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STUDIES COMPARE STENTS AND CARDIAC PROCEDURES FOR LONG-TERM SURVIVAL

Research Indicates Similar Benefits in Procedures, Better Results with Certain Stents

ATLANTA, GA (March 14, 2006) — Cardiologists are continually searching for the most effective and non-invasive methods of treatment for their patients. Two studies presented today at the American College of Cardiology's inaugural *Innovation in Intervention: the i2Summit 06* may provide physicians with more information on treatment decisions that could help make subsequent cardiac procedures unnecessary. Innovation in Intervention: i2 Summit is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions.

Nine-Year Clinical Outcome of Coronary Stenting Versus Coronary Artery Bypass Grafting in Patients With Significant Proximal LAD Stenosis or Multiple Vessel Disease (Abstract 2802-4).

The use of stents (small, lattice-shaped, metal tubes inserted permanently into an artery) has become common practice for the treatment of coronary artery disease (CAD), even in high-risk patients who may not have been eligible previously. These individuals traditionally would have undergone coronary artery bypass graft (CABG), an invasive procedure requiring open chest surgery to "bypass" damaged heart valves. While the use of stenting has continued to grow, physicians have assumed that stenting was not as effective as CABG and instead served as a temporary approach to treatment. In order to confirm the effectiveness of the stenting procedures, researchers from the Texas Heart Institute led a study comparing stenting outcomes to results of CABG in patients with multivessel or single blockage in the heart's critical left anterior descending artery.

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Investigators examined long-term follow up data from 6,479 patients with CAD who underwent CABG (2,634 patients) or received coronary stent implants (3,845 patients) between 1995 and 2003, and calculated nine-year mortality rates among the groups. Results showed that overall mortality was similar between the CABG group and the stented group (OR 0.8; 95% CI, 0.7-1.0; p=0.27). The two procedures also had similar long-term survival in subgroups of patients with diabetes (OR 1.1; 95% CI, 0.8-1.5; p=0.67) or a major left ventricle systolic dysfunction with ejection fraction <35%, a reduced percentage of blood pumped out of the heart with every beat, (OR 0.7; 95% CI, 0.4-1.2; p=0.19).

"Appropriately selected patients with coronary artery disease may be treated effectively with stents as an alternative to surgery," said Shun Kohsaka, M.D., of the Texas Heart Institute and lead author of the study. "Our data shows long-term survival is unaffected by initially choosing the less invasive approach."

Direct and Indirect Comparison Meta-Analysis Demonstrates the Superiority of Sirolimus-Versus Paclitaxel-Eluting Stents Across 5854 Patients (Abstract 2912-74)

While stents have been considered an effective treatment for coronary artery disease, there had always been a concern that plaque could reappear within the device. The use of drug-eluting stents has continued to grow, since they contain drugs that potentially reduce the chance the arteries will become blocked again. However, questions remained regarding which drug-eluting stent is most effective. A team of researchers at Policlinico San Donato in Italy, Middelheim Hospital in Belgium and Medical College of Virginia in Richmond, used the pooled results of 15 independent head-to-head trials to compare the efficacy of sirolimus-eluting stents (SES) to paclitaxel-eluting stents (PES). Sirolimus is an immunosuppressive drug, a chemical agent that suppresses the immune response, and paclitaxel is an antineoplastic agent, which inhibits or prevents the growth and spread of malignant cells.

Researchers studied the results for binary angiographic restenosis (BAR) and target lesion revascularization (TLR) in a total 5,854 patients (2,852 treated with SES and 3,002 treated with PES) at six and twelve months. Results showed a significant reduction in BAR (p<0.0001) and TLR (p=0.0008) among patients treated with SES. BAR is a renarrowing of the previously unblocked artery; TLR is a repeat procedure or bypass surgery to unblock a previously repaired artery.

"We were able to demonstrate a clear superiority of sirolimus-eluting stents compared with paclitaxel-eluting stents in patients undergoing percutaneous coronary interventions to open blocked arteries in the heart," said Giuseppe Biondi-Zoccai, M.D., of Policlinico San Donato and lead author of the study. "While cost is often a consideration in clinical decision-making, we believe the results of our study should be taken into account when deciding which stent to use on patients."

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.06 and the ACC inaugural i2 Summit, the first-ever meeting for interventional cardiologists, will bring together more than 30,000 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.

Innovation in Intervention: i2 Summit is an annual meeting for those practicing coronary and non-coronary interventions. Sponsored by the American College of Cardiology, in partnership with the Society for Cardiovascular Angiography and Interventions and other professional associations, i2 Summit 2006 offers late-breaking interventional clinical trials, peripheral, vascular, coronary and valvular education, live cases from Europe, Asia and the United States, emerging technology / state-of-the-art lectures, expert simulation demonstrations, interactive *Laptop Learning* and general cardiovascular education at ACC.06, held concurrently with i2 Summit, for a dynamic, complete cardiovascular educational experience. i2 Summit consolidates all clinical, educational, practical and community needs into one event and delivers unsurpassed needs-based learning with true objectivity.