First in man SESAME stent trial demonstrates 100 percent acute success rate

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A new study revealed that the novel self-expanding super-elastic all-metal endoprosthesis stent (SESAME StentTM) used in patients undergoing angioplasty of degenerated saphenous vein graft (SVG) lesions has 100% acute success, low 30 day major adverse cardiac events (MACE) rates, and 9-month patency comparable to balloon expandable stents without embolic protection. Results of the study are published in the November issue of *Catheterization and Cardiovascular Intervention*, a peer-reviewed journal from The Society for Cardiovascular Angiography and Interventions.

Percutaneous coronary intervention (PCI), or angioplasty, is a procedure to alleviate plaque buildup due to atherosclerosis. A thin catheter containing a small balloon is inserted into an artery and threaded toward the heart to the blockage. The balloon is then inflated to push back the plaque and restore blood flow to the heart, and a wire mesh tube called a stent is usually put in place to prevent re-blocking.

PCI of old, degenerated saphenous vein grafts (SVGs) is a challenging and risky procedure. Diseased SVGs are complicated, thrombotic lesions associated with a higher risk of plaque and thrombus embolization, making the placement of embolic distal protection devices during PCI difficult. Up to half of patients with SVGs receiving bare metal stents have restenosis or occlusion within 6□□ months following stent implantation. There are no self-expanding stents specifically used to treat SVG disease. Prior adjunctive therapies such as antiplatelet agents and covered stents have not been effective in improving procedural

outcomes of SVG PCI.

The Advanced Bioprosthetic SurfacesTM SESAME stent offers a system that limits plaque protrusion through the stent struts and limits stent strut migration into the underlying plaque. The microporous mesh of the SESAME stent is an improvement over the polymer covers used in other stents for SVG implantation because it allows improved vascular healing and tissue regrowth over the sent (endothelialization). Biocompatibility studies indicate metals are advantageous over polymers, suggesting that a metal membrane should be a good choice for a covered-stent.

The SESAME First in Man trial is a prospective, multicenter registry of 20 nonrandomized consecutive patients with 21 stenotic SVGs treated electively at two centers between February 2005 and August 2005. Patients underwent elective intervention of symptomatic SVG lesions with 50% stenosis. PCI was performed without embolic protection devices.

"The SESAME trial is the first study to prospectively demonstrate that a self-expanding microporous membrane-covered stent can be safely used with a high success rate in treating complex SVG lesions even in the absence of embolic protection devices," comments study leader Steven R. Bailey, MD, FSCAI, from the University of Texas Health Sciences Center in San Antonio. Technical success—successful crossing of the lesion and deployment of the device—was achieved in 100% of lesions using the SESAME stent. A 100% procedural success rate, defined as a residual stenosis of less than 50% stenosis post stent and no MACE, was also achieved.

No procedural or in hospital complications occurred. Follow-up was present in 20 patients at 30 days, with clinical and angiographic evaluation at 9 months. No MACE events occurred at 30 days. At 9

months, 3 patients underwent repeat PCI. Dr. Bailey concluded, "Even in severely degenerate SVG lesions, interventionists can safely achieve a high primary success rate with low MACE during the initial 30 days following the procedure."

More information: "Use of A Self-Expanding Super-Elastic All-Metal Endoprosthesis; to Treat Degenerated SVG Lesions: The SESAME First in Man Trial." Alexander Abizaid, Bonnie Weiner, Steven R. Bailey, Hugo Londero. . Catheterization and Cardiovascular Intervention; Published Online: June 14, 2010 ; (DOI:10.1002/ccd.22687)

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