Product review

Do access-challenged patients need a HeRO?

Early results suggest new graft device reduces infections and improves adequacy

By Lesley Dinwiddie, MSN, RN, FNP, CNN

As quality of care and life expectancy for hemodialysis patients improves, new challenges arise. Otto Johnson has spent the past 10 years on dialysis and has experienced three failed fistulas, one failed graft, and four catheters (TCCs). He is among a growing number of patients who have been relegated to long-term catheters as a last resort when all other vascular access options have been exhausted.

TCCs are the least favorable vascular access due to the increased incidence of bacteremia that is associated with higher morbidity and mortality. Furthermore, TCCs are commonly associated with central venous stenosis, less effective dialysis due to reduced blood flow rates, and frequent catheter dysfunction. Despite these disadvantages, catheter usage is on the rise. The 2007 End Stage Renal Disease Clinical Performance Measures Project (ESRD CPM Project) reports catheter prevalence at 29% (up 2% from the previous year) and a 58% growth in catheter usage from 2002-2006 in the access-challenged population, defined as patients who have exhausted all fistula or graft sites.[2]

Is there any chance of a more reliable and adequate access for patients like Johnson who have been deemed catheter-dependent because of outflow problems? I've become involved in the development and clinical support of a new device that may offer such a solution. Hemosphere Inc. offers a new long-term subcutaneous access, the HeRO (Hemodialysis Reliable Outflow) vascular access device. Recently approved by the U.S. Food and Drug Administration, it is a graft for use in ESRD patients who have exhausted peripheral venous access sites suitable for fistulas or grafts.

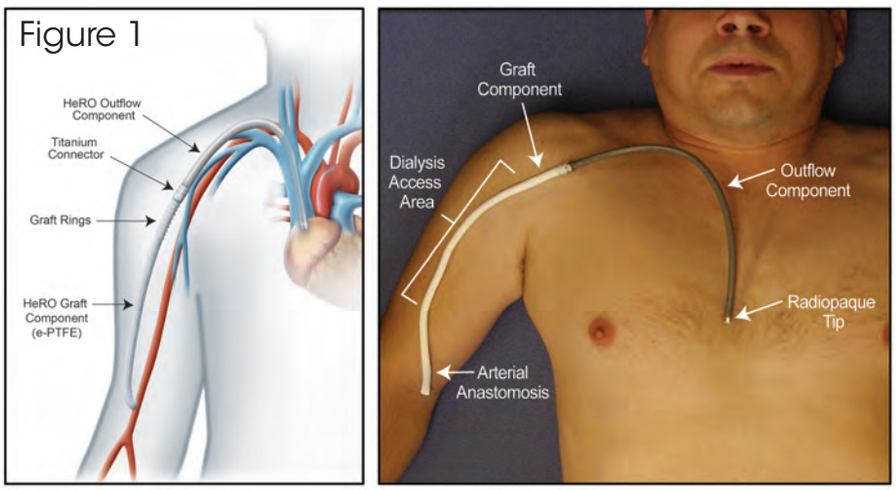
hemosphere™
Restoring Lives, Revolutionizing Care

Johnson received the HeRO two years ago. "I would recommend it to anybody, even before they go through the other accesses in the arm," he said. His vascular surgeon, Kevin Croston, MD, of Specialists in General Surgery, Ltd., Minneapolis placed the device. Croston performs surgery at North Memorial Hospital in Minneapolis and is among the first HeRO™ device access surgeons in the country. "The patients who have received the HeRO device have already had multiple mishaps with other access procedures and have spent half of their time in a declot center or in the hospital awaiting a new access due to infection," Croston said.

The HeRO device is comprised of two components: 1) a conventional 6mm ePTFE graft bonded to a proprietary titanium connector and 2) a 5mm silicone venous outflow component with braided nitinol reinforcement. The distal end of the ePTFE is anastomosed to an artery and the outflow component is tunneled to a venotomy in the central venous system, allowing the radio-opaque tip to be placed in the mid right atrium. This fully subcutaneous implant traverses central venous stenosis, allowing for long-term hemodialysis access (see Figure 1).

The HeRO device is accessed via the conventional ePTFE component with standard cannulation techniques, endorsed by the National Kidney Foundation's Kidney Disease Quality Improvement Initiative guidelines for ePTFE upper arm grafts following vascular access assessment and skin preparation.[2] The assessment for the HeRO

Figure 1



Ms. Dinwiddie is a nephrology nurse consultant based in Cary, N.C., and a member of *NN&I*'s Editorial Advisory Board. She is also a consultant and speaker for Hemosphere Inc. which manufactures the HeRO access device.

varies from a conventional graft in that there are three incisions that define this device: 1) the venotomy incision, 2) the connector incision in the deltopectoral groove; and, 3) the arterial anastomotic incision. Because there is no venous anastomosis, the bruit may be softer and the thrill gentler than in a conventional graft. Use of a light tourniquet to increase pressure in the graft prior to cannulation may be appropriate if necessary. Graft cannulation should always be at least three inches away from the connector site and the outflow component should never be cannulated.

Complications

Complications of this access appear to be those of conventional grafts. Results from the multi-center clinical trial of HeRO showed this device to be a superior alternative to catheters for access-challenged patients. Implanted HeRO subjects represented typical catheter-dependent/access-challenged patients who have progressed in their disease as demonstrated by the high percentage of diabetic patients, many years on dialysis, and large number of previous accesses. In this study, the device and procedure-related bacteremia rate was 69% lower than the control.[3] Further, the only related bacteremias occurred during the bridging period while the TCC was still in place (59% dialyzed with a femoral catheter until HeRO incorporation). After HeRO cannulation and TCC removal, there were no related bacteremias. HeRO adequacy of dialysis, patency, and intervention rates were all comparable to graft literature, a significant improvement over TCCs.

Ideal HeRO candidates include:

- Catheter-dependent patients who have failed all other access options
- Patients dialyzing with fistulas and grafts failing due to venous outflow obstruction
- Patients new to dialysis with poor venous anatomy for peripheral access

All candidates must have a minimum 3 mm diameter in-flow artery and a cardiac ejection fraction greater than 20%.

To date, more than 175 patients have been successfully implanted with the HeRO device since FDA approval. Post-market evaluations of the HeRO device are currently in progress and results will be available in early first quarter, 2009.

HeRO Demographic and Follow-up Data

Total # HeRO subjects	86	**Mean # of previous accesses**	5.4
#. of access-challenged HeRO subjects	36	**% previous fistulas**	65.8 (1-2)
Mean # previous bacteremias	1.8	**% previous grafts**	78.8 (range 1-5)
Mean age (years)	62.7	**% previous catheters**	100 (range 1-16)
Diabetes mellitus	68.4%	**Accumulated follow-up days**	9,931
Mean years on dialysis	5.1	**Mean follow-up months**	8.6

HeRO Study Results

HeRO-related bacteremia rate	0.70/1,000 days	**Primary patency**	44.4%
Mean Kt/V	1.7	**Primary-assisted patency**	94.4%
Rate of intervention	2.5/year	**Secondary patency**	100.0%
		Functional patency	72.2%

References

1. 2007 End Stage Renal Disease Clinical Performance Measures Project (CPM) Table 12 www.cms.hhs.gov/cpmproject/

2. National Kidney Foundation, Kidney Disease Outcomes Quality Initiative guidelines (www.kidney.org)

3. Objective performance criterion based upon tunneled internal jugular catheter literature bacteremia rate of 2.3/1,000 days including prospective or randomized studies of at least 20 patients. Oliver M., Lynch L. Estimate of the risk and rate of hemodialysis catheter-related bacteremia. 2006; Hemosphere Inc. document.