Options for the No-Option Patient

Shant M. Vartanian, MD
Assistant Professor of Surgery
Division of Vascular and Endovascular Surgery

Introduction

• Goals of care
  - Relief of pain
  - Healing wounds
  - Clearing infection
  - Amputation prevention
  - Improving (maintaining) quality of life

• Approximately 10-20% of patient with CLI are “not eligible” for revascularization
  - Un-reconstructible anatomy
  - Prohibitive surgical risk

Natural History

• Decreasing amputation-free survival over last 3 decades
• Improved optimal medical management
• Changes in what is considered “no-option”

• Control groups for “no-option” CLI trials

• Meta-analysis of 11 prospective trials totaling 886 patients
  - Wound care
  - Spinal cord stimulation
  - Pharmologic therapy (Circulase)
  - Gene therapy (Talisman, Tamaris)
  - Growth factor (HGF)
**Natural History**

![Graph showing change in AMI in patients with CLI](image)

**Treatment Options**

- **OMT**
- **Pain control**
- **Wound care**
  - Vacuum assisted closure
- **Revascularization**
  - Surgical
  - Endovascular
- **Primary amputation**
- **Biologic therapies**
  - Growth factors
  - Cell based
  - Gene therapy

**Interruption Pneumatic Compression**

- ArtAssist Device (ACI Medical)
- 3 cycles /min x 3 hours daily
- Clinical results within 1 month
  - Squeeze from the ankle to the knee
  - Emptying venous structures
  - Increasing AV pressure gradient
    - Increased flow
  - Increased popliteal blood flow by U/S

**Interruption Pneumatic Compression**

- Immediate improvement in pedal oxygen saturation with near infrared spectroscopy
- Induction of skeletal muscle gene expression profile that favors vascular remodeling
  - Inc CYR61 and CTGF
- Increased shear stress -> upregulation of MCP1
- Production of NO2, tPA and tissue factor pathway inhibitor
- Increased popliteal flow by duplex
- Increased toe pressures clinically
Intermittent Pneumatic Compression

- 107 patients with CLI at Mayo Clinic from 1998 – 2000
- 101 patients with tissue loss
- 60% of patients had TcPO2 < 20 mmHg

- Followed for 6 months after IPC
- Complete wound healing in 40%

- 7 patients non-compliant with device due to pain

*Int Angiol. 2002 Dec;21(4):360-6.*

Intermittent Pneumatic Compression

- 171 no option patients from 2004 – 2009
- Medically optimized
  - Statin, antiplatelet, HTN control
- Taking at least two medications to control pain
- High anesthetic risk (ASA > 4)
- Unreconstructible anatomy
  - No runoff beyond ankle

- Exclusion
  - Popliteal occlusion
  - DVT
  - Active infection
  - Extensive gangrene

*J Vasc Surg 2011;54:440-7*

Intermittent Pneumatic Compression

- IPC 6 hours/day x 12 weeks
- Mean toe pressure increased from 39 mmHg to 55 mmHg
- Popliteal flow increased from 35 cm/sec to 55 cm/sec

*J Vasc Surg 2010;52:843-9*

Intermittent Pneumatic Compression

- 171 no option patients from 2004 – 2009
- Retrospective matched controls that underwent primary amputation prior to 2004
- Applied same inclusion/exclusion criteria

- Quality of life scores strongly favored IPC
- Cost 1/9 of primary amputation
- Cost benefit strongly favors IPC when using QUALY

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Intermittent Pneumatic Compression

- Comparative effectiveness study 31 patients with CLI and no reconstruction options
- 23 allocated to IPC, 8 observational controls
- IPC 3 hours/day x 3 months
- TcPO2 doubles over 6 months in IPC group
- 6 min walking test scores doubled
- No changes in control group
- QoL SF-36 form
  - Significant improvements in bodily pain component and physical functioning component

Summary

- Intermittent pneumatic compression increases distal perfusion
  - Translates into less pain and accelerated healing
  - Low cost, low risk option
  - Ideal for patients with minor tissue loss or isolated rest pain

Pain Control

- Ischemic rest pain is hard to treat
- Quality of life study including 47 no-option CLI patients
  - 70% taking narcotics
  - Pain component of physical component score responsible for most of the very poor QoL scores
  - Pain scores are high even w/ treatment

Spinal Cord Stimulation

- Electrical stimulation of the dorsal column
- Well accepted treatment for neurogenic pain
- Multiple anecdotal series describing positive microcirculatory effects
- Procedure under local + sedation
Spinal Cord Stimulation

- Multicenter European prospective controlled trial
- Inclusion criteria non-reconstructible CLI
- Underwent a test stimulation for 72 hours
  - Placed into responder (n = 41) or non-responder groups (n = 32)
  - In comparison to a control group w/ no SCS (n = 39)

Eur J Vasc Endovasc Surg 26, 280 ± 286 (2003)

Spinal Cord Stimulation

- Higher limb salvage rate with SCS responder group

Eur J Vasc Endovasc Surg 26, 280 ± 286 (2003)

Spinal Cord Stimulation

- Cochrane Review
- 6 studies with 450 patients
- Improved limb salvage @ 12 months
  - Risk ratio 0.71 CI 0.56 – 0.90
- Significant pain relief w/ SCS
  - Less analgesic use

- Complications
  - Implant problems
  - Infections
  - Need for re-intervention
  - Number needed to harm = 6

- Expensive

Eur J Vasc Endovasc Surg 26, 280 ± 286 (2003)

Case History

- Intermittent pneumatic compression
- At 1 month, pain appreciably better
- Able to sleep at night

- No evidence of tissue loss on exam
- Dependent rubor

- Plan 3 additional months of pneumatic compression
Summary

• No-option patients are not infrequent
• Niche of no-option patients that do well with non-interventional measures

• Intermittent pneumatic compression increases distal perfusion
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  - Low cost, low risk option
  - Ideal for patients with minor tissue loss or isolated rest pain

• Spinal cord stimulation effective at relieving pain and improves perfusion in most
  - Invasive, re-intervention risk and high cost