New Deep Valve Choices 2018:  
Do We Really Need This?  
The Holy Grail?

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Disclosures

• Medtronic Inc. – Scientific Advisory Board
• Vascular Insights – Scientific Advisory Board
• Le Maitre Inc. – Consultant
• Hancock-Jaffe Laboratories - Consultant
Holy Grail: Worth Seeking?

- Chretien de Troyes – Conte de Graal (Story of the Grail) 1180
- King Arthur – *Fisher King* needed Holy Grail to be healed
- C4 – C6 need a functioning deep valve to be healed
- Good enough for King Arthur, good enough for me
The Holy Grail:
A Simple Vessel To Collect The Blood of Christ
Good Enough For These Guys: Monty Python and the Holy Grail
## Valve Options 2018

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>VALVE TYPE</th>
<th>INSERTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>VALVOPLASTY</td>
<td>PRIMARY</td>
<td>BICUSP</td>
</tr>
<tr>
<td>VALVE TRANSPLANT</td>
<td>SECONDARY</td>
<td>BICUSP</td>
</tr>
<tr>
<td>NEOVALVE</td>
<td>SECONDARY</td>
<td>MONOCUSP  (BICUSPID)</td>
</tr>
<tr>
<td>SAIL VALVE</td>
<td>SECONDARY</td>
<td>MONOCUSP  (DIFFERENT)</td>
</tr>
<tr>
<td>BLUELEAF/INTERVENUE</td>
<td>SECONDARY</td>
<td>MONOCUSP</td>
</tr>
<tr>
<td>VENOVALVE</td>
<td>SECONDARY</td>
<td>MONOCUSP</td>
</tr>
</tbody>
</table>
#1 - Sail Valve

- Percutaneous
- Monocusp – sort of
- PTFE
- Physiologic leak
Sail Valve Study

• Iliac veins – 10 pigs

• Femoral vein access – 6 Fr.

• Deployment 100% - expands to 10mm

Sail Valve – Results 4 weeks

- Ascending venogram – all patent

- Descending venogram 8 valves
  5 competent
  1 partial
  2 incompetent malposition/tilt

- Histology – no macroscopic thrombus on valve
#2 - VenoValve

- Porcine derived **monocusp/open** from heart valve
- Hancock-Jaffe Labs – 20 yrs heart valves
- Can tailor inflow/outflow size mismatch*

VenoValve: Percutaneous/Monocusp
Valve implant and insertion: sheep EJV
Venotomy closure and implant
Ascending Venogram
Descending Venogram
VenoValve: Current Status

- FDA submittal – Early feasibility in man as per FDA
- FDA – sheep first 30 and 90 day results. Enoxaparin
- Feasibility trial in United States – Late 2018 C5/C6
  Elias/Gasparis: Principal Investigators
Summary: VenoValve “Back to the future”
Axillary Valve Transplant – 36 years ago*

- **Monocusp** – probably better and simpler – mirrors Maleti

- **Open insertion** – allows exact placement and tailor inflow/outflow

- Better flow dynamics and less size mismatch

Challenges: Things To Think About

• Who needs this?

• Is this first line care or final line care?

• Location of placement or creation – pop, fem, or common fem? Profunda vein status?

• We’ve been at this for > 35 years – 1st year resident
Realistic Algorithm: C4 - C6 Patients

- Wound care and compression
- Superficial – axial/VV
- Deep – Occlusive: NIVL/TIVL (angioplasty/stent)
- Perforator – PAPS
- Deep – Reflux: Valve
Do We Really Need This?

• NO – if you don’t care about a small minority

• YES – if you care about a small minority

• MAYBE – if you are a thoughtful person

• When all else has been done and still a problem
Rules To Live By

• Respect the elders

• Embrace the new

• Encourage the improbable and impractical

• Without bias

• So let’s finally do this – we do need this
Good Enough For Them, Good Enough For The Right Patient

Monty Python and The Holy Grail