SOCIETY OF INTERVENTIONAL RADIOLOGY
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Study Shows New Interventional Radiology Technique Provides Patients with Longer Lasting Option For Maintaining Access for Dialysis

Stent Graft Outperforms "Gold Standard" Balloon Angioplasty

NEW ORLEANS, Louisiana (April 4, 2005) – A large, multi-center trial of 190 patients shows a new nonsurgical interventional radiology technique can benefit the more than 287,000 kidney failure patients undergoing dialysis in the United States each year. Research presented today at the Society of Interventional Radiology's 30th Annual Scientific Meeting shows that a stent graft keeps dialysis access open for at least six months longer than balloon angioplasty, allowing dialysis patients to continue life-preserving treatment without undergoing more invasive procedures.

"Interventional radiologists are constantly working to keep access to the circulatory system open to ensure patients with end stage renal disease can receive regular life-saving dialysis," says lead investigator and interventional radiologist Ziv Haskal, M.D. "This study, the first large study of its kind, shows this new stent graft technique provides improvement over the current treatment by prolonging the function of a patient's bypass nonsurgically – helping them avoid additional invasive procedures and time in the hospital."

Patients with chronic renal failure need regular hemodialysis because their kidneys are no longer functioning properly. Dialysis clears toxic waste out of the patient's body and helps maintain the body's fluid, electrolyte, and acid-base balance. These patients often have a vascular access graft surgically placed in the arm to provide a high flow site for dialysis. These prosthetic fistulas work by connecting a patient's vein with an artery in their forearm, allowing high flow of blood from the artery to flow into the vein.

Over time, the accesses narrow and block off (occlude) due to buildup of intimal hyperplasia (scar tissue). Failing or occluded dialysis access grafts causes 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.

"Stent grafts overwhelmingly perform better than balloon angioplasty for maintaining access in dialysis patients, according to this large scale prospective randomized study," says Dr. Haskal. "In the study, 53 percent of the stent grafts remained open at six months, as compared to just 29 percent of balloon angioplasties. By clinical patency measures, at six

months 81 percent of stent graft patients had functioning accesses—a highly statistically better percent than the gold standard balloon angioplasty group. This is potentially a great boon to a very large number of United States patients who suffer due to the repeated need for invasive procedures to maintain their ability to get dialysis." Interventional radiologists conducting the procedure also had a 99 percent success rate at performing the stent graft. There was no difference in adverse events between the two techniques.

About the Study

Stent Grafts (Abstract 134) – 190 patients participated in a prospective, randomized trial in 16 centers. Treated lesions were less than or equal to 7 cm in length. Upper extremity grafts had diameter stenoses greater than 50 percent and obligate hemodynamic, functional, or clinical abnormalities (per K/DOQI and SIR guidelines).

Ninety-seven patients received stent grafts and 93 balloon angioplasty (percutaneous transluminal angioplasty-PTA). There were no significant differences between graft and PTA cohorts for all criteria (e.g., demographics, graft age, location, size, prior treatments, configurations, anticoagulation, dysfunction criteria, presence of remote lesions, etc.).

A total of 128 total stent grafts were implanted with a 99 percent delivery success rate. Anatomic success of the procedures – less than 30 percent stenosis – occurred in 94 percent of stent graft cases and 73 percent of PTA cases. At six months, binary restenosis – greater than or equal to 50 percent stenosis – occurred in 17.3 percent of stent graft cases and 65 percent of PTA cases. The stent graft group showed a 20 percent treatment area primary patency benefit over PTA of 20 percent – reintervention/loss of function. Clinical patency at 6 months was significantly better than PTA (p=0.014).

Facts on End Stage Renal Disease

- **Medicare**: 250,000 Medicare patients undergo hemodialysis in the United States each year, and half or more will have at least one episode of clotting (thrombosis) of the graft[1,2]
- **Prevalence**: An estimated 4.5 percent of adults 20 years of age and older have physiological evidence of chronic kidney disease (7.4 million adults)[3]
- **Mortality**: Among United States residents, there were 177.6 deaths per 1,000 patient years—76,584 deaths in all patients undergoing ESRD treatment[4]

About Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology's 30th Annual Scientific Meeting in New Orleans. Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments performed using imaging for guidance to treat diseases nonsurgically through the blood vessels or through the skin. By combining diagnostic imaging expertise with advanced procedural skills, interventional radiologists perform minimally invasive treatments that have less risk, less pain, and less recovery time than open surgery. Interventional radiologists pioneered minimally invasive modern medicine with the invention of angioplasty and the catheter-delivered stent, which were first used to treat peripheral arterial disease. More information can be found at www.SIRweb.org.

Interviews and X-ray images are available. Abstracts can be found at www.SIRmeeting.org in the program section and click on scientific sessions.

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1. Centers for Medicare & Medicaid Services (CMS).
2. Vesely T, et al. Society of Interventional Radiology Grand Rounds. 2000.
3. United States Renal Data System. *USRDS 2003 Annual Data Report*. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (NIH), DHHS; 2003. Available at www.usrds.org.
4. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification. *American Journal of Kidney Disease*. 2002;39(2, Suppl. 1):S1-S266.