Treatment of Central Venous Stenosis with the AngioSculpt Balloon

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Basic Principles

- Primary balloon angioplasty and alternative fistulas
- Balloon angioplasty maturation (BAM)
- Surveillance every 3 – 6 months (92.7% positive)
  - Clinical exam
  - Dialysis flow sheets
  - Duplex exams
- Favor repeat angioplasty over stents
- Avoid central stents
- Lose upper extremity access
- Prospective database (7.5 years)
- Role of AngioSculpt balloon

Database
May 2008 – Nov 2015

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Central Lesions</th>
<th>No Central Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td># Patients</td>
<td>1268</td>
<td>390 (30.8%)</td>
<td>878 (69.2%)</td>
</tr>
<tr>
<td># Procedures</td>
<td>8803</td>
<td>4291</td>
<td>4512</td>
</tr>
<tr>
<td>Proc/Pt</td>
<td>7.0</td>
<td>11.0*</td>
<td>5.1*</td>
</tr>
<tr>
<td>Deaths</td>
<td>135</td>
<td>66</td>
<td>69</td>
</tr>
<tr>
<td>Mortality</td>
<td>10.6%</td>
<td>16.9%**</td>
<td>7.9%**</td>
</tr>
</tbody>
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*p<0.001  ** p<0.001

Central Lesions

1. Brachiocephalic veins
2. Subclavian veins
3. Cephalic arch (functional)

Distribution – 390 pts

Cephalic arch lesions - 61.8% "True central lesions" - 38.2%
Mortality with “No Central lesion” – 7.9%* \( p<0.01 \)

- 9.1% of pts – extravasation
- 0.008% incidence per procedure
- 9Fr – covered stent
- NO RUPTURES with “True Central lesions”
- Lower mortality

Stent failure
- 107 required stents – 27.4%
- 11.2% lost upper extremity access
- 4.7% morbidity
- Patency – 80.4% vs 92.2%

AngioSculpt Balloon
- Electropolished, helical scoring element
- 6mm and 8mm diameters
- 6 Fr Sheath, 0.018" wire
- Rectangular scoring edges
- Low dissection rates
- Minimal device slippage
- Gradial stepped inflation
- Prolong inflation times – 2 minutes
- Rotate and re-inflate
- Post-balloon for larger diameters
AngioSculpt Results
- 52 cases of central lesions
  - 9 failures of high pressure angioplasty failure
  - 7 successfully treated with AngioSculpt
  - 2 AngioSculpt failures
    - 1 stented
    - 1 cephalic-axillary vein transposition

AngioSculpt Failure

8mm AngioSculpt
- Failed high pressure angioplasty
- Post balloon – 12mm

Relative Cost

Conclusions
- Central lesions - increased mortality
- Central stents - increased morbidity and decreased fistula patency
- Central lesions increase number of interventions
- Cephalic arch lesions - decreased mortality but higher rupture rates
- AngioSculpt is limited by diameter constraints and cost but has a role in the armamentarium to reduce overall stent use in resistant lesions