Advancing treatment in highly complex lesions – evidence and practice

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

Consulting: Avinger, Biotronik, Cordis, Covidien, Jotec, Terumo,
highly complex SFA lesions

Type C lesions

- Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification
- Recurrent stenoses or occlusions that occurred again after two endovascular interventions

Type D lesions

- Chronic total occlusions involving the popliteal artery
- Chronic total occlusion of trifurcation vessels
55y old male, CTO of right SFA and PI for at least 10 years
Rutherford III, wd 100m CVRF: hypertension, formerly smoker
guidewire loop attempt 2010
Final result

PTA 5x300 in 2 levels, Implanting 6x200 Everflex+ (Covidien) and 5x180 Supera (IDEV)

Leipzig 27.01.2015
DEB technology seems to generate stent-like patency rates without stent
SFA atherosclerosis – mission accomplished?

DEB

POBA

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SFA atherosclerosis – mission accomplished?

“In fact, they should lead to a reconsideration of how we treat patients with claudication, as the highest level of clinical evidence now distinguishes the IN.PACT Admiral drug-coated balloon as a primary therapy for atherosclerosis in the SFA.”

For every complex problem, there is a solution that is simple, neat, and wrong

H.L. Mencken
Who is left behind in current DEB trials?
inclusion criteria In.Pact SFA

- Documented ischemia with Rutherford classification 2, 3, or 4
- Able to walk without assistive devices

http://clinicaltrials.gov/show/NCT01566461
exclusion criteria for In.Pact SFA

- Angiographic evidence of severe calcification
- Target lesion requires treatment with alternative therapies such as stenting, laser, atherectomy, cryoplasty, brachytherapy, re-entry devices
- Chronic kidney disease

http://clinicaltrials.gov/show/NCT01566461
Calcium, the unsolved problem

None/Mild  Moderate  Severe

Scheinert et al 2007

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Calcium remains a limitation for endovascular therapy which is not solved by DEB technology.

**Calcium Limits Vessel Expansion**

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes.

**Calcium May Limit Drug Effect**

1. Freed MS, Manual of Interventional Cardiology.
2. Fanelli DEBELLUM.

Thomas Zeller, MD @ VIVA 2014
57 yo male Rutherford III left leg metabolic syndrome
57 yo male Rutherford III left leg metabolic syndrome

PTA with 4x200, focal PTA with 6x60 Mustang, 40atm

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57 yo male Rutherford III left leg metabolic syndrome

Angioplasty with or without drug elution will never go without stenting

PTA with 4x200, focal PTA with 6x60 Mustang, 40atm
Problem of the moving segment
Results for stents and DEB moving segments

- Joint registry (Supera in CFA and A.pop.)
  12-month primary patency 79%, no long term results
- no results for DEB, results are included under the umbrella term femoropopliteal

2010-2013 21 patients in Münster treated with DA combined with In.Pact DEB for isolated popliteal lesions
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## Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>N / (%)</th>
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<tbody>
<tr>
<td>Age mean ± SD, in years</td>
<td>67±9</td>
</tr>
<tr>
<td>Males</td>
<td>15 (75%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>18 (90%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>7 (35%)</td>
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<tr>
<td>Hyperlipidemia</td>
<td>13 (65%)</td>
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<tr>
<td>Current Tabaco use</td>
<td>10 (50%)</td>
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<tr>
<td>Coronary heart disease</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>Renal disease (GFR&lt; 60 ml/min/1.73m²)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>3 (15%)</td>
</tr>
</tbody>
</table>
Disease Distribution

30% CTOs

- P1: 9 (45%)
- P2: 16 (80%)
- P3: 1 (5%)
- Combined: 5 (25%)
RESULTS

- primary patency 95% DUS (medium fu 18month +/-12month) (n = 19)
- secondary patency 100% (n = 20)
- amputation rate 0%
- procedural mortality 0% overall mortality 5% (n = 1)
- AE 5% (perforation, treated surgically) (n = 1)
- no embolisations (filter use in all subjects)
- mean fluoro time 23.2 ± 9 min,
- mean volume of contrast media used was 169 ± 60 ml.
Conclusions

- Combination therapy DEA + DEB shows unmatched midterm results for popliteal artery lesions at low complication rates.

- Further analysis is needed whether the low reintervention rates justify and compensate the initially higher costs.

(Turbo-/Silverhawk device, filter and DEB)
In RCTs new technologies should be compared with real opponents and not against POBA.
Conclusions:

highly complex SFA lesions need

- concepts that are tailored to patients individual needs and lesion morphology
- DEB standalone therapy gives excellent results in TASC II a-b lesions
- However, calcified lesions, long lesions, lesions of moving segments and lesions with recoil and dissection after angioplasty will need more complex solutions
- This for certain includes combination therapies with nitinol stents, debulking strategies (DEA/Laser) or techniques in the pipeline (e.g. Lithoplasty, biodegradable stents) and surgery
Thank you for your attention