New Reporting Standards for Lower Extremity Endovascular Treatments for Ischemia: How Will They Help Bring Order Out of Chaos?

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Reporting Standards

• Provide uniformity of definitions and classifications
  – Comparative purpose
• Literature review to develop
  – Definitions, scoring systems and classifications
• Identify shortcomings
• Not a clinical practice guideline

20 Years Later

• Complete change of treatment paradigm
• Rapid technology introduction
  – Lateral diffusion
• Device approvals with small sample size
  – Lack of uniform classification and success measures
• Industry-sponsored trials
• Lack of external validity

Keyword “endovascular”

Goals

• Provide author’s and editor’s resource
• Address patient and anatomical outcome divergence
  – Patency = efficacy?
• Adopt and codify SVS initiatives
• Identify areas for future study
• Sections with suggested and required standards

Disclosures

Consultant agreements
- W.L. Gore & Associates
- SilkRoad Medical
- Research and education support
  - W.L. Gore & Associates
  - Bolton Medical
  - Medtronic
  - Cook
  - Carestream
Claudication

• ABI ≤ 0.90 or exercise ABI
• Baseline functional characterization
  – 6MWT
• QoL assessment
  – WIQ
  – SF-36, ICQ, PAC, VascuQOL…
• Very important that other confounding Dx are excluded

PSYCHOLOGY VERSUS PHYSIOLOGY

• QoL measures may lead to better understanding of “responders”

CLI

• Rest pain:
  • Ankle pressure < 40 mm Hg, ABI < 0.4
  • Toe pressure < 30 mm Hg
• Tissue loss:
  • ankle pressure of < 70 mm Hg
  • toe pressure < 50
• Rest pain and tissue loss patients should not be grouped together

Patient Factors

Patient Factors – Important Changes

• Renal function
  – GFR as a continuous variable
  – KDOQI guideline-based classification
    • Stage 0-5
• Functional status based on ADL
**Rx – Important Changes**

- Patient-centered lipid intervention
- Lipid lowering therapy reported separate
  - Pleiotropic effects

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**Anatomy**

- Femoropopliteal / Aortoiliac – TASC II
- Infrapopliteal – SVS Runoff Score (0-19) or Bollinger
- Lack of validated calcium scoring system

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**Intervention**

- Vessel-specific reporting
- Definitive balloon diameter and length
- Stent trials:
  - pre-dilation, and other adjuncts in addition to definitive diameter and length
- Atherectomy trials should report device specific data:
  - Duration, quantitative measures of plaque excision, embolic protection

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**Procedural**

- Intraoperative pharmacology
  - ACT targets if used
- Contrast (volume or mgI/kg)
- Radiation dosimetry
  - Time
  - DAP (Gy-cm²)

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**Outcome**

- Technical success: Residual stenosis < 30%
- Procedural success: Technical success without complications
- Hemodynamic success: < 10 mm Hg gradient, or ABI/TBI increase 0.10
- Patency assessment requires anatomical imaging
- Re-stenosis SVR > 3.0 or PSV > 300 m/s

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**TLR**

- Soft endpoint
- Driven by clinical decisions
- Fails to provide true efficacy data
**Duration**

- 30-day, 1- and 2-year minimum
- 5-year preferred
- Life table analysis

**Disease Outcomes**

- 6MWT and QoL measures for claudication
- OPGs for CLI patients
- Economic studies should be longitudinal

**Complications**

**Summary**

- Evolution into endovascular surgery
- Traditional graft-based anatomical measures can be translated to endovascular
  - Avoid the clinical TLR pitfall
- Disease-specific assessment and outcomes
- Need for longitudinal comparative data
  - Clinical decision
  - Value-based frameworks

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