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GRAFT NEWS BULLETIN

HeRO Graft for Fistula or Graft Salvage

The HeRO Graft Indications for Use includes fistula/graft salvage (see highlighted words below).

Indications for Use:

The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the KDOQI guidelines¹ as patients who:

- Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
- Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography (e.g. fistula/graft salvage).
- Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography.
- Have a compromised central venous system or central venous stenosis (CVS) as determined by history or previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling) or venography.
- Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4.²

Overview of the Procedure:

Typically a short segment of the ePTFE portion of HeRO Graft is connected to the existing vascular access in an end-to-end or end-to-side fashion. One advantage of this method is it eliminates the need for a bridging catheter, thus eliminating the infection risks associated with the use of tunneled dialysis catheters.

See page two for clinical summaries of HeRO Graft fistula/graft salvage.

KEY TAKEAWAYS:

HeRO Graft Indications for Use have been updated to specify inclusion of Fistula & Graft Salvage

Multiple publications describe this use and its advantages

One key advantage is the elimination of the need for a bridging TDC

¹⁾ Vascular Access Work Group. National Kidney Foundation KDOQI clinical practice guidelines for vascular access.

Guideline 1: patient preparation for permanent hemodialysis access. Am J Kidney Dis 2006;48(1Suppl1):S188-91.

Hemodialysis Adequacy 2006 Work Group. National Kidney Foundation KDOQI clinical practice guidelines for hemodialysis adequacy, update 2006. Am J Kidney Dis 2006;48 (Suppl 1):S2-S90.

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The following are examples of clinical cases of HeRO Graft fistula (AVF) and graft (AVG) salvage:

Fistula Salvage:

- Chen G, et al. EJVES Extra. 2011; 22(4):e37-39.
 - o Case report of patient with functioning AVF who developed arm edema due to occluded central venous system refractory to repeated endovascular treatment including two stent placements over two years.
 - o Arm swelling resolved and AVF could be used immediately after being connected to HeRO Graft.
- o Remains functional 6 months later and NO re-interventions were required.
- Bowers V, et al. VASA; 2010 Las Vegas, NV. J Vasc Access, 2010;11(S2):S26-27. Lin J, et al. ASDIN; 2010 Orlando, FL.
 - o Case report of two patients who had HeRO Graft to salvage failing AVF due to central venous stenosis.
 - o The HeRO graft implants avoided the need for use of bridging catheters.
 - o Also highlighted value of collaborative team effort, credited IDT approach with timely communication resulting in saving an AVF.

Graft Salvage:

- Gage S, et al. Ann Vasc Surg. 2011; 25(3):387.e1-5.
 - o Case report of two patients with arm edema due to occluded central venous system: one with functioning AVF, one with functioning AVG.
 - o Both patients underwent multiple interventions, including angioplasty and stenting, yet symptoms recurred.
 - o Rather than abandoning functioning vascular access, the HeRO Graft was implanted which resolved the patients arm edema and saved the access.
 - o HeRO Graft has continued to function for twenty-one months.
- Allan B, et al. J Vasc Surg 2012; 56(4):1127-1129.
- o Two case studies describing use of HeRO Graft to salvage failing AVG and AVF due to occluded subclavian vein and failed attempts at recanalization of the subclavian vein.
- o The salvaged portion of the AVG or AVF was able to be used for dialysis the next day with flow rates of 420-450 ml/min.
- o The patients' HeRO Grafts have continued to function at time of publication for fourteen months (AVG salvage patient) and 5 months (AVF salvage patient).
- o The HeRO Graft resolved one patient's arm edema and pain due to central venous occlusive disease.

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TAKEAWAYS:

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Links to HeRO Graft publications are available at www.herograft.com