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ORIGINAL COMMUNICATION

The scored Patient-generated Subjective Global Assessment (PG-SGA) and its association with quality of life in ambulatory patients receiving radiotherapy

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Objective: To evaluate the scored Patient-generated Subjective Global Assessment (PG-SGA) tool as an outcome measure in clinical nutrition practice and determine its association with quality of life (QoL).
Design: A prospective 4 week study assessing the nutritional status and QoL of ambulatory patients receiving radiation therapy to the head, neck, rectal or abdominal area.
Setting: Australian radiation oncology facilities.
Subjects: Sixty cancer patients aged 24–85 y.
Intervention: Scored PG-SGA questionnaire, subjective global assessment (SGA), QoL (EORTC QLQ-C30 version 3).
Results: According to SGA, 65.0% (39) of subjects were well-nourished, 28.3% (17) moderately or suspected of being malnourished and 6.7% (4) severely malnourished. PG-SGA score and global QoL were correlated ($r = -0.66$, $P < 0.001$) at baseline. There was a decrease in nutritional status according to PG-SGA score ($P < 0.001$) and SGA ($P < 0.001$); and a decrease in global QoL ($P < 0.001$) after 4 weeks of radiotherapy. There was a linear trend for change in PG-SGA score ($P < 0.001$) and change in global QoL ($P = 0.003$) between those patients who improved (5%) maintained (56.7%) or deteriorated (33.3%) in nutritional status according to SGA. There was a correlation between change in PG-SGA score and change in QoL after 4 weeks of radiotherapy ($r = -0.55$, $P < 0.001$). Regression analysis determined that 26% of the variation of change in QoL was explained by change in PG-SGA ($P = 0.001$).
Conclusion: The scored PG-SGA is a nutrition assessment tool that identifies malnutrition in ambulatory oncology patients receiving radiotherapy and can be used to predict the magnitude of change in QoL.
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Keywords: outcome measures; scored Patient-generated Subjective Global Assessment; quality of life; nutritional assessment; cancer

Introduction

The incidence of malnutrition in patients with cancer ranges from 40 to 80% (Ollenschlager *et al*, 1991; Baldwin *et al*, 2001) and most frequently occurs in patients with cancer of the head and neck (van Bokhorst-de van der *et al*, 1999). Malnutrition is of concern as it increases the risk of infections, treatment toxicity and health-care costs and decreases response to treatment, quality of life (QoL) and life expectancy (Grant *et al*, 1994; Ottery, 1996b; Rivadeneira *et al*, 1998; Nitenberg *et al*, 2000).

Medical care is no longer evaluated solely by traditional biomedical indicators (Niezgoda & Pates, 1993) and there is now a focus to have a broader concept of patient outcomes such as QoL (Aaronson *et al*, 1993). The impact of nutrition on QoL has not been well documented, however there are several studies that have observed poorer QoL outcomes in malnourished patients when compared with well-nourished

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patients (Ovesen *et al*, 1993; Larsson *et al*, 1995; Ohrn *et al*, 2001).

The scored Patient-generated Subjective Global Assessment (PG-SGA) is an adaptation of the validated nutrition assessment tool, Subjective Global Assessment (SGA; Detsky *et al*, 1987) and has been specifically developed for use in the cancer population (Ottery, 2000). It is an easy to use nutrition assessment tool that allows quick identification and prioritisation of malnutrition in hospitalized patients with cancer (Bauer *et al*, 2002). The PG-SGA score has been correlated with a number of objective parameters (percentage weight loss, body mass index (BMI)), measures of morbidity (survival, length of stay), and has a high degree of inter-rater reproducibility and high sensitivity and specificity when compared with other validated nutritional assessment tools (Ottery, 1996b; Persson *et al*, 1999; Ottery *et al*, 2002).

QoL was measured in this study using the European Organisation for Research and Treatment of Cancer (EORTC) quality of life questionnaire (QLQ-C30 Version 3; Aaronson *et al*, 1993). This is a valid and reliable cancer-specific QoL tool that has been used extensively in international clinical trials (Bjordal & Kaasa 1992; Hjermstad *et al*, 1995; Coates *et al*, 1997). The aim of this study was to evaluate the use of the scored PG-SGA as a measure of nutritional status in ambulatory patients receiving radiotherapy to the head, neck, abdominal or rectal area and to determine if there is an association between the PG-SGA and QoL scores.

Subjects and methods

All subjects (aged 18 y and over) commencing at least 20 fractions of radiotherapy to the head, neck, abdominal or rectal area at two radiation oncology centres in Australia were eligible for inclusion in the study over a 1 y period. Nutrition support was provided by a combination of nursing and dietetic intervention. Subjects receiving enteral or parenteral nutrition or requiring more than 5 days' hospitalization were ineligible to participate. Subjects who didn't speak English or those with emotional or cognitive problems were also excluded. Subjects were assessed at baseline (prior to radiotherapy) and after 4 weeks of radiotherapy treatment for nutritional status (SGA & PG-SGA, height and weight) and QoL (EORTC QLQ-C30). The study was approved by the Multi-disciplinary Ethics Committee of the hospital and the university and informed written consent was obtained from all participants.

Data collection

Information on age, gender, treatment and diagnosis was obtained from the medical record. Height was measured to the nearest 0.1 cm with a stadiometer (Harpenden, Holtain Ltd, Crosswell, Dyfed, UK). Body weight was measured to the nearest 0.1 kg (Tanita TBF-300P GS, Japan). Whether or not the subject had family/friend/carer support was assessed during the subject interview.

PG-SGA. A researcher experienced in using the scored PG-SGA (Ottery, 2000) assessed all subjects. Each subject was classified as either well-nourished (SGA A), moderately or suspected of being malnourished (SGA B), or severely malnourished (SGA C) and in addition, a total PG-SGA score was calculated. While the PG-SGA score and subjective global rating are related, they are independent assessment and triage systems. The scored PG-SGA consists of two sections: a patient-completed medical component and a clinician portion. The four medical components (weight loss, nutrition impact symptoms, intake and functional capacity) are completed by the patient using a check box format. The clinician eg physician, nurse or dietitian is required to complete the form (diagnosis, age and metabolic stress), conduct a physical examination assessing fat, muscle stores and fluid status and perform a global assessment of nutritional status (SGA). For each component of the PG-SGA, points (0–4) are awarded depending on the impact on nutritional status. Typical scores range from 0–35 with a higher score reflecting a greater risk of malnutrition and scores ≥ 9 indicating a critical need for nutrition intervention and symptom management.

EORTC QLQ-C30 (version 3) was used to assess QoL and completed as described by the authors (Aaronson *et al*, 1993). This patient-based instrument comprises 30 items and five functional scales (physical, role, cognitive, emotional and social), three symptom scales (fatigue, pain and nausea/vomiting), global health status and QoL scales. QLQ-C30 results are linearly converted to a score out of 100, with a higher score reflecting a higher QoL. The QoL scores were calculated according to the scoring manual (Fayers *et al*, 1999).

Statistical methods

Statistical analyses were carried out using SPSS Version 10, 2000 (SPSS Inc., Chicago, IL, USA). All continuous variables were normally distributed, except for percentage weight loss in the previous 6 months, which was transformed (natural log) to improve distribution. Paired student's *t*-tests were used to compare mean PG-SGA scores and global QoL scores at baseline and after 4 weeks of radiotherapy. *t*-Tests were also used to examine the association between PG-SGA, QoL and level of support. Chi-square tests were used to examine the association between PG-SGA and SGA. Analysis of variance (ANOVA) was used to compare PG-SGA scores and global QoL scores for each SGA classification. Correlation analysis was used to examine the association between PG-SGA score and global QoL score. Linear regression was used to examine the linear trend for PG-SGA score and QoL and SGA classification. General linear modelling (GLM) was used to determine the amount of variation in QoL that was attributable to PG-SGA accounting for gender; age; level of

support; BMI; percentage weight loss in the past 6 months; and baseline PG-SGA. Likewise, GLM was used to determine the amount of variation in change in QoL after 4 weeks of radiotherapy that was attributable to change in PG-SGA controlling for gender; age; support; change in BMI and change in percentage weight loss. Statistical significance was reported at the conventional $P<0.05$ level (two-tailed) and the power was adequate for this study at greater than 90%.

Results

Baseline characteristics of the study participants

A sample of 78 patients were eligible for the study and 60 agreed to participate: 85% (51) were male and 15% (9) female. The mean age was 61.9 ± 14.0 y. Eighty-eight percent of subjects were receiving radiotherapy to the head and neck (15% parotid, 13% oesophagus, 13% neck, 10% mouth, 8% vocal cords and 29% other head and neck areas) and 12% of patients were receiving radiotherapy to the abdominal or rectal area. Forty-seven percent of subjects were being treated with post-operative radiotherapy, 3% received pre-operative radiotherapy and the remaining 50% received radiotherapy only and had no plans for surgery. Eighty-five percent (51) of subjects had family/friend/carer support.

Baseline characteristics of the study participants are shown in Table 1. According to SGA, 65.0% (39) were well-nourished and 35.0% (21) malnourished, of which 28.3% (17) of patients were moderately or suspected of being malnourished and 6.7% (4) of patients were severely malnourished. There was a significant linear trend between PG-SGA scores for each of the SGA classifications ($F_{(1,58)}=119.3$, $P<0.001$). There was a significant correlation between PG-SGA score and global QoL ($r=-0.66$, $P<0.001$) at baseline.

Change in nutritional status and patient outcomes after 4 weeks of radiotherapy

There was a significant decrease in nutritional status according to PG-SGA score ($t_{(56)}=-5.79$, $P<0.001$) and SGA ($\chi^2_{(4)}=37.58$, $P<0.001$) after 4 weeks of radiotherapy. According to SGA, 56.7% (34) of subjects maintained their nutritional status, 33.3% (20) experienced a deterioration of nutritional status and 5% (3) had an improved nutritional status after 4 weeks of radiotherapy treatment (Table 2). Five percent (3) of subjects died or were lost to follow-up. The change in PG-SGA score was significantly different between those subjects who improved, maintained or deteriorated in nutritional status according to SGA ($F_{(3,53)}=23.48$, $P<0.001$). There was a significant correlation between change in PG-SGA score and change in global QoL ($r=-0.55$, $P<0.001$) after 4 weeks of radiotherapy. In subjects with little family/friend/carer support, the PG-SGA score was significantly lower ($t_{(58)}=3.39$, $P=0.049$) and QoL was trending towards significant ($t_{(58)}=-1.98$, $P=0.052$) but the low sample size for those subjects with no support may have attenuated this effect. No associations were found between change in PG-SGA ($t_{(55)}=1.44$, $P=0.155$) and change in QoL ($t_{(55)}=-0.57$, $P=0.571$) according to level of support.

There was a significant difference in global QoL scores after 4 weeks of radiotherapy ($t_{(56)}=3.94$, $P<0.001$) and a significant linear trend in change in global QoL score for those patients who improved, maintained or declined in nutritional status according to SGA ($F_{(1,55)}=9.5$, $P=0.003$).

To move one SGA category (ie improvement or deterioration), a change in PG-SGA score of (±9.0 (95% CI = 7.2–10.9) was required. In contrast, a change in PG-SGA score of 3.2 (95% CI = 2.2–4.2) was observed for those subjects who remained in the same SGA category after 4 weeks of radiotherapy.

The PG-SGA score at baseline was significantly correlated with baseline BMI ($r=-0.34$, $P=0.008$) and with percentage weight loss (transformed) in the previous 6 months ($r=0.53$, $P<0.001$). PG-SGA score at baseline significantly predicted 16% of the variation in global QoL four weeks after commencing radiotherapy ($F_{(1,55)}=4.9$, $P=0.032$).

Table 1 Baseline characteristics for patients receiving radiotherapy to the head, neck, abdominal or rectal areas

Baseline characteristics	
n	60
Age (y)	61.9 ± 14.0
Gender (M:F)	51 (85):9 (15)
BMI (kg/m^2)	25.8 ± 4.5
Percentage weight loss in previous 6 months	2.8 (0–21)
Global QoL/QLQ-C30)	70 ± 19.6
PG-SGA score	6.4 ± 5.2
Nutritional status	
SGA A well-nourished)	39 (65)
SGA B (suspected or moderately malnourished)	17 (28)
SGA C (severely malnourished)	4 (7)

Continuous variables presented as mean ± s.d. for normally distributed variables or median (range) for data that are not normally distributed. Categorical variables are presented as counts (%).

Association between nutritional status and QoL

There was a significant correlation between PG-SGA score and global QoL at baseline ($r=-0.66$, $P<0.001$) and after 4 weeks of radiotherapy ($r=-0.61$, $P<0.001$). A significant correlation was also observed between the change in PG-SGA score and change in global QoL after four weeks of radiotherapy ($r=-0.55$, $P<0.001$). Regression analysis determined that 26% of the variation of change in QoL was explained by change in PG-SGA score ($F_{(1,55)}=11.6$, $P=0.001$). Regression analysis showed that a change in PG-SGA score of nine resulted in a change of 17 in the QoL score.

Discussion

Scored PG-SGA as an outcome measure

One of the aims of this study was to evaluate the use of the scored PG-SGA as an outcome measure in ambulatory

Table 2 Change in PG-SGA score, global QoL score, body mass index (BMI) after 4 weeks of radiotherapy treatment to the head, neck, abdominal or rectal areas in patients whose nutritional status deteriorated, maintained or improved according to subjective global assessment classification

Variable	*Deteriorated nutritional status (n = 20)*	*Maintained nutritional status (n = 34)*	*Improved nutritional status (n = 3)*	P[a]
Change in PG-SGA score[b]	9.5 ± 4.2	2.2 ± 3.8	−5.7 ± 3.1	< 0.001
Change in global QoL score[c]	−18.9 ± 15.4	−6.6 ± 15.6	19.4 ± 29.3	0.003
Change in BMI	−0.6 ± 0.9	−0.2 ± 1.4	1.8 ± 1.4	< 0.001
Change in percentage weight loss of past 6/12[b]	−1.8 (−2.8, 0)	0.0 (−10, 12.4)	1.9 (−4, 6.6)	0.008

[a]Linear trend examined by regression analysis.
[b]A negative value for change in PG-SGA score or change in percentage weight loss in the past 6 months reflects an improvement in nutritional status.
[c]A negative value for change in QoL score reflects a deterioration in quality of life. Normally distributed variables are presented as mean ± s.d. and data that are not normally distributed are presented as median (min, max).

patients receiving radiotherapy to the head, neck, abdominal or rectal area. The scored PG-SGA was shown to be accurate at identifying the well-nourished patients from the malnourished patients. The prevalence of malnutrition in the study population was high with 35.0% of patients malnourished at the beginning of treatment. These findings were not unexpected as patients with gastrointestinal and head and neck cancer have the highest incidence of malnutrition and frequently experience weight loss (Shike, 1996; Andreyev *et al*, 1998).

The PG-SGA score can be used as an objective measure to demonstrate the outcome of nutrition intervention. Due to its categorical grouping, it is often difficult to demonstrate an improvement in nutritional status on the basis of SGA. However by performing serial measurements, the change in the PG-SGA score may be used to demonstrate subtle changes in nutritional status. In this study, the PG-SGA score required to move one SGA category was nine. A patient assessed at weekly intervals may be classified as moderately malnourished on both occasions, however the PG-SGA score may reflect clinically important changes.

In addition to SGA, concurrent validity of the PG-SGA score was measured against percentage weight loss in the previous 6 months and BMI. Weight loss does make up one of the domains in the scored PG-SGA, but accounts for less than 10% of the total score. The PG-SGA score was significantly correlated with percentage weight loss in the previous six months in the expected direction ($r = 0.53$, $P < 0.001$). Weight loss has been shown to be a major prognostic factor for decreased length of survival in patients with cancer (Evans *et al*, 1987; Andreyev *et al*, 1998). The scored PG-SGA was significantly but weakly correlated to BMI ($r = -0.34$, $P = 0.008$). However, BMI has limitations as a measure of malnutrition risk as patients who are classified as overweight or obese according to BMI category may have a loss of lean muscle mass which is masked by excess body fat. It is the magnitude of the loss of lean body mass that results in the morbidity and mortality problems associated with malnutrition (Tchekmedyian *et al*, 1992). These data confirm that PG-SGA, while related to and paralleling weight loss, is not a substitute for weight loss and that weight loss alone is an insufficient indicator of nutritional status.

Nutritional status (measured by PG-SGA) and QoL

While the primary concern of cancer treatment is for tumour control, physicians are becoming increasingly aware that the effective management of patients should include the assessment of a broader concept of outcomes such as QoL (Sanders *et al*, 1998; Baldwin *et al*, 2001). This study confirms previous observations that malnutrition has a negative impact on QoL (Ovesen *et al*, 1993; Larsson *et al*, 1995; Ohrn *et al*, 2001), although this was not observed by Hammerlid *et al* (1998). Small *et al* (2002) suggest that, as well as providing a global assessment of the patient's nutritional status, the scored PG-SGA can also be used to evaluate nutritional QoL. However, no published studies investigating the scored PG-SGA as a QoL measure have been identified. This study found that PG-SGA score and QLQ-C30 score are correlated but not identical, suggesting that they measure different domains but that one parallels the other in oncology outpatients receiving radiotherapy to the head, neck, abdominal or rectal areas.

The PG-SGA and QLQ-C30 measure a physical domain, but are not identical. Each, in addition to the common domain measure other unique and contributing areas. Based on the results of 14 published studies, King (1996) suggested that a small difference in QLQ-C30 was less than 5 while a large difference was 15 or greater. Osoba *et al* (1998) concluded that a change of 5–10 in the QLQ-C30 score represented a small change, a difference in score of 10–20 was moderate and a difference of greater than 20 was considered a large clinically significant change. Andreyev *et al* (1998) observed changes of 14–18 units in QoL score between those patients who did and did not lose weight and suggested these were clinically significant. In the current study, it was observed that a change in PG-SGA score of nine was required to move one SGA category. Regression analysis showed that a deterioration in PG-SGA by a score of nine would result in a deterioration in QoL by 17 points. Based on the published data described above, this appears to be clinically significant. These results suggest that in the clinical setting, the scored PG-SGA will not only provide information about nutritional status, but will give an indication to the QoL of the patient.

A potential limitation in the current study was the exclusion of subjects with physical, cognitive, language or emotional problems that prevented them from completing the PG-SGA. However, it was noted that no one was excluded on this basis.

Conclusion

In summary, the scored PG-SGA is a nutrition assessment tool that enables malnourished ambulatory patients with cancer to be identified and triaged for nutrition support. It is suitable for use as an outcome measure in clinical nutrition practice and is associated with QoL in ambulatory patients receiving radiotherapy to the head, neck, abdominal or rectal area. Additionally, changes in PG-SGA score can be used to predict the direction and magnitude of change in QoL.

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