Translation and Cross-cultural Adaptation of the Scored Patient-Generated Subjective Global Assessment (PG-SGA) to the Thai setting

การแปล และการปรับรูปแบบข้ามวัฒนธรรมของ the Scored Patient-Generated Subjective Global Assessment (PG-SGA) ในบริบทประเทศไทย

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ABSTRACT

The Scored Patient-Generated Subjective Global Assessment (PG-SGSA) is a reference tool to assess nutritional status in cancer patients. The objectives of this study are to translate and culturally adapt the original PG-SGA for the Thai setting, evaluate perceived comprehensibility, difficulty and content validity of the Thai version of the PG-SGA in 50 cancer patients and 50 healthcare professionals at King Chulalongkorn Memorial Hospital. The translation and cultural adaptation were done by using the International Society for Pharmacoeconomics and Outcomes Research Principles. The Thai version of the PG-SGA was successfully translated and culturally adapted. It is considered easy to use and comprehensible by patients. However, the difficulty is considered borderline for some professional components, which requires training on the PG-SGA prior to use.

บทคัดย่อ

The Scored Patient-Generated Subjective Global Assessment (PG-SGSA) เป็นเครื่องมืออ้างอิงที่ใช้ประเมินภาวะโภชนาการในผู้ป่วยมะเร็ง การศึกษานี้มีวัตถุประสงค์เพื่อแปล และปรับรูปแบบข้ามวัฒนธรรมของต้นฉบับ PG-SGA สำหรับบริบทประเทศไทย ประเมินความสามารถในการทำความเข้าใจ ความยากง่าย และความเที่ยงตรงเชิงเนื้อหาของแบบประเมิน PG-SGA ฉบับภาษาไทยในผู้ป่วยมะเร็ง 50 คน และบุคลากรทางการแพทย์ 50 คนจากโรงพยาบาลจุฬาลงกรณ์ การแปล และการปรับรูปแบบข้ามวัฒนธรรมดำเนินการตามหลักการของ International Society for Pharmacoeconomics and Outcomes Research แบบประเมิน PG-SGA ได้รับการแปล และปรับรูปแบบข้ามวัฒนธรรมเป็นฉบับภาษาไทยอย่างเสร็จสมบูรณ์ แบบประเมินนี้สามารถนำไปใช้ได้ ง่ายต่อการทำความเข้าใจ และการกรอกข้อมูลสำหรับผู้ป่วย อย่างไรก็ตามแบบประเมินในส่วนที่ประเมินโดยบุคลากรทางการแพทย์ยังมีความยากในการกรอกข้อมูล ซึ่งผู้ใช้แบบประเมินส่วนนี้ควรได้รับการฝึกอบรมก่อนใช้งานจริง

Keywords: PG-SGA, Translation, Cross-cultural adaptation

คำสำคัญ: PG-SGA การแปล การปรับรูปแบบข้ามวัฒนธรรม

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Introduction

Malnutrition is highly prevalent in oncology patients during all phases of the disease and its treatment (Andreyev et al., 1998). The prevalence of malnutrition in cancer patients in Thailand is estimated to be in the range of 30 to 80% (Chantragawee, Achariyapota, 2016). Cancer, as well as anti-cancer treatments may affect the nutritional status of patients resulting in symptoms that interfere with nutritional intake and appetite (Capra et al., 2001). This results in malnutrition and leads to delineation of treatment efficacy, increased complications, raised healthcare costs (Arends et al., 2017; Lis et al., 2012). Thereby, screening, assessment, and monitoring of malnutrition and its risk factors is crucial to triage for timely intervention to improve clinical outcomes (Bauer et al., 2002).

The Scored Patient-Generated Subjective Global Assessment (PG-SGA; ©FD Ottery 2005, 2006, 2015) is a 4-in-1 instrument facilitating proactive screening, assessment, monitoring, and interdisciplinary intervention triage (Jager-Wittenaar, Ottery, 2017). The PG-SGA has been widely used as a reference method for nutrition assessment in oncology patients (Bauer et al., 2002; Jager-Wittenaar, Ottery, 2017), and has also been validated and utilized in non-cancer patients (Jager-Wittenaar, Ottery, 2017). The scored PG-SGA consists of 2 components. The first one, patient-generated component was designed to be completed by the patient. It incorporates four Boxes on weight history, food intake, nutrition impact symptoms, and activities/function. The second one, professional component was developed to be filled by healthcare professionals. It has 5 Worksheets addressing scoring the percentage of weight loss, disease and its relation to nutritional requirements, metabolic demand, physical examination, and the global category rating (Ottery, 1996). In addition, the PG-SGA provides a numerical scoring system, to triage for nutritional recommendations and monitor changes in nutritional risks (Jager-Wittenaar, Ottery, 2017; Sealy et al., 2016)

In Thailand, there were some studies that utilized various Thai version of PG-SGA by straightforward translation in cancer patients (Chantragawee, Achariyapota, 2016; Chantalert, 2009). However, there has been no official Thai translation and cultural adaptation of the PG-SGA available thus far. Health professionals should be able to utilize valid and reliable tools of their own language and culture to further produce high quality patient care (Regnault et al., 2015) and avoid misinterpretation or different conceptualization of health and illness (Acquadro et al., 2008; Beaton et al., 2000). Therefore, a systematic translation and cultural adaptation process is essential for ensuring conceptual, semantic and operational equivalence between the original and new version of the instrument (Beaton et al., 2000; Wild et al., 2005). Conceptual equivalence is related to the validity of conceptual meaning experienced by the people across different cultures. Semantic equivalence refers to the meaning of words in the instrument being the same in both the original and target language (Beaton et al., 2000; Guillemin et al., 1993). The degree to which the items in the instrument are appropriately represented the concept being measured refers to content validity (Polit, Beck, 2006). Moreover, operational equivalence is obtained when the item format, mode of administration, and reading level of the instrument are appropriate for the target culture (Stewart, Napoles-Springer, 2000). In addition, the use of the Thai version of the Scored PG-SGA could promote meta-analysis and comparison of data across countries since the PG-SGA was translated and culturally adapted to several languages (Jager-Wittenaar, Ottery, 2017).

Objectives of the study

In this study, we aimed to systematically translate and culturally adapt the original English PG-SGA for the Thai setting, including exploration of perceived comprehensibility, difficulty, and content validity (relevance) in both patients with cancer and healthcare professionals.

Methodology

Translation and cultural adaptation process of the instrument

Translation and cultural adaptation of the original English version of PG-SGA were conducted following the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient Reported Outcomes by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (Wild et al., 2005).

Step 1: Preparation. The permission request for translation and cultural adaptation of the original English version of the PG-SGA to the Thai setting was sent to the copyright holder of the PG-SGA (Faith Ottery) and an international expert on translation and cultural adaptation of the PG-SGA (Harriët Jager-Wittenaar).

Step 2: Forward translation. After the permission was granted by the copyright holder, two native Thai speakers independently translated and culturally adapted the English version of PG-SGA to the Thai language.

Step 3: Reconciliation. The translations from these 2 forward translators were discussed, compared, and integrated by the project coordinator, the key country person, and the corresponding author. This integrated forward translation was sent to the group of experts (n=9) which included physicians (n=3), nurses (n=3), and dietitians (n=3), to analyze and evaluate the equivalence of content between the original and the integrated forward translation of the Thai version of the PG-SGA. After the expert's consensus was achieved, the first draft Thai PG-SGA was finalized.

Step 4: Back translation. The first draft of the Thai version of the PG-SGA was back translated by two independent native English speakers with no prior knowledge on the scored PG-SGA from certified translation centers (Chalermprakiet Center of Translation and Interpretation, Faculty of Arts, Chulalongkorn University and Translation and Interpretation Center, Faculty of Liberal Arts, Mahidol University).

Step 5, 6: Back translation review and harmonization. The project manager and key in-country person reviewed the back translation results against the original instrument together with the instrument developer and key developer of the PG-SGA, in order to detect any translation discrepancies and ensure the conceptual equivalence between the English and Thai versions. Then the second draft of the Thai version of the PG-SGA was approved for further exploration.

Step 7: Cognitive debriefing. The second draft Thai PG-SGA was explored for comprehensibility and difficulty perceived by cancer patients and healthcare professionals, and the content validity was assessed by professionals only. This study was approved by the Faculty of Medicine, Chulalongkorn University (IRB No.259/59).

Cancer patients: 50 hospitalized cancer patients admitted to the Division of Therapeutic Radiation and Oncology, King Chulalongkorn Memorial Hospital during December 2016 and January 2017 were selected through convenience sampling. The inclusion criteria were as follows: age greater than 18 years, willing to participate in the

study, and able to provide written consent. Participants being illiterate and unable to communicate in the Thai language were excluded.

Healthcare professionals: 50 healthcare professionals were selected from applications advertised by poster invitation to participate in the research at King Chulalongkorn Memorial Hospital. The inclusion criteria were: being a healthcare professional, e.g. physician, nurse, dietitian, or student in nutrition and dietetics, willing to participate in the study, and being able to provide written consent.

Data collection: Cancer patients and healthcare professionals assessed each item of the patient-generated component and professional component of the Thai PG-SGA respectively. Perceived comprehensibility (understandability of wording used in the instrument) and difficulty (ability to complete the instrument) were explored by using a 4-point scale. For comprehensibility, the Thai version of PG-SGA was evaluated with the following scale: 1- Not comprehensible at all / Not clear at all; 2- Not comprehensible / Not clear; 3- Comprehensible / Clear; 4- Very comprehensible / Very clear. For difficulty the scale was as follows: 1- Very difficult; 2- Difficult; 3- Easy; 4- Very easy. Score 1 and 2 of the four point scale were considered “not present” while the scores 3 and 4 were considered “present”. The comprehensibility and difficulty of each item was analyzed by the Item Comprehensibility Index (I-CI) and Item Difficulty Index (I-DI) which are calculated from the number of “present” items divided by the total number of participants (Polit, Beck, 2006; Lynn, 1986). This results in a score ranging from 0 to 1 ($>$ 0.78 is considered excellent, $<$ 0.78 means further analysis of the item is required) (Lynn, 1986). Thereafter, I-CI and I-DI were summarized as Scale Comprehensibility Index (S-CI) and Scale Difficulty Index (S-DI) respectively. Scores of S-CI $\geq$ 0.80 and S-DI $\geq$ 0.80 are considered acceptable scores, and S-CI $\geq$ 0.90 and S-DI $\geq$ 0.90 are considered excellent scores (Polit, Beck, 2006; Lynn, 1986).

Subsequently, relevance was assessed by the professionals only by using a 4-point scale as: 1- Very irrelevant; 2- Irrelevant; 3- Relevant; 4- Very relevant, and Item Content Validity Index (I-CVI) and Scale Content Validity Index (S-CVI) were calculated (Polit, Beck, 2006; Lynn, 1986). Items with no response were excluded from the calculations.

Step 8: Review of the cognitive debriefing results, content validity, and intra-rater reliability. The project coordinator and the corresponding author analyzed and reviewed the results obtained from patients and professionals.

Step 9, 10: Proofreading and final report of translation. The key country person and the key developer of the original PG-SGA ensured the final translation and corrected the format as regards scale and item levels for quality control. Finally, the project manager wrote the final report that clarified methodology used throughout the process.

Statistical analysis

All data were analyzed using the IBM Statistical Package for the Social Sciences (SPSS) version 22.0 for Windows. Demographic data and disease characteristics were reported as frequency and percentages, mean and standard deviation (SD) values.

Results

Translation and cultural adaptation

A Thai translation and cultural adaptation of the original English version of the PG-SGA was developed, and was tested for comprehensibility, difficulty, relevance, and intra-rater reliability. The forward translation step resulted in the two Thai versions of the Scored PG-SGA. In the reconciliation process, consensus by the expert panel was reached and provided the first draft of the Thai PG-SGA version. Then, the back translation, back translation review and harmonization processes were conducted, which resulted in 4 additional cultural adaptations: three items in the patient-generated component and one item in the professional component. In the patient-generated component the items requiring cultural adaptation were: "only nutritional supplements", "mouth sores", and "the remainder of this form is to be completed by your doctor, nurse, dietitian, or therapist". The word "only nutritional supplements" was misunderstood, as a dietary supplement such as vitamin/minerals. Therefore, "*เฉพาะอาหารเสริมเท่านั้น*" was replaced by"*เฉพาะอาหารเสริมทางการแพทย์เท่านั้น*" which conveys the meaning of oral nutrition supplements or medical foods for the patient. The meaning of "mouth sores" was ambiguous. It is understood as "hurting mouth". Then, "*เจ็บปาก*" was replaced by "*เจ็บแสบในช่องปาก*" to help clarify that the pain is located in the whole mouth cavity. As for the explanation of who should complete the professional component, the word "therapist", which means physical therapist in the original PG-SGA, was not relevant in the Thai setting because physical therapists usually do not use this form in their practice. So, the word "*บุคลากรทางแพทย์อื่น*" was utilized to refer to other healthcare professionals. For the professional component, the word "presence of trauma" was translated as "minor injury" which denotes mild level of injury. To tackle with this misinterpretation, the word "(trauma)" was added after the Thai phrase "*มีการบาดเจ็บ*".

Demographic data

50 cancer patients (aged 54.2±12.7 years) were recruited. Slightly more females (54%) than males (46%) participated. The most frequent types of cancer were gynecologic cancers (18%), followed by cancers of the lung (16%), head/neck and esophagus (14% each) and breast (10%). The majority of the participants had a stage II, III, or IV tumor (60%). Regarding education, two-third of the patients had completed primary and secondary school (62%). Almost half of the patient occupations were employees and civil servants (48%).

All 50 professionals included 3 disciplines in similar proportion, physicians (32%), nurses (34%), and dietitians/nutritionist/students in nutrition and dietetics (34%). The majority of the healthcare professionals (78%) were working in the university hospital, with a variety of current expertise including oncology, geriatrics, nephrology, and surgery. As for the familiarity with the PG-SGA, 31 professionals (62%) were not familiar with the PG-SGA. Most of them were physicians, followed by nurses and dietitians/nutritionists/students. 56% of all professionals reported having no experience of the PG-SGA in clinical practice.

Comprehensibility and difficulty

All 50 patients evaluated the patient-generated component of the Thai PG-SGA. The scale index scores showed that all items of the patient component were perceived excellent with regard to comprehensibility (S-CI=0.99;

range S-CI=0.96-1.00) and excellent in easiness to complete (S-DI=0.95; range S-DI=0.90-1.00) (Table 1). All items of the Thai PG-SGA had I-CI and I-DI > 0.78, indicating an excellent level of comprehensibility and difficulty.

Table 1 Evaluation of comprehensibility and difficulty by cancer patients (n=50)

Items		I-CI†	I-DI†
Box 1 Weight	Current weight	1.00	0.96
	Height	1.00	0.96
	Weight 1 month ago	1.00	0.96
	Weight 6 months ago	0.98	0.96
	Weight change in past 2 weeks	1.00	1.00
Box 2 Food intake	Intake change compared to normal intake during the past month	0.98	0.94
	Actual food intake	0.96	0.90
Box 3 Symptoms	Problems that prevented patient from eating enough	0.99	0.92
Box 4 Activities and function	General activity over the past month	0.99	0.98
		S-CI‡	**S-DI‡**
		0.99	**0.95**

Table 2 Evaluation of comprehensibility and difficulty by healthcare professionals (n=50)

Items	I-CI†	I-DI†
Worksheet 1 : Weight		
☐ Scoring weight loss	0.97	0.85
Worksheet 2 : Disease and its relation to nutritional requirements		
☐ Disease characteristics (average of 7 items)	0.92	0.84
☐ Relevant diagnoses	0.90	0.78
☐ Stage of primary illness	0.90	0.80
☐ Age	0.98	0.88
Worksheet 3 : Metabolic demand		
☐ Fever	0.88	0.80
☐ Fever duration	0.86	0.76
☐ Use of Corticosteroids	0.88	0.78
Worksheet 4 : Physical exam		
☐ Muscle status (average of 8 items)	0.91	0.68
☐ Fat status (average of 4 items)	0.91	0.68
☐ Fluid status (average of 4 items)	0.93	0.70
Worksheet 5 : PG-SGA Global Assessment Categories		
☐ Stage A: Well nourished; Stage B: Moderate/suspected malnutrition; Stage C: Severely malnourished	0.98	0.90
Nutrition Triage Recommendations		
☐ Description and recommendations (average of 5 items)	0.99	0.84
	S-CI‡	**S-DI‡**
	0.92	**0.79**

I-CI: Item Comprehensibility Index; I-DI: Item Difficulty Index; S-CI: Scale Comprehensibility Index; S-DI: Scale Difficulty Index; †: I-CI and I-DI $>$ 0.78 are considered excellent and an item score < 0.78 requires further analysis of the item; ‡: S-CI and S-DI $\geq$ 0.90 are considered excellent and $\geq$ 0.80 are considered acceptable

For the evaluation of the professional component of the Thai PG-SGA, the professionals reported excellent comprehensibility (S-CI=0.92; range S-CI=0.86-0.99), and borderline acceptable difficulty to complete (S-DI=0.79; range S-DI=0.68-0.90) (Table 2). All items of Worksheet 4, e.g. the physical examination (muscle, fat, and fluid status), was perceived as moderately difficult (I-DI=0.68-0.70). The item on fever duration in Worksheet 3 had a slightly low borderline level of difficulty (I-DI = 0.76). Moreover, the item on relevant diagnoses in Worksheet 2 and the item on corticosteroids usage in Worksheet 3 were perceived as borderline difficult (I-DI= 0.78).

Content validity

The professionals in this study reported the content validity of the Thai PG-SGA in assessing malnutrition in cancer patients as excellent (S-CVI= 0.95). Scores for content validity on the individual items ranged from 0.86 to 1.00 as shown in Table 3.

Table 3 Evaluation of content validity (relevance) by healthcare professionals (n=50)

Items	I-CVI†	Items	I-CVI†
Box 1 Weight		**Worksheet 2 : Disease and its relation to nutritional requirements**	
☐ Current weight	1.00	☐ Disease characteristics (average of 6 items)	0.97
☐ Height	0.90	☐ Relevant diagnoses	0.94
☐ Weight 1 month ago	0.96	☐ Stage of primary illness	0.94
☐ Weight 6 months ago	0.96	☐ Age	0.90
☐ Weight change in past 2 weeks	0.98	**Worksheet 3 : Metabolic demand**	
Box 2 Food intake		☐ Fever	0.97
☐ Intake change compared to normal intake during the past month	1.00	☐ Fever duration	0.86
☐ Actual food intake	0.97	☐ Use of Corticosteroids	0.90
Box 3 Symptoms		**Worksheet 4 : Physical exam**	
☐ Problems that prevented patient from eating enough	0.95	☐ Muscle status (average of 8 items)	0.92
Box 4 Activities and function		☐ Fat status (average of 4 items)	0.92
☐ General activity over the past month	0.94	☐ Fluid status (average of 4 items)	0.94
Worksheet 1 : Weight		**Worksheet 5 : PG-SGA Global Assessment Categories**	
☐ Scoring of weight loss	0.97	☐ Stage A: Well nourished; Stage B: Moderate/suspected malnutrition; Stage C: Severely malnourished	1.00
		Nutrition Triage Recommendations	
		Description and recommendations (average of 5 items)	0.98
			S-CVI‡ 0.95

I-CVI: Item Content Validity Index; S-CVI: Scale Content Validity Index; †: I-CVI $>$ 0.78 is considered excellent and an item score $<$ 0.78 requires further analysis of the item; ‡: S-CVI $\geq$ 0.90 is considered excellent and $\geq$ 0.80 is considered acceptable

After the cognitive debriefing step, the project coordinator and the corresponding author analyzed and reviewed the results. Proofreading and finalization was completed by the key country person and the key developer of the original PG-SGA regarding the format and adjustment of the letter positioning and to maintain consistency with the original PG-SGA template. The Thai version of the PG-SGA is now available online at www.pt-global.org

Discussion

This study established the first official Thai translation of the Scored PG-SGA, utilizing the ISPOR Principles. The original English version of the PG-SGA was successfully translated and culturally adapted to the Thai setting, as demonstrated by the excellent comprehensibility and difficulty as perceived by patients, and excellent comprehensibility and borderline acceptable in difficulty by professionals. In addition, the Thai PG-SGA scored excellent on content validity, i.e. relevance. The results from the patient component of the Thai PG-SGA are consistent with the results from the PG-SGA translated and culturally adapted for the Dutch setting (S-CI=0.99, S-DI=0.96) and the Portuguese setting (S-CI=0.94, S-DI=0.94) (Pinho, 2015; Sealy et al., 2017; Silva, Pinho, 2015). It appears that the patient component of the Thai PG-SGA successfully describes the content of the instrument without any major adaptation.

The scores on comprehensibility and difficulty perceived by professionals were in the middle range of the results from the testing of the Dutch PG-SGA (S-CI=0.81, S-DI=0.55) and the Portuguese PG-SGA (S-CI=0.99, S-DI=0.97) (Pinho, 2015; Sealy et al., 2017; Silva, Pinho, 2015). Most professionals reported that some barriers emerged when completing the Thai PG-SGA. The lowest scores on difficulty were found from the physical examination, i.e. Worksheet 4, which is consistent with the Dutch and Portuguese findings (Pinho, 2015; Sealy et al., 2017; Silva, Pinho, 2015). As for the overall borderline acceptable scores for difficulty as perceived by professionals, we speculated that professionals may lack knowledge and experience in completion of the items in the professional component of the Thai PG-SGA, which is similar to the Dutch and Portuguese studies. In Thailand, the tools used for nutrition screening/assessment were found to be varied and the PG-SGA at present does not appear to be a commonly used assessment tool (Chittawatanarat et al., 2016). Therefore, training to improve the level of skills or knowledge and providing instruction for the professional component may improve the difficulty of the Thai PG-SGA in healthcare professionals (Acquadro et al., 2014). In fact, training on the use of PG-SGA was found to improve the level of both comprehensibility and difficulty in the Dutch and Portuguese setting (Sealy et al., 2017; Pinto et al., 2016). As for the content validity in assessing malnutrition, the results from professionals indicated that they perceived it as excellent, which is comparable to the findings from the use of the PG-SGA translated and culturally adapted for the Portuguese setting (S-CVI=0.98) (Pinho, 2015; Silva, Pinho, 2015).

The strength of this study is that each step of translation and cultural adaptation was carefully performed in line with the ISPOR Principles, which included multiple translation processes and was tested in both perspective from cancer patients and experts from healthcare professionals. The study was developed together with the copyright holder of the PG-SGA and an international expert on translation and cultural adaptation of the PG-SGA for ensuring the conceptual, semantic, and operational equivalence with the original version. As a consequence, this method has led to the provision of a good quality translated instrument.

Conclusion

The original English version of the PG-SGA was successfully translated and culturally adapted for the Thai setting, using the ISPOR Principles. The Thai version of the PG-SGA showed conceptual equivalence to the original English PG-SGA, and is considered easy to use and comprehensible by cancer patients and healthcare professionals. Moreover, this instrument was found to be easy to complete but borderline difficult for some items of the professional component, which requires training on the PG-SGA for professionals prior to use.

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