Disclosures

• No disclosures for this talk.
Rationale for Endovascular Therapy in CLI

• Patients are often old and infirmed. Many are not considered candidates because of overall health.
• Surgery requires
  • Inflow
  • Outflow
  • Conduit (BTK patency requires autologous vein)
• Active infection problematic for surgery (graft infection or sepsis) Extensive scarring may make surgery difficult
• Progressive disease (Interventions can be repeated easily)
History of Angioplasty


Tools Making Limb Salvage Interventional Therapy Possible

• Better guidewires, support catheters, dedicated crossing tools, re-entry tools.
• Better balloons and specialty balloons.
• Atherectomy devices.
• Distal protection devices.
• Better stent designs and or covered stents for durability.
• Pharmacology (lytics, 2B3A, antiplatelets, anticoagulants)
• Anti-proliferative drugs on stents, balloons, or otherwise
• New access sites (pedal, transcollateral, arch reconstruction)

• OPEN MINDS
• Dorros et al.
• N=284 CLI
• 95% success
• Relief of rest pain and/or improved distal blood flow
• Patients were followed for 5 years
“The TPVA procedural and follow-up results were superior to those of the historical surgical series; the differences in endovascular and surgical survival rates, however, are even more dramatic when the surgical procedural operative mortality is considered. Endovascular procedures offer a significant alternative to surgical procedures.”
BASIL STUDY

“In patients presenting with severe limb ischemia due to infra-inguinal disease and who are suitable for surgery and angioplasty, a bypass-surgery-first and a balloon-angioplasty-first strategy are associated with broadly similar outcomes in terms of amputation-free survival, and in the short-term, surgery is more expensive than angioplasty.”
Peripheral angioplasty as the first-choice revascularization procedure in diabetic patients with critical limb ischemia with or without foot ulcer; prospective study of 1,188 consecutive patients hospitalized and followed between 1999 and 2003.

Ezio Faglia, MD; Luca Dalla Paola, MD; Lanfroi Graziani, MD; Jacques Clerissi, MD; Massimiliano Fusaro, MD; Giacomo Clerici, MD; Livio Gabrielli, MD; Sergio Losa, MD; Andrea Stella, MD; Mauro Gargiulo, MD; Manuela Mantero, MD; Maurizio Caminiti, MD; Sasa Ninkovic, MD; Vincenzo Curci, MD; Alberto Morabito, PhD.

European Journal of Vascular and Endovascular Surgery (manuscript number EFVES2363 Recommended for publication, October 6th, 2004
PTA as the First-choice Revascularization in Diabetics with CLI:

Prospective Study 993 patients between 1999 and 2003

• Conclusion:
  • PTA was safe and feasible
  • Low complication rates (3.4%)
  • High follow up rates (97.8%)
  • Low major amputation rates (1.7%)
  • 5-Year clinical primary patency rates (88%)
  • Stressed a “MULTIDICIPLINARY” approach
  • Again > 90% long term LIMB SALVAGE

Faglla, E., Dalla Paola, L. Graziani  Eur J Vasc Endovasc Surg 29, 620-627 June 2005
The effectiveness of PTA for the treatment of CLI: 10-year experience

• Conclusion
  • 0.9% perioperative mortality
  • Overall technical success = 96.4% (N = 138)
  • Overall clinical success = 92.8% (mean follow up = 14.7 months)
  • Overall 5 year primary patency = 31.4%
  • Overall 5 year secondary patency = 79.6%
  • 5 year limb salvage = 89.1%

“Contemporary” - - 2005!

Ahn, Samuel S. et. al. (J. Vasc. Surg. 2005;41: 423-433)
Decade of LE Endovascular Interventions

Endovascular Interventions
RR = 3.3
(95% CI, 2.9-3.8)

Major Lower-Extremity Amputation
RR = 0.71
(95% CI, 0.7-0.8)

Lower-Extremity Bypass Surgery
RR = 0.58
(95% CI, 0.5-0.7)

Transpedal Approach

• The interventional therapy of critical limb ischemia requires crossing lesions. Often total occlusions that can’t be crossed from above can easily be traversed intraluminally from below.
  • Collaterals
  • Operator can’t discern where true lumen should be
  • Distal cap of occlusion may be softer than the proximal cap
  • “Hibernating vessel”
The pedal approach (via anterior tibial, posterior tibial, or peroneal artery) is a viable approach particularly in limb salvage cases. It is particularly useful when the popliteal and IP vessels are occluded and can’t be crossed from above.
• Advantages of pedal approach
  • Patient is supine
  • Can work from above and below to cross lesions and deliver therapy “FINGER OF GOD”
  • Can use with popliteal and IP occlusions
  • Higher incidence of luminal crossing
  • Less bleeding
  • Cost (may lessen need for re-entry tools)
  • MAY ALLOW SUCCESSFUL CROSSING WHEN ALL ELSE FAILS
• Disadvantages of pedal approach
  • More difficult access (maybe not with US)
  • Smaller vessels
    • Don’t want to occlude a potential distal graft site - Typically only place microcatheters
    • Limited to smaller sheaths when this is the access site from which final therapy must be delivered
    • Active infection or extensive recent cut downs may be problematic
    • Can’t use distal protection
    • Can’t go into vessels below the ankle to restore pedal arches
Transpedal Approach

- Safe with only one vascular occlusion in 342 patients presenting with critical ischemia (most of these cases were performed with nothing larger than a microcatheter placed in pedal vessels.)
- Allows successful intervention in many patients who otherwise have no options
- Can be performed by any interventionist without special equipment
TAMI (Tibiopedal Arterial Minimally Invasive)

- Direct US access of tibial vessels (without mandatory access of vessels from above.)
  - Less bleeding
  - Better crossing
  - Quicker ambulation
  - Capable of performing procedure on patients who can’t lay flat.
Physicians Initial Response to Interventional Therapy
(at least to me)

1\textsuperscript{st}- “It doesn’t work and it is always dangerous. Clearly those performing it don’t understand plaque.”

2\textsuperscript{nd}- “It seems PTA of stenotic iliacs may occasionally work (never occluded iliacs) – an iliac stent trial would be “UNETHICAL.”

3\textsuperscript{rd}- “It is malpractice to intervene below the inguinal ligament”.

4\textsuperscript{th}- “There may be an occasional role for PTA of short SFA stenosis but one should never intervene below the knee or long segment disease.”

5\textsuperscript{th}- “Stents in the SFA are malpractice”.

6\textsuperscript{th}- “You can’t stick the popliteal artery.” “Can’t cross a CTO”

7\textsuperscript{th}- “Atherectomy is just inferior endarterectomy”

8\textsuperscript{th}- “You should never intervene on IP vessels”.

9\textsuperscript{th}- “It would be malpractice to access the IP vessels as you may injure targets”. “But didn’t you just advise a BKA”?

10\textsuperscript{th}- “You can’t intervene below the ankle”

11\textsuperscript{th}- “Intervention just doesn’t last”

12\textsuperscript{th}- ”How can I do this?”
My Advice to Young Interventionists

• Keep an open mind
• Put your patient first and above all
• Follow your dreams with conviction
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The Roosevelt New Orleans
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What’s New on the Vascular Horizon

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