"PAD Characterization Within A Healthcare System"
Disclosures

• Research Grants:
  – Agency for Healthcare Research and Quality
  – American Heart Association
  – AstraZeneca
  – Bristol Myers Squibb
  – Daiichi Sankyo
  – Doris Duke Charitable Foundation
  – Patient-Centered Outcomes Research Institute

• Honoraria:
  – American College of Radiology
  – Mondopoint
Outline

• Background data and research approach
• Issues
• Possible solutions
  – Vascular registries (SVS-VQI, SIR, ACC-PVI)
  – BEST-CLI
  – RAPID
• How do we design “learning healthcare systems” that inform general practice (not specific to devices and procedures) in PAD patients?
Lower Extremity Amputations in North Carolina
All Payors, 2006

Top 5 NC Counties with the highest rate of amputations per 1,000 people

<table>
<thead>
<tr>
<th>County</th>
<th># Amputations FFY 2006</th>
<th>2007 Population</th>
<th>Amputations per 1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gates, NC</td>
<td>15</td>
<td>11,569</td>
<td>1.30</td>
</tr>
<tr>
<td>Warren, NC</td>
<td>21</td>
<td>19,018</td>
<td>1.10</td>
</tr>
<tr>
<td>Northampton, NC</td>
<td>24</td>
<td>21,767</td>
<td>1.10</td>
</tr>
<tr>
<td>Tyrrell, NC</td>
<td>4</td>
<td>3,922</td>
<td>1.02</td>
</tr>
<tr>
<td>Franklin, NC</td>
<td>42</td>
<td>53,303</td>
<td>0.79</td>
</tr>
</tbody>
</table>

Note: Amputation defined as procedure codes 84.10, 84.12-84.18, 84.3
Data Source: Thompson Reuters
Geographic Variation in LE Amputation

Significant variation in P2Y$_{12}$ inhibitor use after peripheral vascular intervention in Medicare beneficiaries

W. Schuyler Jones, MD, a,b Xiaojuan Mi, PhD, a Laura G. Qualls, MS, a Ryan S. Turley, MD, c Sreekanth Vemulapalli, MD, a,b Eric D. Peterson, MD, MPH, a,b Manesh R. Patel, MD, a,b and Lesley H. Curtis, PhD a,b Durham, NC

Am Heart J 2016
Retrospective Analysis

Angiographic Data
- Fluoroscopy time
- Contrast use
- Procedure time
- Supplies used
- Procedure success
- Complications

Duke Cardiovascular Databank

Hemodynamic & Ultrasound Data
- Baseline ABI
- Baseline duplex U/S data
- Follow up patency
- Follow up ABI & duplex U/S

Baseline characteristics
- Occurrence of clinical outcomes:
  - death
  - MI
  - stroke
  - re-hospitalization

Other resources:
- Cost analysis (DCRI)
- Follow up symptom status (chart review)
Manuscript on SFA Recanalization

- Rejected at J Am Coll Cardiol CV Interv (5/27/2015) due to “priority”

Reviewer #1 (Comments for the Author (Required)):
Non randomized

- Rejected at Catheter Cardiovasc Interv (7/21/2015) due to “priority”

No outcomes data

- Rejected at Clin Cardiol (9/2015)
- Rejected at Vasc Med (11/2015)
- Rejected at J Endovasc Therapy (1/2016)
- Rejected at J Interv Cardiol (3/2016)
- Submitted to Ann Vasc Surg (6/2016) – minor revisions
What’s the Problem?

• Current data sources are inadequate
• Heterogeneity complicates our understanding of PAD treatment
  – Anatomy and disease severity varies
  – Multiple specialties with different training, experience, bias
  – Multiple devices available for treating similar lesions:
• Lack of clinical outcomes in electronic health records
• Many single-center studies, very few large heterogeneous datasets
• Need data about real-world treatment from multiple sources
Possible Solutions

• 3 Major U.S. Societies / Registries
  • Society for Vascular Surgery (SVS)
  • Vascular Quality Initiative (VQI)
  • American College of Cardiology (ACC)
    • National Cardiovascular Disease Registry (NCDR)
  • Society of Interventional Radiology (SIR)
    • National Interventional Radiology Quality Registry (NIRQR)

• BEST-CLI

• RAPID (Registry Assessment of Peripheral Interventional Devices)
Figure 1. Diagnostic and Treatment Framework

**PAD**

Less severe

- Asymptomatic
- Atypical Leg Pain
- Intermittent Claudication

More severe

- Critical Limb Ischemia
- Ischemic Rest Pain
- Tissue Ulceration
- Gangrene

**Conservative Treatment**

- Risk Factor Modification
- Medical Therapy & Exercise Training
- Medical Therapy and/or Wound Care

**Diagnostic Imaging**

- Hemodynamic testing
- Ultrasound
- CT angiography
- MR angiography
- Invasive angiography

**DECISION REGARDING REVASCULARIZATION**

* If symptoms persist despite conservative therapy, diagnostic imaging +/- invasive treatment may be indicated

**Endovascular and/or Surgical Revascularization**

**Outcomes**

- Death
- Myocardial Infarction
- Lower Extremity Amputation
- Hospitalization

**Aim 1.** Assess patient-specific factors associated with clinical care and outcomes

**Aim 2.** Assess physician- and health system-specific factors associated with clinical care and outcomes

**Aim 3.** Prospectively assess patient-, physician-, and healthcare-specific factors using a uniform case report form

Current gaps in knowledge:
- Health Literacy
- Patient Preferences
- Anatomy/Severity of Disease
- Physician Preferences
- Access to Care
- Disparities in Care

**Not all patients are offered or choose revascularization**
Duke University & Duke Lifepoint Health Systems
Figure 2
Computable Phenotype

- History of PAD
- History of Endovascular Revascularization
- History of Surgical Revascularization

** via clinical information or administrative claims data

Data Extraction using Retrieve Form for Data Capture (RFD)

Source Document Review and Data Abstraction by Clinical Experts

REDCAP Database

Duke University Hospitals

Duke Lifepoint Hospitals

Medicare Outcomes Dataset

All Patients with ICD-9 and/or ICD-10 codes for PAD in North Carolina

Outcomes of interest include: Death, Myocardial Infarction, Stroke, Lower Extremity Amputation

ICD-10 Diagnosis Codes for PAD:
- I70.2x Atherosclerosis of native arteries
- I70.3x - I70.7x Atherosclerosis of bypass graft(s)
- I73.9 PVD, unspecified

ICD-9 Diagnosis Codes for PAD:
- 440.2x
- 440.3x
- 440.9x
- 443.9
- 707.1
- 444.2x

ICD-9 Procedure Codes:
- Angioplasty: 00.40-00.44, 39.50
- Atherectomy: 39.50
- Stenting: 00.45-00.48, 39.90

CPT Codes:
- Angioplasty: 35450, 35470, 35473, 35474
- Atherectomy: 35492, 35493, 35495
- Stenting: 37205-37208

*** linkage of REDCAP and Medicare datasets

Combined Analytic File
THANKS

• Questions?