Atherectomy for vessel prep (rational – evidence and clinical case)

TIBOR BALÁzs, M.D.
INTERVENTIONAL RADIOLOGIST

CENTER OF INTERVENTIONAL NEURORADIOLOGY AND ENDOVASCULAR THERAPY
BRATISLAVA, SLOVAKIA
Disclosure

Speaker name: Tibor Balazs MD

- I have the following potential conflicts of interest to report:
  - Consulting (Boston Scientific Corporation)
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
  - Other(s)
- I do not have any potential conflict of interest
Primary goal is the re-establishment of pulsatile, straight line flow to the foot.

Over the past decades major advancements have been made in the treatment of PAD.

The “tool box” has expanded with several instruments: cutting/scoring balloons, wires, stents, atherectomy devices, now accompanied by the drug-eluting therapies.

The “leave nothing behind” strategy has gained in popularity, with the aim of leave the treated vessel without stents and intact for potential future treatments and avoid potential stent-related problems.  

1. Optimizing Strategy in Peripheral Vascular Interventions: The Role of JETSTREAM® Atherectomy Nicolas W. Shammas, MD, EJD, MS, FACC, FSCAI, FICA
SFA Lesion Complexity Drives Therapy Selection

- There is little debate that TASC II A and B lesions are best suited for endovascular therapies.
- Although the TASC II committee recommends surgical therapy for TASC C and D lesions, these are now increasingly being handled using an endovascular approach.\(^1\)\(^2\)

2. Trans-Atlantic Inter-Society Consensus (TASC) II Lesion Classification (Type A, B, C, D) for peripheral artery disease
Challenges with complex calcified lesions

- In lot of cases there is an inability to dilate the lesion with higher dissection and perforation rates, leading to bail out stenting, higher stent fracture rates and subsequent lower patency rates

Suboptimal Outcomes

Dissections

Perforation

Embolisation

Limited Drug Uptake

Suboptimal Stent Expansion

F. Fanelli – Cardiovasc Interv Radiol 2014
Mechanical deformation of FP segment

- Stent placement is not advisable in certain anatomical locations

- Severe mechanical impact at flexion points such as the hip and knee joints could provoke stent deformation or fracture leading to arterial occlusion

- Axial compression and bending of the FPA likely play significant roles in FPA disease development and reconstruction failure¹

---

1. Limb flexion-induced axial compression and bending in human femoropopliteal artery segments William Poulson, MD, Alexey Kamenskiy, PhD
Clinical History:

- 79-year-old high risk patient presented with clinical signs of severe, limiting claudication, and rest pain during night in the left calf.
  - Insulin dependent DM (1980) with end organ damage
  - post MI (1984), 3VD,

- Previous ultrasound examination had demonstrated severe calcified stenosis of the P2 segment of the popliteal artery

- Resting ankle-brachial index in the left leg of 1.27 (mediocalcinosis)
Case 1 – Heavily calcified prox. PA

- Ipsilateral antegrade approach from the CFA, selective right FP angiography demonstrated severe stenosis of the PA.
Case 1 – Heavily calcified prox. PA

- Balloon angioplasty - Early recoil
- Plaque modification - rotational atherectomy

Heavily calcified eccentric lesion of the proximal PA (A). High pressure balloon angioplasty (B). Early severe recoil (C). Distal EPD (D) 6-mm X 40-mm Ranger drug coating balloon (Boston Scientific Corporation) angioplasty after plaque modification by JETSTREAM Atherectomy system 2.1 mm, the treated vessel is more compliant (E).
Final angiography showing significant luminal gain. The patient was discharged the following day symptom free.
Use of this device in moderate and severely femoral/popliteal calcified lesions was examined by intravascular ultrasound (IVUS) in a small (n=26) single-center study.

Calcium removal and luminal gain, measured by comparing pre-intervention to post-atherectomy IVUS images

86% of lumen gain was attributed to calcium reduction

Conclusion:

Jetstream atherectomy system removed and modified superficial calcium to achieve significant lumen gain
Case 2 - Extreme calcified occlusion of the left SFA/PA

Clinical History:

- 62 year old high-risk patient with insulin dependent diabetes suffering from micro/macroangiopathy, was admitted to our clinic with CLI of the LE (Rutherford 6), recently after amputation of the little finger of the left leg.
- Non healing ulcer after amputation of the little finger and non healing ulcer of the toe.
Baseline arteriography
Antegrade left CFA approach, arteriography showed the heavily calcified occlusion of the SFA. Multiple wires failed to cross the lesion.

The sharp end of the 0,014" guide wire was used to navigate the Jetstream® XC 2.1 atherectomy system into the plaque. The wire was pulled back and one passage was performed with blades down.
Baseline arteriography and Jetstream procedure

- After successful crossing, the wire was advanced and the created channel was gradually widened by the side blades of the Jetstream® system. Drug-eluting balloon angioplasty followed with good angiographic result. The same Jetstream® XC system was used to open another short occlusion of the PA.
Final arteriography and 6m follow up

- Final arteriography showed the patent SFA and PA. The dorsalis pedis was missing (also at the beginning of the procedure) and only the proximal part of the plantar artery was filling.
- Despite the very poor prognosis the ulcers started to heal.
VESSEL PREPARATION STRATEGY

- Endovascular atherectomy has emerged as a novel, endovascular technology for atheroma removal

- Changing vessel compliance by plaque debulking may allow for:
  - a more uniform angioplasty result with minimal consequent vessel barotrauma and improved luminal gain,
  - decreasing the risk of plaque recoil and dissection, and preventing negative remodeling and neointimal hyperplasia

Endovascular atherectomy devices

- Endovascular atherectomy devices can be divided into four categories according to the mechanism used for atheroma removal:

  - **Directional atherectomy**
    - plaque is removed by guiding the cutting device (cutter) of the catheter directly to the plaque
    - SilverHawk™, TurboHawk™ and the newest HawkOne™
    - Pantheris OCT-guided lumivascular atherectomy device

  - ** Orbital atherectomy**
    - mechanism based on the high-speed rotation of the diamond-coated crown. Plaque debulking area increases with the increase of the rotational speed of the crown.
    - Diamondback 360° Peripheral Orbital Atherectomy System
Endovascular atherectomy devices

- **Laser atherectomy**
  - uses excimer laser (UV) technology to ablate atheroma
  - Turbo-Elite, Turbo-Power and Turbo-Tandem
  - de novo and in-stent restenosis, 10 μm with each pulse of energy (1)

- **Rotational atherectomy**
  - Rotablator™, Phoenix and JETSTREAM rotational atherectomy systems
  - plaque is excised by a concentrically rotating, specially designed tip (burr)
  - indicated for both acute thrombus removal and atherectomy of chronic lesions ¹

JETSTREAM CATHERETER DESIGN

- Differential cutting
- XC Expandable blade technology
- Active Aspiration
- Circumferential rotational clearance
- Front end cutting

Jetstream SC
- Infusion
- Aspiration
- Front End Cutting

Jetstream XC
- Expandable Blades
Vessel Treatment - Options

EBM

Clinical Expertise
Best Evidence
Patient Values
Zeller et al reported on a series of 210 lesions between 2006 and 2007 with the earlier version of the device.

- 31% percent were total occlusions;
- 51% had moderate to high calcium scores;
- and 15% had post-angioplasty restenosis.

The average lesion length was 2.7 cm.

Komplex patients:
- diabetes (47%), hypertension (93.6%), renal disease (15.75%), prior lower extremity revascularization (51.2%), documented coronary disease (16.9%)
Periprocedural results:

- Lesion crossing and debulking success rate was 99% with a mean device activation time of 3.5 minutes
- only 7% of lesions were stented
- minor embolic events were noted in 10% of cases and 4 perforations (2%) occurred

Follow up results:

- At 6 months major adverse events had occurred in 19% of patients. these events were target lesion revascularizations (TLR), which occurred in 15% at 6 months and 26% at 12 months
- The restenosis rate was 38.2% at 1 year based on duplex ultrasound, as per core lab analysis.

### Randomized Controlled Trials (RCT)

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Treatment</th>
<th>Patients and lesions</th>
<th>Bailout stent</th>
<th>Immediate outcomes</th>
<th>Clinical outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shammas et al. [2011].</td>
<td>RCT</td>
<td>SilverHawk versus angioplasty</td>
<td>46 IC and 12 CLI femoropopliteal</td>
<td>27.6 versus 62.1% ($p = 0.017$)</td>
<td>Embolization: 64.7 versus 0.0% ($p &lt; 0.001$)</td>
<td>1-year TLR: 11.1 versus 16.7%</td>
</tr>
<tr>
<td>CALCIUM 360 [2012]</td>
<td>RCT</td>
<td>Orbital versus angioplasty</td>
<td>50 CLI Infrapopliteal vessels</td>
<td>6.9 versus 14.3% ($p = 0.44$)</td>
<td>Success: 93.1 versus 82.4% ($p = 0.27$)</td>
<td>1-year TVR freedom: 93.3 versus 80.0% ($p = 0.14$)</td>
</tr>
<tr>
<td>COMPLIANCE 360 [2014]</td>
<td>RCT</td>
<td>Orbital versus angioplasty</td>
<td>50 patients, 65 lesions Calcified Femoropopliteal</td>
<td>5.3 versus 77.8% ($p &lt; 0.0001$)</td>
<td>N/A</td>
<td>1-year TLR: 18.8 versus 21.7% ($p = 0.99$)</td>
</tr>
<tr>
<td>EXCITE-ISR [2015]</td>
<td>RCT</td>
<td>Excimer laser versus angioplasty</td>
<td>250 IC + CLI In-stent restenosis</td>
<td>4.1%</td>
<td>30-day MAE: 5.8 versus 20.5% ($p &lt; 0.0001$)</td>
<td>6-month TLR: 26.5 versus 48.2% ($p &lt; 0.005$)</td>
</tr>
<tr>
<td>DEFINITIVE AR [2015]</td>
<td>RCT</td>
<td>Hawk + DCB versus DCB alone</td>
<td>102 femoropopliteal</td>
<td>Dissection: 2 versus 19%</td>
<td>N/A</td>
<td>1-year patency: 82.4 versus 71.8%</td>
</tr>
</tbody>
</table>

- **Shammas (2011)** - during follow-up, TLR and TVR were all similar in the AT and angioplasty, but with a small numerical benefit in favor of directional atherectomy. AT plus angioplasty resulted in significantly less bailout stenting, higher macro-embolisation rate.
- **CALCIUM 360 (2012)** - atherectomy could increase the probability of achieving an optimal angioplasty outcome and lead to fewer dissections, decreased bailout stenting rate
- **COMPLIANCE 360 (2014)** – less bail out stenting noted, AT did not yield superior outcomes
- **EXCITE-ISR (2015)** - ELA + PTA was associated with a 52% reduction in TLR
- **DEFINITIVE AR (2015)** - trend in potentially better outcomes in challenging lesion subsets such as severely calcified ones, ≥10 cm lesions and CTOs.
Indications for atherectomy

- Long calcified lesions, complex CTO with/without thrombus
- Bifurcation and “no stent” zones
- High risk patients for open repair
- In-stent restenotic lesions
- Contraindication for stent implantation or for dual antiplatelet therapy

*based on authors experience.*
Proper technique – essential for optimal result

64 y. old patient, CLI - limiting intermittent claudication

Pre-image  Crossing  JETSTREAM XC 2.1  Distal cap technique  Complete  Ranger 6x100  Final

CTO of the distal right SFA (A). JETSTREAM Atherectomy system 2.1 mm keeping the distal part of the lesion intact to act as a “filter” – red arrow (B,C). After treatment of the distal part (D). 6-mm X 80-mm Ranger drug coating balloon catheter (Boston Scientific Corporation) (E). Reconstituted SFA (F).
Without distal embolisation
CONCLUSION

- Recently published or presented randomized trials have shown that atherectomy can accomplish the task of vessel preparation, reducing dissections and bail out stenting.

- Proper technique is essential for excellent results
  - Slow advancement of the cutter, avoid stalling of the device and allow room for aspiration
  - Embolic protection devices have added a level of protection to the outflow vessels (irregular/heavily calcified lesions, ISR, TASC D lesions)

- Respect the limitations no single device is right for every case

- The combination of debulking atherectomy and drug-coated balloons has shown promise in early studies, especially in the treatment of more complex lesions.
Thank you for your attention
Thank you for your attention
Case 6: Atherectomy of Acute Embolic Occlusion of Distal Superficial and Popliteal Artery, Jet XC 2.4

81 y. old patient, ALI lasting 11 days

Acute, long (22cm) embolic occlusion of distal SFA and Popliteal artery

Acute embolic occlusion of the peripheral vessels.

2 passes Blades Down and 1 pass Blades UP with XC 2.4 catheter, resulting in exceptional debulking effect.

JETSTREAM® XC™ 2 additional passes Blades Down.
Atherectomy of Acute Embolic Occlusion of Distal Superficial and Popliteal Artery, Jet XC 2.4

JETSTREAM® XC™
Total activation time 27 min.

Patent SFA/PA arteries post overnight thrombolysis using rt-PA 1mg/hour in total dose 15mg.

Patent posterior and anterior tibial artery

Patent plantar artery and dorsalis pedis
Case 7: Thromb/Atherectomy of Chronic FP bypass occlusion, Jet XC 2.4

87 y. old patient, Repeated stent PTA and TL (12.2015,03.2016), 3 months old occlusion of the FP bypass
Case 7: Thromb/Atherectomy of Chronic FP bypass occlusion, Jet XC 2.4
Case 8: Long segment of Occluded PA and ATA

75 y. old patient, DM type II, CLI - Rutherford Stage 5 (ischemic ulceration), downgrading the lesion by JET SC 1.85
Final angiography – no DE
Bifurcation lesions

Heavily calcified lesions of the CFA and proximal SFA, PFA (A). Plaque modification by JETSTREAM Atherectomy system 2.4 mm (B,C). Two 6-mm X 40-mm Ranger drug coating balloons (Boston Scientific Corporation) angioplasty (D). Final angiography showing significant luminal gain (E).
Case 5: Atherectomy of the Peroneal artery

67 y. old patient, CLI - Rutherford stage 6 (gangrene of the digits)

Critical lesions of the tibioperoneal trunk

Oclusion of all major crural vessels

Due to the heavy calcifications only the wire was able to cross the occlusions of the peroneal artery

1 pass using the SC 1.6 catheter, total activation time 15 min.
Atherectomy of the Peroneal artery

PTA using 2.5x120mm balloon

Patent peroneal artery

Collateral filling of the dorsalis pedis and the plantar artery
Case 4: Atherectomy of the Popliteal Bifurcation – Jet XC 2.1

68 y. old patient, CLI - rest pain in the right foot
Case 4: Atherectomy of the Popliteal Bifurcation – Jet XC 2.1