



PRESS RELEASE

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SYNTAX Trial Affirms Bypass Surgery Superiority in Treatment of Complex Coronary Disease

Major Adverse Cardiovascular or Cerebrovascular Event Rate Shows Drug-Eluting Stents Inferior to Bypass Surgery at One Year

September 2, 2008- The Society of Thoracic Surgeons urges the medical community and the public to take note of the initial results of the SYNTAX (Synergy between PCI with TAXUS drug-eluting stent and Cardiac Surgery) study released yesterday, which found that drug-eluting stent (DES) placement is inferior to coronary artery bypass graft (CABG) surgery as a treatment option for patients with multivessel or left main (LM) coronary disease. The significant study results, released at the European Society of Cardiology (ESC) Congress 2008 in Munich, Germany, have long been anticipated by the medical community, as previous trials had only compared DES versus CABG in low-risk patients.

The SYNTAX study, which was sponsored by Boston Scientific Corporation, is a first-of-its-kind randomized trial of 1,800 patients that compares percutaneous coronary intervention (PCI) using DES head-to-head with CABG in patients with three-vessel and left main disease. Specifically, the study found that at the one-year endpoint, PCI is inferior to CABG for major adverse cardiovascular or cerebrovascular events (death, heart attack, stroke, or repeat revascularization), 17.8% vs 12.1% for multivessel and left main disease.

The SYNTAX trial also provided supportive data regarding the survival benefit of CABG relative to stenting. The study results showed that CABG had a strong trend toward better survival at one year with a 23% relative mortality benefit, consistent with other studies of DES vs CABG. For example, a larger study of DES vs CABG from New York State data, presented by E.L. Hannan, et al, in the *New England Journal of Medicine* [NEJM 2008;358:1781-92] showed a significant mortality benefit of CABG vs DES at 18 months with a 21% relative mortality benefit in three vessel disease and a 35% relative mortality benefit in double vessel disease.

“These results represent a landmark shift in the cardiovascular community. With the growth in stent therapy in the past decade and the relative ease of stent application compared to bypass surgery, patients with multivessel and left main disease who would benefit more from bypass surgery were instead choosing stent therapy – with the assumption that both treatments are equally effective and survival outcomes were the same,” said W. Randolph Chitwood, MD, President of The Society of Thoracic Surgeons.

“However, now we have clear evidence that this is not the case. We need to pass this information on to patients, so that informed treatment decisions can be made.”

“In previous trials, trial design and eligibility criteria prevented high-risk patients who would benefit most from CABG from participating; therefore, no definitive conclusion could be made for the effectiveness of CABG in ‘real world’ patients who had complex coronary disease,” said Michael Mack, MD, Medical Director, Baylor Heart Hospital, who served as one of the study

investigators in the SYNTAX trial. "With these new results, it is critical that *before* stenting is performed clinicians provide patients with full and complete disclosure of the risks and benefits of both drug-eluting and bare metal stents, including the possibilities of decreased survival and increased reintervention."

Robert Guyton, MD, Chief of Cardiothoracic Surgery at Emory Health Care, noted that SYNTAX revealed a 3.3% stent thrombosis rate in one year, much higher than the stent thrombosis rate of "less than 1%" usually cited to patients. The study compared stent thrombosis to a similar rate of symptomatic graft closure in the CABG group. But, said Dr. Guyton, "comparing stent thrombosis with 'symptomatic graft closure' rate is disingenuous - graft closure may cause angina, but rarely does it cause myocardial infarction or muscle loss. The native vessel is still open with graft failure. But stent thrombosis causes sudden complete closure of a major coronary vessel: 40% of stent thrombosis is fatal."

"All patients would choose stenting as the first procedure if mortality were the same," Dr. Guyton said. "However, many patients would rethink their options if they were told that for multivessel coronary disease, bypass surgery is the procedure that gives the best chance of being free from angina and free from repeat procedures. But *most importantly*, patients need to know that if they have stenting instead of coronary bypass as a first procedure, they have a 20 to 40% higher chance of dying in three years."

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The Society of Thoracic Surgeons is a not-for-profit organization representing more than 5,600 surgeons, researchers, and allied health professionals worldwide who are dedicated to ensuring the best possible heart, lung, esophageal and other surgical procedures for the chest. Founded in 1964, the mission of STS is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research and advocacy.

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