Vascular Study Group of New England

17th Semi-Annual Meeting

Monday, November 7, 2011

Maine Medical Center, Portland
Guests from Outside New England

- Cardiac Care Network of Ontario
  - Dan Purdham PhD

- Catholic Health, Buffalo
  - Christine Juliano, Holly Bower

- Indiana University Health
  - Gary Lemmon MD, Katharine Krol MD, Roberta Sutton-Stent RN

- Michigan Surgical Quality Collaborative
  - Max Hutton MD, Majed Tomeh

- Stonybrook University Hospital
  - Shang Loh MD, Olympia Christoforatos RN MS

- Toronto General and St. Michael’s Hospitals
  - Thomas Lindsay MD, Graham Roche-Nagel MD, Tony Moloney MD, Naomi Eisenberg

- University of Utah Medical Center
  - Larry Kraiss MD

- Vascular Society of New Jersey
  - Paul Hauser MD
Guests from New England

- **Cape Cod Healthcare**
  - James Butterick MD

- **The Miriam Hospital**
  - Susan Kenyon RN, Patricia Sullivan RN

- **SVS PSO**
  - Carrie Bosela RN CPC, Administrative Director

- **M2S**
  - Greg Lange, President
  - Jacyln Kinkaid MPH, Becky Ekstrom MPH, Ke Zhang MEM, Maryann Caron MPH, Matt Regan
Administrative Updates

VSGNE
SVS VQI
NESVS Clinical Trials Grant
Invite all providers of VSGNE procedures; cardiology, interventional radiology

> 170 VSGNE Members 2011
>21,000 Procedures Reported

CEA, CAS, oAAA, EVAR, LEB, PVI, TEVAR

[Bar chart showing the trend from 2003 to 2011 with a significant increase in procedures from 2009 onwards.]
VSGNE Procedure Types

- Carotid Artery Stent: 22%
- Open AAA Repair: 14%
- Supra-inguinal Bypass: 10%
- Infra-inguinal Bypass: 9%
- Peripheral Vascular Intervention: 3%
- Endo AAA Repair: 2%
- Carotid Endarterectomy: 1%
Number of Centers Entering Data:

- 2003: 8
- 2004: 9
- 2005: 9
- 2006: 10
- 2007: 11
- 2008: 11
- 2009: 12
- 2010: 21
- 2011: 25
VSGNE Semi-Annual Volume / Center

PVI →
Semi-Annual Procedures per Center

Time Period:
- Jan-Jun 2003
- Jan-Jun 2011

- **CEA**
- **CAS**
- **Infra**
- **Supra**
- **Open AAA**
- **EVAR**
- **PVI**
New Features

- More risk-adjusted benchmarks
- New website
- Smart phone app for Cardiac Risk Index
- Social Security Death Index match
- Current / future audits
Risk-Adjusted Outcomes

- Develop multivariate model to predict expected outcome based on different patient characteristics
- Calculate observed/expected (O/E) ratio
- Allows benchmarking independent of different patient characteristics
- Model only explains portion of the variation (Area under the curve, AUC)
Risk-Adjusted Outcomes

- Previously: CEA, open AAA
- Now: CEA, elective and ruptured AAA for both open and EVAR, infrainguinal bypass
- Special thanks:
  - Yuanyuan Zhao, VSGNE statistician
  - Becky Ekstrom, Becky Lindstrom, M2S
  - Philip Goodney MD
Website Upgrade: www.vsgne.org
Participating Hospitals

Baystate Medical Center, Springfield, MA
Berkshire Medical Center, Pittsfield, MA
Beth Israel Deaconess Medical Center, Boston, MA
Boston Medical Center, Boston, MA
Brigham and Women's Hospital, Boston, MA
Central Maine Medical Center, Lewiston, ME
Charlton Memorial Hospital, Fall River, MA
Concord Hospital, Concord, NH
Cottage Hospital, Woodville, NH
Dartmouth-Hitchcock Medical Center, Lebanon, NH
Eastern Maine Medical Center, Bangor, ME
Elliot Hospital, Manchester, NH
Fletcher Allen Health Care, Burlington, VT
Hartford Hospital, Hartford, CT
Lakes Region General Hospital, Laconia, NH
Massachusetts General Hospital, Boston, MA
MaineGeneral Medical Center, Augusta, ME
Bylaws

I. Mission Statement

The Vascular Study Group of New England (VSGNE) is a voluntary, cooperative group of clinicians, hospital administrators, and research personnel organized to improve the care of patients with vascular disease. By collecting and exchanging information, the group strives to continuously improve the quality, safety, effectiveness and cost of caring for patients with vascular disease.

II. Membership

Hospitals and physicians performing any of the vascular procedures recorded by VSGNE are eligible for full membership if they are located within the New England states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont. Full Membership requires that the member hospital or physician follow the policies and procedures established by VSGNE (see Section VII). Hospitals act as the contracting agent for membership in VSGNE, such that physicians who perform vascular procedures in that hospital are eligible to participate. A majority vote of the VSGNE Executive Committee is required to approve full membership of new hospitals. A hospital which is approved for full membership is hereafter referred to as a “VSGNE Member”.

III. Patient Safety Organization

The VSGNE is an unincorporated association of member hospitals and physicians that use the Society for Vascular Surgery® Patient Safety Organization (SVS PSO) as the vehicle for quality improvement and the M2S, Inc. Pathways product for data collection and quality report generation. Contracts are required between member hospitals and the SVS PSO, M2S, and the Hitchcock Foundation, which acts as the fiduciary agent for VSGNE for regional staff and projects. SVS PSO is a Patient Safety Organization, as defined by The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41), implemented to protect the confidentiality of all data and resulting patient safety work product. SVS PSO is a limited liability company created for the purpose of satisfying VSGNE’s desire for a patient safety organization by the Society for Vascular Surgery (SVS). M2S, Inc. provides web-based services to SVS PSO related to the VSGNE registry, under an administrative services agreement. Under the relevant agreements with each member hospital, SVS PSO will perform common data management services for member institutions, as determined by the VSGNE Quality Committee of the SVS PSO.

Each member hospital must have contracts with SVS PSO and M2S, Inc. (the Hospital Contracts), which affirms adherence to the VSGNE Bylaws. The form of the Hospital Contracts between SVS PSO and M2S, Inc. and member hospitals must be approved by the VSGNE Executive Committee, including the costs for SVS PSO and M2S services. The Hospital Contracts shall include annual charges, based on expected volume and number of procedures performed, for services performed under the Hospital Contracts.
Publications and Presentations

PUBLICATIONS


Coming Soon: Members Only Section for Non-Public Information

VSGNE Meeting Slides

- May 11, 2011 16th Semi-Annual Meeting, Boston Medical Center
- October 28, 2010 15th Semi-Annual Meeting, Dartmouth-Hitchcock Medical Center

Edited to remove Patient Safety Work Product
Cardiac Risk Index

[Click here to access Cardiac Risk Index]

The Vascular Study Group of New England developed an algorithm to predict the likelihood of post-operative myocardial infarction, congestive heart failure, or arrhythmia requiring treatment. The Vascular Study Group Cardiac Risk index (VSG-CRI) applies to carotid endarterectomy, lower extremity bypass, and endovascular and open repair of non-ruptured abdominal aortic aneurysms. Unlike most other cardiac risk predictors, this was developed in a cohort of 8,000 vascular patients and validated in a cohort of 1,800 patients. This process revealed that typical vascular patients had a higher predicted rate of cardiac complications than would be predicted by other available risk models. Details are contained in the following publication:


In order to make this practical in the clinical setting, VSGNE and SVS VQI have partnered with QxMD Software, a company dedicated to creating free, high quality, point-of-care tools for practicing healthcare professionals. You can access these tools by downloading the free smartphone app ‘Calculate by QxMD’ currently available for iPhone, iPad, or Android through the App Store or Android Market. You can obtain detailed information on the QxMD website: [http://www.qxmd.com/apps/calculate-by-qxmd](http://www.qxmd.com/apps/calculate-by-qxmd).

For a direct link to the web-based version of the Vascular Study Group Cardiac Risk Index, select this link. You will be re-directed to the QxMD website.

*Posted October 2011*
The Vascular Study Group of New England Cardiac Risk Index (VSG-CRI) predicts cardiac complications more accurately than the Revised Cardiac Risk Index in vascular surgery patients

Daniel J. Berges, MD, RVT,a Philip P. Goodney, MD, b Yuanyuan Zhao, MD, b Andres Schanzer, MD, c Brian W. Nolan, MD, b Donald S. Likosky, PhD, b Jens Eldrup-Jorgensen, MD, d and Jack L. Cronenwett, MD, b for the Vascular Study Group of New England, Burlington, VT; Lebanon, NH; Worcester, Mass; and Portland, Me

Objective: The Revised Cardiac Risk Index (RCRI) is a widely used model for predicting cardiac events after noncardiac surgery. We compared the accuracy of the RCRI with a new, vascular surgery-specific model developed from patients within the Vascular Study Group of New England (VSGNE).

Methods: We studied 10,081 patients who underwent nonemergent carotid endarterectomy (CEA; n = 5293), lower extremity bypass (LEB; n = 2673), endovascular abdominal aortic aneurysm repair (EVAR; n = 1005), and open infrarenal abdominal aortic aneurysm repair (OAAA; n = 1,110) within the VSGNE from 2003 to 2008. First, we analyzed the ability of the RCRI to predict in-hospital major adverse cardiac events, including myocardial infarction (MI), arrhythmia, or congestive heart failure (CHF) in the VSGNE cohort. Second, we used a derivation cohort of 8208 to develop a new cardiac risk prediction model specifically for vascular surgery patients. Chi-square analysis identified univariate predictors, and multivariate logistic regression was used to develop an aggregate and four procedure-specific risk prediction models for cardiac complications. Calibration and model discrimination were assessed using Pearson correlation coefficient and receiver operating characteristic (ROC) curves. The ability of the model to predict cardiac complications was assessed within a validation cohort of 1873. Significant predictors were converted to an integer score to create a practical cardiac risk prediction formula.

Results: The overall incidence of major cardiac events in the VSGNE cohort was 6.8% (2.5% MI, 3.9% arrhythmia, 1.8% CHF). The RCRI predicted risk after CEA reasonably well but substantially underestimated risk after LEB, EVAR, and OAAA for low- and higher-risk patients. Across all VSGNE patients, the RCRI underestimated cardiac complications by 1.7- to 7.4-fold based on actual event rates of 2.6%, 6.7%, 11.6%, and 18.4% for patients with 0, 1, 2, and ≥3 risk factors. In multivariate analysis of the VSGNE cohort, independent predictors of adverse cardiac events were (odds ratio [OR]) increasing age (1.7-2.8), smoking (1.3), insulin-dependent diabetes (1.4), coronary artery disease (1.4), CHF (1.9), abnormal cardiac stress test (1.2), long-term β-blocker therapy (1.4), chronic obstructive pulmonary disease (1.6), and creatinine ≥1.8 mg/dL (1.7). Prior cardiac revascularization was protective (OR, 0.8). Our aggregate model was well calibrated (r = 0.99, P < .001), demonstrating moderate discriminative ability (ROC curve = 0.71), which differed only slightly from the procedure-specific models (ROC curves: CEA, 0.74; LEB, 0.72; EVAR, 0.74; OAAA, 0.68). Rates of cardiac complications for patients with 0 to 3, 4, 5, and ≥6 VSG risk factors were 3.1%, 5.0%, 6.8%, and 11.6% in the derivation cohort and 3.8%, 5.2%, 6.1%, and 10.1% in the validation cohort. The VSGNE cardiac risk model more accurately predicted the actual risk of cardiac complications across the four procedures for low- and higher-risk patients than the RCRI. When the VSG Cardiac Risk Index (VSG-CRI) was used to score patients, six categories of risk ranging from 2.5% to 14.3% (score of 0-3 to 8) were discernible.

Conclusions: The RCRI substantially underestimates in-hospital cardiac events in patients undergoing elective or urgent vascular surgery, especially after LEB, EVAR, and OAAA. The VSG-CRI more accurately predicts in-hospital cardiac events after vascular surgery and represents an important tool for clinical decision making. (J Vasc Surg 2010;52:674-83.)
Lee’s Revised Cardiac Risk Index (RCRI)

**REVISED CARDIAC RISK INDEX**
(Circulation 1999; 100:1043-1049)

Each risk factor is assigned one point.

1. High-risk surgical procedures

**RISK OF MAJOR CARDIAC EVENT**

<table>
<thead>
<tr>
<th>Points</th>
<th>Class</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>I</td>
<td>0.4%</td>
</tr>
<tr>
<td>1</td>
<td>II</td>
<td>0.9%</td>
</tr>
<tr>
<td>2</td>
<td>III</td>
<td>6.6%</td>
</tr>
<tr>
<td>3 or more</td>
<td>IV</td>
<td>11%</td>
</tr>
</tbody>
</table>

"Major cardiac event" includes myocardial infarction, pulmonary edema, ventricular fibrillation, primary cardiac arrest, and complete heart block

- Chest radiograph showing pulmonary vascular redistribution

4. History of cerebrovascular disease
   - History of transient ischemic attack or stroke

5. Preoperative treatment with insulin

6. Preoperative serum creatinine > 2.0 mg/dL
VSGNNE Cohort 2003-2008
n= 10,081

Composite adverse cardiac events, in-hospital:
1. MI
2. CHF
3. Arrhythmia

Excluded emergency operations (n= 368)
<table>
<thead>
<tr>
<th>Number of RCRI Risk Factors</th>
<th>RCRI Predicted Risk (%)</th>
<th>Actual Event Rates %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Entire cohort (n=9809)</td>
<td>CEA (n=5115)</td>
</tr>
<tr>
<td>0</td>
<td>0.4</td>
<td>2.6</td>
</tr>
<tr>
<td>1</td>
<td>0.9</td>
<td>6.7</td>
</tr>
<tr>
<td>2</td>
<td>6.6</td>
<td>11.6</td>
</tr>
<tr>
<td>≥ 3</td>
<td>11.0</td>
<td>18.4</td>
</tr>
</tbody>
</table>
Composite Adverse Cardiac Events
VSG-CRI Derivation vs. Validation Sets

10 Risk factors
Age
IDDM
CHF
Abnormal cardiac stress
Creatinine ≥ 1.8
Chronic β blockade
Smoking
CAD
CABG/PCI
COPD
### Vascular Study Group Cardiac Risk Index (VSG-CRI)

**Step 1:**
Calculate VSG-RCI Score

<table>
<thead>
<tr>
<th>VSG-CRI Risk Factors</th>
<th># Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 80</td>
<td>4</td>
</tr>
<tr>
<td>Age 70-79</td>
<td>3</td>
</tr>
<tr>
<td>Age 60-69</td>
<td>2</td>
</tr>
<tr>
<td>CAD</td>
<td>2</td>
</tr>
<tr>
<td>CHF</td>
<td>2</td>
</tr>
<tr>
<td>COPD</td>
<td>2</td>
</tr>
<tr>
<td>Creatinine &gt; 1.8</td>
<td>2</td>
</tr>
<tr>
<td>Smoking</td>
<td>1</td>
</tr>
<tr>
<td>Insulin Dependant Diabetes</td>
<td>1</td>
</tr>
<tr>
<td>Chronic β-Blockade</td>
<td>1</td>
</tr>
<tr>
<td>History of CABG or PCI</td>
<td>-1</td>
</tr>
</tbody>
</table>

**Step 2:**
Use VSG-CRI Score To Predict Risk of Adverse Cardiac Outcome

#### Risk of Adverse Cardiac Outcome, by VSG-CRI Score

<table>
<thead>
<tr>
<th>VSG-CRI Score</th>
<th>Risk of Adverse Cardiac Outcome (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3</td>
<td>2.6</td>
</tr>
<tr>
<td>4</td>
<td>3.5</td>
</tr>
<tr>
<td>5</td>
<td>6.0</td>
</tr>
<tr>
<td>6</td>
<td>6.6</td>
</tr>
<tr>
<td>7</td>
<td>8.9</td>
</tr>
<tr>
<td>8 or More</td>
<td>14.3</td>
</tr>
</tbody>
</table>

Example patient: 80 yr-old smoker with history of CAD and prior CABG.

VSG-CRI score = 4 + 1 + 2 -1 = 6
### VSG-CRI Procedure Models

<table>
<thead>
<tr>
<th>CEA</th>
<th>LEB</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. diabetes</td>
<td>1. age</td>
</tr>
<tr>
<td>2. CAD</td>
<td>2. gender</td>
</tr>
<tr>
<td>3. prior CABG or PCI within 5yrs</td>
<td>3. diabetes</td>
</tr>
<tr>
<td>4. CHF</td>
<td>4. COPD</td>
</tr>
<tr>
<td>5. cardiac stress test</td>
<td>5. CHF</td>
</tr>
<tr>
<td>6. aspirin</td>
<td>6. cardiac stress test</td>
</tr>
<tr>
<td>7. clopidogrel</td>
<td>7. statin</td>
</tr>
<tr>
<td>8. statin</td>
<td>8. critical limb ischemia</td>
</tr>
<tr>
<td>9. prior vascular surgery</td>
<td></td>
</tr>
<tr>
<td>EVAR</td>
<td>oAAA</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>1. CHF</td>
<td>1. age</td>
</tr>
<tr>
<td>2. cardiac stress test</td>
<td>2. prior CABG/PCI w/i 5yrs</td>
</tr>
<tr>
<td>3. clopidogrel</td>
<td>3. CHF</td>
</tr>
<tr>
<td>4. AAA size</td>
<td>4. COPD</td>
</tr>
<tr>
<td></td>
<td>5. creatinine &gt;1.8</td>
</tr>
<tr>
<td></td>
<td>6. beta blockers</td>
</tr>
<tr>
<td></td>
<td>7. prior vascular surgery</td>
</tr>
</tbody>
</table>
VSG-CRI calculator

- http://www.vsgnne.org/
- http://www.vascularweb.org/regionalgroups/vsgne/Pages/home.aspx
- To be posted on SVS VQI site
Cardiac Risk Index

Click here to access Cardiac Risk Index

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For a direct link to the web-based version of the Vascular Study Group Cardiac Risk Index, select this link. You will be re-directed to the QxMD website.

Posted October 2011
VSG CRI app

http://www.qxmd.com/

http://www.qxmd.com/calculate-online/vascular-surgery
Next Steps

- Test VSG-CRI in new VSG-NE cohort 2008-2011
  - More centers, more diverse population

- Test VSG-CRI nationally within SVS VQI

- Develop model for MI alone?
  - Stratify for type of MI

- Practice patterns of stress testing

- Is there regional variability in cardiac complications?
Social Security Death Index Match

- SVS PSO purchases SSDI every 6 months
- M2S developed a matching method
- VSGNE patients who have died are identified in SSDI, updated in database
- Over 4,000 late deaths matched to date

- If centers download their data, SSDI death shows up as a new field that may be useful for center-specific research
Audit with Claims Data

- Interval comparison hospital claims with VSGNE data
  - Detect patients not entered
  - Currently underway for 2007-2009 data
  - Requires substantial hand matching because ICD-9 codes are imprecise for vascular

- Working to develop automated system that uses physician CPT claims
  - More precise matching, especially important for PVI procedures
Follow-up

- One-year follow-up required for all procedures

- Voted to extend f/u for EVAR, TEVAR
  - Few adverse endpoints at one year
  - Extend to annual f/u for 5 years

- Web-based system allows multiple follow-up entry
Follow-up Action

- Staff to survey centers to understand successful methods, and problems
- Offer advice based on best practice to low reporting centers
- Remind centers of requirement
- Potentially exclude centers that do not meet a reporting threshold based on Executive Committee review
Vascular Quality Initiative

• New Initiative in 2011

• Mission:
  – To improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information.

• Organization:
  – Regional quality groups
    • Based on Vascular Study Group of New England
  – SVS Patient Safety Organization (formerly VSG PSO)
  – M2S Pathways data collection - reporting system
**PSO Governing Council:** 4 representatives from SVS, 1 from each region, Medical Director (ex officio)

- Conducts business of PSO, report to SVS Board
- Approve recommendations of PSO Quality Committee

Richard Cambria, MD, Chair
Larry Kraiss, MD
Michael Stoner, MD
*Jeb Hallett, MD
*Adam Beck, MD
Jack Cronenwett, MD, Medical Director, ex officio

Anton Sidawy, MD, Vice Chair
Louis Nguyen, MD
*Jens Jorgenson, MD - VSGNE
*Fred Weaver, MD
*Mark Davies, MD

*Representative from each regional group
Vascular Quality Initiative

**PSO Quality Committee:** 1 Representative from each regional RAC plus SVS appointees

- Develop national quality improvement projects
- Recommend best practices based on PSO analyses
- Evaluate requests for de-identified datasets for quality research that involve more than one region

Larry Kraiss, MD, Chair  
**Philip Goodney, MD**  
Jeb Hallett, MD  
Jack Cronenwett, MD, ex officio  

Greg Landry, MD  
**Andres Schanzer, MD**  
Marc Schermerhorn, MD
Results to Date (since February, 2011)

- Achieved PSO accreditation by AHRQ
- Established PSO structure, Governing Council
- Enabled national participation
- Added TEVAR-Complex EVAR and Dialysis Access
Vascular Quality Initiative

100 centers, 29 states + Ontario
> 2000 procedures per month
Vascular Quality Initiative

7 Regional Groups Exist:
- New England
- Mid-Atlantic
- Virginias
- Carolinas
- Florida
- Texas
- Southern California

4 Regional Groups Forming:
- Georgia
- Michigan
- Ontario, Canada
- Rocky Mountain area
### Total Procedures Captured (as of September 30, 2011)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid Endarterectomy</td>
<td>11,708</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>1,034</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>3,737</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>2,460</td>
</tr>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>7,389</td>
</tr>
<tr>
<td>Infra-Inguinal Bypass</td>
<td>6,262</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
<td>1,240</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>104</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>57</td>
</tr>
</tbody>
</table>

Total: 34,137
Vascular Quality Initiative

Additional Benefits to PSO Members

• Data collection meets CMS’ Carotid Artery Stent Facility Recertification requirements
• Meets quality improvement portion of Board Maintenance of Certification requirements
• Allows PQRS reporting for physicians without additional work of claims-based reporting
Data submitted to M2S for SVS VQI can be submitted to CMS for PQRS reporting
New Projects

- Provider billing (CPT) codes for auditing, PQRS
- Working with EMR vendors to incorporate data elements into process of care
- Working with FDA and industry to use VQI data for post-approval device studies
- Provide mechanism for regional groups to use VQI clinical data for efficient research trials
- Develop a mechanism to link Medicare claims data with PSO data to capture events and outcomes > 1 yr
Broad Goal

• Develop a mechanism to merge Medicare claims data with all patients in SVS PSO to populate late outcome events that are difficult to capture > 1 yr
• Use detailed clinical data collected at the time of surgery in the SVS PSO to determine patient and process factors that determine outcomes
• Seek funding to establish a long-term mechanism for claims matching
Link Medicare Claims with VSGNE Data

• Potential funding source:
  – Agency for Healthcare Research and Quality (AHRQ)

• AHRQ Health Information Technology FOA
  – Exploratory and Developmental Grant to Improve Health Care Quality through Health Information Technology (IT) (PAR-08-269; R-21, < $300K over 2 years)
  – Improve health care decision making through the use of integrated data and knowledge management

• Target AHRQ broad approach to healthcare
  – Better patient selection to avoid unnecessary surgery
Leveraging Health IT to Avoid Unnecessary Asymptomatic Carotid Revascularization

• To **identify** which asymptomatic patients are likely to receive unnecessary carotid endarterectomy using a merged registry-claims dataset, and **design** a Health IT tool to convey these findings to providers.

• To **determine** the potential cost savings associated with avoiding unnecessary CEA in asymptomatic patients.
Methods

• Assume CEA in asymptomatic patients who have stroke or death within 2 years of CEA were unnecessary

• Match Medicare claims with VSGNE data
  – Use The Dartmouth Institute for access to Medicare claims
  – Use Medicare claims to identify 2 year stroke/death risk
  – Use VSGNE clinical data to identify patient factors that predict 2 year stroke/death

• Develop a decision making tool to select patients for CEA
  – Smart phone and computer based tool

• Estimate cost of unnecessary CEA in U.S.
NESVS Clinical Trials Project

- NESVS seed grant to initiate RCT using VSGNE data as core data set
  - Central IRB
  - Patient consent forms required
  - Voluntary participation of VSGNE sites
  - Investigator initiated, any topic in VSGNE data

- Key concepts:
  - Using VSGNE data should reduce cost of clinical trial while allowing multiple sites to collaborate
  - NESVS: up to $10,000 per year (3 yr max)
NESVS Clinical Trials Project

- **NESVS Clinical Trials Committee:**
  - Administration, oversight and funding
  - Application review, recommendation to Executive Committee for funding

- **VSGNE/M2S:**
  - Data collection and storage

- **Investigators:**
  - IRB application, patient consent, data audit, data analysis, publication
  - Eligible: members of both NESVS and VSGNE
NESVS Clinical Trials Project

- Applications Due March 1, 2012
- Application forms from NESVS
VSGNE Quality Research Projects

- Proposed by members
- Reviewed by Research Advisory Committee
- Approved by each hospital via Executive Committee member
- Solicit broad VSGNE member participation
- Conduct study, supervised by mentor from Research Advisory Committee
- Present results at VSGNE meetings
### VSGNE RAC Approved Projects

<table>
<thead>
<tr>
<th>PI</th>
<th>Center</th>
<th>Title</th>
<th>Approved by EC</th>
</tr>
</thead>
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<tr>
<td>Jeff Kalish/Alik Farber</td>
<td>BMC</td>
<td>Wound Infection following LE</td>
<td>12/1/2009</td>
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<td>The Significance of Intra-Operative Completion Studies following LE</td>
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<td>Phil Goodney/Sal Scali</td>
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<td>Re-transfusion in CEA</td>
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<td>David Stone</td>
<td>DHMC</td>
<td>Dextran infusion is not associated with Major Bleeding Complications During Perioperative Surgery</td>
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<td>Phil Goodney/Bjoern Suckow</td>
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<td>Functional Outcomes of Amputation following LE</td>
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<td>Jessica Wallen/Phil Goodney</td>
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<td>Impact of Completion Imaging in CEA</td>
<td>5/25/2010</td>
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<td>Phil Goodney</td>
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<td>Brian Nolan</td>
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<td>Jim Argersinger</td>
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<td>Impact of RBC Transfusion on Post-Op Outcomes in AAA</td>
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<td>The Effect of Coumadin on Endoleak Development after EVAR</td>
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<td>Jessica Simon</td>
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<td>Major Adverse Limb Events Associated with LE for Claudication</td>
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<td>Danny Bertges</td>
<td>AHIC</td>
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<td>Validation of VSGNE CRI 2008 - 2010</td>
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<td>Andy Hiol</td>
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<td>Determinants of Smoking Cessation in the VSGNE</td>
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<td>Dave Kawaiyama</td>
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<td>Outcomes Related to Blood Transfusion After LE</td>
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<td>Scott Fogarty</td>
<td>VA</td>
<td>Conduit Limited Patients with CLI</td>
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<td>Donald Bari</td>
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<td>Contralateral Amputation as a Predictor of Outcome after LE</td>
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<td>PVI for Critical Limb Ischemia within the VSGNE</td>
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<td>James McPhay / Matt Monard</td>
<td>Brigham</td>
<td>Fem cuff in below knee prosthetic grafts</td>
<td>7/1/2011</td>
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<td>Marc Schermherlhorn</td>
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<td>Gender Differences in AAA</td>
<td>10/8/2011</td>
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<td>Ben Brooke / Phil Goodney</td>
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<td>Analysis of Variation in Use of Renal Protection in PVI</td>
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<td>Randy De Martino / Phil Goodney</td>
<td>DHMC</td>
<td>Long Term Survival Following AAA</td>
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<td>Jessica Wallen / Phil Goodney</td>
<td>DHMC</td>
<td>Long term mortality following CEA</td>
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<td>S. Patel</td>
<td>MGH</td>
<td>Evolution of Technique and Outcomes for Juxtarenal/Complex AAA</td>
<td>10/8/2011</td>
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<td>Chris Kwolek</td>
<td>MGH</td>
<td>Embolic protection versus flow reversal for Carotid Angioplasty and Sterling</td>
<td>10/8/2011</td>
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</tbody>
</table>
VSGNE at Regional-National Meetings and Peer-Reviewed Publications

Presentations
(16 Unique Presenters)

Publications
(9 Unique First Authors)
Hints Towards Organizing and Managing a Multicenter Research Project in VSGNE

P. Goodney
Nature of VSGNE: Scale

- **Initially (2002)**
  - 6 centers
  - ~20 surgeons

- **Now (2011)**
  - 27 centers
  - ~160+ physicians
Nature of VSGNE: Research Structure

- **Initially (2002)**
  - “Hey, what is our stroke rate for CEA?”

- **Now (2011)**
  - RAC
  - Executive Committee
  - Lots of investigators
  - Lots of analysts
Current Research Environment in VSGNE

- "Good" things:
  - 25,000 + procedures
  - Nearly 30 peer-reviewed publications
  - Multitude of research presentations, grant applications
  - Broad skill set across variety of sites and investigators

- "Bad" things:
  - "Crowded sandbox"
  - Previously studied topics
  - Differential learning curve (analytics, study design)
  - Research bureaucracy
  - Communication across large number of parties
Necessary Element: Collaboration

- Within and across VSG centers, collaboration will be an increasingly important element of successfully completing a research project.

- Outline some examples of how this has been done successfully in recent projects.
Executing Your Multicenter Project

- Conceive idea
- Review VSG variables and outcomes
- Formulate RAC proposal
- Assemble project team
  - Analytic roles
  - Consultant roles
  - Supervisory roles
- Generate Mock Tables and Figures
  - Discuss / Edit Mock Table and Figures
- Perform Univariate analyses
  - Discuss / Interpret / Revise Univariate analyses
- Perform advanced/multivariable analyses
- Circulate tables and figures with actual data
- Assemble abstract/manuscript
  - Revisions, edits, and submission
Executing Your Multicenter Project

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- Discuss / Interpret / Revise Univariate analyses

Perform advanced/multivariable analyses
- Circulate tables and figures with actual data
- Assemble abstract/manuscript
- Revisions, edits, and submission
Role of Collaborators

- Use regular conference calls
  - Keep team on task
  - Use the experience of prior analytic efforts
  - Avoid re-inventing the wheel

- Example
  - VSG-CRI project
  - Dr. Bertges (PI)
    - Organizational efforts
    - Outlining deliverables
      - Abstract deadlines
      - Manuscript edits and versions
      - Assigning tasks
Tips and Tricks

- Make “dummy” tables and figures
  - Allows the group to visualize the final project
- Identify abstract deadlines well in advance
  - Gives colleagues time to review
  - Prevents last-second analytic concern
- Delegate work among colleagues
  - Introduction/Methods/Results
  - Tables/Figures
  - Literature review
- Use the RAC committee member as a resource
Notes From Those Who’ve Done It

- D. Bertges
  - VSG CRI

- J. Kalish
  - Transfusion in LEB

- D. Baril
  - Effect of Amputation in LEB
LUNCH BREAK

30 Minutes
Quality Improvement Publications

- Improve patient selection by developing better outcome prediction:
  - Stroke/death after carotid endarterectomy
  - One year mortality after elective AAA repair
  - Ambulation status after leg bypass
  - Amputation/graft occlusion after leg bypass
  - One year mortality after leg bypass
  - Functional outcome after LEB in CLI patients
  - Amputation-free survival in CLI pts after LEB
  - Cardiac risk prediction for vascular patients
  - Symptomatic AAA outcomes
Quality Improvement Publications

- **Determine best processes of care:**
  - Protamine use during carotid endarterectomy
  - Completion imaging during CEA
  - Plavix and bleeding complications

- **Quality improvement initiatives:**
  - Increase pre-op statin usage
  - Increase pre-op beta-blocker usage
  - Increase patching during conventional CEA
Increased Pre-op Statin Use

- Developed Request Letters to PCPs
- Set 90% Target
- Started QI Initiative

Graph showing the increase in pre-op statin use from 2003 to 2009, with milestones marked at key years.
Increased Pre-op Beta Blocker Use

Rate of Beta Blocker Use

Oct-Dec 2008 88%

Jan-Mar 2003 68%

P<0.001
No Change in Post-op MI Rate

Rate of Beta Blocker Use
Jan-Mar 2003 68%
Oct-Dec 2008 88%

Rate of Post-op MI
Jan-Mar 2003 5.2%
Oct-Dec 2008 5.5%

P < 0.001
p = 0.876
Potential New Beta-Blocker Project

- For medium and high risk patients based on VSGNE Cardiac Risk Index
- Initiate beta-blockers > 1 week pre-op
- Titrate dose to resting HR 55-70
- Check troponins post-op
- ? Automated HR monitoring by phone
- ? RCT or QI project
Quality Improvement Discussion

- Now that VSGNE is a mature group with substantial data collected,

- How can we focus more on regional quality improvement?

- What are the best projects and methods?
Quality Improvement Discussion

- **Reduce complication rates**
  - Use regional variation to identify opportunities
LEB QI Presentations at NESVS

- Use of a postoperative insulin protocol decreases wound infection in diabetics undergoing lower extremity bypass
  - Fuyuki Hirashima, University of Vermont

- Blood transfusion is associated with increased perioperative surgical site infection and graft failure in lower extremity bypass
  - Tze-Woei Tan, Boston Medical Center
QI Discussion Ideas at NESVS

- Quality Improvement Committee
- More concrete deliverables
  - Practice guidelines, standard order sets, care pathways, patient education materials
  - Guidelines for initial testing and followup
- Reduce infections
  - Skin prep, transfusion threshold, glucose Rx
- Open AAA standard care pathway
  - Reduce return to OR, transfusion, MI rates
QI Discussion Ideas at NESVS

- Focus beta blockers on high risk patients
  - Monitor heart rate pre-op
- Revise performance measures
  - Add protamine use during CEA
  - Evaluate processes in other procedures
- Analyze best – worst outcomes
  - Site visits, granular discussions at meetings
- Studies may require temporary variables
  - Glucose levels to study insulin drip
- Focus on efficiency: analyze costs, LOS
VSGNE Future Directions
Recent Quality Analyses

- Dextran during CEA – Kevin Tan
- Conduit type in LEB – Donald Baril
- Completion imaging for LEB – Kevin Tan
Perioperative Use of Dextran Increases Cardiac Complications after Carotid Endarterectomy

Tze-Woei Tan, Jeffrey Kalish
Naomi Hamburg, Robert Eberhardt, Denis Rybin,
Gheorge Doros, Phil Goodney,
Jack Cronenwett, Alik Farber

On behalf of the Vascular Study Group of New England
Background

- Dextran has been theorized to diminish the risk of stroke after carotid endarterectomy (CEA)
  - has been shown to decrease the number of embolic TCD signals
  - use in patients with post-op TCD embolic signals decreases stroke rate
Background

- Dextran use can be associated with bleeding, CHF, renal failure, and allergic reactions.
- Dextran use during CEA varies with center and surgeon practice and its role in the absence of TCD monitoring is uncertain.
Objective

- To evaluate the outcomes of perioperative Dextran use in patients undergoing CEA
Methods

- Patient outcomes compared based on perioperative Dextran use
  - Bivariate analysis
  - Adjusted analyses
    - Multivariable regression
    - Group matching
    - Propensity score matching
Methods

Outcomes:
- Perioperative death, stroke, combined stroke/death, cardiac complications, bleeding complications
- One year survival, stroke
Sample Selection

Consecutive CEA (VSGNE 2003 to 2010)

Perioperative Dextran

Group Matching: CAD, CHF, Plavix, Shunt, Anesthesia
# Demographics of Matched Sample

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N=1856)</th>
<th>Dextran (N=333)</th>
<th>No Dextran (N=1523)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
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</tr>
<tr>
<td>Male</td>
<td>1109 (64.2%)</td>
<td>219 (65.8%)</td>
<td>971 (63.8%)</td>
<td>0.528</td>
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<tr>
<td>Race, n (%)</td>
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<tr>
<td>White</td>
<td>1830 (99.6%)</td>
<td>329 (99.4%)</td>
<td>1501 (99.6%)</td>
<td>0.641</td>
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<tr>
<td>Age, n (%)</td>
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<tr>
<td>35-60</td>
<td>261 (14.1%)</td>
<td>43 (12.9%)</td>
<td>218 (14.3%)</td>
<td>0.157</td>
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<tr>
<td>60-80</td>
<td>1281 (69.0%)</td>
<td>244 (73.3%)</td>
<td>1037 (68.1%)</td>
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<td>80-100</td>
<td>314 (16.9%)</td>
<td>46 (13.8%)</td>
<td>268 (17.6%)</td>
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<td>Smoking</td>
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<tr>
<td>Current</td>
<td>525 (28.3%)</td>
<td>94 (28.2%)</td>
<td>431 (28.3%)</td>
<td>0.961</td>
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<tr>
<td>Prior</td>
<td>934 (50.4%)</td>
<td>170 (51.1%)</td>
<td>764 (50.2%)</td>
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## Clinical History of Matched Sample

<table>
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<tbody>
<tr>
<td>Hypertension, n (%)</td>
<td>1594 (85.9%)</td>
<td>273 (82.2%)</td>
<td>1321 (86.7%)</td>
<td>0.036</td>
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<tr>
<td>CAD, n (%)</td>
<td>521 (28.1%)</td>
<td>94 (28.2%)</td>
<td>427 (28.0%)</td>
<td>0.946</td>
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<tr>
<td>CHF, n (%)</td>
<td>131 (7.1%)</td>
<td>29 (8.7%)</td>
<td>102 (6.7%)</td>
<td>0.195</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>564 (30.4%)</td>
<td>102 (30.6%)</td>
<td>462 (30.3%)</td>
<td>0.948</td>
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<tr>
<td>COPD, n (%)</td>
<td>319 (17.2%)</td>
<td>60 (18.0%)</td>
<td>259 (17.0%)</td>
<td>0.688</td>
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<td><strong>Preoperative Medication</strong></td>
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<tr>
<td>ASA, n (%)</td>
<td>1594 (85.9%)</td>
<td>284 (85.3%)</td>
<td>1310 (86.0%)</td>
<td>0.728</td>
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<td>Plavix, n (%)</td>
<td>211 (11.4%)</td>
<td>40 (12.0%)</td>
<td>171 (11.2%)</td>
<td>0.703</td>
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<tr>
<td>ASA/ Plavix, n (%)</td>
<td>1629 (87.8%)</td>
<td>290 (87.1%)</td>
<td>1339 (87.9%)</td>
<td>0.712</td>
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</table>
## Clinical History of Matched Sample

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<td>Symptomatic, n (%)</td>
<td>449 (24.2%)</td>
<td>83 (24.9%)</td>
<td>366 (24.0%)</td>
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<td>Urgency</td>
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<td>Elective</td>
<td>1686 (90.8%)</td>
<td>294 (88.3%)</td>
<td>1392 (91.4%)</td>
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<td>Urgent</td>
<td>170 (9.2%)</td>
<td>39 (11.7%)</td>
<td>131 (8.6%)</td>
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<td>Anesthesia, n (%)</td>
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<tr>
<td>Local/ Regional</td>
<td>400 (21.6%)</td>
<td>85 (25.5%)</td>
<td>315 (20.7%)</td>
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<tr>
<td>General</td>
<td>1456 (78.4%)</td>
<td>248 (74.5%)</td>
<td>1208 (79.3%)</td>
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### Operative Characteristics of Matched Sample

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<tr>
<td>Type of Surgery, n (%)</td>
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<tr>
<td>Conventional</td>
<td>1415 (76.3%)</td>
<td>269 (80.8%)</td>
<td>1146 (75.3%)</td>
<td>0.033</td>
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<td>Eversion</td>
<td>440 (23.7%)</td>
<td>64 (19.2%)</td>
<td>376 (24.7%)</td>
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<td>Shunt, n (%)</td>
<td>369 (19.9%)</td>
<td>63 (18.9%)</td>
<td>306 (20.1%)</td>
<td>0.650</td>
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<tr>
<td>Patch, n (%)</td>
<td>1212 (65.3%)</td>
<td>202 (60.7%)</td>
<td>1010 (66.3%)</td>
<td>0.056</td>
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</tbody>
</table>
## Perioperative Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Overall (N=1856)</th>
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<th>No Dextran (N=1523)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or Death, n (%)</td>
<td>13 (0.7%)</td>
<td>4 (1.2%)</td>
<td>9 (0.6%)</td>
<td>0.267</td>
</tr>
<tr>
<td>Myocardial Infarct, n (%)</td>
<td>17 (0.9%)</td>
<td>8 (2.4%)</td>
<td>9 (0.6%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Heart Failure, n (%)</td>
<td>14 (0.8%)</td>
<td>7 (2.1%)</td>
<td>7 (0.5%)</td>
<td>0.006</td>
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<tr>
<td>Hospital Mortality, n (%)</td>
<td>3 (0.2%)</td>
<td>1 (0.3%)</td>
<td>2 (0.1%)</td>
<td>0.448</td>
</tr>
<tr>
<td>Return to OR, n (%)</td>
<td>41 (2.2 %)</td>
<td>7 (2.1%)</td>
<td>32 (2.2%)</td>
<td>0.999</td>
</tr>
<tr>
<td>Bleeding</td>
<td>31 (1.8%)</td>
<td>5 (1.6%)</td>
<td>26 (1.8%)</td>
<td>0.999</td>
</tr>
<tr>
<td>Neurological event</td>
<td>5 (0.3%)</td>
<td>0 (0.0%)</td>
<td>5 (0.4%)</td>
<td>0.591</td>
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</table>
# One-Year Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Overall (N=1856)</th>
<th>Dextran (N=333)</th>
<th>No Dextran (N=1523)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-year Mortality, n (%)</td>
<td>44 (3%)</td>
<td>7 (2.5%)</td>
<td>37 (3.1%)</td>
<td>0.699</td>
</tr>
<tr>
<td>1-year Stroke, n (%)</td>
<td>6 (0.4%)</td>
<td>1 (0.4%)</td>
<td>5 (0.5%)</td>
<td>0.999</td>
</tr>
</tbody>
</table>
**Multivariate Analysis of Matched Sample**

**MI**
- Dextran vs. No Dextran: 5.19 (1.87, 14.43)

**CHF**
- Dextran vs. No Dextran: 5.90 (1.88, 18.49)

**Return to OR**
- Dextran vs. No Dextran: 0.93 (0.40, 2.12)

**Stroke or Death**
- Dextran vs. No Dextran: 2.03 (0.61, 6.73)

**1-year Mortality**
- Dextran vs. No Dextran: 0.74 (0.33, 1.70)
Multivariate Analysis of Unmatched Sample

MI
Dextran vs. No Dextran 3.52(1.62,7.64)

CHF
Dextran vs. No Dextran 5.71(2.35,13.89)

Return to OR
Dextran vs. No Dextran 1.01(0.46,2.20)

Stroke or Death
Dextran vs. No Dextran 1.28(0.45,3.64)

1-year Mortality
Dextran vs. No Dextran 0.78(0.36,1.69)

Adjusted Odds Ratio
Multivariate Analysis
Propensity Score Matched Sample

<table>
<thead>
<tr>
<th>Condition</th>
<th>Group 1 vs. Group 2</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>Dextran vs. No Dextran</td>
<td>4.88 (1.83, 13.03)</td>
</tr>
<tr>
<td>CHF</td>
<td>Dextran vs. No Dextran</td>
<td>8.35 (1.89, 36.97)</td>
</tr>
<tr>
<td>Return to OR</td>
<td>Dextran vs. No Dextran</td>
<td>1.11 (0.48, 2.54)</td>
</tr>
<tr>
<td>Stroke or Death</td>
<td>Dextran vs. No Dextran</td>
<td>1.85 (0.56, 6.06)</td>
</tr>
<tr>
<td>1-year Mortality</td>
<td>Dextran vs. No Dextran</td>
<td>0.59 (0.25, 1.38)</td>
</tr>
</tbody>
</table>
Summary

- Perioperative Dextran during CEA does not affect incidence of perioperative stroke

- Perioperative Dextran use is associated with a higher incidence of myocardial infarct and congestive heart failure
Does conduit type influence the outcomes of lower extremity bypasses at one year?

Donald T. Baril MD¹, Scott Fecteau MD², Philip P. Goodney MD³, James McPhee MD⁴, Andres Schanzer MD¹

1. Division of Vascular and Endovascular Surgery, University of Massachusetts Medical School, Worcester, MA
2. Saint Francis Hospital & Medical Center, Hartford, CT
3. Division of Vascular Surgery Dartmouth Hitchcock Medical Center, Lebanon, NH
4. Division of Vascular Surgery, Brigham and Women’s Hospital, Boston, MA

VSGNE 17th Semi-Annual Meeting
Portland, Maine
November 7, 2011
Introduction

- 4-10% of the U.S. population has PAD
- Treatment paradigms for PAD continue to evolve with increasing use of endovascular therapies
- Gold standard for treatment of symptomatic PAD remains surgical bypass
- Lower extremity bypass (LEB) continues to have a non-negligible rate of early and late failure
# Introduction

- Multiple risk factors associated with LEB failures:
  - Prior failed endovascular intervention
  - Renal dysfunction
  - Female gender
  - Diabetes
  - Poor outflow
  - Prior amputation
  - Conduit
    - Prosthetic
    - Alternative vein
    - Spliced vein
    - Cadaveric vein
Objective

- The purpose of this study is to determine the effect of conduit type used in lower extremity bypasses
  - Short term outcomes
  - Long-term outcomes

- Primary end-points:
  - Primary patency, primary-assisted and secondary patency at one-year post-operatively
  - Limb salvage at one-year post-operatively
Methods - Database

- Retrospective analysis of patients undergoing infrainguinal bypass grafts between January 1, 2003 and December 31, 2009

- 12 centers which are members of VSGNE
Study group

- Patients undergoing LEB for CLI
  - Indication = rest pain or tissue loss

- Infrapopliteal target
  - BK popliteal
  - TP trunk
  - Anterior tibial
  - Posterior tibial
  - Peroneal
  - DP ankle
  - PT ankle
Study group

2768 lower extremity bypasses

1779 (64%) Single segment GSV

701 (25.3%) Prosthetic (PTFE or Dacron)

153 (5.5%) Spliced vein

77 (2.8%) Alternative vein (single piece cephalic, basilic, or SSV)

58 (2.1%) Cadaveric vein
## Patient demographics

<table>
<thead>
<tr>
<th></th>
<th>Single segment GSV (1779)</th>
<th>Alternative Vein (77)</th>
<th>Spliced vein (153)</th>
<th>Prosthetic (701)</th>
<th>Cadaveric vein (58)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ±SD)</td>
<td>68.1±11.8</td>
<td>70.4±9.8</td>
<td>69.2±12.1</td>
<td>68.8±11.1</td>
<td>74.3±9.3</td>
<td>0.0005</td>
</tr>
<tr>
<td>Male gender</td>
<td>72.6</td>
<td>80.5</td>
<td>66.7</td>
<td>64.2</td>
<td>63.8</td>
<td>0.0001</td>
</tr>
<tr>
<td>CAD (%)</td>
<td>32.6</td>
<td>52.0</td>
<td>49.0</td>
<td>42.7</td>
<td>51.7</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>COPD (%)</td>
<td>26.0</td>
<td>27.3</td>
<td>29.4</td>
<td>37.5</td>
<td>34.5</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>84.0</td>
<td>96.1</td>
<td>91.5</td>
<td>88.0</td>
<td>93.1</td>
<td>0.007</td>
</tr>
<tr>
<td>Tobacco use (%)</td>
<td>55.5</td>
<td>33.8</td>
<td>50.3</td>
<td>55.4</td>
<td>44.8</td>
<td>0.002</td>
</tr>
<tr>
<td>Prior ipsilateral bypass (%)</td>
<td>7.7</td>
<td>31.2</td>
<td>20.9</td>
<td>15.1</td>
<td>58.6</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Prior ipsilateral PVI (%)</td>
<td>16.6</td>
<td>24.7</td>
<td>24.8</td>
<td>20.4</td>
<td>25.9</td>
<td>0.007</td>
</tr>
<tr>
<td>Prior major amputation (%)</td>
<td>4.2</td>
<td>3.9</td>
<td>5.9</td>
<td>3.9</td>
<td>8.6</td>
<td>0.427</td>
</tr>
<tr>
<td>Graft target</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below knee popliteal (%)</td>
<td>49.2</td>
<td>23.2</td>
<td>21.1</td>
<td>75.2</td>
<td>13.0</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Tibial (%)</td>
<td>50.8</td>
<td>76.8</td>
<td>78.9</td>
<td>24.8</td>
<td>87.0</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
Primary patency

[Graph showing primary patency over time for different types of vein grafts, with statistical significance indicated by P<0.0001]
Primary patency – GSV vs. alternative vein

- GSV: 72.4% at one year
- Alternative vein: 67.1% at one year

P = 0.386
Primary patency – GSV vs. spliced vein

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Primary patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>365</td>
<td>GSV: 72.4% at one year</td>
</tr>
<tr>
<td></td>
<td>Spliced vein: 54.1% at one year</td>
</tr>
</tbody>
</table>

P < 0.0001
Primary patency – GSV vs. prosthetic

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Primary patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GSV 72.4% at one year</td>
</tr>
</tbody>
</table>

\[ P = 0.044 \]
Primary patency – GSV vs. cadaveric vein

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Primary patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.00 (GSV)</td>
</tr>
<tr>
<td>50</td>
<td>0.90 (GSV)</td>
</tr>
<tr>
<td>100</td>
<td>0.80 (GSV)</td>
</tr>
<tr>
<td>150</td>
<td>0.70 (GSV)</td>
</tr>
<tr>
<td>200</td>
<td>0.60 (GSV)</td>
</tr>
<tr>
<td>250</td>
<td>0.50 (GSV)</td>
</tr>
<tr>
<td>300</td>
<td>0.40 (GSV)</td>
</tr>
<tr>
<td>350</td>
<td>0.30 (GSV)</td>
</tr>
<tr>
<td>400</td>
<td>0.20 (GSV)</td>
</tr>
</tbody>
</table>

- GSV: 72.4% at one year
- Cadaveric vein: 51.7% at one year

P < 0.0001
Primary-assisted patency

- GSV
- Prosthetic
- Alternative vein
- Spliced vein
- Cadaveric vein

P<0.0001
Secondary patency

- GSV
- Prosthetic
- Alternative vein
- Spliced vein
- Cadaveric vein

P < 0.0001
Amputation-free survival – GSV vs. alternative vein

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Primary patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GSV</td>
</tr>
<tr>
<td></td>
<td>92.3% at one year</td>
</tr>
<tr>
<td></td>
<td>Alternative vein</td>
</tr>
<tr>
<td></td>
<td>89.0% at one year</td>
</tr>
<tr>
<td></td>
<td>P=0.591</td>
</tr>
</tbody>
</table>
Amputation-free survival – GSV vs. spliced vein

Primary patency (%)

GSV 92.3% at one year
Spliced vein 75.7% at one year  P<0.0001
Amputation-free survival – GSV vs. prosthetic

Primary patency (%)

- **GSV**
  - 92.3% at one year

- **Prosthetic**
  - 92.0% at one year

*P*= 0.037
Amputation-free survival – GSV vs. cadaveric vein

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>GSV</th>
<th>92.3% at one year</th>
<th>Cadaveric vein</th>
<th>65.5% at one year</th>
<th>P&lt;0.0001</th>
</tr>
</thead>
</table>

Primary patency (%)
## Predictors of loss of primary patency

<table>
<thead>
<tr>
<th>Predictor</th>
<th>HR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadaveric vein conduit</td>
<td>2.44</td>
<td>1.37-4.35</td>
<td>0.015</td>
</tr>
<tr>
<td>Spliced vein conduit</td>
<td>2.38</td>
<td>1.61-3.53</td>
<td>0.0013</td>
</tr>
<tr>
<td>Prior contralateral major amputation</td>
<td>2.32</td>
<td>1.51-3.57</td>
<td>0.0001</td>
</tr>
<tr>
<td>Prior ipsilateral bypass</td>
<td>1.55</td>
<td>1.17-2.04</td>
<td>0.0020</td>
</tr>
<tr>
<td>Female gender</td>
<td>1.28</td>
<td>1.04-1.57</td>
<td>0.0184</td>
</tr>
<tr>
<td>Prosthetic conduit</td>
<td>0.71</td>
<td>0.56-0.91</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
# Predictors of limb loss

<table>
<thead>
<tr>
<th>Predictor</th>
<th>HR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior contralateral major amputation</td>
<td>4.44</td>
<td>2.50-7.88</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Cadaveric vein conduit</td>
<td>3.34</td>
<td>1.47-7.59</td>
<td>0.045</td>
</tr>
<tr>
<td>Spliced vein conduit</td>
<td>3.33</td>
<td>1.70-6.53</td>
<td>0.019</td>
</tr>
<tr>
<td>Hemodialysis dependence</td>
<td>3.02</td>
<td>1.71-5.34</td>
<td>0.0001</td>
</tr>
<tr>
<td>Prior ipsilateral bypass</td>
<td>2.20</td>
<td>1.34-3.58</td>
<td>0.0017</td>
</tr>
<tr>
<td>IDDM</td>
<td>1.52</td>
<td>1.01-2.28</td>
<td>0.0448</td>
</tr>
</tbody>
</table>
Discussion – Primary patency

- At one year, no difference in primary patency rates between GSV and prosthetic conduit.

- Both GSV and prosthetic conduits have higher primary patency rates at one year compared to alternative vein, spliced vein, and cadaveric vein conduits.
Discussion - Secondary patency

- At one year, no difference in secondary patency rates between GSV, alternative vein, and prosthetic conduit

- Both GSV and prosthetic conduits have higher secondary patency rates at one year compared to spliced vein and cadaveric vein conduit
Discussion – Limb salvage

- At one year, LEBs performed with GSV have higher rates of limb salvage compared to LEBs performed with prosthetic, alternative vein, spliced vein, and cadaveric vein conduits.
Discussion

- In the short term, prosthetic seems to outperform alternative and cadaveric vein conduits
  - How do we reconcile this?
  - Is this clinically meaningful?

- With regards to vein conduits, to maintain patency, some initial extra work may be necessary to achieve what will probably be improved durability
Next steps

- Assess if prosthetic conduit truly has higher primary patency rates at 1 year compared to GSV

- Analyze data by target vessel
  - Determine if success of prosthetic conduit is due to BK popliteal target vs. tibial target

- Look at more extended follow-up
Completion Imaging after Lower Extremity Bypass: Is Routine Use Justified?

Tze-Woei Tan, Jeffrey Kalish, Naomi Hamburg, Robert Eberhardt, Denis Rybin, Gheorge Doros, Andres Schanzer, Jack Cronenwett, Alik Farber

On behalf of the Vascular Study Group of New England
Background

- Completion Imaging (Angiography or Duplex) after lower extremity bypass (LEB)
  - allows for identification and timely correction of technical problems. May lead to improved patency.
  - Is associated with increased operative time, resource utilization, and risk for unnecessary surgical re-exploration.

- Selective use is indisputable
- Routine use is controversial
Objectives

1. To study the effect of completion imaging use after LEB

2. To compare the strategy of **routine** use of completion imaging with **selective** use
Methods

- Patient outcome analyses
  1. based on whether or not a completion study was performed after LEB
  2. based on surgeon completion study strategy
     - Surgeons were defined as Routine or Selective users of completion studies
     - Patient cohort grouped according to whether the procedure was performed by a Routine or Selective user
Sample Selection

VSGNE LEB Cohort
2003 to 2010

Exclude:
- Acute ischemia, asymptomatic, missing indication
- Bilateral, concomitant procedure
- Died at discharge
- Missing discharge patency
- Surgeon < 10 cases

Completion study
- Arteriogram 89%
- Duplex 11%

3554 LEB
71 Surgeon

2032 LEB
48 Surgeon

Completion
1368 LEB
(67.3%)

None
664 LEB
(32.7%)
# Demographic Characteristics of Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N=2032)</th>
<th>Completion (N=1368)</th>
<th>None (N=664)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1386 (68.2%)</td>
<td>936 (68.4%)</td>
<td>450 (67.8%)</td>
<td>0.800</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1999 (99.1%)</td>
<td>1347 (99.3%)</td>
<td>652 (98.6%)</td>
<td>0.133</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>68.2±11.9</td>
<td>68.5±12.0</td>
<td>67.5±11.8</td>
<td>0.076</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>1064 (52.4%)</td>
<td>742 (54.2%)</td>
<td>322 (48.5%)</td>
<td>0.016</td>
</tr>
<tr>
<td>CAD, n (%)</td>
<td>768 (37.8%)</td>
<td>527 (38.5%)</td>
<td>241 (36.4%)</td>
<td>0.380</td>
</tr>
<tr>
<td>Dialysis, n (%)</td>
<td>157 (7.7%)</td>
<td>121 (8.8%)</td>
<td>36 (5.4%)</td>
<td>0.011</td>
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</tbody>
</table>
## Clinical Characteristics of Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N=2032)</th>
<th>Completion (N=1368)</th>
<th>None (N=664)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Claudication</td>
<td>544 (26.8%)</td>
<td>340 (24.9%)</td>
<td>204 (30.7%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Rest Pain</td>
<td>515 (25.3%)</td>
<td>336 (24.6%)</td>
<td>179 (27.0%)</td>
<td></td>
</tr>
<tr>
<td>Tissue Loss</td>
<td>973 (47.9%)</td>
<td>692 (50.6%)</td>
<td>281 (42.3%)</td>
<td></td>
</tr>
<tr>
<td>Previous Bypass, n (%)</td>
<td>657 (32.3%)</td>
<td>445 (32.5%)</td>
<td>212 (31.9%)</td>
<td>0.801</td>
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<tr>
<td>Urgency, n (%)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>1673 (82.3%)</td>
<td>1150 (84.1%)</td>
<td>523 (78.8%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Urgent</td>
<td>345 (17.0%)</td>
<td>213 (15.6%)</td>
<td>132 (19.9%)</td>
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</table>
## Operative Characteristics of Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N=2032)</th>
<th>Completion (N=1368)</th>
<th>None (N=664)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Graft Origin, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFA/ Profunda/ SFA</td>
<td>1767 (88.8%)</td>
<td>1209 (89.6%)</td>
<td>558 (87.2%)</td>
<td>0.110</td>
</tr>
<tr>
<td>AK Pop/BK Pop/Tibial</td>
<td>222 (11.2%)</td>
<td>140 (10.4%)</td>
<td>82 (12.8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Graft Recipient, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AK Pop/BK Pop</td>
<td>1132 (55.8%)</td>
<td>688 (50.3%)</td>
<td>444 (67.1%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>TP Trunk/AT/PT/Peroneal/ DP Ankle/ PT Ankle/</td>
<td>898 (44.2%)</td>
<td>680 (49.7%)</td>
<td>218 (32.9%)</td>
<td></td>
</tr>
<tr>
<td>Tarsal/ Plantar</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Graft Type, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GSV</td>
<td>1364 (67.1%)</td>
<td>979 (71.6%)</td>
<td>385 (58.0%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Prosthetic</td>
<td>507 (25.0%)</td>
<td>264 (19.3%)</td>
<td>243 (36.6%)</td>
<td></td>
</tr>
</tbody>
</table>
Results

- Discharge: Completion vs. No Completion (p=0.999)
- 1-year Followup: Completion vs. No Completion (p=0.225)

- Graph: Primary Patency over Follow-up (days) with trends for Completion and No Completion (p=0.717)
# Multivariate Analyses of Patient Outcomes

<table>
<thead>
<tr>
<th>Completion vs. No Completion</th>
<th>*Adjusted Estimate</th>
<th>95% Lower CI</th>
<th>95% Upper CI</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge Patency</td>
<td>1.11</td>
<td>0.72</td>
<td>1.70</td>
<td>0.640</td>
</tr>
<tr>
<td>One-year Patency</td>
<td>1.02</td>
<td>0.77</td>
<td>1.35</td>
<td>0.883</td>
</tr>
<tr>
<td>Patency Loss Hazard</td>
<td>0.87</td>
<td>0.65</td>
<td>1.14</td>
<td>0.303</td>
</tr>
</tbody>
</table>

*Adjusted for age, hypertension, indication for surgery (claudication vs. tissue lost), graft origin, graft recipient, graft type
Summary

- No significant difference in patient outcomes based on whether or not a completion study was performed
Surgeon Completion Study Strategy
(Routine vs. Selective)
**Methods**

- Outcomes of surgeons based on routine or selective use of completion studies
  - Routine Completers ($\geq 80\%$ studies)
  - Selective Completers ($< 80\%$ studies)
- Surgeons queried to disclose their completion study strategy
  - Electronic survey (5 questions)
Sample Selection

VSGNE LEB Cohort
2003 to 2010

Exclude:
- Acute ischemia, asymptomatic, missing indication
- Bilateral, concomitant procedure
- Died at discharge
- Missing discharge patency
- Surgeon < 10 cases

Completion study

3554 LEB
71 Surgeon

2032 LEB
48 Surgeon

Routine Completers
16 surgeons
1076 LEB (36.7%)

Selective Completers
32 Surgeons
1860 LEB (63.4%)
# Operative Characteristics of Patients Treated by Routine vs. Selective Completers

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Routine Completers (N=16)</th>
<th>Selective Completers (N=32)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon Caseload</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-20</td>
<td>5 (31.3%)</td>
<td>8 (25%)</td>
<td>0.454</td>
</tr>
<tr>
<td>21-50</td>
<td>4 (25%)</td>
<td>12 (37.5%)</td>
<td></td>
</tr>
<tr>
<td>51-100</td>
<td>3 (18.8%)</td>
<td>9 (28.1%)</td>
<td></td>
</tr>
<tr>
<td>&gt;100</td>
<td>4 (25%)</td>
<td>3 (9.4%)</td>
<td></td>
</tr>
</tbody>
</table>
## Clinical Characteristics of Patients Treated by Routine vs. Selective Completers

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Routine Completers (N=792)</th>
<th>Selective Completers (N=1240)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Claudication</td>
<td>211 (26.6%)</td>
<td>333 (26.9%)</td>
<td>0.341</td>
</tr>
<tr>
<td>Rest Pain/Tissue Loss</td>
<td>581 (73.3%)</td>
<td>907 (73.2%)</td>
<td></td>
</tr>
<tr>
<td>Graft Origin, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFA/Profunda/SFA</td>
<td>687 (89.5%)</td>
<td>1080 (88.5%)</td>
<td>0.511</td>
</tr>
<tr>
<td>AK Pop/ BK Pop/ Tibial</td>
<td>81 (10.5%)</td>
<td>141 (11.5%)</td>
<td></td>
</tr>
<tr>
<td>Graft Recipient, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AK Pop/ BK Pop</td>
<td>423 (53.5%)</td>
<td>709 (57.2%)</td>
<td>0.099</td>
</tr>
<tr>
<td>TP Trunk/Tibial/Tarsal/Plantar</td>
<td>368 (46.5%)</td>
<td>530 (42.8%)</td>
<td></td>
</tr>
<tr>
<td>Graft Vein Type, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GSV</td>
<td>547 (69.1%)</td>
<td>817 (65.9%)</td>
<td>0.028</td>
</tr>
</tbody>
</table>
## Multivariate Analyses: Patient Outcomes based on Surgeon Completion Strategy (Routine vs. Selective Completers)

<table>
<thead>
<tr>
<th></th>
<th>Adjusted Estimate*</th>
<th>95% Lower CI</th>
<th>95% Upper CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge Patency</td>
<td>0.82</td>
<td>0.59</td>
<td>1.13</td>
<td>0.309</td>
</tr>
<tr>
<td>One-year Patency</td>
<td>1.07</td>
<td>0.91</td>
<td>1.23</td>
<td>0.556</td>
</tr>
</tbody>
</table>

*Adjusted for: Indication for surgery, Smoking, Graft origin, Graft recipient, Graft type
Summary

- No significant difference in outcomes of surgeons based on their completion study strategy
## Concordance of Survey and Actual Practice

<table>
<thead>
<tr>
<th>Reported Completion</th>
<th>Actual Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 80%</td>
</tr>
<tr>
<td><strong>All Surgeons</strong></td>
<td></td>
</tr>
<tr>
<td>Routine</td>
<td>14</td>
</tr>
<tr>
<td>Selective</td>
<td>8</td>
</tr>
<tr>
<td><strong>Surgeon who did not change practice</strong></td>
<td></td>
</tr>
<tr>
<td>Routine</td>
<td>10</td>
</tr>
<tr>
<td>Selective</td>
<td>3</td>
</tr>
</tbody>
</table>
Conclusion

- No clear advantage of performing routine completion study after LEB
- Surgeons overestimated their completion study utilization
Regional Variation In Length of Stay
Variation Among Centers

Patients with Post-op Complications

Operation:

- EVAR
- OPEN
- LEB
- CEA

Percentage of Patients with Complications

Cx: MI, CHF, Dysrhythmia, Pulmonary, Renal, Wound, Ischemia, Bleeding, Stroke, Major Amputation
Complications and Post-op Length of Stay

Complications:

- MI
- CHF
- Dysrhythmia
- Pulmonary
- Renal
- Wound
- Ischemia
- Bleeding
- Stroke
- Major Amputation

LOS: Operation date to discharge date

Cx: MI, CHF, Dysrhythmia, Pulmonary, Renal, Wound, Ischemia, Bleeding, Stroke, Major Amputation
Next Meeting

- **Date:** Monday, May 7th
- **Location:** Beth Israel Deaconess, Boston
- **Time:** 10 am – 4 pm