Working Toward the Latest SFA-Pop Objective Performance Goals Using Real-World Data from Registries

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Disclosures

• None relevant to this presentation.

Registry Assessment of Peripheral Interventional Devices

RAPID

• Medical Device Epidemiology Network (MDEpiNet) sponsored
  • Public-private partnership of FDA, industry, medical societies
  • Peripheral artery interventional device evaluation project
  • Large variation in treatment types selected, many different devices, often used off-label, without good evidence ("wild west")
  • Goals:
    • Phase 1: Identify core data elements for device evaluation by registries that could allow data extraction from multiple sources
    • Phase 2: Use this core registry data to create current Objective Performance Goals to evaluate new devices
    • Phase 3: Use real-world evidence from a Coordinated Registry Network to make regulatory decisions about new devices
  • Methods: Multiple working group meetings, ACC, SIR, SVS, FDA, device manufacturers

RAPID Phase 1 Project

2016-2017

mdepinet.org/rapid

Endovascular Today
August, 2016

Registry Assessment of Peripheral Interventional Devices
Core Data Elements, Jones et al, J Vasc Surg, 2018 and Circulation Japan, 2018

RAPID Phase 2 Project 2018-2019

SFA-Popliteal Evidence Development (SPEED)

Objective Performance Goal for SFA-POP Devices

• Mature space, but new drug-coated and other technologies need contemporary comparator group
• Many devices are being used off-label, for patients and disease severity not tested in trials
  • Opportunity to expand labeling by comparing real world off-label performance with up-to-date OPG
• Current OPGs for SFA-POP devices are outdated and no not reflect contemporary practice

SFA-Popliteal Objective Performance Goals Current Status

• VIVA Physicians 2007:
  • 3 PMA trials: 116 patients treated with POBA, Rutherford 2-4
  • Safety: 30 day freedom death, amp, TVR: OPG=88%
  • Efficacy: 1 year patency: OPG = 66%
• Society for Vascular Surgery 2009:
  • 3 RCTs: 838 patients treated with GSV bypass for CLI, 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)
• Not considered relevant OPGs for current new device comparison
Opportunity: 46,108 SFA-POP Interventions is VQI

Society for Vascular Surgery Vascular Quality Initiative

- SFA-POP interventional devices in VQI Registry (2011-2016)
  - Plain balloon angioplasty
    - 18,591 procedures (40%)
  - Self-expanding stents ± balloon angioplasty
    - 19,040 procedures (42%)
  - Atherectomy ± balloon or stent
    - 8,387 procedures (18%)

- All RAPID core data elements are in VQI
- One year follow-up ~ 70% for outcomes

SPEED: 8 OPGs, 3 Arteries, 5 Treatment Types

- One year Kaplan-Meier estimates:
  - Mortality
  - Major amputation
  - Target lesion revascularization
    - Total, plus open surgery vs interventional treatment
  - Binary outcomes:
    - Technical failure
    - Target lesion occlusion (with mean follow-up interval)
  - Treatments in SFA, POP and SFA+POP:
    - Plain Balloon, Stent ± balloon, Atherectomy ± balloon, Other, and All Treatments combined

OPC: Freedom from Target Lesion Revascularization at 1.5 Years

- Un-Adjusted Analysis

  - All device treatments outcomes look similar, BUT:
    - Require adjustment for patient characteristics and disease severity that likely differ by treatment type, and affect outcome

SPEED Covariates for Multivariable OPG Models

- Patient Characteristics
  - Age, sex, race, BMI, smoking, diabetes, creatinine, CAD, ambulatory function, dialysis, CHF, hypertension, COPD
  - Prior inflow, outflow bypass or intervention, amputation
  - Pre-treatment living location, medications

- Disease Severity
  - TASC, treated length, occlusion length, Rutherford class, ABI, run-off score, concomitant lesions treated, urgency

  - All data available from VQI Registry
    - Allow fair comparison of different treatment types when used in different patients and disease severity

RAPID Phase II Project

SFA-POPliteal Evidence Development (SPEED)

2019 Goals:

- Scientific publication describing each risk-adjusted OPC for each treatment type
  - Identification of co-variates that are significantly associated with each OPC (multivariable analysis)
  - Description of differences in the patient / disease / lesion co-variates for each treatment type
- Can be used by industry to compare new devices, estimate sample size for new device trials, and for regulatory applications