Zero Contrast Revascularization of Calcified SFA CTO using Intravascular OCT Guidance

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Disclosure

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

- [ ] Consulting
- [x] Employment in industry: Avinger Inc
- [x] Stockholder of a healthcare company: Avinger Inc.
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
CKD-CLI; SFA CTO

- 47 yo M: 4 yr old non-healing left heel ulcer, s/p failed HBO, skin grafts, aggressive wound care, disabled from wound:
  - HTN
  - DM
  - CMY: EF 25%
  - CKD: Cr 3.7  GFR 14
  - Non-compressible ABI—DUS: occluded L SFA
- Diagnostic CO2 Angio
- CTO Crossing: Ocelot Catheter
- Therapy: Directional Atherectomy + PTA
CKD-CLI; SFA CTO

- Nephrotoxicity concerns - Cr 3.7 (11/11/15)
- 6cm L SFA CTO
- CO2 Angio
CKD-CLI; SFA CTO
Crossing CTO using Zero Contrast / Low Radiation

**OCT Highlights:**
1) eccentric soft plaque isolated to medial wall
2) 180 degrees of healthy vessel wall within CTO
CKD-CLI; SFA CTO
OCT necessary to complete “true lumen” therapy

- Directional Atherectomy (pre-Pantheris FDA Approval)
- Attempt to isolate debulking to medial wall without OCT visualization
CKD-CLI; SFA CTO
Focused adjunctive therapy

“Targeted” POBA, based on OCT evidence of disease distribution
CKD-CLI; SFA CTO
CO2 + OCT Provides Safe & Efficacious Therapy

Final images
1) Zero contrast
2) <1 minute Fluoroscopy for Total Procedure
3) 45 minute skin-to-skin
Radiation Free Technology
X-Ray Radiation for 15-25CM SFA CTOS

29 MINUTES of radiation eliminated per case when using Lumivascular

LE REVASCULARIZATION X-RAY RADIATION EXPOSURE

<table>
<thead>
<tr>
<th>Radiation Time (Mins)</th>
<th>Fluoroscopy Guided Intervention</th>
<th>Lumivascular Guided Intervention</th>
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</thead>
<tbody>
<tr>
<td>Diagnostic</td>
<td>5.99</td>
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<tr>
<td>CTO Crossing</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>Therapy</td>
<td>5.35</td>
<td>21.2</td>
</tr>
</tbody>
</table>

4. Davis, T. Crossing Chronic Total Occlusions using zero fluoroscopy. Vascular Disease Management
CKD – Severely Calcified SFA CTO

PMHx
- 65 yo F, smoker, DM2, HTN, CKD (Cr 3.8mg/dL pre-dialysis)
- Presents with R>L severe symptomatic claudication

Lesion
- R LE 280mm severe Ca+ SFO CTO

Planned Intervention
- CO2 angiography
- OCT guided CTO crossing using Ocelot Catheter
- OCT guided directional atherectomy using Pantheris Catheter
Protecting Media/EEL while Crossing CTO with Eccentric Disease
CO2 – Angiography Post OCT Guided Crossing
Pantheris Targets Antegrade/Retrograde Flap at Distal Cap
CKD – Severely Calcified SFA CTO

Pre-Proximal SFA CTO

Pre-Distal SFA CTO

Post Ocelot CTO Crossing

Post Pantheris
Zero Contrast + Reduced Radiation for CKD

**Lumivascular**
280mm SFA CTO
1) Contrast = 0mL
2) Total Radiation = 0.3 Gy
2) DAP = 56.5 Gy-cm²

**Endovascular**¹
Average 140mm SFA CTO
1) Contrast = 187.8 +/- 72mL
2) Radiation = 39.1 +/- 21.2 min
2) DAP = 210 +/- 212 Gy-cm²

Conclusions

- ESRD represents 20-40% of all PAD patients
- As DM becomes more prevalent, patients with renal impairment will require better solutions for care
- Treat long CTOs and less complex lesions using OCT + CO2 angio
- Opens up treatment to outpatient and OBL settings
- Reduces risk for readmission and co-morbidity exacerbation in CKD patients
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