Reflux - Valve Options 2018

<table>
<thead>
<tr>
<th>INDICATION: INSUFFICIENCY</th>
<th>VALVE TYPE</th>
<th>INSERTION</th>
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<tbody>
<tr>
<td>VAGOTOMY</td>
<td>PRIMARY</td>
<td>BICUSP</td>
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<tr>
<td>VALVE TRANSPLANT</td>
<td>SECONDARY</td>
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<tr>
<td>NOVAVALE</td>
<td>SECONDARY</td>
<td>MONOCUSP</td>
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<td>SAIL VALE</td>
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<tr>
<td>BLUETECH/INTERVENE</td>
<td>SECONDARY</td>
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<tr>
<td>VENOAUGE</td>
<td>SECONDARY</td>
<td>MONOCUSP</td>
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Faculty Disclosure

- **Steve Elias, MD**
  - For the 12 months preceding this CME activity, I or my spouse/partner disclose the following types of financial relationships:
    - Honoraria received from: NONE
    - Consulted for: Hancock-Jaffe Laboratories, LeMaitre Vascular Inc., Medtronic, Vascular Insights,
    - Held common stock in: NONE
    - Research, clinical trial, or drug study funds received from: NONE
  - I will not be discussing any product that is investigational or not labeled for the use under discussion.

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


Valve implant and insertion: sheep EJV

Venotomy closure and implant
Animal Studies - Status

- 8 valves implanted – 30 day assessment
- External jugular sheep – 8mm (2), 10mm (2)
- Common iliac dogs – 8mm (2), 10mm (2)
- Anticoagulation – enoxaparin (sheep), ASA/Plavix (dogs)

Follow Up

- At 5 days and 30 days:
  - Sheep evaluated for patency with duplex ultrasound of the devices
  - Dogs evaluated with IVUS and ascending venography to evaluate patency and any evidence of migration.
- In process of GLP study to evaluate 90 day and 120 day patency of valves in animal model
- Feasability trial in United States – 2019 C5/C6 Elias/Gasparis: Principal Investigators

Summary: VenoValve “Back to the future”
Ayillary Valve Transplant – 36 years ago*

- Monocusp – probably better and simpler – mirrors Maleti
- Open insertion – allows exact placement and tailor inflow/outflow
- Better flow dynamics, less size mismatch, less tilt
- Better control of indications and operators


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