New Performance Goals for SFA Endovascular Treatments: How Good Are Current Devices?

MDEpiNet RAPID Multispecialty Project


Disclosures

• None relevant to this presentation.

Registry Assessment of Peripheral Interventional Devices

• Medical Device Epidemiology Network (MDEpiNet)
  • Public-private partnership of FDA, industry, medical societies
  • Medical device evaluation using real-world evidence from registries

• Registry Assessment of Peripheral Interventional Devices Project
  • Multispecialty (vascular surgery, cardiology, radiology) project designed to evaluate peripheral vascular devices using contemporary registry data
  • Identified minimal core data elements for registry device evaluation
  • All variables incorporated into SVS VQI PVI Registry for use in RAPID

SFA-Popliteal Device Objective Performance Goals (OPGs)

• Current OPGs for SFA-POP do not reflect contemporary practice
  • VIVA Physicians 2007: 116 patients treated with POBA, Rutherford 2-4
    • Safety: 30-day freedom from death, amputation, TVR: OPG=88%
    • Efficacy: 1-year patency: OPG = 66%
  • Society for Vascular Surgery 2009: 838 GSV bypass pts, Rutherford 4-6
    • Safety: 30-day freedom from MACE, MALE: OPG = 92%
    • Efficacy: 1-year freedom from death, MALE: OPG = 71%

• Data > 10 years old, based on < 1000 patients, different endpoints, different disease severity, different comparator (POBA vs Bypass)

RAPID → New SFA-POP Device OPGs

SFA-Popliteal Device Objective Performance Goals

Vascular Quality Initiative PVI Registry Data (2010-2016)

• 21,377 Patients with 1-year follow-up, including:
  • 7,505 Plain Balloon Angioplasty (POBA)
  • 2,510 Atherectomy (± POBA)

• Analyzed each treatment type + “all current treatments”
  • SFA vs. Popliteal; Claudication vs Critical Limb Ischemia
  • Target lesion revascularization (TLR), amputation, death
  • Statistical analysis plan by academics and industry

SFA-Popliteal Treatment Type Differences

• Device selection in VQI varied by lesion severity
  • POBA was used for more focal, mild disease
  • Stenting and atherectomy was used for more diffuse, severe disease

• Device outcomes are specific to lesions for which they were selected
  • OPGs were not designed to compare device types

Other 10%
Atherectomy 32%
POBA 25%
Stent 43%

TASC C/D Lesion 29% 41% 47%
Total Occlusion Length 5.4 cm 8.7 cm 6.7 cm
Total Treated Length 10 cm 14 cm 11 cm
RAPID

SFA-Popliteal Device Objective Performance Goals

One Year Patient Survival

All Treatment Types

Claudication: SFA: 97%  Pop: 95%
Critical Limb Ischemia: SFA: 84%  POP: 83%

Factors Associated with Worse Outcome:
• CLI
• CHF
• Older age
• Renal dysfunction
• Non-ambulatory

Freedom from Major Amputation

All Treatment Types

Claudication: SFA: 99%  Pop: 99%
Critical Limb Ischemia: SFA: 89%  POP: 92%

Factors Associated with Worse Outcome:
• CLI
• Younger age
• Prior amputation

How Good Are Current Devices for PVI Treatment?

Current devices and treatment outcomes exceed 10-year old OPGs
• Indicates value of updating OPGs based on current device performance

10-Year Old SVS and VIVA OPGs

**MDEpiNet RAPID multi-stakeholder group has collaborated to create updated Objective Performance Goals for current SFA-POP devices using real-world evidence from the VQI registry**

**These data allow manufacturers and regulators to more accurately assess the safety and efficacy of new devices**

**They also allow practitioners to benchmark their own results with broad contemporary practice represented by VQI data**

**Future work will update these OPGs with new data and allow device specific comparisons now being collected in VQI**