



INNOVATION IN INTERVENTION

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STUDY IDENTIFIES STEPS TO IMPROVE SAFETY OF RENAL ARTERY STENTING *Platelet Inhibitor Combined with Embolic Protection Device Yields Best Results*

NEW ORLEANS, La. (March 26, 2007) — High blood pressure is the most common chronic medical condition in the United States, and the most common identifiable cause is narrowing of a kidney artery, called renal artery stenosis. Renal artery stenting is a widely performed but controversial procedure for patients with narrowed kidney arteries. Studies have demonstrated little improvement in average kidney function with a significant minority of patients experiencing a decline in kidney function after the procedure.

Use of a platelet inhibitor may make renal artery stenting safer for patients, especially when used in combination with an embolic protection device (EPD), according to a study presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit* in New Orleans, La. EPDs are filters that safely trap and remove much of the debris that may be dislodged during interventional procedures. *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.

Renal artery stenosis not only leads to high blood pressure, or hypertension, but can also lead to chronic failure of the kidney. This is the first study to test whether using glycoprotein IIb/IIIa inhibitors and EPDs would improve renal function following the stenting. To test the value of the combination therapy regimen, a total of 100 patients undergoing renal artery stenting at seven centers were randomized to EPD

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(Angioguard™) or double-blinded use of a glycoprotein IIb/IIIa inhibitor (abciximab) in a 2x2 factorial design. Patients' key functions were recorded, including kidney function, activation of platelets and the presence of platelet-rich thrombus (blood clots) in the filter baskets of the EPDs. The main effects of treatments and their interaction were assessed by percent change in MDRD-derived GFR from baseline to one month. MDRD-derived GFR (glomerular filtration rate) is a widely accepted estimated measure of kidney function, usually based on serum creatinine level, age, sex and race.

Researchers found that an overall improvement in renal function was only observed in patients allocated to both treatments. Abciximab reduced the occurrence of platelet-rich emboli (particles or debris) in the EPD from 42 to seven percent. This difference was highly significant compared to the three other possible allocations in the 2x2 design. EPD alone was not associated with improved renal function, whereas the use of a glycoprotein IIb/IIIa inhibitor showed measurable benefit.

"When examined independently, the platelet inhibitor abciximab appeared to have beneficial effects, but Angioguard did not appear to be noticeably helpful," said Christopher J. Cooper, M.D., of the University of Toledo and lead author of the study. "However, the group treated with both Angioguard and abciximab in combination benefited the most from treatment, illustrating a significant interaction effect. Like many other studies, we are finding that patients benefit from a combination of therapeutic strategies; in this case, the filter and the drug serve patients best when doctors use both in combination."

Dr. Cooper will present the results of the "Embolic Protection and Platelet Inhibition During Renal Artery Stenting" study on Monday, March 26 at 11:30 a.m. CDT in room La Nouvelle Orleans C.

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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.07 and the i2 Summit is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in the treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.