Food intake by Patient-Generated Subjective Global Assessment (PG-SGA)corresponds to energy and protein intake as well as weight change in patients with advanced cancer

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Original Article

Food intake by Patient-Generated Subjective Global Assessment (PG-SGA) corresponds to energy and protein intake as well as weight change in patients with advanced cancer

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SUMMARY

Background & aims: The aim of this study was to test how well the Patient-Generated Subjective Global Assessment (PG-SGA) question about food intake correlates with a well-established measurement of food intake. Furthermore, we wanted to examine if there were any associations between the patients ratings to the question and weight change.
Methods: Data at baseline and after 4–6 weeks was drawn from two studies which combined provided a sample of 85 patients with lung and pancreatic cancer; one of the studies were an intervention study, the other a prospective, observational study. All patients completed the PG-SGA questionnaire, and rated their food intake the past month as unchanged, increased or less than usual. Energy and protein intake was estimated based upon a 24-h dietary recall.

Abbreviations: SGA, Subjective Global Assessment; PG-SGA, Patient Generated Subjective Global Assessment; KPS, Karnofsky Performance Status; ONS, Oral Nutritional Supplements; WHO, World Health Organization.

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Results: Patients reporting a food intake less than usual had a lower energy (24.2 vs 30.3 kcal/kg/day, $p = 0.02$) and protein (1.0 vs 1.2 g/kg/day, $p = 0.07$) intake at baseline compared to patients reporting unchanged or increased food intake. After comparison at 4–6 weeks, patients reporting a food intake less than usual, had a lower energy (24.5 vs 31.7 kcal/kg/day, $p = 0.07$) and protein (0.9 vs 1.3 g/kg/day, $p = 0.003$) intake. Patients reporting a food intake less than usual the past month lost more weight than patients with an unchanged or increased intake (−2.6 kg versus 0.7 kg respectively, $p < 0.001$).

Conclusions: This study show that self-reported food intake measured by PG-SGA corresponds to measured energy and protein intake as well to weight change on a group level. This indicates that patients self-report of food intake can be used as a valid indication of food intake in patients with advanced cancer. Further investigation of the psychometric properties of the question is necessary to evaluate how well the question performs on an individual level.

1. Introduction

Patients are the best sources of information about their own symptoms. This recognition is based on several studies that show systematic underestimation of patient's frequency and severity of symptoms by health care providers [1,2]. The use of patient reported outcome measures (PROMs) is therefore highly recommended in both clinical practice and research [3]. In relation to nutrition in cancer, PROMs are mainly used to provide information about weight change and symptoms that may cause reduced food intake such as anorexia and nausea [4]. Despite strong recommendations in clinical guidelines on nutrition in cancer [5], information on food intake is rarely collected. One of the main reasons for this is probably demanding dietary assessment methods [6]. It is therefore a need for reliable and valid PROMs that reflects actual food intake to simplify the collection of this important information.

The Patient-Generated Subjective Global Assessment (PG-SGA) is widely used to assess and monitor (risk for) malnutrition in cancer patients [7]. PG-SGA has been extensively validated and has shown high degrees of ability to predict clinical outcomes such as shorter survival, postoperative complications and reduced tolerance to chemotherapy [8–12]. The first part of PG-SGA is self-reported by the patient and may be named a PROM [7,9,13]. It includes questions about current and former body weight, the patient's appraisal of own food intake and current type of food/nutrient, nutritional impact symptoms and activities and function [7]. Food intake is covered by the question: “As compared to normal, I would rate my food intake during the past month as either unchanged, more than usual or less than usual”.

To the best of our knowledge, the psychometric properties of the question regarding food intake is not extensively evaluated. Although reliability and validity are essential psychometric properties for any PROM [14], information about how well the question from PG-SGA correlates with well-established measurements of food intake – so called criterion related validity – is lacking [14]. The aim of this study was to evaluate correlation of self-reported food intake by PG-SGA with actual energy and protein intake measured with 24-h dietary recall in patients with advanced cancer. As a further indicator of validity, we also aimed at evaluating the association between food intake by PG-SGA and change in body weight after 4–6 weeks.

2. Methods

2.1. Patients and study design

Data from two different studies were pooled; one multimodal intervention study and one prospective observational study [15,16]. The multimodal intervention study was a multicentre, open, randomized phase II study aiming to investigate the feasibility of a 6-week multimodal intervention for patients with cachexia (ClinicalTrials.gov: NCT01419145) [15]. This study included 46 patients with advanced pancreatic and lung cancer starting chemotherapy, and was conducted between 2011 and 2014. The intervention group received oral nutritional supplements (ONS), Celecoxib and physical exercise, while the control group received standard cancer care. The main goal of the nutritional intervention was to promote energy balance and ensure optimal protein intake [15].

The observational study investigated nutritional challenges in 39 patients with advanced pancreatic cancer and was conducted at a single centre between 2006 and 2008 [16]. The patients were recruited upon referral and monitored every fourth week. All patients received treatment with palliative intent, including dietary counselling (increased meal frequency, energy dense foods and ONS) whenever indicated. Enteral tube feeding or parenteral feeding were not initiated in any of the studies.

2.2. Data collection

At baseline and after 4–6 weeks, patients were instructed to complete the PG-SGA in the intervention study and SGA in the observational study. The question on self-reported food intake is “As compared to normal, I would rate my food intake during the past month as: unchanged, more than usual or less than usual”.

Energy and protein intake was assessed with 24-h dietary recall in both studies and performed by trained study personnel [17]. Patients were asked to recall all food and beverage intake the previous day from midnight to midnight, including ONS. Estimation of portion sizes was performed using a photographic booklet and household measures with a supplementary list of household measurements in weight. The collected information on dietary intake was analyzed by trained personnel using the software Aivo 2000 (Aivo AB, Stockholm, Sweden) or Dietplan 6 Pro. The Norwegian food composition tables were used as the nutrient database software program [18]. Energy and protein intake is presented as total daily intake (kcal/day) and as the total daily intake per kg body weight (kcal/kg/day). Total energy intake per body weight was included due to the diverse patient group in terms of age and gender, and in order to assess if the patients reporting less than usual are more likely to have an inadequate energy intake and more likely to lose body weight. To evaluate predictive validity weight change was used as a criterion. At baseline, self-reported weight change last 6 months was taken from PG-SGA/SGA and actual body weight was assessed using an electronic scale in both studies and patients were instructed to wear light clothes and no shoes at both baseline and after 4–6 weeks. Body mass index (BMI) was measured from body weight (kg)/height (m^2).

In the intervention study, the Karnofsky Performance Status (KPS) scale was used to evaluate physical performance status, while the World Health Organization (WHO) performance status scale was used in the observational study. The score of KPS from the intervention study was converted to the WHO score using the recommended method for conversion [19].

2.3. Statistical analysis

Patient characteristics are presented using descriptive statistics. The categories of self-reported food intake “unchanged” or “more than usual” were combined as one group in the analysis. Correlation between PG-SGA food intake and actual energy intake, protein intake and change in body weight, were assessed separately at baseline and at week 4–6. Student's t-test for independent samples was used to compare means. The categories of self-reported food intake “unchanged” or “more than usual” were combined as one group in the analysis. Simple linear regression models with actual energy intake, protein intake and change in body weight as dependent variables were used to calculate variance

explained by self-reported PG-SGA food intake. Statistical analysis was performed using SPSS version 24.0, 2016 (SPSS Inc, Chicago, IL, USA).

3. Results

The baseline characteristics of the 85 included patients (38 females and 47 males) from the two studies are summarized in Table 1. All patients had data on weight loss and SGA/PG-SGA at baseline, while 83 (98%) had data on energy and protein intake. At 4–6 weeks, 67 (79%) patients had data on body weight and SGA, 62 (73%) on energy and protein intake. All patients had a significant reduction in mean BMI, body weight and WHO performance status from baseline to after 4–6 week ($p < 0.05$ for all variables) (Table 2).

Table 3 and Fig. 1 shows energy and protein intake at baseline and after 4–6 week comparing patients reporting a food intake less than usual and unchanged or increased food intake. At baseline, patients reporting a food intake less than usual had a lower energy and protein intake compared to patients with an unchanged or increased food intake ($p < 0.05$ for all variables except for protein/kg/day with $p = 0.07$). At 4–6 weeks, patients reporting a food intake less than usual had a lower protein intake ($p < 0.05$) and a lower but not statistically significant ($p = 0.07$) energy intake (kcal/kg/day). Explained variation (R^2) ranged from 0.06 to 0.14 for energy and protein intake at both time points (Table 3).

At baseline, mean (SD) weight loss the last 6 months was 10.7 (7.8) % for the patients reporting an intake less than usual and mean (SD) 6.9 (8.2) % for patients reporting an unchanged or increased food

Table 1
Baseline characteristics of the 85 patients.

Characteristics	Value
Age, years, mean (SD)	60.8 (8.8)
Gender, female, n (%)	38 (44.7)
Diagnosis, n (%)	
NSCLC stage III	5 (5.9)
NSCLC stage IV	21 (24.7)
Pancreatic cancer stage I-III	11 (12.9)
Pancreatic cancer stage IV	9 (10.6)
Locally unresectable pancreatic cancer	17 (20.0)
Metastatic pancreatic cancer	16 (18.8)
Recurrent disease after total pancreatic resection	6 (7.1)
Percentage weight loss last 6 months, mean (SD)	9.4 (8.1)
Weight loss last 6 months, n (%)	
<5%	24 (28.2)
5–10%	24 (28.2)
>10%	37 (43.5)

NSCLC, Non-Small Cell Lung Cancer; n, number; SD, Standard Deviation.

Table 2
Nutritional and performance status at baseline and after 4–6 weeks.

Characteristics	Baseline (n = 85)	4–6 weeks (n = 71)
BMI, mean (SD)	23.5 (3.8)	22.96 (3.9)
Weight (kg), mean (SD)	68.2 (13.0)	67.1 (12.8)
ΔWeight (kg), mean (SD)		−0.7 (3.0)
WHO performance status, n (%)		
0	20 (23.5)	11 (15.7)
1	56 (65.9)	41 (58.6)
2	9 (10.6)	17 (24.3)
3	0 (0.0)	1 (1.4)

n indicates number of individuals; BMI, Body Mass Index (measured as kg/m^2); SD, Standard Deviation; WHO, World Health Organization; Δ = differences between baseline and 4–6 weeks.

Table 3
Energy and protein intake and weight change according to self-reported food intake at baseline and after 4–6 weeks.

	Baseline[a]		*p*	R^2	After 4–6 weeks[b]		*p*	R^2
	More than usual/ unchanged (n = 55)	Less than usual (n = 28)			More than usual/ unchanged (n = 34)	Less than usual (n = 28)		
Energy intake (kcal/day)	2049 (785)	1572 (704)	*0.006*	0.09	2035 (898)	1702 (711)	*0.11*	0.04
Energy intake (kcal/kg/day)	30.3 (11.8)	24.2 (11.0)	*0.02*	0.06	31.7 (13.0)	24.5 (13.2)	*0.07*	0.06
Protein intake (g/day)	83.4 (37.8)	65.0 (33.1)	*0.03*	0.06	86.0 (37.8)	64.2 (31.9)	*0.02*	0.09
Protein intake (g/kg/day)	1.2 (0.5)	1.0 (0.5)	*0.07*	0.04	1.3 (0.55)	0.9 (0.48)	*0.003*	0.14
Weight change	6.9 (8.2) %[c]	10.7 (7.8) %	*0.04*	0.05	0.7 (2.2) kg[d]	−2.6 (2.9) kg	*<0.001*	0.30

[a] Student's t-test comparing categories at baseline.
[b] Student's t-test comparing categories after 4–6 weeks. R^2 = explained variance. Data shown as mean (SD).
[c] Weight loss in % last 6 months.
[d] ΔWeight in kg from baseline to 4–6 weeks.

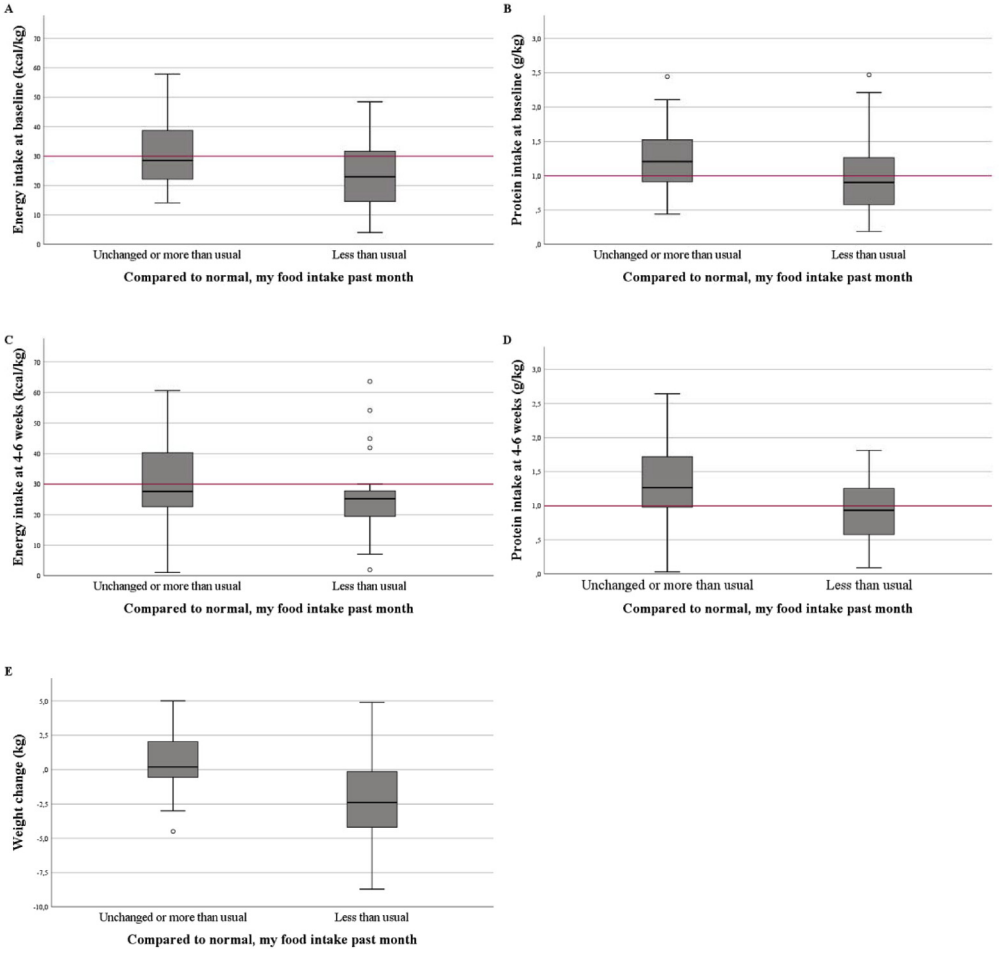

Fig. 1. Box plots of Table 3. (A) Energy intake (kcal/kg) at baseline; (B) Protein intake (g/kg) at baseline; (C) Energy intake (kcal/kg) at week 4–6; (D) Protein intake (g/kg) at week 4–6; (D) weight change from baseline to week 4–6 (kg). Number of patients equal to Table 3. Red line indicates 30 kcal/kg for energy and 1 g/kg for protein.

intake the past month ($p = 0.04$). After 4–6 weeks, patients who reported a food intake less than usual the past month had a mean (SD) decrease in body weight of 2.6 (2.9) kg compared to patients with an unchanged or increased intake that increased their body weight by 0.7 (2.2) kg ($p < 0.001$) (Table 3 and Fig. 1). Explained variation (R^2) was 0.05 for weight change at baseline and 0.30 for weight change after 4–6 weeks (Table 3).

4. Discussion

In this study we found that self-reported food intake by PG-SGA was associated with energy and protein intake measured by 24-h recall on a group level in patients with advanced cancer. We also found associations between self-reported food intake and change in body weight both at baseline and after 4–6 weeks.

To our knowledge, this is the first study to validate the food intake question from PG-SGA by comparing the question with established methods to measure energy and protein intake. Previously, only one study has compared self-reported food intake to measured energy intake (using a 3-day food diary) [20]. In this study food intake from PG-SGA was not used, but a similar scoring of food intake, with the alternatives being normal, reduced or poor/minimal. Results from a small sub-group of 22 patients showed that a reduced or poor/minimal intake was associated with lower energy ($p = 0.04$, no effect size shown) and protein intake ($p = 0.003$, no effect size shown) compared to self-reported normal intake [20].

A statistical significant finding does not in itself provide information about the clinical relevance of research results. In the present study, we found that the difference between the group reporting eating less than usual at baseline and the group reporting increased or unchanged food intake was approximately 500 kcal/day. A difference of 500 kcal is quite large and would most likely be of clinical relevance, as a rule of the thumb is that a deficit of 500 kcal per day leads to a weight loss of approximately 500 g in a week [21]. The clinical relevance of this finding is also confirmed by a difference in weight change between the two groups at 4–6 weeks. The group of patients reporting food intake less than usual at this time point had lost in average −2.6 kg with a high explained variance $R^2 = 0.30$, which strengthens the validity of the PROM. The group reporting unchanged/increased food intake had a stable weight and an average intake of 30.3 kcal/kg/day which is in accordance the recommendation of intakes above ≥29 kcal/kg/day (120 kJ/kg/day) considered required for body weight stabilization in cancer patients [22]. These findings help to substantiate the question as a measure that can be used to provide information about food intake from the patients.

Evidence for an instrument's validity is not absolute, but falls along a continuum from “no evaluation” to “full evaluation” for a given study population [23]. Thus, validity may therefore be described as “continuous” rather than “dichotomous” psychometric indices. For this reason, claiming that an instrument is completely “valid” is inaccurate. Similarly, saying an instrument has been “validated” conveys no information other than to say its performance or psychometric properties have been evaluated. Validation may be looked upon as a process and well-validated PROMs should have several important properties as they are increasingly used in clinical decision-making, clinical research and approval of new therapies [24]. In this study we have demonstrated that the question perform well on a group level but further validation studies are necessary to evaluate how well it performs on an individual level.

In the present study we used the 24-h dietary recall as a criterion when evaluating the validity. It could be argued that a criterion that covers just one day is not comparable with PG-SGA question that is supposed to cover the last month. However, studies investigating psychometric properties of different PROMs have shown a high degree of correlation between patient ratings covering 24 h and longer rating periods [25]. One explanation is that the condition in question does not change much over time or that the patient's answer tends to reflect the most recent period. One other objection to using 24-h dietary recall is that records of food intake for a single day are not representative of a person's usual intake due to day-to-day variation [25]. However, our prospective design in both studies disclosed a high degree of monotony in the individual patient's food choice [16]. In addition, both the 24-h recall method and the question about food intake from PG-SGA are retrospective methods with the same methodological flaws, e.g. gaps and distortions in the memories of intake. Prospective methods of food

intake (3–7 days food diaries) would cover a longer time period and theoretically be a better criterion method [26]. Nevertheless, dietary records tend to be less accurate over time, and due to the concern for poor registration compliance in this frail patient population with advanced cancer, 24-h dietary recall was chosen. The advantages of using the 24-h dietary recall is that it usually has a high respondent rate and respondent burden is fairly low as the time used to complete the interview is short (around 20 min) [27]. A disadvantage is that 24-h dietary recalls reflect intake only on a group level [17], which was in accordance with our observations with low explained variance and large variations within groups. Self-reported food intake can therefore not replace acknowledge food registration methods in cases where more information is needed as mentioned above.

The patients' interpretation of the question "*As compared to normal, I would rate my food intake during the past month as either unchanged, more than usual or less than usual*" can vary considerably. The perception of the words "normal" and "usual" food intake can be affected by whether patients' have had a reduced food intake over a longer period, and that food intake could rapidly change during a month. However, even with a substantial variation in energy and protein intake at both time points in this study, there was a significant difference between the groups, justifying further studies exploring this simple question in order to reduce patient burden and prompt implementation of assessments of nutritional intake in clinical studies. We encourage others to validate this question further and in other populations as well.

5. Conclusion

This study demonstrates an association between self-reported food intake from SGA/PG-SGA and energy and protein intake measured from 24-h dietary recall on a group level. This association was supported by weight loss in the group reporting food intake less than usual and stable weight in the group reporting unchanged/increased food intake. This validation is of clinical relevance since the question regarding food intake is a PROM that can easily be implemented into clinical studies. Using a PROM to collect info about food intake would also minimize the burden of time consuming assessments, which is of importance in patients with advanced cancer.

Statement of authorship

KM, AB, TSS and TRB were responsible for the conception and design; recruitment and data collection was done by AB, GBS, BL, TRB, TSS and SK; KM conducted the statistical analysis; KM, TRB, AB and TSS wrote the paper; all authors read and critically revised the manuscript and approved the final manuscript, and had primary responsibility for final content.

Conflict of interest

The authors declare that they have no conflict of interests.

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Ethics approval and consent to participate

The studies received regional ethical approval from Regional Committees for Medical and Health Research Ethics in Norway and National Research Ethics Service in the United Kingdom. The intervention study also received medical agency approval. Written consent was obtained from all patients.

Data references

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Appendix A. Supplementary data

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