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# RENAL ARTERY STENTING FALLS SHORT IN LARGE RANDOMIZED TRIAL

*Patients with renal artery stenosis did equally well with medical therapy alone*

**CHICAGO, Ill. (April 1, 2008) —** The largest-ever randomized study to evaluate the effectiveness of catheter-based interventions in patients with narrowing of the renal artery has shown that angioplasty and stenting offer no benefit over medical therapy. Among patients who completed one year of follow-up, there were no differences in the change in kidney function, blood pressure control or the rates of major cardiovascular illness, according to the Angioplasty and Stenting for Renal Artery Lesions (ASTRAL) trial.

The ASTRAL trial is being reported today in a Late-Breaking Clinical Trials session at the SCAI Annual Scientific Sessions in Partnership with ACC i2 Summit (SCAI-ACCi2) in Chicago. SCAI-ACCi2 is a scientific meeting for practicing cardiovascular interventionalists sponsored by the Society for Cardiovascular Angiography and Interventions (SCAI) in partnership with the American College of Cardiology (ACC).

The study also found that 3 percent of patients who underwent renal artery intervention experienced a serious procedural complication, including poorly positioned stents and perforation and dissection of the renal artery.

“For 15 years we’ve had the wherewithal to fix renal artery stenosis and restore patency of the renal artery,” said Philip A. Kalra, MD, a consultant nephrologist at Hope Hospital, Salford, and lecturer at the University of Manchester, both in the United Kingdom. “Thousands of patients have had this procedure, but no one has ever demonstrated any benefit in randomized control trial testing.”

About 7 percent of people over age 65—and about 10 percent of people with chronic kidney disease who eventually need dialysis—have narrowing, or stenosis, of the renal artery. There are several links

between renal artery stenosis and cardiovascular disease. For example, in nine out of 10 cases renal artery stenosis is caused by the build-up of atherosclerotic plaque. Many patients with renal artery stenosis also have coronary and peripheral arterial disease; indeed, these conditions share common risk factors. At least 30 percent of older patients with chronic congestive heart failure have renal artery stenosis. Perhaps most important, uncontrolled high blood pressure often prompts physicians to suspect renal artery stenosis—and to treat it with angioplasty and stenting.

To evaluate the clinical effectiveness of renal artery stenting, Dr. Kalra and his colleagues recruited 806 patients with atherosclerotic renal vascular disease (ARVD) from 54 medical centers in the United Kingdom, and four in Australia and New Zealand. Patients had renal failure, with an average serum creatinine of about 2.0 mg/dL. Baseline blood pressure averaged 151/76 mm Hg. More than half were current or ex-smokers, nearly one-third had diabetes and nearly half had coronary artery disease. The degree of renal artery stenosis at baseline was 76 percent, on average.

The researchers randomly assigned patients to catheter-based intervention plus medical therapy or medical therapy alone. Renal artery stenting was successful in widening the renal artery, achieving a residual stenosis of less than 50 percent in 88 percent of patients.

After one year of follow-up, however, there were no differences in the change in serum creatinine—it rose by 0.2 mg/dL in both groups—or in rates of renal events, including acute renal failure. Even in the highest-risk patients—those with a baseline creatinine in the highest third, or who had experienced a rapid deterioration in kidney function in the preceding year—renal artery angioplasty and stenting offered no significant renal functional benefit at one year, but patient numbers in these sub-groups were fairly small.

Blood pressure fell slowly over time, and by four years, averaged 146/74 mm Hg in both groups. At one year, there was no significant difference in the rates of heart attack, stroke, hospitalization for chest pain or heart failure or the need for coronary intervention or bypass surgery. Risk-adjusted mortality was the same in the two groups.

“In this study we were looking at the majority of patients with renal artery stenosis—those in whom there is substantial uncertainty about whether to revascularize,” Dr. Kalra said. “The message is, you don’t put a stent in these patients without more careful evaluation. More often than not, it will make no difference whatsoever in clinical outcomes. However, some patients with renal artery stenosis have more definite indications for revascularization, such as acute renal failure or severe acute heart failure, and they should continue to receive this therapy.”

*Dr. Kalra will present the results of the "Angioplasty and Stenting for Renal Artery Lesions” (ASTRAL) study on Tuesday, April 1 at 10:45 a.m. CDT in the Grand Ballroom, S100.*

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**About SCAI**

Headquartered in Washington, DC, the Society for Cardiovascular Angiography and Interventions is a 4,000-member professional organization representing invasive and interventional cardiologists in over 60 nations. SCAI’s mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI’s annual meeting has become the leading venue for education, discussion, and debate about the latest developments in this dynamic medical specialty.

**About ACC**

The American College of Cardiology is leading the way to optimal cardiovascular care and disease prevention. The College is a 34,000-member nonprofit medical society and bestows the credential Fellow of the American College of Cardiology upon physicians who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.