FIRST CHOICE TREATMENT OF PAOD IN THE COMMON FEMORAL ARTERY

Pro Intervention

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For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from**: Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, B. Braun
- **Consulted for**: Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, Veryan, Intact Vascular, Veryan
- **Common stock**: QT Medical
ENDARTERECTOMY RESULTS

- **Technical success rate:** 92% to 98%
- **Primary Patency at 1-3 year:** 85% to 95%

**But....**

- **Mortality at 30 days:** up to 3.4%
  Predictors (age, dialysis, sepsis, emergency)

- **Major complications at 30 days:**
  - Return to the operating room up to 10%
  - Transfusion >4 units up to 2.8%
  - Wound infection (deep) up to 2%
  - Wound dehiscence up to 0.8%

- **Minor complications:** up to 20%
  - Incl. seromas, wound infection (superficial)

IS THERE ANY ENDOVASCULAR ALTERNATIVE?
BALLONANGIoplastie (PTA) -- Stent
CFA- ENDOVASCULAR THERAPY
1-year Technical Outcomes

- Restenosis rate: 27.6%
- TLR PTA (N=103): 20.9%
- TLR Stent (N=133): 13.1%
- Primary Patency PTA (N=103): 71.3%
- Primary Patency Stent (N=133): 80%

Bonvini et al. JACC 2011
A pooled analysis of common femoral and profunda femoris endovascular interventions

Jonathan Bath¹ and Efthymios Avgerinos²

1694 article titles retrieved using keyword search (see above for details).

1665 articles excluded:
- Not published in English language
- Did not involve common femoral or profunda femoris artery
- Did not involve endovascular therapy

29 potentially relevant clinical reports identified from abstract review and screening. All publications retrieved for full evaluation.

9 reports excluded:
- Case report
- Fewer than 5 cases described in report
- Did not involve common femoral or profunda femoris artery
- Involved a combination of open and endovascular procedures

20 relevant clinical reports identified from full review for inclusion.
Primary patency (PP)

Primary Stenting vs. Bailout Stenting

- **Primary Patency (%)**
  - **Months**:
    - 6: 87% (n=165)
    - 12: 77% (n=575)
    - 24: 73% (n=245)

- **Primary Patency (%)**
  - **Months**:
    - 6: 91.4% (n=90)
    - 12: 75.0% (n=485)
    - 24: 89.0% (n=50)
    - **Selective Stenting**
    - 6: 70.3% (n=195)

*P < 0.05*
VMI-CFA trial

Prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (RB 2-4) CFA disease treatment

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>OLV Hospital, Aalst</td>
<td>47</td>
</tr>
<tr>
<td>AZ Sint-Blasius, Dendermonde</td>
<td>27</td>
</tr>
<tr>
<td>ZNA, Antwerp</td>
<td>4</td>
</tr>
<tr>
<td>IMELDA, Bonheiden</td>
<td>3</td>
</tr>
<tr>
<td>CHU, Nantes</td>
<td>5</td>
</tr>
<tr>
<td>Clinique Rhône Durance, Avignon</td>
<td>13</td>
</tr>
<tr>
<td>CHU, Clermont-Ferrand</td>
<td>1</td>
</tr>
</tbody>
</table>

100 patients
VMI-CFA trial: 1 year results

Primary Patency - 100 patients - 12MFU

Cumulative primary patency rate (%)

Time (days)

Number at risk
100 99 97 97 95 91 84 83 83 81 78 76 8

<table>
<thead>
<tr>
<th>time</th>
<th>baseline</th>
<th>1MFU (30 days)</th>
<th>6MFU (180 days)</th>
<th>6MFU (210 days)</th>
<th>12MFU (365 days)</th>
<th>12MFU (996 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>at risk</td>
<td>100</td>
<td>99</td>
<td>91</td>
<td>84</td>
<td>78</td>
<td>76</td>
</tr>
<tr>
<td>%</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>98,9</td>
<td>95,2</td>
<td>92,8</td>
</tr>
</tbody>
</table>

* Freedom from > 50% restenosis as indicated by DUS PSV-ratio <2,5 in the target lesion – CORE-LAB VERIFIED

Deloose K., LINC 2019
Atherektomie mit / ohne DCB
RESULTS: BALLONANGIOPLASTY VS. ATERECTOMY

Primary Patency

- Angioplasty group: 87.1%
- Atherectomy group: 66.7%
- P = 0.04

Primary Patency Bifurcations

- Angioplasty group: 82.6%
- Atherectomy group: 57.6%
- P = 0.04

Number at risk:
- Angioplasty group:
  - Group: 45, 39, 34, 32, 30
  - Group: 31, 31, 30, 29, 27
- Atherectomy group:
  - Group: 31, 31, 30, 29, 27

Guo et al. Ann Vasc Surg 2018
### CFA-AHERECTOMY: BAD KROZINGEN EXPERIENCE

<table>
<thead>
<tr>
<th><strong>Baseline Characteristics</strong></th>
<th>n=263 (%)</th>
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</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>70 ± 9</td>
</tr>
<tr>
<td>Male sex</td>
<td>180 (68.4)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>238 (90.5)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>91 (34.6)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>237 (90.1)</td>
</tr>
<tr>
<td>Smoker</td>
<td>180 (68.5)</td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>132 (50.2)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>48 (18.3)</td>
</tr>
<tr>
<td>Stroke</td>
<td>32 (12.2)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>69 (26.2)</td>
</tr>
<tr>
<td>COPD</td>
<td>30 (11.4)</td>
</tr>
<tr>
<td>Renal failure*</td>
<td>64 (24.4)</td>
</tr>
<tr>
<td>Claudication</td>
<td>224 (85.2)</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>39 (14.8)</td>
</tr>
</tbody>
</table>
## CFA-Atherectomy: Results

<table>
<thead>
<tr>
<th>Follow-up: 29.8 ±20 months</th>
<th>CD-TLR</th>
<th>37 (15%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Endovascular</td>
<td>20 (8.1%)</td>
<td></td>
</tr>
<tr>
<td>- Surgery</td>
<td>17 (6.9%)</td>
<td></td>
</tr>
</tbody>
</table>

### Rutherford-Becker Class

| - Baseline                 | 3.1 (±0.7) |
| - Follow-up                | 2.0 (±0.6; P<0.001) |

### ABI

| - Baseline                 | 0.46 (±0.23) |
| - Follow-up                | 0.79 (±0.21, P<0.001) |
Kaplan-Meier analysis of survival free from TLR depending on the degree of calcification

TLR – target lesion revascularization
Kaplan-Meier analysis of survival free from TLR for patients treated with POBA and DCB following atherectomy. TLR – target lesion revascularization.
INTERVENTION vs. SURGERY
## Local Complications

<table>
<thead>
<tr>
<th></th>
<th>Surgery (N=61)</th>
<th>Stenting (N=56)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>3 (5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Thrombosis</td>
<td>0 (0)</td>
<td>1 (1.8)</td>
<td></td>
</tr>
<tr>
<td>Lymphorrhoea</td>
<td>2 (3.2)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td><strong>Delayed wound healing</strong></td>
<td><strong>10 (16.4)</strong></td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>False aneurysm</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Paresthesia</td>
<td>4 (6.5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Morbid-mortality rate @ 1 month, n (%)</td>
<td>16 (26)</td>
<td>7 (12.5)</td>
<td><strong>0.05</strong></td>
</tr>
</tbody>
</table>
Survival @ 24 months

- Global survival (%)
- Hazard ratio: 1.3 (95% CI: 0.3-6.0)
- P=0.71

Patency @ 24 months

- Patency (%)
- Hazard ratio: 1.5 (95% CI: 0.5-4.6)
- P=0.48

Freedom from TLR @ 24 months

- Freedom from TLR (%)
- Hazard ratio: 0.8 (95% CI: 0.3-2.5)
- P=0.83

Haemodynamic @ 24 months

- ABI mean, 95% CI

Goueffic Y., JACC Interv, 2017
Summary

Endovascular Treatment of CFA Disease

- Surgery is still considered as the gold standard for CFA treatment
  - Limited availability of controlled data
  - More invasive than endovascular repair
- Peripheral intervention techniques have reached comparable technical outcomes compared to surgery including
  - Stenting
  - Atherectomy w/o DCB
- RCT’s comparing endovascular treatment with surgery are on the way (PESTO-CFA) or already published (TECCO)
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