# How to identify patients to improve limb salvage

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### **Disclosure Statement of Financial Interest**

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

#### **Affiliation/Financial Relationship**

- Grant/Research Support
- Consulting (non-compensated)
- Major Stock Shareholder/Equity

- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

#### Company

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### Critical limb ischemia (CLI)

 Defined as severe obstruction of the arterial circulation which markedly reduces blood flow to the extremities and has progressed to the point of severe pain and tissue threat with either ulceration or frank gangrene

# Why is this important

- Patients with CLI unlike claudicants have an up to 40% progression to major amputation within 6 months of diagnosis
- Majority will lose limb (BKA/AKA) if no revascularization is attempted
- Within 1 year
  - 25% will experience a major amputation
  - 20-25% mortality
- Over 50% mortality in the next 5 years

Allie D J Endovasc Surg 2009

### Amputation

- Less than half of amputees regain the ability to walk
- Less than half survive more than 2-3 years
- Annual costs associated with amputation are \$10-20 billion<sup>1</sup>
  - 10 billion major amputation
  - 13 billion minor amputation
    - Toe, partial foot etc
- Post-amputation care costs \$50,000/family/yr
- SNF \$100,000/patient/year

SAGE group estimates of economic cost of critical limb ischemia

# The "team" approach

- Many examples where a team approach improve outcomes in medicine
  - TAVR
  - Tumor boards
  - Heart team
- All require expertise in their field
- All require collaboration and intellectual respect in all aspects of patient care

### Integrated practice units (IPU)

- All members meet frequently to review patients and upcoming patients as to approach and outcomes expected
- Collaborative approach
- Frequent follow-up with any member allows for early identification of vessel attrition or failure

### **Outcomes of 3 Years of Teamwork on Critical Limb Ischemia in Patients With Diabetes and Foot Lesions**

• 245 patients: treated with percutaneous revascularization (PTA), open surgery (OSR), medical treatment (MT), primary amputation (PA)

|                  | РТА          | OSR           | MT           | PA          |
|------------------|--------------|---------------|--------------|-------------|
|                  | 189<br>(77%) | 44<br>(18.3%) | 11<br>(0.3%) | 1<br>(0.5%) |
| Ulcer recurrence | 1.6%         | 0.8%          | 9.3%         |             |

• Major amputation after revasc: 5.3%, after med therapy: 13.8%

Scatena A, Petruzzi P, et al. Int J Low Extrem Wounds. 2012 Jun;11(2):113-9.

### Regional Intensity of Vascular Care & Risk of Amputation

#### Goodney. JVS. 2013.

- Retrospective Medicare data
- 97,000 PAD admissions
  83,000 Amputations
  77,500 Endovascular
  171,000 Surgical
- Inverse relationship between intensity of vascular care and amputation rates



*Rowe. JVS.2009.49:910-7* 

### Patient evaluation

- How to confirm the diagnosis of suspected CLI?
  - History
  - Physical examination
  - Physiologic assessments of limb/foot perfusion
  - Anatomic imaging

However, we still have issues with speaking the same language!

|                          | Fontaine   |       |          | Rutherford  |  |  |
|--------------------------|--|-------|----------|---|--|--|
| Stage                    | Clinical description   | Grade | Category | Clinical<br>description                                       | Objective<br>description   |  |
| I                        | Asymptomatic   |       | 0        | Asymptomatic  | Normal treadmill test  |  |
| IIa                      | IC,* painfree walking<br>distance >200 m   | Ι     | 1        | Mild IC   | Treadmill exercise limited<br>to 5 min; ankle pressure<br>after exercise >50 mm<br>Hg, but at least 20 mm<br>Hg lower than at rest |  |
|                          |  |       | 2        | Moderate IC   | Between Rutherford 2<br>and 3 disease  |  |
| Πь                       | IC, painfree walking<br>distance <200 m  |       | 3        | Severe IC   | Treadmill exercise limited<br>to <5 min; ankle pressure<br>after exercise <50 mm Hg  |  |
| II<br>(compli-<br>cated) | Lesions without CLI*<br>(ankle pressure<br>>50 mm Hg<br>and/or great<br>toe pressure<br>>30 mm Hg) |       |          |   |  |  |
| ш                        | Rest pain  | п     | 4        | Rest pain   | Ankle pressure <40 mm Hg<br>and/or great toe pressure<br><30 mm Hg; pulse volume<br>recording barely pulsatile or<br>flat          |  |
| IV                       | Ischemic lesion<br>(ulcer, gangrene,<br>necrosis)  | ш     | 5        | Limited<br>ischemic<br>lesion                                 | Ankle pressure <60 mm Hg<br>and/or great toe pressure<br><30 mm Hg; pulse volume<br>recording barely pulsatile<br>or flat          |  |
|                          |  |       | 6        | Extended<br>ischemic<br>lesion (above<br>metatarsal<br>level) |  |  |

\*IC, intermittent claudication; CLI, critical leg ischemia.

### **PARC** definitions

| Fontaine Classification |   | _  |  |     | Rutherford Classification |          |                       |
|-------------------------|---|----|--|-----|---------------------------|----------|-----------------------|
| Stage                   | Symptoms  | -  | Proposed PARC Universal Data Elements  | ÷+1 | Grade                     | Category | Symp to ms            |
| 1                       | Asymptomatic  |    | Asymptomatic   |     | 0                         | 0        | Asymptomatic          |
| н                       | Intermittent claudication/other<br>exertional limb symptoms |    | Mild claudication/limb symptoms<br>(no limitation in walking)  | ••  | 0                         | 1        | Mild claudication     |
| Ila                     |   | ** | Moderate claudication/limb symptoms<br>(able to walk without stopping >2<br>blocks or 200 m or 4 min)    |     | 1                         | 2        | Moderate claudication |
| IIb                     |   |    | Severe claudication/limb symptoms<br>(only able to walk without stopping<br><2 blocks or 200 m or 4 min) | ••  | 1                         | 3        | Severe claudication   |
| Ш                       | Is chemic rest pain   | ** | Ischemic rest pain (pain in the distal<br>limb at rest felt to be due to limited<br>arterial perfusion)  | **  | 11                        | 4        | Ischemic rest pain    |
| IV                      | Ulceration or gangrene                                      |    | Ischemic ulcers on distal leg  | **  | 111                       | 5        | Ischemic ulceration   |
|                         |   |    | Ischemic gangrene  | *** | 84                        | 6        | Ischemic gangrene     |

#### JACC 2015 65; 931-41

Risk stratification based on wound, ischemia and foot infection (WIfI)

- Believe the current system of Fontaine or Rutherford/Becker are outdated and should not include diabetics
- The guidelines for what is CLI has morphed to include diabetics
- WIfI is driven to standardize wound, ischemia and foot infection as to an outcome

JVS 2014; 59: 220-34



| Grade   | Ulcer  |   | Gangrene  |  |  |
|---|--|---|---|--|--|
| 0<br>Clinical description:  | No ulcer   | mptoms + ischemia grade 3); no woun   | No gangrene   |  |  |
| 1   | Small, shallow ulcer(s) o<br>or foot; no exposed b<br>to distal phalanx  | n distal leg<br>one, unless limited   | No gangrene   |  |  |
| Clinical description:   | minor tissue loss. Salvageable with si   | mple digital amputation (1 or 2 digits) of  | or skin coverage.   |  |  |
| 2   | Deeper ulcer with expos<br>tendon; generally not<br>shallow heel ulcer, wit  | ed bone, joint or<br>involving the heel;<br>hout calcaneal involvement  | Gangrenous changes limited to digits  |  |  |
| Clinical description:   | major tissue loss salvageable with mu  | ltiple (≥3) digital amputations or stand  | ard TMA $\pm$ skin coverage.  |  |  |
| 3<br>Clinical description:<br>flap coverage or c  | Extensive, deep ulcer inv<br>midfoot; deep, full thi<br>calcaneal involvement<br>extensive tissue loss salvageable only w<br>complex wound management needed | volving forefoot and/or<br>ckness heel ulcer ±<br>rith a complex foot reconstruction or nor<br>for large soft tissue defect | Extensive gangrene involving forefoot<br>and /or midfoot; full thickness<br>heel necrosis ± calcaneal involvemen<br>or nontraditional TMA (Chopart or Lisfranc) |  |  |
| <i>TMA</i> , Transmetatarsal<br><u>I:</u> Ischemia<br>Hemodynamics/perfus<br>SVS grades 0 (none), | amputation.<br>sion: Measure TP or TcPO <sub>2</sub> if ABI incomp<br>1 (mild), 2 (moderate), and 3 (severe).  | pressible (>1.3)  |   |  |  |
| Grade   | ABI  | Ankle systolic pressure   | TP, TcPO <sub>2</sub>   |  |  |
| 0   | ≥0.80  | >100 mm Hg  | ≥60 mm Hg   |  |  |
| 1   | 0.6-0.79   | 70-100 mm Hg  | 40-59 mm Hg   |  |  |
| 2 3   | 0.4-0.59<br>≤0.39  | 50-70 mm Hg<br><50 mm Hg  | 30-39 mm Hg<br><30 mm Hg  |  |  |

#### JVS 2014; 59: 220-34

### Amputation avoidance

- Easiest is early education for patient and care givers
- Frequent follow-up and surveillance
- Early intervention
  - Surgical
  - Endovascular
  - Wound care
- Early and frequent wound care interventions
- Continue "team approach" for ongoing care

# Multidisciplinary team

- Team mates include
  - Interventionalist
  - Primary care
  - Nutritionist
  - Endocrinologist (diabetologist)
  - Podiatrist
  - ID physician
  - Physician extenders
  - Patients care givers

### Summary

- All patients with suspected CLI need further evaluation
- All patients regardless of entry site can follow a "team" approach to ongoing and continued limb care
- Early revascularization includes surgical and endovascular therapies
  - Both individually
  - hybrid
- Entry into the IPU continues after identification, revascularization and follow-up
- Unfortunately, highly likely patient will need readmission for revascularization