HEMODIALYSIS
VASCULAR ACCESS

What is the order of preference for vascular access options in hemodialysis?

The gold standard for vascular access in hemodialysis patients is the arteriovenous fistula (AVF). The 2006 KDOQI Clinical Practice Guidelines for Vascular Access in Hemodialysis state the order of preference for vascular access as:

- Arteriovenous fistulae are preferred;
- Arteriovenous grafts (AVG) made of synthetic or bio-
- Short and long-term tunneled dialysis catheters (TDC) should be avoided, if possible.

AVFs are associated with the fewest complications and hospitalizations when compared with other access modalities.2,3 According to data from the 2007 United States Renal Data System (USRDS), for patients with a catheter, rates of vascular access infection are four times higher than for those who have a graft, and eight times higher than for those who have a fistula.2 Accordingly, the Fistula First Initiative recommends that catheter use be reduced, and that more patients receive an AVF.4

What are the evidence-based benefits and risks related to use of the HeRO® Graft?

HeRO® Graft is a novel vascular access device designed to address the needs of patients who are not candidates for an arteriovenous fistula or arteriovenous graft due to central venous stenosis or occlusion.6

How is patient suitability for the HeRO® Graft determined?

Patient suitability for the HeRO® Graft is determined by several factors, including the severity of central venous stenosis or occlusion, the presence of previous catheter-related infections, and the overall health of the patient.6

How can clinicians best ensure success after graft placement?

Clinicians can best ensure success after graft placement by following best practices for surgical technique, perioperative care, and postoperative management.6

References:

12. Data presented at American Society of Nephrology, Nov 2010 with data contributed by Duke University, University of Miami, Baylor Health Systems, and Bamberg County Hospital.

DISCLAIMER

Information contained in this Clinical Bulletin is based upon current data available at the time of publication. Information is intended to help clinicians become aware of new scientific findings and developments. This Clinical Bulletin is not intended to define a standard of care and should not be construed as one. Neither should the information be interpreted as prescribing an exclusive course of management.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every health care professional making use of information in this Clinical Bulletin is responsible for interpreting the data as it pertains to clinical decision making in each individual patient.
What are options for patients who are not candidates for an arteriovenous fistula or arteriovenous graft due to central venous stenosis or occlusion?

For patients who are not candidates for an AVF or AVG, or for those in whom these options have failed, the risk of catheter dependency and other catheter-related problems create significant concerns. TDCs are associated with a high incidence of infectious complications and mortality and should not be used unless all other options have failed. Other problems related to catheters include loss of effective dialysis secondary to reduced blood flow rates, mechanical complications, and central venous stenosis (CVS) and/or occlusion. Of the 104,252 patients who began dialysis in 2008, 90,072 patients used either a catheter alone or a catheter with a maturing AVF or AVG.12 Ironically, the continued high rate of TDC placement, with increased risk of CVS or occlusions may eventually preclude the placement of a permanent dialysis access, and thus increase the number of patients dependent upon TDCs for chronic dialysis. CVS leads to outflow obstruction of AVFs or AVGs, severe venous hypertension, arm swelling, and compromise of upper limb access. KDOQI recommends percutaneous intervention with transliminal angioplasty as the preferred treatment for CVS. Stent placement combined with angioplasty is indicated in chronic CVS or if a stenosis recurs within a 3-month period. When there is the need for more than two angioplasty procedures within a 3-month interval, surgery may be considered.14 More severe forms may be treated by ligation of the AVG or AVF, or use of the HeRO Graft, a device that was studied in a multicenter clinical trial demonstrating a statistically significant reduction in bacteremia rates compared with CVCs.15 If these options fail, a change in renal replacement modality to either peritoneal dialysis or renal transplant should be considered.16

This resource focuses on the HeRO (Graftable Outflow HeRO) Graft, an alternative for vascular access in select hemodialysis patients who are catheter-dependent.

What is the HeRO® Graft and its indications for use?

The HeRO Graft is a long-term fully subcutaneous dialysis device that instead of a venous anastomosis, utilizes an outflow component that traverses central venous stenosis to provide continuous outflow into the central venous system.1. It was cleared for use by the Food and Drug Administration (FDA) in 2008, and was classified as a graft. The FDA states that it is indicated for end-stage renal disease patients on hemodialysis who have exhausted all other access options.3

The device has two parts: a 4-mm expanded polytetra-fluoroethylene (ePTFE) graft to be anastomosed to a peripheral artery at one end and with a titanium connector at the other end that connects with a 1.9F silicone tube (outer diameter of 4.3 mm, and inner diameter of 5 mm) that is reinforced with a nitinol braid to prevent kinking (Fig 1). Like standard prosthetic access devices, the HeRO is cannulated by inserting dialysis needles into the graft component once the graft is tissue incorporated.6

| Table 1: Clinical Outcome Comparisons with Historical Controls from the Literature |

<table>
<thead>
<tr>
<th>Multi-Center Data</th>
<th>FDA Clinical Trial HeRO Graft*</th>
<th>Post-Market HeRO Graft**</th>
<th>Catheter Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteremia Rates (infection [90 days])</td>
<td>0.11</td>
<td>0.20</td>
<td>0.18</td>
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<tr>
<td>Intervention Rates (in Patient Month)</td>
<td>1.6-2.4</td>
<td>2.5</td>
<td>1.7</td>
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<tr>
<td>12 Month Secondary Patency Rates</td>
<td>65%</td>
<td>78%</td>
<td>88%</td>
</tr>
<tr>
<td>Adequacy of Dialysis (mean Kt/V)</td>
<td>1.37-1.62</td>
<td>1.70</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Comparisons to AVF and catheters are from literature review on file at Hemosphere, Inc.

How is the HeRO® Graft determined?

Patients should be evaluated for HeRO Graft placement if they have become catheter-dependent or are approaching catheter-dependency because all other peripheral access options have been exhausted. Poor venous outflow should be determined by a history of previous access failures and vengraphy. Failing fistulas or grafts can be suspected to have poor venous outflow by the presence of decreased Kt/V, swollen access arm, and/or collateral vein development. A compromised central venous system or central venous stenosis should be determined by vessel mapping, preferably vengraphy. The preoperative evaluation should include upper extremity arterial and venous duplex studies. If a central venous stenosis or occlusion is suspected from the venous duplex, a central venogram may be needed to clarify venous anatomy before determining the appropriate treatment and/or placing the device. Additionally, a catheter-based arteriogram or CT arteriogram may be helpful if there is any suspicion of an arterial inflow problem at the time of evaluation.

The FDA states that it is classified as a graft and is not intended to be related primarily to hypotension as this device is long (90 cm untrimmed). In order to promote adequate blood flow through the HeRO, it is recommended that the patient maintain a systolic blood pressure of >100 mm Hg and an ejection fraction of >20%.9 Blood pressure trends should be evaluated post-placement and the use of antihypertensive drugs reviewed. Testing for hypercoagulability is indicated if suspected and should be treated with anticoagulants as needed. As with any peripheral access, avoid the use of fistula clamps after needle removal to prevent prolonged pressure on the graft.9 Thrombectomy is relatively quick and uncomplicated should it be necessary. Specific guidelines for using this device are available.11

The “Three Rights to HeRO Graft Success”10

1. The Right Patient
   - Bilateral central venous pathergy
   - Adequate cardiac function
   - Infection-free

2. The Right Surgeon
   - Endovascular skills (or partnered with an interventionalist)
   - Committed and experienced

3. The Right Management by the Interdisciplinary Team
   - Assessment and cannulation as per KDOQI Guidelines for Prevention of access thrombosis and infection

How can clinicians best ensure success after HeRO Graft placement?

Post-placement infection can be prevented by removing the bridging catheter as soon as possible and treating prophylactically with broad spectrum antibiotics. Prophylactic intravenous antibiotic therapy tailored to local bacterial experience should be considered if the patient is at increased risk for infection. Clotting of these grafts occurs and is thought to be related primarily to hypotension as this device is long (90 cm untrimmed). In order to promote adequate blood flow through the HeRO, it is recommended that the patient maintain a systolic blood pressure of >100 mm Hg and an ejection fraction of >20%. Blood pressure trends should be evaluated post-placement and the use of antihypertensive drugs reviewed. Testing for hypercoagulability is indicated if suspected and should be treated with anticoagulants as needed. As with any peripheral access, avoid the use of fistula clamps after needle removal to prevent prolonged pressure on the graft.9 Thrombectomy is relatively quick and uncomplicated should it be necessary. Specific guidelines for using this device are available.11

Figure 2: Examples of Potential HeRO Graft Placement

Left Arm Placement

Right Arm Placement

Figure 1: Components of the HeRO Graft™

Vascular Outflow Component

Arterial Graft Component

Venous Return Component

Connect with a 19F silicone tube (outer diameter of 6.3 mm, and inner diameter of 5 mm) that is reinforced with a nitinol braid to prevent kinking. Like standard prosthetic access devices, the HeRO is cannulated by inserting dialysis needles into the graft component once the graft is tissue incorporated.6

References

1. Nassar, et al. Presented at the American Society of Nephrology, Nov 2010 with data contributed by Duke University, University of Miami, Baylor Health Systems, and Bamberg County Hospital.