Percutaneous DVA (LimFlow Procedure) for No-Option CLI

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Disclosure

• Workshop/Speaker Honourarium:
  Medtronic, Cook, Abbott, Straub Medical, Boston Scientific, Bard
• Consultancy:
  MdStart/LimFlow, Acelity, Abbott, Boston Scientific, Vascuros Medical
• Equity
  LimFlow (patent)

It all began at VEITH 2010...

Professor Pramook Mutirangura, Vascular Surgeon, Thailand

Surgical Data

Concept of Venous Arterialization

Concept of LimFlow
A Recent Case

Protein C deficiency + Thrombocytosis
Severe rest pain

Sep 2016
Extensive POBA

Sep 2016
POBA + CDT of thrombosed arch

Dec 2016
Extensive POBA

Outflow has worsened – Dist distal failure

LimFlow April
2017
Some of the European & US cases..

Medical University of Graz
Graz, Austria
Prof. Dr. Marianne Brodmann

Antonius Ziekenhuis,
Netherlands
Daniel Van den heuvel
Jean Paul DeVries

150mm Covered Stent
7F deliverable
now CE marked
There is perfusion after the graft occludes...
Pilot Study – 7 "No-Option" CLI patients

**Pilot Study – 7 “No-Option” CLI patients**


* Minor complications: two non-ST, non-procedure related elevated MIs; one patient developed spontaneous retroperitoneal bleeding 8 weeks’ post-procedure and was managed conservatively after cessation of anticoagulation.

# three procedure unrelated deaths within 12 months: 2 patients died of pneumonia at 6 and 8 months, respectively; 1 patient had a fatal MI at 7 months following above-the-knee amputation.

**Clinical Summary – all patients to date**

- 43 "No option" patients
- Mean age 68 y.o. (range 36-94 y.o.)
- Majority of male patients (61% male, 39% female)
- 81% of the patients were diabetic
- As of today 22% of patients were on dialysis

Rutherford classification

- 37% Class 4
- 58% Class 5
- Remaining Class 6

**LimFlow pDVA Clinical Program**

- **Pilot Phase**
  - # Patients: 7
  - # Centers: 1
  - Protocol: Single-center, prospective, open-label
  - Enrollment: Sep 2013-Nov 2014
  - Countries: Singapore

- **Pre and Post CE Mark**
  - # Patients: 34
  - # Centers: 9
  - Protocol: Multi-center, prospective, open-label
  - Enrollment: Mar 2015 – Mar 2017
  - Countries: France, Germany, Italy, Netherlands, Singapore

- **OUS Post-Market**
  - # Patients: 50
  - # Centers: 3
  - Protocol: Multi-center, prospective, single-arm
  - Enrollment: Jul 2016 – 2018
  - Countries: U.S., EU, Singapore

- **U.S. Pivotal Trial**
  - # Patients: TBD
  - # Centers: 9
  - Protocol: Multi-center, prospective, efficacy and safety study
  - Enrollment: 2018 Target

**Summary**

- It works
- Safe, effective but there is a learning curve
- Potentially applicable to any Angiosome that cannot be opened via Conventional Techniques
- Sustained Perfusion after graft occlusion is surprising and has potential benefits
- FDA granted Expedited Access Pathway Oct 2017. Site selection on going focussing on ability to deliver quality wound care.

**First 43 LimFlow Patients**

- Survival and Amputation Free Kaplan-Meier

- Reproducible Therapy
- Strong Safety Profile
- Survival in line with patients co-morbidities
- Evident Impact on Wound Healing & Amputation Risk

- 71% patients alive and amputation free 6 months after pDVA