Future Algorithm for Lower Extremity Revascularization: Where Does Vessel Prep Fit?

John R. Laird
Adventist Heart and Vascular Institute
St. Helena, CA
Disclosure

Speaker name: John R. Laird

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cordis, Medtronic
- Stockholder of a healthcare company: Syntervention, Shockwave, Eximo, Reflow, PQ Bypass
- Owner of a healthcare company
- Other(s)
Background

- Femoropopliteal disease remains a challenge to manage with no evidence-based standard treatment defined.
- There is no agreed upon algorithm for SFA treatment.
- Growing acceptance of the important role of drug eluting devices - randomized controlled trials have demonstrated superior patency rates of DCB over PTA at 2-4 years and DES over PTA and BMS at 5 years (in straightforward lesions).
- Long-term durability of DCB/DES in complex disease (long CTO, heavily calcified lesions, ISR) less certain.
- Vessel preparation may be the key to better long-term results in complex disease!
Drugs and Devices!!
Potential Future Algorithm

**Straightforward Lesion**
1. Lesion length $< 15$ cm
2. Occlusion $< 10$ cm
3. Not severely calcified
4. DeNovo lesion
5. No Acute Thrombus

**Complex Lesion**
1. Lesion length $> 15$ cm
2. Occlusion $> 10$ cm
3. Severe calcification
4. Instant Restenosis
5. Acute Thrombus
Potential Future Algorithm

Straightforward Lesion
1. Lesion length < 15 cm
2. Occlusion < 10 cm
3. Not severely calcified
4. DeNovo lesion
5. No Acute Thrombus

Complex Lesion
1. Lesion length > 15 cm
2. Occlusion > 10 cm
3. Severe calcification
4. Instent Restenosis
5. Acute Thrombus

PTA predilatation

Flow-limiting dissection or >50% residual stenosis?
- Drug Eluting Stent

Satisfactory Angiographic Result
- Drug Coated Balloon
Straightforward Lesion Algorithm

- Simple
- Cost effective
- Time efficient
- Low risk of complications
- Favorable long-term outcomes
Complex Lesion

1. Lesion length > 15 cm
2. Occlusion > 10 cm
3. Severe calcification
4. Instant Restenosis
5. Acute Thrombus

Vessel Preparation
Is there a need for vessel prep? What is the role?

- Debulking to increase luminal gain prior to DCB use or to facilitate stent expansion?\(^1,2\)
- Plaque modification to enhance drug uptake?\(^3,4\)
  - Calcified lesions
  - Thrombus containing lesions
  - CTO
- Plaque modification to combat flow-limiting dissections?\(^5\)
  - Calcified lesions
- Minimize the need for permanent metallic endoprosthesis

Tools for Vessel Preparation

Balloons
- Plain Old Balloon Angioplasty
- Cutting Balloons
- Scoring Balloons
- Controlled-inflation Balloon
- Lithoplasty

Atherectomy Devices
- Directional
- Orbital
- Rotational
- Photoablative
Lesion modification using lithotripsy in a balloon

Sonic Pressure Waves are Tissue-selective:
- Hard on hard tissue, Soft on soft tissue

Waves, unfocused and spherical in shape, travel outside balloon:
- Designed to disrupt both superficial, deep calcium

- Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation
- Effective lesion expansion with minimized impact to healthy tissue
- Familiar Balloon-based endovascular technique
- “Front-line” balloon strategy (.014”compatible)
Is the lesion severely calcified?

Yes

- Calcium Debulfing Atherectomy Device

- Specialty Balloon

Flow-limiting dissection or >50% residual stenosis?

Yes

- Woven Nitinol Stent or DES

No

- DCB
Calcified Common Femoral and SFA Disease – Atherectomy + DCB
DEFINITIVE AR: 2-year Extension

Impact of lumen gain at 2 years: trend towards lower TLR with ≤30% residual stenosis after DA

Is the lesion severely calcified?

No

Atherectomy Device of Choice

Flow-limiting dissection or >50% residual stenosis?

Yes

DCB

Flow-limiting dissection or >50% residual stenosis?

No

DES

DCB

No

DES Spot Stenting

DCB
Mar 2015 – Occlusion of SFA Stents
July 2017

• No Claudication
• Normal ABI
Conclusion

• DCB and DES are effective stand alone therapies for straightforward lesions
• The benefits of vessel preparation are most likely to be realized in complex lesions (severe calcification, long occlusion, instent restenosis)
• The marriage of atherectomy and DCB may bring together the best of two worlds – effective plaque modification / debulking paired with sustained drug presence
Future Algorithm for Lower Extremity Revascularization: Where Does Vessel Prep Fit?

John R. Laird
Adventist Heart and Vascular Institute
St. Helena, CA