Vascular Study Group of New England

19th Semi-Annual Meeting

October 25, 2012
Dartmouth-Hitchcock Medical Center, Lebanon, NH
Guests from Outside New England

- Cadence Physician Group, Illinois
  - Joseph Schneider, MD
- Henry Ford Hospital, Michigan
  - Alexander Shepherd, MD
- Methodist Hospital, Texas
  - Mark Davies, MD
- Stanford University, California
  - Ronald Dalman, MD
- Toronto General Hospital, Ontario
  - Graham Roche-Nagel, MD
VSGNE Administrative Support

- Dawn Morrell (M2S)

- support@vsgne.org
David B. Pilcher, M.D.
1934 - 2012

The University of Vermont
Department of Surgery
COLLEGE OF MEDICINE
&
Fletcher Allen Health Care

Remembers

David B. Pilcher, MD
May 11, 1934 - September 4, 2012

David Bogart Pilcher, MD, vascular surgeon and Professor of Surgery at the University of Vermont College of Medicine, dearly loved his craft, his family and Vermont.

Memorial Rounds
Saturday, October 6, 2012
10:00 am - 11:30 am
Davis Auditorium

A light breakfast will be served.
Update on VSGNE and SVS VQI
>29,000 Procedures Reported

CEA, CAS, oAAA, EVAR, LEB, PVI, TEVAR, Access
Organized Regional Groups:
- New England
- Carolinas
- Florida-Georgia
- Southern California
- South
- Virginias
- New York City
- Rocky Mountains
- Illinois
- Wisconsin
- Mid-Atlantic

Organizing Regional Groups:
- Upstate New York
- Indiana
- Chesapeake Valley
- Northern California
- Michigan
- Missouri
- Ohio
- Tennessee/Mississippi
- Minnesota

11 Regional Quality Groups
### Total Procedures Captured (as of September 30, 2012)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid Endarterectomy</td>
<td>18,098</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>2,086</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>6,548</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>3,252</td>
</tr>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>17,637</td>
</tr>
<tr>
<td>Infra-Inguinal Bypass</td>
<td>9,819</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
<td>2,554</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>586</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>1,858</td>
</tr>
</tbody>
</table>

**Vascular Quality Initiative (VQI) Monthly Procedure Volume**

[Graph showing monthly procedure volume from Jan 11 to Sep 12]
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
### CMS Physician Quality Reporting System

<table>
<thead>
<tr>
<th>Year</th>
<th>Bonus</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>2.0%</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>1.5%</td>
<td></td>
</tr>
<tr>
<td>2012-2014</td>
<td>0.5%</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>(Based on 2013 data)</td>
<td>1.5%</td>
</tr>
<tr>
<td>2016 +</td>
<td></td>
<td>2.0%</td>
</tr>
</tbody>
</table>

% of all Medicare Part B claims

Data submitted to M2S for SVS VQI was submitted to CMS for PQRS for 24 VSGNE physicians last year.
• Select Variables of Interest for Analysis
• Add Filters to Select Down the Population of Interest
- Benchmark Results With All Other VQI Participants

### Analytics & Reporting Engine

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>My Results (N=99)</th>
<th>All VQI Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>100.0% (69)</td>
<td>100.0% (187)</td>
</tr>
<tr>
<td>Female</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Missing Value</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>135.2 ± 67.4 (18.0 - 238.0)</td>
<td>132.8 ± 72.5 (18.0 - 273.0)</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>20.3% (19)</td>
<td>14.4% (27)</td>
</tr>
<tr>
<td>Prior (1yr)</td>
<td>40.5% (23)</td>
<td>47.6% (33)</td>
</tr>
<tr>
<td>Current (within y)</td>
<td>39.1% (27)</td>
<td>37.4% (30)</td>
</tr>
<tr>
<td>Missing Value</td>
<td>0% (0)</td>
<td>0.5% (1)</td>
</tr>
<tr>
<td>Creatinine (mg/dl)</td>
<td>1.5 ± 2.0 (0.6 - 14.0)</td>
<td>1.4 ± 1.8 (0.58 - 14.0)</td>
</tr>
<tr>
<td>Urgency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>95.5% (92)</td>
<td>88.9% (199)</td>
</tr>
<tr>
<td>Urgent</td>
<td>13.0% (12)</td>
<td>10.2% (19)</td>
</tr>
<tr>
<td>Emergent</td>
<td>1.1% (1)</td>
<td>1.1% (1)</td>
</tr>
</tbody>
</table>
Vascular Quality Initiative®

Analytics & Reporting Engine

- Download Tabular Report and PDF File
2010-2011 VSGNE Data Audit
Current Status

Site Participation

- 27 sites in VSGNE entered data 2010-2011
  - 93% of sites have submitted CPT claims data
  - 88% of sites have received feedback files
  - 64% of sites have completed their analysis

Validation Analysis

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exact Matches</td>
<td>66%</td>
</tr>
<tr>
<td>Corrected in Claims</td>
<td>9%</td>
</tr>
<tr>
<td>Corrected in VQI</td>
<td>3%</td>
</tr>
<tr>
<td>Properly excluded from VQI</td>
<td>7%</td>
</tr>
<tr>
<td>Procedure Added in VQI</td>
<td>6%</td>
</tr>
<tr>
<td>In VQI, Not in Claims</td>
<td>9%</td>
</tr>
</tbody>
</table>
Physician Characteristics in VQI

- SVS PSO voted to collect physician demographic data for de-identified analysis
  - Board certification type
  - Number of years in practice
  - National Provider Identifier (NPI number)

- This information needs to be entered by data manager at each site
% Physician Characteristics Complete by VQI Region

National Provider Identifier, Board Certifications, and First Year in Practice
Integrating Cost with Quality in AAA Repair

Stanley/Jones

10/25/12
Agenda

Predictive Algorithms

News from the Field, New Findings

Background

FUTURE

PRESENT

PAST
The Past

Background
GLOBAL HEALTH ECONOMICS UNIT

- Marion Couch, MD, PhD, MBA, Interim Chair, Department of Surgery
- Richard Galbraith, MD, PhD, Director, Center for Clinical and Translational Science
  - Christopher Jones, D.Phil, Director
  - Richie Spitsberg, MSc, Information Technology Assistant/Programmer
  - Robert Everett, Jr., PhD, Visiting Professor
  - New Hire, Assistant Professor, Health Economics
  - Ellen Dimick, Coordinator
  - Caroline Rudisill, PhD, MSc, Affiliated
  - Jeffrey Petrozzino, MD, PhD, Consultant
C. Jones, Research Background

Masters in Biology (Oxford)
Doctorate in Health Economics (Oxford)
Post-doc (NICE & Johns Hopkins)
Director, Health Economics (Aequitas)
Director, Global Health Economics (CSLB)
Founder, HERCELUX (Luxembourg)
Board Membership, ICER-CEPAC & ECIPE

Emergent anticoagulant reversal
• PCCs vs. FFP (next slide)
Cost of Anticoagulant Reversal

- Grant Funded
- Collaboration with London School of Economics (LSE)
- Evaluating costs surrounding anticoagulant reversal in FAHC/Vermont/New England
- Access to Vermont Healthcare Claims Uniform Reporting and Evaluation (VHCURES) data
The authors note two limitations:
1. Probability of second hemorrhage not included
2. Probability of mortality over long term not included.

Costs were not identified after the first year or outside of the hospital setting except rehabilitation costs following intracranial hemorrhage (IH).

The model does not take into account how quickly the first reversal is administered and how quickly complete reversal is reached.

Outcomes of failed reversal (24 hours uncorrected) based on bleed type not included.

The setting is in the emergency room (accident & emergency) but the same question could possibly be asked in alternative relevant settings (e.g. during cardiac surgery).
Option 1 – Includes more detail on stroke outcomes.

- Ordering of renal failure and stroke to be discussed based on clinical perspective and data.
- Does not include 90 day mortality.
- For FFP, the majority of data is from Menzin et al. 2011; Menzin et al. 2010.
- Major missing piece is stroke outcomes data for FFP or some way of capturing hematoma growth rates – this may make this option unworkable.

Note: this mapping assumes renal failure is acute.
Factors associated with failure to correct the international normalised ratio following fresh frozen plasma administration among patients treated for warfarin-related major bleeding

An analysis of electronic health records

Joseph Menzin¹; Leigh Ann White¹; Mark Friedman¹; Christine Nichols¹; Jordan Menzin¹; Jan Hoesche²; Garrett E. Bergman²; Christopher Jones³

¹Boston Health Economics, Inc., Waltham, Massachusetts, USA; ²CSL Behring, King of Prussia, Pennsylvania, USA

Failure to correct International Normalized Ratio and mortality among patients with warfarin-related major bleeding: an analysis of electronic health records

J. MENZIN,* J. HOESCHE,† M. FRIEDMAN,* C. NICHOLS,* G. E. BERGMAN,† M. CROWTHER,‡ D. GARCIA§ and C. JONES†

*Outcomes Research, Boston Health Economics, Inc., Waltham, MA; †Global Health Economics, CSL Behring, King of Prussia, PA, USA; ‡St Joseph’s Hospital, McMaster University Faculty of Health Sciences, Hamilton, ON, Canada; and §Department of Internal Medicine, University of New Mexico Health Sciences Center, University of New Mexico, Albuquerque, NM, USA
The Field Has Grown

News from the Field – Health Econ
# Health Economic Publications

1969-2010

Over 35k health economics articles to date & over 1k per year!

Top 150 title words in 1980s

Note: The starting point was our database of 33,000 publications in EconLit with a health JEL code. The relative sizes of the title words reflect the frequency of their occurrence. The words “health,” “care,” “economic” and “analysis” have been removed, as have common words such as “the”, “and”, etc.
Top 150 title words in 2000s

Note: The starting point was our database of 33,000 publications in EconLit with a health JEL code. The relative sizes of the title words reflect the frequency of their occurrence. The words “health”, “cure”, “economic” and “analysis” have been removed, as have common words such as “the”, “and”, etc.
Country focus on health economic articles

Key Methods

Cost-effectiveness (cost/effect)
Cost-utility (cost/QALY)
Cost-benefit ($ only)
Nature of an Economic Evaluation

New Intervention

Target Group

Alternative Intervention

Impact on health status
- i. Survival
- ii. Quality of Life

Impact on costs
- i. Hospitalizations
- ii. Pharmaceuticals
- iii. Procedures
- iv. Patient costs
- v. Community health care

Impact on health status
- i. Survival
- ii. Quality of Life

Impact on costs
- i. Hospitalizations
- ii. Pharmaceuticals
- iii. Procedures
- iv. Patient costs
- v. Community health care
The diagram illustrates the cost-effectiveness of new treatments compared to existing ones. The maximum acceptable incremental cost-effectiveness ratio is shown on the vertical axis, with 'north west' indicating existing treatment dominates and 'south east' indicating new treatment less costly but less effective.

- **North west**: Existing treatment dominates.
- **South west**: New treatment less costly but less effective.
- **North east**: New treatment more effective but more costly.
- **South east**: New treatment more effective and less costly.

The center (C) of the diagram represents the break-even point where the incremental cost-effectiveness ratio is acceptable.
# Basic Exercise: Calculation of Cost Effectiveness

<table>
<thead>
<tr>
<th>Treatment alternatives</th>
<th>Cost</th>
<th>Life expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>b</td>
<td>$20,000</td>
<td>4.5 years</td>
</tr>
<tr>
<td>a</td>
<td>$10,000</td>
<td>3.5 years</td>
</tr>
</tbody>
</table>

Incremental cost-effectiveness ratio = \((C_b - C_a)/(B_b - B_a)\), where \(C\) = cost and \(B\) = benefit
## Basic Exercise: Calculation of Cost Effectiveness

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<tr>
<td>a</td>
<td>$10,000</td>
<td>3.5 years</td>
</tr>
</tbody>
</table>

**Incremental cost-effectiveness ratio** =

Addl $10k / 1 addl year of life = $10k/LYG
What are Quality Adjusted Life Years (QALYs)?

• Method of placing a value on both mortality and morbidity to facilitate combination into one measure of benefit

• Life years weighted by patient’s quality of life

• Quality of life expressed in terms of a utility score: score between 0 (= death) and 1 (= perfect health)
# Basic Exercise:
## Calculation of Cost Utility

<table>
<thead>
<tr>
<th>Treatment Alternatives</th>
<th>Cost</th>
<th>Life expectancy</th>
<th>Utility (QoL)</th>
<th>QALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>b</td>
<td>$20,000</td>
<td>4.5 years</td>
<td>0.8</td>
<td>3.6</td>
</tr>
<tr>
<td>a</td>
<td>$10,000</td>
<td>3.5 years</td>
<td>0.9</td>
<td>3.15</td>
</tr>
</tbody>
</table>

Incremental cost-utility ratio = $(C_b - C_a)/(B_b - B_a)$, C = cost and B = benefit
### Basic Exercise: Calculation of Cost Utility

<table>
<thead>
<tr>
<th>Treatment Alternatives</th>
<th>Cost</th>
<th>Life expectancy</th>
<th>Utility (QoL)</th>
<th>QALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>b</td>
<td>$20,000</td>
<td>4.5 years</td>
<td>0.8</td>
<td>3.6</td>
</tr>
<tr>
<td>a</td>
<td>$10,000</td>
<td>3.5 years</td>
<td>0.9</td>
<td>3.15</td>
</tr>
</tbody>
</table>

**Incremental cost-utility ratio = Addl. $10k / addl. 0.45 QALYs gained = $22,222/QALY gained**
Policy thinking...

Quality = Outcomes / Cost
Health economics thinking...

Incremental Cost-effectiveness Ratio (ICER) = Cost/Improved Outcome at a Reasonable Willingness to Pay (WTP)
The Field Has Grown

News from the Field – Surgery
Economy of the Times

• Value as well as quality are demands of the times.
  – Focus of VSG NE thus far has been centered around quality / avoidance of complications.
  – Here we are looking to integrate cost into our clinical thinking.
Physician As Leader/Manager

- **Evaluate work product of Division**
  - Financial evaluation-profitability
    - Lab value
    - Clinic Staffing
    - Professional billing
  - Budget here is around 4 million

- **Vascular Surgical in patient budgetary approximate $20 mill.**
  - Oversight of cost is largely admin function.
  - Little admin-clinician interaction on economy/strategies of the service line (vascular surgical patients)
    - Staffing
    - ICU availability
    - Contracting for devices.
Division Head

• Evaluate work product of Division
  – RVU-work/doc
  – Financial evaluation-profitability
    • Lab value
      – Techs
      – Study frequencies/reimbursement
    • Clinic Staffing
      – Mid-levels
      – Admin/secretarial help
  – Budget here is around 4 million
Hospital Budgets

• Vascular Surgical in patient budgetary approximate $20 mill.
  – Oversight of cost is largely admin function.
  – Little admin-clinician agreement on economy of the service line.
    • Staffing
    • ICU availability
    • Contracting for devices.
The Present

New Findings
Open vs. EVAR – 8 years

- Timeframe 2003-2011
- VSGNE data comprising 5,199 patients
- Focused on 389 FAHC patients only
- Cost data provided by FAHC
FAHC Total Costs

• Total Cost = Direct Cost + Indirect Cost

• Direct Costs
  • OR, labs, SICU, supply costs, etc.
  • Billed Supplies are typically assessed by working backwards from mark-up strategies

• Indirect Costs
  • Facilities and housekeeping by sq. ft., human resources by number of employees, etc.
  • Assigned through a reciprocal allocation method
• Most EVAR patients have a 1-2 day LOS
• Most Open patients require 5-8 days LOS
• Median costs of EVAR is appx. $10k more expensive than Open AAA Repair on the average

• n=159 for Endo
• n=230 for Open
Direct Cost vs. LOS

Direct Costs for EVAR and Open AAA Repair Patients Based on LOS

- **EVAR**
- **Open**

- **Linear (EVAR)**
- **Linear (Open)**

**Axes:**
- **Y-axis:** Direct Cost (in $)
- **X-axis:** Length of Stay (in days)

**Data Analysis:**
- The scatter plot shows the direct costs for EVAR and Open AAA repair patients categorized by their length of stay.
- The linear regression lines indicate the trend in costs based on the length of stay for both procedures.

**Insight:**
- The costs increase with the length of stay for both EVAR and Open procedures, with EVAR showing a potentially steeper rise in costs.
Indirect Cost vs. LOS

Indirect Costs for EVAR and Open AAA Repair Patients Based on LOS

Length of Stay

Indirect Cost
Total Cost vs. LOS

Total Costs for EVAR and Open AAA Repair Patients Based on LOS

- **EVAR**
- **Open**

Length of Stay

Total Cost

- $0
- $10,000
- $20,000
- $30,000
- $40,000
- $50,000
- $60,000
- $70,000
Statistically Significant Predictors

• Upper Quartile Costs for **Open Patients**
  – Ejection Fraction 30-50%
  – COPD on meds
  – Previous Bypass Patients
  – **Transfer**
  – Age (Mean age in UQ 72.6. Quartiles 1-3 mean age of 68.9)

• Upper Quartile Costs for **EVAR Patients**
  – Presence of Iliac Aneurysms
  – CABG/PTCA < 5 years ago
  – Ejection Fraction < 30%
  – Creatinine (Mean of 1.21 mg/dl)
### Of Upper Quartile Cost

#### Open Upper

<table>
<thead>
<tr>
<th>Preop Variable</th>
<th>Upper Quartile</th>
<th>N (level)</th>
<th>(no., %)</th>
<th>p-value</th>
<th>Odds Ratio OR 95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EF</td>
<td></td>
<td></td>
<td></td>
<td>0.21</td>
<td></td>
</tr>
<tr>
<td>Not done / unknown</td>
<td></td>
<td>23</td>
<td>6 (26.1)</td>
<td>0.73</td>
<td>1.19 0.44 - 3.22</td>
</tr>
<tr>
<td>&lt;= 30%</td>
<td></td>
<td>4</td>
<td>1 (25.0)</td>
<td>0.92</td>
<td>1.13 0.11 - 11.12</td>
</tr>
<tr>
<td>30-50%</td>
<td></td>
<td>23</td>
<td>10 (43.5)</td>
<td>0.04</td>
<td>2.60 1.06 - 6.37</td>
</tr>
<tr>
<td>&gt;= 50% (reference level)</td>
<td></td>
<td>175</td>
<td>40 (22.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td></td>
<td></td>
<td></td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
<td>170</td>
<td>37 (21.8)</td>
<td></td>
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<tr>
<td>Not Treated</td>
<td></td>
<td>29</td>
<td>8 (27.6)</td>
<td>0.49</td>
<td>1.37 0.56 - 3.34</td>
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<tr>
<td>On Meds</td>
<td></td>
<td>25</td>
<td>11 (44.0)</td>
<td>0.02</td>
<td>2.82 1.18 - 6.74</td>
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<tr>
<td>On Home Oxygen</td>
<td></td>
<td>6</td>
<td>2 (33.3)</td>
<td>0.51</td>
<td>1.80 0.32 - 10.20</td>
</tr>
<tr>
<td>HXBYPASS</td>
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<td></td>
<td></td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>10</td>
<td>6 (60.0)</td>
<td>4.85</td>
<td>1.32 - 17.83</td>
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<tr>
<td>No</td>
<td></td>
<td>220</td>
<td>52 (23.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer</td>
<td></td>
<td></td>
<td></td>
<td>0.048</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>7</td>
<td>4 (57.1)</td>
<td>4.17</td>
<td>0.91 - 19.23</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>223</td>
<td>54 (24.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>upper quartile</td>
<td></td>
<td>58</td>
<td>72.6 (7.8)</td>
<td></td>
<td>1.07 1.03 - 1.12</td>
</tr>
<tr>
<td>quartiles 1-3</td>
<td></td>
<td>172</td>
<td>68.9 (7.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### EVAR Upper

<table>
<thead>
<tr>
<th>Preop Variable</th>
<th>Upper Quartile</th>
<th>N (level)</th>
<th>(no., %)</th>
<th>p-value</th>
<th>Odds Ratio OR 95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ILIACANEURYSM</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>118</td>
<td>23 (19.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unilateral</td>
<td></td>
<td>22</td>
<td>10 (45.5)</td>
<td>0.01</td>
<td>3.44 1.32 - 8.94</td>
</tr>
<tr>
<td>Bilateral</td>
<td></td>
<td>18</td>
<td>7 (38.9)</td>
<td>0.07</td>
<td>2.63 0.92 - 7.52</td>
</tr>
<tr>
<td>CABGPTCA</td>
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<td></td>
<td></td>
<td>0.04</td>
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</tr>
<tr>
<td>None</td>
<td></td>
<td>108</td>
<td>24 (22.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5 yrs ago</td>
<td></td>
<td>24</td>
<td>11 (45.8)</td>
<td>0.02</td>
<td>2.96 1.18 - 7.45</td>
</tr>
<tr>
<td>&gt;= 5 yrs ago</td>
<td></td>
<td>27</td>
<td>5 (18.5)</td>
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<td>0.01</td>
<td>8.57 1.55 - 47.38</td>
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<td>30-50%</td>
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<td>38</td>
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<td>1.15 1.03 - 1.29</td>
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<td>quartiles 1-3</td>
<td></td>
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</tr>
</tbody>
</table>

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Global Health Economics Unit
Center for Clinical and Translational Science
Statistically Significant Predictors

- **Lower Quartile Costs for Open Patients**
  - CABG/PTCA > 5 years ago
  - Age
  - Creatinine (Mean of 0.97 mg/dl)

- **Lower Quartile Cost for EVAR Patients**
  - No presence of Iliac Aneurysm
  - Dialysis
Of Lower Quartile Cost

<table>
<thead>
<tr>
<th>Preop Variable</th>
<th>Open Lower</th>
<th>Upper Quartile</th>
<th>p-value</th>
<th>Odds Ratio OR 95% C.I.</th>
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<td></td>
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<td>&lt; 5yrs ago</td>
<td>44</td>
<td>12 (27.3)</td>
</tr>
<tr>
<td></td>
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<td>&gt;= 5 yrs ago</td>
<td>20</td>
<td>9 (45.0)</td>
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<td></td>
<td><strong>0.03</strong></td>
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<td>1.30</td>
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<td></td>
<td>0.61 - 2.77</td>
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<td><strong>2.83</strong></td>
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<td></td>
<td></td>
<td>1.09 - 7.35</td>
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<tr>
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<td>Dialysis</td>
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<td>No</td>
<td>165</td>
<td>37 (22.4)</td>
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<tr>
<td></td>
<td></td>
<td>Unilateral</td>
<td>44</td>
<td>12 (27.3)</td>
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<td>Bilateral</td>
<td>20</td>
<td>9 (45.0)</td>
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<td><strong>0.03</strong></td>
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<td>1.09 - 7.35</td>
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<th>p-value</th>
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<td>20</td>
<td>9 (45.0)</td>
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<td><strong>2.83</strong></td>
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<td>1.09 - 7.35</td>
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N mean(sd) p-value Odds Ratio OR 95% C.I.

<table>
<thead>
<tr>
<th>Preop Variable</th>
<th>Open Lower</th>
<th>Upper Quartile</th>
<th>p-value</th>
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<td>Dialysis</td>
<td>3</td>
<td>3 (100)</td>
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<td>0.93</td>
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<td></td>
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<td>0.89 - 0.97</td>
</tr>
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Age

<table>
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<tr>
<th>Quartiles 2-4</th>
<th>Lower quartile</th>
<th>upper quartile</th>
<th>p-value</th>
<th>Odds Ratio OR 95% C.I.</th>
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<td>58</td>
<td>172</td>
<td>0.007</td>
<td>0.86</td>
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<tr>
<td></td>
<td>66.8 (7.1)</td>
<td>70.9 (7.6)</td>
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<td>0.77 - 0.96</td>
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<tr>
<td>Creatinine</td>
<td>lower quartile</td>
<td>quartiles 2-4</td>
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<td>0.07</td>
<td>0.97</td>
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<tr>
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<td>0.97 (0.26)</td>
<td>1.19 (0.71)</td>
<td></td>
<td>0.77 - 0.96</td>
</tr>
</tbody>
</table>
Questions

• Can we identify predictive factors to successful aneurysm repair?
• Can we predict cost-effective treatments for individual patients?

Median Total Cost
EVAR = $30,728
Open = $21,158

Predictors
Certain pre-op conditions (smoking, CHF, iliac aneurysm, etc.) linked to higher cost patients

Median LOS
EVAR = 2 days
Open = 7 days
* Wider cost distribution for EVAR
The Future?

Predictive Algorithms

FUTURE

PRESENT

PAST
The Premise
The Premise
The Premise
Logistic regression

Equation:

- \( \ln(\text{odds}(y)) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots \)
- where \( \ln = \) natural log
  - \( y = \) outcome variable (e.g., upper quartile of cost)
  - \( \beta_0, \beta_1, \text{etc.} = \) model coefficients (slopes)
  - \( x_1, x_2, \text{etc.} = \) predictor variables
Predicting the *Prob* of an Outcome

- Predicted probability (*prob*) of outcome *y* for specific values of *x_1*, *x_2*, etc.:

\[
prob(y) = \frac{e^{(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots)}}{1 + e^{(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots)}}
\]
Integrating Cost as an Outcome

• Tool available to analyze “high risk cost” similar to tools for “high MI risk” or “high mortality risk”

• Eventual development of center specific (??Physician specific) modeling that will predict cost over 5 years based on complications / reinterventions over that time period.
Integrating Cost as an Outcome

• Each member of NNE has a unique hospital makeup.
  – Unique skill set amongst physicians
  – Unique set of resources
    • Hybrid suite
    • Angio suites
  – Unique set of complication rates/mortalities based on LOCAL results.
Integrating Cost as an Outcome

– What may be “best practice” in one hospital may not be in another.
  • Contracting may make cost of stent graft better in one hospital.
  • Bed / ICU availability may drive local goals in another.
  • Economic variables can be addressed in a way that clinical outcomes can be monitored.
Take Away Messages

• Responsible. Knowledge of cost is expected out of automechanics, construction managers – why not us.
• Not designed to say one procedure is “better”.

• Information like this will help us become a player in contracting and in the management of inpatient cost.
• It is pretty clear that each hospital chooses a unique definition for “direct” and “indirect” cost. I don’t know if cost is comparable center to center but relative cost is.
Thank You....Questions?

Marion Couch, MD, PhD, MBA
Richard Galbraith, MD, PhD
Andrew Stanley, MD
Antonio DiCarlo, MD
Caroline Ridisill, DPhil
Carol Durett, Strategic Planning
Richie Spitsberg, MSc
Andy Shen, BS
Ellen Dimick, Business Support
New Quality Reports

- Contained in folder
- First comparison with other regions
- New PQRS measures by center
- Carotid LOS, details – Brian Nolan
PQRS measure #158: Use of Patch during Elective Conventional Carotid Endarterectomy by VSGNE Centers

2,112 procedures, 2011 to September 2012

X-axis set at the overall VSGNE rate = 98%
Centers with 5 or more procedures

Rate is significantly different from the overall rate
* p<0.05, ** p<0.01
PQRS measure #158: Use of Patch during Elective Conventional Carotid Endarterectomy by VQI Regions

6,053 procedures, 2011 to September 2012

- X-axis set at the overall VQI rate = 94%

Rate is significantly different from the overall rate
- * p<0.05
- ** p<0.01
PQRS Measure #257: Statin Therapy at Discharge after Infra-inguinal Bypass by VSGNE Centers

1,696 procedures, 2011 to September 2012

Excluding patients who died in hospital and patients transferred to another hospital.

X-axis set at overall VSGNE rate = 76%

Centers with 10 or more procedures.

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
PQRS Measure #257: Statin Therapy at Discharge after Infra-inguinal Bypass by VQI Regions

4,295 procedures, 2011 to September 2012

Excluding patients who died in hospital and patients transferred to another hospital

X-axis set at overall rate = 70%

Regions with 10 or more procedures

Rate is significantly different from the overall rate:
* p<0.05,
** p<0.01
PQRS Measure #258: Rate of Discharge to Home by Post-operative day 7 for Elective Open Repair of Small AAAs by VSGNE Centers

141 procedures, 2011 to September 2012

Small AAA: Men AAA diameter <= 6cm
Women AAA diameter <= 5.5cm

X-axis set at overall VSGNE rate = 55%

Centers with 10 or more procedures

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
PQRS Measure #258: Rate of Discharge to Home by Postoperative day 7 for Elective Open Repair of Small AAAs by VQI Regions

532 procedures, 2011 to September 2012

Small AAA: Men AAA diameter <= 6cm
Women AAA diameter <= 5.5cm

X-axis set at the overall VQI rate = 51%

Regions with 10 or more procedures

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
PQRS measure #259: Rate of Discharge to Home by Post-operative Day 2 for Elective EVAR of Small AAAs by VSGNE Centers

761 procedures, 2011 to September 2012

Small AAA: Men AAA diameter <= 6cm
Women AAA diameter <= 5.5cm

X-axis set at the overall VSGNE rate = 74%

Centers with 10 or more procedures

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
PQRS measure #259: Rate of Discharge to Home by Post-op day 2 for Elective EVAR of Small AAAs by VQI Regions

2,440 procedures, 2011 to September 2012

Small AAA: Men AAA diameter <= 6cm
Women AAA diameter <= 5.5cm

X-axis set at the overall rate = 70%

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
PQRS measure #260: % Asymptomatic Patients Discharged to Home by Post-operative day 2 after Carotid Endarterectomy by VSGNE Centers

X-axis set at the overall VSGNE rate = 85%
Centers with 5 or more procedures

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
PQRS measure #260: % Asymptomatic Patients Discharged to Home by Post-operative day 2 after Carotid Endarterectomy by VQI Regions

5,128 procedures, 2011 to September 2012

X-axis set at the overall VQI rate = 83%

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
% Asymptomatic Patients Discharged to Home by Post-operative day 2 after CAS by VSGNE Centers

400 procedures, 2005 to September 2012

Centers

- **A**: 57%
- B: 82%
- C: 83%
- D: 85%
- E: 88%
- F: 95%
- G: 96%
- H: 96%
- I: 100%

X-axis set at the overall rate = 92%

Centers with 5 or more procedures

Rate is significantly different from the overall rate
- * p<0.05
- ** p<0.01
% Asymptomatic Patients Discharged to Home by Post-operative day 2 after CAS by VQI Regions

995 procedures, 2005 to September 2012

X-axis set at the overall VQI rate = 86%

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
In-hospital Mortality Rate after Non-Ruptured Open AAA Repair
Observed and Expected by VSGNE Centers

Centers with 40 or more patients
1709 patient procedures, 2003 to June 2012

Overall death rate
VSGNE = 2.8%
VQI = 2.9%
AUC = 0.69

adjusted for:
COPD, creatinine, site of proximal clamp

Due to rarity of events, centers need 186 procedures for a reliable estimate.
In-hospital Mortality Rate after Non-Ruptured Open AAA Repair
Observed and Expected by VQI Regions

2,483 patient procedures, 2003 to September 2012

Overall death rate
VQI = 2.9%
AUC = 0.69

adjusted for:
COPD, creatinine, site of proximal clamp

Due to rarity of events, centers need 186 procedures for a reliable estimate.
% Patients with Length of Stay > 8 Days after Non-Ruptured Open AAA Observed and Expected by VSGNE Centers

Centers with 15 or more patients
1,661 patient procedures, 2003 to June 2012
(Excludes in-hospital deaths)

Overall rate LOS > 8 days
VSGNE = 31%
VQI = 34%
AUC = 0.66

adjusted for: age, COPD,
proximal clamp position, distal anastomosis

Significantly lower or higher than expected:
* p<0.05
**p<0.01
% Patients with Length of Stay > 8 Days after Non-Ruptured Open AAA
Observed and Expected by VQI Regions

1,225 patient procedures, 2010 to September 2012
(Excludes in-hospital deaths)

Overall rate LOS > 8 days
for VQI = 34%
AUC = 0.66

adjusted for: age, COPD,
proximal clamp position, distal anastomosis

Significantly higher than expected:
* p<0.05
**p<0.01
% Patients with Length of Stay > 2 Days after Non-Ruptured EVAR
Observed and Expected by VSGNE Centers

Centers with 13 or more procedures
2,750 patient procedures, 2003 to June 2012 (Excludes in-hospital deaths)

Overall rate LOS > 2 day
VSGNE = 28%
VQI = 35%
AUC = 0.70

adjusted for: age, gender, race, congestive heart failure, COPD, creatinine, stress test, living nursing home, max AAA diameter >6.5 cm, hypogastric intentionally covered, concomitant procedure

Significantly lower or higher than expected:
* p<0.05
**p<0.01
% Patients with Length of Stay > 2 Days after Non-Ruptured EVAR
Observed and Expected by VQI Regions

4,146 patient procedures, 2010 to September 2012 (Excludes in-hospital deaths)

Overall rate LOS > 2 days for VQI = 35%
AUC = 0.70

adjusted for: age, gender, race, congestive heart failure, COPD, creatinine, stress test, living nursing home, max AAA diameter >6.5 cm, hypogastric intentionally covered, concomitant procedure

Significantly higher than expected:
* p<0.05
**p<0.01
% Patients with Length of Stay > 1 Day after Elective CEA
Observed and Expected by VSGNE Centers

Centers with 17 or more patients
8,621 patient procedures, 2003 to June 2012
(Excludes in-hospital deaths, previous ipsilateral CEA, concomitant CABG)

Overall rate LOS > 1 day
VSGNE = 24%
VQI = 30%
AUC = 0.65

adjusted for: age, gender, race, hypertension, diabetes, pre-op beta blocker, CAD, CHF, COPD, stress test, previous arterial PTA/Stent, pre-op ASA/Plavix, ipsilateral cortical symptoms, contralateral cortical symptoms, vertebrobasilar symptoms, prior radiation therapy, pre-op MRA

Significantly lower or higher than expected:
* p<0.05
**p<0.01
% Patients with Length of Stay > 1 Day after Elective CEA
Observed and Expected by VQI Regions

6,747 patient procedures, Jan 2011 to Sept 2012
(Excludes in-hospital deaths, previous ipsilateral CEA, concomitant CABG)

Overall rate LOS > 1 day for VQI = 30%
AUC = 0.65

adjusted for: age, gender, race, hypertension, diabetes, pre-op beta blocker, CAD, CHF, COPD, stress test, previous arterial PTA/Stent, pre-op ASA/Plavix, ipsilateral cortical symptoms, contralateral cortical symptoms, vertebrobasilar symptoms, prior radiation therapy, pre-op MRA

Significantly higher than expected:
* p<0.05
** p<0.01
Factors that determine length of stay after CEA: Opportunities to avoid hospital financial losses

Brian Nolan, Julia Glazer, David Kuwayama, David Stone, Phillip Goodney, Andres Schanzer, Marc Schermerhorn, Jens Eldrup Jorgenssen, Richard Powell, Andrew Stanley, Jack Cronenwett
Prolonged Length of Stay

- LOS > 1 day after elective CEA incurs financial losses for the hospital

![Graph showing cost and payment margins over different lengths of stay.](image-url)
Prolonged Length of Stay After CEA Incidence in VSGNE
Prolonged Length of Stay After CEA
Variation Across VSGNE Centers
Questions

Do all patients experiencing prolonged LOS following CEA require prolonged LOS?

Is there an opportunity to improve profitability by increasing the proportion of patients discharged on POD #1?
Objectives

• Determine factors which contribute to prolonged LOS after CEA

• Identify factors which may be leveraged as targets of process improvement initiatives (e.g. “care paths”)
Sample

- Patients undergoing elective CEA
- No concomitant procedures
- Admitted same day as surgery
- 7108 CEA
- 23 VSGNE centers, 2003 - 2011
## Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>LOS ≤ 1 d (n=5864)</th>
<th>LOS &gt; 1 d (n=1244)</th>
<th>p-value</th>
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<tbody>
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<td>Age</td>
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<td>72</td>
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<tr>
<td>Symptomatic</td>
<td>32%</td>
<td>35%</td>
<td>0.036</td>
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<tr>
<td>Female</td>
<td>39%</td>
<td>49%</td>
<td>0.000</td>
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<tr>
<td>History of CHF</td>
<td>9%</td>
<td>15%</td>
<td>0.000</td>
</tr>
<tr>
<td>History of CAD</td>
<td>31%</td>
<td>35%</td>
<td>0.001</td>
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<tr>
<td>Positive stress test</td>
<td>10%</td>
<td>15%</td>
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<td>DM (oral agent or insulin)</td>
<td>8%</td>
<td>10%</td>
<td>0.026</td>
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<td>History of COPD</td>
<td>17%</td>
<td>20%</td>
<td>0.015</td>
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<td>COPD (on O2)</td>
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<td>3%</td>
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<td>Renal Insufficiency</td>
<td>5%</td>
<td>7%</td>
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<tr>
<td>Hypertension</td>
<td>88%</td>
<td>90%</td>
<td>0.073</td>
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# System Characteristics

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<th>LOS &gt; 1 d (n=1244)</th>
<th>p-value</th>
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<td><strong>Annualized surgeon volume</strong></td>
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<td></td>
</tr>
<tr>
<td>≤ 15</td>
<td>23%</td>
<td>47%</td>
<td>0.000</td>
</tr>
<tr>
<td>16 to 29</td>
<td>27%</td>
<td>24%</td>
<td>0.051</td>
</tr>
<tr>
<td>30 to 49</td>
<td>35%</td>
<td>16%</td>
<td>0.000</td>
</tr>
<tr>
<td>≥ 50</td>
<td>16%</td>
<td>13%</td>
<td>0.044</td>
</tr>
<tr>
<td><strong>Annualized center volume</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 80</td>
<td>14%</td>
<td>34%</td>
<td>0.000</td>
</tr>
<tr>
<td>81 to 119</td>
<td>20%</td>
<td>13%</td>
<td>0.000</td>
</tr>
<tr>
<td>120 to 240</td>
<td>17%</td>
<td>18%</td>
<td>0.294</td>
</tr>
<tr>
<td>&gt; 240</td>
<td>20%</td>
<td>11%</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>Operative day</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monday</td>
<td>18%</td>
<td>18%</td>
<td>0.744</td>
</tr>
<tr>
<td>Tuesday</td>
<td>27%</td>
<td>25%</td>
<td>0.185</td>
</tr>
<tr>
<td>Wed</td>
<td>21%</td>
<td>20%</td>
<td>0.680</td>
</tr>
<tr>
<td>Thursday</td>
<td>18%</td>
<td>13%</td>
<td>0.000</td>
</tr>
<tr>
<td>Friday</td>
<td>16%</td>
<td>24%</td>
<td>0.000</td>
</tr>
</tbody>
</table>
## Complications

<table>
<thead>
<tr>
<th></th>
<th>LOS $\leq$ 1 d (n=5864)</th>
<th>LOS $&gt; 1$ d (n=1244)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any complication</td>
<td>6%</td>
<td>24%</td>
<td>0.000</td>
</tr>
<tr>
<td>Multiple complications</td>
<td>0.2%</td>
<td>7%</td>
<td>0.000</td>
</tr>
<tr>
<td>Cranial nerve injury</td>
<td>4%</td>
<td>7%</td>
<td>0.000</td>
</tr>
<tr>
<td>Post-op ipsilateral sx</td>
<td>0.2%</td>
<td>4%</td>
<td>0.000</td>
</tr>
<tr>
<td>Post-op contralateral sx</td>
<td>0.1%</td>
<td>2%</td>
<td>0.000</td>
</tr>
<tr>
<td>Reperfusion syndrome</td>
<td>0.1%</td>
<td>1%</td>
<td>0.000</td>
</tr>
<tr>
<td>MI</td>
<td>0.2%</td>
<td>5%</td>
<td>0.000</td>
</tr>
<tr>
<td>Dysrhythmia</td>
<td>1%</td>
<td>6%</td>
<td>0.000</td>
</tr>
<tr>
<td>CHF</td>
<td>0.1%</td>
<td>4%</td>
<td>0.000</td>
</tr>
<tr>
<td>Return to OR</td>
<td>1%</td>
<td>6%</td>
<td>0.000</td>
</tr>
<tr>
<td>IV med for hypertension</td>
<td>8%</td>
<td>21%</td>
<td>0.000</td>
</tr>
<tr>
<td>IV med for hypotension</td>
<td>10%</td>
<td>23%</td>
<td>0.000</td>
</tr>
</tbody>
</table>
**Independent Predictors of LOS > 1 Day**

<table>
<thead>
<tr>
<th>Factor</th>
<th>O.R.</th>
<th>95% C.I.</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>1.6</td>
<td>1.4</td>
<td>1.9</td>
</tr>
<tr>
<td>Positive stress test</td>
<td>1.6</td>
<td>1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>History of CHF</td>
<td>1.3</td>
<td>1.0</td>
<td>1.7</td>
</tr>
<tr>
<td>COPD requiring O2</td>
<td>2.3</td>
<td>1.4</td>
<td>3.6</td>
</tr>
<tr>
<td>Low volume surgeon (≤15 cases / yr)</td>
<td>3.1</td>
<td>1.9</td>
<td>5.0</td>
</tr>
<tr>
<td>Surgery performed on Friday</td>
<td>1.5</td>
<td>1.2</td>
<td>1.9</td>
</tr>
<tr>
<td>General anesthesia</td>
<td>2.6</td>
<td>1.3</td>
<td>5.0</td>
</tr>
<tr>
<td>Any complication</td>
<td>4.5</td>
<td>3.5</td>
<td>5.8</td>
</tr>
<tr>
<td>IV med for hypertension</td>
<td>3.5</td>
<td>2.8</td>
<td>4.5</td>
</tr>
<tr>
<td>IV med for hypotension</td>
<td>2.9</td>
<td>2.4</td>
<td>3.7</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>2.8</td>
<td>1.4</td>
<td>5.5</td>
</tr>
<tr>
<td>60-69</td>
<td>2.8</td>
<td>1.5</td>
<td>5.5</td>
</tr>
<tr>
<td>70-79</td>
<td>3.9</td>
<td>2.0</td>
<td>7.7</td>
</tr>
<tr>
<td>80-89</td>
<td>5.2</td>
<td>2.6</td>
<td>10.5</td>
</tr>
<tr>
<td>&gt;90</td>
<td>11.8</td>
<td>3.5</td>
<td>39.3</td>
</tr>
<tr>
<td>Symptom status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TIA</td>
<td>1.1</td>
<td>0.9</td>
<td>1.4</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>1.4</td>
<td>1.1</td>
<td>1.9</td>
</tr>
<tr>
<td>Major stroke &gt; 1 month</td>
<td>1.6</td>
<td>1.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Major stroke &lt; 1 month</td>
<td>2.7</td>
<td>1.4</td>
<td>5.0</td>
</tr>
</tbody>
</table>
Rates of Observed v. Predicted LOS $\geq 1$
Day by Center
• Logistic model = odds ratios
  - Likelihood a patient with a given exposure (e.g. a preop stroke, O2 dependent COPD, a complication) will experience a prolonged los.

• To improve timely discharge, what we want to know if how much each exposure contributes to the pool of patients experiencing prolonged los.
  - That will depend not only on the likelihood the exposure leads to the outcome, but how common the exposure is. Example – Age > 90
Contributions to Prolonged LOS

- Any MAE: 21%
- Low Volume Surgeon: 28%
- IV med for hypertension: 15%
- IV med for hypotension: 11%
- CEA on Friday: 2%
- General Anesthesia: 6%
- O2 Dep COPD: 1%
- Symptom Status: 2%
- Age: 7%
- CHF: 1%
- Positive Stress: 2%
- Female Gender: 4%
- Full Model: 0%
- Unexplained: 1%
Summary

• Wide variation in LOS following CEA
• Patient comorbidities responsible for only 17% of prolonged LOS
• Systematic inefficiencies or biases associated with low surgeon volume, operative day and anesthesia type accounts for 36% of prolonged LOS and could be targets of process improvement measures.
• Reducing complications and the need for IV BP meds post-op would also be expected to significantly decrease prolonged LOS.
Open vs. Endovascular Repair of Popliteal Artery Aneurysm (OVERPAR) Trial

Alik Farber, Phil Goodney, Mohammad H. Eslami

Vascular Study Group of New England

Universitas Bostoniensis

New England Society for Vascular Surgery
Open Repair of PAA (OPAR)

- Standard of care
- Results: Limb salvage rate 96.2% at one year

(Johnson et al., *J Vasc Surg* 2008; 48: 845-510)
Endovascular Popliteal Aneurysm Repair (EPAR)

- Single centers studies established safety and efficacy of EPAR (Tielli et al., J Endovasc Ther 2003; 10; 111-6)

- Retrospective multi-center case series (Midy et al., J Vasc Surg 2010; 51: 850-6)
  - 96.5% “global” limb salvage rate
  - Primary and secondary patency rates: 82.3% and 87.5% at three years

“Comparable to open surgical results”
EPAR vs OPAR

• A recent meta analysis showed similar results (Lovegrove et al., *Eur J Vasc Endovasc Surg* 2008; 36:96-100)

• Prospective, randomized, single center trial of EPAR vs OPAR (Antonello et al., *J Vasc Surg* 2005; 42: 185-93)
  – Similar graft and limb salvage rates
  – Severe power limitation; only 30 patients enrolled

• Equipoise is present
OVERPAR Trial

A prospective, multicenter randomized trial of open surgical bypass vs. endovascular popliteal artery stent graft repair in asymptomatic patients

Trial sponsored by NESVS and orchestrated through VSGNE
OVERPAR Trial

• Primary hypothesis:
  – Major adverse limb event (MALE)-free survival is lower in the EPAR vs OPAR group.

• Secondary hypotheses:
  – EPAR will be associated with
    • more secondary interventions
    • improved independent living status
    • increased ambulatory status
    • improved quality of life
    • and decreased LOS
OVERPAR Trial

- Primary Outcome:
  - MALE-free survival
    - adjusted from OPG guidelines to include minor interventions
OVERPAR Trial

• Secondary Outcomes
  – Clinical
    • Composite MALE - POD (perioperative death)
    • Freedom from secondary interventions
    • Number of intervention
    • Primary, primary-assisted and secondary patency rates
    • Procedure duration
    • 30-day freedom from perioperative MACE
    • Other perioperative complications
  – Functional status and quality of life
  – Resource utilization (LOS)
**Trial Entry Criteria**

**Inclusion**
- Age ≥ 35 years
- Popliteal artery aneurysm ≥ 2 cm in diameter w/o thrombus
- Candidate for either open/endo as judged by the enrolling investigator
- >2cm of normal neck proximal and distal to the popliteal artery aneurysm
- Patient signs consent

**Exclusion**
- Symptomatic or thrombosed PAA
- SFA occlusion
- <2 cm of normal artery to accommodate stent seal
- Life expectancy <2 years
- Hypercoagulable state
- Any infrainguinal revascularization procedure w/in 12 wks
- Immunosuppressive meds, chemo/XRT
- Pregnancy/lactation
- Allergy to stainless steel or nitinol
- Anaphylactic reaction to dye
- Refusal to sign a consent
Patients with asymptomatic PAA eligible for repair

LE CTA of affected limb
To plan surgery

Yes

Informed consent

Yes

1:1 randomization

Stent Group

Open Group

Excluded

No

4 year study: mean follow-up of 2.5 years
Randomization

- Participating sites will contact study coordinator at BMC
- For each center, sealed opaque envelopes indicating EPAR or OPAR will be stored in blocks of 6 (3 for each procedure)
- Upon receiving a phone call, the study coordinator at BMC will open an envelope and relay the result (OPAR or EPAR) to the site study coordinator
Sample Size Calculation

- MALE survival curves estimated using data from the largest series of OPAR and OPG data describing patients with PAD who underwent bypass.
- Assumption: patients will be accrued uniformly over three years and then followed for one additional year past accrual period.
  - 50% loss to follow-up within ten years (~7% after first year and 20% after 3 years).

<table>
<thead>
<tr>
<th>1-year Rates</th>
<th>OPAR</th>
<th>EPAR</th>
<th>Hazard Ratio</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>MALE</td>
<td>20%</td>
<td>35%</td>
<td>1.53</td>
<td>80%</td>
</tr>
</tbody>
</table>

- **148** (74 in each group) patients to achieve power of .8 for two-sided test with a type I error bound of .05 using a balanced design.
Study Feasibility Using VSGNE

• 329 OPARs performed within VSGNE (2003-2011)
  – 263 for asymptomatic PAA (80%)
  – The number of sites has gradually increased
  – Estimate: ~40 OPAR annually

• In 2010, the first year that PVIs were included at VSGNE, 40 EPARs were performed.

• Projected enrollment: 50 patients/year assuming exclusion of symptomatic PAA (~20%) and screening failures (~20%)
Patient Follow-up

Scheduled post-op visits (months)

0  1  12  24  36  48

History and physical evaluation
Arterial Duplex of the graft/stent
ABI (if possible)
QOL Patient Survey\(^\circ\) (patients can fill out and send back)

\(^\circ\)Morgan et al. *J Vasc Surg* 2001; 33: 679-87
## Budget

<table>
<thead>
<tr>
<th></th>
<th>Year 1 ($)</th>
<th>Year 2 ($)</th>
<th>Year 3 ($)</th>
<th>Year 4 ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Trial Coordinator</td>
<td>2000</td>
<td>4000</td>
<td>4000</td>
<td>0</td>
</tr>
<tr>
<td>Statistical Support and randomization scheme</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>0</td>
</tr>
<tr>
<td>Site coordinator support</td>
<td>5000 ($100/pt enrolled)</td>
<td>5000 ($100/pt enrolled)</td>
<td>5000 ($100/pt enrolled)</td>
<td>0</td>
</tr>
<tr>
<td>IRB fees</td>
<td>2000</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>10,000</strong></td>
<td><strong>10,000</strong></td>
<td><strong>10,000</strong></td>
<td><strong>0</strong></td>
</tr>
</tbody>
</table>
Study Contacts

• Clinical Coordinator Center
  – Alik Farber, MD
  – Mohammad H. Eslami, MD
  – Philip Goodney, MD

• Data Coordinating Center
  – Marina Malikova PhD
  – Gheorghe Doros, PhD
14 VSGNE centers agreed to participate

- Connecticut
  - Danbury Medical Center
  - Hartford Hospital
  - YALE
- Maine
  - Maine Medical Center
- Massachusetts
  - Bay state Medical Center
  - Boston Medical Center
  - Brigham and Women’s Hospital
  - BI Deaconess Hospital
  - Charlton Memorial Hospital/St. Anne Hospital
  - Massachusetts General Hospital
  - Tufts Medical Center
- New Hampshire
  - Cardiothoracic Surgical Associates
  - Dartmouth Medical Center
- Vermont
  - UVT Hospitals
Participating VQI Centers Outside of VSGNE

• University of Indiana
• University of VA at Charlottesvillle
• University of Arkansas
Deliverables

• Protocol
• Consent Form
• QOL questionnaire
• Revised VSGNE forms (not on line yet)
• Email address: OVERPAR trial@gmail.com
What has been done

- IRB submission at BMC is complete
- Every center previously agreed to participate has received a package via email:
  - Protocol to be used for IRB submission
  - ICF to be used for IRB submission
  - Copy of the proposed revised VSGNE forms
  - A copy of the QOL questionnaire
**Proposed changes to VSGNE forms: LEB form**

<table>
<thead>
<tr>
<th>History</th>
<th>Right:</th>
<th>Left:</th>
<th>Pre-Rx:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indication</strong></td>
<td>Asymptomatic</td>
<td>Claudication</td>
<td>Pre-Rx ABI</td>
</tr>
<tr>
<td></td>
<td>Rest Pain</td>
<td>Tissue Loss</td>
<td>Pre-Rx TBI</td>
</tr>
<tr>
<td></td>
<td>Acute Ischemia</td>
<td>Not Treated</td>
<td></td>
</tr>
<tr>
<td><strong>Pathology</strong></td>
<td>Not Treated</td>
<td>Occlusive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aneurysm</td>
<td>Aneurysm</td>
<td></td>
</tr>
<tr>
<td>If popliteal artery aneurysm:</td>
<td>Patient is enrolled in OVER-PAR</td>
<td>Patient is not enrolled due to:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Randomization Failure:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient is randomized in OVER-PAR</td>
<td>Anatomic considerations</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical contraindication</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient refused to consent for trial</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Physician did not enroll for other reasons</td>
<td></td>
</tr>
<tr>
<td>Ambulation</td>
<td>Amb</td>
<td>Amb w/Assistance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wheelchair</td>
<td>Bedridden</td>
<td></td>
</tr>
<tr>
<td>Previous:</td>
<td>Right:</td>
<td>Left:</td>
<td></td>
</tr>
<tr>
<td>Inflow Bypass</td>
<td>No</td>
<td>No</td>
<td>Pre-Rx ABI</td>
</tr>
<tr>
<td>Inflow PTA/Stent</td>
<td>No</td>
<td>No</td>
<td>Pre-Rx TBI</td>
</tr>
<tr>
<td>Leg Bypass</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Leg PTA/Stent</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Major Amputation</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Minor Amputation</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
**Proposed changes to VSGNE forms:**

**LEB LTF form**

### Vascular Quality Initiative - Infra-I nguinal Bypass Follow-Up

<table>
<thead>
<tr>
<th>Last Name</th>
<th>Medical Record Number</th>
<th>Social Security Number</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>Medical Record Number</th>
<th>Social Security Number</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Visit code (not required)</th>
<th>Zip/Postal Code</th>
<th>Procedure: Infra-I nguinal Bypass</th>
</tr>
</thead>
</table>

**Patient is a subject in OVER-PAR Trial **

### Infra-I nguinal Bypass

<table>
<thead>
<tr>
<th>Current Ambulation</th>
<th>Ipsilateral Symptoms</th>
<th>Patency Judged By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amb</td>
<td>Asymptomatic</td>
<td>Doppler Only</td>
</tr>
<tr>
<td>Amb w/Assistance</td>
<td>Claudication</td>
<td>Palpable Graft Pulse</td>
</tr>
<tr>
<td>Wheelchair</td>
<td>Rest Pain</td>
<td>Palpable Distal Pulse</td>
</tr>
<tr>
<td>Bedridden</td>
<td>Tissue Loss</td>
<td>ABI Increase &gt; 0.15</td>
</tr>
</tbody>
</table>

**Current Patency**

<table>
<thead>
<tr>
<th>Primary</th>
<th>Symptomatic</th>
<th>Patency Judged By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prim-Assisted</td>
<td>Claudication</td>
<td>Doppler Only</td>
</tr>
<tr>
<td>Secondary</td>
<td>Rest Pain</td>
<td>Palpable Graft Pulse</td>
</tr>
<tr>
<td>Occluded</td>
<td>Tissue Loss</td>
<td>Palpable Distal Pulse</td>
</tr>
</tbody>
</table>

**If Occluded, Date**

<table>
<thead>
<tr>
<th>Stenosis: 0-50%</th>
<th>50-75%</th>
<th>&gt;75%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Proposed changes to VSGNE forms: PVI form

<table>
<thead>
<tr>
<th>History</th>
<th>Right: Asymptomatic</th>
<th>Left: Claudication</th>
<th>Pre-Rx: Pre-Rx ABI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rest Pain</td>
<td>Tissue Loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acute Ischemia</td>
<td>Not Treated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not Treated</td>
<td>Occlusive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aneurysm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If popliteal artery aneurysm:
- Patient is enrolled in OVER-PAR
- Patient is randomized in OVER-PAR

Patient is not enrolled due to:
- Anatomic considerations
- Medical contraindication
- Patient refused to consent for trial
- Physician did not enroll for other reasons

Randomization Failure:
- Patient refused randomization plan
- Physician disagreed with proposed plan

Ambulation:
- Amb
- Wheelchair
- Amb w/Assistance
- Bedridden

Previous:
- Inflow Bypass
- Inflow PTA/Stent
- Leg Bypass
- Leg PTA/Stent
- Major Amputation
- Minor Amputation

Right: No Yes Left: No Yes

Right: No Yes Left: No Yes

Right: No Yes Left: No Yes
### Proposed changes to VSGNE forms: PVI form

Under “Procedure detail”

<table>
<thead>
<tr>
<th>Technical Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful</td>
</tr>
<tr>
<td>Stenosis ≥30% or 10 mm Gradient</td>
</tr>
<tr>
<td>Technical Failure</td>
</tr>
</tbody>
</table>

For popliteal artery aneurysm: Endoleak

Yes [ ] No [ ]

Type of endoleak

<table>
<thead>
<tr>
<th>Number Lesions Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
</tr>
<tr>
<td>Total Occlusion Length (cm)</td>
</tr>
<tr>
<td>Total Treated Length (cm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1st Treatment Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA</td>
</tr>
<tr>
<td>Stent, Self-Expand</td>
</tr>
<tr>
<td>Stent, Balloon-Expand</td>
</tr>
<tr>
<td>Stent Graft</td>
</tr>
</tbody>
</table>

For popliteal artery aneurysm: Number of stent grafts used

For popliteal artery aneurysm: Type(s) of stent grafts used
Proposed changes to VSGNE forms: PVI form LTF

Vascular Quality Initiative - Peripheral Vascular Intervention Follow-Up

Last Name ___________________________ First Name ___________________________ Middle Initial □

Date of Birth ___________________________ Medical Record Number __________

Social Security Number ___________________________

Visit code (not required) ___________________________ Zip/Postal Code ___________________________

Surgeon ___________________________ Procedure: ___________________________

Surgery Date ___________________________ Side: ___________________________

Patient is a subject in OVER-PAR Trial: □

General Information
Proposed changes to VSGNE forms: **PVI form**

### Peripheral Vascular Intervention

<table>
<thead>
<tr>
<th>Current Ambulation</th>
<th></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Amb</td>
<td>Amb w/ Assistance</td>
</tr>
<tr>
<td></td>
<td>Wheelchair</td>
<td>Bedridden</td>
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</table>

<table>
<thead>
<tr>
<th>Indication</th>
<th>Right:</th>
<th>Left:</th>
</tr>
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<tbody>
<tr>
<td>Asymptomatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Claudication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue Loss</td>
<td></td>
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<table>
<thead>
<tr>
<th>ABI</th>
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</table>

<table>
<thead>
<tr>
<th>TBI</th>
<th></th>
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</thead>
</table>

Percent Stenosis on Duplex of stent graft (OVER-PAR patients only):

- 0-50%  
- 50-75%  
- >75%  

<table>
<thead>
<tr>
<th>Major Amputation</th>
<th>Right:</th>
<th>Left:</th>
</tr>
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<tbody>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BK Amp</td>
<td></td>
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</tr>
<tr>
<td>AK Amp</td>
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</tr>
<tr>
<td>Minor Amp</td>
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---

**For popliteal artery aneurysm: Endoleak**

<table>
<thead>
<tr>
<th>Current Patency Patency</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>5th</th>
<th>6th</th>
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</thead>
<tbody>
<tr>
<td>Primary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Prim-Assisted</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Secondary</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Occluded</td>
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<table>
<thead>
<tr>
<th>Patency Judge</th>
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<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>5th</th>
<th>6th</th>
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<tbody>
<tr>
<td>Palpable Distal Pulse</td>
<td></td>
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<tr>
<td>ABI Increase &gt; 0.15</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>MRA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duplex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTA</td>
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<td>Angio</td>
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<table>
<thead>
<tr>
<th>Site Re-Intervention</th>
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<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>5th</th>
<th>6th</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td></td>
<td></td>
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<tr>
<td>Percutaneous</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
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<tr>
<td>Access site infection</td>
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<td></td>
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<tr>
<td>Stent graft infection</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombolysis of stent graft</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombectomy of stent graft</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
What is needed from each Center

- **Apply to IRB**
  - Make sure that your IRB knows that this trial is an **investigator sponsored** trial and should be exempt from fees
  - We can help

- **Enroll patients**
  - Follow-up scheme is similar to standard practice
  - Follow up is slightly longer
  - Modified VSGNE forms for PVI and LEB
Why Participate and Enroll?

- Study answers a relevant question
- Will provide level I data
- Uses data collection resources already in place for VQI
- Case study for running prospective trials on a modest budget
Thank You
VSGNE Caregiver Meeting

- Kristine Chaisson, RN
LUNCH BREAK
45 Minutes

Next Meeting:
Monday May 6, 2013
Tufts Medical Center
Boston, MA
Focus on Carotid Endarterectomy and Stenting

- Summary of VSGNE practice and outcomes
  - Jack Cronenwett

- Audience interaction re patient selection
  - Phil Goodney

- Risk stratification for CEA and CAS
  - Brian Nolan

- Results of redo CEA and CAS
  - Marc Schermerhorn

- Optimal therapy for asymptomatic carotid stenosis
  - Rich Cambria
Death or Stroke Rate after Elective Primary CEA
Observed and Expected by VSGNE Centers

Centers with 40 or more patients
8,848 patient procedures, 2003 to June 2012
(Excludes: previous ipsilateral CEA, concomitant CABG)

Overall stroke or death rate:
VSGNE = 0.99%
VQI = 1.1%
AUC = 0.65

adjusted for: age, Hypertension, previous arterial major amp, ASA/Plavix, degree of contralateral stenosis and ipsilateral ICA stenosis, ipsilateral cortical symptoms

Significantly lower or higher than expected:
* p<0.05, **p<0.01
Due to rarity of events, centers need 246 procedures for a reliable estimate.
Death or Stroke Rate after Elective Primary CEA Observed and Expected by Regions

14,182 patient procedures, 2003 to September 2012
(Excludes: previous ipsilateral CEA, concomitant CABG)

Overall stroke or death rate:
VQI = 1.0%
AUC = 0.65

adjusted for: age, Hypertension, previous arterial major amp,
ASA/Plavix, degree of contralateral stenosis and ipsilateral
ICA stenosis, ipsilateral cortical symptoms

Significantly lower or higher than expected:
* p<0.05, **p<0.01
Due to rarity of events, centers need 246 procedures for a reliable estimate.
Death or Stroke Rate after Elective Primary CAS
Observed and Expected by VSGNE Centers

Centers with 10 or more patients
395 patient procedures, 2003 to June 2012
(Excludes: previous ipsilateral CEA, concomitant CABG)

Overall stroke or death rate:
VSGNE = 2.3%
VQI = 3.0%
AUC = 0.85
adjusted for: age, race, ipsilateral ocular symptoms,
ipsilateral cortical symptoms

Due to rarity of events, centers need 218 procedures for a reliable estimate.
Death or Stroke Rate after Elective Primary CAS
Observed and Expected by Regions

14,182 patient procedures, 2003 to September 2012
(Excludes: previous ipsilateral CEA, concomitant CABG)

Overall stroke or death rate:
VQI = 1.0%
AUC = 0.65

adjusted for: age, race, ipsilateral ocular symptoms,
ipsilateral cortical symptoms

Significantly lower or higher than expected:
* p<0.05, **p<0.01
Due to rarity of events, centers need 170 procedures for a reliable estimate.
Percentage of Carotid Endarterectomies Performed on Asymptomatic Patients by VSGNE Centers

2,569 procedures, Jan 2011 to Sept 2012

Excludes re-do CEA & concomitant CABG
X-axis set at overall VSGNE rate = 62%
Centers with 5 or more procedures

Rate is significantly different from the overall rate
* p<0.05
** p<0.01
Percentage of Carotid Endarterectomies Performed on Asymptomatic Patients by VQI Regions

7,837 procedures, Jan 2011 to Sept 2012

Rate is significantly different from the overall rate
* p<0.05
** p<0.01

Excludes re-do CEA & concominant CABG
X-axis set at overall VQI rate = 62%
Percentage of Carotid Artery Stents Performed on Asymptomatic Patients by VSGNE Centers

704 procedures, Jan 2005 to Sept 2012

Excludes re-do CEA
X-axis set at overall VSGNE rate = 54%
Centers with 5 or more procedures

Rate is significantly different from the overall rate
* p<0.05, ** p<0.01
Percentage of Carotid Artery Stents Performed on Asymptomatic Patients by VQI Regions

1,296 procedures, Jan 2005 to Sept 2012

- Regions
- Excludes re-do CEA
- X-axis set at overall VQI rate = 51%

Rate is significantly different from the overall rate
- * p<0.05
- ** p<0.01
Carotid Endarterectomy and Stenting

How do we select patients?
Risk Stratified Outcomes of CEA and CAS in the VSGNE

Nolan BW, Spangler E, Goodney PP, Schanzer A, Powell RJ, Stone DH, Schermerhorn ML, Indes J and Cronenwett JL,
OBJECTIVES

• Compare outcomes in risk stratified patients undergoing CEA and CAS.

• Identify opportunities for improving selection between CEA or CAS.
SAMPLE

• CEA, 9756
  ▪ 146 surgeons
    • 1 to 717 CEA per surgeon; median 28
  ▪ 26 centers
    • 7 to 2244 per center; median 97

• CAS, 623
  ▪ 59 providers
    • 19 by providers also performing CEA
    • 1 to 139 per provider; median 4
  ▪ 13 centers
    • 8 also performing CEA
    • 3 to 189 per center; median 17
### Symptom Status

<table>
<thead>
<tr>
<th>Condition</th>
<th>CEA (n=9756)</th>
<th>CAS (n=623)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>60%</td>
<td>57%</td>
<td>0.092</td>
</tr>
<tr>
<td>TIA</td>
<td>26%</td>
<td>27%</td>
<td>0.434</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>11%</td>
<td>12%</td>
<td>0.290</td>
</tr>
<tr>
<td>Major Stroke ≥ 1-mo</td>
<td>2%</td>
<td>1%</td>
<td>0.535</td>
</tr>
<tr>
<td>Major Stroke &lt; 1-mo</td>
<td>1%</td>
<td>2%</td>
<td>0.055</td>
</tr>
</tbody>
</table>
# Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>CEA (n=9756)</th>
<th>CAS (n=623)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70</td>
<td>69</td>
<td>0.106</td>
</tr>
<tr>
<td>Female</td>
<td>40%</td>
<td>35%</td>
<td>0.120</td>
</tr>
<tr>
<td>History of ipsilateral CEA</td>
<td>2%</td>
<td>35%</td>
<td>0.001</td>
</tr>
<tr>
<td>Contralateral &gt;60% stenosis</td>
<td>26%</td>
<td>21%</td>
<td>0.005</td>
</tr>
<tr>
<td>Contralateral occlusion</td>
<td>6%</td>
<td>14%</td>
<td>0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>88%</td>
<td>90%</td>
<td>0.212</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>80%</td>
<td>82%</td>
<td>0.075</td>
</tr>
<tr>
<td>Any CAD</td>
<td>32%</td>
<td>40%</td>
<td>0.001</td>
</tr>
<tr>
<td>Positive stress test</td>
<td>10%</td>
<td>12%</td>
<td>0.038</td>
</tr>
<tr>
<td>CHF</td>
<td>8%</td>
<td>16%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any COPD</td>
<td>22%</td>
<td>26%</td>
<td>0.011</td>
</tr>
<tr>
<td>O2 Dep COPD</td>
<td>1%</td>
<td>4%</td>
<td>0.001</td>
</tr>
<tr>
<td>NIDDM</td>
<td>17%</td>
<td>17%</td>
<td>0.978</td>
</tr>
<tr>
<td>IDDM</td>
<td>9%</td>
<td>11%</td>
<td>0.014</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>6%</td>
<td>5%</td>
<td>0.904</td>
</tr>
<tr>
<td>Anti-plt agent</td>
<td>91%</td>
<td>97%</td>
<td>0.001</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>76%</td>
<td>68%</td>
<td>0.001</td>
</tr>
<tr>
<td>Statin</td>
<td>79%</td>
<td>82%</td>
<td>0.057</td>
</tr>
</tbody>
</table>
## In-Hospital Outcomes Asymptomatic

<table>
<thead>
<tr>
<th>Event</th>
<th>CEA (n=5677)</th>
<th>CAS (n=355)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or death</td>
<td>0.7%</td>
<td>0.9%</td>
<td>0.207</td>
</tr>
<tr>
<td>Stroke, death or MI</td>
<td>1.7%</td>
<td>1.6%</td>
<td>0.885</td>
</tr>
<tr>
<td>Any major stroke</td>
<td>0.3%</td>
<td>0.2%</td>
<td>0.823</td>
</tr>
<tr>
<td>Any ipsilateral stroke</td>
<td>0.5%</td>
<td>0.7%</td>
<td>0.623</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.1%</td>
<td>0.2%</td>
<td>0.577</td>
</tr>
</tbody>
</table>
## In-Hospital Outcomes

### Symptomatic

<table>
<thead>
<tr>
<th>Event</th>
<th>CEA (n=3859)</th>
<th>CAS (n=267)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or death</td>
<td>1.4%</td>
<td>5.5%</td>
<td>0.001</td>
</tr>
<tr>
<td>Stroke, death or MI</td>
<td>2.3%</td>
<td>6.4%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any major stroke</td>
<td>0.5%</td>
<td>2.0%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any ipsilateral stroke</td>
<td>1.0%</td>
<td>4.1%</td>
<td>0.001</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.4%</td>
<td>1.2%</td>
<td>0.029</td>
</tr>
</tbody>
</table>
**Risk Stratified Sample**

9541 CEA

- 227 prior ipsilateral CEA

Potential candidates for either CEA or CAS (Eliminate treatment biases)

9314 CEA

- 5551 (60%) Asymptomatic
- 3758 (40%) Symptomatic

623 CAS

- 204 (33%) prior ipsilateral CEA
- 70 anatomic high risk only

349 CAS

- 188 (53%) Asymptomatic
- 160 (46%) Symptomatic
RISK STRATIFICATION
SURVIVAL - ANY CAROTID REVASCULARIZATION

<table>
<thead>
<tr>
<th>Year</th>
<th>Survival</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>96%</td>
</tr>
<tr>
<td>2</td>
<td>93%</td>
</tr>
<tr>
<td>3</td>
<td>89%</td>
</tr>
<tr>
<td>4</td>
<td>85%</td>
</tr>
<tr>
<td>5</td>
<td>80%</td>
</tr>
</tbody>
</table>
## Risk Stratification

**Survival - Any Carotid Revascularization**

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>HR</th>
<th>p-value</th>
<th>95% Conf. Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 70 - 79</td>
<td>2.0</td>
<td>0.001</td>
<td>1.7</td>
</tr>
<tr>
<td>Age ≥ 80</td>
<td>4.2</td>
<td>0.001</td>
<td>3.6</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>1.3</td>
<td>0.003</td>
<td>1.1</td>
</tr>
<tr>
<td>Major stroke ≥ 1-mo</td>
<td>3.1</td>
<td>0.001</td>
<td>2.1</td>
</tr>
<tr>
<td>Major stroke &lt; 1-mo</td>
<td>2.0</td>
<td>0.001</td>
<td>1.4</td>
</tr>
<tr>
<td>Contralateral stenosis &gt; 60%</td>
<td>1.3</td>
<td>0.001</td>
<td>1.2</td>
</tr>
<tr>
<td>Contralateral occlusion</td>
<td>1.6</td>
<td>0.001</td>
<td>1.3</td>
</tr>
<tr>
<td>DM - oral meds</td>
<td>1.2</td>
<td>0.019</td>
<td>1.0</td>
</tr>
<tr>
<td>DM - insulin</td>
<td>1.8</td>
<td>0.001</td>
<td>1.5</td>
</tr>
<tr>
<td>History of tobacco use</td>
<td>1.5</td>
<td>0.001</td>
<td>1.3</td>
</tr>
<tr>
<td>O2 dependent COPD</td>
<td>3.6</td>
<td>0.001</td>
<td>2.7</td>
</tr>
<tr>
<td>History of CHF</td>
<td>1.8</td>
<td>0.001</td>
<td>1.5</td>
</tr>
<tr>
<td>History of CAD</td>
<td>1.2</td>
<td>0.024</td>
<td>1.0</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>1.5</td>
<td>0.001</td>
<td>1.3</td>
</tr>
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</table>
## Risk Stratification

### Survival - Any Carotid Revascularization

<table>
<thead>
<tr>
<th>Risk Score</th>
<th>5-Year Survival</th>
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</thead>
<tbody>
<tr>
<td>0-5</td>
<td>93%</td>
</tr>
<tr>
<td>6-9</td>
<td>87%</td>
</tr>
<tr>
<td>9-12.5</td>
<td>78%</td>
</tr>
<tr>
<td>&gt;12.5</td>
<td>63%</td>
</tr>
</tbody>
</table>

Normal Risk
73% CEA
65% CAS

High Risk
27% CEA
35% CAS
# Risk Stratification

**Survival - Any Carotid Revascularization**

<table>
<thead>
<tr>
<th></th>
<th>NL Risk (n=6963)</th>
<th>High Risk (n=2700)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>67</td>
<td>76</td>
<td>0.001</td>
</tr>
<tr>
<td>Female</td>
<td>40%</td>
<td>35%</td>
<td>0.001</td>
</tr>
<tr>
<td>Symptomatic</td>
<td>38%</td>
<td>48%</td>
<td>0.001</td>
</tr>
<tr>
<td>Contralateral &gt;60% stenosis</td>
<td>23%</td>
<td>32%</td>
<td>0.001</td>
</tr>
<tr>
<td>Contralateral occlusion</td>
<td>5%</td>
<td>9%</td>
<td>0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>87%</td>
<td>90%</td>
<td>0.001</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>77%</td>
<td>85%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any CAD</td>
<td>29%</td>
<td>41%</td>
<td>0.001</td>
</tr>
<tr>
<td>Positive stress test</td>
<td>10%</td>
<td>12%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any COPD</td>
<td>20%</td>
<td>27%</td>
<td>0.001</td>
</tr>
<tr>
<td>O2 Dependent COPD</td>
<td>0%</td>
<td>6%</td>
<td>0.001</td>
</tr>
<tr>
<td>CHF</td>
<td>4%</td>
<td>21%</td>
<td>0.001</td>
</tr>
<tr>
<td>NIDDM</td>
<td>16%</td>
<td>17%</td>
<td>0.001</td>
</tr>
<tr>
<td>IDDM</td>
<td>7%</td>
<td>15%</td>
<td>0.001</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>2%</td>
<td>15%</td>
<td>0.001</td>
</tr>
<tr>
<td>Anti-plt agent</td>
<td>91%</td>
<td>90%</td>
<td>0.001</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>75%</td>
<td>77%</td>
<td>0.001</td>
</tr>
<tr>
<td>Statin</td>
<td>81%</td>
<td>74%</td>
<td>0.001</td>
</tr>
</tbody>
</table>
## Risk Stratified Outcomes
### Normal Risk, Asymptomatic

<table>
<thead>
<tr>
<th>Event</th>
<th>CEA (n=4789)</th>
<th>CAS (n=148)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or death</td>
<td>0.6%</td>
<td>0.0%</td>
<td>0.360</td>
</tr>
<tr>
<td>Stroke, death or MI</td>
<td>1.4%</td>
<td>0.0%</td>
<td>0.154</td>
</tr>
<tr>
<td>Any major stroke</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.526</td>
</tr>
<tr>
<td>Any ipsilateral stroke</td>
<td>0.4%</td>
<td>0.0%</td>
<td>0.468</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.1%</td>
<td>0.0%</td>
<td>0.725</td>
</tr>
</tbody>
</table>
## Risk Stratified Outcomes

**Normal Risk, Symptomatic**

<table>
<thead>
<tr>
<th>Event</th>
<th>CEA (n=2838)</th>
<th>CAS (n=127)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or death</td>
<td>1.0%</td>
<td>4.7%</td>
<td>0.001</td>
</tr>
<tr>
<td>Stroke, death or MI</td>
<td>1.8%</td>
<td>6.3%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any major stroke</td>
<td>0.4%</td>
<td>1.6%</td>
<td>0.048</td>
</tr>
<tr>
<td>Any ipsilateral stroke</td>
<td>0.8%</td>
<td>3.1%</td>
<td>0.005</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.1%</td>
<td>1.6%</td>
<td>0.001</td>
</tr>
</tbody>
</table>
Risk Stratified Outcomes
Normal Risk, Survival

Kaplan-Meier survival estimates

<table>
<thead>
<tr>
<th></th>
<th>CEA</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>98%</td>
<td>97%</td>
<td></td>
</tr>
<tr>
<td>96%</td>
<td>92%</td>
<td></td>
</tr>
<tr>
<td>93%</td>
<td>85%</td>
<td></td>
</tr>
<tr>
<td>91%</td>
<td>84%</td>
<td></td>
</tr>
<tr>
<td>87%</td>
<td>70%</td>
<td></td>
</tr>
</tbody>
</table>

P = 0.003
## Risk Stratified Outcomes

**High Risk, Asymptomatic**

<table>
<thead>
<tr>
<th>Event</th>
<th>CEA (n=1519)</th>
<th>CAS (n=72)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or death</td>
<td>1.3%</td>
<td>0.0%</td>
<td>0.327</td>
</tr>
<tr>
<td>Stroke, death or MI</td>
<td>2.6%</td>
<td>0.0%</td>
<td>0.169</td>
</tr>
<tr>
<td>Any major stroke</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.626</td>
</tr>
<tr>
<td>Any ipsilateral stroke</td>
<td>1.0%</td>
<td>0.0%</td>
<td>0.397</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.663</td>
</tr>
</tbody>
</table>
## Risk Stratified Outcomes

**High Risk, Symptomatic**

<table>
<thead>
<tr>
<th>Event</th>
<th>CEA (n=1387)</th>
<th>CAS (n=76)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke or death</td>
<td>1.9%</td>
<td>7.9%</td>
<td>0.001</td>
</tr>
<tr>
<td>Stroke, death or MI</td>
<td>2.9%</td>
<td>7.9%</td>
<td>0.015</td>
</tr>
<tr>
<td>Any major stroke</td>
<td>0.6%</td>
<td>5.3%</td>
<td>0.001</td>
</tr>
<tr>
<td>Any ipsilateral stroke</td>
<td>1.3%</td>
<td>5.3%</td>
<td>0.006</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>0.7%</td>
<td>1.3%</td>
<td>0.559</td>
</tr>
</tbody>
</table>
RISK STRATIFIED OUTCOMES
HIGH RISK, SURVIVAL

Kaplan-Meier survival estimates

<table>
<thead>
<tr>
<th>CEA</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>93%</td>
<td>91%</td>
</tr>
<tr>
<td>85%</td>
<td>81%</td>
</tr>
<tr>
<td>78%</td>
<td>73%</td>
</tr>
<tr>
<td>70%</td>
<td>53%</td>
</tr>
<tr>
<td>64%</td>
<td>40%</td>
</tr>
</tbody>
</table>

P=0.005
SUMMARY

- Low – moderate risk patients
  - Asymptomatic
    - CEA and CAS have similar outcomes
    - Acceptable long term survival
  - Symptomatic
    - CAS has inferior outcomes (Stroke or death 4.7% CAS v 1.0% CEA)

- High risk patients
  - Asymptomatic
    - CEA and CAS has equivalent outcomes
    - ? Benefit due to poor long term survival (5-yr: CEA 63%, CAS 40%)
  - Symptomatic
    - CAS has inferior outcomes (Stroke or death 7.9% CAS v 1.9% CEA)
Redo-surgery versus stenting
in patients with restenosis
after prior carotid endarterectomy

Margriet Fokkema, Brian Nolan, Robert Cambria,
Richard Powell, Andrew Stanley, Gert Jan de
Borst, Marc Schermerhorn
on behalf of the VSGNE
Background

- Restenosis after CEA in the VSGNE (median FU 1 yr)
  - > 50% → 10%
    - 50%-79% → 7.9%
    - 80%-99% → 1.7%
    - Occlusion → 0.5%
  - Decreased slightly over time
    - Patching during CEA was protective

Abstract

BACKGROUND: Level I evidence shows conventional carotid endarterectomy (CEA) with patch angioplasty results in lower rates of restenosis. However, whether this information has affected practice patterns and outcomes in real-world vascular surgery settings is unclear.

METHODS: Within the Vascular Study Group of New England (VSGNE), we studied 2981 patients undergoing 2981 first-time CEAs between January 1, 2003, and June 31, 2008. Rates of restenosis (defined by duplex ultrasound imaging at the 1-year follow-up) were estimated using life-table analysis. Cox proportional hazards models were used to identify multivariable predictors of postoperative restenosis ≤ 1 year.

RESULTS: Across 58 surgeons and 11 hospitals, we studied 2611 conventional CEAs (88% of all CEAs) and 370 eversion CEAs (12% of CEAs). Median follow-up was 12.8 months (range, 1-35 months). The proportion of conventional CEAs performed with patching increased...
Literature

- Redo-CEA vs. Primary CEA
  
  *Redo carotid endarterectomy versus primary carotid endarterectomy. Reoperation for recurrent carotid stenosis: Early results and late outcome in 199 patients*  
  
  Patrick J. O’Hara, MD, a Norman R. Hertzer, MD, a Matthew T. Karafa, MS, b Edward J. Mascha, MS, b Leonard P. Krajewski, MD, a and Edwin G. Beven, MD, a Cleveland, Ohio
  
  As safe as primary CEA
  
- Primary CAS vs. CAS after ipsi CEA
  
  *Society of vascular surgery vascular registry comparison of carotid artery stenting outcomes for atherosclerotic vs nonatherosclerotic carotid artery disease.*
  
  White RA, Sicard GA, Zwolak RM, Sidawy AN, Schermerhorn ML, Shackelton RJ, Siami FS; SVS Outcomes Committee.
  
  Stroke risk lower in restenotic lesions than primary lesions
  
- Redo-CEA vs. CAS after ipsi CEA
  
  ?
Nolan et al. 2012

Patients with prior ipsilateral CEA in the VSGNE:
• 172 CEA vs. 144 CAS (SX + ASX)
Prior ipsilateral CEA

- Independent predictor for stroke or death in all patients (SX + ASX) undergoing revascularization (CEA + CAS)

$\rightarrow$ OR 3.2 95% CI 1-2.4
Objective

• To investigate
  • Outcome of CAS vs. CEA in symptomatic patients with restenosis after prior ipsilateral CEA
  • Outcome of CAS vs. CEA in asymptomatic patients with restenosis after prior ipsilateral CEA
  • Safety of re-intervention compared to primary intervention
Methods

• **Endpoints:**
  - 30-day
    - Stroke/death
    - Stroke/death/MI
  - At discharge
    - Cranial Nerve Injury (after CEA)
  - Long-term follow-up
    - Restenosis ≥ 50%
    - Restenosis ≥ 80%
Methods (2)

- VSGNE 2003-2011

- Pt undergoing CAS or CEA
  - Concomitant CABG excluded (n=221)

- Pt with prior ipsilateral CEA
  - Tertiary interventions excluded (n=6)
Results

**CEA N = 9357**

**CAS N = 663**

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary CEA</td>
<td>N = 9145</td>
</tr>
<tr>
<td>Redo-CEA</td>
<td>N = 212</td>
</tr>
<tr>
<td>Primary CAS</td>
<td>N = 443</td>
</tr>
<tr>
<td>CAS after CEA</td>
<td>N = 220</td>
</tr>
</tbody>
</table>
## Preoperative characteristics

<table>
<thead>
<tr>
<th></th>
<th>Redo-CEA (%)</th>
<th>CAS after CEA (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (mean years)</strong></td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>58</td>
<td>63</td>
</tr>
<tr>
<td><strong>Symptomatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sx ≥50% ICA stenosis</td>
<td>99</td>
<td>100</td>
</tr>
<tr>
<td><strong>Asymptomatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asx ≥70% ICA stenosis</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td><strong>Anatomical High Risk</strong></td>
<td>NA</td>
<td>64</td>
</tr>
<tr>
<td><strong>Refused surgery</strong></td>
<td>NA</td>
<td>17</td>
</tr>
</tbody>
</table>

Smoking, Hypertension, Diabetes, CHF, CAD, Renal disease, ASA>3  **NS**
### 30-day outcome: SX patients

<table>
<thead>
<tr>
<th></th>
<th>Stroke/death N (%)</th>
<th>Stroke/death/MI N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ipsi CAS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 69</td>
<td>3 (4.4)</td>
<td>4 (5.8)</td>
</tr>
<tr>
<td><strong>Redo- CEA</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 76</td>
<td>3 (4.0)</td>
<td>5 (6.6)</td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>OR (95% CI)</strong></td>
<td>1.1 (0.2-5.7)</td>
<td>0.9 (0.2-3.4)</td>
</tr>
</tbody>
</table>
# 30-day outcome: ASX patients

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Stroke/death N (%)</th>
<th>Stroke/death/MI N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAS</strong></td>
<td>3 (2.0)</td>
<td>5 (3.3)</td>
</tr>
<tr>
<td>N = 151</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CEA</strong></td>
<td>4 (3.0)</td>
<td>6 (4.4)</td>
</tr>
<tr>
<td>N = 136</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>P-value</strong></td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td><strong>OR (95% CI)</strong></td>
<td>0.7 (0.15-3.04)</td>
<td>0.7 (0.2-2.5)</td>
</tr>
</tbody>
</table>
stroke or death - within procedure

SX patients

OR 2.2 (0.7-7.5)  
P = 0.2

7.5%  
OR 0.6 (0.2-2.0)  
P = 0.6
stroke or death - within procedure

ASX patients

OR 3.4 (1.2-9.5)

P = 0.04*

OR 2.8 (0.5-17.2)

P = 0.4
Predictors for stroke or death – in SX patients –

- **CEA**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior ipsil CEA</td>
<td>2.3</td>
<td>0.7-7.5</td>
<td>0.17</td>
</tr>
</tbody>
</table>

- **CAS**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior ipsil CEA</td>
<td>0.65</td>
<td>0.17-2.44</td>
<td>0.52</td>
</tr>
</tbody>
</table>
Predictors for stroke or death – in ASX patients –

- **CEA**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior ipsil CEA</td>
<td>3.6</td>
<td>1.2-10</td>
<td>0.02</td>
</tr>
</tbody>
</table>

- **CAS**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior ipsil CEA</td>
<td>3.1</td>
<td>0.48-19.9</td>
<td>0.24</td>
</tr>
</tbody>
</table>
Cranial nerve injury at discharge

- After redo-CEA: 6.1% (N=13)
- Compared to primary CEA: 5.2% (N=473)
  OR 1.2 95% CI 0.7 – 2.1, P = 0.8
Long term follow-up

• Available for restenosis
  • 61% CAS, median 337 days
  • 64% CEA, median 355 days
## Restenosis at long-term FU

<table>
<thead>
<tr>
<th></th>
<th>Restenosis $\geq 50%$</th>
<th>Restenosis $\geq 80%$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Ipsi CAS</td>
<td>23 (17.2)</td>
<td>2 (1.5)</td>
</tr>
<tr>
<td>Redo-CEA</td>
<td>20 (14.8)</td>
<td>6 (4.4)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.6</td>
<td>0.3</td>
</tr>
<tr>
<td>OR (95% CI)</td>
<td>1.2 (0.6-2.3)</td>
<td>0.3 (0.1-1.6)</td>
</tr>
</tbody>
</table>
Restenosis $\geq 80\%$ – within procedure

OR $2.7 \ (1.1-6.2)$ $P = 0.03^*$

OR $0.6 \ (0.1-3.0)$ $P = 0.7$
Summary

• Patients undergoing CAS or CEA after prior CEA have:
  • similar pre-operative characteristics
  • similar post-op 30-day outcome
  • similar risk of restenosis at follow-up

• SX and ASX pt. undergoing redo-CEA have:
  • Increased 30-day stroke or death rate compared to primary CEA
  • No increased risk for cranial nerve injury
  • Increased risk for restenosis ≥ 80%

• SX pt. undergoing CAS after prior CEA have:
  • Decreased 30-day stroke or death rate compared to primary CAS

• ASX pt. undergoing CAS after prior CEA have:
  • Increased 30-day stroke or death rate compared to primary CAS
Conclusion

• For patients with symptomatic restenosis after prior CEA, CAS seems a reasonable treatment

• For patients with asymptomatic restenosis after prior CEA, both CAS and redo-CEA have increased risk compared to primary procedure ~ 3%

• One should carefully weigh the risk and benefits of re-intervention, particularly for patients who are asymptomatic
Carotid Stenosis: Surgery Still the Best Option

Richard P. Cambria, M.D.
Chief, Division of Vascular and Endovascular Surgery
Massachusetts General Hospital

Robert R. Linton, MD Professor of Vascular and Endovascular Surgery
Harvard Medical School
OVERVIEW

• The pathology/pathophysiology of stroke related to Carotid Stenosis → Rationale for Intervention

• Clinical decision-making → predicated on natural history . . . Esp. in asymptomatic patients → Role, limitations modern medical therapy

• The CEA vs. CAS data and firestorm
FUNDAMENTAL GOALS OF CEA

• Owing to collateral circulation, it was never about “Bringing blood to where it ain’t”
  - Fundamentally different from coronary, renal, leg
FUNDAMENTAL GOALS OF CEA

• Rather about removal of a dynamic disease process wherein plaque events either have already or HAVE THE POTENTIAL to cause thromboembolic stroke
  – Prediction? Control with med therapy

• Where then rationale for lumenal expansion with an uncovered stent?
FUNDAMENTAL GOALS OF CEA

- Rather about removal of a dynamic disease process wherein plaque events either have already or HAVE THE POTENTIAL to cause thromboembolic stroke
  - Prediction? Control with med therapy
- Where then rationale for lumenal expansion with an uncovered stent?
ASYMPTOMATIC STENOSIS: NATURAL HISTORY / RISK STRATIFICATION

- Consistent data

- Stroke risk (5.5% per year if ≥ 75%) increases with increasing degree of stenosis and progression under observation

Chambers, Norris NEJM ‘86
Progression of Carotid Stenosis Detected by Duplex Ultrasonography Predicts Adverse Outcomes in Cardiovascular High-Risk Patients

Schila Sabeti, MD; Oliver Schlager, MD; Markus Exner, MD; Wolfgang Mlekovitch, MD; Jasmin Amighi, MD; Petra Dick, MD; Gerald Maurer, MD; Kurt Huber, MD; Renate Koppensteiner, MD; Oswald Wagner, MD; Erich Minar, MD; Martin Schillinger, MD

Background and Purpose—The progression of carotid stenosis reflects the activity of atherosclerotic disease and may...

- **2-fold (p=0.03)** risk of stroke with carotid lesion progression
- **70%** patients on statins
ASYMPTOMATIC STENOSIS: NATURAL HISTORY / RISK STRATIFICATION

NATURAL HISTORY DATA
NASCET Study

THE CAUSES AND RISK OF STROKE IN PATIENTS WITH ASYMPTOMATIC INTERNAL-CAROTID-ARTERY STENOSIS


ASYMPTOMATIC STENOSIS: NATURAL HISTORY / RISK STRATIFICATION

* NASCET f/u.......NEJM 2000;342:1693

lesions contralateral to symptomatic lesion and verified by angiography

Annual overall risk 3.2% (large artery 2%/yr), highest risk for 75-99% lesions (18.5% @ 5 yrs!!!) and STROKE not TIA was first event in 80% of cases
### % ECST Stenosis

<table>
<thead>
<tr>
<th>% Stenosis</th>
<th># Stroke/TIA</th>
<th># Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-69</td>
<td>10 (5.1%)</td>
<td>194</td>
</tr>
<tr>
<td>70-89</td>
<td>54 (9.1%)</td>
<td>593</td>
</tr>
<tr>
<td>90-99</td>
<td>44 (13.4%)</td>
<td>328</td>
</tr>
</tbody>
</table>

### % NASCET Stenosis

<table>
<thead>
<tr>
<th>% Stenosis</th>
<th># Stroke/TIA</th>
<th># Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-69</td>
<td>29 (8.2%)</td>
<td>352</td>
</tr>
<tr>
<td>70-89</td>
<td>37 (10.7%)</td>
<td>344</td>
</tr>
<tr>
<td>90-99</td>
<td>21 (19.3%)</td>
<td>109</td>
</tr>
</tbody>
</table>

Overall, 10% patients had events @ 3 years!
ASYMPTOMATIC STENOSIS: THE QUEST FOR RISK STRATIFICATION

From the Society for Vascular Surgery

Asymptomatic internal carotid artery stenosis and cerebrovascular risk stratification

- A combination clinical/duplex criteria can predict high/low risk groups
- In 923 patients with $\geq 70\%$ ECST stenoses, 46% had 5 year stroke risk range 5-30%!

J Vasc Surg 2010;52:1486-96
Has Modern Medical Therapy made Intervention for Asymptomatic Stenosis Obsolete?

- Current (2011) Practice Guidelines → NO
- Major Transatlantic Differences
- What is the evidence?
Our debators, Peter Schneider and Ross Naylor, offer reasoned and passionate arguments to defend their differing approaches.
Statins in Stroke Prevention and Carotid Atherosclerosis
Systematic Review and Up-to-Date Meta-Analysis

<table>
<thead>
<tr>
<th>Studies</th>
<th>Difference in LDL (mmol/L)</th>
<th>Statin-allocated</th>
<th>Control-allocated</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GREACE</td>
<td>1.9</td>
<td>9/800 (1.1%)</td>
<td>17/800 (2.1%)</td>
<td></td>
</tr>
<tr>
<td>AFCAPS/TexCAPS</td>
<td>0.9</td>
<td>14/3304 (0.4%)</td>
<td>17/3301 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Post-CABG</td>
<td>1.1</td>
<td>18/676 (2.7%)</td>
<td>16/675 (2.8%)</td>
<td></td>
</tr>
<tr>
<td>GISSI</td>
<td>0.3</td>
<td>20/2138 (0.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WOSCOPS</td>
<td>1.1</td>
<td>46/3302 (1.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARE</td>
<td>1.0</td>
<td>52/2081 (2.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSSS</td>
<td>1.8</td>
<td>56/2221 (2.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASCOT</td>
<td>1.1</td>
<td>89/5168 (1.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROSPECT</td>
<td>1.0</td>
<td>135/2891 (4.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIPID</td>
<td>1.0</td>
<td>169/4512 (3.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALLHAT</td>
<td>0.6</td>
<td>209/5170 (4.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPS</td>
<td>1.0</td>
<td>444/10269 (4.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All studies</td>
<td>1.0</td>
<td>1261/42 532 (3.0%)</td>
<td>1544/42 507 (3.6%)</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity $\chi^2_{11} = 11.5; p = 0.4$

- **0.79 (0.73–0.85)**
- **p < 0.0001**
SPARCL: High Dose Atorvastatin vs Placebo In Patients with Prior CVA/TIA

The New Bible

"... Medical intervention alone is now best for stroke prevention."
Differences In Study Populations from the Systematic Review* Drive the Review Conclusions

The Change in Minimum Stenosis Thresholds in Studies Over Time Mirrors the Reported Decline In Stroke Rates

Changes in Minimum % Stenosis and Ipsilateral Stroke Rate Over Time Used by the Abbott Paper

0.0% 0.5% 1.0% 1.5% 2.0% 2.5% 3.0% 3.5%

Ipsilateral Stroke Rate

Publication Year

Reported Ipsilateral Stroke Trend
Minimum Stenosis Trend (not reported in paper)
BEST MEDICAL THERAPY: SMART STUDY

- 221 patients monitored with questionnaires/BMT
- Stroke in 2.7% over nearly 4 years but 7% were referred for carotid intervention
- Less than half patients had 70-99% lesions!

Stroke 2007;38:1470-1475
“Ipsilateral stroke in only 0.34%/year with BMT”
Another 2% had TIA
101 pts with > 50% BUT only 32 with 70-99% and 3 of these had strokes!!!
Stroke Risk of Carotid Stenosis in REACH

- Pts (3164) with asymptomatic ≥ 70% compared to those without same
- 1 yr risk TIA/Stroke ≈ 6.5% (2 fold) and highly significant

> 70% all pts on statins

High cardiovascular event rates in patients with asymptomatic carotid stenosis: the REACH registry*

F.T. Aichner a, R. Topakian a, M.J. Alberts b, D.L. Bhatt c, H.-P. Haring a, M.D. Hilst d, G. Montalescot e, S. Goto f, E. Touze g, J.-L. Mas h, P.G. Steg h and J. Röther i, for the REACH Registry Investigators

* Academic Teaching Hospital Wagner-Jauregg, Linz, Austria; “Northwestern University Medical School, Chicago, IL, USA; “Cleveland Clinic, Cleveland, OH, USA; 4 Foothills Medical Centre, Calgary, AB, Canada; 5 INSERM U-856 et Université Paris VI, Paris, France; 6 Tokai University School of Medicine, Isehara, Japan; 7 Hôpital Sainte-Anne, Paris, France; 8 INSERM U-698 et Université Paris VII – Denis Diderot, Hôpital Bichat-Claude Bernard, Paris, France; 9 Klinikum Minden, Hannover Medical School, Minden, Germany

Conclusion: Asymptomatic carotid artery stenosis was associated with high 1-year rates of cardiovascular and cerebrovascular ischaemic events. Stroke was powerfully predicted by prior cerebrovascular ischaemic events.
Late Results - ACST

10-year stroke prevention after successful carotid endarterectomy for asymptomatic stenosis (ACST-1): a multicentre randomised trial

Summary

Background If carotid artery narrowing remains asymptomatic (ie, has caused no recent stroke or other neurological symptoms), successful carotid endarterectomy (CEA) reduces stroke incidence for some years. We assessed the long-term effects of CEA in asymptomatic patients.

Stroke risk:

5 yr – 4.1% CEA vs 10% medical

CEA reduces long-term stroke risk.... in asymptomatic pts.
STATIN USE IN ACST

OPTIMAL MED Rx BECAME PART OF ACST!

The Lancet 2010:376
ACST – 10 yr Results

BENEFIT OF CEA – DESPITE STATINS

On lipid-lowering therapy before stroke:

Gain at
5 years: 3.4% (95% CI 1.5 – 5.2), p=0.0005
10 years: 5.8% (95% CI 2.1 – 9.6), p=0.002

Not on lipid-lowering therapy before stroke:

Gain at
5 years: 10.8% (95% CI 6.6 – 15.1), p<0.0001
10 years: 6.2% (95% CI -0.4 – 12.8), p=0.07

“... patients with tight (≥ 60% NASCET) carotid stenosis cannot have the risk from it completely abolished by medical treatment alone.”
Low confidence that intervention preferred to medical therapy in asymptomatic patients
Progression of Asymptomatic Carotid Stenosis Despite Optimal Medical Therapy

Valy Boulom MD, Mark F. Conrad MD MMSc, Shankha Mukhopadhyay MS, Ashu Garg MD, Virendra I. Patel MD, Richard P. Cambria MD

Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, Harvard Medical School, Boston, MA
Progression of Asymptomatic Carotid Stenosis Despite Optimal Medical Therapy

- 906 carotids (801 patients) with Asymptomatic Moderate Carotid Stenosis (50-69% by Duplex US)
- 6 year follow-up interval

- Statin use 84%
- LDL always normal (<100) 56.4%
- Optimal medical therapy (aspirin, statin, LDL <100) 29.4%
Optimal medical therapy failed to prevent progression of moderate carotid stenosis

<table>
<thead>
<tr>
<th>5-year Actuarial Outcome</th>
<th>Cohort (n=906)</th>
<th>OMT Yes (n=266)</th>
<th>OMT No (n=640)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Lesion Progression</td>
<td>61.5%</td>
<td>60.6%</td>
<td>61.7%</td>
<td>0.37</td>
</tr>
<tr>
<td>Freedom from Ipsilateral Symptoms</td>
<td>87%</td>
<td>85%</td>
<td>87.9%</td>
<td>0.17</td>
</tr>
<tr>
<td>Freedom from Ipsilateral CEA/CAS</td>
<td>71.7%</td>
<td>67.5%</td>
<td>73.6%</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Submitted - NESVS
BMT: THE GUY WITH THE NEW BOAT

“DON’T BURY YOUR TRAILER TOO DEEP”
Quality Committee Report

- Wound infection after infra-inguinal bypass
- Final prediction model - VQI
- VSGNE physician survey
- Hospital improvement opportunities
Wound Infection

* **VQI Skin prep workgroup:** Adam Beck, Jason Chiriano, Jack Cronenwett, Mark Davies, Alik Farber, Karen Homa, Jeff Kalish, Megan Tracci, Magdiel Trinidad, Mark Wyers

* **Infra-inguinal**
  * 7,908 VQI procedures
  * 2003 to June 2012

* Several variables associated with wound infection
  * **BMI:** OR = 1.35
  * **Skin prep:** OR = 0.62 protective
    * chlorhexidine or chlorhexidine with alcohol (Chloraprep)
  * **Tissue loss:** OR = 1.38
  * **Graft recipient (distal: below knee):** OR = 1.3
  * **Transfusion ≥ 3 units:** OR = 2.7
Model

★ Multivariate logistic regression model
★ ABI <0.35 on procedure side was associated with higher odds of infection (OR 1.5)
★ Chlorhexidine or chlorhexidine with alcohol was associated with lower odds of infection (thus protective; OR 0.5)
★ Transfusion > 3 units was associated with higher odds of infection (OR 3.3)
★ Surgery time longer than 220 minutes was associated with higher odds of infection (221 to 290 minutes OR 2.1, Greater than 290 minutes OR 2.9)
★ Area under ROC curve = 0.707
## Analyses

### Significant Odds Ratio

<table>
<thead>
<tr>
<th></th>
<th>ABI &lt;.35</th>
<th>Chlorhexidine</th>
<th>Transfusion ≥ 3 Units</th>
<th>Surgery Time 221 to 290 &amp; &gt;290 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full model</strong></td>
<td>1.5</td>
<td>0.52</td>
<td>3.3</td>
<td>2.1 &amp; 2.9</td>
</tr>
<tr>
<td><strong>Stratify</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue loss</td>
<td>1.8</td>
<td>0.47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No tissue loss</td>
<td>3.6</td>
<td></td>
<td></td>
<td>1.9 &amp; 2.2</td>
</tr>
<tr>
<td><strong>Hierarchical model:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full model</td>
<td>1.6</td>
<td></td>
<td>2.5</td>
<td>2.4</td>
</tr>
<tr>
<td>Tissue loss</td>
<td></td>
<td>0.47</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>No tissue loss</td>
<td></td>
<td></td>
<td>3.0</td>
<td>Continuous 2.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute ischemia 2.0</td>
</tr>
</tbody>
</table>
Infection Prevention Survey #2

Alik Farber MD
Biannual Meeting
Dartmouth-Hitchcock Medical Center, Lebanon, NH
Thursday, October 24, 2012
Purpose

• to better understand infection prevention practices as they apply to infra-inguinal bypass within VSGNE
• to focus on parameters not well assessed in the database and where there was variability
• to link practice patterns to individual surgeon’s wound infection outcome so as to identify which practices correlate with good outcomes.
Methods

• 17 point survey sent out electronically to VSGNE membership
Methods

- Surgeon name linked to his/her surgeon ID in the registry of infrainguinal bypasses within VSGNE to get volume of procedures and wound infection rates.

- Surgeons were grouped according to their individual wound infection rates: ≤4% and >4% – 4% was the median wound infection rate

- Fisher exact test to assess for an association with the responses to each survey question.
Results

- 41 surveys completed
  - 1 survey had only 2 questions completed
  - 1 had no name
  - 2 surgeons completed survey twice
- 37 individuals (out of 186) responded to the survey (20%)
  - 67 individuals (out of 175) responded to the first survey (38% response rate)
Results

• 35 respondents have entered infrainguinal LEB data within VSGNE

• 2,694 infrainguinal bypass procedures were performed by these 35 surgeons between 2003 and June 2012

• 5,547 total infrainguinal bypasses performed within this timeframe
  – respondents performed 48% of the procedures

• 134 VSGNE surgeons performed infrainguinal bypasses within this timeframe
  – respondents represent 26% of these surgeons
32 surgeons had more than 10 procedures.
Choice of perioperative antibiotic
For patients without allergies I use ...
Preoperative shower
I routinely prescribe pre-operative shower to my patients ...
Pre-operative skin preparation
I use IobanR adhesive in...

- few cases 19%
- most cases 65%
- only if prosthetic use is anticipated 16%
When I use lobanR adhesive I cover...

- Area of planned incisions: 44%
- All exposed skin: 34%
- Only groin: 22%
Groin lymphatics
To control groin lymphatics I primarily use...

- Electrocautery: 41%
- Ties: 34%
- Harmonic Scalpel: 6%
- Sutures: 9%
- Clips: 10%
Irrigation
I use routine wound irrigation...

- Yes, with antibiotics: 41%
- Yes, without antibiotics: 41%
- No: 9%
Wound closure
In closing the subcutaneous tissue in the groin I use ...
Not including the skin, I close my groin wound in:

- 1 layer: 3%
- 2 layers: 28%
- 3 layers: 69%
In closing skin in the groin I use...

- staples: 38%
- subcuticular closure: 50%
- interrupted closure sutures: 12%
In closing skin in the leg separate from the groin I use...

- Staples: 56%
- Subcuticular closure: 31%
- Interrupted closure sutures: 13%
Type of Arterial Patch
When patching the femoral artery that was endarterectomized during infrainguinal bypass, I usually use...

- Bovine pericardium: 85%
- Dacron: 6%
- Vein: 9%
Trainee Involvement
A resident or fellow participates in most of my cases ...
Use of chlorhexidene on the neck
I use chlorhexidine on the neck before a carotid endarterectomy ...
Use of chlorhexidine in the presence of open wounds
I use chlorhexidine in the presence of open wounds adjacent to the operative field ...

- Yes, including the wound: 25%
- Yes, but I use iodine on the wound: 31%
- No: 44%
Use of MRSA screening
My patients undergo pre-operative MRSA screening ...

- Yes, routinely: 28%
- Yes, selectively: 31%
- No: 41%
Blood transfusion
In the intra-operative or post-operative setting, for patients without active severe coronary disease, please choose the hemoglobin value below which blood transfusion is used in your practice...

- 6 g/dl: 6%
- 7 g/dl: 34%
- 8 g/dl: 38%
- 9 g/dl: 9%
- 10 g/dl: 13%
Management of Hyperglycemia
At the hospital that I perform the majority of my cases, we manage postoperative hyperglycemia...

- with uniform consultation of an endocrinologist or diabetologist: 16%
- with a subcutaneous sliding scale protocol: 34%
- with a standardized insulin infusion protocol: 41%
- on an individual patient to patient basis without a standardized insulin protocol: 9%
- with uniform consultation of an endocrinologist or diabetologist: 16%
Surgeon Information
Number of Surgeons (n=32) by Wound Infection Category

- 11 surgeons with 0% wound infection
- 12 surgeons with >4% wound infection
- 9 surgeons with >0% to ≤4% wound infection
Number of Procedures (n=2,688) by Surgeon Wound Infection Rate

- 1544 procedures >0% to <4% wound infection
- 732 procedures >4% wound infection
- 412 procedures 0%, wound infection
In closing skin in the groin, I use

- Subcuticular closure: 65%
- Staples: 30%
- Interrupted closure sutures: 5%
- Fisher's exact test: p=0.048
Summary

• There is significant variability in practice patterns with regard to infrainguinal bypass and factors that may be related to development of wound infection

• Analysis was limited by low response rate

• Use of subcuticular closure in the groin was associated with decreased odds of wound infection

• This presents an opportunity for Quality Improvement.
Hospital Opportunity

Wound infection

Expected Rate

Chlorhexidine

Transfusion ≥ 3 Units

Procedure > 220 minutes
Wound Infection Rate after Infra Inguinal Byass Procedure
Observed and Expected by VSGNE Centers

5,552 patient procedures, 2003 to October 2012

Overall rate Wound Infection
VSGNE = 4.8%
VQI = 4.5%
AUC = 0.65

VSGNE Centers
adjusted for: skin preparation, ankle/brachial systolic pressure index, transfusion, length of procedure

Significantly lower or higher than expected:
* p<0.05
**p<0.01
Transfusion $\geq 3$ Units

![Bar chart showing center and overall rates of transfusion for different VSGNE Centers. The chart displays a range of percentages from 0% to 40% for both center and overall rates, with a notable increase in the overall rate for one particular center.]
Procedure Time > 220 min

Center rate
Overall rate

VSGNE Centers
## Center Opportunity Profile for Improvement

### Wound Infection

<table>
<thead>
<tr>
<th>Center</th>
<th>Wound Infection Rate</th>
<th>Expected Infection Rate</th>
<th>Significant Obs. vs. Exp.</th>
<th>Chlorhexidine</th>
<th>Transfusion &gt;= 3 units</th>
<th>Procedure time &gt; 220 minutes</th>
<th>Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0%</td>
<td>1%</td>
<td>33%</td>
<td>60%</td>
<td>2%</td>
<td>43%</td>
<td>Switch to Chlorhexidine</td>
</tr>
<tr>
<td>B</td>
<td>0%</td>
<td>2%</td>
<td>100%</td>
<td>3%</td>
<td>3%</td>
<td>35%</td>
<td>Reduce number of transfusions</td>
</tr>
<tr>
<td>C</td>
<td>0%</td>
<td>5%</td>
<td>100%</td>
<td>29%</td>
<td>71%</td>
<td>Reduce time in surgery</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>0%</td>
<td>3%</td>
<td>100%</td>
<td>7%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>1%</td>
<td>1%</td>
<td>15%</td>
<td>20%</td>
<td>65%</td>
<td>Switch to Chlorhexidine; Reduce number of transfusions; Significantly lower infection rate than VQI overall rate - is infection recorded accurately?</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>1%</td>
<td>2%</td>
<td>92%</td>
<td>18%</td>
<td>71%</td>
<td>Almost 100% Chlorhexidine; Reduce number of transfusions</td>
<td></td>
</tr>
</tbody>
</table>

### Predictors of wound infection

- **Highlighted risk predictors:** Chlorhexidine below 100% usage; Transfusion above 1 standard deviation from overall rate; Procedure time 75% or greater

**NOTE:** Centers with 0% infection rate have less than 77 procedures (not enough procedures to adequately determine if significantly lower) - review wound infection definition and data recording procedure.
## Center Opportunity Profile for Improvement

**Wound Infection**

<table>
<thead>
<tr>
<th>Center</th>
<th>Wound Infection Rate</th>
<th>Expected Infection Rate</th>
<th>Significant Obs. vs. Exp.</th>
<th>Chlorhexidine</th>
<th>Transfusion &gt;= 3 units</th>
<th>Procedure time &gt; 220 minutes</th>
<th>Center Improvement Opportunity</th>
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</thead>
<tbody>
<tr>
<td>Q</td>
<td>5%</td>
<td>3%</td>
<td></td>
<td>82%</td>
<td>15%</td>
<td>82%</td>
<td>Almost 100% Chlorhexidine; Reduce number of transfusions; Reduce time in surgery</td>
</tr>
<tr>
<td>R</td>
<td>5%</td>
<td>1%</td>
<td>**</td>
<td>0%</td>
<td>7%</td>
<td>59%</td>
<td>Switch to Chlorhexidine</td>
</tr>
<tr>
<td>S</td>
<td>6%</td>
<td>0%</td>
<td>**</td>
<td>100%</td>
<td>4%</td>
<td>78%</td>
<td>Reduce time in surgery</td>
</tr>
<tr>
<td>T</td>
<td>7%</td>
<td>3%</td>
<td></td>
<td>73%</td>
<td>30%</td>
<td>50%</td>
<td>Almost 100% Chlorhexidine; Reduce number of transfusions</td>
</tr>
<tr>
<td>U</td>
<td>8%</td>
<td>2%</td>
<td>*</td>
<td>100%</td>
<td>8%</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>8%</td>
<td>1%</td>
<td>**</td>
<td>97%</td>
<td>4%</td>
<td>58%</td>
<td>Almost 100% Chlorhexidine</td>
</tr>
<tr>
<td>W</td>
<td>10%</td>
<td>1%</td>
<td>**</td>
<td>28%</td>
<td>2%</td>
<td>37%</td>
<td>Switch to Chlorhexidine</td>
</tr>
<tr>
<td>X</td>
<td>12%</td>
<td>5%</td>
<td>**</td>
<td>19%</td>
<td>23%</td>
<td>71%</td>
<td>Switch to Chlorhexidine; Reduce number of transfusions</td>
</tr>
</tbody>
</table>

Significant difference of observed from expected wound infection: * p<0.05, **p<0.01

Highlighted risk predictors: Chlorhexidine below 100% usage; Transfusion above 1 standard deviation from overall rate; Procedure time 75% or greater

**NOTE:** Centers with 0% infection rate have less than 77 procedures (not enough procedures to adequately determine if significantly lower) - review wound infection definition and data recording procedure.
Shared quality data results in increased protamine use and reduced bleeding complications after carotid endarterectomy in the Vascular Study Group of New England

Patel, Reshma B, Beaulieu, Peter, Goodney, Philip P, Stanley, Andy Cronenwett, Jack L, Stone, David H, Bertges, Daniel J

University of Vermont College of Medicine, Burlington, VT
University of New England College of Osteopathic Medicine, Biddeford, ME
Dartmouth Hitchcock Medical Center, Lebanon, NH
Protamine reduces bleeding complications associated with carotid endarterectomy without increasing the risk of stroke

David H. Stone, MD, a Brian W. Nolan, MD, a,b Andres Schanzer, MD, c Philip P. Goodney, MD, a Robert A. Cambria, MD, d Donald S. Likosky, PhD, b Daniel B. Walsh, MD, a and Jack L. Cronenwett, MD, a for the Vascular Study Group of Northern New England, Lebanon, NH; Worcester, Mass; and Bangor, Me

Objectives: Controversy persists regarding the use of protamine during carotid endarterectomy (CEA) based on prior conflicting reports documenting both reduced bleeding as well as increased stroke risk. The purpose of this study was to determine the effect of protamine reversal of heparin anticoagulation on the outcome of CEA in a contemporary multistate registry.

Methods: We reviewed a prospective regional registry of 4587 CEAs in 4311 patients performed by 66 surgeons from 11 centers in Northern New England from 2003-2008. Protamine use varied by surgeon (38% routine use, 44% rare use, 18% selective use). Endpoints were postoperative bleeding requiring reoperation as well as potential thrombotic complications, including stroke, death, and myocardial infarction (MI). Predictors of endpoints were determined by multivariate logistic regression after associated variables were identified by univariate analysis.

Results: Of the 4587 CEAs performed, 46% utilized protamine, while 54% did not. Fourteen patients (0.64%) in the protamine-treated group required reoperation for bleeding compared with 42 patients (1.66%) in the untreated cohort (P = .001). Protamine use did not affect the rate of MI (1.1% vs 0.91%, P = .51), stroke (0.78% vs 1.15%, P = .2), or death (0.23% vs 0.32%, P = .57) between treated and untreated patients, respectively. By multivariate analysis, protamine (odds ratio [OR] 0.32, 95% confidence interval [CI], 0.17-0.63; P = .001) and patch angioplasty (OR 0.46, 95% CI, 0.26-0.81; P = .007) were independently associated with diminished reoperation for bleeding. A single center was associated with a significantly higher rate of reoperation for bleeding (OR 6.47, 95% CI, 3.02-13.9; P < .001). Independent of protamine use, consequences of reoperation for bleeding were significant, with a four-fold increase in MI, a seven-fold increase in stroke, and a 30-fold increase in death.

Conclusion: Protamine reduced serious bleeding requiring reoperation during CEA without increasing the risk of MI, stroke, or death, in this large, contemporary registry. In light of significant complications referable to bleeding, liberal use of protamine during CEA appears warranted. (J Vasc Surg 2010;51:559-64.)
Objective

To evaluate whether protamine usage after CEA increased in response to this VSGNE data

VSGNE Presentation April 2009
SVS Presentation June 2009
JVS Publication March 2010
Methods

• 10,059 CEAs from January 2003-June 2011
  60% asymptomatic 40% symptomatic

• Centers and surgeons were categorized as “original” or “new” joined post 2009

• Protamine use by surgeon
  • Rare (<10%)
  • Selective (10-80%)
  • Routine (>80%)

• Statistical Process Control

Original
12 Centers
67 Surgeons

New
14 Centers
113 Surgeons
P Chart: Percent of Patients with CEA procedure that received Protamine per month
All VSGNE Centers

- April 2009 VSGNE presentation
- June 2009 SVS presentation
- March 2010 journal publication

Percentages:
- Jan-03 to Apr-03: 43%
- May-03 to Jan-04: 52%
- Feb-04 to Dec-04: 62%

Graph shows data from January 2003 to December 2012.
P Chart: Percent of Patients with CEA procedure that received Protamine
VSGNE old Centers

June 2009 SVS presentation
63%
52%
April 2009 VSGNE presentation
March 2010 journal publication
43%
Frequency of Protamine Use by Surgeon for the Original Centers Participating in the VSGNE

Before 2009:
- Rare: 45.1%
- Selective: 18.3%
- Routine: 36.6%

After 2009:
- Rare: 41.8%
- Selective: 23.6%
- Routine: 34.5%

Statistical Significance:
- P = 0.553
- P = 0.038
- P = 0.013
Post Operative Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Protamine Yes</th>
<th>Protamine No</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>1</td>
<td>1.2</td>
<td>0.52</td>
</tr>
<tr>
<td>Stroke or Death</td>
<td>1.1</td>
<td>1.1</td>
<td>0.80</td>
</tr>
<tr>
<td>RTOR Bleed</td>
<td>0.5</td>
<td>1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Protamine usage categories</td>
<td>POMI ( P = 0.832 )</td>
<td>Re-op for bleeding ( P = 0.017 )</td>
<td>Stroke or death ( P = 0.765 )</td>
</tr>
<tr>
<td>----------------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>------------------</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Rare</td>
<td>722</td>
<td>9</td>
<td>720</td>
</tr>
<tr>
<td></td>
<td>(98.8%)</td>
<td>(1.2%)</td>
<td>(98.5%)</td>
</tr>
<tr>
<td>Selective</td>
<td>1,058</td>
<td>10</td>
<td>1,060</td>
</tr>
<tr>
<td></td>
<td>(99.1%)</td>
<td>(0.9%)</td>
<td>(99.2%)</td>
</tr>
<tr>
<td>Routine</td>
<td>1,816</td>
<td>19</td>
<td>1,827</td>
</tr>
<tr>
<td></td>
<td>(99%)</td>
<td>(1%)</td>
<td>(99.6%)</td>
</tr>
</tbody>
</table>
Conclusion

• Protamine use was increased by VSGNE surgeons coincident with the presentation and publication of VSGNE-derived data showing the benefit of protamine

• Improvements in process of care can be achieved in regional quality groups by sharing safety and efficacy data
One Year Follow-up

- VQI and VSGNE require that a follow-up form be entered for at least 80% of patients at least 9 months after their procedure, based on in person or telephone visit.
Follow-up reported at 9 months or more (phone or office) for procedures done between January 2009 and September 2010 by VSGNE Centers (excludes patients who died)

Center rate
Overall rate = 59%
Goal > 80%

Procedures: CAS, CEA, EVAR, INFRA, OPEN, PVI, SUPRA
One Year Follow-up - Success

- Develop a clear plan with key roles
- Communicate the plan to all staff
- Include in performance evaluation
- Physician champion partners with data manager, emphasizes importance

- Develop mechanism to identify patients needing follow-up reporting
One Year Follow-up - Success

- **Paper office records**
  - Print report of patients needing follow-up each month, using web-based system
  - Be sure each patient has an appointment
  - Flag chart with colored sticker
  - Print follow-up form and attach to chart for use during office visit
One Year Follow-up - Success

- **Electronic office records**
  - Print report of patients needing follow-up each month, using web-based system
  - Be sure each patient has an appointment
  - Work with EMR vendor to flag VSGNE Pts
  - Develop a template to insure that needed data are recorded during office visit
  - Transfer data to web-based system
One Year Follow-up - Failure

- “I didn’t know follow-up was required”
- “No one is assigned to do this”
- “Our physicians won’t take time in the office to help with this”
- “Our physicians don’t think this is important”
- “We don’t know which patients need follow-up”
- “I am too busy. There is no reward for doing this extra work”
Follow-Up Following Lower Extremity Bypass:

Wound Infections within the first 30 days after discharge
Current “State of Affairs”

• VQI datasets collect information at:
  – Discharge
  – 1 Year Follow-up
    • (some, but not all, report outcomes in between)

• CDC definition of SSI:
  – 30 day outcome
  – Our ability to harmonize with CDC definitions is limited
Solution

• 30-day follow up form

• Simple

• Short

• Harmonizes with CDC SSI endpoints
Details

• Online form will be developed by M2S
• Must be based on office visit after discharge (minimum 30 days)
• Record wound infection at 30 days (or sooner if it occurs) as:
  – Superficial
  – Deep
  – Disruption
• If yes:
  – Treated with antibiotics (Y/N)
  – Required hospital admission (Y/N)
  – Required operative incision and drainage (Y/N)
Details

• In addition, require entry of ABI or TBI if this was not included during admission
When To Use the 30-Day LEB Form

- 30 day follow up visit
- Wound Infection Issues ONLY
- ABIs (if not on discharge form)
<table>
<thead>
<tr>
<th>When To Use the 30-Day LEB Form</th>
<th>When NOT To Use the 30-Day LEB Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 30-day follow up form</td>
<td>• Graft thrombosis, revision, etc. after discharge</td>
</tr>
<tr>
<td>• Wound Infection Issues ONLY</td>
<td>• Late infection after 30 days</td>
</tr>
<tr>
<td>• ABIs (if not on discharge form)</td>
<td>• These, and other routine issues will still be handled by the regular LEB follow-up form</td>
</tr>
</tbody>
</table>
Next Meeting

- **Date:** Monday, May 6, 2013
- **Location:** Tufts Medical Center
- **Time:** 10 am – 4 pm
- **Caregivers meeting:** 8-10 am