinical instrument used to evaluate the nutritional status, and is the reference method for assessing the nutritional status of patients with cancer recommended by expert groups, such as the Oncology Nutrition Dietetic Practice Group of the ADA, American Society of Parenteral and Enteral Nutrition, and the European Society for Clinical Nutrition and Metabolism. The PG-SGA is also the most complete method for nutritional assessment, because it simultaneously evaluates relevant prognostic aspects for patients with advanced cancer, such as changes in body weight, food intake, symptoms that might impact nutrition, the performance status and the results of a physical examination.^{16 25–27} A recent study showed that the scored PG-SGA was an independent prognostic factor for survival, and thus could be a useful tool for evaluating nutrition during palliative care.²⁸

It is well known that cancer cachexia can increase treatment-related toxicity, aggravate the symptom burden, worsen the quality of life and shorten survival times for patients. A PG-SGA Score ≥ 9 is frequently used to indicate a critical need for improved symptom management and/or nutritional intervention.^{29 30} Nevertheless, in our study, using a cut-off for the PG-SGA Score ≥ 6.5 provided 79.8% sensitivity and 72.3% specificity, while using a cut-off of 7.5 provided 72.7% sensitivity and 78.2% specificity (table 4). Our results suggest that defining the cut-off point ≥ 6.5 might be suitable in clinical practice for diagnosing cancer cachexia.

Zhou *et al*³¹ recently developed and validated a clinically applicable scoring system to classify cachexia stages in patients with advanced cancer, which comprises the following five components: weight loss, a simple questionnaire about sarcopenia, the Eastern Cooperative Oncology Group status, appetite loss and abnormal biochemistry. The cachexia staging score is a clinically applicable tool with excellent discrimination for classifying cachexia stages. However, as a screening or assessment tool, it is too complex and requires too much time to complete.

The PG-SGA is a simple-to-use tool that is recommended by several professional nutrition associations worldwide. The purpose of this study was to evaluate if the PG-SGA can be used as a screening tool for cancer cachexia. The results showed that the sensitivity, specificity and NPV were all good. Because of the low prevalence of cancer cachexia, the PPV is not very high. However, a low PPV is acceptable for early screening, especially for cachexia, which can cause great harm to patients with cancer, and because overtreatment for cachexia is unlikely to result in adverse effects for the patient.

There are some limitations that exist in our study. First, our study was conducted in patients with many different cancers. Because the incidence of cancer cachexia varies based on the cancer type, there might be some cancer types where it is not practical to use PG-SGA. Second, although we suggest that PG-SGA can be used as a tool to screen patients for cancer cachexia, a subsequent evaluation will be needed, because PG-SGA cannot be effectively used to define the extent of cachexia. It might be useful to employ PG-SGA as an initial screening tool, and then subsequently use the tool developed by Zhou *et al*³¹ to classify the extent of cachexia.

In conclusion, patients with pancreatic, oesophageal and gastric cancers had the highest incidence of cachexia. Patients with cachexia had a worse nutritional status based on BMI, hand grip strength, albumin, prealbumin and PG-SGA Score. We suggest that PG-SGA can be used as a screening tool in the early diagnosis of cancer cachexia to help minimise the adverse impact of this syndrome by allowing prompt intervention.

Author affiliations

¹Department of Comprehensive Oncology, National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

²Department of Nutrition, Third Military Medical University Daping Hospital and Research Institute of Surgery, Chongqing, China

³Department of Epidemiology, Zhengzhou University, Zhengzhou, China

⁴Cancer Center, The First Hospital Of Jilin University, Changchun, China

⁵Cancer Center, Renmin Hospital of Wuhan University, Wuhan, China

⁶Department of Gastrointestinal Oncology, Tianjin Medical University Cancer Institute and Hospital, National Clinical Research Center for Cancer, Tianjin Key Laboratory of Cancer Prevention and Therapy, Tianjin, China

⁷Department of Clinical Nutrition, The First People's Hospital of Kashi, Xinjiang, China

⁸Department of Radiation and Medical Oncology, Wuhan University Zhongnan Hospital, Wuhan, China

⁹Department of Oncology, Tumor Hospital of Harbin Medical University, Harbin, China

¹⁰Department of General Surgery, Xiangya Hospital Central South University, Changsha, China

¹¹Department of Nutrition, Third Affiliated Hospital of Kunming Medical College, Tumor Hospital of Yunnan Province, Kunming, China

¹²Department of Radiotherapy, Sichuan Cancer Hospital and Institute/Sichuan Cancer Center, School of Medicine/University of Electronic Science and Technology of China, Chengdu, China

¹³Department of Gastrointestinal Surgery/Clinical Nutrition, Capital Medical University Affiliated Beijing Shijitan Hospital, Beijing, China

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Contributors All authors made contributions to data acquisition and interpretation. HS designed the INSCOC Study. HS and JC were involved in the development of study concept. MC, CXS, HX and CHS were major contributors in the data analysis, and MC drafted the manuscript. CS and HX revised the manuscript critically for important intellectual content. Authors MC, CXS, HX, CHS, CW, ZF, YB, JW, CX, GC, ZC, LZ, TL, LD, LX, LY, JC and HS read and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Obtained.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. The processed data required to reproduce these findings cannot be shared at this time as the data also form part of an ongoing study.

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