CRITICAL LIMB ISCHEMIA

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Critical Limb Ischemia

- Manifestation of PAD that describes patients with chronic ischemic rest pain, ulcers or gangrene
# Clinical Classification

<table>
<thead>
<tr>
<th>Stage</th>
<th>Fontaine</th>
<th>Rutherford</th>
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<tbody>
<tr>
<td>I</td>
<td>Asymptomatic</td>
<td>0 0 Asymptomatic</td>
</tr>
<tr>
<td>IIa</td>
<td>Mild claudication</td>
<td>I 1 Mild claudication</td>
</tr>
<tr>
<td>IIb</td>
<td>Moderate to severe claudication</td>
<td>I 2 Moderate claudication</td>
</tr>
<tr>
<td>III</td>
<td>Ischemic rest pain</td>
<td>II 4 Ischemic rest pain</td>
</tr>
<tr>
<td>IV</td>
<td>Ulceration or gangrene</td>
<td>III 5 Minor tissue loss</td>
</tr>
<tr>
<td></td>
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<td>III 6 Major tissue loss</td>
</tr>
</tbody>
</table>

Taken from TASC II, Nogren et al, 2007
Survival

Survival (%)

Year

0 2 4 6 8 10 12

100

Normal subjects

Asymptomatic PAD

Symptomatic PAD

Severe symptomatic PAD

CLI Prognosis

- Worse than that of patients with intermittent claudication
- Diagnosis is a poor predictor for life and limb
- Patients should have aggressive modification of their cardiovascular risk
- Much of the care is palliative in nature, which is very important when considering revascularization or amputation
Natural History

Fig. A5. Fate of the patients presenting with chronic critical leg ischemia. CLI – critical limb ischemia.

Taken from TASC II, Nogren et al, 2007
Goals of treatment of CLI

- Relieve ischemic pain
- Heal ischemic ulcers
- Prevent limb loss
- Improve patient function and quality of life
- Prolong survival
Treatment of CLI

- Medical treatment alone
- Primary Amputation
- Revascularization
  - Surgical bypass
  - Endovascular treatments
Surgical bypass limb salvage rates depend on

- Level and extent of vascular obstruction
- Availability of a conduit for bypass grafting
- Ability to create straight-line flow to the foot
- Surgical expertise
- Morbidity and mortality rates associated with these procedures can be substantial
The FIRST Endovascular Treatment

Laura Shaw 82 y/o gangrene and painful left foot

Charles Dotter, *Circulation* 1964
Our Approach

- H&P
- Noninvasive testing to confirm disease and plan intervention
- License to treat multiple levels all at once
- License to revascularize below the knee
- Multidisciplinary! Wound/surgical care, primary care, etc.
Tip: access

- Anterograde access if you know the patient’s disease is limited to distal SFA and below knee
- Contralateral access for all other cases
- For below knee work place a sheath or guide cath in distal SFA or popliteal
Tip: Crossing

- 018 system (Quick cross, CXI) with wire (Terumo glidewire, V18) or 014 (mailman, prowater, spartacore, CTO wires)
- 035 4 fr diagnostic catheter (Slip cath, Glidecath) and Glidewire will work also
- Subintimal reentry into tibial vessels can be difficult
- Consider pedal access
Technical goal

- Achieving at least straight-line flow to the foot
- Maximizing perfusion pressure to the wound
  - Angiosomal anatomy
- Balloon angioplasty is our predominate tibial treatment
- Worst case scenario is converting a patient with claudication to acute limb ischemia
  - Stenting below the knee is for bailout only
- Know when to declare victory and retreat
Lida et al showed improved amputation free survival at 4 years if the target vessel was revascularized according to the angiosome model.
Case

- 59 y/o female
- Nonhealing RLE painful 2\textsuperscript{nd} toe ulceration for 2 months
- Risk factors:
  - IDDM (A1C 7.9)
  - ESRD on dialysis
  - HTN
- Exam:
  - R fem 2+
  - R pop 1+
  - Nonpalp pedal pulses
- CTA
  - No inflow disease
  - SFA patent
  - Popliteal stenoses
  - Single vessel runoff via the AT which is diseased proximally
Above the knee pop disease
Prox AT disease
2.5 mm balloon
3.5 mm balloon

2+ palp DP
Case

- 63 y/o non healing right great toe ulceration for about a month
- Risk factors:
  - IDDM
  - HTN
  - Hyperlipidemia
  - Nonsmoker
- Exam:
  - 2+ Palpable femoral pulses
  - Non-palpable right popliteal or pedal pulses
CTA

- No rate limiting inflow disease.
- Shelf calcific plaque at the distal aorta which we avoided going near by anterograde access
- Severe diffuse mid to distal SFA disease with likely adductor canal occlusion
- Single vessel posterior tibial runoff with disease
- No distal DP target
Severe SFA disease

Pop is healthy across the joint

Prox occlusion of the AT and peroneal arteries
- single vessel PT runoff with multifocal severe stenoses

- NO reconstituted DP
Posterior tibial BEFORE

Plasty to 2.5 mm

AFTER
SFA BEFORE

Plasty with suboptimal results.

Subsequent stent.

AFTER
At procedure

3 month follow-up
Case

- 71 y/o male h/o diabetes (A1C 6.1) HTN, hypercholesterolemia
- Ulcer, getting worse over 4 weeks
- 2+ palpable left femoral artery pulse
- No palpable popliteal or pedis pulse
- Dorsalis pedis was 1+ dopplerable
Findings:
1. Focal severe stenosis of the distal left superficial femoral artery
2. No continuous left runoff vessel with proximal occlusion of the anterior tibial artery
3. Reconstitution of the distal left anterior tibial artery with filling of the dorsalis pedis
Short segment severe stenosis of the distal SFA

Ballooned to 6 mm with good result
No continuous runoff vessel with occlusion at the tibioperoneal trunk

Distal target
Anterograde re-entry was unsuccessful

Pedal access
SAFARI

- When anterograde access cannot be achieved, retrograde access into the true lumen of the distal vessel can be obtained, the two accesses are met and a “floss wire” is created.
- Intervention is then performed over the floss wire from the groin access.
- This technique is called Subintimal Arterial Flossing with Anterograde Retrograde Intervention (SAFARI), first performed in the United States at UVA by David Spinosa.
Subintimal Arterial Flossing with Antegrade–Retrograde Intervention (SAFARI) for Subintimal Recanalization to Treat Chronic Critical Limb Ischemia

David J. Spinoza, MD, Nancy L. Harthun, MD, Eric A. Bissonette, MS, Dorothy Cage, RN, MSN, ACNP, Daniel A. Leung, MD, John F. Angle, MD, Klaus D. Haghighi, MD, John A. Kern, MD, Ivan Crosby, MD, Harry A. Wellens, Gary D. Hartwell, DSc, and Alan H. Matsunoto, MD

PURPOSE: To describe the technique of subintimal arterial flossing with antegrade–retrograde intervention (SAFARI) to improve technical success for the performance of subintimal recanalization when there is failure to reenter the distal true lumen or when there is a limited segment of patent distal target artery available for reentry.

MATERIALS AND METHODS: Subintimal recanalization was attempted in an antegrade direction in all patients. If reentry into the distal true lumen was unsuccessful or a short segment of target artery was present, retrograde access was obtained in the distal target artery (popliteal, anterior tibial/dorsalis pedis, or posterior tibial) and a retrograde subintimal channel was created. A guide wire was used to connect the retrograde and antegrade subintimal channels simultaneously to create a “flossing” guide wire. The subintimal tract was dilated with balloon angioplasty with or without stent implantation. Limb salvage, amputation-free survival, and survival rates over time were determined.

RESULTS: The SAFARI technique resulted in successful subintimal recanalization creating straight-line flow to the foot in all 21 limbs in 20 patients in which the technique was attempted. Antegrade–retrograde access was performed with the femoral artery and the following vessels: popliteal, n = 18; anterior tibial/dorsalis pedis, n = 13; and posterior tibial, n = 2 (two limbs involved multiple accesses). All procedures were successful. The limb salvage rate with SAFARI was 90% (95% CI, 74%-100%) at 6 months.

CONCLUSIONS: The SAFARI technique can be useful for completing subintimal recanalization when there is failure to reenter the distal true lumen from an antegrade approach or when there is a limited distal target artery available for reentry. The SAFARI technique improves technical success in the performance of subintimal recanalization. Limb salvage rates are comparable to those with antegrade subintimal recanalization.

SAFARI—chronic critical limb ischemia; SAFARI—subintimal arterial flossing with antegrade–retrograde intervention; SFA—superficial femoral artery.

SUBINTIMAL recanalization is receiving increasing attention as a potential treatment for limb salvage in patients with chronic critical limb ischemia (CCLI). Subintimal recanalization was first described by Bolia et al (1) for the treatment of the long superficial femoral artery (SFA) in 1989 and of tibial occlusions in 1994 (2). Since that time, interventionists outside the United States have treated the potential benefits of subintimal recanalization for the treatment of CCLI (3–9). These authors reported limb salvage rates to be comparable to those with arterial surgical bypass, with fewer complications when subintimal recanalization is used to treat CCLI. However, technical success is limited by the inability to reenter the true lumen in as many as...
Pedal access was obtained at the anterior tibial artery at the ankle joint. A 0.018” wire was passed retrograde, and “jays” as it enters the subintimal space at the level of occlusion.
The pedal wire traverses the subintimal space with the assistance of a 3 Fr microcatheter. The pedal wire is directed into the groin-approach catheter.

The two accesses meet in the subintimal space at the proximal anterior tibial artery.

The pedal wire is pushed through the groin access and a “floss wire” is established. Intervention is then performed over the floss wire.
The entire tract is balloon dilated to 2.5 mm
Followup angiogram shows creation of fast in-line flow to the foot via the anterior tibial artery with filling of the dorsalis pedis.

In-line flow maximizes the potential for wound healing.
SAFARI

Day of procedure  2 month office followup  3 months
SAFARI

Case

- 69 y/o diabetic male ABI 0.46
- Wound started 4 weeks ago, getting worse
- CTA showed no inflow disease, but severe SFA and runoff disease
SAFARI

Single vessel peroneal runoff

Reconstituted AT and PT
Attempted anterograde recanalization of the SFA was unsuccessful even after attempted use of crossing device (Outback).
So in this case SAFARI was used to help recanalize the SFA. The popliteal artery was accessed.
The popliteal access wire was directed into the groin sheath in the subintimal space and “body floss” wire established.

The recanalized SFA was angioplastied.
SAFARI

Ultimately required a stent at the distal SFA
Then the AT and PT Occlusions were addressed From anterograde approach.

Pedal access was not required.

First the AT occlusion was crossed
SAFARI

2.0 mm Balloon

Excellent result
SAFARI

Then the PT was recanalized and balloon angioplastied
The final result was recreation of a three vessel runoff, essentially normal large vessel anatomy.
Day of revascularization

Two weeks post

6 weeks post
Crazy case

- 71 y/o male
  - Smoking history 2-3 ppd
  - No additional risks
  - Bilateral AKAs due to PVD
    - No vein conduit
  - Lost right thumb in lawn mower accident
Entirely forearm runoff disease.

Inflow and brachial artery are widely patent.
Other tips and tricks

- Carbon dioxide angiography
- Mixed arterial/venous ulcers and venous ulcers
- Sorting through the “device madness”
- Using tibial access/tibial recannalization to sell yourself
Case

- 63 y/o M painful heel ulcer 2-3 months
  - DM2
  - HTN
  - Stents placed years ago at OSH
  - GFR 28
  - ABI 0.56
(balloon too big for this vessel)
Venous ulcers
Venous vs mixed arterial-venous

- Venous ulcers
  - ABI results?
  - If abnormal and patient has an arteriogram, the presence of hyperemia excludes arterial insufficiency as the etiology
  - Tx
    - Compression/Una boot
    - Vein workup/EVLT

- Mixed arterial/venous
  - Treated for both
  - Partial/reduced compression dressing
Hyperemia
Device Madness

- Atherectomy
- Drug coated technology
- Future technologies
Atherectomy

Okay, fine. Open the CSI

Post 1.25 mm CSI drill bit,
Followed by 2.0 mm plasty
Drug technology
- Zilver PTX – Paclitaxel coated (Taxol)
- Released Jan 2013
Future of SFA Intervention?

Amaranth Bioabsorbable Stent
Flexibility Similar to Nitinol Stents

- Vascular response of BVS comparable to non-biodegradable DES

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<thead>
<tr>
<th></th>
<th>1 month</th>
<th>6 months</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
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<tr>
<td>Absorb BVS Cohort A</td>
<td><img src="image1.png" alt="Image of Absorb BVS Cohort A" /></td>
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Concord Vein & Vascular Center
Located at 212 LePhillip Court NE, Suite 200 in Concord, NC.

Procedures offered:
- Varicose Veins - EVLT

Contact this location:
Phone: 704-786-0052
Fax: 704-788-2379
Summary

- Distal access techniques significantly increase possibilities for revascularization and optimize success, both technical and clinical.
- We can accomplish more than in-line flow
  - more flow = faster healing
- Always do what’s best for the patient