RAPID

SPEED

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

Jack Cronenwett, Pablo Morales, Robert Thatcher, Co-Chairs

Daniel Bertges, Misti Malone, Melanie Raska, Co-Chairs

Mitchell Krucoff, Danica Marinac Dabic, Key Advisors

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Registry **A**ssessment of **P**eripheral **I**nterventional **D**evices

- Initiated under the MDEpiNet PASSION Program
  - **P**redictable **A**nd **S**u**S**tainable **I**mplementation **O**f **N**ational Registries for Cardiovascular Devices
  - Infrastructure: Duke Cardiovascular Research Institute
- Goal
  - Interoperable data flow across registries and EMR systems for total product life cycle device evaluation
- Why peripheral artery treatment?
  - Large variation in patients, disease severity, arteries involved, physician specialty, and treatment types selected
  - Many different devices used, often off-label, without good evidence
  - "Wild West" of cardiovascular care

RAPID

Wild West of Cardiovascular Disease

Wild West of Cardiovascular Disease

New Sheriffs in Town

Volunteer Posse

- Academic Societies
- Device Manufacturers
- Agencies
- Related Companies

8th Meeting since 2015

- Weekly leadership calls
- Multiple committees
  - Clinical
  - Statistical
  - Protocol
  - GUDID
  - Informatics
  - Marketing
  - Governance

RAPID Phase 1 Project

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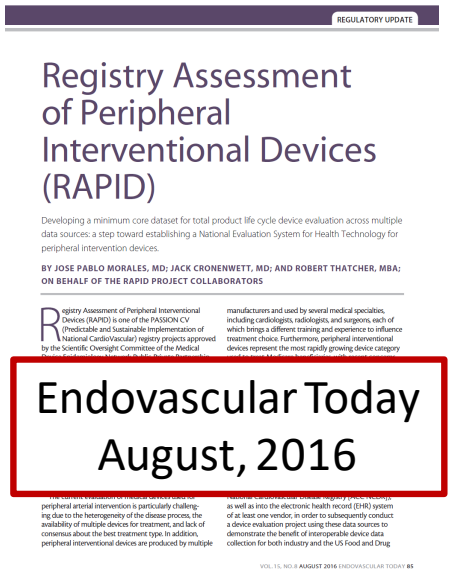
- Identified minimal set of ~ 100 data elements for peripheral artery device evaluation that could allow data extraction from multiple sources, including unique device identifiers



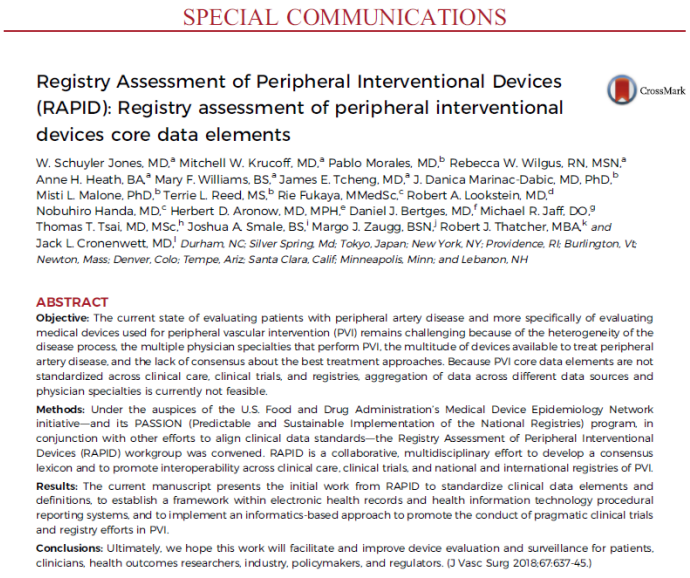
REGULATORY UPDATE

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

Endovascular Today
August, 2016



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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Background: 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 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.

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

RAPID Phase 2 Project

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- Implement RAPID core data element collection in registries and EMR systems to allow interoperable data extraction
  - RAPID data elements incorporated into Society for Vascular Surgery Vascular Quality Initiative (VQI) registry in September, 2017
  - RAPID data elements included in Medstreaming Vascular Information System (outpatient EMR), with direct linkage to VQI
  - Both use API with Access GUDID to identify devices using underlying GMDN terminology
- Continue informatics and UDI work begun in Phase 1
  - Improve the quality of Access GUDID data for device identification
  - Identify additional needed UDI data not contained in Access GUDID
  - Select and define general patient data elements needed for device evaluation projects that are not in the RAPID core data elements

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RAPID Phase 3 Project

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- Initiate a device evaluation project using RAPID core data elements derived from a registry
- Objective Performance Goals for SFA-Popliteal treatment
  - Plain balloon angioplasty, stenting, atherectomy
- Why SFA-Popliteal?
  - Available OPGs > 10 years old, don't reflect contemporary treatment
  - Many new devices being developed for SFA-Popliteal treatment
  - Potential to reduce device evaluation costs by using OPGs instead of a control group when appropriate
  - Potential to expand indications of current devices being used off-label by comparison with contemporary OPGs

SPEED SFA-Popliteal EvidencE Development

SFA-Popliteal EvidencE Development

- Clinical Work Group – Daniel Bertges
  - Selected treatment types, outcomes, exclusion criteria
  - Selected relevant co-variates for multivariable analysis
    - Patient, disease and lesion characteristics
- Statistical Work Group – Roseann White
  - Defined Statistical Analysis Plan
  - Reviewed analyses done by statisticians
- Statisticians / Analysts
  - FDA - Yu-Ching Cheng – Target Lesion Revascularization Rate
  - Cornell - Tianyi Sun – Amputation Rate
  - Dartmouth - Niveditta Ramkumar – Survival Rate
- Many analytic considerations successfully addressed by these groups during many conference calls

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SFA-Popliteal EvidencE Development

- SPEED Planned Work Product
  - Scientific publication describing each OPC for each treatment type (and all treatments combined)
  - 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 their devices, estimate sample size for new device trials, and for regulatory applications

SPEED

Today's RAPID Agenda

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- Evolving regulatory universe
  - FDA, NEST, EU MDR, ICVR
- OPG results and lessons learned from SPEED
  - TLR, Amputation, Mortality rates
- Using UDI to evaluate devices based on real world evidence
  - UDI, AUDI, anatomy standards, implementing GUDID, GMDN
- Using real world evidence for regulatory decisions
  - Industry, regulatory and statistical perspectives
  - Using the VISION infrastructure for claims-based long term outcomes
  - Potential for data collection from multiple sources
- RAPID for prospective and randomized device clinical trials
- Planning the next phase of RAPID

RAPID Leadership Transition

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- MDEpiNet Public-Private Partnership leadership structure
  - Academia, Regulatory, Industry
- Co-Chairs since 2015:
  - Jack Cronenwett – Dartmouth, SVS VQI
  - Pablo Morales – FDA
  - Robert Thatcher – 4C Medical Technologies (previously CSI)
- New Co-Chairs since 2018:
  - Daniel Bertges – University of Vermont, SVS VQI
  - Misti Malone – FDA
  - Melanie Raska – Boston Scientific
- Key Advisors
  - Mitchell Krucoff – Duke
  - Danica Marinac-Dabic - FDA