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SURGICAL VENTRICULAR RECONSTRUCTION IN HEART FAILURE PATIENTS NOT JUSTIFIED

*STICH Trial Concludes that SVR Increases Costs without Improving Quality of
Life or Providing Other Clinical Benefits*

Orlando, FL – The first major clinical trial to compare different operative approaches to a specific surgical problem found that patients with ischemic heart failure who undergo surgical ventricular reconstruction (SVR) in addition to coronary artery bypass graft (CABG) surgery have no better post-operative quality of life than patients who undergo CABG surgery alone, according to research presented today at the American College of Cardiology's 58th Annual Scientific Session. ACC.09 is a premier cardiovascular medical meeting, connecting cardiologists and cardiovascular specialists to the latest and most innovative findings in cardiovascular science.

Patients who suffer a heart attack sometimes develop scar tissue on the front wall of their heart due to loss of blood flow to this area of heart muscle. These scars, which cannot contract like normal heart muscle, can cause progressive weakening and force the heart to grow larger and more abnormally shaped in order to maintain blood flow to the body. Over the past 25 years, cardiac surgeons developed the SVR procedure to eliminate these scars and reshape the left ventricle to produce a more normally shaped heart in the belief that this would improve heart function and patient outcomes. Investigators of the Surgical Treatment for Ischemic Heart Failure (STICH) trial have already reported at this meeting that the SVR procedure failed to improve longevity or reduce the number of cardiac-related hospitalizations any more than CABG surgery alone.

In addition to these clinical outcomes, the STICH investigators examined whether the SVR procedure benefited patients through improved quality of life reflected as either psychological well-being or better physical functioning. This portion of the study substantially augments the clinical outcome data because a major goal of treatment is to improve patients' quality of life, and finding patients' symptoms and function improved would be an important argument for performing the procedure, even if it didn't improve patients' overall survival. Despite achieving

the surgical remodeling as planned, the trial concluded that patients who had the SVR procedure in addition to CABG surgery did not experience an improvement in these quality of life outcomes over patients who had CABG surgery without SVR. Moreover, in a subset of 200 patients in the United States with cost information, the SVR procedure substantially increased the costs of the operation and post-operative care by an average of more than \$14,500.

“STICH shows that sometimes what seems like a good idea for treating patients based on our models of disease understanding does not actually work,” said Daniel Mark, M.D., M.P.H., Director of Outcomes Research at the Duke Clinical Research Institute and lead investigator of the economic and quality of life substudy.” STICH also offers evidence that it is possible to subject what surgeons do in the operating room to the bright light of randomized clinical trial testing to help refine the surgical care of our patients.”

STICH includes two international, randomized clinical trials comparing different treatment strategies for patients with ischemic heart failure. The trial, which is sponsored by the National Heart, Lung, and Blood Institute, enrolled 1000 patients with symptomatic heart failure, an anterior wall scar and a left ventricular ejection fraction ≤ 0.35 . For the quality of life substudy, investigators collected a battery of instruments including the Kansas City Cardiomyopathy Questionnaire (KCCQ), which evaluates the effects of heart failure symptoms on quality of life.

Both treatment groups significantly improved their KCCQ scores compared with a pre-operative assessment, and these observed improvements in disease-specific health status occurred rapidly and were sustained throughout three years of follow-up. However, quality of life scores did not differ between the two treatment groups at baseline or at any follow-up interval. Similarly, depressive symptoms decreased significantly post-operatively in both treatment groups but were not different between each group at any point during follow-up. Additionally, 4 percent of pre-operative patients had New York Heart Association Class I symptoms and 15 percent had Class IV symptoms, while postoperatively 40 percent of the survivors were Class I and 2 percent were Class IV demonstrating an overall marked improvement in heart function for both groups.

These results are being published online Monday, March 30 in the American Heart Journal (www.ahjonline.com).

Results of the second STICH trial, which compares the use of CABG surgery with use of medical therapy alone to treat heart failure patients, are expected to be reported in 2011.

Dr. Mark will present the study “Quality of Life Outcomes with Surgical Ventricular Reconstruction in Symptomatic Heart Failure: Results from the STICH Trial” on Tuesday, March 31 at 11:38 a.m. in Hall A2.

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The American College of Cardiology (www.acc.org) works to influence health care policy and represents the majority of board certified cardiovascular care specialists through education, research, promotion, and the development and application of standards and guidelines. ACC.09 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.