2-Year Outcomes of Directional Atherectomy and Anti-Restenotic Therapy in CFA Disease

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Disclosure

Speaker name:
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☐ 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
Surgery is still considered the gold standard for CFA.

Compared with surgery EVT of CFA are feasible, safe and effective with lower complication and mortality rate.

Several strategies have been investigated for CFA: PTA, Stenting, DAART.

Stenting seems to be better than PTA but there are some concerns about fractures, stent compression and further treatment compromise.

DCBs alone have shown good results in CFA but there are some doubts on their efficacy in calcified lesions.

DAART has showed promising results in SFA and CFA.
**Endoarteriectomy**

Proven acute and long-term Results
Plaque excitation
No additional materials

- Invasive
- Mortality and Complications
- Patient discomfort

**Endovascular**

Less invasive
Re-doing
Safety
Patient compliance

- No advantage vs CEA
- Stent implantation
- Compromise further treatment

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**DAART “Ideal – Technique”**

Good acute and long-term results
No additional materials (stent)
Less invasivity
Safety and Good patient’s compliance

**DAART**

Maximizes lumen Gaining (Gain)
Improves Drug efficacy in calcified lesions (Mantain)
Minimizes Bailout Stenting (Leaving Nothing Behind)
Combined use of directional atherectomy and drug-coated balloon for the endovascular treatment of common femoral artery disease: immediate and one-year outcomes

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Follow-up completion 30 (100%)
Rutherford Class 2.2±1.2
ABI 0.8±0.1
Major or Minor amputations in CLI pz 1 (3%)
Limb salvage rate (CLI patients) 8/8(100%)
Re-hospitalizations (any cause) 5 (16%)*
Restenosis Rate (>50%) 3 (10%)
Repeat percutaneous angioplasty 2 (6%)
In-stent Restenoses 1/3 (30%)
12 M secondary patency 29 (97%)
pz sent to surgery 1 (3%)
Method I

2013-2018, 131 patients underwent PTA of CFA in our institution due to CLI (28 [21.2%]) or LLC (103 [78.8%]). DAART Performed in 96 - 2Y FU completed in 78

Demographic

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Male gender</td>
<td>64 (82%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>71 ±15</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>51 (65%)</td>
</tr>
<tr>
<td>Smoking status:</td>
<td></td>
</tr>
<tr>
<td>Previous smoker</td>
<td>52 (66%)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>7 (9%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
</tr>
<tr>
<td>NIDDM</td>
<td>29 (37%)</td>
</tr>
<tr>
<td>IDDDM</td>
<td>13 (17%)</td>
</tr>
<tr>
<td>Renal failure:</td>
<td></td>
</tr>
<tr>
<td>CC &lt;30 ml/min</td>
<td>11 (14%)</td>
</tr>
<tr>
<td>Dialysis</td>
<td>8 (10%)</td>
</tr>
</tbody>
</table>

Clinical Presentation

<table>
<thead>
<tr>
<th>Ruth. class</th>
<th>% of Patients</th>
<th>ABI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>4 (5%)</td>
<td>0.75 ± 0.13</td>
</tr>
<tr>
<td>4</td>
<td>42 (52%)</td>
<td>0.58 ± 0.12</td>
</tr>
<tr>
<td>5</td>
<td>20 (26%)</td>
<td>0.31 ± 0.06</td>
</tr>
<tr>
<td>6</td>
<td>12 (15%)</td>
<td>0.26 ± 0.20</td>
</tr>
</tbody>
</table>

Baseline Ruth Class was 4,7±1,2
Method II
Angiographic Findings

Lesion Locations

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nr of lesions</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>CFA (1-0-0)</td>
<td>18</td>
<td>22.5%</td>
</tr>
<tr>
<td>CFA + SFA (1-1-0)</td>
<td>33</td>
<td>42%</td>
</tr>
<tr>
<td>CFS + SFA + PFA (1-1-1)</td>
<td>18</td>
<td>22.5%</td>
</tr>
<tr>
<td>CFA + PFA (1-0-1)</td>
<td>9</td>
<td>11%</td>
</tr>
<tr>
<td>Conc. Treat. In/outflow</td>
<td>21</td>
<td>27%</td>
</tr>
</tbody>
</table>

Lesions Characteristics

- Total occlusion: 14 (19%)
- MLL (mm): 48.0 ± 17
- MLD (mm): 0.8 ± 0.9
- Calcium Score > 3: 61 (78%)
**Method III**

**Procedure**

- Contralateral femoral cross-over access with 8-7F Sheath
- Distal embolization Protection Device
- Pre-dilatations limited to total occlusion with undersized balloon.
- Both diseased SFA and PFA were treated with DA and DCB on both.
- Stent used only as bail-out

**Materials**

- Spider Filter 5-7 mm (Medtronic)
- TurboHawk/HawkOne (Medtronic)
- DCB: In-Pact Admiral (Medtronic)

**Follow-up**

- Patients were followed clinically (free walking distance and ABI) and with DUS at 1, 3 and every 6 months.
- Patients with impaired functional status and/or duplex deterioration were referred to angiographic evaluation.
RESULTS I

Procedural Results

- Procedural success was 100%.
  (crossing the lesion and treating the lesion with DAART)
- No distal embolization occurred.
  In 31 cases a significant amount of debris was found in the distal protection system.
- No procedure or access site complication
  (Perforation, A-V fistula)

Acute Outcome

- Acute angiographic success was 100% (residual stenosis < 30%)
- Bailout stenting was used in 4 cases (5.1%)
- No death and or major amputation in the first 30 Days.
RESULTS II
Long-term FU (24 months)

Any Amputation 1/78 (1.2%)

limb salvage rate (CLI) 27/28 (98%)

Symptoms Driven Rev 8 (11%)

DUS RR (PSVR>2.4) 10 (12.8%)

ISR 3/4 (75%)

TL Repeated Rev. 3

Sent to surgery 4

<table>
<thead>
<tr>
<th></th>
<th>0-6 m</th>
<th>0-12 m</th>
<th>0-24 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1 (1.2%)</td>
<td>1 (1.2%)</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Amputation</td>
<td>0%</td>
<td>0%</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>TLR</td>
<td>1 (1.2%)</td>
<td>3 (4.5%)</td>
<td>10 (12.8%)</td>
</tr>
</tbody>
</table>

Free from TLR, Occlusion, >50% Restenosis

- 1y m Primary Patency = 89.8%
- 2y Primary Patency = 87.2%
RESULTS III
24 month FU (24 ± 18 months)

- **Secondary Patency (%):**
  - 91%

- **Total Nº of stent used:**
  - N=4

- **Bailout Stenting %:**
  - 20%
  - 5.1%

- **Re-PTA and Surgery Nº of Patients treated:**
  - **0-6 m:**
    - Re-PTA: 1 (1.2%)
    - Surgery: 1 (1.2%)
  - **0-12 m:**
    - Re-PTA: 2 (2.5%)
    - Surgery: 3 (3.8%)
  - **0-24 m:**
    - Re-PTA: 3 (3.8%)
    - Surgery: 4 (5.1%)

- **Last 40 Patients:**
  - Bailout Stenting n=1 (2.5%)
CONCLUSION

Our data suggest that endovascular therapy of CFA is safe and effective in the long run.

We believe that DAART strategy may have some advantages compared to the other EVT's:

– Similar to surgery but “less invasive” (plaque removal).
– Improves DCB efficacy in calcified lesion.
– Applies the “leaving nothing behind” theory.

It's time to start a randomised trial to compare DAART to Surgery and/or other endovascular strategies.
2-Year Outcomes of Directional Atherectomy and Anti-Restenotic Therapy in CFA Disease

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