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A Japanese translation, cultural adaptation, and linguistic and content validity confirmation of the Scored Patient-Generated Subjective Global Assessment

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Abstract

Purpose The Scored Patient-Generated Subjective Global Assessment (PG-SGA[®]) is a globally recognized and used nutritional screening, assessment, monitoring, and triaging tool. The aim of this study was to translate and culturally adapt the original English PG-SGA for the Japanese speaking populations and to assess its linguistic validity (i.e., comprehensibility, difficulty) and content validity, as perceived by Japanese patients and healthcare professionals.

Methods In accordance with methodology used in previous Dutch, Thai, German, and Norwegian PG-SGA studies, we followed the ten steps of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice for Translation and Cultural Adaptation for Patient-Reported Outcome Measures. The study enrolled 50 patients and 50 healthcare professionals (HCPs) to evaluate the comprehensibility and difficulty of the translated and culturally adapted PG-SGA. The HCPs also evaluated the content validity of the translation. We evaluated each item and quantified scale indices for content validity (item content validity index (I-CVI), scale content validity index (S-CVI)), comprehensibility (item comprehensibility index (I-CI), scale comprehensibility index (S-CI)), and difficulty (item difficulty index (I-DI), scale difficulty index (S-DI)).

Results Patients evaluated the comprehensibility and difficulty of the patient component as excellent (S-CI = 0.97, S-DI = 0.96). The professionals rated the Japanese version of both components of the PG-SGA as very relevant (S-CVI = 0.94). The professionals evaluated the comprehensibility of the professional component as being acceptable (S-CI = 0.88) but difficult (S-DI = 0.69), based predominantly on items related to physical examination (I-DI = 0.33–0.67).

Conclusion The PG-SGA was systematically translated and culturally adapted for the Japanese setting according to the ISPOR process. The Japanese version of the PG-SGA was perceived as comprehensive, easy to use, and relevant. Perceived difficulty in professional components, specifically in the context of metabolic demand and physical examination, will require appropriate training for professionals in order to optimize implementation.

Keywords Patient-Generated Subjective Global Assessment · PG-SGA · Malnutrition · Cancer · Screening · Assessment · Validity

Introduction

Malnutrition is highly prevalent in patients with cancer, with estimates ranging from 20 to 70%, depending on diagnosis, stage, age, and method of assessment [1]. Malnutrition has been associated with poor prognosis [2], resistance to

anti-tumor treatment [3], increased therapy toxicity [4], impaired physical function [5], and quality of life (QOL) [5].

The Nutrition Care Process (<https://www.andecal.org/npc>) consists of four steps: nutritional assessment, nutritional diagnosis, nutritional intervention, and nutritional monitoring and evaluation [6]. The first option of nutritional intervention for malnutrition is nutritional counseling; other options are oral nutritional supplements, artificial nutrition, symptom management, and drug therapy [1]. A previous meta-analysis revealed that nutritional intervention can improve global QOL, loss of appetite, and emotional

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function [7]. Before nutritional intervention, nutritional risk screening and assessment are important to appropriately target intervention [1]. The European Society for Clinical Nutrition and Metabolism guideline on nutrition in cancer patients recommends nutritional screening and malnutrition risk assessment using validated tools [1].

The Patient-Generated Subjective Global Assessment (PG-SGA[®]) is a well-validated tool, demonstrating good concurrent and predictive validity [8–10]. The PG-SGA is used for nutritional screening, assessment, monitoring, and triaging for nutritional interventions in patients with cancer and has included the conceptual definitions in nutritional oncology guidelines worldwide [1, 11]. The patient component consists of the PG-SGA Short Form (PG-SGA SF), with inclusion of data from Boxes 1–4. This includes weight history, food intake, nutrition impact symptoms, and activities/function. The PG-SGA SF is recognized as a patient-reported outcome measure as it is designed to be completed by the patients themselves [12]. The professional component includes scoring of the percentage of weight loss; catabolic conditions in relation to nutritional requirements; metabolic demand due to fever and corticosteroid use; physical assessment; global categorization; and point-based triage for nutritional interventions [11].

There is no Japanese version of PG-SGA that has undergone translation/back translation/cultural adaptation/linguistic validation using the ten steps of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) process [13, 14]. Therefore, the aim of this study was to systematically translate and culturally adapt the original English PG-SGA for the Japanese speaking population, to assess its comprehensibility and difficulty (i.e., linguistic validity) as perceived by patients and healthcare professionals, and to assess its content validity by healthcare professionals.

Methods

The full ISPOR process includes translation/back translation, cultural adaptation, and linguistic validation. Assessment of comprehensibility, difficulty, and content validity was conducted between June 2015 and January 2019, with permission from and in collaboration with the key creator and copyright holder of the PG-SGA (FDO). The study in which comprehensibility, difficulty, and content validity of the Japanese version of the PG-SGA were evaluated was performed in the National Cancer Center Hospital East, Seirei Mikatahara General Hospital, and Osaka City General Hospital, between October 2017 and February 2018. The study was approved by the medical ethics committee of the National Cancer Center Hospital East (IRB-approval No. 2017–106).

Development of the Japanese version of the PG-SGA was performed according to the 10 steps of the ISPOR “Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-reported Outcome Measures” [14]. The specifics of the ISPOR process as applied to PG-SGA translations was described in a Dutch study [15], which served as the basis for the development of other language versions of the PG-SGA [15–18].

Each of the steps of the ISPOR process for translation of patient-reported outcome (PRO) tools is integral to maintaining the integrity of the tool: purpose, intent, and meaning. Step 1 (Preparation Phase) was performed by the researchers and the creator of the PG-SGA (FDO). Step 2 (Forward Translation) was performed by two native Japanese speakers using the PG-SGA forward translation template developed by the creator of the PG-SGA. Step 3 (Reconciliation) was performed by all members of the team including physicians, pharmacists, dietitians, and physical therapists. Step 4 (Back Translation) was performed by two native English speakers living in Japan and fluent in both languages. Step 5 (Back Translation review) and Step 6 (Harmonization), also known as reconciliation, were performed by all members of the team, after which the first formatted template of the Japanese version of the PG-SGA was generated.

Subsequently, Step 7 (Cognitive Debriefing) was performed to evaluate the comprehensibility, difficulty, and content validity of the Japanese version of the PG-SGA. Using the Consensus-based Standards for the Selection of Health Measurement Instruments [19], a convenience sample of 50 patients and 50 healthcare professionals were enrolled in the study.

Patients diagnosed with cancer, aged ≥ 20 years, who were inpatients or outpatients of palliative care wards in the above-mentioned hospitals and who were able to fully understand Japanese were included in the study. Patients who had severe symptoms or patients who had difficulty to complete the questionnaire were excluded. Clinicians non-consecutively recruited the patients who met above criteria at the outpatient clinic or palliative care unit. After giving signed informed consent, patients answered questionnaires to evaluate the comprehensibility and difficulty of the patient component of the PG-SGA. The questionnaires consisted of 36 four-point Likert scale questions for comprehensibility, six four-point Likert scale questions for difficulty, four open-ended questions for comments on the Japanese wording, and four questions for demographics.

Healthcare professionals who worked at the above hospitals for 5 years or more and who reported no experience with use of the PG-SGA were asked to participate in the study. After giving signed informed consent, the healthcare professionals answered questionnaires to evaluate the content validity of both the patient and the professional component and to evaluate the comprehensibility and difficulty of the

professional component of the PG-SGA. The questionnaires consisted of 39 four-point Likert scale questions for comprehensibility, 35 four-point Likert scale questions for difficulty of the professional component of the PG-SGA, and 74 four-point Likert scale questions for content validity, eight open-ended questions for comments on the Japanese wording, and six questions for demographics of the healthcare professionals.

Step 8 (Review of Results) was performed by all members of the team. Finally, Step 9 (Proofreading of Final Version) and Step 10 (Final Report) were performed by all members of the team.

Statistical analysis

Assessment of comprehensibility, difficulty, and content validity was performed using the methodology used in previous studies for the Dutch, Thai, German, and Norwegian versions of the PG-SGA [8, 15, 16, 18]. Before calculating item and scale scores, we converted the four-point Likert scales to a dichotomous not present (0) and present (1), as in previous studies [8, 15, 16, 18]. Specifically, scores of 1 (very irrelevant/very unclear/very difficult) and 2 (irrelevant/unclear/difficult) from the four-point Likert scales were converted to 0 and scores of 3 (relevant/clear/easy) and 4 (very relevant/very clear/very easy) were converted to 1.

Item indices were calculated by dividing the number of respondents who rated “present” by the total number of respondents. Indices were calculated for each item for comprehensibility (I-CI), difficulty (I-DI), and content validity (I-CVI).

The scale index of each construct was calculated by averaging all the item indices for the respective construct (Scale CI [S-CI], Scale DI [S-DI], and Scale CVI [S-CVI]). The

study for both patients and professionals calculated S-CI and S-DI for the PG-SGA-SF.

The study for professionals calculated S-CI, S-DI, and S-CVI using the professional components of the PG-SGA, in addition to a total scale index for the full PG-SGA. Scores of I-CVI, I-CI, and I-DI greater than 0.78 were considered excellent, and those of less than 0.78 required further analysis of the item [20]. Scores of S-CVI, S-CI, and S-DI of 0.80 to 0.89 were considered acceptable, and those of 0.90 or greater were considered excellent [20].

Continuous data were summarized using mean \pm standard deviation (SD). Categorical variables are presented as frequencies (number) and percentage. All analyses were performed using Excel 2016 (Microsoft Corp., Redmond, WA, USA).

Results

Steps 1–7

The first six steps of the ISPOR process produced the pre-final version of the Japanese version of the PG-SGA. For the evaluation of comprehensibility, difficulty, and content validity (Step 7), a total of 50 patients and 50 professionals completed the questionnaires. Table 1 summarizes participant characteristics. Patient ages were 65.5 ± 10.4 years and 22 (44%) were female. The most common types of cancer were lung ($n = 10$), colorectal (7), breast (7), and hepato-biliary, and pancreas (7). The mean duration of working experience for HCPs was 14.3 ± 8.3 years. Most professionals were nurses (18), physicians (13), or pharmacists (8).

The indices for comprehensibility and difficulty evaluated by the patients, and the indices for content validity evaluated by the professionals are shown in Table 2. The

Table 1 Backgrounds of both groups

| | Patients | | Healthcare professionals | |
|-----------------------------|----------|------------|---|--------------------|
| | N | (%) | N | (%) |
| Age (mean \pm SD) | 65.6 | ± 10.4 | The average years of experience (mean \pm SD) | 14.3 \pm 8.3 yrs |
| Sex (%) | | | Current profession | |
| Female | 22 | (44) | Nurse | 18 (36) |
| Education | | | Physician | 13 (26) |
| ≤ 12 yrs | 25 | (51) | Pharmacist | 8 (16) |
| Cancer site | | | Dietitian | 6 (12) |
| Lung | 10 | (20) | Rehabilitation specialist | 5 (10) |
| Colorectal | 7 | (14) | | |
| Breast | 7 | (14) | | |
| Hepato-biliary and pancreas | 7 | (14) | | |
| Esophagus and stomach | 3 | (6) | | |
| Others | 16 | (32) | | |

Table 2 Indices for content validity, comprehensibility, and difficulty for patient component of the Japanese version of the Patient-Generated Subjective Global Assessment

| Items | Patients' comprehensibility I-CI (n = 50) | Patients' difficulty I-DI (n = 50) | Professionals' content validity I-CVI (n = 50) |
|---|--|---------------------------------------|---|
| Box 1: Weight | | | |
| I currently weigh about ___ kg | 1.00 (n = 49) | 0.94 (n = 48) | 0.98 (n = 50) |
| I am about ___ cm tall | 1.00 (n = 48) | | 0.98 (n = 50) |
| One month ago I weighed about ___ kg | 1.00 (n = 49) | | 1.00 (n = 50) |
| Six months ago I weighed about ___ kg | 0.98 (n = 48) | | 0.96 (n = 50) |
| Weight—decreased, not changed, increased | 0.96 (n = 48) | 0.94 (n = 48) | 0.90 (n = 50) |
| Box 2: Food intake | | | |
| As compared to my normal intake, I would rate my food intake during the past month as | 0.94 (n = 49) | 0.98 (n = 48) | 0.96 (n = 49) |
| Unchanged; more than usual; less than usual | 0.94 (n = 50) | | 0.96 (n = 50) |
| I am now taking | 0.90 (n = 49) | 0.96 (n = 48) | 0.90 (n = 48) |
| Normal food but less than normal amount | 0.96 (n = 49) | | 0.82 (n = 50) |
| Little solid food | 0.92 (n = 49) | | 0.86 (n = 50) |
| Only liquids | 0.96 (n = 49) | | 0.92 (n = 50) |
| Only nutritional supplements | 0.94 (n = 48) | | 0.92 (n = 50) |
| Very little of anything | 0.96 (n = 49) | | 0.98 (n = 50) |
| Only tube feedings or only nutrition by vein | 0.96 (n = 49) | | 0.94 (n = 49) |
| 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) | 0.96 (n = 48) | 0.98 (n = 48) | 0.98 (n = 48) |
| No problems eating | 0.98 (n = 47) | | 0.86 (n = 50) |
| No appetite, just did not feel like eating | 1.00 (n = 47) | | 1.00 (n = 50) |
| Nausea | 1.00 (n = 47) | | 1.00 (n = 50) |
| Constipation | 1.00 (n = 48) | | 1.00 (n = 50) |
| Mouth sores | 0.98 (n = 48) | | 0.98 (n = 50) |
| Things taste funny or have no taste | 0.98 (n = 49) | | 1.00 (n = 50) |
| Problems swallowing | 1.00 (n = 48) | | 1.00 (n = 50) |
| Pain; where? | 1.00 (n = 47) | | 1.00 (n = 50) |
| Vomiting | 0.98 (n = 48) | | 0.98 (n = 50) |
| Diarrhea | 0.98 (n = 48) | | 0.96 (n = 50) |
| Dry mouth | 1.00 (n = 48) | | 0.96 (n = 50) |
| Smells bother me | 1.00 (n = 48) | | 1.00 (n = 50) |
| Feel full quickly | 1.00 (n = 49) | | 0.98 (n = 50) |
| Fatigue | 1.00 (n = 48) | | 1.00 (n = 50) |
| Other | 1.00 (n = 47) | | 0.96 (n = 50) |
| Box 4: Activities and function | | | |
| Over the past month, I would generally rate my activity as | 0.96 (n = 48) | 0.98 (n = 48) | 0.98 (n = 48) |
| Normal with no limitations | 1.00 (n = 48) | | 1.00 (n = 50) |
| Not my normal self, but able to be up and about with fairly normal activities | 1.00 (n = 48) | | 0.96 (n = 50) |
| Not feeling up to most things, but in bed or sitting in a chair less than half the day | 0.92 (n = 48) | | 0.86 (n = 50) |
| Able to do little activity and spend most of the day in bed or chair pretty much bedridden, rarely out of bed | 0.98 (n = 47) | | 1.00 (n = 50) |
| Pretty much bedridden, rarely out of bed | 0.98 (n = 47) | | 1.00 (n = 50) |
| | S-CI | S-DI | S-CVI |
| Scale indices for patient components | 0.97 | 0.96 | 0.96 |

patients evaluated the comprehensibility and difficulty of the patient component of the Japanese version of the PG-SGA as excellent (S-CI=0.97 and S-DI=0.96, respectively) with all items considered as excellent as well. The professionals evaluated content validity of the patient components as excellent (S-CVI=0.96) with all items acceptable or excellent (I-CVI=0.82–1.00).

The indices for content validity, comprehensibility, and difficulty evaluated by professionals are shown in Table 3. The professionals evaluated the content validity of the professional component as excellent (S-CVI=0.93) with all items acceptable or excellent (I-CVI ranging from 0.82 to 1.00). Comprehensibility of the professional component was evaluated as acceptable (S-CI=0.88); however, individual items of I-CI ranged from 0.62 to 1.00. I-CI scores were low especially in Worksheet 3 (Metabolic demand) and Worksheet 4 (Physical examination). Difficulty was lower (S-DI=0.69) than predefined cut-off point for acceptable (0.80). Individual I-DI scores were low for the items relevant diagnosis, cancer stage, Worksheet 3 (Metabolic demand), and especially Worksheet 4 (Physical examination).

Content validity of the full PG-SGA was evaluated as excellent (S-CVI=0.94).

Steps 8–10

After completion of Step 7 of the ISPOR process, all members of the team reviewed the results, reconciled Japanese words based on answers to open-ended questions, and finalized the Japanese version of the PG-SGA. Participants had difficulty in distinguishing words “liquids” and “nutritional supplements.” Therefore, the authors decided to change “liquids” and “nutritional supplements” into “Omoyu” and “Eiyozai,” respectively, in Japanese for clarification of the specific meaning. The final Japanese version was published at www.pt-global.org on 27 January 2019. The final version of the Japanese PG-SGA is presented in Fig. 1a (Patient component) and Fig. 1b (Professional component).

Discussion

A Japanese version of the PG-SGA was developed by systematically translating and culturally adapting the original English PG-SGA using the ISPOR process for translation of patient reported outcomes <https://www.anddeal.org/ncp>. The results of Step 7 (Cognitive Debriefing) of the ISPOR process showed that the Japanese version of PG-SGA was comprehensible, easy, and relevant for patients and professionals.

The PG-SGA SF was also perceived as comprehensible and easy (S-CI=0.97 and S-DI=0.96) by Japanese patients with cancer, which was similar to previous studies on the Dutch (0.99 and 0.96), Thai (0.99 and 0.95), German (0.96

and 0.91), and Norwegian (0.99 and 0.98) versions of the PG-SGA-SF [8, 15, 16, 18]. Although the education levels of the patients in the Japanese study were lower than those in the Norwegian study, the current study population perceived PG-SGA-SF as comprehensible and easy to answer. The professionals evaluated the PG-SGA SF as highly relevant (S-CVI=0.96), which was even higher than in the studies on the Dutch (0.95) and German (0.90) versions, and lower than in the study on the Norwegian version (0.99).

The professional component was also perceived as highly relevant (S-CVI=0.93), which was comparable with the results of previous studies on the Dutch (0.81), Thai (0.93), German (0.90), and Norwegian (0.92) versions of the PG-SGA. The professional component of the Japanese PG-SGA was perceived as difficult (S-DI=0.69), similar to previous studies on the Dutch (S-DI=0.55) and Norwegian (S-DI=0.66) versions of the PG-SGA. Our results were lower than in the studies on the Thai (S-DI=0.79) and German (S-DI=0.72) versions of the PG-SGA; however, in the Thai study, 40% of the professionals were familiar with the PG-SGA [18].

More knowledge about or experience with the PG-SGA may result in higher scores for individual items, especially in Worksheet 3 (Metabolic demand) and Worksheet 4 (Physical examination). Education and training may be critical to improve comprehensibility and difficulty. A Dutch study showed that a single training in the use of PG-SGA increased comprehensibility (increasing S-CI from 0.69 to 0.95) and difficulty (increasing S-DI from 0.57 to 0.86) [15]. Therefore, to optimally implement the Japanese version of the PG-SGA as a nutritional risk assessment tool, training in the use of the PG-SGA is recommended for healthcare professionals.

The Japanese version of the PG-SGA-SF was perceived as comprehensive and easy to answer by both patients and professionals. Additionally, the content validity of the PG-SGA-SF was acceptable. A previous study using the Dutch PG-SGA showed that patients with cancer could quickly fill in the PG-SGA SF, within less than 5 min [21]. Therefore, the Japanese version of the PG-SGA SF may be a useful nutritional screening instrument, provide an important patient-reported outcome parameter in nutritional monitoring and evaluation, and serve as a standard nutritional monitoring and evaluation instrument.

The use of the Japanese version of the PG-SGA may enable the creation of a proactive malnutrition policy to identify and address risk factors for malnutrition. A previous study showed that patients who completed the PG-SGA SF increased their awareness of malnutrition risk [21]; therefore, the availability of a Japanese version of the PG-SGA SF may help to further increase awareness of malnutrition risk in Japanese patients themselves. Furthermore, the availability of a Japanese version of the

Table 3 Indices for content validity, comprehensibility, and difficulty for professional component of the Japanese version of Patient-Generated Subjective Global Assessment

| Items | Comprehensibility I-CI (n = 50) | | Difficulty I-DI (n = 50) | | Content validity I-CVI (n = 50) | |
|---|------------------------------------|----------|-----------------------------|----------|------------------------------------|----------|
| Worksheet 1 – Scoring weight loss: to determine score, use 1-month weight data if available. Use 6-month data only if there is no 1-month weight data. Use points below to score weight change and add one extra point if patient has lost weight during the past 2 weeks. Enter total point score in Box 1 of PG-SGA | 0.98 | (n = 48) | 0.88 | (n = 40) | 0.98 | (n = 47) |
| Scoring weight (Wt) loss | 1.00 | (n = 49) | 0.83 | (n = 36) | 1.00 | (n = 49) |
| Worksheet 2 – Disease and its relation to nutritional requirements: score is derived by adding 1 point for each of the following conditions | 1.00 | (n = 48) | 0.96 | (n = 45) | 1.00 | (n = 49) |
| Cancer | 1.00 | (n = 49) | 0.98 | (n = 47) | 0.98 | (n = 50) |
| AIDS | 0.98 | (n = 49) | 0.94 | (n = 47) | 0.96 | (n = 50) |
| Pulmonary or cardiac cachexia | 0.96 | (n = 49) | 0.83 | (n = 48) | 0.94 | (n = 50) |
| Chronic renal insufficiency | 1.00 | (n = 49) | 0.94 | (n = 48) | 0.98 | (n = 50) |
| Presence of decubitus, open wound or fistula | 0.96 | (n = 49) | 0.96 | (n = 48) | 0.94 | (n = 50) |
| Presence of trauma | 0.96 | (n = 48) | 0.94 | (n = 47) | 0.92 | (n = 50) |
| Age greater than 65 | 1.00 | (n = 49) | 0.98 | (n = 47) | 0.92 | (n = 50) |
| All relevant diagnoses | 0.90 | (n = 49) | 0.74 | (n = 47) | 0.94 | (n = 49) |
| Primary disease staging (circle if known or appropriate) I II III IV Other _____ | 0.92 | (n = 49) | 0.77 | (n = 47) | 0.88 | (n = 49) |
| Worksheet 3 – Metabolic demand: score for metabolic stress is determined by a number of variables known to increase protein and caloric needs. Note: score fever intensity or duration, whichever is greater. The score is additive so that a patient who has a fever of 38.8 °C (3 points) for < 72 h (1 point) and who is on 10 mg of prednisone chronically (2 points) would have an additive score for this section of 5 points | 0.74 | (n = 47) | 0.67 | (n = 43) | 0.88 | (n = 48) |
| Fever | 0.94 | (n = 49) | 0.94 | (n = 48) | 1.00 | (n = 50) |
| Fever duration | 0.84 | (n = 49) | 0.77 | (n = 48) | 0.82 | (n = 50) |
| Corticosteroids | 0.94 | (n = 49) | 0.92 | (n = 48) | 0.92 | (n = 48) |
| Worksheet 4 – Physical exam: exam includes a subjective evaluation of three aspects of body composition: fat, muscle, and fluid. Since this is subjective, each aspect of the exam is rated for degree. Muscle deficit/loss impacts point score more than fat deficit/loss. Definition of categories: 0 = no abnormality, 1+ = mild, 2+ = moderate, 3+ = severe. The ratings in these categories are not additive but are used to clinically assess the degree of deficit (or presence of excess fluid) | 0.70 | (n = 47) | 0.41 | (n = 46) | 0.93 | (n = 43) |
| Temples (temporalis muscles) | 0.77 | (n = 47) | 0.38 | (n = 48) | 0.90 | (n = 48) |
| Clavicles (pectoralis and deltoids) | 0.77 | (n = 47) | 0.46 | (n = 48) | 0.85 | (n = 48) |
| Shoulders (deltoids) | 0.79 | (n = 47) | 0.50 | (n = 48) | 0.90 | (n = 48) |
| Interosseous muscles | 0.79 | (n = 47) | 0.50 | (n = 48) | 0.85 | (n = 48) |
| Scapula (latissimus dorsi, trapezius, deltoids) | 0.74 | (n = 47) | 0.52 | (n = 48) | 0.88 | (n = 48) |
| Thigh (quadriceps) | 0.85 | (n = 47) | 0.54 | (n = 48) | 0.92 | (n = 48) |
| Calf (gastrocnemius) | 0.85 | (n = 47) | 0.56 | (n = 48) | 0.92 | (n = 48) |
| Global muscle status rating | 0.83 | (n = 47) | 0.56 | (n = 48) | 0.92 | (n = 48) |
| Orbital fat pads | 0.62 | (n = 47) | 0.33 | (n = 48) | 0.83 | (n = 47) |
| Triceps skin fold | 0.79 | (n = 47) | 0.52 | (n = 48) | 0.90 | (n = 48) |
| Fat overlying lower ribs | 0.79 | (n = 47) | 0.44 | (n = 48) | 0.92 | (n = 48) |
| Global fat deficit rating | 0.83 | (n = 47) | 0.52 | (n = 48) | 0.90 | (n = 48) |
| Ankle edema | 0.85 | (n = 47) | 0.65 | (n = 48) | 0.91 | (n = 47) |
| Sacral edema | 0.77 | (n = 47) | 0.54 | (n = 48) | 0.81 | (n = 47) |
| Ascites | 0.85 | (n = 47) | 0.67 | (n = 48) | 0.91 | (n = 47) |
| Global fluid status rating | 0.83 | (n = 47) | 0.50 | (n = 48) | 0.94 | (n = 47) |
| Global Assessment Categories stage A, well nourished; stage B, moderate/suspected malnutrition; stage C, severely malnourished | 0.89 | (n = 46) | 0.81 | (n = 48) | 0.98 | (n = 48) |

Table 3 (continued)

| Items | Comprehensibility I-CI (n = 50) | Difficulty I-DI (n = 50) | Content validity I-CVI (n = 50) |
|---|------------------------------------|-----------------------------|------------------------------------|
| Nutritional triage recommendations: additive score is used to define specific nutritional interventions including patient and family education, symptom management including pharmacologic intervention, and appropriate nutrient intervention (food, nutritional supplements, enteral, or parenteral triage) | 0.96 (n = 47) | 0.82 (n = 49) | 1.00 (n = 49) |
| First-line nutrition intervention includes optimal symptom management | | | |
| 0–1 No intervention required at this time. Re-assessment on routine and regular basis during treatment | 0.96 (n = 47) | | 0.98 (n = 49) |
| 2–3 Patient and family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and lab values as appropriate | 0.98 (n = 47) | | 1.00 (n = 49) |
| 4–8 Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3) | 0.96 (n = 47) | | 1.00 (n = 49) |
| ≥ 9 Indicates a critical need for improved symptom management and/or nutrient intervention options | 0.96 (n = 47) | | 1.00 (n = 48) |
| | S-CI | S-DI | S-CVI |
| Scale indices for the professional component | 0.88 | 0.69 | 0.93 |
| S-CVI full PG-SGA | | | 0.94 |



患者自記式による主観的包括的評価 (PG-SGA)
1~4 欄は患者さんが記入してください。
[第 1~4 欄で PG-SGA 短縮版 (SF) と呼ばれます]

患者 ID 番号

| | |
|---|--|
| <p>1. 体重 (ワークシート 1 を参照)</p> <p>私の現在および最近の体重についてまとめると: 私の現在の体重は約 _____ kg です。 私の身長は _____ cm です。</p> <p>1ヶ月前の私の体重は約 _____ kg でした。 6ヶ月前の私の体重は約 _____ kg でした。</p> <p>この 2 週間に私の体重は: <input type="checkbox"/> 減りました (1) <input type="checkbox"/> 変わっていません (0) <input type="checkbox"/> 増えました (0)</p> <p style="text-align: right;">第 1 欄 <input type="checkbox"/></p> | <p>2. 食事の摂取: 私の普段の食事量と比べて、この 1 カ月間の食事量は:</p> <p><input type="checkbox"/> 変わっていない (0) <input type="checkbox"/> 普段より多い (0) <input type="checkbox"/> 普段より少ない (1)</p> <p>私の今の食事は: <input type="checkbox"/> 普通の食事だが、通常量よりは少ない (1) <input type="checkbox"/> 固形物をほんの少し (2) <input type="checkbox"/> 重湯など流動食のみ (3) <input type="checkbox"/> 栄養剤のみ (3) <input type="checkbox"/> ほとんど何も食べられない (4) <input type="checkbox"/> チューブや点滴による栄養のみ (0)</p> <p style="text-align: right;">第 2 欄 <input type="checkbox"/></p> |
| <p>3. 症状: 私は以下のような問題があって、この 2 週間十分に食べられない状況が続いています (当てはまるものすべてをチェック):</p> <p><input type="checkbox"/> 問題なく食べられた (0) <input type="checkbox"/> 嘔吐 (3) <input type="checkbox"/> 食欲がなかった、または食べようという気にならなかった (3) <input type="checkbox"/> 下痢 (3) <input type="checkbox"/> 吐き気 (1) <input type="checkbox"/> 口の渇き (1) <input type="checkbox"/> 便秘 (1) <input type="checkbox"/> においが気になる (1) <input type="checkbox"/> 口の中の痛み (2) <input type="checkbox"/> すぐに満腹になる (1) <input type="checkbox"/> 味がおかしい、または味がしない (1) <input type="checkbox"/> だるさ (1) <input type="checkbox"/> 飲み込みにくい (2) <input type="checkbox"/> 痛み; どこですか? (3) _____ <input type="checkbox"/> その他 (1) ** _____ **例: 気分の落ち込み、経済的な問題、歯の問題</p> <p style="text-align: right;">第 3 欄 <input type="checkbox"/></p> | <p>4. 活動と機能: この 1 カ月間の私の活動を全般的に評価すると:</p> <p><input type="checkbox"/> 何の制限もなく普通に活動できた (0) <input type="checkbox"/> 普段通りではないが、起き上がっておむね普通に近い活動ができた (1) <input type="checkbox"/> ほとんどのことができなと思われたが、ベッドや布団、または椅子で過ごすのは半日以下だった (2) <input type="checkbox"/> ほとんど活動できず、一日の大半をベッドや布団、または椅子で過ごした (3) <input type="checkbox"/> ほとんど横になっていてベッドや布団から出ることはまれだった (3)</p> <p style="text-align: right;">第 4 欄 <input type="checkbox"/></p> |
| <p>ここからは担当医、看護師、栄養士またはセラピストが記入します。ありがとうございました。</p> <p>©FD Ottery 2005, 2006, 2015 v3.22.15 Japan 19-011 v01.27.19 email: faithottervmdphd@gmail.com or info@pt-global.org</p> | |
| <p>第 1~4 欄の合計点 <input type="checkbox"/> A</p> | |

Fig. 1 The Japanese version of the Scored Patient-Generated Subjective Global Assessment (PG-SGA®)

患者自記式による主観的包括的評価 (PG-SGA)

ワークシート1 体重減少のスコア判定

第1欄の点数の決定には、可能ならば過去1ヶ月間の体重データを使用する。過去1ヶ月間の体重データがない場合に限る。過去6ヶ月間の体重データを使用する。体重変動の採点には、以下の点数を使用し、患者の体重がこの2週間減少している場合はもう1点加算する。合計点をPG-SGAの第1欄に記入する。

| 1ヵ月間の体重減少 | 点数 | 6ヵ月間の体重減少 |
|-----------|----|-----------|
| 10%以上 | 4 | 20%以上 |
| 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% |

ワークシート1のスコア

第1~4欄の合計点 (1枚目を参照) A

5. ワークシート2 - 疾患とその栄養必要量との関係:

スコアは以下の各項目に該当する毎に1点加算して求める:

- がん
- AIDS
- 呼吸器疾患または心疾患による悪液質
- 慢性腎不全
- 褥瘡、開放創または瘻孔あり
- 外傷あり
- 65歳以上

その他の関連する診断 (具体的に) _____

原疾患の病期 (分かっている場合、あるいは適切なものを○で囲んでください) _____

1, II, III, IV, その他 _____

ワークシート2のスコア B

6. ワークシート3 - 代謝による必要量の増加

タンパク質やエネルギーの必要量を増やすことがわかっている要因の数によって、代謝ストレスのスコアを計算する。注意: 熱の高さか持続期間のスコアの高い方を採用する。スコアは加算制で、例えば72時間未満の(1点)38.8°Cの発熱(3点)、プレドニゾン10mgの長期投与を受けている(2点)患者は、この項の合計点は5点となる。

| 代謝ストレス | なし (0) | 軽度 (1) | 中等度 (2) | 重度 (3) |
|-----------|--------|---------------------------------|---|---------------------------------|
| 発熱の高さ | なし | > 37.2 and < 38.3 | ≥ 38.3 and < 38.8 | ≥ 38.8 °C |
| 発熱の持続時間 | なし | < 72 hours | 72 hours | > 72 hours |
| コルチコステロイド | なし | 低用量 (< 10 mg プレドニゾン換算量/日) | 中等用量 (≥ 10 and < 30 mg プレドニゾン換算量/日) | 高用量 (≥ 30 mg プレドニゾン換算量/日) |

ワークシート3のスコア C

7. ワークシート4 - 身体所見

身体所見は、体組成の3要素: 体脂肪、筋肉、体液の主観的評価を行う。主観的評価であるため、所見の各領域は程度によって評価される。筋肉量の減少は脂肪量の減少よりもスコアに大きく影響する。カテゴリの定義: 0=異常なし、1+=軽度、2+=中等度、3+=重度。これらのカテゴリの(筋肉量・体脂肪量)の減少のスコアは加算式ではなく、(筋肉量・体脂肪量)の減少(または過剰な体液貯留)の程度を臨床的に評価するために用いる。

| 筋肉の状態 | 0 | 1+ | 2+ | 3+ |
|-------------------|---|----|----|----|
| 側頭部 (側頭筋) | 0 | 1+ | 2+ | 3+ |
| 鎖骨下部 (胸筋&三角筋) | 0 | 1+ | 2+ | 3+ |
| 肩 (三角筋) | 0 | 1+ | 2+ | 3+ |
| 手背間筋 | 0 | 1+ | 2+ | 3+ |
| 肩甲骨 (広背筋、僧帽筋、三角筋) | 0 | 1+ | 2+ | 3+ |
| 大腿 (大腿四頭筋) | 0 | 1+ | 2+ | 3+ |
| ふくらはぎ (腓腹筋) | 0 | 1+ | 2+ | 3+ |

筋肉の状態の総合評価 0 1+ 2+ 3+

| 体脂肪の蓄積 | 0 | 1+ | 2+ | 3+ |
|-----------|---|----|----|----|
| 眼窩脂肪体 | 0 | 1+ | 2+ | 3+ |
| 上腕三頭筋皮下脂肪 | 0 | 1+ | 2+ | 3+ |
| 下部肋骨を覆う脂肪 | 0 | 1+ | 2+ | 3+ |

体脂肪の減少の総合評価 0 1+ 2+ 3+

| 体液の状態 | 0 | 1+ | 2+ | 3+ |
|---------|---|----|----|----|
| くるぶしの浮腫 | 0 | 1+ | 2+ | 3+ |
| 仙骨部の浮腫 | 0 | 1+ | 2+ | 3+ |
| 腹水 | 0 | 1+ | 2+ | 3+ |

体液の状態の総合評価 0 1+ 2+ 3+

体組成の悪化 (筋肉や脂肪の減少や体液の貯留) に対する全体的な程度を主観的に評価して、身体所見のスコアを計算する。

低下なし score = 0 points

軽度の低下 score = 1 point

中程度の低下 score = 2 points

重度の低下 score = 3 points

前述のように、筋肉量の低下は体脂肪の減少または過剰な体液貯留よりも重視される。

ワークシート4のスコア D

PG-SGA 合計スコア (A+B+C+Dの合計スコア)

PG-SGA カテゴリ総合評価 (ステージ A, B, または C)

Clinician Signature _____ RD RN PA MD DO Other _____ Date _____

ワークシート5 PG-SGA 総合評価カテゴリ

| カテゴリ | Stage A 栄養状態良好 体重減少なし | Stage B 中等度の栄養障害/栄養障害の疑い 1ヵ月間の体重減少率≤5% (6ヵ月間で≤10%) または、体重減少の進行 栄養摂取量の明らかな減少 | Stage C 高度の栄養障害 1ヵ月間 体重減少率>5% 6ヵ月間で>10% または、体重減少の進行 栄養摂取量の重度の不足 |
|-------------------|-----------------------------|--|--|
| 栄養摂取 | 不足なし、または最近著明な改善あり | NISあり (PG-SGAの第3欄) | NISあり (PG-SGAの第3欄) |
| 栄養状態に影響する症状 (NIS) | 取が可能な状態 | 中等度の機能低下、または最近悪化 | 重度の機能低下、または最近著しく悪化 |
| 身体所見 | 低下なし、または最近著明な改善あり | 筋肉量、かつ/または、発熱時の筋緊張、かつ/または、皮下脂肪の軽度~中等度の減少 | 低栄養状態の明らかな所見 (例: 重度の筋肉量、または脂肪量の低下 または、浮腫も認める可能性あり) |

栄養トリアージの推奨: 患者および家族への教育をはじめとする栄養学的介入や、薬物治療を含む症状管理、適切な栄養介入 (食品、栄養補助食品、経腸栄養または静脈栄養などの選択) を決定するために、全体の合計点を使用する。

はじめに行われる栄養介入には、**症状マネジメントを最大限行うことを含む**。

PG-SGAスコアに基づくトリアージ

0-1 現時点で介入は不要。治療中は日常におよび定期的に再評価を行う。

2-3 症状の調査 (第3欄) および検査値に基づいて、薬物療法とともに、栄養士、看護師、またはその他の医療者が、患者および家族への教育を必要があれば行う。

4-8 症状の調査 (第3欄) に基づき、看護師または医師と連携して栄養士が介入する必要がある。

2 9 症状マネジメントの改善および/または栄養介入の選択が緊急に必要である。

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Fig. 1 (continued)

PG-SGA may allow monitoring of nutritional status and malnutrition risk factors during hospital stay.

A potential limitation is the sampling. Both patients and professionals were not consecutively recruited, which may have resulted in selection bias. However, this may not affect the present results given that the education level of patients was generally low, and was lower than the Norwegian study, which may have underestimated the results rather than overestimated. Another potential limitation could be the generalizability. Since this study was performed in three large cities in Japan (Kashiwa, Hamamatsu, Osaka), the present study can be considered as generalizable to Japanese speaking patients with cancer, but not to Japanese speaking patients without cancer.

Conclusion

The PG-SGA was systematically translated and culturally adapted for the Japanese setting according to the ISPOR process. The Japanese version of the PG-SGA was perceived as comprehensive, easy to use, and relevant. Perceived difficulty in professional components, specifically in the context of metabolic demand and physical examination, will require appropriate training for professionals in order to optimize implementation.

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Author contribution Tomofumi Miura: study design; protocol writing; patient enrollment; analysis; and manuscript development.

Rikako Elgersma: patient enrollment; analysis; review, input, and approval of manuscript.

Ayumi Okizaki: patient enrollment; analysis review, input, and approval of manuscript.

Mihoko Kazawa Inoue: patient enrollment; review, input, and approval of manuscript.

Koji Amano: patient enrollment; review, input, and approval of manuscript.

Masanori Mori: patient enrollment; review, input, and approval of manuscript.

Haruka Chitose: patient enrollment [review, input, and approval of manuscript].

Yoshihisa Matsumoto: patient enrollment; review, input, and approval of manuscript.

Harriët Jager-Wittenaar: study design; analysis; review, input, and approval of manuscript.

Faith D. Ottery: permission and collaboration; back translation review; review, input, and approval of manuscript.

Data availability Data is not available because of ethical issues.

Code availability Excel 2016.

Declarations

Ethics approval The study was approved by the medical ethics committee of the National Cancer Center Hospital East (IRB-approval No. 2017–106).

Consent to participate Participants were enrolled after giving signed informed consent.

Consent for publication Participants were informed about publication of aggregate results.

Conflict of interest Faith D. Ottery is the creator of the PG-SGA[®], co-creator of the Scored PG-SGA, the copyright holder of the PG-SGA and its derivatives, as well as co-developer of a PG-SGA-based Pt-Global app/web tool. Harriët Jager-Wittenaar was a co-developer of the PG-SGA-based Pt-Global app/web tool.

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