

SUPERFICIAL FEMORAL AND POPLITEAL EVIDENCE DEVELOPMENT (**SPEED**)

A Nest Coordinating Center Demonstration Project

Overview of the Statistical Analysis Plan

THANK YOU

Industry

- Jin Wang, Abbott Vascular
- Hugo Xi, Abbot Vascular
- Terry Liao, Boston Scientific
- Melanie Raska, Boston Scientific
- Scott Snyder, Cook Medical
- Ying Wan, CR Bard
- Alan Saunders, CR Bard
- Aimin Feng, CR Bard
- Joseph Griffin, Intact Vascular
- Patrick Wang, Medtronic
- Justin Recknor, W.L. Gore

Food and Drug Administration

- Nelson Lu, Therapeutic Statistic Branch, DOB
- Yu (Audrey) Zhao, Therapeutic Statistic Branch, DOB
- Wei-Chen Chen, Therapeutic Statistic Branch, DOB
- Yu-Ching Cheng, Epidemiology Evaluation and Research Branch, DOE
- Jiping Chen, Product Evaluation Branch, DPS
- Joshua Chetta, Investigational Device Exemption, CTS
- Misti Malone Peripheral Interventional Devices Branch, DCD
- Subok Park Epidemiology Evaluation and Research Branch, DOE

Academia and Professional Society

- Roseann White, Duke Clinical Research Institute
- Sharon-Lise Normand, Harvard SOM
- Philip Goodney, Society for Vascular Surgery
-



AGENDA

- Data Source
- Data Quality
- Data Access
- Data Selection
- Assessing Data Completion
- Covariates and Outcomes
- Analysis populations





The Goal Of SPEED is to use the VQI Database to
Develop Contemporary, Dynamic Objective
Performance Goals (OPG) for Superficial Femoral
(SFA) & Popliteal Artery Endovascular Interventions.

VQI participating center and physicians



SPEED: Overview of SAP

DATA SOURCE

Vascular Quality Initiative Peripheral Vascular Intervention Registry (PVI) was established in 2011 to record

- distributed network of regional quality groups
- function under an AHRQ-listed Patient Safety Organization
- cloud based data collection and reporting system.
- vascular procedure in 12 separate registries across the United States
- Recording
 - patient demographics,
 - comorbidities
 - procedure detail including device class
 - in-hospital and one-year outcomes

5/2/2018

DATA QUALITY

- On an annual basis, will compare formatted claims data with clinical data entered into the VQI registry, and matches patients and procedures between the data sources.
- A record where the patient and procedure identifiers collected in the VQI registry accurately match the claims data record is considered an exact match and are considered validated.
- Records that cannot be validated will be communicated back to the participating sites to investigate and make the necessary changes. There are three categories of invalid data matches:
 - Missing VQI Record
 - Missing Claims Record
 - Inexact Match of likely the same patient/procedure
- Participating Centers are required to investigate all invalid data matches and provide a written confirmation that records have been reviewed and corrections have been made where appropriate.
- All claims collection and submission, and reconciliation of the feedback reports are the responsibility of the contracted VQI entity. The data manager for each contracted entity is the primary contact for the validation process.

DATA ACCESS

- The Center for Devices and Radiological Health (CDRH) at FDA has entered into a “Data Use Agreement” with the Vascular Quality Initiative Peripheral Vascular Intervention Registry (VQI)
 - allow access to VQI de-identified patient level data file based on the requirements listed in the DUA.
 - Only FDA personal will have access to the de-identified individual patient data
- The data will be used in this analysis in accordance with established procedures and project team member role

DATA SELECTION

- **Patients with lesions in the SFA or POP that were treated with angioplasty, stent, and atherectomy**
- **Inclusion**
 - Treatment of symptomatic atherosclerotic arterial occlusive disease of the superficial femoral and/or popliteal arteries
 - Symptomatic disease ranging from intermittent claudication (leg pain with exercise) to critical limb ischemia (including ischemic rest pain and/or tissue loss).
 - Elective or urgent procedures
 - Where the index and follow-up falls within January 2010 to September 2016
- **Exclusion**
 - Aneurysmal disease of the superficial femoral or popliteal arteries and non-atherosclerotic etiology
 - Treatment for acute limb ischemia
 - Treatment of common femoral artery or profunda femoral artery occlusive disease
 - Emergency procedures
 - Patients treated with PVI and concomitant femoral endarterectomy at any time prior to the index procedure
 - Surgery

DATA COMPLETENESS

- The following are being reported at the Patient, Limb, artery, and lesion level depending on the variable
 - # missing for covariate collected at 30 day and 1 year
 - # missing for each outcome
 - # missing for each covariate
 - # missing for any outcome
 - # missing for any of the covariates
 - # missing for any of the covariates or outcomes
- The above information, in consultation with the protocol team, will used to determine if any of the covariates are imputed



COVARIATES OF INTEREST

Patient Level

- Age
- Ambulatory Status
- ASA Class
- CAD Symptoms
- Concomitant CFA Endarterectomy
- COPD
- Creatinine
- Cx Req Admission
- Date of Death
- Diabetes
- Dialysis
- Discharge Anticoagulant
- Discharge ASA
- Discharge P2Y12 Antagonist
- Discharge Statin
- Discharge Status
- Distal Embolization
- Gender
- Height
- Hypertension
- Indication
- Number of lesions
- Pathology
- Pre-admin Living
- Pre-op ASA
- Pre-op Chronic Anticoagulant
- Pre-op P2Y12 Antagonist
- Pre-op Statin
- Prior CHF
- Prior Major Amp
- Race
- Side
- Smoking
- Urgency
- Weight

Limb Level

- Access Guidance
- Arterial Dissection
- Arterial Perforation
- Artery Treated
- Inflow Bypass
- Inflow PTA/Stent

Lesion Level

- Adjuncts
- Balloon/stent Max Diameter (mm)
- TASC
- Technical Result
- Total Occlusion Length
- Total Treated Length (cm)
- Treatment Required
- Treatment Type

Artery Level

- Distal Run Off Score (AT, PT, Peroneal)
- Leg Bypass
- Leg PTA/Stent
- Major Amputation
- Minor Amputation
- Number of Arteries Treated
- Pre-Rx ABI
- Pre-Rx TBI
- Proximal Run Off Score (SFA, Prof, Pop)

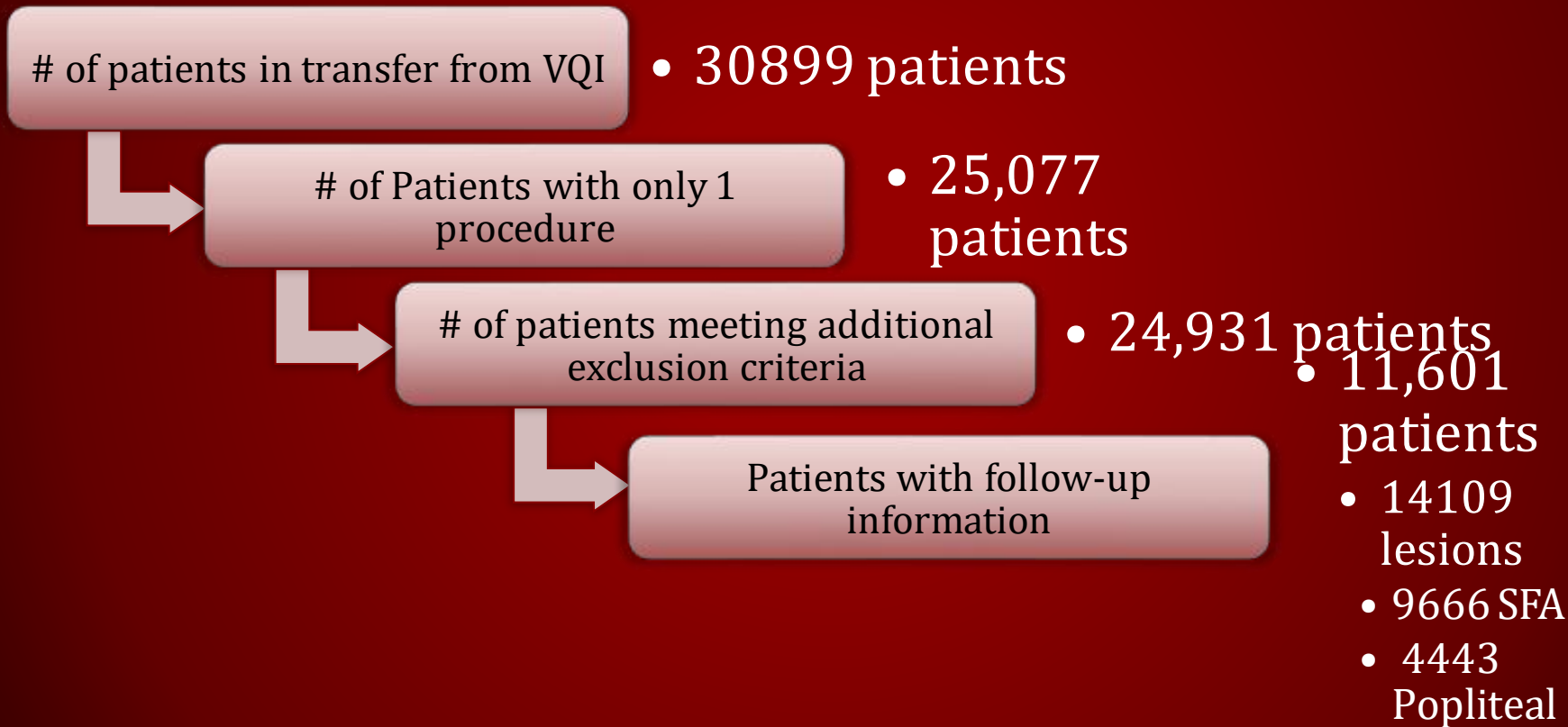
OUTCOMES OF INTEREST

- Mortality, any cause
- Major amputation: below or above knee amputation rate of index limb
- Amputation free survival (AFS): composite of freedom from mortality and major amputation
- Target lesion revascularization (TLR): repeat intervention (open surgical or percutaneous) on the index artery(ies)
 - Open surgery: any endarterectomy or infrainguinal bypass of target lesion previously treated with PVI
 - Interventional: any angioplasty, atherectomy, stent or stent graft or thrombolysis performed on target lesion previously treated with PVI
- Target lesion occlusion: binary loss of patency or occluded at follow-up
- Target Vessel Revascularization: Any new qualifying procedure within the target vessel
- Technical failure: inability to cross lesion (with wire or device) or occlusion, or superficial femoral-popliteal artery dissection or perforation requiring treatment, or distal embolization requiring treatment, or residual stenosis $\geq 30\%$. Excludes access site complications. Excludes device malfunction that is not specifically captured in VQI. .

ANALYSIS POPULATIONS

- **Patients will be first separated into two cohorts:**
 - Cohort I: Patients with only 1 qualifying procedure
 - Cohort II: Patients with more than 1 qualifying procedure
 - Cohort III: All procedures
- **Cohort I, II and III will be broadly separated into three groups based on which artery that the treated lesion is located:**
 - A. Patients where the index procedure has treated lesions that are located in the SFA alone
 - B. Patients where the index procedure has treated lesions that are located in the Popliteal Artery alone
 - C. Patients where the index procedure has treated lesions in either the SFA or the Popliteal Artery or both
- **For Cohort I, II and III groups A –C, objective performance goals (OPG) will be developed for the following sets of procedures :**
 1. All patients with any of the following: PTA, Stent, or Atherectomy
 2. Percutaneous Transluminal Angioplasty(PTA) only
 3. Stent with or without PTA
 4. Atherectomy with or without PTA
 5. Stent + Atherectomy

INITIAL POPULATION



SUMMARY

- Analyses for completeness
 - 24 tables for 58 covariates x 9 outcomes ~11,136 calculations to assess for completeness
- Analyses
 - 3 cohorts × 3 sets of arteries × 5 sets of treatments × 8 outcomes x 58 covariates (univariate + 1 multivariable) ~ 20,880 analyses
- Status
 - 768 calculations to assess completeness
 - only ~10,500 calculations left to go
 - 1 cohort (Cohort I) × 2 sets of arteries (SFA and POP) × 1st treatment group (patient with any of POBA, Stent or Atherectomy) × 1 outcome (TLR) × 32 covariates = 64
 - Only 20,830 analyses left to go

We are just getting started

NEXT STEPS

- Complete the remaining 4,032 analyses for Target lesion revascularization (TLR)
- Complete 2,640 analyses for each outcome in the following order:
 - Major amputation
 - Mortality
 - Amputation free survival
 - Target lesion revascularization (TLRR) by each subgroup
 - Open surgery
 - Interventional
 - Target lesion occlusion
 - Technical failure



SPEED

THANK YOU