LUTONIX DCB in AV Access: A Single Center Experience

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting – Bard and Boston Scientific
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Disclaimer

• The opinions and clinical experiences presented herein are for informational purposes only and may not be predictive for all cases. Individual results may vary depending on a variety of patient specific attributes.

• The results and data presented herein reflect Dr. Steiner’s clinical experience in a single-center, investigator-initiated and funded study. These results have not been published or peer-reviewed. Bard /Lutonix has not sponsored or funded these studies, nor has Bard/Lutonix validated underlying test methods or data presented herein.

• These results are presented for general education purposes only and may not be predictive for all patients or of Lutonix DCB usage.
Disclaimer, continued

• The physician has been compensated by Lutonix for the time and effort to present this information.

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Introduction

• Use of DCB in femoropopliteal arterial lesions well established

• Use in AV fistulas not well studied
  – Restenosis
  – Repeat interventions
  – Loss of fistula
  – Failure to mature
  – Dialysis per fistula/line dialysis
Physiology AV fistulas

- High pressure $\rightarrow$ Low Pressure
  - Vessel wall stress $\rightarrow$ Endothelial NO
- High Shear stress gradient $\rightarrow$ Endothelial cell damage
  - Intimal hyperplasia
- Compliance mismatch $\rightarrow$ Pulsatile wall stress
  - Intimal hyperplasia
- Traumatic Balloon dilation $\rightarrow$ Neointimal proliferation
Histology of AV stenoses

Venous intimal hyperplasia

Chang et al (2004) – Increase in proliferation index, intima and media in aggressive restenotic lesions vs primary stenotic lesions

Venous Intimal Hyperplasia

- Duplex native AV fistulas
  - Intimal hyperplasia
  - Fibrotic stenosis
Fistuloplasty of Juxta-anastomotic stenoses: Plain balloon fistuloplasty vs DCB

Walton H, Errete L, Ramskold L, Cloran J, Guest M, Selvakumar S, Metcalfe M, Steiner K

• Native AV fistulas
• Juxta-anastomotic stenosis
• 93 Consecutive Patients
  • 75 PBA (81%)
  • 18 DEB (Lutonix Bard) (19%)
• 20 month period
• Technical success rate 100%
• No complications
## Results

<table>
<thead>
<tr>
<th></th>
<th>PBA</th>
<th>DCB</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Patency</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Months</td>
<td>96%</td>
<td>100%</td>
<td>0.2</td>
</tr>
<tr>
<td>6 Months</td>
<td>68%</td>
<td>92%</td>
<td>0.048</td>
</tr>
<tr>
<td>12 Months</td>
<td>33% (n=30)</td>
<td>80% (n=5)</td>
<td>0.024</td>
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<th>PBA</th>
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<tbody>
<tr>
<td><strong>Primary Assisted Patency</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Months</td>
<td>100%</td>
<td>100%</td>
<td>N/A</td>
</tr>
<tr>
<td>6 Months</td>
<td>98%</td>
<td>100%</td>
<td>0.32</td>
</tr>
<tr>
<td>12 Months</td>
<td>87%</td>
<td>100%</td>
<td>0.19</td>
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<tr>
<td>Increase in Volume Flow (Mls/min)</td>
<td>399</td>
<td>693</td>
</tr>
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Further Follow up

20 consecutive patients DCB – 1 died
12 months 12 patients - 3 transplanted
- 1 died

<table>
<thead>
<tr>
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Juxta-anastomotic fistuloplasty DCB

- Patane et al 2014
  - 26 consecutive patients mature RCF
  - Juxta-anastomotic stenoses DCB
  - Technical and clinical success 100%
  - No complications
  - PP 6 months 96% 12 months 82%
  - SP 24 months 95%
  - Only one fistula lost
- Mortamais et al 2013
  - PBA Juxta-anastomotic lesions
  - SP 12 months 76.1%
Conclusions

• Balloon angioplasty of juxta-anastomotic stenoses using DCB is safe and effective

• DCB group
  – Primary patency rates higher (p<0.05 at 6 months)
  – Less repeat interventions
  – Greater increase in Volume Flow

• Larger numbers, prospective randomised control trials are needed.

• Cost analysis
Venous intimal hyperplasia; A target for drug elution?
Don't worry, I'll find a good site soon.
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