Validity of the Patient Generated Index as a Quality-of-Life Measure in Radiation Oncology

Susan S. Tavernier, PhD, RN, APRN-CNS, AOCN®, Susan L. Beck, PhD, APRN, AOCN®, FAAN, Margaret F. Clayton, PhD, RN, FNP-CS, Marjorie A. Pett, MStat, DSW, and Donna L. Berry, PhD, RN, AOCN®, FAAN

Purpose/Objectives: To evaluate psychometric properties of an instrument designed to measure individualized health-related quality of life (HRQOL).

Design: Repeated measures of self-reported quality of life.

Setting: An outpatient radiation therapy department in the western part of the United States.

Sample: 86 adults with cancer receiving their first course of radiation therapy.

Methods: The Patient Generated Index (PGI), the National Comprehensive Cancer Network's Distress Thermometer (DT), and the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire–Core-30 (QLQ-C30).

Main Research Variables: Convergent validity, responsiveness, sensitivity, and response shift.

Findings: PGI scores were inversely correlated with scores on the DT ($r = -0.49, -0.55, -0.44$; $p < 0.001$), as well as the role ($r = 0.31, 0.4, 0.38$; $p < 0.01$), emotional ($r = 0.33, 0.41, 0.33$; $p < 0.01$), social functioning ($r = 0.27, 0.49, 0.42$; $p < 0.05$), pain ($r = -0.29, -0.39, -0.39$; $p < 0.01$), and fatigue ($r = -0.35, -0.25, -0.47$; $p < 0.05$) QLQ-C30 subscales at all measurement times. The PGI was responsive to those reporting high or low DT scores ($t = 4.42, 3.32, 2.9$; $p < 0.05$). A small-to-moderate effect size was detected in those who had an increase (effect size = 0.51) or decrease (effect size = 0.38) in HRQOL over time. Participants reconceptualized HRQOL over time.

Conclusions: Data supported the PGI as a valid measure of individualized HRQOL.

Implications for Nursing: The PGI potentially provides a more patient-centered measure of HRQOL in patients with cancer. Additional testing is needed in larger, more diverse groups.

Health-related quality of life (HRQOL) research has a rich history in oncology nursing. Its measurement is important for the evaluation of interventions designed to improve HRQOL, an outcome that is sensitive to oncology nursing interventions (Given et al., 2003). Several widely used and respected HRQOL instruments exist, and most are constructed of a set of items using Likert-type scale response options. Although the items usually represent domains of HRQOL (e.g., symptom severity, health status, functional levels), they do not allow the respondent to report the relevance or importance of the item to one's HRQOL (Carr & Higginson, 2001; King, 2006; Moons, Budts, & De Geest, 2006). A need exists for HRQOL measures that allow patients to determine the constructs that define their quality of life. Such measures can have a significant influence on decision making in clinical practice (Donaldson, 2004; Efficace et al., 2007; Fitzpatrick, 1999; Levine & Ganz, 2002; Osoba, 2002).

The Patient Generated Index (PGI) uses a novel approach to measure HRQOL that can be adapted to disease and treatment conditions (Ruta, Garratt, Leng, Russell, & MacDonald, 1994). The PGI directs respondents to define and rate their own HRQOL by identifying important areas of life affected by illness and treatment, reporting the degree of impact during the past week for each area, and rating each area in terms of importance to quality of life. Use of the PGI in patients with cancer is minimal to date (Camilleri-Brennan, Ruta, & Steele, 2002; Lewis et al., 2002; Llewellyn, McGurk, & Weinman, 2006), with no reported studies of use in radiation oncology. The purpose of the current study was to examine the psychometric properties of the PGI in a radiation oncology patient population. Findings report the construct validity, sensitivity and responsiveness of the PGI.

Literature Review

Patient-centered care is a primary component of quality health care (Institute of Medicine, 2001), a fact supported in a report from the Picker Institute (2004)

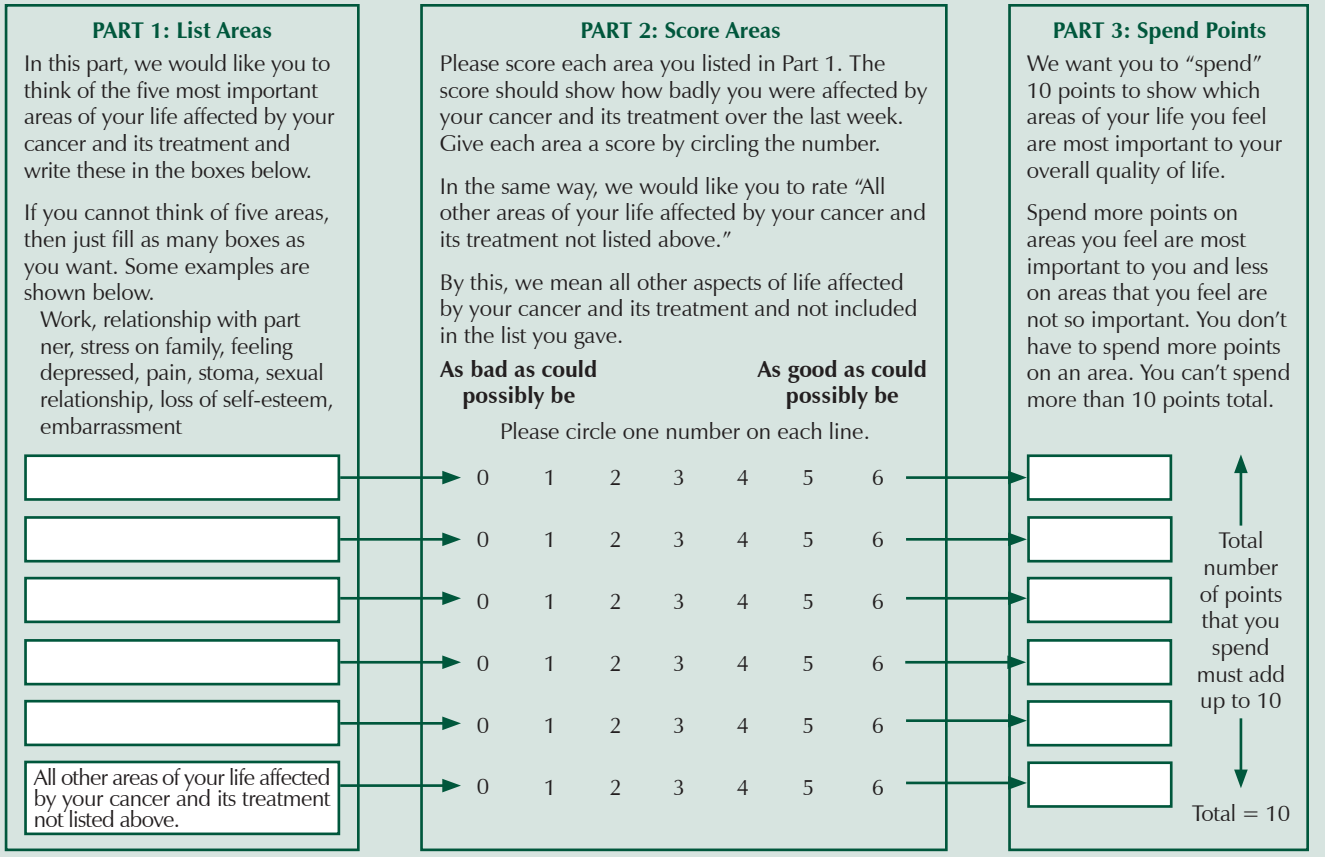

Figure 1. Patient Generated Index, Version 3

Note. Figure courtesy of Danny Ruta. Used with permission.

that asserts research instruments should provide concordance between the healthcare intervention and the values of the patient. Within patient-centered care, the needs and values of patients provide the basis for individualized care and patients are the source of control in decision making about their health. Communication and decisions become more meaningful for the patient and the clinician when the impact of cancer and its treatment on the individual is assessed from the patient's perspective (Levine & Ganz, 2002; Lindblad, Ring, Glimelius, & Hansson, 2002; Patel, Veenstra, & Patrick, 2003).

The study of HRQOL in oncology often has used tools such as the Functional Assessment of Cancer Therapy (Cella et al., 1997), the Functional Living Index–Cancer (Schipper, Clinch, McMurray, & Levitt, 1984), and the European Organisation for Research and Treatment of Cancer (EORTC) Quality-of-Life Questionnaire–Core-30 (QLQ-C30) (Aaronson et al., 1993). These surveys have advanced healthcare professionals' understanding of how cancer affects HRQOL; however, they do not evaluate the relevance of survey items for the respondent, with evidence suggesting the tools do not capture all aspects of HRQOL and may measure areas that have little relevance to the respondent (Bowling, 1995; Donaldson, 2004; Frost & Sloan, 2002; Soni & Cella, 2002; Sprangers, 2002). The PGI is a tool with the potential to overcome such a limitation.

Validity of the Patient Generated Index

The PGI has been used primarily in noncancer-related chronic illness populations outside the United States, with only three studies involving patients with cancer (Camilleri-Brennan et al., 2002; Lewis et al., 2002; Llewellyn et al., 2006). Construct validity of the PGI has been evaluated by correlations with other HRQOL measurements, most commonly the SF-36®, SF-12®, and the QLQ-C30. The SF-36 is a survey in which 36 items comprise eight subscales of physical (e.g., physical function, role, bodily pain, general health) and mental health (e.g., vitality, social functioning, mental health, role-emotional). The SF-12 is a shorter version of the SF-36. The QLQ-C30 is a cancer-specific measure of HRQOL with five functional subscales, three symptom subscales, six single-symptom items, and a global quality-of-life subscale. Although no gold standard exists for criterion validity, strong evidence supports the validity of these three tools as generic measures of quality of life (SF-36 and SF-12) and cancer-related quality of life (QLQ-C30) (Frank-Stromborg & Olsen, 2003).

Camilleri-Brennan et al. (2002) evaluated the validity of the PGI using the SF-36 in a group of patients with colorectal cancer who completed the instruments before and after surgery. The study provided the strongest support for construct validity (r = 0.46–0.59) of the PGI when compared to findings from other studies of noncancer populations in which the SF-36 was used (Ahmed, Mayo, Wood-Dauphinee, Hanley, & Cohen, 2005; Griffiths, Jayasuriya, & Maitland, 2000; Macduff & Russell, 1998; Ruta & Garratt, 1994; Ruta, Garratt, & Russell, 1999).

Llewellyn et al. (2006) studied 55 patients with newly diagnosed head and neck cancer and validated the use of the PGI with the SF-12 and QLQ-C30. Correlations with the QLQ-C30 were strongest in the global quality of life and health domain (r = 0.46) and the SF-12 role emotional domain (r = 0.48). When compared to Camilleri-Brennan et al.'s (2002) study, which used interview methods to complete the PGI, lower QLQ-C30 subscale correlation coefficients were reported by Llewellyn et al. (2006) when the participants self-completed the PGI.

The third study involved patients receiving palliative care services (Lewis et al., 2002). The authors reported a patient preference for the PGI as opposed to the McGill Quality of Life Questionnaire (Cohen, Mount, Strobel, & Bui, 1995). Psychometric analyses were not included.

Correlations with standardized HRQOL tools provide some support for the construct validity of the PGI. However, these findings indicate the PGI is not consistently or highly correlated with other measures of HRQOL, suggesting that the predetermined indicators in the SF-12 and QLQ-C30 may or may not be congruent with how individuals define HRQOL or value the constructs measured.

The ability of the PGI to detect change in HRQOL over time is supported through findings of standardized response means (SRM), also called effect size. The only study of patients with cancer reporting changes in PGI scores over time was by Camilleri-Brennan et al. (2002). With scores ranging from 0–10, PGI scores improved from a preoperative average of 4.8 points to 6.1 points postoperatively ($\bar{X}$ = 1.01, SD = 1.71, SRM = 0.59). The effect size was larger than any of the subscale effect sizes measured concurrently using the SF-36 and QLQ-C30.

Response shift can be defined in terms of recalibration in scores over time or as reconceptualization of the concept (Schwartz & Sprangers, 1999). When response shift occurs because of recalibration, a survey respondent scores an item differently because of a new numeric baseline used for comparison. However, when response shift occurs because of reconceptualization, a respondent scores an item differently because of a new definition of the concept being assigned a numeric value. Recalibration was not measured in any of the studies of patients with cancer using the PGI. Camilleri-Brennan et al. (2002) reported that patients with head and neck cancer listed more areas of importance postoperatively, with an average of 3.2 areas listed preoperatively and 3.6 areas three months postoperatively.

Methods

Design

The current prospective study used repeated measures. Surveys were completed at four separate times: prior to the start of radiation (Time 1); once during treatment

Table 1. Participant Characteristics

Characteristic	Radiation Alone (N = 52) $\bar{X}$	Radiation Alone (N = 52) SD	Radiation and Chemotherapy (N = 34) $\bar{X}$	Radiation and Chemotherapy (N = 34) SD
Age (years)	65	16.31	60	11.41
Number of comorbidities	3.15	2.32	2	1.8
Days since diagnosis[a]	329.02	724.13	87.44	149.6
Characteristic	**n**	**%**	**n**	**%**
Gender				
Female	35	67	16	47
Male	17	33	18	53
Education				
High school or less	15	29	12	35
Undergraduate college	30	58	16	47
Graduate school or more	6	12	6	18
No response	1	1	–	–
Household annual income ($)				
Less than 25,000	12	23	8	24
25,000–34,999	14	27	11	32
35,000–74,999	15	29	9	26
75,000 or more	6	12	5	15
No response	5	10	1	3
Tumor type[b]				
Breast	25	48	5	15
Colorectal	4	8	8	24
Head and neck	2	4	6	18
Lung	6	12	7	21
Non-Hodgkin lymphoma	4	8	3	9
Prostate	2	4	–	–
Other	9	17	5	15
Previous treatment[c]				
Surgery	25	48	8	24
Chemotherapy	5	10	3	9
Surgery and chemotherapy	10	19	5	15
None	12	33	18	53

[a] T = 2.25, p = 0.03, confidence interval = 25.68–457.49
[b] Chi square = 17.01, degrees of freedom = 6, p = 0.009
[c] Chi square = 8.74, degrees of freedom = 3, p = 0.03
Note. Because of rounding, not all percentages total 100.

Table 2. Pearson r Correlations of PGI With DT and QLQ-C30 Subscales

Scale	Before Radiation	During Third Week	End of Treatment
DT	–0.49***	–0.55***	–0.44***
Global health status or quality of life	0.27*	0.45***	0.59***
Physical functioning	0.21	0.19	0.27*
Role functioning	0.31**	0.4***	0.38***
Emotional functioning	0.33**	0.41***	0.33**
Cognitive functioning	0.17	0.24*	0.38***
Social functioning	0.27*	0.49***	0.42***
Fatigue	–0.35**	–0.25*	–0.47***
Nausea or vomiting	–0.14	–0.25*	–0.39***
Pain	–0.29**	–0.39***	–0.39***
Dyspnea	–0.22	–0.02	–0.38**
Insomnia	–0.2	–0.14	–0.23
Appetite loss	–0.24*	–0.28*	–0.25*
Constipation	–0.14	–0.08	–0.38***
Diarrhea	–0.12	–0.17	–0.06
Financial difficulties	–0.15	–0.32**	–0.13

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

DT—Distress Thermometer; PGI—Patient Generated Index; QLQ-C30—Quality-of-Life Questionnaire–Core-30

days 11–15 (Time 2); 48 hours after Time 2 for those participating in test-retest reliability (Time 3) (these findings were reported elsewhere); and within two days of the last day of radiation therapy (Time 4). Data from Time 1, 2, and 4 were used for validity testing. Convergent validity, a type of construct validity, was evaluated using the National Comprehensive Cancer Network's Distress Thermometer (DT) (Holland et al. 2006) and the QLQ-C30 (Aaronson et al., 1993). Sensitivity using known group methods was conducted using two different groupings of participants: those receiving radiation therapy only versus those receiving radiation therapy concurrently with chemotherapy, and those with a DT score equal to or higher than five versus those with a DT score less than five. Responsiveness to change over time was evaluated using PGI scores from three time measurements. Reconceptualization of HRQOL was evaluated by using the index of change (IOC) score developed by the creator of the PGI (Ruta et al., 1994).

Instruments

The surveys were completed at each measurement time point before or after a regularly scheduled appointment for radiation treatment. Participants were asked to complete the surveys in the order provided: PGI, DT, and QLQ-C30. Permission was obtained to use each of the surveys and scoring conducted according to the originating authors.

Patient Generated Index: The PGI was completed in three parts (see Figure 1). Part 1 had participants list up to five areas of life that were most important and had been affected by cancer and its treatment. A sixth area, "all other areas," was preprinted. In Part 2, the participant reflected on the previous week and rated the extent to which each area had been affected using a Likert-type scale ranging from 0 (as bad as could possibly be) to 6 (as good as could possibly be). In Part 3, respondents divided 10 points among the areas listed in Part 1, giving more points to the area that was most important to their overall quality of life. Scoring of the PGI creates an index value, which could range from 0–100, with higher scores indicating a higher level of HRQOL. The index score was calculated using the following equation:

$$PGI = [\sum (\text{area score} \times \text{points spent}/10)] / 6 \times 100$$

Distress Thermometer: The DT is a single-item measure recommended for use in the oncology clinical setting as a screening tool of patient distress (Holland et al., 2006). Concurrent validity has been supported primarily using the Hospital Anxiety and Depression Scale (HADS) (Holland et al., 2006). Study findings support moderate-to-strong correlations between the DT and HADS (Pearson r = 0.51–0.7) (Akizuki, Yamawaki, Akechi, Nakano, & Uchitomi, 2005; Gil, Grassi, Travado, Tomamichel, & Gonzalez, 2005; Ransom, Jacobsen, & Booth-Jones, 2006). The studies also identified a cutoff score of 4 or 5 on the DT, and provided sensitivity (the ability to detect) and specificity (the ability to rule out) in meeting *Diagnostic and Statistical Manual of Mental Disorders* (4th edition) diagnostic criteria for anxiety and depression (Akizuki et al., 2005; Holland et al., 2006; Jacobsen et al., 2005; Ransom et al., 2006). More reports identified a score of 5 to support sensitivity, however, so that score was used as the cutoff point between those with low levels of distress (less than 5) and those with high levels of distress (equal to or greater than 5).

Quality-of-Life Questionnaire–Core-30: The QLQ-C30 measures multiple dimensions of quality of life. Strong evidence exists to support its reliability and validity in the oncology population (Bottomley, Scott, Vanvoorden, Fayers, & Greimel, 2002). The QLQ-C30 consists of 30 items that comprise five functional subscales (i.e., physical, role, cognitive, emotional, social), three symptom subscales (i.e., fatigue, pain, nausea and vomiting), and six single-symptom items (i.e., dyspnea, loss of appetite, insomnia, constipation, diarrhea, financial difficulties). The QLQ-C30 also includes a two-item global quality-of-life subscale with ratings for overall quality of health and quality of life. The QLQ-C30 uses a four-point Likert scale ranging from 1 (not at all) to 4 (very much) for all items except the global quality-of-life questions, which use a seven-point scale ranging from 1 (very poor) to 7 (excellent). Scores are standardized to a 0–100 scale, with higher subscale scores

indicating higher function, higher quality of life, and more occurrences of symptoms.

Setting and Sample

The study took place at a hospital-based outpatient comprehensive community cancer center in Boise, ID. Radiation treatments were provided at two locations using Novalis® shaped beam and intensity-modulated radiation therapy.

Convenience sampling methods were used. Adequacy of the sample size was estimated to require 64 participants, using a priori power analysis for a one-tailed independent t-test comparing two groups, alpha set at 0.05, medium effect size of 0.3, and power set at 80%. To account for potential attrition, the sample size was increased by 15%, resulting in the enrollment of 86 patients. Participants had to have a documented malignancy, be at least 18 years old, and be able to speak and read English. Patients who had received prior radiation, were to receive brachytherapy or seed implants, had a diagnosis of dementia or a psychotic disorder, or who were not able to complete the first measurement prior to the first radiation treatment were excluded.

Procedure

The study was approved by the institutional review board and informed written consent was obtained from eligible candidates agreeing to participate. The daily simulation schedule was reviewed to determine eligibility. Eighty-six of 98 (88%) eligible patients consented to participate in the study, with one dropping out prior to completing any surveys.

Consenting participants completed the three surveys while in the radiation oncology department area. Demographic information was collected from participants with the first set of surveys. Participants were given the option to self-complete the survey or have the investigator assist by reading the questions or transcribing the respondent's responses. If requested, participants could view the areas identified in Part 1 of the PGI from the previous survey.

Table 3. Survey Score Averages at Each Time Measure

	Before Radiation			During Third Week			End of Treatment		
Survey	**N**	**$\bar{X}$**	**SD**	**N**	**$\bar{X}$**	**SD**	**N**	**$\bar{X}$**	**SD**
PGI[a]									
Overall	77	51.86	27.22	72	51.99	22.16	67	55.81	24.55
Radiation only	45	55.78	26.42	42	51.94	23.69	43	56.01	25.86
Radiation and concurrent chemotherapy	32	46.35	27.79	30	52.06	20.21	24	55.45	22.53
Decrease[b]	30	68.33	23.09	27	50.53	25.06	29	44.2	18.79
Increase[b]	32	38.7	21.83	30	52.38	16.69	33	65.93	22.03
DT[c]									
Overall	83	4.23	2.82	80	3.92	2.39	70	4.07	2.78
Radiation only	50	3.8	2.81	48	3.77	2.43	45	3.71	2.82
Radiation and concurrent chemotherapy	33	4.88	2.75	32	4.16	2.36	25	4.72	2.65
QLQ-C30 subscales[d]									
Global quality of life and health	85	62.25	2.21	80	60.83	2.19	70	63.57	2.12
Physical function	84	76.01	2.29	79	75.42	2.22	70	73.27	2.48
Role function	85	64.71	3.26	80	63.75	3.06	70	63.81	3.27
Emotional function	85	70.52	2.32	80	74.48	2.02	70	72.26	2.25
Cognitive function	85	80	1.97	80	79.17	2.13	70	79.52	2.33
Social function	85	72.16	2.61	80	66.46	2.6	70	68.1	2.64
Fatigue	85	37.12	2.68	80	43.19	2.44	70	43.97	2.66
Nausea or vomiting	85	8.43	1.4	80	13.75	2.23	70	10.95	1.81
Pain	85	30	3.17	80	25.63	2.53	70	29.05	2.96
Dyspnea	85	18.82	2.83	80	15.83	2.54	69	19.32	2.77
Insomnia	85	38.82	3.41	80	30.42	3.19	70	33.81	3.33
Appetite loss	84	20.63	3.14	80	30.83	3.47	69	24.15	3.42
Constipation	84	17.46	2.9	80	13.75	2.64	69	17.87	2.53
Diarrhea	85	6.67	1.69	79	14.77	3.05	70	9.05	1.96
Financial problems	85	25.49	3.55	80	27.92	3.41	70	24.76	3.19

[a] PGI scores range from 0–100; higher scores indicate higher health-related quality of life.
[b] Decrease and increase groups equal PGI score decreases or increases over time.
[c] DT scores range from 0–10; higher scores indicate more distress.
[d] Higher scores indicate higher level of function, quality of life, and more severe symptoms.
DT—Distress Thermometer; PGI—Patient Generated Index; QLQ-C30—Quality-of-Life Questionnaire–Core-30

Table 4. Repeated Measures Analysis of Variance of PGI and DT Scores

Scale	SS	df	MS	F	p	η^2
PGI[a]						
Time	515.99	1.73	298.66	0.71	0.49	0.01
Error	39,047.88	93.3	418.54			
DT[b]						
Time	3.27	2	0.16	0.33	0.72	0.01
Error	652.06	130	5.02			

[a] Greenhouse-Geisser correction conducted when Mauchly test of spehericity was not met.

[b] Mauchly test of sphericity met.

df—degrees of freedom; DT—Distress Thermometer; MS—mean square; PGI—Patient Generated Index; SS—sum of squares

Analyses

Data were analyzed using SPSS®, version 16.0. Statistical significance was set at 0.05 and nonparametric tests were conducted if normal distribution assumptions were unmet. Because no differences existed in the findings between parametric and nonparametric analyses, parametric values were reported. One component of the study was an analysis of feasibility (Tavernier, 2009); therefore, missing data on the PGI were not imputed. Missing data in QLQ-C30 surveys were managed according to EORTC scoring guidelines.

Pearson correlations were used to assess associations between the PGI, DT, and QLQ-C30 at each measurement time. Strength of correlations was determined using coefficient of determination values. A repeated measure analysis of variance was used to evaluate change over time by treatment group and direction of change in HRQOL scores. The effect size was reported using the standardized response mean. The sensitivity of the PGI to detect differences between the two treatment groups and participants scoring less than 5 or greater than or equal to 5 on the DT was analyzed using an independent t-test.

Response shift was evaluated using the IOC score, which was calculated by comparing items listed in Part 1 of the PGI for each participant at each measurement time. For each change (deletion or addition of an area) made, a one-half point was assigned (D.A. Ruta, personal communication, October 12, 2006). For example, if a participant listed the same items in Part 1 in his or her first and second survey, the IOC would be zero. If someone listed "embarrassment" at Time 1 and at the second survey listed "embarrassment" and "stress," the IOC is 0.5. If that same person listed only stress on the second survey, the IOC score is 1 because of the deletion of "embarrassment" and addition of "stress." The maximum possible IOC score is 5. Three IOC scores were calculated: Time 1 to Time 2; Time 2 to Time 4; and Time 1 to Time 4.

Findings

Description of Sample

Eighty-six people consented to participate in the study. Four participants elected to drop out during the study (one became too ill to complete surveys; three did not provide reasons). One participant dropped out prior to completing any surveys and was excluded from data analyses. The sample of 86 was primarily Caucasian (93%) women (59%) with at least some college education (68%) who earned less than $35,000 annually (56%) (see Table 1). Participant age ranged from 20–88 years old, with 25% of the sample being 20–54 years old and 25% being 74 years or older ($\bar{X}$ = 65). The group receiving radiation only had been diagnosed longer ($\bar{X}$ = 329 days versus 87 days) prior to consenting to the study (t = 2.25, degrees of freedom (df) = 52.56, p = 0.03), had different tumor types (primarily breast cancer) (chi square = 17, df = 6, p = 0.009), and had been more heavily pretreated with surgery, chemotherapy, or both (71%).

A positive correlation existed between age and PGI scores prior to starting radiation and during the third week of treatment (r = 0.32, p < 0.01 and r = 0.24, p < 0.05, respectively). In addition, during the third week of radiation, PGI scores positively correlated with the number of comorbidities (r = 0.248, p < 0.05) and total radiation dose received (r = 0.36, p < 0.05). All other relationships between the PGI and demographic variables were statistically insignificant. The final set of surveys were administered within the last two days of treatment, which varied based on the recommended radiation dose and body area being treated ($\bar{X}$ = 49; range = 55 days). Despite the variability, the number of treatment days did not correlate with PGI scores throughout the study.

Convergent Validity

PGI scores were low-to-moderately inversely correlated with the DT at all measurement times (r = –0.49, –0.55, –0.44 at Times 1, 2, and 4, respectively) (see Table 2). Of the statistically significant findings, the PGI had a weak association with the global health

Table 5. Patient Generated Index Score Changes During Radiation Therapy

Time	N	$\bar{X}$	Maximum Decrease	Maximum Increase	SD
Pretreatment to third week	66	0.35	–78[a]	58	27.8
Third week to end of treatment	60	2.21	–62	55	21.68
Pretreatment to end of treatment	62	3.8	–62	77	31.81

[a] Negative value indicates Patient Generated Index score was lower at the later measurement.

Table 6. Change Over Time for Steps 1 and 2 of the Patient Generated Index

Variable	Before Radiation	During Third Week	End of Treatment	F	p	η^2
Number of areas identified in Part 1						
$\bar{X}$	3.25	3.3	3.29	0.32	0.71	0.005
SD	1.34	1.18	1.26			
Average rating of areas in Part 2						
$\bar{X}$	4.08	4.15	4.17	0.61	0.54	0.009
SD	1.65	1.33	1.36			

scale of the QLQ-C30 at Time 1, but a low-to-moderate association at Times 2 and 4 (r = 0.27, 0.45, 0.59 at Times 1, 2, and 4, respectively). Emotional, role, and social functional subscales demonstrated consistently low-to-moderate correlations with PGI scores at each survey time. Symptom scores on the QLQ-C30 demonstrated negative associations with the PGI, specifically fatigue and pain, maintaining statistically significant yet weak associations at each measurement. The association between the PGI and QLQ-C30 global health scale, physical functioning, and cognitive functioning strengthened over time but were not consistently statistically significant.

Responsiveness

PGI, DT, and QLQ-C30 subscale scores are reported in Table 3. No statistical differences were found in PGI or DT scores over time (see Table 4). Only the fatigue subscale of the QLQ-C30 detected change over time (F = 3.74, p = 0.03), with fatigue scores increasing at each measurement. Although not statistically significant, PGI score means increased over time and were consistently lower in the group receiving radiation concurrently with chemotherapy. In addition, support for responsiveness to change over time is supported by a pattern of strengthening correlations over time.

Individual PGI scores changed by as much as 78 points between measurement times, with positive change values representing an increase (or improvement) in the PGI index score from the earlier measure (see Table 5). The concurrent treatment group had a higher average increase in PGI index scores (9.9 points from Time 1 to Time 4) than the radiation alone group (0.17 average change in scores from Time 1 to Time 4). Using absolute values of 0.2–0.4 representing a small magnitude of change, 0.5–0.7 as medium change, and 0.8 or greater as a large change, the PGI detected a small overall change in HRQOL from preradiation to the end of radiation (standardized response $\bar{X}$ of 0.21). However, no change over time was detected in unweighted scores provided in Part 2 of the PGI (see Table 6).

The authors noted that the direction of change in PGI scores was in both directions, indicating that some participants experienced an increase in HRQOL, whereas others reported a decrease in HRQOL. Additional analysis of those whose PGI scores increased (n = 31) revealed the average change in PGI scores went from 38.7 before radiation began and increased to an average score of 65.93 at the end of radiation therapy. Conversely, those with scores decreasing over time (n = 35) went from an average PGI score of 68.33 before radiation began to 44.2 at the conclusion of therapy. The group with an increase in PGI scores over time was younger ($F = 4.21$, $p < 0.05$). The group reporting a decrease in PGI scores had a larger proportion of participants who had received previous treatment for their cancer ($X^2 = 4.69$, $p < 0.05$). A repeated measure analysis of variance was conducted, with a moderate effect detected in PGI scores changing over time within the two groups (see Table 7).

Sensitivity

No differences in scores were detected by the PGI between the two treatment groups (radiation alone versus concurrent) at any time measure. In addition, no difference in DT scores was detected between treatment groups at any time measure. However, differences were detected in PGI scores when grouped by DT scores of less than 5 or equal to and greater than 5 at each of the three time periods (see Table 8), with individuals scoring less than 5 on the DT having higher PGI scores. Notably, about half of the sample rated their distress level as

Table 7. PGI Sensitivity to Change Over Time According to the Direction of Change

Group	SS	df	MS	F	p	η^2
Decrease in PGI scores						
Time	7,026.47	2	3,513.23	13.84	<0.001	0.38
Error	11,673.53	46	253.77			
Increase in PGI scores						
Time	10,566.9	2	5,283.45	29.07	<0.001	0.51
Error	10,178.45	56	181.76			

df—degrees of freedom; MS—mean square; PGI—Patient Generated Index; SS—sum of squares

Table 8. Sensitivity of Patient Generated Index in Detecting Differences Between Treatment and Distress Groups

Group	t	df	p	CI
Before radiation				
Treatment group	1.51	75	0.07	–3.01–21.86
DT group	4.42	68.15	<0.01	13.61–36.06
During third week				
Treatment group	–0.02	70	0.49	–10.76–10.52
DT group	3.32	70	<0.01	6.53–26.15
End of treatment				
Treatment group	0.09	65	0.46	–12.03–13.14
DT group	2.9	65	<0.01	5.19–28.02

CI—confidence interval; DT groups—Distress Thermometer scores less than 5 and Distress Thermometer scores of 5 or more

Note. Treatment groups are radiation only and radiation with concurrent chemotherapy.

Note. p values are one-tailed.

being a 5 or higher (48%, 44%, and 45% at Times 1, 2, and 4, respectively).

Response Shift

Response shift was evaluated in terms of reconceptualization of HRQOL. Study participants made an average of three changes in areas identified in Part 1 of the PGI between measurement times (see Table 9). The number of areas identified in Part 1 of the PGI did not significantly change over time.

Discussion

The PGI was designed to measure individualized HRQOL. Because this may differ from standardized measures of HRQOL, moderate correlations with the QLQ-C30 and DT support construct validity of the PGI. The PGI was most strongly associated with the QLQ-C30 global health status, role, social, and emotional functional subscales and the pain and fatigue symptom scales. The QLQ-C30 functional subscale correlates with the PGI are psychosocial in nature. With the exception of pain and fatigue, the PGI did not demonstrate individuated HRQOL consistently being related to physical functioning or other symptom severity scales.

QLQ-C30 subscale score averages at the pretreatment phase were within 9 or fewer points to the combined tumor type radiation pretreatment sample used in the EORTC quality-of-life group reference values (Bottomley et al., 2002) with the following exceptions: The study group had a lower physical functioning score average (64.71 versus 73) and a higher degree of financial worry (25.49 versus 13.2). The differences may be due in part to differences in study samples (European versus American), more colorectal and fewer prostate cancer types represented in the study sample, and possibly that 56% of the study group had received some type of previous treatment for their cancer.

Interestingly, no differences in PGI scores were found between treatment groups and treatment was confounded by type of cancer. The authors anticipated a difference based on the assumption of people receiving combined modality treatment experiencing more toxicity and, therefore, having a lower level of HRQOL, yet this assumption was supported only with the symptoms of pain and fatigue. That introduces the possibility that individualized HRQOL may be influenced more greatly by factors that are not treatment- or symptom-specific.

Forty-four to forty-eight percent of the patients in the current study rated their distress level in the range associated with high risk for clinical depression and/or anxiety over the three measurement times. The rate of high DT scores in participants in the study is higher than that reported in a pooled analysis of DT findings in patients with cancer from 38 studies (Mitchell, 2007). The association between distress and individualized HRQOL and the ability of the PGI to detect differences in those with high versus low levels of distress may indicate a theoretic disposition toward HRQOL defined as happiness and current affect, or even in terms of the natural capacity of the individual (Moons et al., 2006). Based on the high frequency of family and relationships being identified in Part 1 of the PGI (see Table 10), one may speculate that higher levels of distress on the DT are related to the associated stress and worry about family and relationships expressed by respondents. Additional research correlating the areas identified in Part 1 of the PGI and the second part of the DT may elucidate the sensitivity demonstrated by the PGI in the current study.

Two clear trajectories were observed in this population—those who improved and those who got worse. The PGI detected change over time when scores were divided into those having an increased PGI index between the first and last measurement and those who had a decreased PGI index score between the first and last measurements. Average scores for the two groups converged during the third week of treatment. The current study did not intend to identify factors contributing the changes in PGI scores. However, those who experienced a decrease in PGI scores over time

Table 9. Reconceptualization of Health-Related Quality of Life: Response Shift

	Index of Change Scores			
Time Period	N	$\bar{X}$	Mode	SD
Pretreatment to third week	79	1.65	1.5	1.1
Third week to end of treatment	67	1.48	2	0.97
Pretreatment to end of treatment	70	1.8	1	1.1

Note. Data from Time 3 were not used for validity testing.

were more likely to be older adults and more heavily pretreated with surgery, chemotherapy, or both.

The PGI did not detect significant changes in HRQOL overall or by treatment group. The average change in PGI scores between measures ranged from 0.35–3.8. In one previous study, average changes fell within the study range ($\bar{X}$ = 1.01) (Camilleri-Brennan et al., 2002). Jenkinson, Stradling, and Petersen (1998) reported higher change scores of an average 27 points. That may, in part, be a result of the differences in study populations (cancer versus obstructive sleep apnea) or the intervention between PGI measures (radiation versus continuous positive pressures airway therapy).

The PGI may not be sensitive to changes in HRQOL over time for the entire sample because of the effects of a reconceptualized HRQOL as participants attempted to find meaning within the experience of their own cancer and its treatment. The diagnosis of cancer produces a response in which the individual evaluates the meaning of the disease and its impact on other areas of life. A change in the definition of abstract construct is referred to as response shift (DeVellis, 2006), which also has been described as adjustment, coping, or assimilation (White, 2004). An example of this is found in a study measuring spiritual quality of life in 103 patients with cancer receiving radiation (Johnson et al., 2007) in which the authors noted that different survey items explained spiritual well-being at different times during treatment. In the current study, the changes in areas identified in Part 1 may have had a washout effect on PGI scores. By changing the areas of impact between PGI measures, the rating and weighting of the different areas may remain the same, resulting in similar scores. Participants made an average of three changes to the areas listed in Part 1 of the PGI over time. The IOC scores in this study were similar to those reported elsewhere of 2.05 (Griffiths et al., 2000) and 1.34 (Haywood, Garratt, Dziedzic, & Dawes, 2003).

The average change in PGI scores over time in the current study was in the positive direction, suggesting a slight improvement in HRQOL during treatment. The group receiving concurrent chemotherapy experienced a higher average increase in individualized HRQOL than the group receiving radiation therapy alone, which might be a result of the treatment having a greater effect on the tumor. HRQOL findings are not routinely reported in radiation therapy clinical trials, making it difficult to provide comparisons. The difference may be accounted for by the higher PGI score at baseline in the group receiving radiation therapy alone. The improvement in HRQOL in the current study also may be explained by the reconceptualization of HRQOL that occurred. An additional explanation for the overall increase in HRQOL, as measured by the PGI, may be related to a higher level of resilience seen in patients with cancer undergoing radiation therapy, which is an area worth further investigation (Strauss et al., 2007).

The study findings are limited by the small, relatively homogenous and nonrandomly selected sample. Larger studies with more diverse samples are warranted.

Table 10. Frequency of Most Important Areas of Life Affected by Cancer and Its Treatment[a]

Area	Before Radiation	During Third Week	End of Radiation
Depression or anxiety	20	22	21
Family (unspecified)	13	16	16
Friends (unspecified)	8	7	5
Work (unspecified)	20	14	11
Relationships (unspecified)	3	2	1
• Sexual relationship	5	5	1
• With spouse, partner, or children	14	11	10
• With friends, coworkers, or others	3	1	1
Stress (self, work, friends, unspecified)	12	10	14
Stress on family	30	21	19
Stress on spouse or partner	4	6	8
Activity	12	12	6
Loss (unspecified)	9	15	11
Time for treatments	2	6	2
Faith, spirituality, God, or church	4	5	4
Financial, cost, and insurance	6	8	9
Embarrassment	3	4	6
Social life	3	2	3
Physical symptoms			
• Pain, no pain, or comfort	13	18	25
• Energy, stamina, fatigue, or tired	13	13	15
• Eating or appetite	7	7	2
• Appearance	2	1	1
• Health	1	5	3
• Skin	–	1	2
• Nausea or no nausea	1	–	1
• Short of breath	1	1	2

N = 85

[a] Areas listed are those identified in Part 1 of the Patient Generated Index by study participants.

Research and Clinical Implications

The current study was the first to evaluate the PGI in a population of patients with cancer receiving radiation therapy. Such an approach remains appealing because of the ability to focus on aspects of HRQOL that are most important to the patient. Construct validity was supported by correlations between PGI and two other measures, one of distress and one of global HRQOL.

Discriminate validity was partially supported by PGI scores detecting differences in those participants with reported distress at a clinically relevant level; however, PGI scores did not discriminate between patients receiving two different types of cancer treatment, which may be a result of the small sample size. The lack of difference in PGI scores between treatment groups also challenges the assumption that radiation alone has less of an effect on HRQOL than combined modality treatment.

The PGI was sensitive to change over time when the direction of the change in HRQOL was known. For that to be meaningful in future research and clinical practice, frequent assessment of HRQOL and determination of the direction of change is suggested.

In addition, although the mean PGI scores increased over time for the entire group, a subgroup of patients had scores that decreased. That depicts how statistical reports may inadequately address what is observed in the clinical setting. Based on these data, the PGI may have clinical relevance as a tool for the oncology clinician to use in assessing how a patient with cancer defines HRQOL, thereby assisting in providing individualized care in those areas that are most meaningful to the patient.

Prior to its use in clinical trials, additional research with the PGI is suggested both in larger samples and in samples more representative of ethnic and racial diversity, as well as better controlled for types of cancer. Research to understand its use in practice also is recommended.

Susan S. Tavernier, PhD, RN, APRN-CNS, AOCN®, is an oncology clinical nurse specialist at Saint Alphonsus Regional Medical Center in Boise, ID when this article was written; Susan L. Beck, PhD, APRN, AOCN®, FAAN, is a professor, Margaret F. Clayton, PhD, RN, FNP-CS, is an assistant professor, and Marjorie A. Pett, MStat, DSW, is a research professor, all in the College of Nursing at the University of Utah in Salt Lake City; and Donna L. Berry, PhD, RN, AOCN®, FAAN, is the director of the Phyllis F. Cantor Center for Research in Nursing and Patient Care Services at the Dana-Farber Cancer Institute in Boston, MA. This article presents findings from the lead author's dissertation and was funded in part by a National Cancer Institute training grant (R25 CA093831 [K. Mooney, principal investigator]), Sigma Theta Tau Mu Gamma Chapter, and the University of Utah George S. and Dolores Dore Eccles Scholarship Fund. Tavernier can be reached at susatave@sarmc.org, with copy to the editor at ONFEditor@ons.org. (Submitted April 2010. Accepted for publication April 26, 2010).

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