Clinical Trial Highlights

ALPHA: T-Wave Alternans Testing Hospital

A noninvasive microvolt T-wave alternans (TWA) test in patients with nonischemic cardiomyopathy can identify patients who do not need an implantable cardiac defibrillator (ICD), said Gaetano M. De Ferrari, MD, of San Matteo Hospital, Pavia, Italy, who presented the results of the T-Wave Alternans in Patients with Heart Failure Trial (ALPHA). ALPHA enrolled 446 patients with New York Heart Association (NYHA) class 2 and 3 heart failure with cardiomyopathy of nonischemic origin and left ventricular ejection fraction (LVEF) of <40%. Patients underwent TWA testing and were followed for 18 to 24 months. Abnormal tests were observed in 65% and normal tests in 35% of patients.

Patients with an abnormal TWA test had a four-fold higher risk of the primary endpoint—cardiac death and life-threatening arrhythmias (p=.001). They also had a four-fold higher total risk of death (p=.002), and a five-fold higher risk of arrhythmic death, life-threatening arrhythmias, and hospitalizations (p=.004). The negative predictive value for the primary endpoint was 98.7% at 12 months and 97.3% at 18 months.

"Patients with a normal TWA test have a very good prognosis and are unlikely to benefit from ICD therapy," Dr. De Ferrari said.

EVEREST: Modest Gains from Tolvaptan in Heart Failure

Results from the EVEREST trial, presented by Marvin A. Konstam, MD, of Tufts-New England Medical Center indicated that in patients with acute decompensated heart failure, tolvaptan, an oral nonpeptide vasopressin V_2-receptor blocker, did not reduce mortality or hospitalizations but did provide modest symptomatic relief.

EVEREST (Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study with Tolvaptan) consisted of two prospective, randomized, double-blind, placebo-controlled trials at 359 sites in North America, South America, and Europe. The combined study population included 4,133 patients who received 30 mg/day of tolvaptan or placebo within 48 hours of hospital admission. The primary composite endpoint was change from baseline at day 7 or hospital discharge in patient global assessment (by visual analog scale) and body weight. Tolvaptan was associated with additional weight loss of 0.6 kg in one trial and 0.9 kg in the other (p<.0001). There were no significant differences in global clinical status improvement in either trial. A number of secondary endpoints were favorably affected by tolvaptan (Table 1).