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Stent Grafts Top "Gold Standard" Balloon Angioplasty for Dialysis Patients

New England Journal of Medicine Publishes First Study To Show Minimally Invasive Interventional Radiology Approach for End-Stage Kidney Disease Patients "Superior" in Treating Blocked Access

FAIRFAX, Va.—A randomized multicenter study of 190 patients at 13 medical centers shows—for the first time—the "superior" benefit of stent grafts over balloon angioplasty for maintaining function of dialysis access grafts in kidney failure patients who undergo dialysis. Until now, no other therapy has proven more effective than angioplasty. At six months, the stent grafts allowed dialysis patients to continue life-saving treatment with significantly fewer interruptions and invasive procedures, according to a study published in the Feb. 11 issue of the New England Journal of Medicine. Hemodialysis is the leading treatment for more than 340,000 patients in the United States with end-stage renal disease or kidney failure.

"Stent grafts are a game changer for dialysis patients, especially for those who suffer due to the repeated need for invasive procedures to maintain their ability to get dialysis," said Ziv J Haskal, M.D., FSIR, vice chair of strategic development and chief of vascular and interventional radiology at the University of Maryland Medical Center in Baltimore, Md.

"This study—the first large prospective controlled study of its kind—shows that this novel therapy (stent grafts) provides clear improvement over balloon angioplasty by prolonging the function of a patient's bypass without surgery—helping individuals avoid additional invasive procedures and time in the hospital," noted Haskal, who is also professor of radiology and surgery at the University of Maryland School of Medicine. "Stent grafts overwhelmingly performed better than balloon angioplasty for maintaining access in dialysis patients, providing superior patency and freedom from repeat interventions," added the lead investigator and co-author of "Stent Graft Versus Balloon Angioplasty for Failing Dialysis-access Grafts." He noted, "What we've done is arguably supersede the results of surgery by improving the flow dynamics beyond those achievable with an operation."

Thirteen participating sites—including academic, community-based, inpatient and freestanding outpatient dialysis centers—enrolled 190 patients (69 men, 121 women) with failing arteriovenous (AV) grafts in this study, said Haskal. Ninety-seven patients received stent grafts, with 93 undergoing balloon angioplasty (percutaneous transluminal angioplasty or PTA). There were no significant differences between graft and PTA groups with respect to demographics or relevant medical history. Nearly 51 percent of dialysis accesses treated with stent grafts remained open at six months, as compared to just 23 percent of those treated with balloon angioplasties. Treating physicians had a nearly 94 percent success rate at implanting the stent grafts. There were no differences in adverse events between the two approaches.

"Interventional radiologists work to keep access to the circulatory system open to ensure that patients with end-stage renal disease can continue to receive regular life-saving dialysis," noted Society of Interventional Radiology President Brian F. Stainken, M.D., FSIR, who represents the national organization of nearly 4,500 doctors, scientists and allied health professionals dedicated to improving health care through minimally invasive treatments. "This study is another example of the way in which interventional radiologists pioneer advances to improve health care for patients—in this case, specifically for kidney failure patients," added Stainken, an interventional radiologist who is also president of the Imaging Network of Rhode Island and chair of the diagnostic imaging department at Roger Williams Medical Center in Providence, R.I.

When kidneys fail—called chronic kidney or end-stage renal disease—treatment in the form of regular dialysis (or hemodialysis) is needed to replace the kidney's job of ridding the body of toxic waste products to maintain fluid, electrolyte and acid–base balance. Before dialysis can begin, patients often have a vascular access graft surgically placed in the arm to provide a high-flow site. This prosthetic fistula (or passageway) works by connecting a patient's vein with an artery in his or her forearm, allowing high flow of blood from the artery into the vein.

Over time, the accesses narrow and block off (occlude) due to buildup of scar tissue. Failing or occluded dialysis access grafts cause considerable morbidity, discomfort and inconvenience for dialysis patients due to the need for invasive procedures to reestablish access flow or to graft abandonment and reoperation. When failure occurs, per National Kidney Foundation Guidelines, an interventional radiologist normally performs a balloon angioplasty to reopen the fistula and regain access for dialysis.

More information about the Society of Interventional Radiology, interventional radiologists, angioplasty and stent placement can be found online at www.SIRweb.org.

"Stent Graft Versus Balloon Angioplasty for Failing Dialysis-access Grafts," which appears in the Feb. 11 issue of the New England Journal of Medicine, was co-written by Ziv J Haskal, M.D., FSIR, FAHA, FACR, University of Maryland Medical Center, Baltimore, Md.; Scott O. Trerotola, M.D., FSIR, Hospital of the University of Pennsylvania, Philadelphia, Pa.; Bart L. Dolmatch, M.D., FSIR, University of Texas/Southwestern Medical Center, Dallas, Texas; Earl Schuman, M.D., Oregon Surgical Consultants, Portland, Ore.; Sanford D. Altman, M.D., Open Access Vascular Access Center, Miami, Fla.; Samuel W. Mietling, M.D., Vascular Access Center, Augusta, Ga.; Scott S. Berman, M.D., Vascular Surgery, Tucson Ariz.; Gordon McLennan, M.D., FSIR, Indiana University School of Medicine, Indianapolis; Clayton K. Trimmer, DO, University of Texas/Southwestern Medical Center, Dallas, Texas; John Ross, M.D., Bamberg County Hospital and Nursing Center, Bamberg, S.C.; and Thomas M. Vesely, M.D., FSIR, Vascular Access Center of Frontenac Grove, Frontenac, Mo.

References

National Kidney Foundation: More than 485,000 Americans are being treated for kidney failure, also called end-stage renal disease, or ESRD. Of these, more than 341,000 are dialysis patients and more than 140,000 have a functioning kidney transplant. Dialysis treatment (2006): 354,754 U.S. residents with ESRD received dialysis; United States Renal Data System (USRDS) 2008 Annual Data Report. United States Renal Data System Web site, www.usrds.org/adr.htm (accessed October 31, 2008).

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About the Society of Interventional Radiology

Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-ray, MRI and other imaging to advance a catheter in the body, such as in an artery, to treat at the source of the disease internally. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine. Today, interventional oncology is a growing specialty area of interventional radiology. Interventional radiologists can deliver treatments for cancer directly to the tumor without significant side effects or damage to nearby normal tissue.

Many conditions that once required surgery can be treated less invasively by interventional radiologists. Interventional radiology treatments offer less risk, less pain and less recovery time compared to open surgery. Visit www.SIRweb.org.

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