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ORIGINAL ARTICLES

Predictors of death within six months in patients with advanced AIDS

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ABSTRACT

Objectives: This study sought to identify potential predictive variables of death within 6 months in patients with advanced AIDS.

Methods: Investigators enrolled a consecutive series of patients with advanced AIDS admitted to a skilled nursing facility in New York City over a 1-year period. Demographic, clinical, laboratory, and outcome data were abstracted from medical records using a standardized data collection instrument.

Results: Of the 152 patients enrolled during the study period, 61 patients (40%) died within 6 months from date of admission. Serum albumin, percent deviation from ideal body weight, and number of comorbidities at the time of admission proved to be the best combination of predictors of death within 6 months.

Significance of results: The decrease in AIDS mortality over the past decade, along with an increase in prevalence due to longer survival, has been attributed primarily to the successful use of highly active antiretroviral therapy (HAART). HAART regimens, however, can also produce both short-term adverse effects and long-term complications. The prognostic model developed by this study may be useful in guiding treatment decisions in patients with advanced AIDS for whom a more palliative care plan may be sought.

KEYWORDS: Acquired Immunodeficiency Syndrome/mortality, Adult, Antiretroviral therapy, Highly active, Decision making, Palliative care

INTRODUCTION

Highly active antiretroviral therapy (HAART) has been one of the most successful medical innovations in treating AIDS. It has led to a decrease in the incidence of opportunistic infections, a marked decrease in AIDS mortality, and an increase in AIDS prevalence due to longer survival (Palella et al., 1998; Moore & Chaisson, 1999; Carrasco & Tyring, 2001).

Along with these benefits, HAART regimens can also produce both short-term adverse effects and long-term complications. These include response failure due to drug resistance, systemic symptoms, hepatotoxicity, metabolic and lipodystrophic disorders, and insulin resistance associated with coinfection with hepatitis C virus. Poor adherence or simply advanced disease also can lead to HAART response failure (Detels et al., 1998; d'Arminio Monforte et al., 1998; Gallant, 2000; Max & Sherer, 2000; Jain et al., 2001; Reisler, 2001; Duong et al., 2001). In a recent study of patients with advanced AIDS who were

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admitted to a long-term care facility, we reported a 15% mortality within 3 months of admission (Brechtl et al., 2001). Patients who died had been maintained on HAART regimens until death. Of the patients who survived longer than 3 months, 25% could not tolerate a HAART regimen.

These results highlight the challenge for patients and physicians who must make difficult treatment decisions about initiating or continuing HAART in advanced AIDS. Identifying predictors of death in this population could provide valuable guidance. A reliable predictive model could help optimize patient care by alleviating burdensome, perhaps ineffective, medication loads while providing a more palliative, quality-of-life approach.

Studies of prognostic indicators of disease progression and death are abundant for the pre-HAART era and earlier stages of infection (Friedland et al., 1992; Mocroft et al., 1995; Hanson et al., 2002). Specifically, plasma HIV-1 RNA viral load levels and CD4+ cell counts have demonstrated high predictive value (Mellors et al., 1996, 1997; O'Brien et al., 1996). Unfortunately, these markers are less predictive in patients with advanced AIDS, irrespective of antiretroviral regimens (Spino et al., 1997; Cozzi Lepri et al., 1998; HIV Surrogate Marker Collaborative Group, 2000). The purpose of the present study, therefore, was to identify the best predictors of death within 6 months in patients with advanced AIDS and to develop a prognostic model that could be used to guide patient management decisions.

METHODS

Setting and Subjects

This retrospective cohort study examined a consecutive series of AIDS patients admitted to Terence Cardinal Cooke Health Care Center (the Center) between January 1 and December 31, 1999. The Center, which is located in Manhattan, is a 729-bed skilled nursing facility that includes a 156-bed AIDS Discrete Unit (the Unit). Patients in the Unit are provided with full-time medical supervision; their health is too poor or unstable for them to be discharged. The goal of the Unit is for patients to improve clinically receiving aggressive and supervised medical care as tolerated. Patients are not admitted specifically for end-of-life care, although such care is anticipated for patients who decline during their course of treatment. All study subjects had been referred to the Center from acute care hospitals because of advanced illness requiring ongoing, skilled nursing care; thus investigators refer to these patients as having "advanced AIDS."

Data Collection

We abstracted demographic, clinical, laboratory, and outcome data from medical records using a standardized data collection instrument. Demographic data included age, gender, and ethnicity. Clinical data included height, weight, comorbidites (e.g., cancer, nephropathy, thrombocytopenia), HIV transmission group (heterosexual, homosexual, IV drug use), and CDC AIDS Category and AIDS-defining conditions (as specified by the 1993 revised CDC-Defined Classification for HIV Infection; Centers for Disease Control and Prevention, 1992). Laboratory data included hemoglobin, hematocrit, white blood count, lymphocyte count, platelet count, albumin, CD4 count, HIV-1 RNA viral load, serum ALT, and serum AST. We noted whether a patient had died within 6 months of admission and, for patients who were discharged before 6 months had elapsed, we requested a search from the National Death Index (Centers for Disease Control and Prevention, 2005) to ascertain those patients' survival status at 6 months. Given that there is an estimated 1-year lag between a death and its entry into the National Death Index, data were requested from the National Death Index in 2001.

This study was approved by the Center's Institutional Review Board.

Analysis

Univariate analyses utilized chi-square tests for categorical variables and *t* tests for continuous variables to evaluate the association between each independent variable (demographics, clinical descriptors, laboratory values, and several constructed variables) and the outcome variable (death at 6 months). Constructed variables included number of comorbidities, number of AIDS-defining conditions, and "weight deviation percent" (percentage difference between a patient's actual and ideal body weight at the time of admission). For a man, the ideal weight was calculated as 106 lbs. for the first 5 ft. of height plus 6 lbs. for each additional inch, and for a woman, it was calculated as 100 lbs. for the first 5 ft. plus 5 lbs. for each additional inch (Wilkes, 1999). In addition, the distributions of all continuous laboratory variables between survivors and nonsurvivors were examined to determine whether using cutoff points to create dichotomous variables would yield satisfactory predictions; such variables produce more intuitive, easy-to-apply prognostic guidelines.

After completing the univariate analyses, we conducted a multiple logistic regression analysis to select a combination of variables to include in a

final prognostic model. This analysis considered as potential predictors all independent variables having a p value <0.25 in the univariate analysis (Hosmer & Lemeshow, 2000). Once variables for the final model had been selected, continuous variables were evaluated to confirm the assumption of linearity in the logit. Variables were also evaluated for interaction, and any interaction terms that rendered a p value <0.05 were added to the final model. The Hosmer–Lemeshow chi-square was used to assess model fit (Hosmer & Lemeshow, 2000). All analyses were performed using STATA data analysis software (StataCorp, 1997).

RESULTS

A total of 152 patients with AIDS were admitted to the Center in 1999. Over 82% of patients were between the ages of 30 and 60 and 76% were male. In terms of race, 53.9% of patients were black, 28.3% Hispanic, and 17.8% white. For those patients for whom HIV transmission data were available (76.3%), the majority had become infected with HIV through intravenous drug use (59.5%), a third by heterosexual contact (30.2%), and the remainder by homosexual contact (10.3%). All patients had advanced AIDS in that they fell into CDC AIDS Category A3 or above as follows: A3, 5.9%; B3, 15.1%; C1–C3, 78.9%. Forty-eight percent of patients were on HAART at the time of admission to the Center. A comparison of these variables between those 61 patients who died within 6 months of admission (nonsurvivors) and those 91 patients who survived are presented in Table 1. The results of the univariate analyses for the clinical and laboratory data are presented in Tables 2 and 3. (In Table 3, median values were used for the comparison of those variables with skewed distributions that were statistically significant.)

In comparing the distribution of continuous laboratory variables between survivors and nonsurvivors, the following dichotomous variables were created (with cutoff points shown in parentheses): hemoglobin (10 g/dl), hematocrit (30%), lymphocytes (1000/mm^3), albumin (3.0 g/dl), CD4 count (50/mm^3), platelet count (100,000/mm^3), and serum AST (250 IU/L). Survivors and nonsurvivors had similar distributions of age, serum ALT, HIV

Table 1. *Overview of study patients (N = 152), by survival status at 6 months*

Descriptor	Nonsurvivors (n = 61)		Survivors (n = 91)		P value[a]
	No.	(%)	No.	(%)	
Age (years)	48.5	(range: 23–72)	46.2	(range: 25–78)	
Gender					
Female	13	(21.3)	23	(25.3)	
Male	48	(78.7)	68	(74.7)	
Ethnicity					
Black	36	(59.0)	46	(50.5)	
Hispanic	16	(26.2)	27	(29.7)	
White	9	(14.8)	18	(19.9)	
HIV transmission group					
Heterosexual	15	(24.6)	20	(22.0)	
Homosexual	5	(8.2)	7	(7.7)	
Intravenous drug use	24	(39.3)	45	(49.5)	
Unknown	17	(27.9)	19	(20.9)	
CDC AIDS category[b]					
A3	2	(3.3)	7	(7.7)	<0.01
B3	5	(8.2)	18	(19.8)	
C1	0	—	2	(2.2)	
C2	7	(11.5)	12	(13.2)	
C3	47	(77.0)	52	(57.1)	
Receiving HAART[b]					
Yes	24	(39.3)	49	(53.8)	
No					

[a]P value refers to the significance of the difference between nonsurvivors and survivors with respect to each variable. If no p value is given, then the difference was not statistically significant ($p > 0.05$).
[b]Upon admission.

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Table 2. *AIDS-defining conditions and comorbidities in study patients (N = 152), by survival status at 6 months*

	Nonsurvivors (n = 61)		Survivors (n = 91)		P value[a]
	No.	(%)	No.	(%)	
AIDS-defining condition[b]					
Candidiasis	14	(23.0)	12	(13.2)	
Cryptococcosis	2	(3.3)	1	(1.1)	
Cytomegalovirus	8	(13.1)	4	(4.4)	
Herpes simplex	5	(8.2)	6	(6.6)	
HIV dementia	18	(29.5)	23	(25.3)	
HIV wasting	24	(39.3)	18	(19.8)	0.01
Kaposi's sarcoma	2	(3.3)	2	(2.2)	
Lymphoma	5	(8.2)	5	(5.5)	
Mycobacterium avium	12	(19.7)	9	(9.9)	
Mycobacterium tuberculosis	2	(3.3)	6	(6.6)	
Pneumocystis pneumonia	17	(27.9)	15	(16.5)	
Pneumonia, recurrent	3	(4.9)	10	(11.0)	
Promyelocytic leukemia	3	(4.9)	4	(4.4)	
Toxoplasmosis	5	(8.2)	3	(3.3)	
Comorbidity[b]					
Anemia	53	(86.9)	70	(87.9)	
Cancer	6	(9.8)	5	(5.5)	
Cardiomyopathy	2	(3.3)	1	(1.1)	
Congestive heart failure	4	(6.6)	2	(2.2)	
Chronic Obstructive Pulmonary Disease	2	(3.3)	5	(5.5)	
Endocarditis	1	(1.6)	2	(2.2)	
Hepatic failure	12	(19.7)	1	(1.1)	<0.01
Nephropathy	8	(13.1)	9	(9.9)	
Sepsis	1	(1.6)	1	(1.1)	
Thrombocytopenia	25	(41.0)	16	(17.6)	<0.01

[a]*P* value refers to the significance of the difference between nonsurvivors and survivors with respect to each variable. If no p value is given, then the difference was not statistically significant ($p > 0.05$).
[b]Upon admission.

viral load, and white blood cell count, so cutoff points were not established for these variables. To facilitate its use in a prognostic guideline, we converted weight deviation percent to a categorical variable with six ranges: >0, 0 to −9%, −10% to −19%, −20% to −29%, −30% to −39%, and −40% to −49%.

The final multivariate prognostic model included albumin (OR 2.5 [1.1, 5.6], $p = 0.03$), ideal body weight deviation (OR 1.7 [1.3, 2.3], $p < 0.01$), and number of comorbidities (OR 2.0 [1.3, 3.0], $p \leq 0.01$; see Fig. 1). Thirty-seven percent of survivors versus 74% of nonsurvivors had an albumin level ≤ 3.0 g/dl ($p < 0.01$). Almost half of nonsurvivors (49%) fell below their ideal body weight by 20% or more as compared to 23% of survivors ($p < 0.01$). Finally, 33% of survivors versus 56% of nonsurvivors had two or more comorbidities ($p < 0.01$). Of the 34 nonsurvivors with two or more comorbidities, 94% had been diagnosed with anemia, 68% with thrombocytopenia, 35% with hepatic failure, and 24% with nephropathy. The predicted probability of death within 6 months based on this prognostic model is detailed in Figure 2.

Two variables that were significantly associated with mortality in the univariate analyses (serum AST and hepatic failure) were not included in the final multivariate model because their estimates were unstable, as indicated by extremely wide confidence intervals. The Hosmer–Lemeshow chi-square (2.6; $p = 0.96$) revealed good model fit. Because no interaction terms showed statistical significance, none were included in the final model.

Using the data that generated the model, a probability cutoff value of 0.50 for predicting death within 6 months yielded 67% sensitivity and 80% specificity. Raising the probability cutoff to 0.70 decreased sensitivity to 33% and increased specificity to 96%. A higher cutoff increasing specificity (reducing false-positive classifications) at the ex-

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Table 3. *Laboratory values in study patients (N = 152), by survival status at 6 months*

Measure[a]	Nonsurvivors (n = 61) Mean	Nonsurvivors (n = 61) Range	Survivors (n = 91) Mean	Survivors (n = 91) Range	P value[b]
Hemoglobin, g/dl	10.3	6.9–16.4	11.4	7.1–14.5	<0.01
Hematocrit, %	30.9	20.7–48.0	34.1	21.0–43.3	<0.01
Lymphocyte, mm^3	1080.0	64.0–4928.0	1206.9	60.0–6336.0	
Albumin, g/dl	2.5	1.0–4.8	3.2	0.9–4.1	<0.01
CD4, mm^3	84.3	1.0–576.0	117.5	0–464.0	
Serum ALT, IU/L	43.2	6.0–225.0	41.8	9.0–153.0	
	Median	Range	Median	Range	
White cell count, mm^3	4900	1000–16400	4800	600–26400	
Platelet, mm^3	166,500	11,000–498,000	226,000	15,000–675,000	0.04
HIV viral load, copies/ml	47,046	0–912,732	13,605	0–2,657,300	0.03
Serum AST, IU/L	48	12–237	42	14–276	0.04

[a]Upon admission.
[b]P value refers to the significance of the difference between nonsurvivors and survivors with respect to each variable. If no p value is given, then the difference was not statistically significant ($p > 0.05$).

pense of decreasing sensitivity (increasing false-negative classifications) may provide an acceptable trade-off in guiding decision making with such a model, assuming patients and physicians would prefer to err on the side of aggressive treatment (Table 4).

DISCUSSION

This study identified a combination of three descriptors—albumin level, deviation from ideal body weight, and number of comorbidities—that were good predictors of death within 6 months in patients with advanced AIDS. Our findings are consistent with previous studies that have shown decreased albumin to be an independent predictor of death in patients with AIDS (Turner et al., 1996; Sabin et al., 2002; Wheat et al., 2002), and undernutrition—one of the major causes of low albumin—to be common in these patients (Salomon et al., 2002). Furthermore, deaths attributable to comorbidities are increasing with the improved manage-

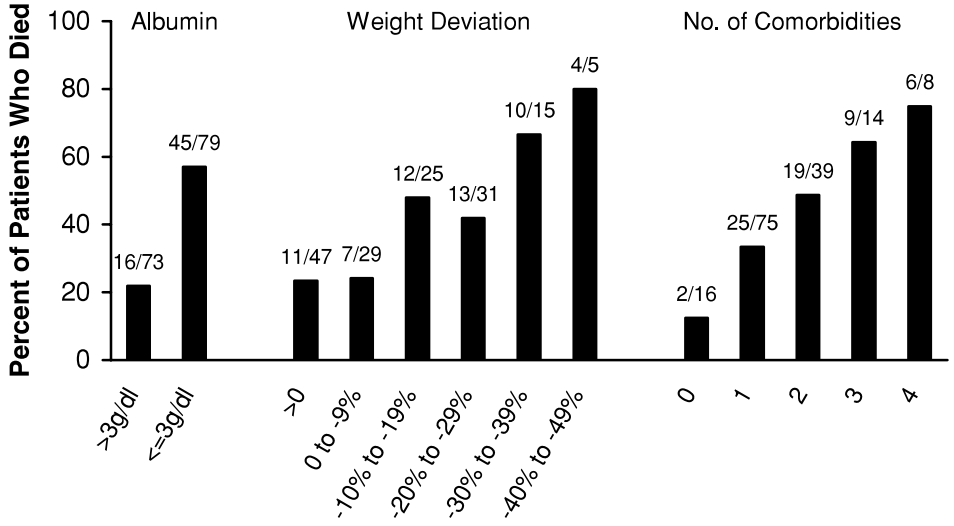

Fig. 1. Percent of patients who died within 6 months, according to albumin level, deviation from ideal body weight, and number of comorbidities (N = 152).

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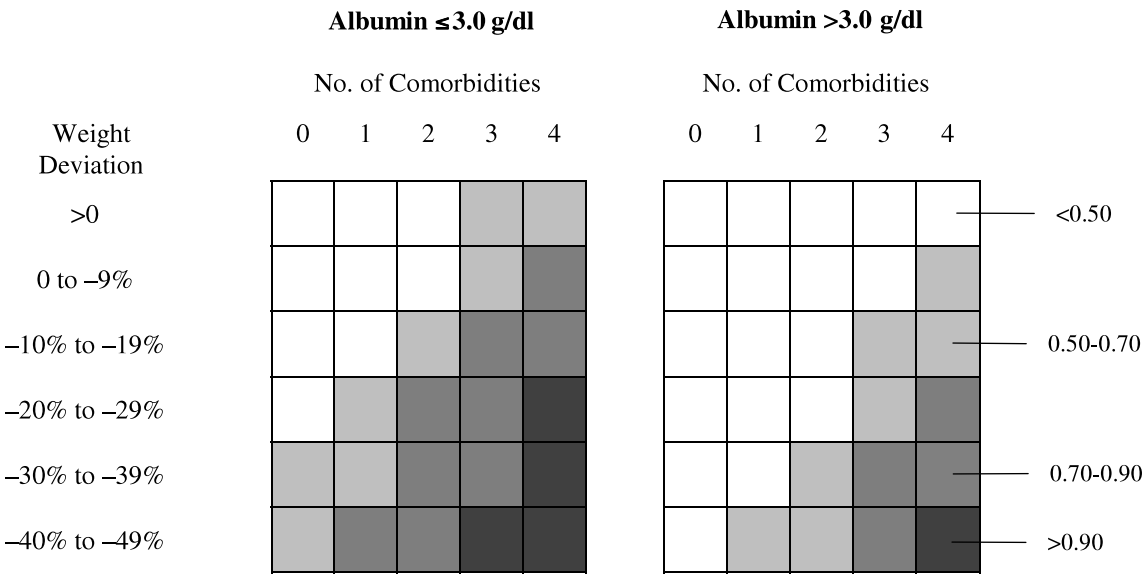

Fig. 2. Predicted probability of death within 6 months, based on a logistic prediction model that combines albumin level, deviation from ideal body weight, and number of comorbidities. Degree of shading indicates the predicted probability of death within 6 months (<0.50, 0.50–0.70, 0.70–0.90, or >0.90) associated with each combination of predictor values.

ment of this disease. According to a 2000 report, for example, deaths from opportunistic infections decreased significantly between 1995 and 1999 (from 20.9% to 8.5%; $p < 0.05$), whereas deaths from hepatic failure increased significantly (from 0% to 6%; $p < 0.05$; Sansone & Frengley, 2000).

It is possible that such differences could alter the risk of death predicted by our model. It is important to emphasize, therefore, that the model in Figure 2, which is based on data for a single long-term care facility, is intended for patients with advanced disease based on CDC AIDS category and the need for continual skilled nursing care—that is, patients similar to the population from which the model was derived. The demographic profile of our patients resembles that of AIDS populations in other large metropolitan areas in the southern, north-central, and northeastern regions of the United States (Centers for Disease Control and Prevention, 2000; Welch et al., 2002); however, the clinical profile of our

Table 4. *Performance of prognostic model using probability cutoff values 0.50 or 0.70 (N = 152)*[a]

		Probability cutoff = 0.50, actual outcome		Probability cutoff = 0.70, actual outcome	
		Died	Survived	Died	Survived
Predicted outcome	Die	41	18	20	4
	Survive	20	73	41	87
Sensitivity		67% (41/61)		33% (20/61)	
Specificity		80% (73/91)		96% (87/91)	
Pos. predictive value		69% (41/59)		83% (20/24)	
Neg. predictive value		78% (73/93)		68% (87/128)	
False-positive rate		31% (18/59)		17% (4/24)	
False-negative rate		22% (20/93)		32% (41/128)	

[a]Predictions are based on a logistic regression model that includes albumin level, deviation from ideal body weight, and number of comorbidities.

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patients differs in some respects from other series of patient with AIDS (Welch et al., 2002). Therefore, until the model has been independently validated in other groups of patients with advanced AIDS, its predictions must be considered with caution.

Based upon input from patients and family, other research has identified certain key components that result in what is perceived as high-quality end-of-life care. These include interactions with health care professions to provide physical comfort and emotional support to patients and their families as well as information to facilitate shared decision making (Teno et al., 2004). To meet these expectations and provide such care, it is necessary to equip patients and families with the tools to share in such delicate and yet crucial matters. This study has taken an early step to develop such a tool for patients with advanced AIDS. Numerous studies have developed end-of-life decision aids for terminally ill cancer patients, but few have looked to provide similar help to those living with AIDS.

Early treatment decisions can have a profound impact on the ultimate course of HIV disease and a patient's quality of life. We are now capable of turning this disease into a manageable condition for many, though not all, patients through informed and judicious use of drug therapy. The prognostic model presented here may be useful as a building block in predicting short-term survival in patients with advanced AIDS. It should, at minimum, heighten sensitivity to the appropriateness of withholding or withdrawing HAART in certain patients.

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