Novel Prosthetic Device for Vascular Access in the Patient on Hemodialysis with End-Stage Renal Disease

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Of the more than 450,000 prevalent patients with end-stage renal disease (ESRD) in 2002, 62% were receiving hemodialysis treatment.[1] For hemodialysis patients, obtaining and maintaining patency remains a major problem. And although there has been a marked increase in the use of fistulae for vascular access in the United States over the past several years, vascular access using synthetic grafts remained the largest vascular access segment of patients at the end of 2003.[2]

Approximately 70% of all failures in synthetic grafts are due to thrombosis,[3] usually at the venous anastomosis. It has been postulated that turbulence as the blood flow from the graft enters the vein at the anastomosis site promotes hyperplasia at the venous anastomosis.[4,5] A novel prosthetic device has been developed (GRAFTcath, Inc. Eden Prairie, MN) that eliminates the venous anastomosis. Instead, a standard polytetrafluoroethylene (PTFE) graft segment transitions to a catheter-like system that enters the venous system at the internal jugular and outflows into the right atrium-superior vena cava junction to provide the patient with arteriovenous access.

In addition to eliminating the major problem with synthetic grafts, this prosthetic device also provides several innovative design features that should offer significant improvements versus a catheter. Similar to a standard synthetic graft, the device is fully implanted and access is achieved through a standard graft; therefore, we anticipate a low infection rate similar to that for standard synthetic grafts. The prosthetic device is designed with high, continuous flow rates of approximately 1,000 mL/min, which the literature indicates should provide for increased patency rates compared with a standard catheter. Because access is achieved in the graft portion of the device, typical catheter dysfunction associated with fibrin sheaths and sucking in of the vein wall should be eliminated.

A randomized, multicenter clinical study has been initiated to compare this novel prosthetic device to a standard PTFE vascular graft. Ten clinical sites will be included in the study, with a goal of enrolling 130 patients. Twenty-two patients have been enrolled in the study to date. One patient had an explant owing to infection, and one patient had to have the fistula ligated because of congestive heart failure. Patients will be followed up for 1 year, and comparison to results with standard ePTFE grafts will be made.

Early technical results and early outcomes will be discussed at the symposium.

References

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