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Selecting patients for heart transplantation: Comparison of the Heart Failure Survival Score (HFSS) and the Seattle Heart Failure Model (SHFM)

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chronic heart failure;
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prognostic model;
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BACKGROUND: The Heart Failure Survival Score (HFSS) risk-stratifies patients with chronic heart failure (CHF) referred for heart transplantation using 7 parameters, including peak VO_2. The Seattle Heart Failure Model (SHFM) is a 20-variable model that combines clinical, laboratory and therapeutic data. Although both models have excellent accuracy, only the HFSS was derived and validated in patients referred for transplantation, and the HFSS and SHFM have not been directly compared.

METHODS: We tested the accuracy of the SHFM and compared the HFSS and SHFM in 715 patients referred for heart transplantation.

RESULTS: Over a follow-up of 962 ± 912 days, 354 patients died or received an urgent heart transplantation or a ventricular assist device. One-year event-free survival was 89%, 72% and 60%, respectively, for the low-, medium- and high-risk HFSS strata, and 93%, 76%, and 58%, respectively, for the low-, medium- and high-risk SHFM strata. The HFSS and SHFM were modestly correlated ($R = -0.48$, $p < 0.001$). In receiver operating characteristic curve analysis, areas under the curves (AUCs) for the HFSS and SHFM were comparable (1 year: 0.72 vs 0.73; 2-year: 0.70 vs 0.74, respectively) and incremental to New York Heart Association class. The 1- and 2-year combined HFSS+SHFM AUCs were 0.77 and 0.76, respectively, significantly better than the HFSS or SHFM alone.

CONCLUSIONS: The HFSS and SHFM provide accurate and comparable risk stratification in CHF patients referred for transplantation. Combining the HFSS and SHFM improves predictive ability.

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Chronic heart failure (CHF) is associated with high mortality, but risk may be difficult to assess, ranging from 5% to 75% mortality per year.[1] Therefore, assessing mortality risk becomes a critical component in the evaluation of a candidate for heart transplantation,[2] especially under the current circumstances of severe donor organ shortage. New York Heart Association (NYHA) class correlates with prognosis, but it is subjective. Peak oxygen consumption (VO_2) is used in transplant selection but has limitations when used alone.[3] Therefore, we developed the Heart Failure Survival Score (HFSS), which effectively risk-stratifies patients under evaluation for heart transplantation using 7 parameters, including peak VO_2.[4] The HFSS has been validated and found to be more accurate than peak VO_2 alone in numerous settings.[5–10]

The Seattle Heart Failure Model (SHFM) was derived from the PRAISE I clinical trial database[1] and has been validated in numerous settings.[11–14] However, 98% of events in the SHFM derivation and validation databases were death, rather than transplantation or left ventricular assist device (LVAD) implantation.[11,15] The SHFM provides risk strata, an estimation of 1-, 2- and 5-year survival rates, a mean life expectancy and an estimated survival curve, using 20 commonly obtained clinical, pharmacologic, device and laboratory parameters, but

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with NYHA class rather than peak VO_2 as a measure of functional capacity.[1]

Although both models have been broadly validated and have excellent accuracy, they were derived and validated in very different populations. The aim of this study, specifically in patients referred for heart transplantation, was to: (1) assess the prognostic accuracy of the SHFM; and (2) compare the HFSS and SHFM.

Methods

Study patients and data collection

Seven hundred fifteen consecutive patients with systolic heart failure referred to the Columbia University Medical Center for heart transplant evaluation underwent cardiopulmonary exercise testing and collection of variables in the HFSS and SHFM. Clinical characteristics are listed in Table 1. Review of the data was approved by the local human investigations committee.

The HFSS includes 7 parameters: resting heart rate (HR); mean blood pressure (mBP); left ventricular ejection fraction (LVEF); serum sodium; presence or absence of ischemic heart disease; presence or absence of intraventricular conduction defect (IVCD); and peak VO_2. Peak VO_2 was determined during maximal treadmill exercise using a modified Naughton protocol and a metabolic cart (Medical Graphics, Minneapolis, MN). LVEF was determined using echocardiography or contrast/radionuclide ventriculography. The presence of IVCD was defined as QRS interval of $\geq$ 120 milliseconds due to left or right bundle branch block, non-specific intraventricular conduction delay or ventricular-paced rhythm. Dichotomous variables were coded as: 1 = present and 0 = absent. The HFSS was derived in each patient from the 7 clinical parameters. Each variable for the continuous and dichotomous variables was multiplied by a model coefficient, derived from a proportional hazard model. The 7 products were summed and the absolute value determined according to the following equation: HFSS = [(0.0216 * resting HR) + (−0.0255 * mBP) + (−0.0464 * LVEF) + (−0.047 * serum sodium) + (−0.0546 * peak VO_2) + (0.608 * presence or absence of IVCD) + (0.6931 * presence or absence of ischemic heart disease)].[4] For the HFSS, risk strata were defined as a low risk ($\geq$ 8.10), medium risk (7.20 to 8.09) or high risk ($\leq$ 7.19), using previously described cut-offs.[4]

The SHFM score was derived in each patient from 20 variables, including clinical characteristics (age, gender, NYHA class, weight, LVEF, systolic blood pressure [sBP], ischemic etiology), medications (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, β-blocker, statin, aldosterone blocker, loop diuretic equivalent dose, allopurinol), device therapy (implantable cardioverter-defibrillator, cardiac resynchronization therapy) and laboratory data (lymphocyte percentage and serum sodium, hemoglobin, uric acid, total cholesterol), as previously described.[1] We used the electronic medical record to collect data on all variables required to calculate the SHFM score. Missing continuous variables were imputed as the mean for all patients in the data set. The SHFM score was rounded to the nearest integer between 0 and 4 (patients with scores < 0 were considered to have a score of 0). Risk strata were defined as low risk (score 0), medium risk (score 1) or high risk (score $\geq$ 2).

Outcomes

Outcome events were defined as death, urgent transplantation (United Network of Organ Sharing [UNOS] Status 1) or LVAD implantation. Patients who were transplanted as non-urgent (UNOS Status 2) were censored alive on the date of the transplant. Vital status of patients lost to clinical follow-up was assessed using the Social Security Death Index.

Statistics

Baseline characteristics for patients with and without events were compared by chi-square tests (categorical variables) and unpaired *t*-tests (continuous variables) (Table 1). Pearson's correlations were calculated between the HFSS and SHFM (Figure 1A) and also between the peak VO_2 alone and the SHFM (Figure 1B) (but not between the peak VO_2 and the HFSS, because the peak VO_2 is a heavily weighted component of the HFSS). Event-free survival rates for the different HFSS and SHFM risk strata were determined using the Kaplan–Meier method and compared by log-rank test (Figure 2). Components of the HFSS and SHFM were entered into Cox regressions as single variables (univariate) (Table 2) or in combination (multivariate) (Table 3). The 1- and 2-year AUC receiver operator characteristic curve (AUC of ROC) was calculated for the HFSS and SHFM separately and in combination (Figure 3), and also for NYHA in isolation. Statistical significance between AUC values was tested by the method of Hanley and McNeil.[16]

To evaluate the predictive ability of a combined HFSS+SHFM, a new score was created. Both variables were entered into a Cox regression model (as continuous variables). Both variables were multiplied by its associated β-coefficient and the products were summed to determine a patient's risk score.

All analyses, except for the comparison between AUCs, were performed using SPSS, version 11.0 (SPSS, Inc., Chicago, IL). Statistical comparisons were considered significant at $p < 0.05$.

Results

Baseline characteristics and outcomes

The clinical characteristics and outcomes are listed in Table 1. The mean HFSS was 8.04 ± 0.89 and the mean SHFM score was 0.822 ± 0.933. The HFSS and SHFM were modestly correlated ($R = -0.48$, $p < 0.001$; Figure 1A), but more so than the peak VO_2 alone vs SHFM ($R = -0.36$, $p < 0.001$; Figure 1B).

During a mean follow-up of 962 ± 912 days, 354 outcome events (49.5%) occurred; 170 patients underwent urgent heart transplantation, 148 patients died, 36 received LVAD implantation, 35 patients underwent elective transplant, and the remaining 326 patients were alive without transplant at last follow-up. Table 1 shows a comparison of the clinical characteristics between patients with and without events.

The Kaplan–Meier event-free survival curves stratified by low-, medium- and high-risk HFSS and SHFM strata are

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