Sub-intimal recanalization of peripheral occlusive disease with IVUS guided true lumen re-entry.

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Disclosure

Speaker name:

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
Chronic total occlusions (CTO)

- CTO are present up to 40% in patients with PAD

- Sub-intimal Angioplasty is a common strategy for CTO

- 15-25% failure rate to re-entry true lumen
  - Intraluminal crossing may be not possible
  - Calcification
  - Lesion length
  - CTO Cap Morphology
Luminal Re-entry Techniques

- Standard Hydrophilic wire/Catheter / and 0.018 wires
- Back end of Hydrophilic wire
- CTO wire / Angled catheter
- SAFARI / Cart / Retrograde access
- Standard re-entry devices: Outback
- Pioneer Plus: IVUS guided re-entry

- Re-entry Device allow controlled true-lumen re-entry, increasing technical success for complex cases
Luminal Re-entry Devices

• Accuracy
  • Avoid Collateral/side-branch occlusion => ischemia
  • Prevent Vessel compromise at arterial bifurcation => jeopardize profunda

• Reduce:
  • length of Angioplasty Segment
  • procedure time
  • contrast
  • risk of complications
IVUS Pioneer Plus

- 6Fr Compatible device
- Dual wire system: 0.014 system
- 24G Needle => re-entry non-hydrophilic guide wire
Insert the Pioneer Plus catheter over the 0.014" subintimal guidewire.

Use IVUS to precisely target reentry. IVUS is used in order to localize the true lumen by the presence of flow. The Pioneer Plus catheter should be rotated so the true lumen (identified by the ChromaFlo feature) is at the 12 o'clock position.

Needle will deploy at 12:00 position
Rotate the catheter no more than 180 degrees: gently
Rotate catheter using ChromaFlo as a guide.
Set distance using the 1 mm marks.
3. Deploy the nitinol needle to create a pathway to the true lumen.

4. Advance a non-hydrophilic 0.014” guidewire through the needle into the true lumen. This guidewire will be used to facilitate the placement of subsequent catheters after the Pioneer Plus catheter is removed.

5. Retract the needle and remove the Pioneer Plus catheter. The vessel is now ready for additional interventions.
Needle Deployment

1. Set the depth of the Needle: 3, 5 or 7 mm – adjusting the Red Ring
2. Slightly rotated Blue Ring
3. Advance Blue Ring forward, deploying the needle
Needle Deployment

Needle Exits catheter ~ 7 mm
Below IVUS Transducer
Advance Wire
Technical Tips

1. If the device doesn’t track, pre-dilate sub-intimal tract – avoid damage the device
Technical Tips

1. After re-entry, pre-dilate the track with a 3 mm balloon,
2. Change to a 0.035 support catheter and change the wire if a better support is needed;
3. Utilize IVUS after treatment to identify residual stenosis (re-entry point) and check Angioplasty results
IVUS for PAD

1. ChromaFlo
2. Vessel size
3. Plaque Morphology: fibrous, fibro-fatty, calcified
4. Plaque Geometry: Eccentric or concentric
5. Guidewire position: sub-intimal or true lumen
IVUS for PAD

1. Detection of Calcium Severity:
   >270 degrees reduce effectiveness of DEB
2. Detection of Dissection
3. Detection of Thrombus
4. Stent sizing
5. Stent Apposition and expansion
Summary – IVUS Pioneer Plus

1. Increase technical success for Sub-intimal angioplasty
2. Enable accuracy in re-entry points
3. Reduce procedure time
4. Reduce contrast
5. Fast learning curve
Conclusions

1. Pioneer Plus is our first line re-entry device

2. Use complementary IVUS for Angioplasty and Stenting
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