

Lower Extremity Peripheral Artery Disease

Comments to MEDCAC

Jeffrey G. Carr, MD, FACC, FSCAI

JULY 22, 2015



Financial Disclosure

Consultant: Medtronic, Spectranetics (major association)

Advisory Board: Boston Scientific, Medtronic (minor association)

Research Support: Spectranetics, Cardiovascular Systems, Inc., Medtronic (minor association)

Faculty Educator: Astra Zeneca, Medtronic (major association)

Cardiovascular Coalition: Board Member (No financial support)

Outpatient Endovascular and Interventional Society: Immediate Past President (No financial support)

About the CardioVascular Coalition



About the CardioVascular Coalition

- Represents 149 freestanding centers in 26 states
- Established to provide policymakers with a greater understanding of the value of freestanding providers of endovascular interventions
- Key focus of the CVC is the utilization of appropriate vascular interventions to prevent non-traumatic amputations in patients

Amputation Prevention

- Vemulapalli et al. observed overall arterial testing rate of 68.4%:
 - Preamputation ABI rate of only 47.5%
 - Angiography rates of 38.7% (invasive angiography), 5.6% (MR angiography), 6.7% (CT angiography)
- 43,000 Medicare patients/year receive amputations
- Encouraging revascularization over amputation could reduce Medicare spending by up to \$2 billion over 10 years.

Interventions to Improve IC and CLI

- Although medical therapy advances have reduced CV major adverse events (MAE) (death, MI and stroke), these agents have not been demonstrated to improve QOL and critical limb ischemia (CLI) outcomes.
- Alternatively, endovascular device innovations and technology advances have allowed providers to treat patients who were previously only candidates for medical therapy and conservative management.

Interventions to Improve IC and CLI

- AHRQ 2013 study predominately analyzed Percutaneous Transluminal Angioplasty (PTA) and bare metal stents as the primary endovascular revascularization modalities.
- Atherectomy reduces in-stent restenosis, barotrauma to vessel, and dissection rates compared to PTA and stents.
- Several atherectomy devices (directional, orbital, rotational, excisional, laser), drug eluting stents, drug coated balloons have been approved since 1998 with significant evolution/adoption for past 10 years.

Interventions to Improve IC and CLI

- Until recently, there have been no established definitions or consensus of clinical trial endpoints for PAD trials.
- The Peripheral Academic Research Consortium (PARC) was constituted in 2011 to standardize PAD definitions and create consistency in future PAD trials.
- Culminated in a manuscript published in JACC in March of 2015 entitled, “Consensus Definitions for Evaluation of Patients With Lower Extremity Peripheral Artery Disease PARC (Peripheral Academic Research Consortium).”

Trials Published Since the AHRQ 2013 study

There are several trials that have been published since the AHRQ 2013 study, including:

- Clever
- Definitive LE
- Excite ISR
- Calcium 360/Compliance 360
- Zilver PTX
- InPACT SFA

New and Pending Trials

There are several current and pending clinical trials which will add more evidence to the questions the MEDCAC is considering, including:

- The LIBERTY Observational Study
- The BEST Trial
- The VIVA-BEST CLI (vCLI) Companion Registry
- The RAPID Project
- IN.PACT Global Clinical Study

Conclusion

- IC and CLI patients benefit from a comprehensive approach including risk factor modifications, exercise, and revascularization.
- Interventions that ultimately result in limb preservation offer the best possible clinical outcome.
- Vascular diagnostics are underutilized in CLI patients despite proven benefits of revascularization.
- Increased use of vascular care procedures associated with lower amputation rates and healthcare spending.
- Standardization of outcomes definitions and future data will increase knowledge base for evidence-based medicine.