

Hypoalbuminemia Predicts Heart Failure Deaths

BY MITCHEL L. ZOLER
Philadelphia Bureau

NEW ORLEANS — Patients with heart failure who also have hypoalbuminemia have a two- to threefold increased risk of death, compared with patients with normal serum albumin levels, according to data on about 1,000 patients.

It's possible that this elevated mortality risk may be controlled using nutritional supplements or treatments aimed at cutting the inflammation associated with hypoalbuminemia, Tamara Horwich, M.D., said at the annual scientific sessions of the American Heart Association.

It's unclear what links hypoalbuminemia with worse survival during heart failure, but several candidate mechanisms exist. These include hemodilution, cardiac cachexia, biventricular heart failure, reduced colloid osmotic pressure causing pulmonary edema, and reduced tolerability and use

of optimal medical therapy, said Dr. Horwich, a cardiologist at the University of California, Los Angeles.

Results from prior studies had linked hypoalbuminemia with a higher risk of death in a variety of disease states, including cancer, end-stage renal disease, infections, and cardiac surgery. But until now, few studies had examined whether a similar association exists in patients with heart failure.

Dr. Horwich and her associates reviewed case records for 1,162 heart failure patients with who were treated at UCLA Medical Center from December 1983 through June 2004. Some patients were excluded because their left ventricular ejection fraction was greater than 40% or they had inadequate follow-up. The study focused on the 1,039 eligible patients who remained. Their average age was 52 years, and their mean ejection fraction was 23%.

Patients were diagnosed with hypoalbuminemia if their

serum albumin was less than 3.4 g/dL. About 25% of the patients in this study had hypoalbuminemia, a prevalence consistent with reports from prior studies of heart failure patients. Low albumin levels were most prevalent in lean patients, with a prevalence of 29%, but hypoalbuminemia was also common in overweight and obese patients, with prevalences of 15% and 20%, respectively.

The 1-year survival rate among patients who were hypoalbuminemic at baseline was 68%, compared with more than 80% for those with normal baseline serum albumin levels.

In a multivariate analysis that took into account a number of potential confounders, including age, gender, and body mass index, patients who had low serum albumin were 2.8-fold more likely to die, compared with patients with a serum albumin level within the normal range, Dr. Horwich said. ■

ICDs Appear to Be Economical for Patients With Heart Failure

BY MITCHEL L. ZOLER
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NEW ORLEANS — Treatment with a single-chamber, implantable cardioverter defibrillator is cost-effective for patients with moderate to severe heart failure and a left ventricular ejection fraction of 35% or less, according to results of the Sudden Cardiac Death in Heart Failure Trial.

An economic analysis of the results of SCD-HeFT showed that placing an implantable cardioverter defibrillator in all patients who met entry criteria would cost about \$33,000 for each added life-year, Daniel B. Mark, M.D., reported at the annual scientific sessions of the American Heart Association.



This means that ICD treatment for these patients is cost-effective and "economically attractive" because the cost for each additional year of life saved was less than the consensus maximum in the United States of \$50,000 per added life-year, the cost of Medicare's dialysis program, said Dr. Mark, director of the outcomes research and assessment group at Duke University, Durham, N.C.

Still, actually putting these devices in all U.S. patients who fit the clinical profile would rack up a staggering cost of perhaps as much as \$50 billion a year, said William Weintraub, M.D., director of the Center for Outcomes Research at Emory University, Atlanta.

SCD-HeFT enrolled 2,521 patients with stable heart failure with symptoms that placed them into either New York Heart Association class II or III; 70% had class II disease. On top of standard heart failure treatment, patients were randomized to receive 200-400 mg/day amiodarone, treatment with an ICD, or placebo, and they were followed for a mean of 46 months. The trial, and the economic analysis, were sponsored by Medtronic Inc., maker of the ICD used.

During follow-up, mortality was about 36% in both the placebo and amiodarone groups and about 28% in the ICD group, a

statistically significant 23% relative drop.

The mean 5-year cost per patient on amiodarone exceeded the \$43,077 cost with placebo, so amiodarone is not an economically viable alternative. The mean 5-year cost in the ICD group was \$61,967, but because ICD treatment saved lives, compared with placebo, the cost increment could be subjected to a cost-effectiveness analysis. The mean life expectancy in the placebo group was about 8.4 years, compared with 10.9 years in the ICD group, yielding an average gain of nearly 2.5 years for each patient who got an ICD.

'Seven lives saved for every 100 patients ... very few treatments in cardiology have this impact.'

DR. MARK

When ICD therapy cost was calculated using a 3% discount for all costs and life expectancy, the result was \$33,192 per added life-year. The cost of ICD therapy per added life-year generally remained below the \$50,000 maximum even using different cost assumptions. For example, the cost per added life-year remained less than \$40,000 whether or not treatment was limited to patients with left ventricular ejection fractions of 30% or less, to patients aged 65 years or older, or to patients with a QRS interval of 120 msec or more.

ICD therapy was as cost-effective in patients with ejection fractions of 30%-35% as in patients with ejection fractions below 30%.

The Centers for Medicare and Medicaid Services recently removed several exclusions for ICD coverage, including those for patients with high QRS intervals, or left ventricular ejection fractions of 30%-35% (INTERNAL MEDICINE NEWS, Feb. 15, 2005, p. 1). CMS previously focused on the fact that during 5 years of follow-up, ICDs saved seven lives for every 100 patients who received ICDs, and the agency had sought to avoid paying for ICDs in the 93% of patients who seemed to get no benefit, Dr. Mark said.

SCD-HeFT was not designed to identify criteria to easily distinguish responders from nonresponders, he noted. Even so, "seven lives saved for 100 patients treated is a huge therapeutic impact. Very few treatments in cardiology have this impact," he said. ■

Disease Management for HF May Not Yield Cost Savings

BY BRUCE JANCIN
Denver Bureau

NEW ORLEANS — Participation in a disease management program for heart failure resulted in a moderate survival benefit but no objective improvement in functional capacity, no reduction in health care utilization, and no cost savings in the largest and most rigorous study to date of any disease management program.

The lack of demonstrable cost savings is a key finding. Disease management has become a trendy public policy issue now, with Medicare and many state Medicaid programs actively pushing disease management programs for depression, diabetes, and other chronic diseases as a means of saving money, Autumn Dawn Galbreath, M.D., observed at the annual scientific sessions of the American Heart Association.

"There's a great deal of money being spent on disease management at this time, in anticipation of promised cost savings. According to our study, those promises may be empty," said Dr. Galbreath, vice chairman for clinical programs in the department of medicine at the University of Texas, San Antonio.

Prior studies which concluded that disease management programs are both clinically effective and cost-effective were small, nonrandomized, and/or based upon relatively homogeneous HMO populations. Recognition of these deficiencies provided the impetus for the South Texas Congestive Heart Failure Disease Management Project, in which 1,069 patients with systolic or diastolic heart failure were randomized 2:1 to a disease management program or usual care and followed for 18 months, she explained.

The subjects in the disease management group were assigned a nurse case manager who provided in-depth patient education and recommended

medication changes in accord with national heart failure guidelines to the patient's primary care physician, although whether or not to follow the recommendations was left to the physician's discretion.

Patients randomized to disease management survived an average of 76 days longer than controls over the course of 18 months of follow-up. But their performance on a standard 6-minute walking test wasn't significantly better than that of controls, and neither was their mean left ventricular ejection fraction. The disease management program did not reduce hospitalizations, office or ER visits, procedures, or medications.

Subgroup analysis suggested the survival benefit was greatest in patients with New York Heart Association class III and IV systolic heart failure. But even in these patients with more severe heart failure, disease management didn't result in economic savings.

"If you factor in the cost of having to pay for the disease management services, disease management actually costs money over and above the cost of traditional care," Dr. Galbreath said.

The investigators plan to analyze the data further to obtain cost-benefit ratios. ■

VERBATIM

'We need to put the guaiac cards [for in-office testing] in a locked drawer labeled "use only in case of emergency."'

Dr. Harold C. Sox, editor of the Annals of Internal Medicine, on screening for colorectal cancer by primary care physicians, p. 69.