Can Performance Status (PS) be Determined Accurately by Patients? Results of a Prospective Trial Evaluating ECOG and Karnofsky PS as well as Patient-Rated PS

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Background: PS is accepted as a key factor in comparing arms of clinical trials, in patient monitoring, and in determining treatment eligibility. While both the ECOG and KPS scales have validity and wide acceptance, accuracy depends on a clear understanding of the scale definitions. Since both are observer-rated, they are prone to rater or investigator bias. Additionally, observer scoring contrasts to preferred patient-rating in patient reported outcomes.

Methods: We prospectively evaluated both PS scales, and a Patient-Rated PS (a visual analog scale [VAS] of activity) in patients with NSCLC. Observers rating the ECOG and KPS had written definitions of each scale category. The Patient-Rated PS VAS is part of the validated QL scale, the LCSS. Patients completed the VAS on paper, and on a computerized (electronic) handheld device (LCSS-QL). All patients were part of the Quality of Life COMET study, and were enlisted in 9 clinics in Ontario. Eligibility: advanced NSCLC, KPS > 60, no prior chemotherapy, receiving initial courses of docetaxel + platinum. Patients completed all 3 scales immediately prior to chemotherapy.

Results: The 75 patients entered had the following characteristics: 41% men; median age: 68 (range 46-81); Stage IV: 73%; KPS median: 80% (range 60%-100%); ECOG median: 1 (range 3 – 0). Using the electronic format, there was moderately high correlation between the Patient-Rated PS VAS and a) KPS (Pearson r, 0.66) and b) ECOG (Pearson r, 0.62). A similar result (Pearson r, 0.89) was obtained between the electronic and paper format for the VAS scale.

Conclusions: These results indicate that patients can rate their own performance status rapidly and easily with one VAS question. There is moderately high correlation between Patient-Rated PS and that collected by observers. Future prospective trials should evaluate whether the Patient-Rated PS more accurately predicts survival and response than either the ECOG or KPS scales.

Background

- Performance Status is one of the most widely accepted patient evaluations used in clinical practice and in clinical trials in oncology.
- Performance status scales are basically measures of a patient's ability to carry out normal activities.
- Both the Karnofsky Performance Scale (KPS) and the ECOG Performance Scale are used in many countries. Oncologists have generally found these scales easy to use in typical practice.
- Baseline values of both scales have shown correlations with survival and with anti-tumor response for several different malignancies, including lung cancer, when used as part of prospective clinical trials.
- Nonetheless, problems can be found with either scale:
  - Physicians and nurses often overestimate both patient performance status and survival
  - For the scales to be used best and for comparability, health care professionals should adhere to the specified definitions for the various categories, but they often do not
  - As observer determined scales, both are prone to rater or observer bias
- Additionally, observer scoring contrasts to the preferred patient rating in patient-reported outcomes.
- If patients can accurately and easily determine their own performance status, observer bias would be eliminated, a valuable parameter would be preserved, and the data would come directly from those experiencing the cancer.

Study Objectives

- To evaluate if a patient-determined performance status, using a visual analog scale, could be performed easily in a clinical practice setting by patients receiving their initial chemotherapy as part of a clinical trial.
- To test if the patient-determined performance status VAS score would correlate well with:
  - An observer-rated KPS score
  - An observer-rated ECOG score
- To determine if the patient-rated VAS scores would correlate well if measured by using the LCSS scales on either the paper or electronic versions (LCSS-QL).

Methods

- All patients had advanced NSCLC, KPS $\geq$ 60, no prior chemotherapy, and are receiving their initial courses of docetaxel + platinum.
- Patients were entered in the community settings of 10 COMET Group clinics in Ontario, Canada.
- 102 patients with non-small cell lung cancer were prospectively evaluated.
- All patients were evaluated with both the KPS and ECOG PS scales immediately prior to their initial chemotherapy treatments. Definitions of the categories of both scales (KPS and ECOG) were given to the observers, as part of the observer version of the electronic LCSS (LCSS-QL).
- Additionally, patients completed both the paper and electronic LCSS formats, which include the patient-determined VAS for performance status. The original paper LCSS form is administered first, followed by the computer version to prevent bias of prior computer experience.
- A patient demographic and evaluation form (with time of completion / ease of use) is also administered.

Demographic and Disease-related Characteristics of the Sample of Patients with NSCLC (N = 102)

Characteristic	*Median or #*	*Range or %*
Age	68	(42 - 81)
Age Group		
< 45 years	0	0%
45 – 72 years	46	73%
> 72 years	17	27%
Gender		
Male	56	55%
Female	46	45%
Stage of Disease		
IIIa	1	1%
IIIb	21	21%
IV	80	78%
ECOG Performance Status		
2	28	27%
1	63	62%
0	11	11%
Karnofsky Performance Status		
60%	7	7%
70%	14	14%
80%	49	48%
90%	25	24%
100%	7	7%

Instruments

Patients complete the LCSS both paper and electronic formats.

- Original paper version (LCSS)

  Patient version
  Items measured on a 100-mm visual analogue scale (0=best score)
  Total score = mean of 9 items
  Average symptom burden index (ASBI) = mean of 6 symptoms

  Observer version
  6 categorical scales

- A new computerized version (LCSS-QL):
  – Preserves both the patient and the observer versions
  – Hand-Held PC device using the pocket PC stylus
  – Provides immediate color graphic reporting of current scores and change over time
- LCSS published reliability and validity (see Hollen et al. *Cancer* 1994; 73: 2087-2098, and ***www.lcss-ql.com*** for full reference list)
- Demographic forms for the patient, observer, and the physician
- Evaluation forms to capture time to completion and perceptions of acceptability (patient, observer, physician)

Patient-Rated PS Visual Analog Scale (VAS)

Directions: Please place a mark along the line where it would best describe the symptoms of your lung cancer **DURING THE PAST DAY** (within the last 24 hours).

How much has your illness affected your ability to carry out normal activities?

Not at all — So much that I can do nothing for myself

Instruments

Electronic and Paper Formats for Lung Cancer Symptom Scale (LCSS) Scores of All Items, including the Patient-Rated PS VAS (in italics)

LCSS Score or Item	Electronic LCSS: Means (SD)	Paper LCSS: Means (SD)
Total Score	32.94 (18.09)	32.31 (17.60)
Symptom Score	28.41 (17.15)	27.75 (16.07)
Appetite	32.36 (26.02)	29.49 (26.60)
Fatigue	41.99 (25.49)	43.68 (26.30)
Cough	26.60 (23.63)	26.99 (24.26)
Dyspnea	36.01 (28.28)	37.57 (30.55)
Hemoptysis	7.79 (13.80)	6.75 (15.83)
Pain	25.73 (24.92)	22.09 (24.59)
Symptom Distress	36.74 (26.36)	35.51 (27.23)
Patient-Rated PS (Activities)	**45.00 (26.68)**	**44.81 (30.84)**
Global HRQL	44.17 (26.06)	43.88 (28.53)

KARNOFSKY PERFORMANCE SCALE (KPS)

Grade:	Definition:
100	Normal, no complaints, no evidence of disease.
90	Able to carry on normal activity, minor signs or symptoms of disease.
80	Normal activity with effort, some signs or symptoms of disease.
70	Cares for self. Unable to carry on normal activity or to do active work.
60	Requires occasional assistance, but is able to care for most needs.
50	Requires considerable assistance and frequent medical care.
40	Disabled, requires special care and assistance
30	Severely disabled, hospitalization is indicated although death not imminent.
20	Hospitalization necessary, very sick, active supportive treatment necessary.
10	Moribund, fatal processes progressing rapidly.
0	Dead

ECOG PERFORMANCE STATUS SCALE*

Grade:	Definition:
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

** As published in Oken, M.M., et al.: Am J Clin Oncol 5:649-655, 1982.*

Results

Feasibility: Acceptance of the Patient Rated PS VAS is high, using either the paper format or the newer electronic LCSS-QL. In fact, the entire electronic completion time for the total 9-item LCSS patient scale, including the Patient-rated PS VAS, takes a mean of 2.2 minutes (SD 1.51 minutes). Thus, the single Patient-rated PS VAS question takes less than 20 seconds (likely as fast or faster than an observer carefully administering the KPS or ECOG scales.

Correlations: Coefficient between the electronic and paper versions for the Patient-Rated PS: 0.89 (Pearson r); Patient-rated PS VAS and the KPS: 0.46 (Pearson r); Patient-rated PS VAS and the ECOG PS: 0.43 (Pearson r).

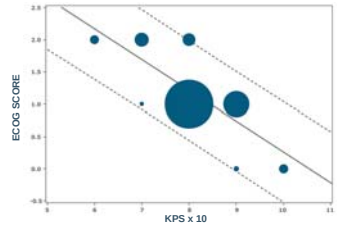
Results

Patient-Rated PS Scores versus ECOG PS

ECOG Score	Number of Patients	Patient-Rated PS: Median
0	11	95
1	63	54
2	28	34

Correlation: Patient-rated PS VAS and the ECOG PS: 0.43 (Pearson r)

Comparing the Distribution of KPS Scores with ECOG PS Scores (N=102)



Sensitivity / Specificity: KPS (0.85 / 0.88); ECOG PS (0.96 / 0.64)

Patient-Rated PS Scores versus Karnofsky PS

KPS	Number of Patients	Patient-Rated PS: Median
100	7	90
90	25	78
80	49	51
70	14	37
60	7	26

Correlation: Patient-rated PS VAS and the KPS: 0.46 (Pearson r)

Conclusions

- These results demonstrate that patients can rate their own performance status rapidly and easily with one VAS question. There is excellent acceptance among patients of this self-rating procedure.
- This simple VAS question eliminates observer bias and allows performance status scores to be based entirely on patient input.
- The Patient-rated PS VAS can be administered as a single question, using just a piece of paper and measured easily in millimeters without any calculation needed or access to categorical definitions. It can also be entirely automated as part of the LCSS-QL computerized validated quality of life scale. Either method requires only seconds of patient time for the single question, to 2 minutes for the full quality of life instrument.
- Both the KPS and ECOG scales have excellent sensitivity results; however, the better specificity result for the KPS favor it over the ECOG scale for accuracy in clinical decision making.
- The moderate correlations between the Patient-rated PS VAS and both the KPS and ECOG scales indicate that fairly similar information can be obtained with the use of any of these methods.
- Future trials should evaluate whether the Patient-rated PS VAS can outperform the two older observer PS scales in predicting survival at all PS ranges, or in predicting response or determining appropriateness for treatment.