How Have Drug Delivery And Retrograde Access Changed The Paradigm For SFA/Pop Treatment? The Game Has Changed

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Disclosures
• Royalties (modest): Cook
• Board: VIVA nonprofit 501C3
• Entered patients into some trials being discussed
• Scientific Advisory Board: Abbott, Medtronic, Boston
• Consulting: CSI, Silk Road Medical, Profusa, Surmodics

Femoral-popliteal Endovascular Therapy
What has changed in the past 5 years?

Crossing lesions
• Attitude
• Wire skills
• Retrograde access

Extending patency
• Stent designs
• Long-term studies
• Drug delivery

Crossing Lesions Algorithm
• OLD-Cannot cross from proximal direction:
  Try again or bypass
• NEW-Retrograde approach

1. Branches and collaterals take off with a caudal angle: wire from above gets lost but wire from below seeks larger artery.
2. Distal end of the occlusion is often softer than the proximal end.
3. Safer than I thought it would be.

Use stump of occluded anterior tibial artery
Calcified SFA-pop occlusion
Occluded AT
343 limbs over 14 months
Intention to cross antegrade
Failure to cross antegrade 17.8%
Success with retrograde approach 86.3%
Pedal access site occlusion 2%
Other local complications 8%
(perforation and hematoma)

Sabri et al. J Vasc Interv Radiol 2015;26:29

University of Texas Experience
21 patients
Technical success 95%
No access-related complications


Retrograde Access: Complications
Cook Tibio-Pedal Registry of Retrograde Access

Event Type |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Local pain of access site</td>
</tr>
<tr>
<td>Infection of access site</td>
</tr>
<tr>
<td>Bleeding of access site</td>
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<tr>
<td>Nerve injury</td>
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<tr>
<td>Acute vessel thrombosis</td>
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<tr>
<td>Compartment syndrome</td>
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<tr>
<td>Urgent surgical re-access thrombosis</td>
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</tbody>
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Mustapha TCT 2014
Current Results of Drug Coated Balloons and Drug-Eluting Stents

PTA vs Stent

RCT Data: PTA vs Stent

- Resilient
- FACT
- 4EVER
- Dorability
- Astro
- Vienna
- Vienna-3

Lesion length (cm)

12-month Primary Patency

RCT Data: PTA vs Stent

- IN.PACT SFA
- Free from Primary Patency Event (%)

100 90 80 70 60 50 40 30 20 10 0

0 1 2 3 4 5 6 7 8 9 10 11 12 13

Months from Randomization Date

Survival %

Time  Lutonix DCB Standard PTA P-value

365 days 73.5% 56.8% 0.001

Proportions-based difference was 65.2% for DCB vs. 52.6% for standard PTA 12.6% difference

Tepe et al. Circ 2015;131:495

Rosenfield et al. NEJM 2015;373:145

DCB

82.3% @ day 365

PTA

70.9% @ day 365

Lyden, TCT 2016

Illumenate 12 Month Patency RCTs of DCB vs PTA

Primary Patency-DCB for Long Lesions

Lesions >15cm

Mean lesion length 25cm

49.5% occlusions

Primary patency at 1 year=83.2%

Schmidt et al. JACC Cardiovasc Interv 2016;9;715

Lesions >15cm

Mean lesion length 24cm

65.3% occlusions

Primary patency:

1 year= 79.2%

2 years=53.7%

Mean length 26cm

Provisional Stent

LL 15-25 cm:

40.4% (63/156)

33.3% (33/99)

LL > 25 cm:

52.6% (30/57)

Schneider CX 4/16

Zeller et al. J Endovasc Ther 2014;21;359

Mean lesion length 19cm

53% occlusions

Primary patency at 1 year:

DCB= 76.1%

DES= 69.6%

Mean lesion length 25cm

Zilver PTX

IN. PACT

Baseline 30 days 6MFU 12MFU

Zilver PTX

Tar 57 52 43 21

P = 0.550

% 100 100 97.9 78.1

BYPASS

Tar 57 51 35 26

% 100 96.3 80.9 68.7

M Bosiers LINC 2016

Zilverpass Trial: Zilver PTX versus above-knee fem-pop

78.1%

68.7%

Mean lesion length: 25cm

DES for Femoral-popliteal

Zilverpass Trial: Zilver PTX versus above-knee fem-pop

Mean lesion length 25cm

Imperial Trial: Eluvia versus Zilver PTX

Log-rank p<0.0119

Mean lesion length 25cm
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Conclusion

• Retrograde access has changed our approach
  – Appears to be safe and effective.
  – Significantly increases success rate for crossing occlusions.
  – Set a time limit for antegrade attempts at crossing.
• Drug delivery has changed our expectations.
  – Now a part of routine decision-making.
  – Both DCB and DES show promise for improving patency, including for long lesions.
  – Not yet clear how best to deliver drug. DCB and DES paradigms very different.