Highlights From ISET

Renaissance Study Shows Efficacy of Express SD Stent in Renal Artery Disease

January 23, 2006—Boston Scientific Corporation (Natick, MA) announced results from its Renaissance trial, which was designed to study the safety and effectiveness of the Express SD renal stent in treating renal artery disease. The results were presented by the study's Principal Investigator, Krishna Rocha-Singh, MD, at the International Symposium on Endovascular Therapy (ISET 2006), which was held on January 22-26 in Miami Beach. According to the company, Renaissance is a prospective, single-arm, multicenter study involving 100 patients at 14 sites in the US. The primary endpoint of the study is restenosis at 9 months. The restenosis rate was compared to a benchmark of 40% determined by a literature review of similar endpoints in patients undergoing balloon angioplasty of the renal artery. The restenosis rate for the Express SD was 21.3%.

Dr. Rocha-Singh also reported a major adverse event rate of 10.5%, including no in-hospital events and no reported stent thromboses, and a low target lesion revascularization rate of 8.4%. The trial also demonstrated a follow-up success, with 93 of the 100 patients having ultrasound performed at 9 months postimplantation.

The company stated that these results will be used to seek FDA approval for the Express SD renal stent for use in the renal arteries. The investigators will continue to monitor the progress of the study patients with annual follow-up to 5 years." The Renaissance study provides critical insight into the occurrence and treatment of renal artery disease," commented Dr. Rocha-Singh. "Physicians have seen poor results treating this disease with a balloon alone, so it's gratifying to see an improved outcome when incorporating the Express SD renal stent."

RESILIENT Data Demonstrate Improved Outcomes

January 24, 2006—John R. Laird, Jr, MD, presented the 12-month data from the RESILIENT Trial at ISET 2006. RESILIENT is a multicenter, prospective, randomized trial comparing balloon angioplasty to stenting for SFA and proximal popliteal artery disease using the Lifestent NT (Edwards Lifesciences, Irvine, CA). The trial included a 20-patient roll-in phase and a pivotal 206-patient randomized trial in which there is a 2:1 randomization between stenting and balloon angioplasty.

The primary endpoints of the pivotal trial are target lesion and target vessel revascularization at 12 months postprocedure. Important secondary endpoints include primary and secondary patency at 6 and 12 months (determined by duplex ultrasound), the usual measures of acute success, and quality of life. For those patients who underwent balloon angioplasty, crossover to stenting was discouraged, but could be performed for a major dissection of grade C or greater, or an occlusive complication that could not be managed with additional measures, such as prolonged balloon dilatation, vasodilators, and pharmacologic agents. Bailout stenting will be considered a target vessel revascularization or a primary endpoint.

Inclusion criteria include *de novo* or restenotic nonstented lesions in the SFA or proximal popliteal artery down to 3 cm above the knee joint. The reference vessel must be between 4 mm and 6.5 mm in diameter. Lesions up to 15 cm in length were treated in patients who had at least one patent runoff vessel. Follow-ups were scheduled for 30 days, 6 months, and 12 months after the procedure, and then annually up to 3 years. Doppler examination will be performed at 30 days, 6 months, and 12 months, as well as x-ray evaluation at 6, 12, and 18 months looking for evidence of stent fracture.

Dr. Laird reported that at 30 days, there was significant improvement in the ankle-brachial index (ABI) from baseline (.76 to .97). At 6 months, the ABI was well maintained at .93, and 100% of the patients had improvement in at least one Rutherford category. There were no target vessel or target lesion revascularizations, and no stent fractures were identified. The duplex primary patency at 6 months was 93.3%. The majority of these patients have been reviewed out to 12 months: the ABI is fairly well maintained at .86 and 94.4% of patients have improved in at least one Rutherford category. There have been some target lesion revascularizations (10% at 12 months), with a primary clinical patency of 90%. At 12 months, there have been no stent fractures.

Dr. Laird concluded that the preliminary findings of the phase 1 trial demonstrate excellent outcomes of this novel flexible nitinol stent design. At 12 months, there were no safety issues, there was a 0% stent fracture rate, a 90% clinical patency, and overall improvement in quality of life.

Six-Month Results of FAST Show Improved Outcomes

January 24, 2006—The acute results and 6-month outcomes of the Femoral Artery Stenting Trial (FAST) were presented by Hans Krankenberg, MD, at ISET 2006. The FAST Trial is a prospective, randomized, controlled, multicenter trial designed to assess the efficacy of Luminexx nitinol stent (C.R. Bard, Inc., Murray Hill, NJ) implantation versus stand-alone balloon angioplasty (PTA) in patients with superficial femoral artery (SFA) disease. Two hundred forty-four patients were randomized into the two study arms (121 in the PTA arm, 123 in the stent arm). Thirteen patients in the PTA arm underwent additional stent implantation, for a crossover of 11%. The primary endpoint was binary restenosis (≥ 50% stenosis on ultrasound) at 12 months. The secondary endpoints were periprocedural complications (hematoma, AV fistula, false aneurysm, subacute occlusion, non-TL PTA/stenting, distal embolization, and vessel injury) at 30 days; binary restenosis on Doppler US; primary assisted and secondary patency; walking distance/ankle-brachial index; TLR; and major adverse events (death, amputation) at 6 and 12 months; and stent fractures at 12 months.

The key inclusion criteria were Rutherford classification ≥ 2, and angiographically determined single *de novo* SFA lesion ≥ 1 cm from origin, a target lesion length of 1 cm to 10 cm, target lesion stenosis of 70% to 100%, a patent popliteal artery, and at least one patent infrapopliteal artery (for distal runoff). Key exclusion criteria were angiographically determined lesion extension into the proximal popliteal artery, previous stent impantation in the SFA, SFA lesion length ≥ 10 cm, restenotic/reoccluded target lesion, acute (≤ 4 weeks) thrombotic occlusion, and untreated ipsilateral pelvic stenosis.

Dr. Krankenberg noted that lesion length at baseline, as determined by visual estimate, was 44.5 mm in the PTA arm and 45.2 mm in the stent arm. Technical success (defined as residual stenosis <30%) was 79% in the PTA arm and 93% in the stent arm; procedural complications were reported to be low. The 6-month intention-to-treat results were binary restenosis on Doppler US (38.3% for the PTA arm vs 25.5% for the stent arm), target vessel revascularization (12.4% for the PTA arm vs 6.5% for the stent arm), ankle-brachial index at rest (mean improvement of .12 for the PTA arm vs .18 for the stent arm), and major adverse events (two amputations [1.6%; after pre-existing gangrene] and one death [0.8%; due to colon cancer] in the stent arm vs none in the PTA arm). The 6-month results per protocol were binary restenosis on Doppler US (41.5% for the PTA arm vs 24.5% for the stent arm).

Dr. Krankenberg concluded that the 6-month interim analysis of the FAST Trial indicated a trend toward improved outcomes in binary restenosis, target lesion revascularization, and ankle-brachial index after stent placement. There were no safety issues related to stent placement.

EKOS Ultrasound Shown to Benefit Clot Treatment

January 23, 2006—EKOS Corporation (Bothell, WA) announced that two studies presented by Thomas McNamara, MD, at ISET 2006, demonstrated positive results from using the EKOS ultrasound-enhanced drug delivery system. Dr. McNamara presented data from a 13-center ongoing observational study involving clots in 99 patients, 66 with peripheral arterial occlusion (PAO) and 33 with deep vein thrombosis (DVT).

In the PAO group, 1.3% of patients experienced major bleeding after treatment with the ultrasound-enhanced delivery system. The bleeding caused bruising but was not fatal. After 17.5 hours of treatment with the new system, clots were completely dissolved in 58 of the 66 patients (88%). Overall, ultrasound-enhanced delivery resulted in a 28% improvement in dissolution of clots and a 92% reduction in bleeding complications compared to conventional treatment. In the 33-patient DVT group, 5% experienced nonfatal major bleeding that caused bruising. After 23.3 hours, clots were completely dissolved in 23 of the 33 patients (70%). In the National Venous Registry's DVT studies of conventional clot-busting therapy, 31% to 38% of clots were completely dissolved after 36.8 to 53.4 hours and 11.4% had major bleeding. Ultrasound-enhanced delivery more than doubled the number of patients whose clots were completely dissolved and resulted in a 56% reduction in bleeding complications compared to conventional treatment.

According to EKOS, the new device delivers drugs in the same manner as the conventional catheter system, with the addition of a central wire that has six to 30 tiny ultrasound transducers, depending on the size of clot, situated 1.5 inches apart on the wire. When the drug is delivered, the transducers emit high-frequency, low-energy ultrasound waves to both loosen the clot fibers and force the drug through the clot. The clots dissolve faster and fuller with the more fibrin that the drug touches. The new device's ultrasound does not cause temperature changes nor does it damage tissue, Dr. McNamara stated. ■

If you are interested in purchasing the educational sessions from ISET on multimedia CD-ROM ($229), including the live audio in MP3 format and available slides, or the Live Case Studies on DVD, contact Digitell, Inc., at 1-800-679-3646, or visit their online store at www.netsymposium.com.