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Variability of Performance Status Assessment between Patients with Hematologic Malignancies and Their Physicians

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Abstract

This study was conducted to determine the incidence of inter-observer variability in Eastern Cooperative Oncology Group (ECOG) performance status (PS) rating between patients with leukemia and lymphoma and their physicians. ECOG PS was assessed at diagnosis by patients and their physicians and stratified by disease subtype, gender, age, disease stage and education. Association between patient and physician rated PS and overall survival (OS) was stratified by subtype and prognostic risk score. Overall, 65% of patients and physicians rated PS the same. Age, disease stage and disease subtype were significant predictors of PS disagreement. PS was a significant predictor of OS irrespective of assessment by patients or physicians across all subtypes except those with Hodgkin lymphoma. These findings suggest the need for physicians to better communicate with patients when determining PS, as PS is a strong predictor of survival and is critical in treatment decisions, including determining fitness for cancer treatment.

Keywords

performance status; leukemia; lymphoma; inter-observer agreement; overall survival; cancer

Introduction

Performance status (PS) is a measurement of a patient's functional capabilities and is prognostic of overall survival (OS) in patients with cancer.[1, 2] PS is rated, generally by a physician, using one of two scoring systems, either the Karnofsky Performance Status score or the Eastern Cooperative Oncology Group Performance Status score (ECOG PS).[1, 2]

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However, PS is a subjective measure with no gold standard of measurement.[3] Despite these limitations, PS is frequently used as a surrogate for determination of overall fitness for chemotherapy and treatment including participation in clinical trials. Although there have been multiple studies performed to validate the use of these tools, there are limited data available regarding the frequency of inter-observer agreement of PS rating between patients and clinicians. Patients should be the best suited to rate their own functional status. Previous studies have sought to determine if patients and their physicians rate PS similarly, and have suggested low inter-observer agreement between patients with solid tumors and oncologists [4, 5, 6, 7, 8, 9, 10] with very limited data in patients with hematologic malignancies.[11]

The goal of our study was to compare patient and physician rated PS in patients with newly diagnosed hematologic malignancies, namely, lymphoma and leukemia, to determine the frequency of inter-observer variability. In addition, we sought to identify determinants of disagreement in PS (i.e. age, gender, education level, tumor type and stage of disease), and determine whether patient or physician rated PS was a better predictor of OS.

Methods

Study population

This study was reviewed and approved by the human subjects Institutional Review Board at the Mayo Clinic and the University of Iowa, and written informed consent was obtained from all participants. Newly diagnosed lymphoma and leukemia patients were prospectively enrolled within 9 months of diagnosis in the University of Iowa/Mayo Clinic Specialized Program of Research Excellence Molecular Epidemiology Resource from 2002-2008.[12] Participants were asked to complete an enrollment questionnaire, which included demographics, medical history, and ECOG PS (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, e.g., light house work, office work; 2 – Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours; 3 – Capable of only limited self-care, confined to bed or chair more than 50% of waking hours; 4 – Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair).[2] In addition, PS was independently assessed by a physician at time of initial clinical evaluation. Because patients could be surveyed at any point within the first 9 months from diagnosis, the timing of initial patient PS assessment was variable with respect to the start of lymphoma treatment. Therefore, we only included patients who completed the questionnaire and rated PS within 1 month of diagnosis in this analysis to avoid the possible influence of treatment effects on PS. Patients were systematically contacted every 6 months for 3 years and then annually thereafter for event-free and overall survival. Disease progression, relapse and cause of death were validated with a review of medical records or with the patient's treating physician.

We grouped patients into the following histologic subtypes: Hodgkin lymphoma (HL), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), and non-Hodgkin lymphoma (NHL). For purposes of analysis, we subdivided patients with NHL into two groups based on typical clinical characteristics, aggressive and indolent NHL. NHL subtypes considered aggressive included diffuse large B-cell lymphoma, mantle cell lymphoma,

follicular grade III lymphoma, non-cutaneous T-cell lymphomas, and others (Burkitt lymphoma, etc.). Other subtypes were considered indolent.

Statistical analysis

Chi-square and Wilcoxon rank-sum tests were used to assess the association of PS disagreement with prognostic or demographic factors; Cox proportional hazards models and c-statistics were used to evaluate the association of PS with OS. Weighted kappa statistics were used to compare inter-observer agreement between patients and physicians. PS was stratified by lymphoma subtype (HL, CLL/SLL, NHL) as well as by gender, age, education level and disease stage.

Results

Of the 3621 patients enrolled from 2002-2008, 1018 did not return the baseline questionnaire, 1286 were excluded for returning the baseline questionnaire > 1 month from diagnosis, 6 were excluded due to lack of physician-reported PS and 42 were excluded for lack of patient-reported PS, leaving 1269 eligible for analysis. The patients who completed the questionnaire >1 month from diagnosis and were therefore excluded had similar age, gender, stage, Rai score, International Prognostic Score (IPS), and International Prognostic Index (IPI) to those included in the analysis. Of the 1,269 patients included, 58% were male; 275 had chronic lymphocytic leukemia (CLL), 127 had Hodgkin lymphoma (HL), and 867 had non-Hodgkin lymphoma (NHL). A detailed description of patient and disease demographics is illustrated in Table 1.

Frequency of agreement

Overall, 65% of patients (n=829) and physicians rated PS the same (Table 2). Among patients who reported a PS 0-1, 70% agreed with their physician's PS assessment, while agreement decreased to 31% among those who reported a PS ≥ 2. Among those that disagreed, patients tended to rate themselves higher (i.e. worse functional capability) than their physicians. When analyzing the agreement by disease subtypes, we found that the weighted kappa was similar, with kappa 0.34 overall, 0.35 for NHL, 0.34 for CLL/SLL and 0.39 for HL. Patient and physician reported PS by histologic subtype is illustrated in Table 3.

Predictors of disagreement

Age > 60 was a significant predictor of disagreement between patient and physician rated PS overall when compared to those ≤ 60 (39% vs. 30%; p=0.001). This finding was significant in patients with CLL/SLL (32% vs. 19%; p=0.014) and NHL (42% vs. 32%; p=0.004), but not in those with HL (29% vs. 34%; p=0.65).

Across disease subtypes, the level of PS disagreement increased with more aggressive disease. This finding was significant in those with HL (p=0.027) and NHL (p<0.0001) as IPS and IPI increased respectively. The trend for Rai stage was suggestive in those with CLL/SLL, however, was not statistically significant (p=0.27).

When classified by lymphoma subtype, the frequency of patient and physician rated PS disagreement was highest among patients with NHL (37%) compared to HL (33%) and CLL/SLL (27%). Within the NHL subtypes, there was a higher percentage of disagreement among those with aggressive (45%) vs. indolent (25%) disease ($p<0.0001$). There were no significant associations for gender or education level with PS rating among subtypes or overall.

Correlation between PS and OS

Patient and physician-rated PS were both significant predictors of OS in univariate models and also when adjusted for subtype and subtype specific risk score (Table 4). The prognostic ability for PS was similar for both patient rated and physician rated assessment overall (c-statistic=0.76 for both patient and physician rated PS) and in those with HL (c-statistic=0.85 for both patient and physician rated PS) and NHL (c-statistic=0.76 for both patient and physician rated PS). However, patient-rated PS was better for prognostication in CLL/SLL (c-statistic=0.75; $p<0.0001$), compared to physician-rated PS (c-statistic=0.67; $p=0.002$). Neither patient rated (c-statistic=0.63; $p=0.86$) nor physician rated (c-statistic=0.11; $p=0.85$) PS was a significant predictor of OS among patients with HL.

Discussion

In this study of over 1200 leukemia and lymphoma patients, we found that patients and physicians frequently rated PS at diagnosis differently. When disagreement was present, patients tended to rate their PS worse than clinicians. Age, disease stage, and disease subtype were significant predictors of PS disagreement between patients and physicians. This data adds to the current literature on PS reporting in patients with solid tumors [4, 5, 6, 7] and the limited published data in those with hematological malignancies.[11]

Our findings are similar to previous studies of PS agreement in patients with solid malignancies, where agreement between patient and physician was reported in only about half of cases (with weighted kappa statistics ranging from 0.17[6] to 0.53[4], with 0=no agreement and 1=perfect agreement).[5, 7, 8, 9, 10] Similarly, in acute leukemia patients, there was no correlation between physician-rated PS and patient-reported fatigue and physical function quality of life scores at diagnosis.[11]

We found that age, disease stage, and disease subtype were significant predictors of PS disagreement between patients and physicians. Patients that were older or had more advanced disease and/or more aggressive disease subtypes were more likely to disagree with their physician’s PS assessment. It is not entirely clear why these particular characteristics predicted PS disagreement among patients and their physicians. In older patients, use of a comprehensive and less subjective measure of functional status, such as a geriatric assessment tool, may be a more accurate way of assessing PS. Additionally, older patients are more likely to have other comorbid conditions which could be affecting their PS rating. Jolly, et al [13] reported that among their cohort of 984 geriatric cancer patients (aged 65-99), who had both a self-rated and physician rated KPS of ≥ 80, brief geriatric assessment revealed that 69% of patients had at least one deficit identified. Among those with more aggressive or advanced disease, there may be some bias introduced on the part of

the physician when assessing the patent's eligibility for treatment or inclusion in a clinical trial. Alternatively, those with more aggressive or advanced disease may have coexisting depression which could be affecting their PS rating. Jeon, et al [6] found that depression was a significant factor in disagreement in PS rating, leading depressed patients to overestimate their PS when compared to their physicians. Lee, et al [9] reported that patients that disagreed with their physician's PS assessment tended to score lower on physical well-being assessments, in that those with either poorer physical well-being or worse pain were more likely to rate their PS higher than their physician.

Our findings differ from previously reported data. Bladgen et al [5] reported no significant associations with disease stage among their cohort of lung cancer patients, and although no significant associations with gender were found, oncologists scored females more pessimistically than males. Jeon et al [6] reported no significant differences in agreement between gender, type of cancer or cancer stage, however males and patients with stage IV disease were noted to have higher, yet insignificant, rates of agreement. Similarly, Ando et al [4] found that gender significantly correlated with the incidence of PS disagreement with less agreement in females compared to males (37% vs. 54%; p=0.037). Lee, et al [9] reported that age was a significant predictor of disagreement among their cohort of breast cancer patients, with older patients less likely to rate their PS worse than their physician (OR-0.92 per year of age; 95% CI 0.89-0.96). Interestingly, they also found that those with no evidence of disease were more likely to rate their PS better than their physician (OR 0.31; 95% CI 0.13-0.75). The differences between our findings and previously reported data may be due to differences between patients with hematologic malignancies and those with solid tumors. When disagreement occurred in our study, patients tended to rate themselves higher (i.e. worse functional capability) than their physicians, which is similar to previous studies that have shown that physicians tend to rate patients more optimistically than patients rate themselves.[4, 5, 6, 7, 8]

We found that disagreement was highest among patients with aggressive NHL, with similar degrees of disagreement among those with indolent NHL and CLL/SLL. These differences could be due to the heterogenous nature of NHL, the varied behavior of each subtype and the many treatment options available. We attempted to mitigate this by separating NHL by aggressiveness, however, significant heterogeneity remains despite this division.

PS was a significant predictor of OS irrespective of assessment by patients or physicians across all subtypes, with the exception of HL. The lack of prognostic ability of PS among patients with HL may be related to the good prognosis of this subtype as well as the small sample size of our cohort. These findings are similar to previous studies and support the use of PS as a prognostic indicator.[4, 5, 7] Although patient reported outcomes are becoming increasingly incorporated into clinical trial design, inclusion in trials still relies on the physician rated PS. While it is important to communicate with patients effectively while assessing PS, some limitations could be seen if PS was assessed solely by the patient rather than the physician. If a patient is unrealistic regarding their disease state or functional status, they may underestimate their PS in an effort to receive treatment when it may otherwise be inappropriate. Conversely, patients with coexisting depression may overestimate their PS which could possibly exclude them from treatment. Depression is often overlooked or

undiagnosed in cancer patients.[14] Having patients rate their PS could serve as a way to screen for depression as well as open a dialogue between patient and physician if disagreement exists.

This study has a number of strengths. This is the largest known cohort of patients with hematologic malignancy in whom PS disagreement between physicians and patients has been assessed. Moreover, the patients included in this cohort were undergoing a variety of treatments including observation, chemotherapy, and participation in clinical trials. Limitations to this study include the fact that our cohort of patients consist primarily of Caucasians who live in the Midwest U.S., which may restrict the generalizability to other patient populations. Additionally, patients may have already started treatment by the time of their patient rated PS, however, we attempted to limit this by excluding patients who completed their questionnaires >1 month from diagnosis and found no differences in patient or disease characteristics between those included in the analysis and those who were excluded on the basis of timing of PS rating.

In conclusion, we report that for patients with lymphoma and chronic leukemia, PS is prognostic of OS, whether assessed by patients or their physicians. However, there is disagreement 35% of the time. The frequency of PS disagreement between patients and physicians was highest among those older than 60, those with advanced stages of disease, and those with aggressive lymphoma subtypes. Treatment related decisions including whether a patient will be able to tolerate chemotherapy or is a candidate for enrollment in a clinical trial are frequently dependent upon PS rating, and thus have significant clinical implications on patient care. These findings highlight the weaknesses in our tools that determine fitness for chemotherapy and suggest the need for physicians to effectively communicate when assessing PS, particularly with older patients, those with aggressive NHL, and those with advanced disease. Future areas of study should include analysis of less subjective measures of functional status in older patients with hematologic malignancies, such as comprehensive geriatric assessments.

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Table 1

Patient Characteristics

	Total (N=1269)	CLL/SLL (N=275)	HL (N=127)	NHL (N=867)
Age at diagnosis				
N	1269	275	127	867
Median	61.0	64.0	39.0	62.0
Range	(18.0-91.0)	(36.0-91.0)	(18.0-89.0)	(18.0-90.0)
Gender				
Female	529 (42%)	93 (34%)	55 (43%)	381 (44%)
Male	740 (58%)	182 (66%)	72 (57%)	486 (56%)
Highest education level				
Missing	525 (41%)	76 (28%)	67 (53%)	382 (44%)
High school or less	208 (16%)	54 (20%)	13 (10%)	141 (16%)
Some college/vocational school	215 (17%)	54 (20%)	15 (12%)	146 (17%)
College graduate or higher	321 (25%)	91 (33%)	32 (25%)	198 (23%)
Age Group				
≤ 60	609 (48%)	103 (38%)	103 (81%)	403 (47%)
> 60	660 (52%)	172 (63%)	24 (19%)	464 (54%)
Ann Arbor Stage				
Missing	283 (22%)	275 (100%)	1 (1%)	7 (1%)
I-II	357 (28%)	n/a	72 (57%)	285 (33%)
III-IV	629 (50%)	n/a	54 (43%)	575 (66%)
Rai Stage				
Missing	1012 (80%)	18 (7%)	127 (100%)	867 (100%)
0	123 (10%)	123 (45%)	n/a	n/a
1	108 (9%)	108 (39%)	n/a	n/a
2	18 (1%)	18 (7%)	n/a	n/a
3	2 (<1%)	2 (1%)	n/a	n/a
4	6 (1%)	6 (2%)	n/a	n/a
IPI				
Missing	516 (41%)	275 (100%)	0 (0%)	241 (28%)

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	Total (N=1269)	CLL/SLL (N=275)	HL (N=127)	NHL (N=867)
0	115 (9%)	n/a	46 (36%)	69 (8%)
1	198 (16%)	n/a	46 (36%)	152 (18%)
2	208 (16%)	n/a	20 (16%)	188 (22%)
3	146 (12%)	n/a	9 (7%)	137 (16%)
4	78 (6%)	n/a	6 (5%)	72 (8%)
5	8 (1%)	n/a	0 (0%)	8 (1%)
IPS				
N	127	n/a	127	n/a
Median	3.0		3.0	
Range	(1.0-6.0)		(1.0-6.0)	

CLL/SLL: Chronic lymphocytic leukemia/Small lymphocytic lymphoma; HL: Hodgkin lymphoma; NHL: non-Hodgkin lymphoma; IPI: International Prognostic Index; IPS: International Prognostic Score for HL

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Table 2

Frequency of performance status (PS) rating agreement between leukemia/lymphoma patients and their physician

	N (% agreement of physician rating with patient rating) Patient reported PS					
Physician reported PS	**0**	**1**	**2**	**3**	**4**	**Total**
0	656 (78%)	160	23	4	0	843
1	105	120 (42%)	44	14	0	283
2	21	23	26 (31%)	14	1	85
3	0	12	10	25 (51%)	2	49
4	1	1	3	2	2 (22%)	9
Total	783	316	106	59	5	1269

PS: Performance status

Table 3

Performance status (PS) disagreement for all leukemia and lymphoma survivors and the subtypes of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL)

	Overall Disagreement			CLL/SLL Disagreement			HL Disagreement			NHL Disagreement	
	N (%)	p-value		N (%)	p-value		N (%)	p-value		N (%)	p-value
Age		**0.001**	**Age**		**0.014**	**Age**		0.65	**Age**		**0.004**
≤ 60	609 (30%)		≤ 60	103 (19%)		≤ 60	103 (34%)		≤ 60	403 (32%)	
> 60	660 (39%)		> 60	172 (32%)		> 60	24 (29%)		> 60	464 (42%)	
Gender		0.37	**Gender**		0.78	**Gender**		0.11	**Gender**		0.37
Female	529 (33%)		Female	93 (28%)		Female	55 (26%)		Female	381 (36%)	
Male	740 (36%)		Male	182 (26%)		Male	72 (39%)		Male	486 (39%)	
Education		0.48	**Education**		0.58	**Education**		0.85	**Education**		0.61
High school or less	208 (36%)		High school or less	54 (26%)		High school or less	13 (23%)		High school or less	141 (41%)	
Some college	215 (35%)		Some college	54 (30%)		Some college	15 (27%)		Some college	146 (38%)	
College graduate	321 (32%)		College graduate	91 (22%)		College graduate	32 (31%)		College graduate	198 (36%)	
Subtype		**0.006**	**Rai Stage**		0.27	**IPS**		**0.027**	**IPI**		**<0.0001**
CLL/SLL	275 (27%)		0	123 (24%)		1	17 (12%)		0-1	221 (29%)	
HL	127 (33%)		1	108 (29%)		2	746 (26%)		2	188 (44%)	
NHL	867 (37%)		2-4	26 (39%)		3	37 (38%)		3	137 (48%)	
						4-6	27 (52%)		4-5	80 (61%)	
Aggressiveness		**<0.0001**									
Indolent NHL	355 (25%)					**Ann Arbor Stage**		0.056	**Ann Arbor Stage**		**0.002**
Aggressive NHL	532 (45%)					I-II	72 (26%)		I-II	285 (30%)	
CLL/SLL	275 (27%)					III-IV	54 (43%)		III-IV	575 (41%)	
									Subtype		**<0.0001**
									FL	241 (26%)	
									DLBCL	295 (46%)	
									MCL	57 (44%)	
									Post FL	128 (22%)	
									T-Cell	68 (43%)	

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	Overall Disagreement		CLL/SLL Disagreement		HL Disagreement			NHL Disagreement	
	N (%)	p-value	N (%)	p-value	N (%)	p-value		N (%)	p-value
							Other NHL	78 (62%)	

CLL/SLL: Chronic lymphocytic leukemia/Small lymphocytic lymphoma; HL: Hodgkin lymphoma; NHL: non-Hodgkin lymphoma; IPS: International Prognostic Score; IPI: International Prognostic Index; FL: Follicular lymphoma; DLBCL: Diffuse large B-cell lymphoma; MCL: Mantle cell lymphoma; T-Cell: T-cell lymphoma

Table 4

Overall survival for all leukemia and lymphoma survivors and the subtypes of CLL, HL and NHL

		Patient-reported PS					Physician-reported PS			
		HR	**95% CI**	**p-value**	**c-index**		**HR**	**95% CI**	**p-value**	**c-index**
Overall										
	0	reference	–			0	reference	–		
	1	1.88	1.41-2.50			1	1.59	1.18-2.13		
	2	2.19	1.50-3.19	<**0.0001**	0.76	2	2.34	1.58-3.47	<**0.0001**	0.76
	3	4.01	2.62-6.17			3	3.72	2.35-5.88		
	4	14.98	5.27-45.53			4	1.93	0.76-4.91		
CLL										
	0	reference	–			0	reference	–		
	1	3.43	1.63-7.24			1	2.68	1.05-6.86		
	2	15.88	4.46-56.52	<**0.0001**	0.75	2	3.83	0.95-12.03	**0.002**	0.67
	3	45.93	9.65-218.7			3	13.12	1.72-100.11		
	4	–	–			4	–	–		
HL										
	0	reference	–			0	reference	–		
	1	0.27	0.03-2.32			1	0.47	0.05-4.30		
	2	1.35	0.29-6.26	0.63	0.86	2	2.71	0.49-14.89	0.11	0.85
	3	1.25	0.25-6.28			3	1.97	0.37-10.48		
	4	–	–			4	7.23	0.63-82.97		
NHL	0									
	1	reference	-			0	reference	–		
	2	1.75	1.27-2.41			1	1.52	1.11-2.09		
	3	1.90	1.27-2.85	<**0.0001**	0.76	2	2.11	1.37-3.25	<**0.0001**	0.76
	4	3.63	2.28-5.75			3	3.67	2.26-5.98		
	0	17.20	5.91-50.07			4	1.57	0.56-4.40		

HR: hazard ratio; CI: confidence interval; PS: performance status; CLL: chronic lymphocytic leukemia; HL: Hodgkin lymphoma; NHL: non-Hodgkin lymphoma