Latest Data and Concepts on Deep Venous Arterialization in the US

Peter A. Schneider, MD
University of California San Francisco
Disclosure

Speaker name: Peter A. Schneider

I have the following potential conflicts of interest to report:

- Consulting: Boston Scientific, Surmodics, Silk Road, Medtronic, Cagent, LimFlow, Acotec, Abbott (DSMB)
TADV-Transcatheter Arterialization of the Deep Veins

65 y/o Diabetes, CKD, smoking, and hyperlipidemia

Nonhealing wound at location of 5th toe amputation
TADV-Transcatheter Arterialization of the Deep Veins

Patient Selection

• Type I “No option” by angiogram-desert foot
• Wounds
  • Stable enough to last the 4-6 weeks of fistula maturation
  • Minimal or no infection
• Patients with motivation, social support
• Adequate inflow and appropriate donor vessel
• Interrogate pedal veins with ultrasound for thrombosed or diseased vessels
TADV-Transcatheter Arterialization of the Deep Veins

Pedal Mapping Lateral Plantar Vein

- Map and mark pedal venous loop and note any thrombus, spasm, or vascular anomaly
- Both transverse and longitudinal imaging is important to avoid accessing in a valve
- Best target is lateral plantar vein

Courtesy of Dr. Jorge Martinez Trabal
LimFlow Procedure

AV Alignment

AV Crossing

Valvulotome

Straight Extension Stent Deployment

Tapered Crossing Stent Deployment

Venous Arterialization Achieved
TADV-Transcatheter Arterialization of the Deep Veins

AV Crossing and Forward Valvulatome

**Where to cross?**
- Donor vessel: Usually proximal posterior tibial artery to vein
- Avoid covering collaterals to retain distal tibial flow

**Crossing Devices**
- 6Fr Arterial Catheter with crossing needle
- 4Fr Venous Catheter basket
- Visual alignment under fluoroscopy
- Through-and-through wire

**Manage Valves**
- Lyse valves prior to stent deployment, including as distally as possible in the lateral plantar vein
- Confirm all valves open with a balloon inflation to nominal
TADV - Transcatheter Arterialization of the Deep Veins

Post-Procedure Duplex – Volume Flow

Ideal flow rate in DVA = 100-300 ml/min

High volume flow may indicate non-nutritive flow

Trend in decreased flow may indicate stenosis

Early venous shunting through a perforator before reaching distal the foot. May require coiling.
<table>
<thead>
<tr>
<th>Enrollment</th>
<th>ALPS Registry</th>
<th>PROMISE I (EFS)</th>
<th>PROMISE II U.S. Pivotal*</th>
<th>PROMISE International &amp; UK</th>
<th>CLariTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>Complete</td>
<td>Complete</td>
<td>Presented 11/22 at VIVA</td>
<td>Enrolling</td>
<td>Enrollment Complete, in Follow-up</td>
</tr>
<tr>
<td># Centers</td>
<td>4</td>
<td>7</td>
<td>20</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td># Patients</td>
<td>32</td>
<td>32</td>
<td>105</td>
<td>40+</td>
<td>~200</td>
</tr>
<tr>
<td>Protocol</td>
<td>Multi-center, retrospective</td>
<td>Multi-center, prospective, single-arm</td>
<td>Multi-center, prospective, efficacy and safety study</td>
<td>Multi-center, prospective, single-arm</td>
<td>Prospective registry on natural progression of high-risk CLTI patients</td>
</tr>
<tr>
<td>Primary Endpoint</td>
<td>AFS at 6 mos.</td>
<td>AFS at 6 mos.</td>
<td>AFS at 6 mos.</td>
<td>AFS at 12 mos.</td>
<td>AFS at 12 mos.</td>
</tr>
<tr>
<td>Secondary Endpoints</td>
<td>Wound healing, patency, perfusion</td>
<td>Wound healing, patency, perfusion</td>
<td>Wound healing, patency, perfusion</td>
<td>Wound healing, patency, perfusion</td>
<td>Minor amputations, change in Rutherford classification</td>
</tr>
</tbody>
</table>
PROMISE I

- PROMISE I-Early Feasibility Study (EFS) of the LimFlow System in no-option CLTI patients in the US
- Launched mid-2017, enrollment completed 2019, enrolled 32 patients
- The clinical study was conducted to:
  - Establish clinical safety to move into a pivotal study
  - Identify and address operator challenges
  - Determine patient characteristics and therapeutic parameters that impact performance

ALPS

- ALPS-retrospective analysis conducted to evaluate results of no-option CLTI patients treated with LimFlow
- Sites in Netherlands, Leipzig, Paris and Singapore
- Analysis of 32 consecutive patients treated with LimFlow
- From July 2014 to June 2018
TADV Clinical Data

PROMISE I & ALPS 24 Month AFS

6 Month
P1 AFS= 74%
ALPS AFS= 84%

12 Month
P1 AFS= 70%
ALPS AFS= 71%

24 Month
P1 AFS= 59%
ALPS AFS= 67%

Schmidt et al J Endovasc Ther 2020;27:658
Promise II Pivotal Trial

6 Month Data

Survival = 87%
Limb Salvage = 76%
AFS = 66%

No. at Risk
Overall survival 105 92 87 79 75 69 67 55 54 48 43 40 29
Freedom from target limb amputation 105 92 87 78 74 69 67 55 52 48 42 40 28
Amputation-free survival 105 92 87 78 74 69 67 55 52 48 42 40 28
TADV-Transcatheter Arterialization of the Deep Veins
Lessons Learned

**Patient selection**
- Requires salvageable tissue and stable wound
- Anatomical considerations – Appropriate donor vessel

**DVA Maturation and Tissue Perfusion**
- Requires 4-6 weeks for tissue granulation to start
- Edema can occur in the treated limb after DVA and typically resolves within 3-4 weeks
- Preserve native arterial perfusion and manage pedal loop outflow during maturation process
- Monitor changes in foot tissue color (mottling, cyanosis, changes from pre-op)

**Wound care**
- Multidisciplinary collaboration required
- Minor amputation management, debridement, timing
Conclusions

• Transcatheter Arterialization of the Deep Veins is safe and technically feasible.

• Limb salvage for patients with “no-option” revascularization achievable in majority of patients.

• Continued development: patient selection, techniques, methods to improve outcomes, address specific subgroups such as dialysis.