The Evidence Base for Clinical Decision Making in Lower Extremity Treatments is Poor: Guidelines are Often Based on Shaky Foundations

What is Needed and Are Things Improving?

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What is the Goal of Guidelines Documents?

- Bring together a broad range of physician experts to scour the medical literature and provide state-of-the-art recommendations on the diagnosis and treatment of a condition
- Hope that practicing clinicians who pride themselves on caring for their patients in the most effective manner (ie guidelines directed) will use them

Sounds good…..but does it work?

We Have a Long History of PAD Guidelines

TASC I

Published in the Fall, 2005


Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation

Published in the Fall, 2005

Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)


Published 2007

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Conflicts of Interest

- Consultant
  - Boston Scientific (non-compensated)
  - Medtronic
  - Primacare
  - Sanki
  - Vascutek
  - Venarum

- Equity
  - Efemoral
  - Embocure Inc
  - Janacare, Inc
  - MC10
  - PQ Bypass, Inc
  - Primacare
  - Savo V, Inc
  - Vascular Therapies, Inc

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We Even Have Guidelines on How to Perform the ABI!

[Circulation](https://circ.ahajournals.org/content/130/19/1467)

Measurement and Interpretation of the Ankle-Brachial Index: A Scientific Statement From the American Heart Association


Circulation, published online November 16, 2012.

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Here's The Rub....

Table 1. Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care

[Updated August 2015]
How Helpful is it to a Practicing Clinician

• When a recommendation is graded with
  • Limited Data
  • Expert Opinion
• If the level of evidence is
  • Class IIb (Weak!!!)
• Most importantly….if the patient on the procedure table isn’t included in guidelines...

Is This Patient Included in Any Guidelines?

• Female, Age 80, HTN  and CAD. Smoker
• ABI = .32
• CLI: rest pain
• Previous; Aortobifem bypass. Femtibial bypass x2 with multiple thromboses
• Occluded SFA  grafts

Are Guidelines Improving?

• If you want a source for modern literature, yes
• If you want more practical recommendations on management of common PAD conditions....
  • Probably not

What is Needed?

• If guidelines are going to insist on Class 1/Level A evidence
  • Our only option is to perform more clinical trials of more common PAD scenarios
    • Who will pay for this?
    • Will physicians enroll?
• One other solution....
  • Guidelines based on multispecialty expert consensus without the mandate of only randomized multicenter clinical trials.