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Stenting dramatically improves treatment access for dialysis patients

Abstract of the year: RENOVA trial results show stent grafts keep access sites open significantly longer than angioplasty alone

NEW ORLEANS (April 15, 2013)—Kidney failure patients on dialysis derive long-term benefit from the minimally invasive placement of a stent that improves the function of dialysis access grafts, according to 12-month trial results being presented at the Society of Interventional Radiology's 38th Annual Scientific Meeting in New Orleans.

"Results of the study exceeded our expectations, and that is a boon for dialysis patients," said Ziv J Haskal, M.D., FSIR, lead author and professor of vascular and interventional radiology at the University of Maryland School of Medicine in Baltimore. "Dialysis is very demanding, and anything that prevents access sites from failing and reduces the need for invasive treatments of surgery will dramatically improve patients' quality of life—while reducing health care costs," he added.

Every year nearly 400,000 people undergo dialysis, said Haskal. Doctors access and filter the blood through delicate grafts or veins that often collapse because they can't handle the high-pressure circuit of purified blood being fed back into the body, forcing doctors to continually reopen them or create new treatment access sites. Twelve-month results of RENOVA, a prospective, multicenter, randomized trial, show these dialysis sites can be successfully kept open using tiny scaffolds called stent grafts for far longer than previously reported. In the study—named SIR's Abstract of the Year—270 dialysis patients treated for collapsed access sites at 28 U.S. centers were randomized and 138 subjects underwent stent grafts while the remaining 132 had balloon angioplasty. After 12-month follow-up, researchers found that two and half times more patients in the stent graft group were able to continue to use their dialysis access grafts, than those who were being treated by balloon angioplasty alone (without invasive interim procedures). Until this data, grafts have been considered short-term solutions, with 75 percent requiring invasive interventions in under a year, said Haskal.

An estimated 1 in 10 Americans has some form of chronic kidney disease, according to the National Institutes of Health. End-stage renal disease means the kidneys have failed and can no longer filter waste products from the blood. This condition is fatal without a kidney transplant or dialysis to prevent blood poisoning. An arteriovenous fistula is the gold standard for dialysis access and involves creating a natural blood vessel bypass, but many patients, especially those who are too ill to undergo the invasive surgery, have an arteriovenous graft—a plastic tube sewn into the vein, which easily clogs, explained Haskal.

"This area where the graft is sewn in, that allows blood to flow back up the arm toward the heart, has particular turbulence," said Haskal. "That turbulence, like a river bend, tends to incite tissue growth at the sides. Just like a river depositing sediment along a bend, these veins thicken and narrow. More than 100,000 angioplasties are performed a year due to this narrowing. What this stent method does is not only reopen the vein, but turn the graft into an inline flow, so that the blood enters the vein at a more natural angle," he added.

Highlights

- Dialysis patients benefit from minimally invasively placed stent grafts, which keep access sites open longer, according to RENOVA trial 12-month results.
- Stent grafts keep dialysis access sites open 2 1/2 times longer than balloon angioplasty.
- Nearly 400,000 people undergo dialysis every year due to kidney failure.
- Interventional radiology treatments offer less risk, less pain and less recovery time than surgery and are a major advance in medicine.

The stents, made of a medical-grade plastic, are implanted at the time of balloon angioplasty, a minimally invasive technique interventional radiologists perform using just a small incision and medical imaging to guide it to the narrowed vein. A small balloon is inflated expanding the vein and setting the stent in place. The resulting reduction of wear and tear due to these stent grafts helps dialysis access sites stay healthy and open months and even years longer than researchers had hoped.

"It was a wholly foreign concept when we started," said Haskal. "People told me it was crazy. Anecdotally we now have patients who have these stent grafts that are still open after three years. That is practically unheard of," said Haskal, who is also editor of the Journal of Vascular and Interventional Radiology. "This controlled study proves that we can achieve durable long-term solutions for these patients, reducing their invasive procedures and thus improving their quality of life," he added.

More information about the Society of Interventional Radiology, interventional radiologists and minimally invasive treatments can be found online at www.SIRweb.org.

Abstract 237: "Twelve-month Results of the RENOVA Trial: A Prospective Multicenter Randomized, Concurrently Controlled Comparison of the Flair® Endovascular Stent Graft vs. Balloon Angioplasty in Dialysis Access Grafts," Z. J Haskal, interventional radiology, University of Maryland, Baltimore, SIR 38th Annual Scientific Meeting, April 13–18, 2013. This abstract can be found at www.SIRmeeting.org.

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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. This year, [SIR celebrates 40 years](http://www.SIRweb.org) of innovation and advances in interventional radiology. Visit www.SIRweb.org.

The Society of Interventional Radiology is holding its 38th Annual Scientific Meeting April 13-18 at the Ernest N. Morial Convention Center, New Orleans. The theme of the meeting is 'IR Reaching Out,' adopted to illustrate the many ways the Annual Scientific Meeting provides valuable education to attendees with a broad range of diverse clinical interests and practice settings.

Local interviews and medical illustrations are available by contacting SIR's communications department staff: Ellen Acconcia, SIR communications manager/practice areas, eaconcia@SIRweb.org, (703) 460-5582, or Maryann Verrillo, SIR director of communications and public relations, mverrillo@SIRweb.org, (703) 460-5572.