

RAPID



SPEED

Registry Assessment of Peripheral Interventional Devices: SFA-Popliteal Evidence Development

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Why RAPID?

Heterogeneity of Peripheral Artery Treatment

- **Variable Patient Conditions**
 - Age, gender, diabetes influence outcomes
- **Variable Disease Severity**
 - Claudication (life style) vs. Critical Ischemia (limb threat)
 - Differing lesion length, occlusion vs. narrowing, calcification
- **Variable Disease Location**
 - Large (iliac), Medium (SFA, popliteal), Small (tibial) Arteries
- **Variable Physician Specialty, Training, Experience**
 - Cardiologists, radiologists, surgeons
- **Variable Treatment Options**
 - Numerous device types, on- and **off-label use in practice**



RAPID Methods

Public-Private Partnership Volunteer Work

- 6 Face-to-Face Workshops before today
 - June 5 and November 6, 2015
 - April 13 and September 14, 2016
 - May 25 and October 4, 2017
- Weekly leadership conference calls
- Multiple specialized workgroup calls
 - Phase 1: Clinical, Informatics, GUDID
 - Phase 2: Informatics, GUDID, Protocol, Governance, Marketing
- Funding:
 - Contributions by multiple manufacturers
 - MDEpiNet
 - In-kind contribution by many volunteers



RAPID Partners

- **Medical Societies / Registries**

- American College of Cardiology (**ACC**)
 - National Cardiovascular Disease Registry (**NCDR**)
- Society for Vascular Surgery (**SVS**)
 - Vascular Quality Initiative (**VQI**)
- Society of Interventional Radiology (**SIR**)

- **U.S. Agencies**

- FDA (**CDRH** pre- and post-market, and **CEDR**)
- Agency for Healthcare Research and Quality (**AHRQ**)
- Centers for Medicare and Medicaid Services (**CMS**)
- Department of Defense (**DOD**) Healthcare Resources
- Office of the National Coordinator (**ONC**)
- National Heart, Lung and Blood Institute (**NHLBI**)
- National Library of Medicine (**NLM**)
- GMDN Agency



RAPID Partners

• **Peripheral Vascular Device Manufacturers**

- 4C Medical Technologies
- Abbott
- Aortic Medical Inc.
- BDI Peripheral Intervention
- Becton Dickinson
- Boston Scientific
- Cardiovascular Systems Inc.
- Cook Medical
- Intact Vascular, Inc.
- Medtronic
- Mercator MedSystems
- WL Gore

• **Related Companies / Organizations**

- AHRMM
- American Uro-GYN Society
- Aspire Bariatrics, Inc.
- Brooks Medtech, LLC
- Cardiac Interventions Today
- Cognitive Medical Systems
- Cook Research, Inc.
- ECRI Institute
- Healthjump Inc.
- IQVIA
- M2S/Medstreaming
- National Ctr for Health Research
- NEST cc



RAPID Goals/Progress

mdepinet.org/rapid

- **Phase I:** Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used – **Completed!**

REGULATORY UPDATE

Registry Assessment of Peripheral Interventional Devices (RAPID)

Developing a minimum core dataset for total product life cycle device evaluation across multiple data sources: a step toward establishing a National Evaluation System for Health Technology for peripheral intervention devices.

BY JOSE PABLO MORALES, MD; JACK CRONENWETT, MD; AND ROBERT THATCHER, MBA; ON BEHALF OF THE RAPID PROJECT COLLABORATORS

Registry Assessment of Peripheral Interventional Devices (RAPID) is one of the PASSION CV (Predictable and Sustainable Implementation of National Cardiovascular) registry projects approved by the Scientific Oversight Committee of the Medical

manufacturers and used by several medical specialties, including cardiologists, radiologists, and surgeons, each of which brings a different training and experience to influence treatment choice. Furthermore, peripheral interventional devices represent the most rapidly growing device category.

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peripheral arterial intervention is particularly challenging due to the heterogeneity of the disease process, the availability of multiple devices for treatment, and lack of consensus about the best treatment type. In addition, peripheral interventional devices are produced by multiple

as well as into the electronic health record (EHR) system of at least one vendor. In order to subsequently conduct a device evaluation project using these data sources to demonstrate the benefits of interoperable device data collection for both industry and the US Food and Drug

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SPECIAL COMMUNICATIONS

Registry Assessment of Peripheral Interventional Devices (RAPID): Registry assessment of peripheral interventional devices core data elements



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ABSTRACT

Objective: The current state of evaluating patients with peripheral artery disease and more specifically of evaluating medical devices used for peripheral vascular intervention (PVI) remains challenging because of the heterogeneity of the disease process, the multiple physician specialties that perform PVI, the multitude of devices available to treat peripheral artery disease, and the lack of consensus about the best treatment approaches. Because PVI core data elements are not standardized across clinical care, clinical trials, and registries, aggregation of data across different data sources and physician specialties is currently not feasible.

Methods: Under the auspices of the U.S. Food and Drug Administration's Medical Device Epidemiology Network initiative—and its PASSION (Predictable and Sustainable Implementation of the National Registries) program, in conjunction with other efforts to align clinical data standards—the Registry Assessment of Peripheral Interventional Devices (RAPID) workgroup was convened. RAPID is a collaborative, multidisciplinary effort to develop a consensus lexicon and to promote interoperability across clinical care, clinical trials, and national and international registries of PVI.

Results: The current manuscript presents the initial work from RAPID to standardize clinical data elements and definitions; to establish a framework within electronic health records and health information technology procedural reporting systems; and to implement an informatics-based approach to promote the conduct of pragmatic clinical trials and registry efforts in PVI.

Conclusions: Ultimately, we hope this work will facilitate and improve device evaluation and surveillance for patients, clinicians, health outcomes researchers, industry, policymakers, and regulators. (J Vasc Surg 2018;67:637-45.)

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REVIEW

Registry Assessment of Peripheral Interventional Devices (RAPID)

— Registry Assessment of Peripheral Interventional Devices Core Data Elements —

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Methods and Results: Under the auspices of the U.S. Food and Drug Administration's Medical Device Epidemiology Network initiative—and its PASSION (Predictable and Sustainable Implementation of the National Registries) program, in conjunction with other efforts to align clinical data standards—the Registry Assessment of Peripheral Interventional Devices (RAPID) workgroup was convened. RAPID is a collaborative, multidisciplinary effort to develop a consensus lexicon and to promote interoperability across clinical care, clinical trials, and national and international registries of PVI. The current manuscript presents the initial work from RAPID to standardize clinical data elements and definitions, to establish a framework within electronic health records and health information technology procedural reporting systems, and to implement an informatics-based approach to promote the conduct of pragmatic clinical trials and registry efforts in PVI.

Conclusions: Ultimately, we hope this work will facilitate and improve device evaluation and surveillance for patients, clinicians, health outcomes researchers, industry, policymakers, and regulators.

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



RAPID Goals

- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used
- **Phase II:** Demonstrate the feasibility of data extraction interoperability across registries and hospital EHRs that provide patient-level data for core data elements.
- **Phase III:** Use a coordinated registries network (CRN) for studies supporting a regulatory decision.



RAPID Goals: May 17, 2017 Decisions

- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used
- Phase II: **Expanded Phase II to include use of data extracted from VQI to create contemporary Objective Performance Goals for SFA and Popliteal interventions, which could assist regulatory decision making for new devices**
interoperable data that provide patients with information that
- Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision.



RAPID Phase II Project

SFA-**P**opliteal **E**vidence **E** Development (**SPEED**)

- **Why SPEED?**

- Mature space, but new drug-coated and other technologies need contemporary OPGs
- Many devices are being used off-label, for patients and disease severity not tested in trials
 - Opportunity to expand labeling by comparison with OPGs
- Current objective performance goals for SFA-POP devices do not reflect contemporary practice



SFA-Popliteal Objective Performance Goals

Current Status

- **VIVA (2007) and SVS (2009) OPGs**
 - Based on < 1200 patients
 - Different OPGs (66% vs 39% for one year stenosis, TVR)
 - Different disease severity (Rutherford 2-4 vs 4-6)
 - One based on superiority compared with plain balloon angioplasty
 - One based on non-inferiority compared with vein bypass surgery
 - Based on data now more than 10 years old
- **Opportunity predicted for SPEED**
 - “We hope that as the body of available clinical evidence becomes larger, the performance goals can be updated and further refined to reflect more robust data from endovascular approaches, from which performance goals can be generated for use in evaluating the next generation of devices.”

-Kumar, Brooks, Cavanaugh, Zuckerman: J Vasc Surg 2009



Treatment Types Selected for SPEED Analysis

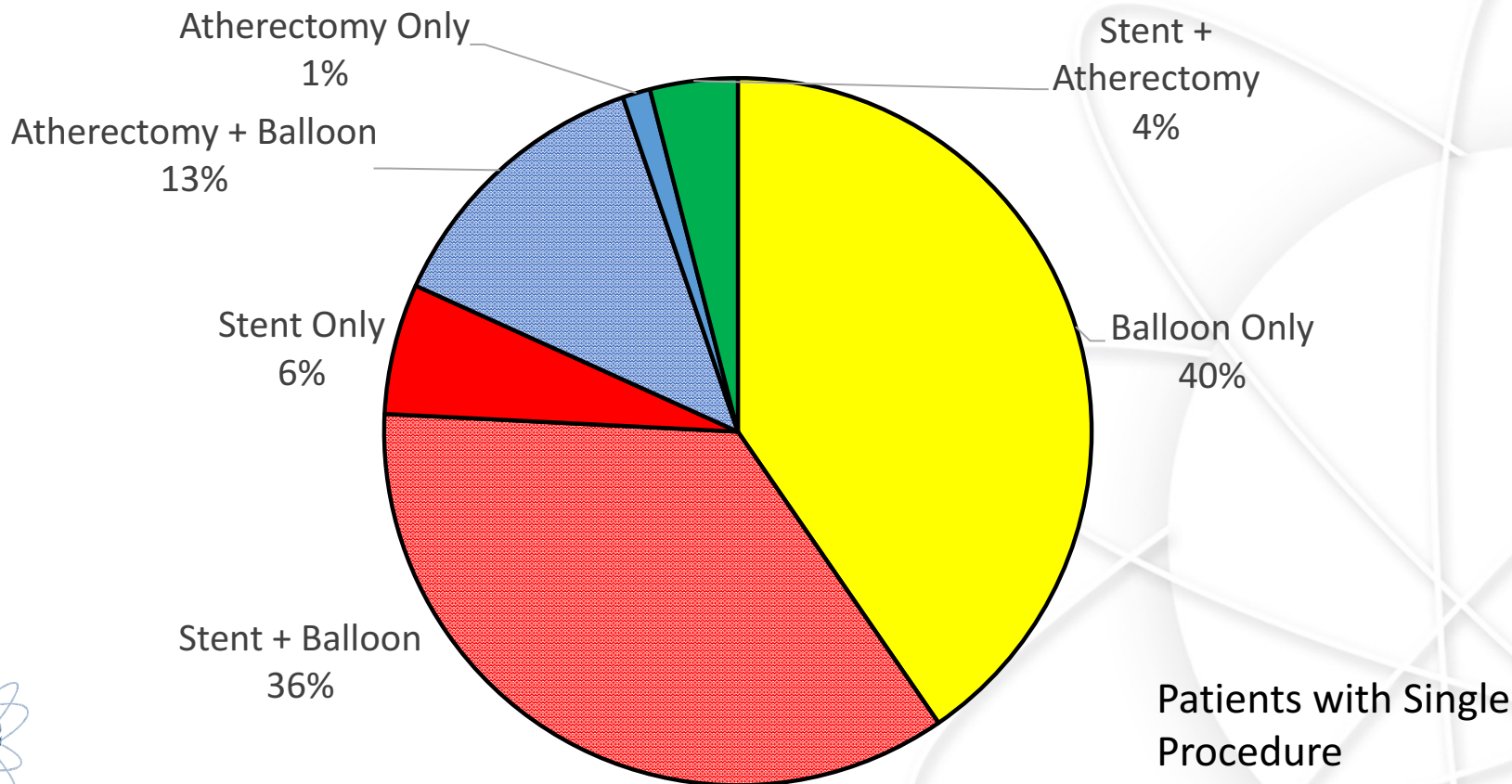
27,427 SFA or POP Interventions from VQI, Jan 2010-Sept, 2016

Balloon Only: 40% (18,591)

Atherectomy \pm Balloon: 14% (6,545)

Stent \pm Balloon: 42% (19,040)

Stent + Atherectomy: 4% (1,842)



RAPID Phase II Project

SFA-Popliteal Evidence Development (SPEED)

Clinical Work Group

- Selected treatment types to analyze
- Selected outcomes to analyze for OPGs
- Selected relevant co-variates for multivariable analysis
 - Patient, disease and lesion characteristics
- Defined inclusion/exclusion criteria

Statistical Work Group

- Developed statistical analysis plan
- Analysis done by FDA team (Nelson Lu)



RAPID Phase II Project

SFA-Popliteal Evidence Development (SPEED)

Work Product:

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



Rapid Phase II Additional Important Work

- **Informatics and GUDID Work Group**
 - Improve the quality of Access GUDID data for more accurate device identification in RAPID
 - Identify supplemental UDI data not contained in Access GUDID that are needed for RAPID
 - Select core general data elements (not specific to PAD) needed to define patient risk factors in RAPID
- **Educational Outreach Work Group**
 - Plan for dissemination of RAPID process, learnings

