



A Prospective Evaluation of the Attitudes of Patients, Physicians and Nurses using a Computer-Assisted Quality of Life Instrument (LCSS-QL) in a Multi-center Clinical Trial in Non-Small Cell Lung Cancer (NSCLC)

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Abstract

Background: The LCSS has been computerized (LCSS-QL) for inexpensive hand-held devices (pocket PC) to increase feasibility, reliability, and automatically record data. The correlation coefficient between the paper form and the electronic version is excellent ($r=0.98$). This analysis determines the acceptability and value of the LCSS-QL as assessed by patients and health care professionals.

Methods: NSCLC patients utilized LCSS-QL in a clinical trial and also completed a form evaluating their experiences after their first and third treatment cycles. All received docetaxel and platinum. Eleven physicians and nurses administered LCSS-QL and completed an evaluation form. The form evaluated: time required, satisfaction with the process, value of assessment, impact on communication, resource utilization.

Results: The evaluation form was completed by 128 patients (cycle 1) and 94 (75%) completing cycle 3. Baseline characteristics: Stage III/IV 29/71%, median KPS 90%, 56% male; median age 69 yrs.

	Patients Agreeing	MDs/RNs Agreeing
LCSS-QL was easy to use:	98%	91%
Report from LCSS-QL was easy to use and apply:	81%	81%
QL evaluation enhanced satisfaction with clinic visit:	81%	73%
LCSS-QL improved communication and awareness:	81%	84%
Using LCSS-QL required < 3 minutes of my time:	87%	100%

All physicians considered their time per patient was not lengthened and 80% felt that QL evaluation could save time. 67% of nurses felt the instrument could save time, while 83% felt that patient time was lengthened. Utilization: 67% of professionals reported QL evaluation would earlier identify patients not benefiting from chemo; 91% were more aware of pain issues.

Conclusions: Patients and professionals found using a validated QL instrument in a computerized form via a hand-held device was easy, added value and satisfaction while enhancing communication and awareness of PRO issues. The electronic format added no physician time. These results indicate that this QL evaluation method should be used more frequently in clinical trials and patient management.

Background

Surveys have demonstrated that most oncologists would like to incorporate Patient Reported Outcomes (PROs), including quality of life and symptom assessment, into clinical trials and typical patient management. Nonetheless, few do so formally due to barriers of 1) insufficient time in typical clinical settings; 2) insufficient staff and resources, and 3) lack of availability of a practical and validated QL / PRO instrument. (Ref: Morris et al. Quality of Life Research 1998).

Based on such information, we undertook a project to demonstrate that it would be possible to overcome all the above stated barriers. We chose the Lung Cancer Symptom Scale (LCSS), which is an extensively used paper measure based on a tested model and which has been validated with good psychometric properties (Ref: Hollen et al. Cancer 1994¹). Additionally, the LCSS is a practical QL instrument designed to minimize patient and staff burden in clinical trials and patient management. We felt that it could be made markedly more feasible by conversion into a computerized format utilizing a simple and inexpensive hand-held device (pocket PC).

The first step in this process involved the demonstration that the electronic (computerized) format retained the extensively tested properties of the paper form. The initial 63 patients completed both the paper and electronic versions. The correlation between the two formats was very high (Ref: Kuruvilla et al. Proc ASCO 2005²), supporting the use of the electronic format (now called the LCSS-QL).

The purpose of the current study was to evaluate prospectively the acceptability and practicality of the computerized LCSS-QL among patients, physicians and nurses in terms of 1) the time required and impact on clinic time; 2) the ease of use of the LCSS-QL, its reports, and its data management features, especially for a multicenter trial; and 3) the effect of the use of the instrument on communication, patient and professional satisfaction.

Study Objectives

- To determine the actual time required by patients for QL / PRO evaluation using the electronic LCSS-QL.
- To assess the percentage of patients, nurses, and physicians who perceived that the time needed for completing their tasks with the LCSS-QL was less than 3 minutes.
- To assess the impact of use of the LCSS-QL on nurse and physician consultation regarding the host antibody settings.
- To evaluate the perceptions of nurses and physicians of the impact of use of the LCSS-QL on their awareness of patients' QL issues and lung cancer symptoms.
- To assess the impact of use of the LCSS-QL on communication between patients and their nurses and physicians.
- To determine the satisfaction of patients as well as the health care professionals' satisfaction with use of the LCSS-QL.

Methods

- The psychometric trial used a methodological design to evaluate the feasibility, reliability, and validity of a computer-generated QL instrument specific to patients with lung cancer – the Lung Cancer Symptom Scale electronic version (LCSS-QL).
- All patients had advanced NSCLC, KPS ≥ 60 , no prior chemotherapy, and received their initial chemotherapy consisting of docetaxel + platinum.
- Patients were entered in the community settings of 12 COMET Group clinics in Ontario, Canada.
- 142 patients with non-small cell lung cancer were included in the study; 137 had baseline evaluation forms. 103 (75%) completed evaluation forms at visit 3 addressing the acceptability of the LCSS-QL, including time of completion and ease of use of the LCSS-QL. 33 of 36(92%) healthcare professionals completed evaluation forms.

TABLE 1. Demographic and Disease-Related Characteristics of the Sample of Patients with NSCLC (N = 103)

Characteristic	Characteristic	Median or #	Range or %
Age		67	(56-81)
Age Group	< 45 years	3	3%
	45-72 years	78	76%
	> 72 years	22	21%
Gender	Male	59	57%
	Female	44	43%
Last Grade Completed		12	(4-24)
Stage of Disease	IIIa	1	1%
	IIIb	20	20%
	IV	81	79%
Karnofsky performance Status	60%	6	6%
	70%	14	14%
	80%	41	40%
	90%	32	31%
	100%	9	9%
Self Rated Computer Experience:	(1 = none, 10 = maximum)	Mean = 3.5	SD 2.94

TABLE 2. Demographics of the Physicians and Nurses in the Study and Treating these Patients

Characteristic	Physicians (n = 11)	Nurses (n = 19)
Age (mean / median)	49 / 51	49 / 48
Years in Oncology (mean / median)	18 / 15	13 / 15
Gender:		
Male:	12	0
Female:	2	19
Self Rated Computer Experience:	7.6	7.2
(1 = none, 10 = maximum)		

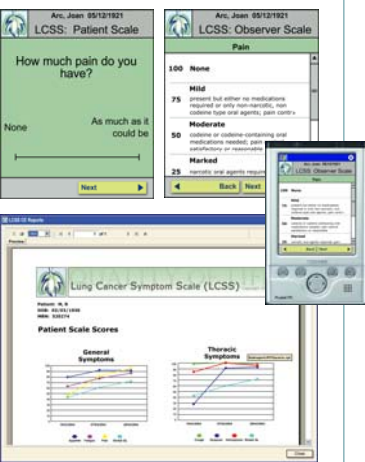
Instruments

The first 63 patients completed both the paper and electronic formats. Patients, physicians, and nurses (most were oncology nurses) completed the evaluation forms assessing ease of use, the time required, communication and satisfaction issues.

The LCSS (paper version) and the LCSS-QL (computerized version) have published feasibility, reliability and validity analyses (for the LCSS, see ref #2 below and website www.lungcancer.com for full reference list; correlation of the LCSS-QL with the paper version (see Kuruvilla et al. Proc ASCO 2005²).

Patient version
 - Items measured on a 100-mm visual analogue scale (0=best score)
 - Individual items include: **Therapeutic Symptoms**: cough, dyspnea, hemoptysis; **General Items**: pain, fatigue, appetite; and **Summary Items**: quality of life, symptom distress, overall level.
Observer version
 - 6 categorical scales including: cough, dyspnea, hemoptysis, pain, fatigue, appetite
The computerized version (LCSS-QL)
 - Preserves both the patient and the observer versions
 - Uses a Hand-Held Pocket PC with a touch sensitive screen and supplied stylus
 - Provides immediate color graphic reporting of current scores and change over time
Demographic forms for the patients, observers, and physicians
Evaluation forms to capture time to completion and perceptions of acceptability (patients, observers, and physicians)

Examples of Pocket PC Screens and Computer Reports



Results: Reliability and Correlation of the Formats

- Feasibility:** Acceptance of the LCSS-QL by 103 patients, 19 nurses, and 14 physicians has been excellent. Patient completion time was excellent (mean, 2.4 minutes; SD 1.43) for 100 patients.
- Reliability:** Cronbach's alpha were high for the paper (0.84) and electronic (0.88) versions (see Table 4). They meet Nunnally and Bernstein's (1994) recommended guideline for reliability of greater than 0.70 for new measures and 0.80 for existing measures.
- Validity:** Means and correlation coefficients between the paper and electronic forms were ≥ 0.90 (924 - 926) for several correlation methods, including two that reduce measurement bias (see Tables 3 & 4).

TABLE 3. Electronic and Paper Formats for Lung Cancer Symptom Scale (LCSS) Scores and Items

LCSS Score or Item	Electronic Means (SD) (N = 93)	Paper Means (SD) (N = 93)
Total Score	32.94 (18.09)	32.31 (17.60)
Symptom Score	28.36 (17.19)	27.75 (16.07)
Appetite	28.36 (26.92)	24.99 (28.60)
Fatigue	41.99 (25.49)	43.88 (26.30)
Cough	26.60 (23.43)	26.99 (24.26)
Dyspnea	36.01 (28.28)	37.57 (26.55)
Hemoptysis	7.79 (3.89)	6.78 (6.83)
Pain	25.73 (24.59)	25.99 (24.52)
Symptom Distress	36.74 (26.36)	35.51 (27.23)
Normal Activities	45.09 (26.89)	44.81 (26.24)
Globoc HQL	44.17 (26.66)	43.88 (26.33)

TABLE 4. Electronic and Paper Formats for the (LCSS): Reliability and Correlation Results

LCSS Score or Item	Pearson R ¹	KCC ²	Lin's CCC ³	Lower Bound CI ⁴	Upper Bound CI ⁴	Cronbach Alpha Hand	Cronbach Alpha Paper
Total Score	0.926	0.925	0.924	0.920	0.926	N/A	N/A
Symptom Score	0.870	0.871	0.870	0.867	0.864	N/A	N/A
Appetite	0.805	0.806	0.805	0.800	0.824	0.873	0.826
Fatigue	0.714	0.716	0.714	0.703	0.656	0.857	0.823
Cough	0.808	0.809	0.808	0.803	0.812	0.881	0.833
Dyspnea	0.814	0.815	0.814	0.803	0.840	0.868	0.830
Hemoptysis	0.633	0.635	0.633	0.627	0.659	0.900	0.853
Pain	0.804	0.805	0.804	0.807	0.849	0.877	0.834
Symptom Distress	0.725	0.727	0.725	0.720	0.742	0.867	0.815
Normal Activities	0.889	0.890	0.889	0.884	0.902	0.866	0.812
Globoc HQL	0.908	0.909	0.908	0.905	0.917	0.857	0.806

¹ Pearson r non-nominal-ordinal method (shaded < b> not provided for comparison. ² KCC or Intraclass Correlation Coefficient. ³ CCC or Agreement Correlation Coefficient. ⁴ CI = Confidence Interval for CCC. Patients in all columns (N=93).

Results

Table 5. Patient Responses to Questions Concerning Ease of Use and Communication (N = 103)

FEASIBILITY:	%	95% Conf Interval
The quality of life instrument was easy to use.	98%	(92-99%)
The hand-held device was easy to read.	97%	(93-100%)
Percent of patients needing < 3 min to learn to use the electronic questionnaire.	83%	(75-90%)
COMMUNICATION AID:		
The LCSS-QL helped me in speaking with my doctor or nurse.	77%	(65-82%)
The LCSS-QL increased awareness of my quality of life and symptoms of lung cancer.	74%	(69-85%)
The LCSS-QL helped me be thorough in discussing my symptoms and feelings about my quality of life.	83%	(75-90%)
OVERALL:		
Filling out an electronic quality of life instrument prior to each visit with my doctor is acceptable.	97%	(92-99%)

Continued responses of "sometimes true" and "very true" on Likert scale except for two reversed items.

Table 6. Physician and Nurse Responses to Questions Concerning Time, Communication, Satisfaction, and Awareness (30 to 33 responses to each question)

	MDs	RNs	TOTAL	95% Conf Interval
Time needed to Complete Summary Report is < 3 min.	85%	—	85%	(57 - 98%)
Time needed to Review Observer Scale is < 3 min.	—	89%	89%	(67 - 99%)
Having the Summary Report could save time for me.	77%	—	77%	(42 - 95%)
The LCSS-QL lengthened my consultation time.	0%	47%	47%	(24 - 71%)
The LCSS-QL could help save time, overall.	85%	66%	76%	(57 - 89%)
The LCSS-QL enhanced my communication with the patient.	84%	80%	88%	(72 - 97%)
The LCSS-QL enhanced my satisfaction with patient's visit.	93%	84%	88%	(72 - 97%)
The LCSS-QL increased my awareness of quality of life issues and symptoms of lung cancer.	85%	80%	81%	(76 - 90%)

Continued responses of "sometimes true" and "very true" on Likert scale except for two reversed items.

Table 7. Physician and Nurse Responses to Questions Concerning Ease of Use and Utilization Issues (30 to 33 responses to each question)

	MDs	RNs	TOTAL	95% Conf Interval
The Summary Report is easy to interpret.	85%	95%	91%	(76 - 98%)
Instructions for the observer are easy to follow.	—	100%	100%	(82-100%)
The data entry system is easy to use.	—	100%	100%	(82-100%)
The Observer Scale is easy to use.	—	100%	100%	(82-100%)
The LCSS-QL could help me identify patients not benefiting from chemo earlier than usual practice.	91%	66%	77%	(62 - 92%)
The LCSS-QL could allow me to order fewer X-Rays or CT scans than usual practice.	46%	—	46%	(17 - 77%)
The LCSS-QL could help me identify pain and palliation issues earlier than usual practice.	100%	79%	87%	(69 - 96%)
After this study, I would use the LCSS-QL in my daily practice.	92%	84%	88%	(71 - 97%)
I would recommend using the LCSS-QL to colleagues.	92%	84%	88%	(71 - 97%)

Continued responses of "sometimes true" and "very true" on Likert scale except for two reversed items.

Conclusions

- This simple electronic QL / PRO instrument has high acceptance by patients, nurses, and physicians
 - It requires only 2 minutes of a patient's time, and can be performed every 3 weeks in the clinic
 - Physicians report that it takes no extra time on their part
 - About half of the nurses report that it takes some extra time for them (< 3 minutes)
 - Both physicians and nurses express that use of the LCSS-QL can save time overall
 - Patients found the LCSS-QL was easy to read, understand, and complete
- Patients, nurses and physicians report that use of the LCSS-QL
 - Improves communication between patients and health care professionals
 - Enhances the satisfaction of all groups with the clinic visit
 - Improves awareness of QL issues and the symptoms of lung cancer
- Health care professionals indicate that the use of the instrument:
 - Improves earlier recognition of pain and palliation issues.
 - May identify patients progressing on chemotherapy at an earlier time than usual care
 - May allow somewhat less use of expensive and intrusive imaging techniques
- Convergence between the two formats (paper and electronic) is high, and existing psychometric properties for the original measure can be generalized to the new format.
- Feasibility, reliability, and validity testing confirms that this electronic LCSS format provides a validated and practical way to bring QL evaluation into patient management and facilitate assessment of this endpoint in practice settings or clinical trials.

References
 1. Morris J, Perez D, Mahoe B. The use of quality of life data in clinical practice. Quality of Life Research 1998;7:85-91.
 2. John Stewart, Christine Chin, Baron Cassata, Lorna Barakat, Johanna Beaulieu, Phyllis Beale, Candy Caronville, Pat Changchien, Marisa Couder, Barbara Ott, Linda Del Rizzo, Norman De Vin, Nancy Doyle, Kim Ferguson, Erwan Gagnier, Jocelyne Gravel, Shelly Hogg, Karim Hoggan, Cindy John, Samar Khoury, Nathalie Koscinski, Heather Kintner, Berna Lando, Sylvia Lewis, Jonathan Lavoie, Maryjo Leighton, Louise Philippe, Meghan, Kim Marsh-Grey, Jane Palminteri, Hedy Papenburg, Linda Parra, Clara Petras-Omagnoto, Linda Phipps, Laura Troick, Andrea Walsh

3. Hollen PJ, Gralla RJ, Kiro M, Cinc C, Blawan CP, Grunberg SM, Crawford J, Neuhoff AJ. Measurement of quality of life in a patients with lung cancer in a multi-center trial. Psychometric assessment of the Lung Cancer Symptom Scale. Cancer 1994;73:2027-2036.
 4. Kuruvilla PJ, Krieger H, Zidekel L, Meharchand JM, Solow H, Leighl NB, Chiv C, Stewart AJ, Hollen PJ, Gralla RJ. Assessing quality of life and patient reported outcomes in clinical trials and clinical practice. A study using a hand-held computer form of the value LCSS instrument in patients with non-small cell lung cancer (Abstract #8082). Proc ASCO 2006, 24: 2006-22: 46a.
 5. Nunnally JC. Behavioral. Psychometric Theory (ed 3). New York, NY: McGraw-Hill, 1994.

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