No Option CLI- A Rising Epidemic and an Overview of Solutions

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DISCLOSURE:
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<tr>
<th>Company</th>
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<tr>
<td>Abbott Vascular</td>
<td>Consultant/Advisory Boarder</td>
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<td>Angiodroid</td>
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<td>Consultant</td>
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<td>TERUMO</td>
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CLI: A fast growing Public Health challenge

- **CLI a Global Epidemic**
  - >3.8M patients in US & EU\(^1\)
  - 23% increase in Incidence in 10 years
  - 43% increase in Prevalence by 2030

- **Multiple risk and growth factors**
  - Explosion in Diabetes (2.5% CAGR: 2014–2035)
  - Aging Baby Boomers (3.2% CAGR: 2015–2025)
  - Increased Life expectancy

- **Heavy Economic Burden**


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The “NO Option” Patient Population

"No Option" patients **cannot** be treated Endovascularly or Surgically because:
- Disease Progression ("Desert Foot")
- 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*

Prognosis of untreated CLI

2 meta-analyses, 24 studies, 2400+ patients:

- 12-month results
  - 20% healed wounds
  - 20% deaths
  - 25% amputations
  - 35% persistent wounds
- Low healing rate with conservative treatment
- Improvement needed for 4 out of 5 patients

- Benoit et al. JVS 2011, Meta-analysis on control group of no option critical limb ischemia
- Abu Dabrh et al. JVS 2015, Meta-analysis on natural history of untreated severe or critical limb ischemia
Avoiding Limb Amputation

Mortality Rates Post-Amputation (5 Year Horizon)

- Up to 10% die before hospital discharge
- 20-37% have major complications
- Average 19 Hospital Admissions / year
- $800k in per patient direct healthcare cost

- 6 out of 10 patients with a PAD/Diabetes combination will be dead one-year after amputation
- 5-year Survival rate post amputation is similar to that of pancreatic cancer

Mortality Rates:
- Peri-operative 6-8 4.2-10.4%
- 1-year 3.4 9.1-33%
- 5-year 3.9 25.6-61.5%
Failure of the distribution system of the forefoot (Ca++ DM+Dialysis + Prolonged Corticosteroid Therapy)
Solutions for real SAD NO-Option: DVA

- Create a communication between artery and vein in BTK;
- Destroy valves;
- Waiting for arterialization;

- Open Surgery (P. Mutirangura Technique);
- Percutaneous Lim Flow (S. Kum Technique);
- Hybrid (R. Ferraresi Technique);
Solutions for real SAD NO-Option: DVA

Pedal bypass with deep venous arterialization: Hybrid flow restoration in critical limb ischemia and unreconstructable distal arteries.

B. Mutirangura 2011

Percutaneous deep venous arterialization in patients with critical limb ischemia.

S. Kum 2018

Hybrid Foot Vein Arterialization in No-Option Patients with Critical Limb Ischemia: A Preliminary Report.

R. Ferraresi 2018

Methods: The procedure was previously described in our initial experience. CLTI angiography is performed to identify the presence of collateral arteries. Technical success was achieved in all patients. In the majority of patients, the inflow and outflow arteries were identified, and the procedure was performed to establish an endovenous vascular access. The procedure was performed in 5 of 7 patients to maintain patency of one or more veins, and two underwent major amputations with significant arterial outflow.

Purpose: To describe a preliminary experience with hybrid foot vein arterialization (HFVA) technique combining femoral and axillary approaches.

Materials and Methods: Between May 2015 and February 2018, 24 patients (mean age 68±12 years, 20 men) with 36 no-option CLI limbs underwent HFVA in our series. Among them, grade 4 limb ischemia and foot infection, and the wound classification grade 3 in 10 (43.2%) limbs, grade 2 in 10 (43.2%), and grade 3 in 16 (66.7%). Surgical bypass was done on the median marginal vein or a posterior tibial vein, followed by extra-anastomosis of foot vein collaterals. A "tension-free" surgical approach was used to treat foot lesions.

Results: At a mean follow-up of 10.8±2 months, limb salvage was achieved in 25 (89%) limbs and wound healing in 16 (64%). 9 patients presented an unhealed wound. Eleven (31%) patients underwent a major amputation (2 below the knee and 9 thigh). One patient with an unhealed wound and open bypass died of myocardial infarction.

Conclusions: HFVA is a promising technique able to achieve acceptable rates of limb salvage and wound healing in no-option patients generally considered candidates for an amputation approach. Further studies are needed to standardize the technique and better identify patients who can benefit from this approach.

Keywords: critical limb ischemia; foot vein arterialization; limb salvage; no-option CLI; peripheral artery disease; venous arterialization.
Solutions for NO-Option: in the middle of DVA

King of Lim-Flow

King of Hybrid
Solutions for Desert Foot in BAD

C.S. 56 yo
Diabetes, Hypertension
CLI, TcPO2 = 3 mmHg
Gangrene I, II and III toes
TUC 3D
Two consecutive antegrade failures
The Very First Good case
Acute and @3 years fu

![Dissection Image](Image)

![Vascular Image](Image)

![Foot Images](Images)

Dismission

2014/03
Leverage proven techniques

Fully percutaneous procedure

Reproducible therapy
74 yy old male

- Chronic Myeloid Leukemia, responsive to current treatment
- Rest pain and 1-2° toe suffering
- TcPO2 5 mmHg

Images courtesy of Dr. R. Ferraresi, Bergamo, Italy
- 5 months after PDVA
- 3.5 months after TMT amputation
Hybrid Technique

Courtesy of R. Ferraresi
Abano DVA in SAD
CONCLUSIONS

• DVA can be considered a promising solution for NO-Option Patients;

• Needs changing in foot surgeons mind;

• Surgical and Hybrid need Vascular Surgeons ;

• Percutaneous for all the others?
SAVE THE DATE

MARCH 21ST & 22ND 2019

PADOVA ITALY

CLIC

Critical Limb Ischemia Course

Course Directors:
M. Manzi, MD
L. M. Palena, MD

Live cases from Policlinico Abano

NH Laguna Palace Hotel - VENICE/MESTRE - ITALY

COURSE FOCUSED ON DIABETIC FOOT
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