Does Type and Timing of Revascularization Affect the Outcome of Foot Amputations

Alexander Reyzelman DPM
Co-Director, Center for Limb Preservation
University of California, San Francisco
No Disclosures
Purpose:
- To review a 12-year experience with lower extremity minor amputations and investigate which risk factors best predict patient survival and limb loss.

Hypothesis:
- Multidisciplinary approach to the treatment of foot ulcerations in patients with PVD can lead to excellent rates of limb salvage regardless of glucose control.
Methods & Materials:

- January 1, 1990 – December 15, 2001 – 12 years
- 670 patients with PVD underwent 920 minor amputations (interphalangeal, ray, or TMA) on 747 limbs at the Beth Israel Deaconess Medical Center
  - 468/670: males
  - 616/670: + Diabetes Mellitus
  - 74/670: Actively used Tobacco; 63/670: Quit tobacco use < 2 years
  - 435/670: +Hypertension
  - 480/670: + Coronary Artery Disease
  - 137/670: +Renal insufficiency; 92 were dialysis dependent.
• An arterial bypass procedure was performed <30 days before or concurrent with the minor amputation in 485 limbs (64.9%).

• A subsequent bypass was performed <30 days of the initial amputation in 73 limbs (9.8%)

• Indications for delayed bypass included:
  – Active infection (35/73 patients)
  – Surgeon preference 12/73 patients
  – Nonhealing of the minor amputation (26/73 patients)
    ▪ ***out of the 26 patients, 21 occurred during the first half of the study and only 5 occurred in the latter half
Results:

- Patients who received a delayed bypass after the initial amputation were found to have a diminished limb salvage regardless of the cause of the delay (ie: infection, surgeon preference or non-healing of initial amp – 77.4% vs. 90.2%)
• **Conclusion**

  • Recommended Protocol for limb salvage:
  
  • Prompt surgical drainage of any underlying infection. Debridement of uninfected necrotic tissue is **NOT** performed as an initial procedure.
  
  • Evaluation for peripheral ischemia: if a clearly palpable DP or PT is not present, angiography is performed.
  
  • Final debridement, amputation, and wound closure can then be accomplished under conditions of optimal perfusion.
  
  • ***after adhering to this protocol of not delaying bypass, they noticed that the # of non-healing amputation sites decreased from 21 in the first 5 years to just 5 patients within the remaining 6 years of the study.***
Early revascularization after admittance to a diabetic foot center affects the healing probability of ischemic foot ulcer in patients with diabetes.


**Purpose:** To examine the relationship between *time to revascularization and the probability of healing without major amputation* in patient with diabetes and ischemic foot ulcer at a diabetic foot center

**Methods & Materials**

- 478 patients
- Inclusion Criteria:
  - +DM, foot ulcer (wagner grade 1-5 at or below the ankle), systolic toe pressure <45mmHg/systolic ankle pressure < 80mmHg
  - 315 patients had PTA
  - 158 patients had open bypass surgery
  - 15 patients – no vascular reconstruction was possible
Early revascularization after admittance to a diabetic foot center affects the healing probability of ischemic foot ulcer in patients with diabetes.


Results

• Type of Revascularization:
  – No difference between patients who had PTA or reconstructive surgery regarding ulcer progression

• Timing to Revascularization (Median time was 3-18 weeks):
  – Patients who had shorter time to revascularization < 8 weeks of presentation to the foot center had a higher probability of healing without major amputation over time.

Figure 1. Probability of ulcer healing without major amputation in relation to time to revascularization.
When should salvage foot procedure be performed following a revascularization procedure?

- Multiple studies have reported that adequate tissue oxygenation for healing has been described as having transcutaneous oxygen tension (TcPO2) of 30mmHg.
- TcPO2 measurements have a higher diagnostic accuracy than the ABIs, pulse volume recordings, and toe pulse reappearances in identifying foot ischemia.
Purpose:

- To Compare TcPO2 measurements on the 1\textsuperscript{st}, 2\textsuperscript{nd}, & 3\textsuperscript{rd} postoperative days after bypass surgery with the preoperative value and to determine if there was an optimal waiting period after revascularization surgery for maximal tissue oxygenation.
Materials & Methods:

- 11 patients with severe foot ischemia (TcPO2 pressures of less or equal to 30mmHg) with non-healing wound, gangrene or limb threatening ischemia were included.

- TcPO2 pressures: measured at the dorsal aspect of the first IM space of the affected foot

- All readings were taken at least 1 inch distal to the first metatarso-cuneiform joint to avoid the TCPO2 electrode placement over the 1st IM space perforator artery.
Results:

• All bypasses remained patent on POD3.

• POD1
  – 6 out of 11 patients had an increase in TcPO2
  – 3 patients had the same pre-op TcPO2 value
  – 2 patients showed a decrease in TcPO2 value

• POD2
  – 9 patients showed an increase in TcPO2 value

• POD3
  – 10 patients showed an increase in TcPO2 value
  – 1 patient had a decreased TcPO2 value compared to their pre-op value.

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Mean pre- and postoperative TcPO2 measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>TcPO2 Measurement</td>
<td>Mean (mm Hg)</td>
</tr>
<tr>
<td>Preoperative</td>
<td>9.27</td>
</tr>
<tr>
<td>POD1</td>
<td>17.73</td>
</tr>
<tr>
<td>POD2</td>
<td>0.36</td>
</tr>
<tr>
<td>POD3</td>
<td>36.82</td>
</tr>
</tbody>
</table>
Discussion/Conclusion:

• At least 3 days following a lower extremity revascularization procedure is required to achieve higher tissue perfusion on the affected foot for wound healing.

• However, it is important to note that:
  – Although on POD3 10/11 patients showed an increase in TcPO2 compared to their pre-op TcPO2 values, only 4 of the 10 patients had TcPO2 value of higher than 30mmHg.
Infrainguinal Bypass Surgery for CLI

- Bypass with autogenous vein is the “gold standard”
- Results well documented in hundreds of reports: anecdotal > retrospective > randomized trials
- Versatile: results in complex situations (anatomic, patient related) well established
- Low mortality, good durability
- BUT—there are limitations and risks:
  - Wound and other complications
  - Prolonged recovery
  - Vein quality and availability
  - Surveillance and reintervention
  - Technically demanding procedures
- Outcomes poorer for suboptimal conduit, higher medical risk
Limitations of Surgical Bypass

- Limitation #1: Generally only perform revascularization to one runoff vessel.

- Limitation #2: Cannot always target the angiosome of the wound.

- Limitation #3: Difficult to perform inframalleolar bypass.
Trends in Treatment of Chronic Limb Ischemia

J Vasc Surg 2009;50:54-60
Podiatry care, statins, and thoughtful revascularization strategies
Basil Trial

- The only trial to compare efficacy of balloon angioplasty first vs. bypass first for patients with limb threatening ischemia
- 452 pts over 5 yr period
- 30 day mortality was similar between the two groups
- There was no difference in the primary endpoint of AFS

Lancet, 2005
Approximately 70% of the study population survived for 2 years or more.

Initial randomization to open bypass was associated with a significantly improved overall survival and a trend of increased amputation-free survival.

Patients who underwent surgery following failed angioplasty did worse than patients who underwent bypass as initial therapy.

J Vasc Surg 2010;51:5S-17S.
BASIL: Amputation Free Survival

For patients surviving at least 2 years, randomization to bypass was associated with a trend towards increased amputation free survival.

Mean increase in AFS: 5.9 mos (p=0.06)
BASIL: Overall Survival

For patients surviving at least 2 years, randomization to bypass first was associated with a significant increase in subsequent overall survival of 7.3 months (p=0.02)
Bypass first versus bypass after failed angioplasty

Worse Amputation free survival: $p=0.006$

Trend towards worse overall survival $p=0.06$
A Selective Revascularization Strategy

<table>
<thead>
<tr>
<th>Surgical Risk</th>
<th>Average (&lt;5% mort)</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Expectancy</td>
<td>≥ 2 years</td>
<td>Limited</td>
</tr>
<tr>
<td>Severity of Ischemia</td>
<td>Major tissue loss</td>
<td>Minor ulcer</td>
</tr>
<tr>
<td>Anatomy</td>
<td>Multi-level, TASC C/D</td>
<td>Single level, TASC A-C</td>
</tr>
<tr>
<td>Vein availability</td>
<td>GSV or good alternate</td>
<td>Inadequate</td>
</tr>
</tbody>
</table>

BYPASS FAVORED

ENDO FAVORED
Summary:

▪ Early intervention is critical to prevention of major amputations, healing of foot amputations and foot ulcers in general

▪ Type of revascularization should take into account several factors such as patient, type/extent of wound, and anatomy

▪ Endo first strategy may not always be the best strategy and may not be risk free
Thank You
Does Type and Timing of Revascularization Affect the Outcome of Foot Amputations

Alexander Reyzelman DPM
Co-Director, Center for Limb Preservation
University of California, San Francisco