HeRo Device: Indications And Outcomes

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From 2002 to 2006 there was a 58% increase in the number of patients with end-stage renal disease (ESRD) who depend on tunneled dialysis catheters (TDC) for hemodialysis (HD)[1]. This is in the face of recommendations from the National Kidney Foundation Kidney Dialysis Outcome Quality Initiative (KDOQI) for the preferential creation of autogenous dialysis access for these patients. This is a problem because TDCs are associated with increased infection and bacteremia rates which are one of the main causes of morbidity and a preventable cause of death in hemodialysis patients. As a result of this increasing frequency of TDC usage, over 40% of patients presenting for dialysis access have central vein obstruction which affect the long-term patency of further distal access sites. Moreover, TDCs are associated with poorer dialysis flow rates with less effective dialysis and frequent malfunctions compared to arteriovenous fistula and grafts.

A new device to circumvent these issues, the Hemodialysis Reliable Outflow (HeRO) Vascular Access Device, has been approved by the United States Food and Drug Administration (FDA) for the use in ESRD patients who have exhausted all other peripheral vascular access options. Two previous multicenter clinical trials have demonstrated that the device can be implanted with high technical success, low morbidity, and with patency, intervention, and bacteremia rates that were better than TDCs and comparable to conventional HD grafts (unpublished date). To date, there have been no reports on how to reduce complication rates or improve patency of this device. The purpose of this study is to determine factors which improve patency, reduce infection, and ultimately improve performance of the HeRO device.

The HeRO device is a dual component system consisting of a 6-mm internal diameter subcutaneous expandable polytetrafluoroethylene (ePTFE) graft and a 5-mm internal diameter braided nitinol reinforced silicone outflow component. The silicone outflow component is first placed similar to a central venous catheter, thus bypassing problems of more proximal central venous obstruction. The graft component is placed in the upper arm similar to an arteriovenous graft, typically over the biceps muscle, and both components are connected subcutaneously through a titanium connector after a counter incision in the deltopectoral groove. The device is totally subcutaneous with no exposed components The device can be placed in either upper extremity depending on patient anatomy with adjuvant venoplasty of any associated venous obstruction.

We performed a retrospective review of all HeRO device implantations by our group from May 2008 to 2009. The criteria for device placement followed closely with FDA-approved guidelines, which included all patients older than 18 who were dependent on a TDC for hemodialysis or were currently undergoing dialysis through a poorly functioning arteriovenous fistula or graft. All patients had undergone previous vein mapping, venography, and/or upper extremity angiography and were found to have no other upper extremity arteriovenous access options. Patients were excluded from the study if there was known or suspected active infection, significant arterial insufficiency, ejection fraction 20%, systolic blood pressure > 200 mmHg, degenerative connective tissue disease, or known bleeding diathesis. The primary endpoints were infection rates, thrombotic complications, and patency. The study was designed to identify which factors which adversely affected the aforementioned outcomes. Secondary endpoints were morbidity and mortality. The study design and protocol was approved by the Institutional Review Board.

The definition of a HeRO device-related infection was the same as that used by the Centers for Disease Control and Prevention for catheter-related bacteremia. This included the postoperative occurrence of at least one positive blood culture, one or more clinical manifestations of infection (e.g. fever, hypotension) and no other source of infection. Bacteremia data were calculated as a rate per 1000 HeRO days or catheter days as commonly used in the catheter literature. HeRO days were defined as the number of days from HeRO implantation to removal, ligation, or death.

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A total of 42 procedures were performed yielding 40 successful implants (95%). One implant was removed after 6 hours due to upper extremity numbness and severe pain. A second procedure could not be done in a patient with refractory superior vena cava stenosis. After multiple attempts to angioplasty the stenoses, the procedure was aborted. The patient eventually required a thigh arteriovenous graft.

Characteristics of the patient population are listed in (Figure 2). The mean age was 57.5 years and the study population was largely African American with almost half of patients with insulin-dependent diabetes. Over half were receiving dialysis through a femoral TDC prior to device implantation. In addition, the mean total number of dialysis catheters per patient was 7.2 prior to implantation. Sixty percent of patients had the device placed ipsilateral to the previous TDC. The device was also implanted over the wire through the same implantation site in almost a third of the population (32.5%).

A total of 8 HeRO device infections occurred over a mean follow-up of 8.9 months producing an overall device-related infection rate of 1.09 per 1000 catheter days. All infected devices were removed. Seven of these infections were in insulin-dependent diabetics (17.5% vs. 2.5%, p=0.007). The number of prior TDCs was very strong risk factor for device-related infections such that there were no infections in patients who received less than 5 previous TDCs (p=0.021). There was a trend toward increasing infection after placing the HeRO device at a site in an over-the-wire fashion through the previous TDC although this was not statistically significant (p=0.055).

There were a total of 21 thrombotic complications over 8.9 months of follow-up. Patients taking Plavix were less likely to develop device thrombosis such that there were no thrombotic complications in patients taking Plavix preoperatively (p=0.025). This protective affect was not seen in any other antiplatelet or anticoagulant medications. Again, only one patient who had less than 5 prior TDC developed a device thrombosis (p=0.005) illustrating the high risk of multiple TDCs on complications.

Overall primary patency was 42.5% over a mean 8.9 months. Secondary patency was 77%. Thirty-day mortality was 13% not related to the procedure and one-year survival was 72.5%.

This study was designed to identify a subset of patients in an already high-risk population in which the HeRO device could be implanted with better patency, lower thrombotic complications, and decreased infection rates. All of the patients in the study were access-challenged with an average of over 7 TDCs per patient with over half of these in the femoral site. This is higher than other populations studied that were using the HeRO device. We have identified insulin-dependent diabetes mellitus as a risk factor in these high risk patients. In addition, prior TDC usage (> 5) also leads to increased infectious and thrombotic complications. Plavix was also the only medication providing a protective affect against device thrombosis.

In this high risk patient population, the HeRO device can be placed successfully with relatively low morbidity. Factors which may optimize performance of the HeRO device include the postoperative use of plavix, use of the device earlier in traditional dialysis access algorithms, and possibly the administration of broad spectrum antibiotics perioperatively.

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