Percutaneous deep venous arterialization with the LimFlow procedure

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Disclosure

Speaker name:
Marianne Brodmann

I have the following potential conflicts of interest to report:
- [x] 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
Unmet Need: Lower Limb Ischemic Amputations

- Lethal
  - High perioperative mortality (5-10%)

- Risky
  - High major complication rate (20-37%)

- Costly
  - Direct cost per amputation $45-$65k
  - $800k Life Time Cost per Amputee in US

- NEJM 2009, 361:1368-75
- Norgren and al, JEVS 33, S1-S70 (2007)
The “No Option” Patient Group

Endovascular procedures
Bypass surgery
Wound care
Amputation

“No Option” patients cannot be treated endovascularly or surgically because:
• Disease Progression (“Desert Foot”) or
• Failed Interventions (“Angioplasty Frequent Flyers”)

1. These patients have no remaining acceptable target vessels for intervention
2. Patients with Ischemic Foot Wounds typically do not heal without successful reperfusion.
3. Amputation is the only remaining therapeutic option
4. No Option Patients represent 14-20% of CLI population

pDVA Procedure quick overview
Safe, Reproducible, fully Percutaneous Foot Perfusion

**Key Procedure Steps**  Artery to Vein Crossing

**Ultrasound AV Positioning Kit:**
Intended to determine optimal Crossing point safely and reproducibly
pDVA Procedure quick overview
Safe, Reproducible, fully Percutaneous Foot Perfusion

Key Procedure Steps  Pedal Arch Reconstruction

Push Valvulotome:
Designed to maximize outflow by rendering vein valves incompetent
pDVA Procedure quick overview
Safe, Reproducible, fully Percutaneous Foot Perfusion

Key Procedure Steps  Percutaneous Bypass Creation

Covered Stents
Conical and straight Covered Stents to maximize outflow to the foot
Restored Perfusion:
LimFlow Clinical Example*

LimFlow Patient #5
* Videos courtesy of Dr. S. Kum, Changi Hospital, Singapore
Wound Healing: LimFlow Clinical Example*

PRE-LIMFLOW

34 WEEKS POST-LIMFLOW

400 DAYS post-LimFlow

LimFlow Patient #5

*Slide courtesy of Dr. S. Kum, Changi Hospital, Singapore

* 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.
Pilot Study – 12 months Endpoints

12 Month Endpoints*

- Complete Wound Healing: 57% (6 Months), 71% (12 months)
- Limb Salvage: 86% (6 Months), 71% (12 months)
- Perfusion - TcPO2: 59 mmHg

* Data Source: Journal of Endovascular Therapy website – July 2017
Patient Demographics

Clinical Experience

- 66 treated “No option” patients
- Mean age 72 y.o. (range 31-89 y.o.)
- Majority of male patients (61% male, 39% female)
- 74% of the patients were diabetic
- Over 20% of patients are on dialysis

Rutherford classification

- 67%
- 30%
- 6%

Class 4

Class 5

Class 6
Clinical Summary
First 43 LimFlow Treated Patients

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

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# LimFlow pDVA Clinical Program

<table>
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<th>Pilot</th>
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Ideal Treatment Environment

- Prosthetist
- Diabetologist
- Plastic Surgery
- Podiatrist
- Ischemic Foot
- Vascular Specialist
- Nurses
- Infectious Disease Specialist

Amputation Prevention Multidisciplinary Team
Key Pearls for pDVA Patients

- Recommendations to your wound treatment team
  - Ensure they Follow a well recognized advanced treatment (such as TIME)
  - Inform them of differences to expect compared to normal revascularization
    - foot Swelling
    - delayed wound healing
  - Insist they contact you before considering further procedures on the patient

- Infection Management in “No-Option” patient is potentially the most important treatment to avoid major amputation

- Infection management / Infection prophylaxis
  - Regular wound swab/ culture to identify the bacterial burden
  - Treatment: Local, Systemic, or both
  - Control swab after 2 weeks*

* Two weeks challenge; WUWHS Consensus Document 2008
Wound infection in clinical practice: shaping the future. Carville K et al
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