HeRO

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Disclosures

Consulting, Clinical Trials and Opinion

- Hemosphere
- Ark Therapeutics
- Baxter
- Lemaitre
- Johnson & Johnson/Ethicon
- Endologix
- Zymogenetics
- Gore Medical
- Atrium Medical
- NovoNordisk
- Pervasis Therapeutics
- Nanovasc

Research

- American Heart
- ACS
- NIH
- ADA
- HHMI
Heroes
Hemodialysis with Reliable Outflow (HeRO)
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
C.W. 50 yo BF with No Access

State-of-the Art???
State-of-the Art???

Death via Catheter Sepsis!!

Transhepatic Permcath

C.W. 50 yo BF with No Access
Proposed Solution

Central Venous Recanalization

With Hemodialysis Reliable Outflow as adjunct
Occluded SVC with Access to the RA via the L Subclavian Vein

- 66 year old woman with multiple extremity access grafts currently dialyzed through a left internal jugular TDC
- History of prior SVC occlusion managed with angioplasty and stenting
History Of Occluded SVC, but access to the SVC via the Subclavian
## Implantation Specifics

### HeRO Implant Side

<table>
<thead>
<tr>
<th>HeRO Implant Side</th>
<th>% (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>58.5 (24/41)</td>
</tr>
<tr>
<td>Left</td>
<td>39.0 (16/41)</td>
</tr>
<tr>
<td>Right → Left</td>
<td>2.4 (1/41)</td>
</tr>
</tbody>
</table>

![Diagram showing implantation specifics](image-url)
## Implantations Specifics

### Outflow Vein

<table>
<thead>
<tr>
<th>Outflow</th>
<th>% (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVC</td>
<td>90.2 (37/41)</td>
</tr>
<tr>
<td>Azygos</td>
<td>7.3 (3/41)</td>
</tr>
<tr>
<td>IVC</td>
<td>2.4 (1/41)</td>
</tr>
</tbody>
</table>
# Patency & Intervention Rates

<table>
<thead>
<tr>
<th></th>
<th><strong>Duke 6 months</strong></th>
<th><strong>Multi Center Trial 8.6 months mean f/u</strong></th>
<th><strong>AVG literature 6 months</strong></th>
<th><strong>TDC literature 6 months</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary, %</td>
<td>68.3  a</td>
<td>38.9</td>
<td>58</td>
<td>50 5, 6</td>
</tr>
<tr>
<td>Secondary, %</td>
<td>87.8  b</td>
<td>72.2</td>
<td>76</td>
<td>55 5, 6</td>
</tr>
<tr>
<td><strong>Intervention Rates, per year</strong></td>
<td>1.38</td>
<td>2.5</td>
<td>1.6-2.4 3, 4</td>
<td>5.8 5, 6</td>
</tr>
</tbody>
</table>


a. (n/N) 19/28 patients
b. (n/N) 32/36 patients
## Infection Rates

<table>
<thead>
<tr>
<th>HeRO Cohorts</th>
<th>No.</th>
<th>Total Days</th>
<th>Bacteremia events</th>
<th>Bacteremia rate/1000 days</th>
<th>(TDC) Control rate/1000 days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duke</td>
<td>41</td>
<td>10,058</td>
<td>10</td>
<td>1.29</td>
<td>2.3</td>
</tr>
<tr>
<td>Multicenter</td>
<td>36</td>
<td>9931</td>
<td>7</td>
<td>0.70</td>
<td></td>
</tr>
<tr>
<td><strong>Bridging Period</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duke</td>
<td>39</td>
<td>2729</td>
<td>10</td>
<td>3.66</td>
<td>1.6-5.5</td>
</tr>
<tr>
<td>Multicenter</td>
<td>32</td>
<td>1373</td>
<td>7</td>
<td>5.10</td>
<td></td>
</tr>
<tr>
<td><strong>Alone</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duke</td>
<td>35</td>
<td>7120</td>
<td>3</td>
<td>0.42</td>
<td>2.3</td>
</tr>
<tr>
<td>Multicenter</td>
<td>29</td>
<td>8525</td>
<td>0</td>
<td>0.00</td>
<td></td>
</tr>
</tbody>
</table>

The HeRO Body Floss
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
Results

**CVR Specifics**

<table>
<thead>
<tr>
<th>Description</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>Successful implants, % (n/N)</th>
<th>93.3% (14/15)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Side of body, % (n/N)</strong></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>64 (9/14)</td>
</tr>
<tr>
<td><strong>Insertion vein, % (n/N)</strong></td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td>36 (5/14)</td>
</tr>
<tr>
<td>Internal Jug</td>
<td>29 (4/14)</td>
</tr>
<tr>
<td>External Jug</td>
<td>14 (2/14)</td>
</tr>
<tr>
<td>Other</td>
<td>21 (3/14)</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