CENTRAL VENOUS RECANALIZATION AND SUBSEQUENT IMPLANTATION OF THE HeRO® DEVICE IN CATHETER DEPENDENT PATIENTS

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Disclosures

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• P. Joshua O’Brien – none
• Charles Y. Kim - none
• Jeffrey H. Lawson – Hemosphere, Inc.
  - research funding
  - consultant
The Problem: Central venous occlusion

- Recurrent central venous instrumentation
- Central venous catheters
- Balloon Angioplasty
- Central venous stents
- Shear stresses
- HD associated Inflammation
- Aggressive venous intimal hyperplasia
Current Options

• Lower extremity AV access
  - increased risk of infection
  - greater risk for LE steal
Current Options

Direct bypass to right atrium or CV reconstruction

- Requires sternotomy or thoracotomy
- High morbidity
- Sternal wounds
- Graft infections
- Pleural or pericardial effusions
Current Options

• “Destination” Dialysis Catheter
  - Increased infection risk
  - poorer dialysis adequacy
  - greater number of interventions
  - highest cost to healthcare system
Proposed Solution

Central Venous Recanalization

With Hemodialysis Reliable Outflow as adjunct
Recanalization Procedure

- Upper and lower extremity venous access
- Multi-projection imaging
- Low profile catheters
- Sharp recanalization
- Through-and-through guidewire access
- Balloon angioplasty
- Access place-holder
Right BCV & SVC Occlusion

Collateral veins

Occluded Left BCV stent
Axillary and Femoral vein access

- Low profile directional catheters
- Long rigid sheath
- TIPS needle
Crossed occlusion

- Through and through venous access
- “body floss”
- “trackability”
Balloon Angioplasty

- Dilate tract
Low profile catheter implanted as place-holder
A Brief Review

- **HeRO™ Hemodialysis Reliable Outflow**
- Hybrid vascular access device “graft-cath”
- 2 primary components: ePTFE graft with Titanium connector 6mm ID, and radiopaque silicone outflow component with braided nitinol reinforcement 5mm ID
- Common access veins include: Subclavian and Internal Jugular
- End stage access device
- Indicated for catheter dependent patients with central venous stenosis and/or occlusion
Cut down on catheter for access
Wire access to IVC
Peel-away sheath
Outflow component
Connect Outflow component to PTFE

Silicone outflow component
ePTFE graft
Tunnel graft and obtain inflow
Patients and Methods

- Single center retrospective review
- 18 ESRD patients
- All with total central venous occlusion
- All dialysis catheter dependent (femoral or trans-hepatic)
## Results

### Demographics

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Age, mean (range)</td>
<td>50.1 (25-74)</td>
</tr>
<tr>
<td>Male, % (n/N)</td>
<td>46 (8/18)</td>
</tr>
<tr>
<td>Race, % (n/N)</td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>78 (14/18)</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>22 (4/18)</td>
</tr>
<tr>
<td>BMI, mean (range)</td>
<td>32.6 (16-48.2)</td>
</tr>
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</table>
# Results

## CVR Specifics

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful CVR, % (n/N)</td>
<td>83.3 (15/18)</td>
</tr>
<tr>
<td>Thru &amp; Thru access, % (n/N)</td>
<td>67 (10/15)</td>
</tr>
<tr>
<td>Catheter placed, % (n/N)</td>
<td>87 (13/15)</td>
</tr>
<tr>
<td>CVR to HeRO (days), mean (range)</td>
<td>32.5 (0-148)</td>
</tr>
</tbody>
</table>
## Results

### HeRO Implant Specifics

<table>
<thead>
<tr>
<th></th>
<th>Successful implants, % (n/N)</th>
<th>Side of body, % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Right</td>
</tr>
<tr>
<td></td>
<td></td>
<td>64 (9/14)</td>
</tr>
<tr>
<td>Insertion vein, % (n/N)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td></td>
<td>36 (5/14)</td>
</tr>
<tr>
<td>Internal Jug</td>
<td></td>
<td>29 (4/14)</td>
</tr>
<tr>
<td>External Jug</td>
<td></td>
<td>14 (2/14)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>21 (3/14)</td>
</tr>
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</table>
## Patency Rates

<table>
<thead>
<tr>
<th>Patency</th>
<th>6 months</th>
<th>12 months</th>
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</thead>
<tbody>
<tr>
<td>Primary, % (n/N)</td>
<td>57% (4/7)</td>
<td>50% (2/4)</td>
</tr>
<tr>
<td>Secondary, % (n/N)</td>
<td>100% (7/7)</td>
<td>100% (4/4)</td>
</tr>
</tbody>
</table>
Results

- Intervention
  - Overall 71% FFI
- Infection
  - 1 HeRO related infection
  - required interposition replacement of ePTFE
- Death
  - 3 deaths (21%)
  - All unrelated to recanalization or HeRO implant
Conclusions

• Central venous recanalization is feasible
• HeRO device allows for durable access
• Maintain upper body access
• Patency & intervention is acceptable
• Reduced cost to healthcare system
• Reduced morbidity and mortality
Thank You

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