Combined use of Directional Atherectomy and DCB for the treatment of the CFA: immediate and one-year outcomes.

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Disclosure

Speaker name:
Angelo Cioppa MD

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)

X I do not have any potential conflict of interest
Background I

✓ Surgery is still the gold standard treatment of Common Femoral Artery.

✓ Some concerns about “ostile” groin, surgery’s complications and invasivity especially in diabetics, obeses and cardiopatics.

✓ Endovascular treatments have been started in selected cases in the last decades.

✓ From recently published data: Stenting is better than POBA but restenosis rate, fractures, stent compression and further treatment compromission remain an issue.

✓ No evidence for DCB in Common Femoral Artery.

✓ DAART... has showed promising results in SFA.
Background II

**Endoarteriectomy**
- Proven acute and long-term results
- Plaque excision
- No additional materials

**Endovascular**
- Less invasive
- Re-doing
- Safety
- Patient compliance

- ✓ Invasive
- ✓ Complications
- ✓ Patient discomfort

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

**DAART “Ideal – Technique”**
- Good acute and long-term results
- No additional materials (stent)
- Less invasivity
- Safety and Good patient’s compliance

**AIM OF THE STUDY**
was to evaluate the safety, efficacy and one-year clinical results of the combination of DA and DCB for the endovascular treatment of common femoral artery lesions
### Patient population

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Nr of patients</td>
<td>30</td>
</tr>
<tr>
<td>Male gender</td>
<td>25 (84%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>78 ±12</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>21 (70%)</td>
</tr>
<tr>
<td>Smoking status:</td>
<td></td>
</tr>
<tr>
<td>Previous smoker</td>
<td>21 (70%)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>18 (60%)</td>
</tr>
<tr>
<td>NIDDM</td>
<td>12 (40%)</td>
</tr>
<tr>
<td>IDDDM</td>
<td>6 (20%)</td>
</tr>
<tr>
<td>Renal failure:</td>
<td>8 (25%)</td>
</tr>
<tr>
<td>CC &lt;30 ml/min</td>
<td>5 (15%)</td>
</tr>
<tr>
<td>Dialysis</td>
<td>3 (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>4</td>
<td>15 (50%)</td>
<td>0.58 ± 0.12</td>
</tr>
<tr>
<td>5</td>
<td>6 (20%)</td>
<td>0.31 ± 0.06</td>
</tr>
<tr>
<td>6</td>
<td>7 (24%)</td>
<td>0.26 ± 0.20</td>
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</tbody>
</table>

Baseline Rutheford Class was 4.7 ± 1.2

June 2012-October 2014, 30 patients underwent PTA of CFA in our institution due to CLI (10 [30%]) or LLC (20 [70%]).
## Method II

### Angiographic Findings

### Lesions Location

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Number (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nr of lesions</td>
<td>30</td>
</tr>
<tr>
<td>CFA (1-0-0)</td>
<td>5 (15%)</td>
</tr>
<tr>
<td>CFA + SFA (1-1-0)</td>
<td>15 (50%)</td>
</tr>
<tr>
<td>CFS + SFA + PFA (1-1-1)</td>
<td>7 (25%)</td>
</tr>
<tr>
<td>CFA + PFA (1-0-1)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Conc. Treat. In/outflow</td>
<td>7 (23%)</td>
</tr>
</tbody>
</table>

### Lesions Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total occlusion</td>
<td>6 (20%)</td>
</tr>
<tr>
<td>MLL (mm)</td>
<td>41±15</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>0.7±0.9</td>
</tr>
<tr>
<td>Calcium Score &gt; 3</td>
<td>26 (88%)</td>
</tr>
</tbody>
</table>
Method III

Procedural Protocol

• **Contralateral femoral cross-over access with 8F Sheath.**

• **Distal Embolization Protection Device.**

• **Pre-dilatations limited to total occlusion with undersized balloon.**

• **All the cases with involved SFA and PFA were treated with DA and DCB on both.**

• **Stent was used only as bail-out (after long-repeated infl.).**

• Results were also verified with IVUS guidewire.
Method IV: Materials

Distal Embolization Device **Spider Filter 160-320, 5-7 mm** (Medtronic)

DA was performed with **TurboHawk System**. (Medtronic)

**DCB:** **In-Pact Admiral** (Medtronic)

Sizing was 1:1 to RVD and 10 mm longer than stenosis. Inflation time was at least 180”.

**IVUS** was performed (**Opticross-18–Boston 30MHz**) before and after DA and DCB dilatation to evaluate results and or the presence of Flow limiting dissection.
Follow-up

- Patients were followed with clinical assessment and arterial duplex examination at 1, 3.6 and 12 months.
- Patients with clinical (free walking distance - ABI) and/or duplex deterioration were referred to angiographic evaluation.

**RESULTS I: Procedural Results**

- Procedural success meaning ability to cross lesion with filter-wire and to treat the lesion with DA was achieved in all the patients (100%).
- IVUS minimal luminal diameter (MLD) was
  - 2.2±1.2 mm at baseline
  - 5.2±0.8 mm after DA
  - 6.5±1.4 mm after DCB
- No distal embolization occurred. In two cases a significant amount of debris was collected distally in the filter.
RESULTS II: Acute Outcome

- Acute angiographic success was 100% (residual stenosis <30%)
- Bailout stenting was used in 3 cases (10%).
- No angiographic or access site complications (perforation, A-V fistula)
- No death and or major amputation occurred.

RESULTS III: @12 month FU (366 ± 101 days)

- Major or minor amputations: 0
- Ruth. Class: 2.2 ± 1.2
- ABI: 0.8 ± 0.1
- Limb salvage rate (CLI): 100%
- Re-Hospitalization: 5 (16%)*
- Restenosis Rate (PSVR>2.4): 3 (10%)
  - TLR: 2 (6%)
  - ISR: 1 (30%)
- 12M secondary Patency: 29 (97%)

* 3 TLR; one myocardial infarction, one CHF.
EXAMPLE PROCEDURE

Ph1: Baseline
Ph2: It's performed aterectomy (TurboHawk)
Ph3: obtained a good result
Ph4: it's optimized with Kissing DCB 3’ – nominal Pressure
Ph5: recover of numerous debries from the SpiderFx and the tank of the TH.

Role Of distal Protection

FINAL RESULT

In-Pact 7.0-40
In-Pact 4.0-40
CONCLUSION

These data suggest that DAART may represent a potential alternative therapeutic strategy for the treatment of CFA lesions.

Further randomised trials are needed to confirm our hypothesis.
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