



Original Article

Translation and validation of the patient-Generated Subjective Global Assessment against the Mini-Nutritional Assessment for patients with gastric cancer

Ji Yea Lee^a, Eui Geum Oh^{b,*}, Woo Jin Hyung^c, Hyoung-Il Kim^c

^a College of Nursing, Yonsei University, Seoul, South Korea

^b College of Nursing and Mo-Im Kim Research Institute, Yonsei University, Seoul, South Korea

^c Department of Surgery, College of Medicine, Yonsei University, Seoul, South Korea

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ABSTRACT

Objective: This study aimed to (1) translate the PG-SGA into Korean according to a translation guideline, (2) validate the translated version against the Mini-Nutritional Assessment, and (3) determine the prevalence of malnutrition in patients with gastric cancer.

Methods: The translation of the PG-SGA was based on the Guidelines for Translation by the International Society for Pharmacoeconomics and Outcomes Research Task Force for Translation and Cultural Adaptation Group. The translated version was validated in 226 patients with gastric cancer, using the area under the receiver operating characteristic curve analysis (AUC-ROC), measures of sensitivity, specificity, and the Youden index. The prevalence of malnutrition was analyzed using descriptive statistics.

Results: The AUC-ROC Korean version of the PG-SGA was 0.85, and a score of 12 was the most optimal cut-off score, with a sensitivity of 78.6% and a Youden index of 0.54. One-third of participants were malnourished, and 70% of them had more than one physical symptom affecting their food intake.

Conclusions: The Korean version of the PG-SGA is an effective and valid assessment tool for evaluating malnutrition in patients with gastric cancer. A new cut-off score could be used in patients with gastric cancer to assess malnutrition.

Introduction

Approximately, 40% of patients with cancer are reported to experience malnutrition, either due to cancer itself or its treatment.¹⁻³ The prevalence of malnutrition in patients with gastrointestinal, esophageal, and pancreatic cancers is relatively high, whereas malnutrition in patients with prostate and breast cancer is relatively low.^{2,3}

Gastric cancer is the fifth most common cancer worldwide, with more than 70% of all gastric cancer cases occurring in Asia.⁴ The incidence of malnutrition is approximately 50–60% in patients with gastric cancer.^{2,5} The high incidence of malnutrition is associated with anatomical changes and the effects of reconstruction after gastrectomy, which is the primary treatment for gastric cancer.⁶ Patients frequently experience various physical symptoms, such as indigestion, postprandial fullness, dysphagia, nausea, and diarrhea, after gastrectomy that could lead to malnutrition and weight loss.^{6,7} Hence, a well-validated malnutrition assessment tool

is essential to identify and monitor patients needing early nutritional intervention.^{8,9}

The Patient-Generated Subjective Global Assessment (PG-SGA) is a well-known malnutrition assessment tool for patients with cancer. It has been well validated among various cancer populations in diverse clinical settings.¹⁰ The PG-SGA has been translated and validated in many languages, including German, Greek, Italian, Japanese, and Portuguese.¹¹ The biggest feature of the PG-SGA is that it includes the assessment of various symptoms related to food and nutritional intake, unlike other nutritional assessment tools. This feature of PG-SGA makes it a more suitable tool for patients with gastric cancer as these patients experience various physical symptoms affecting their diet after surgery. A well-translated and validated PG-SGA can assist healthcare providers in screening for and diagnosing nutritional deficiencies in patients with cancer.

In South Korea, PG-SGA was validated in patients with stroke and geriatric patients,^{12,13} but neither study had undertaken a thorough

* Corresponding author.

E-mail address: euigeum@yuhs.ac (E.G. Oh).

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translation process. Only a well-translated instrument can collect valid data, and the translation process should be performed in accordance with evidence-based guidelines using a systematic approach to enhance the instrument's validity.^{14–17} Therefore, an appropriately translated and validated Korean version of the PG-SGA is required.

For the validation of an instrument, a comparative measurement is essential. Various nutritional assessment tools exist, such as Mini-Nutritional Assessment, Malnutrition Universal Screening Tool (MUST), Nutritional Risk Screening-2002 (NRS-2000), and Global Leadership Initiative on Malnutrition (GLIM); however, each has a limitation in its use as a suitable comparative measurement tool in this study. MUST was originally developed for use in the community setting, not in a clinical setting,¹⁸ and NRS-2000 was reported to demonstrate inconsistent validity among different inpatient groups.¹⁹ GLIM was deemed not suitable for this study as it includes anthropometry measurement.²⁰

We, therefore, selected the Mini-Nutritional Assessment Short Form (MNA-SF) as a comparative instrument. MNA-SF is an internationally renowned instrument with high sensitivity, specificity, and reliability.²¹ It is recommended by international nutritional organizations, such as the American Society for Parenteral and Enteral Nutrition and the European Society for Parenteral and Enteral Nutrition.²² Although the MNA-SF was originally developed for use in elderly patients, it has been validated in diverse age groups as well as various other patient groups, and evidence suggests that it is now one of the most used nutritional assessment tools in adult patients with cancer.^{23,24}

This study aimed to translate the PG-SGA into Korean in accordance with guidelines provided by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and determine the validity of the PG-SGA for evaluating malnutrition in patients with gastric cancer compared to the MNA-SF as the existing standard. Additionally, the prevalence of malnutrition in our study population was assessed using the Korean version of PG-SGA.

Methods

Study design

This was a validation study of the Korean version of the PG-SGA in relation to the MNA-SF. The study comprised two steps: (1) translation of the PG-SGA into Korean and (2) validation of the PG-SGA against the MNA-SF as the reference standard.

Participants

The study included 226 patients with gastric cancer at the Gastric Cancer Center of * University Hospital. The inclusion criteria were patients over 18 years old who received gastrectomy after a cancer diagnosis. The exclusion criteria were patients who refused to participate in the study and who did not know about their cancer diagnosis. The sample size of over 200 was determined based on the previous study.²⁵ Due to the study's timeline, all patients who visited the outpatient department were screened for eligibility during the data collection period.

Measures

Participant characteristics

Demographic data, such as gender, age, marital status, educational level, and employment status, were assessed. For clinical data, cancer classification and staging, chemotherapy status, type of gastrectomy, time after surgery (months), comorbidities, and reasons for gastric cancer screening were retrieved from electronic medical records.

Patient-Generated Subjective Global Assessment

The PG-SGA comprises two sections: a patient-generated section and a professional-filled section.¹¹ First, the patient-generated section consists of four boxes. Box 1 consisted of items related to current weight,

weight history, and weight changes within two weeks. Box 2 comprises items of recent changes in food intake. Box 3 included various symptoms within two weeks affecting intake. Box 4 consisted of items regarding changes in activity levels and function. Second, the professional-filled section included items related to diagnosis, such as disease stage, age, components of metabolic demand, and physical assessment. Scores range from 0 to 52 (0–36 in the patient-generated section; 0–16 in the professional-filled section); a high score indicates malnourishment; and a score > 9 indicates a critical need for nutritional intervention.¹¹ The permission to translate PG-SGA (version 4.3.20) into Korean was obtained from the developer of the PG-SGA, Dr. Faith Ottery.

Mini-Nutritional Assessment Short Form

The MNA-SF comprises six items: changes in food intake, changes in weight, mobility, psychological stress, neuropsychological problems, and body mass index.²² Scores on the MNA-SF range from 0 to 14, and there are three classifications: malnourished (score: 0–7), at risk of malnutrition (score: 8–11), or normal nutritional status (score: 12–14).²² To assess validity and sensitivity, we operationalized the MNA-SF as a binary variable based on the scoring guide: malnutrition (score: 0–7) and normal (score: 8–14).

Data collection

Data were collected from March 2021 to May 2021. After receiving approval from the clinical department, the main researcher met the patients waiting for their follow-up visits at the outpatient department. After explaining the details of the study, the researcher obtained written consent from those patients who agreed to participate. After participants completed both the MNA-SF and the patient section of the PG-SGA, the researcher completed the healthcare provider section of the PG-SGA.

Data analysis

Descriptive statistics of the mean, standard deviation, and percentage were used to describe the participant characteristics. The area under the receiver operating characteristic curve analysis (AUC-ROC) was used to compare the PG-SGA to the MNA-SF. Validity was assessed by analyzing the sensitivity, specificity, positive and negative predictive values, and Youden index of the PG-SGA compared with the MNA-SF. Accordingly, the cut-off scores of the PG-SGA for patients with gastric cancer were determined. Statistical analyses were performed using SPSS version 25.

Ethical consideration

This study was approved by the Institutional Review Board of Yonsei University Health System in Seoul, Korea (IRB No. 4-2021-0014). When the patients met the main researcher at the outpatient clinic, they were informed about the purpose of the study, the procedures used for data collection, the estimated time required to complete the questionnaires, the expected benefits, and possible harms. In addition, the researcher explained the process for ensuring anonymity/confidentiality, and participants were informed that they had the right to withdraw from the study at any time.

Results

Translation

The translation of the PG-SGA was conducted as per the Guidelines of the Translation of Patient-Reported Outcome Measures of the ISPOR Task Force for Translation and Cultural Adaptation Group using the following five steps: (1) preparation, (2) forward translation, (3) reconciliation, (4) back translation, and (5) backward translation review and harmonization.¹⁷ After these five steps, four patients and five healthcare providers were asked to evaluate the Korean version of the PG-SGA for

comprehensibility/difficulty and provide comments or suggestions. Two bilinguals (JL & YB) participated in the translation process. One (JL) had graduated from a university in the USA and is working in an international broadcasting agency. The other (YB) had graduated from the Graduate School of Interpretation and Translation, Hankuk University of Foreign Studies (Seoul, Korea), and is a certified interpreter and translator with more than five years of work experience.

Preparation

One bilingual (JL) performed forward translation on the original PG-SGA and completed the initial draft.

Forward translation

At least two independent forward translation versions were preferred to enhance the quality of the translation. Hence, along with the initial translation draft by JL and YB, another forward translation version was obtained from a researcher who had translated it into Korean and used it in her previous study.¹³

Reconciliation

The first bilingual translator (JL) reviewed the two forward translation versions and reconciled them into a single version after additional translation. Some medical terms and Sino-Korean vocabularies were replaced with easy ones, and sentences were improved in terms of coherence.

Backward translation

The second bilingual translator (YB) back-translated the reconciled Korean version to English. The back-translated version and the original English version of the PG-SGA were reviewed. The back-translated version was almost identical to the original version, except for slight differences in word order.

Back translation review and harmonization

After the back translation, the first author and two bilingual translators (JL & YB) reviewed the independent five versions together (the original PG-SGA, the two forward-translated versions, the reconciled version, and the back-translated version). The discrepancies among the five versions were identified and discussed, and the final translated Korean version of the PG-SGA was derived.

Evaluation of comprehensibility

The draft of the PG-SGA Korean version was reviewed by four patients and five healthcare providers (four nurses and one doctor). The patients were two men and two women between the ages of 60 and 70. The healthcare providers were one man and four women in their 30s, and their clinical experience ranged from 5 to 8 years. The researcher asked the patients and healthcare providers about any words, phrases, or sentences that were (1) awkward, (2) unclear, or (3) difficult to understand. The healthcare providers were asked to evaluate Box A from the perspective of an older patient.

One patient commented that one sentence was too long to understand. One nurse commented that the older patients might have trouble understanding the word “tube feeding,” as medical jargon for “tube feeding” was used. Also, the doctor commented that it is unclear whether the “Now I am taking” item is only for people who have answered they eat less than usual. Additional amendments were made based on their feedback and the final Korean version of PG-SGA was completed (Supplementary material).

Validation

Participant characteristics

More than half of the participants were men (58%), and the mean age of the sample was 61.4 years. Most patients were married (82.3%), had an educational level above high school (73.9%), and were unemployed (68.2%). Most were diagnosed with stage 1 cancer (70.4%) and had a subtotal gastrectomy (74.8%). Their time after gastrectomy ranged from

three weeks to five years, with a median of six months. About half of the patients had comorbidities, including hypertension (61.4%), type II diabetes mellitus (28.7%), dyslipidemia (12.3%), coronary artery disease (9%), pulmonary disease (7%), and other diseases, such as benign prostate hypertrophy, hypothyroidism, and herniated lumbar disc. Most of the participants were diagnosed after taking a national cancer screening diagnostic test (58.4%), followed by private health screening (19.9%), and diagnostic tests due to the development of physical symptoms (17.7%) (Table 1).

Validity of the Patient-Generated Subjective Global Assessment

The AUC-ROC value for the PG-SGA was 0.85 (Fig. 1). Table 2 shows the sensitivity, specificity, positive predictive value, and negative predictive value. The original PG-SGA suggests a cut-off score of 9 as malnutrition and a need for nutrient intervention. However, a cut-off score of 12 was considered optimal for patients with gastric cancer in this study, with the highest Youden's index and sensitivity (Table 2) after calculating Youden's index, sensitivity, specificity, and positive and negative predictive value using the cut-off scores of 8–13, based on the MNA-SF. Although the specificity of the cut-off score of 11 is higher than that of 12, it may be beneficial to prioritize sensitivity (ie., the percentage of patients accurately identified as having malnutrition) over specificity (ie., the percentage of patients accurately evaluated as well-nourished) when investigating the validity of nutritional assessments.

Nutritional status and physical symptoms affecting nutritional intake

Table 3 shows the nutritional status of the participants using the cut-off value of 12 and the distribution of patient-reported physical

Table 1
Characteristics of patients (N = 226).

Variables	Categories	n (%)	M ± SD
Gender	Male	131 (58.0)	61.4 ± 11.4
	Female	95 (42.0)	
Age (years)			
Marital status	Married	186 (82.3)	
	Not married	40 (17.7)	
Education	≥ High school	167 (73.9)	
	< High school	59 (26.1)	
Employment	Unemployed	154 (68.2)	
	Employed	72 (31.8)	
Cancer stage	I	159 (70.4)	
	II	37 (16.4)	
	III	25 (11.1)	
	IV	1 (0.004)	
Type of gastrectomy	Subtotal	169 (74.8)	Median: 6
	Total	57 (25.2)	
Time after gastrectomy	3 weeks	32 (14.2)	
	3 months	56 (24.8)	
	6 months	42 (18.6)	
	9–12 months	18 (8.0)	
	15–24 months	33 (14.6)	
	30–36 months	20 (8.8)	
Currently receiving CTx	42–60 months	24 (10.6)	
	No	203 (89.8)	
	Yes	23 (10.2)	
Comorbidities	No	104 (46.0)	
	Yes ^a	122 (54.0)	
	HTN	75 (61.4)	
	DM II	35 (28.7)	
	Dyslipidemia	15 (12.3)	
	CAD	11 (9.0)	
	Pulmonary disease	9 (7.0)	
	Others	69 (56.6)	
	Reasons for screening	National cancer screening	132 (58.4)
Private health screening		45 (19.9)	
Physical symptoms		40 (17.7)	

CAD, coronary artery disease; CTx, chemotherapy; DM II, type II diabetes mellitus; HTN, hypertension; M, mean; SD, standard deviation.

^a Multiple responses possible.

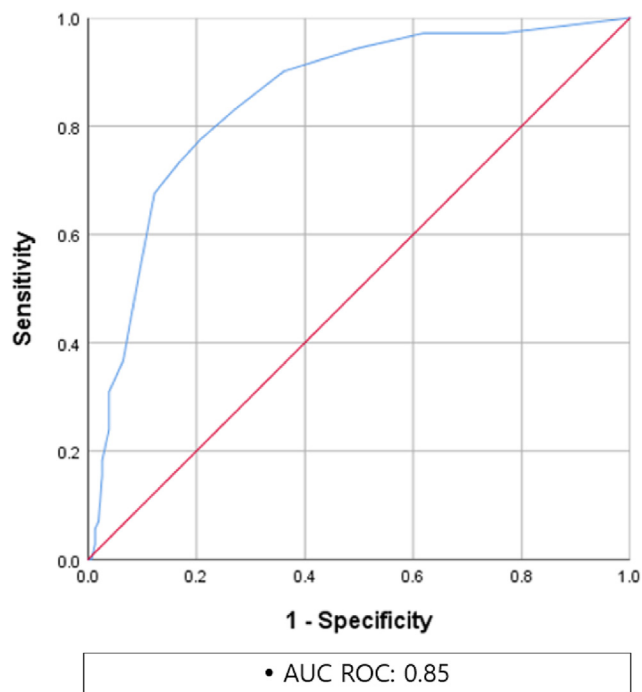


Fig. 1. Receiver operating characteristic curve for the PG-SGA. AUC, Area under the curve; PG-SGA, Patient-Generated Subjective Global Assessment; ROC, Receiver operating characteristic curve. Note. MNA-SF was used as the reference standard.

symptoms using the PG-SGA. Approximately 30% of the participants were malnourished, and the proportion of malnourished patients gradually decreased as the time after gastrectomy increased (Fig. 2). However, approximately 70% of the participants reported more than one physical symptom that affects food intake. The most prevalent symptom was diarrhea (27.9%), followed by loss of appetite (16.8%), nausea, and feeling full quickly (11.9%, each). The participants were also instructed to write their symptoms if the symptoms they had were not on the symptom lists, and feeling bloated was the most common among unlisted symptoms (10.6%).

Discussion

This study aimed to translate the Korean version of the PG-SGA and assess its validity compared to the MNA-SF. The prevalence of malnutrition and symptoms related to dietary intake in our study population were also assessed using the PG-SGA.

To the best of our current knowledge, this is the first study to translate the PG-SGA into Korean. We believe that the steps of the ISPOR, as well as detailed feedback and comments from patients and healthcare providers, yielded a user-friendly and well-adapted Korean version of the PG-SGA. A systematic and scientific translation process can help reduce measurement bias and assist in collecting valid data.²⁶ We suggest that other researchers avoid a direct translation and consider various aspects, such as colloquial expressions, jargon, word clarity, subtle nuances,

Table 2 Sensitivity and specificity of the PG-SGA using a different cut-off score.

	PG-SGA (≥ 11)	PG-SGA (≥ 12)	PG-SGA (≥ 13)
Youden's index	0.485	0.539	0.473
Sensitivity	72.2%	78.6%	73.9%
Specificity	76.3%	75.3%	73.4%
Positive predictive value	72.2%	78.6%	73.9%
Negative predictive value	76.3%	75.3%	73.4%

PG-SGA, Patient-Generated Subjective Global Assessment. Note. MNA was used as the reference standard.

Table 3 Distribution of malnutrition and physical symptoms affecting intake (N = 226).

Variables	Categories	n (%)
Nutritional status*	Well nourished	155 (68.9)
	Malnourished	71 (31.4)
Physical symptoms	None	68 (30.1)
	One or more ^a	158 (69.9)
	Diarrhea	63 (27.9)
	Loss of appetite	38 (16.8)
	Nausea	27 (11.9)
	Feel full quickly	27 (11.9)
	Fatigue	22 (9.7)
	Loss of taste	21 (9.3)
	Vomiting	21 (9.3)
	Constipation	19 (8.4)
	Difficulty swallowing	7 (3.1)
	Dry mouth	6 (2.7)
	Bothersome smell	6 (2.7)
	Pain	6 (2.7)
	Mouth sore	3 (1.3)
Others (written answers)	51 (22.6)	
Feeling bloated	24 (47.0)	
Indigestion	12 (23.5)	
Stomach discomfort	5 (10.0)	
Etc. (no energy, dizziness, dental problems, acid reflux, cold sweat)	10 (19.6)	

PG-SGA, Patient-Generated Subjective Global Assessment. Note. PG-SGA with a cut-off score of 12 was used as the reference standard.

^a Multiple responses possible.

linguistic context, and cultural differences when translating an instrument.²⁷

An AUC of 0.85 demonstrated that the PG-SGA is an appropriate tool for assessing malnutrition in patients with gastric cancer compared to the MNA. The AUC indicates how well the measure can differentiate the positivity or negativity of the criterion.²⁸ An AUC of 0.5 indicates non-informative accuracy, 0.5 < AUC ≤ 0.7 indicates low accuracy, 0.7 < AUC ≤ 0.9 indicates moderate accuracy, 0.9 < AUC < 1 indicates high accuracy, and an AUC of 1 indicates perfect accuracy.²⁸ Hence, healthcare providers could well-evaluate malnutrition using PG-SGA.

Different optimal cut-off scores must be applied for different target populations, particularly when the target population's clinical characteristics are closely related to the clinical condition that the tool is measuring. The original PG-SGA defines a score > 9 as severely malnourished¹¹; however, this study showed that a cut-off score of 12 had the highest sensitivity. Researchers might consider using a cut-off score of 12 when using PG-SGA for patients with gastric cancer and it is important for researchers to identify in what population the measurement tool was originally validated before using it.

Notably, 70% of the patients reported more than one physical symptom related to eating, while only approximately 30% of the participants were classified as malnourished. This indicates that many people are classified as well nourished but experience physical symptoms related to their intake. In one study of patients with cancer treated in an acute care setting, 17% of the patients were severely malnourished, but 72% reported having more than one symptom.²⁹ In a study targeting patients receiving chemotherapy, 17% were found to be malnourished when assessed using the PG-SGA, but 59% of them reported nutritional impact symptoms.³⁰ Patients classified as nourished may also experience dietary symptoms that could affect their eating habits, which could further influence their quality of life.³¹ Hence, patients should be routinely assessed for malnutrition and managed as necessary. We believe that PG-SGA can assist healthcare providers in assessing various physical symptoms experienced by patients that hindered food intake.

Moreover, our findings demonstrated that malnutrition was highly prevalent among patients within 12 months after gastrectomy. This finding is consistent with previous studies showing that the weight loss and physical symptoms patients with gastric cancer experience are most prevalent within the first year after surgery.^{32,33} Although the routine

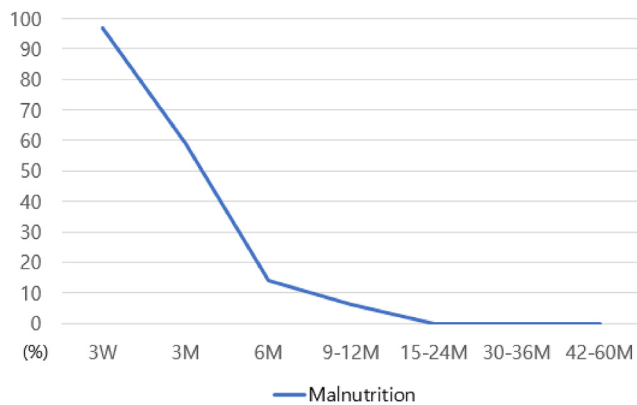


Fig. 2. Distribution of malnourished patients at different timepoints after surgery. M, months; W, weeks; Note. PG-SGA with cut-off score 12 was used as the reference standard.

assessment of nutritional status in patients with gastric cancer is always important, healthcare providers need to pay extra attention to patients after gastrectomy for their first 12 months.

The implications of this study are, first, that an evidence-based, systematic process is essential in the translation of the measurement, since inadequate or inappropriate translation might harm the validity of the data. As inadequately translated assessment tools could hinder the accumulation of meaningful evidence, researchers who translate any assessment tool need to have a great sense of responsibility. Second, different optimal cut-off scores should be determined based on the different target patient groups. This study suggests healthcare providers a new cut-off score for evaluating malnutrition in patients with gastric cancer who had gastrectomy in South Korea. This new cut-off score should also be evaluated in a similar population in different settings in South Korea, as well as in other Asian countries. Third, healthcare providers can have more detailed information about nutritional issues the patients are currently experiencing using this instrument. As most nutritional assessments or screening tools do not include items regarding dietary symptoms experienced by patients, these symptoms are likely neglected. By using the Korean version of PG-SGA, healthcare providers can thoroughly assess and manage these symptoms. Lastly, our study revealed that the prevalence of malnutrition was significantly high within six months after gastrectomy in patients with gastric cancer. Healthcare providers should pay close attention to those with gastrointestinal cancer for six months after surgery.

Limitations

The limitation of this study is that the MNA-SF, the reference instrument used in this study, is a patient-reported measurement and using an objective nutritional index could have provided stronger evidence. Similar studies using other nutritional assessment tools as the reference criteria, such as the Global Leadership Initiative on Malnutrition Criteria, might further increase the validity of the Korean version of PG-SGA in patients with gastric cancer. Additionally, since the PG-SGA was validated only in patients with gastric cancer, it should be validated for other patient groups. Furthermore, we only included patients with gastric cancer who underwent gastrectomy; hence, a new cut-off score might not be applied to patients with advanced gastric cancer who only received chemotherapy and/or radiotherapy. In addition, this study was conducted at a single hospital in South Korea, limiting the generalizability of the study findings. Lastly, a bigger sample size might have yielded more valid results.

Conclusions

A well-translated Korean version of the PG-SGA is an effective and valid assessment tool for evaluating malnutrition in patients with gastric

cancer. It could assist healthcare providers in assessing malnutrition in patients with gastric cancer who have undergone gastrectomy, as well as subjective symptoms they have related to food intake.

Author contributions

Conceptualization: Ji Yea Lee, Eui Geum Oh; Methodology: Ji Yea Lee, Eui Geum Oh; Data curation: Ji Yea Lee, Woo Jin Hyung, Hyoung-Il Kim; Writing – original draft: Ji Yea Lee; Writing – review & editing: Eui Geum Oh, Hyoung-Il Kim.

Declaration of competing interest

None declared.

Funding

Nil.

Ethics statement

This study was approved by the Institutional Review Board of Yonsei University Health System in Seoul, Korea (IRB No. 4-2021-0014).

Appendix A. The Korean version of PG-SGA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.apjon.2022.100148>.

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