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Original article

Linguistic and content validation of the translated and culturally adapted patient-generated subjective global assessment (PG-SGA)

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SUMMARY

The Patient-Generated Subjective Global Assessment (PG-SGA) is an instrument to screen, assess and monitor malnutrition and risk factors, and to triage for interventions. After having translated and culturally adapted the original PG-SGA for the Italian setting, according to International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Principles, we tested linguistic validity, i.e., perceived comprehensibility and difficulty, and content validity (relevance) of the Italian version of the PG-SGA in patients with cancer and a multidisciplinary sample of healthcare professionals (HCPs).

Methods: After the translation and cultural adaptation of the original PG-SGA for the Italian setting, the *patient component* (i.e., PG-SGA Short Form (SF) was tested for linguistic validity (i.e., comprehensibility and difficulty) in 120 Italian patients with cancer and 81 Italian HCPs. The full PG-SGA, i.e., *patient and professional component* of the PG-SGA, was tested for content validity, i.e., relevance, in 81 Italian HCPs. The data were collected by a questionnaire and evaluations were operationalized by a 4-point scale. Through item and scale indices we evaluated the comprehensibility (I–CI, S–CI), difficulty (I–DI, S–DI) and content validity (I–CVI, S–CVI). Scale indices 0.80–0.89 were considered acceptable, and scale indices ≥ 0.90 were considered excellent.

Results: Patients perceived comprehensibility and difficulty of the PG-SGA SF (Boxes) as excellent (S–CI = 0.98, S–DI = 0.96). Professionals perceived comprehensibility of the professional component (Worksheets) as excellent (S–CI = 0.92), difficulty as acceptable (S–DI = 0.85), and content validity of the full PG-SGA as excellent (S–CVI = 0.92). Dietitians gave higher scores (indicating better scores) on comprehensibility, difficulty, and content validity of Worksheet 4 (physical exam) than the other professions. In Worksheet 4, four items were considered most difficult to complete and were considered below acceptable range. Relevance was perceived as excellent by professionals for both the patient component (S–CVI = 0.93) and the professional component (S–CVI = 0.90), resulting in S–CVI = 0.92 for the full PG-SGA. Slight textual modifications were implemented resulting in the final version of the Italian PG-SGA.

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Conclusions: Translation and cultural adaptation of the original PG-SGA resulted in the Italian version of the PG-SGA that maintained its original purpose and meaning and can be completed adequately and easily by patients and professionals. The Italian PG-SGA is considered relevant for screening, assessing and monitoring malnutrition and risk factors, as well as triaging for interventions by Italian HCPs.

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1. Introduction

Early identification, diagnosis and treatment of malnutrition and metabolic disorders are of critical importance in patients with cancer. The prevalence of malnutrition ranges from 20% to 70% in patients with cancer according to primary cancer, stage of disease, age and assessment instrument used [1]. Nutritional evaluation serves as a basis for the diagnosis of malnutrition and it includes the cause, severity and type of malnutrition [1,2].

Malnutrition can be defined as “a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease”. Malnutrition can result from starvation, disease or advanced ageing (e.g. >80 years), alone or in combination [3].

Due to the disease and toxicity associated with the treatments, cancer patients are at risk of malnutrition, which is associated with reduced tolerance to anticancer therapy, treatment interruptions, prolonged length of stay, hospital readmissions, reduced quality of life, and poor prognosis [4–7]. For all those reasons, nutritional risk screening and assessment of malnutrition should be carried out regularly in all cancer patients undergoing anticancer treatment and in those with an expected survival of more than a few months to target the nutritional intervention [1,2].

The Scored Patient-Generated Subjective Global Assessment (PG-SGA) (copyright FD Ottery, 1996, 2001, 2005, 2006, and 2015) is a patient-reported outcome (PRO) [8] widely used both in clinical practice and in research, as it is the reference method for evaluation of nutritional status of patients with cancer [9]. The instrument has high sensitivity and specificity in patients with cancer, in both inpatient and outpatient care, and is recommended by several national and international guidelines [9]. As a 4-in-1 instrument, it is an easy to complete instrument for nutritional screening, evaluation, interventional triage, and monitoring of interventional success [9]. The PG-SGA contains items concerning nutrient balance, body shape, size and composition, function and inflammatory activity [10]. It identifies specific nutritional impediments allowing personalized medical and nutritional interventions [9]. Uniquely, the PG-SGA evaluates the patient's status as a dynamic rather than a static process, assessing nutritional status over time and in response to nutritional interventions [9]. Moreover, this instrument includes both patient and professional reported items showing both perspective in the nutritional status of patient (a patient-generated component, also known as the PG-SGA Short Form) and a professional component [3,6]. The PG-SGA includes items on weight history irrespective of body mass index, and is able to identify the risk of malnutrition in overweight/obese patients in a more accurate way as compared to other instruments [10]. The numerical scoring system allows for triaging for interdisciplinary interventions, as well as monitoring outcomes of the proactive interventions by nurse, dietitian and/or physician [9,11].

The scoring of the PG-SGA has been described in detail elsewhere [10]. The PG-SGA has been validated in multiple languages [12–18] and used in several clinical settings. Although it is not an

oncology-specific instrument, in patients with cancer it has demonstrated both concurrent validity (i.e., association with anthropometry, biochemistry, clinical and cancer-related characteristics of patients), and predictive validity (i.e., association with clinical outcomes like quality of life, postoperative complications, length of hospital stay, and survival [9,19–21]).

An Italian version of the PG-SGA was not available yet, while it is needed. Developing a new language version of an instrument not only requires a translation but also cultural adaptation, and evaluation of the linguistic validity and content validity (relevance). Therefore, the aim of this study was to assess the linguistic and content validity of the systematic translation and cultural adaptation of the original English PG-SGA into an Italian language version, to ensure conceptual, semantic, and operational equivalence to the original instrument [12,22,23].

2. Methods

2.1. Study population

The study was performed at the Medical Oncology: Internistic & Geriatric Supportive Care Unit of the Fondazione IRCCS, Istituto Nazionale dei Tumori (INT) of Milan, Italy and at Azienda Socio Sanitaria Territoriale (ASST) Spedali Civili, Brescia, Italy.

All outpatients undergoing oncologic treatments who accessed the Supportive Care Unit for the treatment of symptoms and toxicities related to the therapies were invited to participate in the study. The HCPs were recruited at INT and at ASST Spedali Civili, Brescia, Italy.

Inclusion criteria for patients were: age ≥ 18 years, diagnosis of solid or hematologic malignancy, undergoing oncologic therapy/therapies, and written signed informed consent. Exclusion criteria for patients were: cognitive impairments assessed by the Mini-Mental State Examination (MMSE < 24), severe symptoms or toxicities, difficulties to complete the questionnaires, being participant in another clinical trial.

Inclusion criteria for HCPs were: working as dietitian or physician, being a dietetics student, not having used the PG-SGA previously.

2.2. Measures and procedure

The original English PG-SGA (© FD Ottery 2005, 2006, 2015 v3.22.15) (<https://pt-global.org/wp-content/uploads/2021/02/PG-SGA-Metric-version-4.3.20-std-logo.pdf>) was used for translation and cultural adaptation of the PG-SGA to the Italian setting, following the ten steps of the ISPOR Principles [22], which are briefly explained in Table 1S.

The study was approved by the Ethical Committee of INT of Milano in July 2017 (n. INT 135/17). All patients and HCPs involved in the study gave their written informed consent to participate and to answer the questionnaires anonymously.

The PG-SGA form consists of two pages (Fig. 1). Page one is patient-generated (hereby called the *patient component*) and



Valutazione soggettiva globale riportata dal paziente tramite punteggio Scored Patient Generated Subjective Global assessment (PG-SGA)

Anamnesi: Le sezioni da 1 a 4 sono strutturate per essere completate dal paziente. [Le sezioni da 1 a 4 vengono definite "PG-SGA Short Form (SF)"]

1. Peso (vedi Foglio di lavoro 1)

Riepilogo del mio peso attuale e recente:

Attualmente peso circa ____ kg
Sono alto circa ____ cm

Un mese fa pesavo circa ____ kg
Sei mesi fa pesavo circa ____ kg

Nelle ultime due settimane il mio peso è:

☐ ____ diminuito (1) ☐ rimasto invariato (0) ☐ aumentato (0)

Sezione 1 ☐

3. Sintomi: ho avuto i seguenti problemi che mi hanno impedito di alimentarmi adeguatamente nelle ultime due settimane (mettere un segno su tutte le opzioni pertinenti)

☐ nessun problema nel mangiare (0) ☐ vomito (3)
☐ mancanza di appetito, semplicemente non avevo voglia di mangiare (3) ☐ diarrea (3)
☐ nausea (1) ☐ secchezza della bocca (1)
☐ costipazione (1) ☐ gli odori mi infastidiscono (1)
☐ ulcere in bocca (2) ☐ mi sento sazio rapidamente (1)
☐ i cibi hanno un sapore strano o non hanno sapore (1) ☐ stanchezza (1)
☐ problemi di deglutizione (2)
☐ dolore; dove? (3) _____
☐ altro (1) ** _____

****Esempi:** depressione, motivi economici, problemi dentali

Sezione 3 ☐

Dati identificativi del paziente

2. Apporto di cibo: Rispetto alla mia alimentazione normale, durante il mese precedente il mio consumo di cibo:

☐ è rimasto invariato (0)
☐ è stato superiore al solito (0)
☐ è stato inferiore al solito (1)

Attualmente, sto assumendo

☐ un'alimentazione normale, ma in quantità inferiore al solito (1)
☐ piccole quantità di cibo solido (2)
☐ solo liquidi (3)
☐ solo integratori alimentari (sostitui del pasto) (3)
☐ quantità molto piccole di qualsiasi alimento (4)
☐ solo alimentazione con sondino o solo nutrizione endovenosa (0)

Sezione 2 ☐

4. Attività fisica e funzioni:

Durante il mese scorso, la mia attività fisica è stata:

☐ normale, senza nessuna limitazione (0)
☐ non del tutto normale, ma sono stato in grado di alzarmi dal letto e di portare a termine quasi normalmente le mie solite attività (1)
☐ non me la sento di fare la maggior parte delle cose, ma passo a letto o seduto meno della metà della giornata (2)
☐ in grado di svolgere qualche attività, trascorro la maggior parte della giornata a letto o seduto (3)
☐ sostanzialmente costretto a letto, mi alzo raramente (3)

Sezione 4 ☐

Il resto del questionario dovrà essere completato dal Suo medico, infermiere, dietista o terapista. Grazie.

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Punteggio cumulativo delle Sezioni da 1 a 4 ☐ **A**

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

Scheda 1 - Punteggio corrispondente alla perdita di peso

Per determinare il punteggio utilizzare i dati sul peso relativi a 1 mese, se disponibili. Utilizzare i dati su 6 mesi solo in mancanza dei dati sul peso relativi a 1 mese. Utilizzare i punti indicati sotto per il punteggio relativo alla variazione di peso e aggiungere un punto extra se il paziente ha perso peso nelle ultime 2 settimane. Inserire il punteggio totale nella Sezione 1 del Scored Patient Generated Subjective Global Assessment- PG-SGA.

Calo ponderale in 1 mese	Punti	Calo ponderale in 6 mesi
10 % o superiore	4	20 % o superiore
5 - 9,9 %	3	10 - 19,9 %
3 - 4,9 %	2	6 - 9,9 %
2 - 2,9 %	1	2 - 5,9 %
0 - 1,9 %	0	0 - 1,9 %

Punteggio numerico Scheda 1 ☐

Punteggio cumulativo delle sezioni da 1 a 4 (Fare riferimento al lato 1) ☐ **A**

5. Scheda 2 - La malattia e la sua relazione con i requisiti nutrizionali:

Il punteggio è ottenuto aggiungendo 1 punto per ciascuna delle condizioni seguenti:

☐ Cancro
☐ AIDS
☐ Cachessia polmonare o cardiaca
☐ Insufficienza renale cronica
 Altre diagnosi significative (specificare) _____
 Stadio della malattia primaria (cerchiare, se noto o pertinente) I II III IV Altro _____

☐ Presenza di decubiti, ferite aperte o fistole
☐ Presenza di traumi
☐ Età superiore a 65 anni

Punteggio numerico ricavato dalla Scheda 2 ☐ **B**

6. Scheda 3 - Fabbisogno metabolico

Il punteggio relativo allo stress metabolico è determinato da una serie di variabili che notoriamente aumentano il fabbisogno proteico e il catabolismo. Nota: dai un punteggio alla intensità della febbre o alla sua durata, a seconda di quello che sia maggiore. Il punteggio è cumulativo, quindi un paziente con febbre a 38,9°C (3 punti) per < 72 ore (1 punto) in trattamento cronico con 10 mg di prednisone (2 punti), per questa sezione otterrebbe un punteggio cumulativo pari a 5 punti.

Stress	nessuno (0)	basso (1)	moderato (2)	elevato (3)
Febbre	assenza di febbre	> 37,2 e < 38,3	≥ 38,3 e < 38,8	≥ 38,8 °C
Durata della febbre	assenza di febbre	< 72 ore	72 ore	> 72 ore
Corticosteroidi	nessuna assunzione di corticosteroidi	basse dosi (< 10 mg di equivalenti del prednisone/die)	dosi moderate (≥ 10 mg e < 30 mg di equivalenti del prednisone/die)	alte dosi (≥ 30 mg di equivalenti del prednisone/die)

Punteggio numerico ricavato dalla Scheda 3 ☐ **C**

7. Scheda 4 - Esame obiettivo

L'esame comprende una valutazione soggettiva di 3 aspetti della composizione corporea: grasso, muscolo e liquidi. Essendo soggettiva, ciascun aspetto dell'esame è classificato per gradi. Il deficit o la perdita muscolare influisce maggiormente sul punteggio rispetto al deficit/perdita di grasso. Definizione delle categorie: 0 = nessuna anomalia, 1+ = lieve, 2+ = moderato, 3+ = grave. La valutazione del deficit per queste categorie non è cumulativa, ma è utilizzata per valutare il grado del deficit (o la presenza di liquidi in eccesso) dal punto di vista clinico.

Stato muscolare

	0	1+	2+	3+
tempie (muscolo temporale)				
clavicole (pettorali e deltoidi)				
spalle (deltoidi)				
muscoli interscapi				
scapola (grande dorsale, trapezio, deltoidi)				
coscia (quadricipite)				
polpaccio (gastrocnemio)				

Valutazione globale dello stato muscolare 0 1+ 2+ 3+

Depositi di grasso

	0	1+	2+	3+
corpi adiposi periculiari				
piega cutanea del tricipite				
strato di grasso sulle costole inferiori				

Valutazione globale del deficit lipidico 0 1+ 2+ 3+

Stato di idratazione

	0	1+	2+	3+
edema del caviglie				
edema sacrale				
ascite				

Valutazione globale dello stato di idratazione 0 1+ 2+ 3+

Il punteggio per l'esame obiettivo è determinato dal punteggio soggettivo complessivo del deficit corporeo totale.

	nessun deficit	Deficit lieve	Deficit moderato	Deficit grave
punteggio = 0 punti				
punteggio = 1 punto				
punteggio = 2 punti				
punteggio = 3 punti				

Punteggio numerico ricavato dalla Scheda 4 ☐ **D**

Punteggio totale del PG-SGA (score numérique total de A+B+C+D) ☐

Valutazione globale delle categorie del PG-SGA (Stadio A, Stadio B o Stadio C) ☐

Scheda 5. Valutazione globale delle categorie del Scored PG-SGA

Categoria	Stadio A	Stadio B	Stadio C
Peso	Buono stato di nutrizione Nessuna perdita di peso OR recent non-fluid weight gain	Moderata/soggetta malnutrizione Perdita ≤ 5% in 1 mese (≤ 10% in 6 mesi) OPPURE Perdita progressiva di peso	Grave malnutrizione Perdita > 5% in 1 mese (> 10% in 6 mesi) OPPURE Perdita progressiva di peso
Apporto nutrizionale	Nessun deficit OPPURE Recente e significativo miglioramento	Consistente riduzione dell'introito alimentare	Grave deficit nell'introito alimentare
Sintomi di scarso apporto nutrizionale (NIS)	Nessun deficit OPPURE Recente e significativo miglioramento che consente un apporto nutrizionale adeguato	Presenza di sintomi ad impatto nutrizionale (sezione 3 del Scored Patient Generated Subjective Global assessment PG-SGA)	Presenza di sintomi ad impatto nutrizionale (sezione 3 del Scored Patient Generated Subjective Global assessment PG-SGA)
Funzionalità	Nessun deficit OPPURE Recente e significativo miglioramento	Moderato deficit funzionale OPPURE Recente peggioramento	Grave deficit funzionale OPPURE Recente peggioramento
Esame fisico	Nessun deficit OPPURE deficit cronico, ma con un recente miglioramento clinico	Evidenza di perdita della massa muscolare da lieve a moderata e/o del tono muscolare alla palpazione e/o perdita del grasso sottocutaneo	Chiari segni di malnutrizione (ad es., grave perdita di massa muscolare, grasso, possibile edema)

Raccomandazioni per il triage nutrizionale: il punteggio cumulativo viene utilizzato per definire specifici interventi di carattere nutrizionale che comprendono l'educazione del paziente e della famiglia, il controllo della sintomatologia incluso l'intervento farmacologico, e un idoneo intervento con nutrienti (alimenti, integratori, triage enterale o parenterale).

L'intervento nutrizionale di prima linea include il controllo ottimale dei sintomi.

Triage basato sul punteggio del Scored Patient Generated Subjective Global Assessment PG-SGA

0-1 Nessuna necessità di intervento in questa fase. Rivalutazione routinaria periodica in corso di trattamento.

2-3 Educazione del paziente e della famiglia a cura del dietista, dell'infermiere o di altro specialista con intervento di tipo farmacologico in base all'indagine sulla sintomatologia (Scheda 3) e i valori di laboratorio a seconda dei casi.

4-8 È necessario l'intervento di un dietista, coadiuvato da un'infermiera o dal medico in base alla sintomatologia (Scheda 3).

≥ 9 Indica la necessità immediata di un migliore controllo dei sintomi e/o opzioni di intervento per l'apporto di nutrienti.

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Fig. 1. The final version of the Italian version of the scored Patient-Generated Subjective Global Assessment (PG-SGA) including the *patient component* (Page 1, Box 1-4) and *professional component* (Page 2, Worksheet 1-5).

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includes four boxes, in which the patients give information about their current and former weight (Box 1), change in food intake and current type of food/nutritional intake (Box 2), symptoms that impact food intake (i.e., nutrition impact symptoms, Box 3), and level of activity and function (Box 4). Page two (hereby called the *professional component*) includes five worksheets that are completed by the HCPs. They provide a score for weight loss, an evaluation of the patient's diagnosis, an assessment of the metabolic demands, and a nutrition-focused physical examination. Finally, based on the evaluation of Box 1 to 4 and Worksheet 4 (i.e., nutrition focused physical examination), the patient is categorized as either Stage A: Well nourished, Stage B: Moderate or suspected malnutrition, or Stage C: Severely malnourished [1–3]. In addition, the total PG-SGA score of each box and worksheet is summarized, to triage for specific nutritional interventions.

Similar to the previous translation and cultural adaptations and validity testing of other language versions of the PG-SGA [12–18,24], patients were instructed to rate comprehensibility and difficulty of the *patient component* on a 4-point Likert scale (1 = unclear/very difficult; 2 = unclear/difficult; 3 = clear/easy; 4 = very clear/very easy). Open ended questions were posed to ask for suggestions on the Italian wordings used for the items. Finally, demographic data including gender, age, medical diagnosis, cancer stage, level of education, current profession, and cognitive functioning (e.g., MMSE score) were collected for each patient.

HCPs were instructed to rate content validity, comprehensibility, and difficulty [25–27] of the *professional component*, and content validity of the *patient component* of the PG-SGA. Ratings were on a 4-point Likert scale (1 = very irrelevant/very unclear/very difficult; 2 = irrelevant/unclear/difficult; 3 = relevant/clear/easy; 4 = very relevant/very clear/very easy). A four-point scale was used, to avoid having a neutral and ambivalent midpoint and to dichotomize the results of each item [25,28]. Additional open-ended questions regarding suggestions for potential changes in the Italian wordings of the PG-SGA items were included at the end of the questionnaire. Finally, their demographics, current profession, years of working experience in current profession, work setting, their patient population(s), working with/familiarity with the PG-SGA, and clinical experience with the PG-SGA were collected.

2.3. Statistical analyses

First, item scores of 1 and 2 were recoded to 0, indicating 'not present'. Similarly, scores of 3 and 4 were recoded to 1, indicating 'present', as described earlier by Sealy et al. [12]. For each item, indices were calculated for comprehensibility (I–CI), difficulty (I–DI), and content validity (I–CVI). These indices were calculated by dividing the number of respondents who considered the item to be 'present' by the total number of respondents. Item indices <0.78 are considered inadequate and require further analysis [12]. The scale indices for comprehensibility, difficulty and content validity (S–CI, S–DI, and S–CVI) were calculated by averaging all the item indices for the respective construct. Scale indices between 0.80 and 0.89 were considered acceptable and from 0.90 as excellent [12]. The patients' indices refer to the comprehensibility and difficulty of the patient component of the PG-SGA. The HCPs' indices refer to both the patient and professional components of PG-SGA. Specifically, the HCPs assessed the content validity of the patient component and the comprehensibility, difficulty, and content validity of the professional component. Calculation of the index scores was performed in Excel.

Continuous variables are presented as means and range. Categorical variables are presented as frequencies (number) and percentage. Statistical analyses were performed using SPSS version 27.

3. Results

In a cross-sectional study design, between August 2017 and January 2018, comprehensibility and difficulty of the full PG-SGA (i.e., PG-SGA Short Form (SF) and professional component) were tested in a sample of patients with cancer and in a multidisciplinary sample of HCPs, and content validity was tested in HCPs only (Tables 2S and 3S of Supplementary file).

One hundred and twenty patients and 81 HCPs met the inclusion criteria and were invited to participate in the study accepted. All patients and HCPs signed the informed consent.

All included patients (n = 120, mean age 60.27, SD = 12.85, 45% female) completed the questionnaire. Most of them had a relatively high level of education (23% primary and secondary school level, 77% university or high school level). Forty-six patients had hematological malignancies, seventy-two had solid tumors and two had unknown primary cancers.

All included HCPs completed the questionnaire. Out of the 81 HCPs, 30% were from INT. The sample included clinical dietitians (45%), physicians (25%), and dietetics students (30%). The mean number of years of experience within their respective fields was 3.5 (SD = 2.35) years. Only 16% of the professionals were familiar with the PG-SGA, but none had used it in clinical practice.

The item response rate for the professionals and the patients was both 100%. The comprehensibility, difficulty, and content validity indices of the *patient component* of the PG-SGA as reported by the patients and professionals (content validity only) are presented in Table 1. Comprehensibility and difficulty as perceived by the patient group were excellent, with S–CI = 0.98 and S–DI = 0.96. No item indices were below 0.78. Content validity for the patient component as perceived by the professionals was excellent (S–CVI = 0.93).

The results for the professional component of the PG-SGA are presented in Table 2. Overall, the professionals perceived comprehensibility as excellent (S–CI = 0.92). Although Worksheet 4 was considered the most difficult part (4 item indices were below 0.78), difficulty of the professional components of the PG-SGA was adequate (S–DI = 0.84).

For content validity, 4 item indices related to Worksheet 4 were slightly below acceptable range. Slight modifications were implemented resulting in the final version of the Italian PG-SGA. Nonetheless, content validity was considered excellent for both the *patient component* (S–CVI = 0.93) and the *professional component* (S–CVI = 0.90), resulting in a full S–CVI = 0.92.

Significant differences in the scale indices of the *professional component* of the PG-SGA ($p < 0.01$) were found between the dietitians, physicians, and dietetics students (Table 3). Dietitians gave higher scores in difficulty and content validity than physicians and dietetics students, while both dietitians and dietetics students scored higher than physicians on comprehensibility score.

4. Discussion

Translation and cultural adaptation of the English PG-SGA (© 2005) according to ISPOR Principles resulted in an Italian version of the PG-SGA Italian that maintained its original purpose, meaning and format. The Italian version of the PG-SGA can be completed adequately and easily by patients and professionals and has an excellent content validity. Following the ISPOR Principles during the development phase of the Italian PG-SGA enabled safeguarding of conceptual, semantic, and operational equivalence to the original PG-SGA.

The study results are consistent with findings from studies on similar ISPOR-based translations and cultural adaptations of the PG-SGA for the Dutch, Tri-Country German, Thai, Norwegian,

Table 1Comprehensibility, difficulty, and content validity for the *patient component* of the Italian version of the Patient-Generated Subjective Global Assessment.

Items	I–CI ^a	I–DI ^a	I–CVI ^b
Box 1: Weight			
I currently weigh about _kg	1.00	0.96	0.99
I am about _cm tall	1.00	0.99	0.99
One month ago, I weighted about _kg	0.99	0.95	0.98
Six month ago, I weighted about _kg	1.00	0.94	0.96
Weight (decreased/not changed/increased)	0.92	0.95	0.96
Box 2: Food Intake			
As compared to my normal intake, I would rate my food intake during the past month as	0.89	0.97	0.99
Unchanged; more than usual; less than usual	0.97	0.97	0.95
I am now taking:	1.00	0.96	0.96
Normal food but less than normal amount	0.98	0.96	0.85
Little solid food	0.98	0.96	0.85
Only liquids	0.99	0.99	0.94
Only nutritional supplements	1.00	0.96	0.90
Very little of anything	0.98	0.94	0.83
Only tube feedings or only nutrition by vein	0.99	0.96	0.95
Box 3: Symptoms			
I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply)	0.99	0.97	1.00
No problems eating	0.99	0.97	0.91
No appetite, just did not feel like eating	1.00	0.95	0.86
Nausea	0.98	0.97	0.96
Constipation	0.97	0.95	0.95
Mouth sores	0.99	0.97	0.96
Things taste funny or have no taste	0.99	0.97	0.93
Problems swallowing	0.98	0.96	0.98
Pain; where?	0.99	0.97	0.98
Other	0.97	0.96	0.92
Vomiting	0.98	0.96	0.98
Diarrhea	0.98	0.97	0.98
Dry mouth	0.99	0.97	0.93
Smells bother me	0.98	0.97	0.90
Feel full quickly	0.98	0.97	0.90
Fatigue	1.00	0.99	0.85
Box 4: Activities and Function			
Over the past month, I would generally rate my activity as	0.99	0.96	0.92
Normal with no limitations	0.98	0.95	0.85
Not my normal self, but able to be up and about with fairly normal activities	0.98	0.95	0.91
Not feeling up to most things, but in bed or chair less than half the day	0.96	0.96	0.95
Able to do little activity and spend most of the day in bed or chair	0.96	0.97	0.95
Pretty much bedridden, rarely out of bed	0.97	0.97	0.96
S-scale Indices PG-SGA Short Form	0.98	0.96	0.93

Note: I–CI: Item Comprehensibility Indices, I–DI: Item Difficulty Indices, I–CVI: Item Content Validity Indices.

^a CI and DI were assessed by patients.^b CVI was assessed by healthcare professionals.

Greek, Japanese, and Danish settings [12–16,18,24]. The high scores on comprehensibility (S–CI = 0.98) and difficulty (S–DI = 0.96) for the patient component of the Italian PG-SGA, i.e., the Italian PG-SGA SF, are in line with the Dutch [12], Tri-Country German [16], Thai [18], Norwegian [14], Greek [15], Japanese [13], and Danish [24] studies. In these studies, S–CI ranged from 0.96 to 0.99 and S–DI from 0.91 to 0.99. The excellent scores in the current study implicate that the patient component of the Italian PG-SGA is comprehensible and easy to complete by Italian patients. The consistency in high scores in the various studies can be explained by the systematic translation and cultural adaptation approach across the various studies. The original wording of the items in Boxes 1 to 4 aimed to be easily completed by patients and therefore was phrased in laymen language. In the subsequent new language versions, cultural adaptation ensured that the conceptual meaning of the original wording were safeguarded. In the current study, similar to the results of the Greek study (S–CI = 0.94) [15], Italian HCPs rated comprehensibility of the professional component of the PG-SGA better (S–CI = 0.92) than the Danish (S–CI = 0.71) [24] Norwegian (S–CI = 0.78) [14], the Dutch (S–CI = 0.87) [12], Tri-Country German (S–CI = 0.87) [16], Japanese (S–CI = 0.88) [13] and Thai HCPs (S–CI = 0.92) [18]. The Italian HCPs also rated difficulty (S–DI = 0.84) better than the

Dutch (S–DI = 0.55 [12], Norwegian (S–DI = 0.66) [14], Japanese (S–DI = 0.69) [13], Tri-Country German (S–DI = 0.72) [16], and Thai (S–DI = 0.79) HCPs [18], but worse than the Greek HCPs (S–DI = 0.90) [15].

The results of the current study are encouraging and even better than the results of the studies on the other PG-SGA language versions, given the high scores on comprehensibility and difficulty for both the patient and professional component of the Italian PG-SGA. After a short training for patients and HCPs, this easy-to-use PRO allows to identify in patients with malnutrition or at risk of malnutrition in any care setting, both in presence and through telemedicine. Being easy to understand and simple to fill in allows HCPs to optimize clinical practice by facilitating a routine assessment of the nutritional status of the patients [29].

The majority of patients with cancer evaluated had a relatively high level of education (i.e., 23% primary and secondary education, 77% university or secondary education). We think this is a coincidence, since all consecutive patients were enrolled and none refused to participate in the study. Overestimation of the patients' results due to a higher-than-average education level cannot be excluded. However, while in the study on the linguistic validation of the Danish PG-SGA, the proportion of patients with higher education was lower (40% university level), the patient component of

Table 2

Comprehensibility, difficulty, and content validity for the *professional component* of the Italian version of the Patient-Generated Subjective Global Assessment as reported by healthcare professionals.

Items	Item CI	Item DI	Item CVI
Worksheet 1 – Scoring Weight Loss	0.94	0.81	0.96
Scoring Weight Loss	0.94	0.90	0.95
Worksheet 2 e Disease and its relation to nutritional requirements	0.96	0.89	0.99
Cancer	0.95	0.91	0.98
AIDS	0.94	0.91	0.94
Pulmonary or cardiac cachexia	0.95	0.87	0.99
Chronic renal insufficiency	0.96	0.89	0.96
Presence of decubitus, open wound, or fistula	0.95	0.92	0.94
Presence of trauma	0.95	0.90	0.90
Age greater than 65	0.96	0.92	0.91
All relevant diagnoses	0.97	0.91	0.96
Primary disease staging	0.94	0.89	0.95
Worksheet 3 – Metabolic Demand	0.92	0.91	0.97
Fever	0.94	0.87	0.93
Fever duration	0.92	0.87	0.94
Corticosteroids	0.94	0.90	0.94
Worksheet 4 – Physical Exam	0.84	0.80	0.97
Temples (temporalis muscles)	0.86	0.76	0.77
Clavicles (pectoralis & deltoids)	0.92	0.78	0.73
Shoulders (deltoids)	0.92	0.78	0.78
Interosseous muscles	0.82	0.67	0.72
Scapula (latissimus dorsi, trapezius, deltoids)	0.90	0.81	0.76
Thigh (quadriceps)	0.94	0.87	0.89
Calf (gastrocnemius)	0.92	0.86	0.83
Global muscle status rating	0.95	0.86	0.90
Orbital fat pads	0.84	0.76	0.79
Triceps skin fold	0.87	0.84	0.83
Fat overlying lower ribs	0.85	0.73	0.81
Global fat deficit rating	0.91	0.78	0.91
Ankle edema	0.95	0.90	0.94
Sacral edema	0.91	0.89	0.89
Ascites	0.91	0.85	0.94
Global fluid status rating	0.96	0.89	0.93
Worksheet 4 – Global Assessment Categories			
Stage A: well nourished. Stage B: moderate/suspected malnourished. Stage C: Severely malnourished	0.95	0.87	0.99
Nutritional Triage Recommendations	0.90	0.84	0.94
0–1 No intervention required at this time. Re-assessment on routine and regular basis during treatment	0.91	0.87	0.91
2–3 Patient & family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and lab values as appropriate	0.91	0.86	0.94
4–8 Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3)	0.94	0.85	0.96
≥9 Indicates a critical need for improved symptom management and/or nutrient intervention options	0.94	0.82	0.94
Scale Indices professional component	0.92	0.84	0.90

Note: CI: Comprehensibility Indices, DI: Difficulty Indices, CVI: Content Validity Indices. Indices below acceptable range are marked in bold.

Table 3

Comprehensibility, difficulty, and content validity of the Italian version of the Patient-Generated Subjective Global Assessment (PG-SGA) by profession.

Variables	Item CI	Item DI	Item CVI
Profession			
Clinical dietitians (n = 36)	0.96	0.94	0.95
Physicians (n = 20)	0.85	0.79	0.86
Dietetics students (n = 25)	0.94	0.78	0.86

Note: CI: Comprehensibility Indices, DI: Difficulty Indices, CVI: Content Validity Indices.

the PG-SGA was perceived comprehensible and easy to complete by the patients [24].

For Italian HCPs, in Worksheet 4-Physical Exam, four item indices were considered most difficult to evaluate and considered below acceptable range, i.e., temples (I-DI = 0.76), interosseous muscles (I-DI = 0.67), orbital fat pads (I-DI = 0.76), and fat overlying lower ribs (I-DI = 0.73). As difficulty is mostly related to available knowledge or skills, perceived difficult can be improved by training. In fact, previous research demonstrated positive effects of a single session of training on both difficulty and comprehensibility of the PG-SGA. In that study, comprehension of the individual items of Worksheet 4-Physical Exam increased from 0.41 to 0.50 pre-

training to 0.91–0.97 post-training, and perceived difficulty improved from 0.13 to 0.17 pre-training to 0.53–0.71 post-training ($p < 0.001$) [29].

In the current study, physicians gave lower scores on comprehensibility, difficulty, and content validity of the PG-SGA when compared to dietitians. Their scores on comprehensibility also differed from dietetics students (that scored similarly to dietitians), while their perceived difficulty and their content validity scores were very similar. We speculate that students and physicians missed some specific knowledge. Lack of knowledge may impact comprehensibility, but especially difficulty and content validity, because lack of knowledge will make it difficult to understand what is meant with a certain question or answering option, and it may also be perceived as less relevant.

A major strength of this study is that the Italian version of the PG-SGA was developed according to the same methodology as used in previous translations and cultural adaptations of the PG-SGA, in which the ISPOR Principles were used. Using the same high international standard, as well as developing the Italian PG-SGA in close collaboration with the developer of the PG-SGA and an internal expert regarding translation and cultural adaptation of the PG-SGA, ensured that the conceptual meaning of the wordings in the original PG-SGA were maintained in the Italian version of the PG-SGA.

Another strength of the current study was the large number of both patients and HCPs participating in the cognitive debriefing and linguistic and content validity testing.

A limitation of the study might be that the population is limited to cancer patients. However, the PG-SGA has extensively been validated in terms of concurrent and predictive validity in multiple populations, including patients with cancer, geriatric patients, surgery, and nephrology. The current study was a linguistic validation, and there is no reason to expect that comprehensibility and difficulty of the PG-SGA itself will differ across these various types of patients. The translation and cultural adaptation focuses on choosing wordings for the questions and answering options that are common in the Italian patient population independently of the condition of the patient.

The current study has several implications for clinical practice and research. The good results in our study on comprehensibility, difficulty and content validity indicate that both the patient component and professional component of the Italian version of the PG-SGA are suitable for use by both patients and HCPs. The PG-SGA and PG-SGA Short Form are validated and sensitive instruments that can easily be used as nutritional screen by patients (PG-SGA Short Form) and as nutritional screen, assessment or monitoring instrument by trained professionals (Full or Short Form) [9]. As the participants in the study came from various Italian regions, the PG-SGA SF can be used in all Italian regions without any modification of the wordings. The availability of the Italian version of the PG-SGA facilitates patient-centric identification of malnutrition or malnutrition risk, and allows for monitoring of nutritional status and risk factors for malnutrition across the chain of health-care [9,30]. In addition, utilizing the PG-SGA may help to increase awareness of malnutrition risk in patients [31]. Finally, the availability of the Italian PG-SGA enables the inclusion of the instrument in Italian guidelines and multicenter studies, as well as multinational studies.

5. Conclusion

Translation and cultural adaptation of the original English PG-SGA to the Italian setting resulted in an Italian version of the PG-SGA that maintained its original purpose and meaning, and can be completed adequately and easily by patients and professionals. The high scores on content validity of both the patient and HCPs component indicate that the Italian PG-SGA is considered a relevant malnutrition instrument by the Italian HCPs.

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Contribution of each author

Design of the study: Ripamonti C, and Jager-Wittenaar H Practical performance: Arena F, Di Pede P, Guglielmo M, Toffolatti L, Gandell i M Data analysis: Chiesi F Preparation of the manuscript:

Ripamonti C, Jager-Wittenaar H, Chiesi F, in equal amount Critical review of the manuscript: Bossi P, Laviano A Each author filled in the conflict of interest.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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