Photoablation and DCB in in-stent restenosis

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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
• Single Center US Experience Registry in treating very long segment highly symptomatic chronic SFA total in-stent occlusions.
Inclusion Criteria

- Documented chronic total occlusion (≥2 mos) of SFA stents ≥ 18 cm
- Rutherford 3 or 4 classification (no mild claudicants or established tissue loss)
- At least one patent run-off vessel
- No type 3 or 4 stent fractures
- Lesions crossable
- TIMI 3 flow before DEB
Background: fem-pop ISR

ISR vs. de-novo: different pattern, higher restenosis burden

Initial (de-novo) lesion

Dense rubbery cap of smooth muscle cells

Hydrated collagen matrix (watery sponge; 60-80% of NIH volume)

Calcium: rare

Thrombus: can be present, but typically a small part of the total volume

Recanalization, Debunking and Plaque Modification

**Photochemical:**
- Molecular bond break

**Photothermal**
- Thermal energy

**Photomechanical**
- Kinetic energy

- Recanalization (Pilot Channel)
- Plaque vaporization
- Limited embolization
- No moving blades
- Only FDA approved Atherectomy for ISR
Laser in long fem-pop ISR

EXCITE ISR RCT
Laser + PTA vs. PTA in fem-pop ISR
- 250 Patients (169 ELA+PTA vs. 81 PTA)
- Occlusive ISR: 30.5% vs. 36.8%
- Mean ISR length: ~19 cm

Laser + PTA better than PTA, proportionally better in longer lesions

Primary Patency

Laser + PTA vs. PTA @ 6-month: 71.1% vs. 56.4% (p=0.004)

Laser + DCB pre-Clinical Insights

Reduced % stenosis and intimal thickness with Laser+DCB vs. DCB alone at 28 days in pre-clinical ISR model

Rabbit model of (carotid) CTO ISR treated by Laser + DCB vs. DCB alone
Laser + DCB in ISR: Clinical Insights

- SFA-ISR case series (N=14) ~13 cm, treated with Laser+DCB
- Time to first TLR (after PTA) = 8 months

Reduced TLR rate and time-to-TLR vs. initial PTA treatment
1 TLR (7%) at 3 years

Laser+DCB vs. DCB in long, occlusive ISR: RCT

12-month Primary Patency
ELA + DCB vs. DCB:
66.7% vs. 37.5% (p=0.01)

Significant reduction of TLR and MAE and improved wound healing with Laser + DCB vs. DCB alone at 12 months

- Single center randomized trial (Laser+DCB vs. DCB)
- N=48; CLI: 100%; Diabetes: 100%
- Occlusive ISR (Tosaka III): 100%
- mean ISR treated length: 22.4±9.4 cm (Laser + DCB) vs. 25.9±8.7 cm (DCB)

Planned Follow-up Evaluation

- Pre procedural ABI, Duplex, Rutherford
- 1 month clinical evaluation
- 6 month clinical evaluation, ABI, Art Duplex
- 1 yr clinical evaluation, ABI, Art Duplex
- Yearly clinical evaluation, ABI, Art Duplex
Treatment Protocol

- All SFA treatment via contralateral approach to avoid prolonged compression of treated artery.
- Following angiography lesion crossed and treated with Turbo-Elite laser catheter (2 passes at 1mm/sec advancement rate).
- Repeat angiography.
- PTA with non-compliant balloon to reference vessel size for 2 minutes).
- Repeat Angio.
- Drug-Eluting PTA of entire treated segment avoiding treatment miss (Two minute inflations).
- Angiography.
24 patients treated between Feb 2015 – June 2015

- 22 Rutherford 3
- 2 Rutherford 4 (Both had severe Profunda disease).
- Lesion length 18cm – 43cm (mean 28cm)
- Pt age 48 - 78
- 19 males 5 females
- Reference vessel diameter
  - 4mm 2 pts
  - 5mm 19 pts
  - 6mm 3 pts
Baseline hemodynamics

• ABI 0.3 – 0.76 (Mean .52)
• Duplex – Totally occluded segment
Acute Treatment Outcomes

• All lesions were crossed (in 3 cases laser step by step approach was required)
• Following laser atherectomy angiography disclosed a patent channel with TIMI 3 flow in 23/24. One pt had TIMI 2 flow treated successfully with local 2B/3A administration
• Following intial PTA 22/24 widely patent with TIMI 3 flow. 2 had TIMI 1 flow treated successfully with local 2B/3A
• Following DEB all 24 had excellent angiographic result with TIMI 3 flow.
Follow-up

• 24 patients treated within time period to assess 6 month outcomes
• 2 patients did not return for visits or follow-up but were reached by phone (Patients stated they were a symptomatic)
• 1 patient could not be reached
• 21 patients returned to office for full evaluation
Clinical findings in 21 patients at 6 mos

- 18 pts Rutherford 0
- 2 pts Rutherford 2
- 1 pt Rutherford 3
Objective findings at 6 mos

- ABI .52 – 1.3 (Average .92)
- Art Duplex
  - 19 patients, no significant stenosis PSVR <2
  - 1 patient, total SFA occlusion (had stopped anti-platelet drugs)
  - 1 patient, had several high grade lesions
Major Adverse Events at 6 mos

• 1 pt had clinically driven TLR → Laser + DEB with good initial result
• No deaths or CVA
• No major bleeding requiring transfusion
Conclusion

• The treatment of long-segment SFA in-stent occlusions is challenging and has been historically associated with poor patency. Laser de-bulking followed by DEB is feasible. These initial outcomes are encouraging but longer-term evaluation is needed.
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