Endovascular first or CLI

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Disclosure

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Advisory Board /Consultant:
Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies
Misconceptions about endovascular therapy in BTK arteries

Extremely dangerous – perforations, compartment syndrome, amputation

„Burns the last bridges“ destroys surgical landing zones

Very poor patency, not worth it
BTK Retrograde Approach: Literature Review

- 19 articles, 1905 retrograde interventions
- Access to the vessel successful in 94.4 %
- Technical success of the intervention 85.0 %
- Acute distal occlusion 0.4 %
- Compartment 0 %

RHA Welling, et al. JEV T 2018
Crossing-success 95.1 %
(only CTOs with failed crossing-attempt from antegrade)

Complications at distal access:
periprocedural: 0.7% occlusions / stenosis

Complications at distal access during FU:
median FU-time (234d): 2.0 % occlusions / stenosis
Does prior EVT burn bridges for bypass-surgery?

Single center retrospective comparison of patients undergoing pedal bypass after prior endovascular treatment (EVT) or no prior EVT

C. Uhl et al., *J Vasc Surg* 2014

<table>
<thead>
<tr>
<th></th>
<th>No prior PTA</th>
<th>Prior PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N patients</strong></td>
<td>39</td>
<td>36</td>
</tr>
<tr>
<td><strong>Limb salvage (@ 1y)</strong></td>
<td>71.6 %</td>
<td>82.3 %</td>
</tr>
<tr>
<td><strong>30-day graft-occlusion</strong></td>
<td>17.9 %</td>
<td>19.4 %</td>
</tr>
</tbody>
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Prior PTA does not effect the outcome of pedal bypass surgery
Prior Endovascular Intervention is Not Detrimental to Pedal Bypasses for Ischemic Wounds

Single center retrospective analysis 2006-2013 of patients with tissue-loss undergoing pedal-bypass surgery

Mohapatra A, et al., J Vasc Surg 2018

<table>
<thead>
<tr>
<th></th>
<th>No prior PTA</th>
<th>Prior PTA</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>N patients</td>
<td>95</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>Wound-healing (@ 1y)</td>
<td>34.8 %</td>
<td>63.8 %</td>
<td>0.01</td>
</tr>
<tr>
<td>Amputation-free survival</td>
<td>76.2 %</td>
<td>72.1 %</td>
<td>0.68</td>
</tr>
<tr>
<td>Survival</td>
<td>87.6 %</td>
<td>78.3 %</td>
<td>0.50</td>
</tr>
</tbody>
</table>
EVT after failed bypass can be extremely complex

65 year female, CLI left RB 5 failed distal-fem-crural bypass left

Impossible to connect GWs from antegrade and retrograde
EVT after failed bypass can be extremely complex.
EVT after failed bypass can be extremely complex
Patency of Endovascular Therapy BTK is outstanding using drug-eluting stents for short lesions

- n patients: 144
- Mean stented length (mm): 34 ± 14
- Mean clinical FU (mo): 31 ± 20
- Major amputations (%): 2.8

Werner et al., JEV T 2012
Absorb BVS 36 Month Results

Monocentric, prospective registry
48 patients, 55 limbs, mean lesion-length 20.1 mm
DES in short BTK-lesions

47 Y DM-Patient, Ruth 4

3.5/33mm Cypher
Restenosis-rate of long diffuse BTK-disease

PTA of 77 BTK-arteries, lesion-length 184 mm, restenosis @ 3 mo 69%

Schmidt et al. Catheter Cardiovasc Intervent 2010
Disease-pattern in CLI ‘real-world’ today

Disease pattern in CLI „real world“
- 1449 patients with RB 5 / 6 (2010 – 2013)
- Below-the-knee-disease in 95 %

<table>
<thead>
<tr>
<th></th>
<th>Below-the-ankle (arch excluded)</th>
<th>Arch disease</th>
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</thead>
<tbody>
<tr>
<td>DM-pts.</td>
<td>52 %</td>
<td>23 %</td>
</tr>
<tr>
<td>DM + ESRD-pts.</td>
<td>73 %</td>
<td>50 %</td>
</tr>
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</table>

Courtesy R. Ferraresi
Although technical success and durability of PTA was inferior to bypass, the limb-salvage rate was the same.
Role of Secondary Interventions for CLI-Patients Treated Endo

Repeat angioplasty plays a significant role, assisted primary and secondary patency rates correlate to limb salvage rate.

PTA vs bypass CLI-patients with BTK- disease

Singel center comparison, propensity matched limb pairs

<table>
<thead>
<tr>
<th>1 year results</th>
<th>Bypass (n=125)</th>
<th>Angioplasty (n=125)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency</td>
<td>54.4 %</td>
<td>51.4 %</td>
<td>0.014</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>84.4 %</td>
<td>65.8 %</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Freedom from reintervention</td>
<td>64.4 %</td>
<td>71.2 %</td>
<td>ns</td>
</tr>
<tr>
<td>Limb salvage</td>
<td>90.4 %</td>
<td>94.2 %</td>
<td>ns</td>
</tr>
</tbody>
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S.D. Patel et al., *BJS* 2016
PTA for infrainguinal vessels with CLI: OLIVE prospective multicenter Registry

- Isolated BTK-lesions or BTK involved: 83% (259/312)
- Only fem-pop-lesions: 17% (53/312)

1-year results
- Major amputation-rate 7.8%
- Repeat endovascular treatment 31.7%
- Bypass surgery 2.6%

3-year major amputation-rate 12.1%

Below-knee endovascular interventions have better outcomes compared to open bypass for patients with critical limb ischemia

Caitlin W Hicks¹, Alireza Najafian², Alik Farber³, Matthew T Menard⁴, Mahmoud B Malas¹, James H Black III¹ and Christopher J Abularrage¹

Data from the 2008-2014 Vascular Quality Initiative (VQI)

<table>
<thead>
<tr>
<th>1 year FU results</th>
<th>Bypass</th>
<th>EVT</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>N patients</td>
<td>500</td>
<td>2066</td>
<td></td>
</tr>
<tr>
<td>primary patency</td>
<td>73 %</td>
<td>81 %</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>secondary patency</td>
<td>86 %</td>
<td>92 %</td>
<td>&lt; 0.001</td>
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<tr>
<td>major amputation</td>
<td>14 %</td>
<td>12 %</td>
<td>0.18</td>
</tr>
<tr>
<td>mortality</td>
<td>4 %</td>
<td>6 %</td>
<td>0.15</td>
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How is Primary Patency defined?

Surgical:
Assessing flow through the bypass: open or closed?

Endovascular:
Absence of binary restenosis (PSV≥2.0; 2.4; 2.5)

Center based evaluation by duplex and / or assessment of pulse in both groups.  

Hicks et al. Vascular Medicine 2017
What shall we believe?

let’s wait for
BASIL- 2 and BEST-CLI
Open bypass and endovascular procedures among diabetic foot ulcer cases in the US from 2001-2010

G.H. Skrepnek., et al. JVS 2014

211534 cases undergoing revascularization

Open vs. endovascular procedures

Amputation-rates
Long and difficult or..

a quick and most often easy procedure
Endovascular first or CLI

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