Optimizing the SFA in CLI

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Disclosure

Speaker name: ..............................................................................................................

I have the following potential conflicts of interest to report:

-Consulting ✗
-Employment in industry □
-Stockholder of a healthcare company □
-Owner of a healthcare company □
-Other(s) ✗

☐ I do not have any potential conflict of interest
How to optimize the SFA in CLI?

Well, recanalize it and make it patent

But by what means?
What lesions do we face in CLI patients

More multilevel (SFA+POP)
More renal insufficiency
More diabetes
Older
Longer lesions

- Compared to claudicants

IN.PACT Global registry, CLI subgroup
The Data Dilemma in SFA-Treatment concerning the CLI Population

Inclusion criteria for SFA-DCB RCDs excluded Rutherford 5/6 or CLI numbers were small (e.g. In.Pact SFA¹, Biolux PI²)

Most trials mixed ICL & CLI patients

Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>DRB n = 30 (n / %)</th>
<th>PTA n = 30 (n / %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD) yrs</td>
<td>70 ± 10</td>
<td>71 ± 10</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>11 / 37</td>
<td>9 / 30</td>
</tr>
<tr>
<td>Hypertension</td>
<td>23 / 77</td>
<td>21 / 70</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>18 / 60</td>
<td>19 / 63</td>
</tr>
<tr>
<td>Smoking</td>
<td>19 / 63</td>
<td>22 / 73</td>
</tr>
<tr>
<td>History of Peripheral Arterial Disease</td>
<td>18 / 60</td>
<td>20 / 67</td>
</tr>
<tr>
<td>History of previous PTA</td>
<td>17 / 57</td>
<td>18 / 60</td>
</tr>
</tbody>
</table>

Rutherford Classification

<table>
<thead>
<tr>
<th></th>
<th>DRB n = 30 (n / %)</th>
<th>PTA n = 30 (n / %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 2 Moderate</td>
<td>7 / 23</td>
<td>9 / 30</td>
</tr>
<tr>
<td>Class 3 Severe</td>
<td>17 / 57</td>
<td>17 / 57</td>
</tr>
<tr>
<td><strong>Class 4 Ischemic Rest Pain</strong></td>
<td>4 / 13</td>
<td>2 / 7</td>
</tr>
<tr>
<td>Class 5 Minor Tissue Loss</td>
<td>2 / 7</td>
<td>2 / 7</td>
</tr>
</tbody>
</table>


DES in CLI

DESAFINADO Registry

DES for Arteria Femoralis IN Asian Diabetic Foot

Study Population (n = 64)

<table>
<thead>
<tr>
<th>Age, mean±SD</th>
<th>70±12.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (male)</td>
<td>38 (59)</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>26 (41)</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>50 (78)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>48 (75)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>55 (86)</td>
</tr>
<tr>
<td>Dialysis dependent renal failure</td>
<td>11 (17)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rutherford</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
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<tr>
<td>4</td>
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<td>5</td>
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<table>
<thead>
<tr>
<th>Runoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

Steven Kum @LINC2020
12 Month Primary Patency – Total Cohort

Total Cohort
PP = 84 %

PSVR < 2.4
If DES are used full lesion coverage works best

12 Month Primary Patency – Coverage subtype

**Total Lesion Coverage with DES**
\[ \text{mean } LL = 201 \pm 136 \]
\[ PP = 91\% \]

**“Hybrid” lesion coverage with DES/DCB**
\[ \text{mean } LL = 153 \pm 86 \]
\[ PP = 80\% \]

**BMS/POBA + DES**
\[ \text{mean } LL = 211 \pm 143 \]
\[ PP = 42\% \]
Options for the patients above the patency curve
65 year old female
Right leg Rutherford IV, ABI 0.3
Contralateral approach
Multiple treatment locations
  - Proximal SFA: ISR TOSAKA III/ 140mm
  - Popliteal artery: Denovo CTO / 40mm based on an ideopathic dissection from PII down to TP-trunc
  - AT: Denovo High Grade Stenosis / 10mm
PROXIMAL SFA: ISR & CTO

Fluoro Series

Post CTO Crossing
Treating Proximal Lesion
Post Pantheris

OCT Image

Stent Struts
Diseased Tissue (ISR)
PROXIMAL SFA: VIDEO OF ISR TREATMENT

OCT Loop

What to Look For

- Clear visualization of stent struts
- Real-time information allowing physician to cut up to stent struts
DISTAL SFA: DENOVO CTO

OCT Image

Fluoro Series

Treating non-stented segment

Pre Treatment

Post Pantheris
DISTAL SFA: DENOVO CTO

Visualization allows reliable removal of disease while leaving arterial structures intact.
Directional cutting in combination with onboard imaging allows for precise targeting of problem areas.
Dissection flap, which may cause acute and long-term issues if left behind, can be removed effectively.
AT: HIGH GRADE STENOSIS

<table>
<thead>
<tr>
<th>Pre-Treatment</th>
<th>Pantheris Treatment AT</th>
<th>PT Touch Up</th>
</tr>
</thead>
</table>

Fluoro Series
FINAL RESULT

PROXIMAL SFA

PRE

PRE - DISTAL SFA

POST

DISTAL SFA / AT

PRE - AT

POST

ABI post procedure 1,2, Rutherford 0
Conclusion

▪ The best treatment option for SFA-disease in CLI-patients is still to be defined since head-to-head comparisons are rare
▪ Paclitaxel based SFA devices show clear superiority in TLR reduction in CLI patients
▪ If stented there is more evidence for full lesion coverage than spot stenting
▪ INSIGHT Trial (multicenter, multinational, single arm) evaluates the role of image-guided atherectomy + DCB in ISR, results are expected for end 2020
Thank you for listening
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