The HeRO Device: Benefits, but complications

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Disclosure

Speaker name:

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- I have the following potential conflicts of interest to report:
  - Consulting
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
  - Other(s)

- I do not have any potential conflict of interest
Consuming the ‘real estate’

• Renal Replacement Therapy journey
  – 2 or more lines (tunneled)
  – 3 or more fistulae
  – 1-2 AV Graft(s)
  – 1-2 Transplants

• An increasing access challenge

• Especially if CVP!
15% to 25% of patients with dialysis access failure have CVS as the only identifiable hemodynamic cause. Kerlan RK, 2012
Venous Hypertension
What could we do?

• Leave them on a line (wherever we can place one)
• Consider a ‘Heroic Intervention’

Any procedure or intervention that seeks to treat or bypass Central Venous Pathology (CVP) to enable:

- Autologous access or grafts to function
- Treatment / prevention of venous hypertension
- Avoidance of TCC’s
Heroic Options:

• Use of Lower Limbs
• Angioplasty / Stenting CVS
• Atypical / Exotic access / bypass procedures
• HeRO graft Insertion
Hemodialysis

Reliable Outflow

Arterial Graft Component
6mm (ID) x 50cm

Titanium Connector
6mm - 5mm (ID), 2.5° taper

Venous Outflow Component
5mm (ID), 6.3mm (OD), 19F (OD) x 40cm (customizable length)

HeRO Graft bypasses central venous stenosis
Oxford HeRO Experience

- First UK implantation July 2013
- 25 implantations to date
- FLIXENE graft used in 16 cases to enable CVC removal
- 8 cases onto existing AVF / AVG
- 1 patient with bridging PD catheter
- Bilateral venograms and CTV in all to plan atrial access
- 12 Right sided and 12 left sided implantations
- 1 left groin implantation
Oxford HeRO Experience

• 1 SVC recannalisation and 18 plasty to place outflow
• Teicoplanin 800mg on induction
• 20 patients beyond 6 months 14 patients beyond 1 year
• 3 patients DWFG in first year (due to other causes)
• Censured 1 year **primary patency 54%**
• Censured 1 year **secondary patency 91%**
• 1.2 interventions per patient in first year
• 1 needle site abscess but No bacteraemia
But what are the benefits and complications?
# Clinical Outcomes (US data)

<table>
<thead>
<tr>
<th>Clinical Outcomes</th>
<th>HeRO Graft Gage, et al(^8)</th>
<th>HeRO Graft Nassar, et al(^2)</th>
<th>HeRO Graft Katzman, et al(^1)</th>
<th>Catheter Literature(^1)</th>
<th>ePTFE Graft Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteremia Rates</td>
<td>0.14</td>
<td>0.13</td>
<td>0.70</td>
<td>2.3</td>
<td>0.11(^5)</td>
</tr>
<tr>
<td>(Device/Implant related Infections/1,000 days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequacy of Dialysis (mean Kt/V)(^6)</td>
<td>Not Reported</td>
<td>1.6</td>
<td>1.7</td>
<td>1.18–1.46</td>
<td>1.37–1.62(^1)</td>
</tr>
<tr>
<td>Cumulative Patency (at 1 year)</td>
<td>91%</td>
<td>68%</td>
<td>72%(^4)</td>
<td>37%</td>
<td>65(^1)</td>
</tr>
<tr>
<td>Intervention Rate (per year)</td>
<td>1.5</td>
<td>2.2</td>
<td>2.5</td>
<td>5.8</td>
<td>1.6–2.4(^1)</td>
</tr>
</tbody>
</table>

\(^{6}\) Note: Every 0.1 decrease in Kt/V is estimated to increase the mortality rate by 7%\(^6\) and is significantly (P<0.05) and independently associated with 11% more hospitalisations and 12% more hospital days.\(^7\)

\(^{4}\) 8.6 months

**References**
2) Nassar et al., Semin Dial 2014.
3) Gage et al., EJVES 2012.
4) Dageforde et al., JSR 2012.
Multi-center Experience of 164 Consecutive Hemodialysis Reliable Outflow [HeRO] Graft Implants for Hemodialysis Treatment

S.M. Gage a,*, H.E. Katzman b, J.R. Ross c, S.E. Hohmann d, C.A. Sharpe e, D.W. Butterly f, J.H. Lawson a, g

- Data collected from 4 large volume centres
- 2092 HeRO Months
- Mean follow up 12.2 months (0.07 -32.9 months)
- 29 Deaths during follow up period

<table>
<thead>
<tr>
<th></th>
<th>12 Months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>48.8% (39.9 -57)</td>
<td>42.9% (33.3 – 52)</td>
</tr>
<tr>
<td>Secondary Patency</td>
<td>90.8% (84.9 – 94.4)</td>
<td>86.7% (78.9 -91.8)</td>
</tr>
<tr>
<td>Intervention Rates</td>
<td>1.5 per year (1.3 -1.67)</td>
<td></td>
</tr>
<tr>
<td>Bacteraemia</td>
<td>0.14/1000 implant days v 2.3/1000 catheter days</td>
<td></td>
</tr>
</tbody>
</table>
- 8 RCT’s / Observational studies of 409 patients reviewed
- Primary End Point - 1 year primary & secondary patency
- Secondary End Points
  - Early Failure, Steal, Bacteraemia, Interventions

Table 2. Summary table for demographic of patients of included studies.

<table>
<thead>
<tr>
<th>First author (reference)</th>
<th>Number of HeRO</th>
<th>Age</th>
<th>African American (%)</th>
<th>Male sex (%)</th>
<th>Diabetes (%)</th>
<th>Previous central catheter use (%)</th>
<th>Mean number of previous accesses</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Katzman^5</td>
<td>38</td>
<td>62.7</td>
<td>37</td>
<td>50</td>
<td>68</td>
<td>100</td>
<td>5.4</td>
<td>29</td>
</tr>
<tr>
<td>Gage^6</td>
<td>164</td>
<td>55.9</td>
<td>78</td>
<td>49</td>
<td>46</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Steerman^7</td>
<td>60</td>
<td>58.2</td>
<td>88</td>
<td>49</td>
<td>61</td>
<td>100</td>
<td>3.1</td>
<td>32</td>
</tr>
<tr>
<td>Kokkosis^8</td>
<td>12</td>
<td>52</td>
<td>73</td>
<td>92</td>
<td>46</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Wallace^9</td>
<td>21</td>
<td>54.8</td>
<td>58</td>
<td>47</td>
<td>53</td>
<td>NS</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Nassar^10</td>
<td>52</td>
<td>62.9</td>
<td>46</td>
<td>46</td>
<td>65</td>
<td>NS</td>
<td>NS</td>
<td>28.9</td>
</tr>
<tr>
<td>Kudlaty^11</td>
<td>20</td>
<td>57.1</td>
<td>91</td>
<td>45</td>
<td>60</td>
<td>NS</td>
<td>NS</td>
<td>29.2</td>
</tr>
<tr>
<td>Torrent^12</td>
<td>41</td>
<td>55</td>
<td>88</td>
<td>34</td>
<td>55</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = not specified.
• Mean Patency Rates across the 8 studies
  – Primary 21.9% (9.6 – 37.2%)
  – Secondary 59.4% (39.4 – 78%)
• Early Failure rates 9.2% (1.9 – 19.9%)
• Pooled Dialysis Access Associated Steal 6.3%
• 0.14 – 0.7 Bacteraemia / 1000 days
• 1.5 – 3 interventions per patient per year
UK & Ireland HeRO Outcomes

• Retrospective review of 52 HeRO graft placements across 9 centres from first insertion in 2013 to early 2016

• All 52 HeRO placements analysed

• Outcomes reviewed:
  – Primary and Secondary Patency
  – Infections
  – Interventions
  – HeRO Days (implant to graft loss or abandonment)
UK & Ireland HeRO Outcomes

• Median follow-up 290 days (range 10-966 days)
• 622 HeRO months follow-up,
• 17,988 HeRO days
• 11 patients died with functioning graft (21%)
• Primary patency 51.2% at 6/12 and 40.9% at 1 year
• Secondary patency 84.8% at 6/12 and 76.5% at 1 year
• 4 infections after 30 days (2 grafts removed)
• 114 interventions to retain patency (2.2 per graft)
# (Case) Reported Complications

<table>
<thead>
<tr>
<th>Intraoperative</th>
<th>Early Post Operative (&lt;30 Days)</th>
<th>Long Term (&gt;30 Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Vein Rupture</td>
<td>Bleeding</td>
<td>Thrombosis</td>
</tr>
<tr>
<td>Pneumothroax</td>
<td>Seroma / Haematoma</td>
<td>DASS</td>
</tr>
<tr>
<td>Air Embolus</td>
<td>Thrombosis</td>
<td>Infection</td>
</tr>
<tr>
<td>Wrong site Placement of Outflow component</td>
<td>DASS</td>
<td>Outflow Stent Migration (inwards and outwards)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>Infection</td>
<td>Stenosis (inflow / connector)</td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td>Fibrin Sheath</td>
</tr>
</tbody>
</table>

- Pulmonary Emboli
- Arrhythmia / Syncope
• 43 year old male, ESRF and newly diagnosed PE
• Presented with worsening SOB and positional syncope
• Outflow component prolapsed through Tricuspid Valve into Right Ventricle
• Intermittent prolapsing as arm elevated causing syncope
• Echo = severe TR and dilated RV
• Instantaneous clinical and echo improvement after HeRO removed
Key Benefits

• Only fully subcutaneous AV device for CVP
• Increased needling surface area c/w AVF / standard AVG
• Reliable venous outflow as central and no anastomosis
• Excellent secondary patency rates
• Good dialysis adequacy data
• Cost saving compared with radiology plasty / CVC
• Improved quality of life for patients
# Financial Benefits

**Patient 1** — (New AVF previous line Hx & CVS)

<table>
<thead>
<tr>
<th>Details</th>
<th>Pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 x plasty of central stenosis in one year</td>
<td>£5220</td>
</tr>
<tr>
<td>HeRO graft</td>
<td>£2400</td>
</tr>
<tr>
<td>AVG Creation</td>
<td>£1494</td>
</tr>
<tr>
<td>Overnight Stay Post surgery</td>
<td>£500</td>
</tr>
<tr>
<td>Implantation Total Cost</td>
<td>£4394</td>
</tr>
<tr>
<td>Profit margin</td>
<td>£826</td>
</tr>
<tr>
<td>Additional income from dialysis on AVG for year</td>
<td>£4836</td>
</tr>
<tr>
<td><strong>Total Profit</strong></td>
<td><strong>£5662</strong></td>
</tr>
</tbody>
</table>
## Financial Benefits

### Patient 2 - Dialysis via a line

<table>
<thead>
<tr>
<th>Details</th>
<th>Pounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x plasty and stenting of central stenosis in a year</td>
<td>£5980</td>
</tr>
<tr>
<td>Radiological Line Placement</td>
<td>£500</td>
</tr>
<tr>
<td>HeRO graft</td>
<td>£2400</td>
</tr>
<tr>
<td>AVG Creation</td>
<td>£1494</td>
</tr>
<tr>
<td>Overnight Stay Post surgery</td>
<td>£500</td>
</tr>
<tr>
<td>Implantation Total Cost</td>
<td>£4394</td>
</tr>
<tr>
<td>Profit margin</td>
<td>£2086</td>
</tr>
<tr>
<td>Additional income from dialysis on AVG for year</td>
<td>£4836</td>
</tr>
<tr>
<td>3 x declotting of HeRO and bed stays in first year</td>
<td>£4500</td>
</tr>
<tr>
<td><strong>Total Profit</strong></td>
<td><strong>£2422</strong></td>
</tr>
</tbody>
</table>
What about this cost?

Approx. £15k per stay!
The ‘priceless’ patient views

“It has made my life better”

“It generally makes me feel better about myself”

“Much easier to maintain good personal hygiene”

“It is very good. I was often in hospital with my line but not now that I have HeRO”

“I had many problems with lines, the HeRO graft is so much better and has made a real difference”
Closing Remarks

HeRO:

• The only fully subcutaneous AV option that offers long term access in CVS
• High maintenance but excellent secondary patency rates
• Low bacteramia rates c/w CVC
• A cost saving c/w CVC / Radiological interventions
• Does carry PE / Cardiac risk but case numbers small
• Improves quality of life for patients on dialysis