Clinical targets and patient outcome goals in BTK intervention

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Disclosure

I have the following potential conflicts of interest to report: consulting, travel reimbursement, teaching courses, training, proctoring:

Medtronic, Boston Scientific, Abbott, LimFlow, Terumo, Cook, Biotronik, Asahi, Shire, Kardia, Orbus
Clinical targets and patient outcome goals in BTK intervention

Old targets
1. Limb salvage
2. Wound healing

New targets
1. A functional limb through limb salvage or leg amputation
2. Biomechanics & flow-guided foot surgery
3. Patient centered approach
Restenosis after POBA in BTA vessel

Basal Angio

1° PTA

2° PTA

3° PTA

4° PTA

5° PTA
26 months of recurrent pain, inability to walk, infections, dressings, hospitalizations, multiple “minor” amputations… This is what we call “limb salvage”!
Limb salvage alone cannot be considered a goal in BTK-CLI treatment: we must save something useful for walking!

Fighting for an “impossible mission” in BTK-CLI can lead to months of:

- **Inability to walk**
- **Chronic wound**
- **Need for daily dressing**
- **Repeated infections**
- **Repeated hospitalization**
- **Personal & family desperation**
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Wound healing and time-to-healing are wonderful targets in the physician’s mind, however we must save something useful for walking!
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3. Patient centered approach
Patient’s goal is maintaining independence; the key is maintaining ambulation via limb salvage or prosthesis

Think biomechanics!

Prof Chris Attinger

VSS, JVS 10:108, 1995
Buzato MA, âcta Chir Belg 102:248, 2002
Active pts demand function

Patients with good neuromuscular capacity can have an active life wearing a modern prosthesis.
After BKA, ambulation rate 16% to 78%

Risk of not wearing prosthesis
- 10x: Non-ambulatory pre-op
- 4.4x: AKA
- 2.7x: > 60 yy
- 3x: homebound
- 2x: CAD

Taylor S, JVS 42:227, 2005
Courtesy Prof Chris Attinger
Fragile pts demand independence
Ambulation via limb salvage or amputation is the ONLY goal

Salvage or amputation should be viewed as giving the pt a new leg and should be done with equal attention to detail

Think biomechanics!

Courtesy Prof Chris Attinger
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The functional foot

- Reconstruction must optimize function in residual leg or foot

- Reconstruction goal is a functional foot that redistributes weight to avoid high pressure points on the plantar foot

- Most diabetics are insensate and cannot recognize high pressure points

- Failure to make this the primary concern will lead to sub-optimal or no-function

Courtesy Prof Chris Attinger
Use every tool at your disposal:

- **Control infection**
- **Prepare wound bed**
- **Optimize blood flow**
- **Think biomechanics!**

**Forces:**

- **Sagittal plane (Peak Plantar Forces)**
  - Between the foot and the shoe/ground
  - Easier to measure

- **Transverse/Frontal plane (Shear Forces)**
  - Between the underlying structures (bone) and the plantar soft tissue structures
  - Between the plantar soft tissue structures and the shoe/ground
  - Harder to measure

Courtesy Prof Chris Attinger
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<th>Type</th>
<th>Tissue</th>
<th>Flow</th>
<th>Biomechanical needs</th>
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• Proximal open TMA with accurate sparing of pedal-plantar loop vessel
• Bone coverage by connective tissue substitute
• Skin graft
Small Artery Disease (SAD)
Tension-free surgery
avoid any tension that could precipitate local necrosis: dermal substitute, VAC etc.
Foot surgery must be always tailored on biomechanics & blood supply

Forces:
- Sagittal plane (Peak Plantar Forces)
  - Between the foot and the shoe/ground
  - Easier to mesure
- Transverse/Horizontal plane (Shear Forces)
  - Between the underlying structures (bone) and the planter soft tissue structures
  - Between the plantar soft tissue structures and the shoe/ground
  - Harder to mesure

Use every tool at your disposal:
- Control infection
- Prepare wound bed
- Optimize blood flow
- Think biomechanics!

Flow-guided surgery: what is the best forefoot amputation for this patient?
Consider 3 key points

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Critical limb ischemia is a “bag” in which we put every patient with PAD and foot suffering.

**Recommendation 16. Clinical definition of critical limb ischemia (CLI)**

- The term critical limb ischemia should be used for all patients with chronic ischemic rest pain, ulcers or gangrene attributable to objectively proven arterial occlusive disease. The term CLI implies chronicity and is to be distinguished from acute limb ischemia [C].
Causes of PAD

- ESRD-HD
- Type 1 DM
- Inflammatory disorders
- Smoking
- Type 2 DM

Patient status

- Life & QoL expectancy
- Walking capacity
- Comorbidities
- Social contest
- Family support

CLI

Foot lesion

- Type of minor/major amputation
- Tissue lesion
- Biomechanical strategy
- Infection

Obstruction pattern

- Below-the-ankle & small vessel disease
- BTK disease
- Iliac/FEM/POP disease
- Calcium
The prevalence of CLI in ESRD-HD pts ranges between 4-17%.

In our CLI pts:

- 30% are ESRD-HD
- 16% have >2.0 mg/dL serum creatinine

The prevalence of CAD and cerebral artery disease in PAD pts is 40-60%.

In our CLI pts >70% have a history of CAD and >30% cerebrovascular disease
Overall survival remains poor in CLI pts regardless of the procedure-related success.

Patients do not always experience significant gains in their QoL after limb salvage interventions, despite reasonable graft patency, amputation-free survival, and limb salvage rates.

We should maximize a patient-centered outcomes.
CLI is a complex disorder. We can treat it only pursuing a patient-centric approach in a multidisciplinary team.

**Aggressive therapy in term of:**
- Revascularization
- Aggressive wound care
- Foot biomechanics
- Rehabilitation

**Palliative therapy in term of:**
- Treatment modulation
- Revascularization?
- Symptoms control
- Comfort care (QoL)
- Minimal wound care
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