VSGNE 2011
27 Participating Hospitals

25 - 950 Hospital Beds
VSGNE 2011
27 Participating Hospitals

14 Community - 13 Academic

“Real World Practice”
### Maine

**Central Maine Medical Center, Lewiston**
- Pietro Gualdalupi, MD
- Allan Ingraham, MD
- Pamela Rietschel, MD
- Sarat Vaddineni, MD

**Eastern Maine Medical Center, Bangor**
- Robert Cambria, MD
- Robert Clough, MD
- Larry Flanagan, MD
- Lisa Floyd, MD
- Terrance Fournier, MD
- Felix Hernandez, MD
- Matthew McKay, MD
- Andrew Sherwood, MD
- Peter Ver Lee, MD
- Alan Wiseman, MD

**Maine General Medical Center, Augusta**
- Cristobal Alvarado, MD
- Mark Bolduc, MD

**Maine Medical Center, Portland**
- Christopher Baker, MD
- Paul Bloch, MD
- Scott Buchanan, MD
- David Burkey, MD
- David Butzel, MD
- Robert Ecker, MD
- Robert Hawkins, MD
- William Herbert, MD
- Peter Higgins, MD
- Jens Jorgensen, MD
- M. Usman Nasir Khan, MD

**Mercy Hospital, Portland**
- Paul Bloch, MD
- Robert Hawkins, MD
- Christopher Healey, MD
- William Herbert, MD
- Peter Higgins, MD
- Jens Jorgensen, MD

### New Hampshire

**Catholic Medical Center, Manchester**
- Yvon Baribeau, MD
- Jeffrey Beachley, MD
- William Clutterbuck, MD
- Patricia Furey, MD
- Patrick Mahon, MD
- Benjamin Westbrook, MD

**Concord Hospital, Concord**
- Eric LeeLemans, MD
- Joseph Meyer, MD
- Richard Murphy, MD
- William Tanski, MD
- Christopher Danielson, MD
- Kenneth Danielson, MD

**Cottage Hospital, Woodsville**
- Christopher S. Danielson, DO
- Kenneth S. Danielson, MD

**Dartmouth-Hitchcock Med Ctr, Lebanon**
- Jack Cronenwett, MD
- Mark Fillinger, MD
- Philip Goodney, MD
- Brian Nolan, MD
- Richard Powell, MD
- Eva Rucellio, MD
- David Stone, MD
- William Tanski, MD
- Daniel Walsh, MD
- Robert Zwolak, MD

**Elliot Hospital, Manchester**
- Larry Hoopp, MD
- William Wilson, MD

**Lakes Region General Hospital, Laconia**
- Sam Aldridge, MD
- David Coleman, MD
- Glenn Fusione, MD
- John Vignati, MD

### Massachusetts

**Baystate Medical Center, Springfield**
- James Arcello, MD
- Mark Bean, MD
- Laura Feldman, MD
- Aram Fereshtehian, MD
- Gregory Giugliano, MD
- Neal Hadro, MD
- Mark Hirko, MD
- Ashquel Islam, MD
- Jeffrey Kaufman, MD
- Amir Lotfi, MD
- Ngogu Njuguna, MD
- Mark Norris, MD
- Sang Won Rhee, MD
- Steven Weinsier, MD
- Hao Wu, MD

**Berkshire Medical Center, Pittsfield**
- Wilfred Carney, MD
- Michael Cohn, MD
- Eugene Curletti, MD
- Christian Galvez-Padilla, MD
- Jose Heisecke, MD
- Richard J. Stadlig, MD

**Boston Medical Center, Boston**
- Alik Farber, MD
- Jeffrey Kalish, MD
- Jonathan Woodson, MD

**Charlton Memorial Hospital, Fall River**
- David Bigatel, MD
- Ibrahim Eld, MD
- Martin Fogle, MD
- Nosheen Javed, MD
- Michael Meuth, MD

**Massachusetts General Hospital, Boston**
- David Brewster, MD
- Richard Cambria, MD
- Mark Conrad, MD
- Christopher Kwokle, MD
- Glenn LaMuraglia, MD
- Virendra Patel, MD
- Michael Watkins, MD

**Tufts Medical Center, Boston**
- Kevin Daly, MD
- James Estes, MD
- Neil Halin, MD
- Mark Iafrati, MD
- Harry Ma, MD
- William Mackey, MD
- Noah Rosen, MD
- Andrew Weintraub, MD

### Massachusetts Continued

**University of Massachusetts Medical Center, Worcester**
- Mohammad Alchter, MD
- Elias Arous, MD
- Paris Badligh, MD
- Kurt Barringhaus, MD
- Mohammad Estam, MD
- Daniel Fisher, MD
- Subhash Guleri, MD

**St Anne’s Hospital, Fall River**
- David Bigatel, MD
- Ibrahim Eld, MD
- Martin Fogle, MD

**St Luke’s Hospital, Fall River**
- Salman Bashir, MD
- Stephen Keith, MD
- Michael Merport, MD
- Roger Rosen, MD

### Connecticut

**St. Francis Hospital, Hartford**
- Surendra Chawla, MD
- Scott Fecteau, MD
- Tim Lehmann, MD
- Arshad Quadri, MD
- Steve Ruby, MD
- Eugene Sullivan, MD
- Jack Thayer, MD

**Yale New Haven Hospital, New Haven**
- Mehi Arici, MD
- John Aruny, MD
- Ricardo Cordido, MD
- Brian Coyle, MD
- Jeptha Curtis, MD
- Ralph DeNatale, MD
- John Forrest, MD
- Richard Gusberg, MD
- Faisal Hasan, MD
- Jeffrey Indes, MD
- Carlos Mena, MD
- Hamid Mojibian, MD
- Bart Muhls, MD
- Jeffrey Pollak, MD
- Eric Reiner, MD
- Michael Remetz, MD
- Bauer Sumpio, MD
- Tom Sweeney, MD
- Craig Thompson, MD
- Edward Tufidy, MD

### Vermont

**Fletcher Allen Health Care, Burlington**
- Julie Adams, MD
- Daniel Bertges, MD
- Michael Ricci, MD
- Andrew Stanley, MD
- Georg Steinthurms, MD

### New Hampshire Continued

**Waltham Hospital, Waltham**
- William Tanski, MD

### Massachusetts Continued

**Beth Israel Deaconess Hospital – Boston MA**

**Bigham & Women’s Hospital – Boston MA**

**Hartford Hospital – Hartford, CT**

**Rutland Regional Medical Center – Rutland VT**

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> **Members 2011**

**Maine General Medical Center, Augusta**
- Cristobal Alvarado, MD
- Mark Bolduc, MD

**Maine Medical Center, Portland**
- Christopher Baker, MD
- Paul Bloch, MD
- Scott Buchanan, MD
- David Burkey, MD
- David Butzel, MD
- Robert Ecker, MD
- Robert Hawkins, MD
- Christopher Healey, MD
- William Herbert, MD
- Peter Higgins, MD
- Jens Jorgensen, MD
- M. Usman Nasir Khan, MD

**Mercy Hospital, Portland**
- Paul Bloch, MD
- Robert Hawkins, MD
- Christopher Healey, MD
- William Herbert, MD
- Peter Higgins, MD
- Jens Jorgensen, MD

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> **158 VSGNE Members 2011**
18,000 Procedures Reported

CEA, CAS, oAAA, EVAR, LEB, PVI (2003-2010)
Guests from Other Regions

- Adam Beck, MD; Salvatore Scali, MD; Julie Mayo
  - University of Florida, Gainesville, FL

- Jeb Hallett, MD
  - Roper St Francis, Charleston, SC

- Gary Giangola, MD
  - Jewish Health System, New York City, NY

- Mark Davies, MD, PhD, MBA
  - Methodist Hospital, Houston, TX

- Apostolos Tassiopoulos, MD; Olympia Christoforatos, RN, MS
  - Stonybrook University Hospital, Stonybrook, NY

- Larry Kraiss, MD & Bjoern Suckow, MD
  - University of Utah Medical Center, Salt Lake City, UT

- Eyal Ben-Arie, MD
  - Piedmont Hospital, Atlanta, GA

- Grace Wang, MD
  - Hospital of University of Pennsylvania, Philadelphia, PA
Sample graphs in guests’ folders
- Sent to each center before meeting
- Available in real time on the web
Elective Endo AAA Repair

This patient safety work product generated within the VSG PSO, LLC, is considered privileged and confidential according to the provisions of 42 CFR Part 3
Risk Adjusted Cumulative O-E Difference for Death After OAAA

1201 VSGNE Elective Open Aortic Aneurysm Repairs Jan 2003 to June 2010

Data Source: VSGNE database

More strokes/deaths than expected
Operating as expected
Fewer strokes/deaths than expected

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This patient safety work product generated within the VSG PSO, LLC, is considered privileged and confidential according to the provisions of 42 CFR Part 3
Infra-Inguinal Bypass Mortality or Major Amputation by Surgeon

Set Parameters

Start Date: 01/01/2003
End Date: 05/29/2010
Diabetes: All
Dialysis: All
Pre-Adm Living: All
Statin Use: All
Indication: All
Pathology: Occlusive
Ambulation Pre-Op: All
Prosthetic: All
Submit

Infra-inguinal Bypass Mortality or Major Amputation by Surgeon
Arranged by Increasing Annualized Rate
n= 3027

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Infra-Ingual Bypass Mortality or Major Amputation by Center

Set Outcome Variables
Post-Op Status: Mortality or Major Amputation

Set Parameters
Start Date: 01/01/2003, End Date: 09/30/2010
Diabetes: All
Pathology: Occlusive
Ambulation Pre-Op: All
Pre-Adm Living: All
Prosthetic: All

Infra-inguinal Bypass Mortality or Major Amputation by Center
Arranged by Increasing Annualized Rate
n = 3284

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How to Generate VQI Reports
Through Clinical Data Pathways

Logging In -

- Go to https://vsgne.m2s.com
- Enter your username and password
- Select the PSO tab in the upper right corner

Navigate to the PSO Tab -

- ‘Report for’ dropdown
  - The dropdown will contain the VSGNE as a selection and All VQI Participants.
- Reports
  - Reports are organized in 3 groups: 12 chart reports, Surgeon level reports and Center level reports
    - Click on the link of the report you want to execute
    - Enter responses to required selection criteria (example - date range, complications, post op status)
    - Click the submit button to generate the report
  - **12 Chart Report**
    - The Reports show how a center is performing as compared with their regional group over time on 12 quality metrics.
    - Blue line – Group (example VSGNE)
    - Red line – Your institution
    - Red dashed line – Group goal
    - Yellow & Green dots represent recorded min & max data points for each year
Agenda - Administrative Topics

- SVS VQI update – select representative
- PQRI update
- New features – TEVAR, followup intervals
- PVI data, first year perspective
- Suprainguinal bypass data
- Dialysis access form – Long term follow-up
- Missing variables, eg, postop ABI, TBI
- Missing one year follow-up, EVAR f/u
- Validation using claims data, status
The Vascular Quality Initiative
A collaborative of regional quality improvement groups collecting and analyzing data in an effort to improve patient care.

As of May 1, 2011 - 70 participating centers with regional study groups forming throughout the U.S. and Canada:
- New England, the Mid-Atlantic, the Carolinas, Florida, Texas, and Southern California have established groups.
- Many other regional groups organizing.

Data analyses governed by SVS Patient Safety Organization (SVS PSO).

Utilizes M2S’s web-based platform, Clinical Data Pathways for data entry and report generation.
SVS PSO

**PSO Governing Council:** 4 representatives from SVS, 1 from each region, 1 at large, Medical Director (ex officio)

- VSGNE Quality Committee
- Carolinas Quality Committee
- Florida Quality Committee
- So. Calif Quality Committee

- VSGNE Research Advisory Committee
- Carolinas Research Advisory Committee
- Florida Research Advisory Committee
- So. Calif Research Advisory Committee

**PSO Research Advisory Council:** 1 Representative from each regional RAC plus SVS appointees
**SVS VQI Summary**

**Total Procedures Captured (As of End of Q1 2011)**

- **Total**: 23,205
- **Carotid Endarterectomy**: 9,241
- **Infra-Inguinal Bypass**: 4,660
- **Endo AAA Repair**: 2,609
- **Open AAA Repair**: 2,032
- **Carotid Artery Stent**: 650
- **Peripheral Vascular Intervention**: 3,172
- **Supra-Inguinal Bypass**: 709

**Centers Entering Data**

- **Region**: New England, Mid-Atlantic, Carolinas, Florida, Texas, Southern CA, At-Large, Total
  - New England: 27
  - Mid-Atlantic: 3
  - Carolinas: 9
  - Florida: 5
  - Texas: 2
  - Southern CA: 4
  - At-Large: 20
  - **Total**: 70

**NESVS = 80%**

**Monthly Procedure Volume**
PQRS and VSGNE

- Optional reporting for VSGNE members by M2S – qualifies for Medicare bonus
- Must report at least 3 quality measures for 80% of relevant procedures performed
- Current measures relevant to VSGNE:
  - Periop antibiotics (3 measures):
    - Given < 1 hr preop, correct Abx, stop <24 hr
  - Patch conventional carotid endarterectomy
- Future measures:
  - Dialysis access % autogenous, others
M2S PQRS Submissions 2010

- Data successfully submitted for 27 MDs
  - 20 VSGNE members
- All met 80% criteria based on audit of CPT claims data submitted to M2S
  - 16 did not have to submit any additional cases
  - 4 had to submit <10% additional cases
  - 7 had to submit 22-88% of cases (general form)
- Will qualify for 2% bonus of total Medicare Part B reimbursement
To complete 3 relevant peri-operative antibiotic measures
PQRS

CMS Physician Quality Reporting System
Formerly PQRI (initiative)

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<th>Supplement*</th>
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<tr>
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% of all Medicare Part B claims

* If participate in maintenance of board certification program approved by CMS
Thoracic and Complex EVAR (TEVAR) Form

Procedure

History

Post-Op

History Information
- Genetic History
- Prior Aortic Surgery
- Ejection Fraction
- Maximum TAA Diameter
- Minor Axis TAA Diameter

Concomitant Procedure
- LCCA
- L Subclavian
- CIA
- RTS
- RT Int Iliac
- LT Int Iliac
- Femoral Repair
- Iliac Aneurysm

Post-Op Information
- Vasopressors Required
- Myocardial Infarction
- Cerebrovascular Events
- Spinal Status at Discharge
- Respiratory
- Leg Compartment Syndrome
- Return to OR
- Discharge Medications
- ASA
- Platelets
- Pen-Op Antibiotic Ordered
- Start time
- 1st/2nd Gen Cephalosporin

Transfusion
- Units PRBC
- CH2
- Leg Ischemia/Embol
- Wound Complication

Total Procedure Time
- EBL
- Distal Diameter
- mm
- cm
- Distal Attachment Zone
- mm
- ml
- Total Procedure Time
- minutes
Thoracic and Complex EVAR (TEVAR) Form Follow-up

Follow-Up

NOTE: All follow-up data should be from a post-discharge visit. Do not include data of sequelae that occurred during the hospital admission.

Patient Info
- Last Name: Test
- First Name: Test
- DOB: 05/23/1965
- MRN: 12345
- SSI: 123-45-5789
- Visit Code: 113
- Zip/Postal Code: 123213
- Surgeon: Surgeon, Test
- Procedures: Thoracic and Complex EVAR
- Surgery Date: 03/01/2011

General Information
- Date of Contact
- Contact By
- Current Smoking
- Current Living Status
- Current Medications
  - ASA
  - Plavix
  - Coumadin
  - Beta Blocker
  - Statin

Thoracic and Complex EVAR
- Current Max TAA Diameter
- Current Endoleak?
- Dissection False Lumen Status
- Number New Interventions
- Date of First Intervention
- Performed for:
  - Endoleak
  - Branch Stenosis/Occlusion
  - Conversion to Open Repair?
  - Sac Growth
  - Dissection Extension
  - Symptom Rupture
  - Migration
- Performed for:
  - Infection
  - Other Op Related to Endo
  - Bypass for Branch Failure
Enhanced Procedure Requiring Follow-Up Report

Report Enhanced by:
1. Advanced filtering features, including surgery date range, surgeon, procedure type and without a follow-up between specific months range.
2. “Print Selected Follow-Up Forms” feature that allows follow-up forms to be selected and printed individually.
Features Released Since November Meeting

- Thoracic and Complex EVAR (TEVAR) form and Follow-up form
- CAS Data Download for Facility Certification with CMS
- Concomitant Procedure Feature
  a. Automatic creation of concomitant procedures
  b. Auto-population and synchronization of shared fields
- Enhancements to major outcomes and complication reports
  a. “Save as image” feature
  b. Date and time stamp of when the report is generated
- Upgrade of the Procedures Requiring Follow-Up Report
  a. Advanced filtering features
  b. “Print Selected Follow-Up Forms” feature
- Follow-up Data Download feature
- PVI Follow-Up Form
- ABI and TBI Validation
  a. Either ABI or TBI is required for the treated leg(s)
  b. No entry is required if major amputation has occurred
- Security Upgrade – Password / Login
- Multiple Procedure Dataform updates
PVI Data – First Year

1527 Procedures, 2492 Arterial Segments

1 Segment: 54%
2 Segments: 31%
3 Segments: 10%
>4 Segments: 3%
PVI Process Characteristics

- 96% Femoral access
  - 39% Ultrasound guidance
- Fluoro time mean 16 min
- Contrast mean 110 ml
- Closure device – 71% none
  - Angioseal 10%, Perclose 9%, Mynx 6%
- Heparin 93%
  - Protamine 23%
Technical success: 95%
  • Residual stenosis 2.8%, Occlusion 2.5%

Access site complication: 5%
  • Operation required: 0.7%

Distal embolization: 1.5%

Complication requiring admission: 5%
## TASC Classification (%)

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<th>Com Iliac</th>
<th>Ext Iliac</th>
<th>Com Fem</th>
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</table>
PVI Outcome Reporting - 12-Panel

1,2: Discharge meds: Antiplatelet, statin

3,4: Volume, % with one year follow-up

5,6: CLI (%), TASC (% C or D)

7,8: Claudication, one year:
   Improvement rate, reintervention rate

9-12: Critical limb ischemia, one year:
   Function =/+ (amb, living, symptoms)
   Reintervention, surgical bypass rates
   Amputation-free survival rate
Supra-Inguinal Bypass

490 Operations 2009-2010

- Axillo-Fem
- Aorto-Fem
- Fem-Fem
- Other
Hemodialysis Access Form

- Currently in preparation

- Two follow-up intervals:
  - 1-3 mo in surgeon office
  - 12 mo in nephrologist office or dialysis center

- How to accomplish one year follow-up
  - Email link to designated individual
Dialysis – 1-3 Month Followup

- Procedure to translocate basilic fistula: (no, yes - if yes, date)
- Access patent: (yes, no - Judged by (thrill/bruit, duplex)
- Access used for dialysis: (never, current, failed - if current, date started. If failed, date started, date failed)
- Current dialysis: no, yes via catheter, yes via this access, yes via other access
- Wound infection (no, req Abx, req I&D, req removal)
- Steal (no, req DRILL, PAI, removal)
- Arm swelling (no, req vein Rx, req removal)
- Medications: ASA, Plavix, Statin, Coumadin
Dialysis – One Year Followup

- **Current dialysis:** (no, yes via catheter, yes via this access, yes via other access)
- **Access used for dialysis:** (no, yes, if yes, start date, stop date)
- **Current function:** (not being used, adequate for dialysis, used but inadequate)
- **Access revised by interventional technique:** (no, PTA, stent, lysis plus PTA or stent, if yes, date, n)
- **Access revised by surgical technique:** (no, patch angioplasty, thrombectomy plus patch, more extensive, if yes, date, n)
Hemodialysis Access Long-term Follow-Up Contact

1. Administrative module to set up the long-term follow-up contact:

   - First Name: John
   - Last Name: Smith
   - Center/Location: NH Dialysis Facility
   - Email: smith@NHdialysis.org
   - Phone: 603-222-8888 (xxx-xxxx-xxxx)

2. After setup,
Commonly Missing Data

- **Pre-op**: ABI/TBI, Hb, HbA1c, height, weight, contralateral ICA stenosis, creatinine
- **Post-op**: ABI/TBI
- **Follow-up**: smoking status, carotid duplex, endoleak type, date of reintervention

Data manager at each site can submit an incomplete form if fields cannot be completed.
Commonly Missing Data

- These variables are potentially important for risk-adjustment, or as outcome measures.

- Post-op ABI/TBI:
  - Often not obtained until first office visit.
  - Establish policy that values within 6 weeks of surgery must be entered as an early follow-up form if this variable is not completed at discharge?

- Monitor sites for form completion by variable
  - Inform sites that are outliers
  - Require improvement
One Year Follow-up

Note: Includes procedures through December 2009
Numerator includes follow-ups completed by Office Visit or Phone
Arranged by Ascending Follow-Up for 2003 - 2007
EVAR

- Follow-up at one year yields limited data about endoleak rate or sac expansion.

- Agreed to add required follow-up
  - Should we include TEVAR?

- Select time interval beyond one year:
  - Two years
  - Three years
  - Five years
Provider – Hospital Demographics for Risk-Adjustment

- **Provider:**
  - Birth year, year training completed
  - Board certified in vascular surgery, general surgery, cardiothoracic surgery, cardiology, radiology, interventional radiology (Y,N)

- **Hospital:**
  - Number of inpatient beds
  - Teaching hospital (Y,N)

- **Question:** Use in blinded research analyses?
Validation – 2007-2009 Data

- **Hospital receives report of potential data entry errors**
  - Review patient identifiers, dates
  - Edit patient data online if appropriate

- **Hospital receives reports of potentially missing procedures**
  - Review procedures
  - Enter procedure online if appropriate
VSGNE – Next Projects

- Complete risk adjusted outcome reports for all procedures
  - At least one primary outcome variable
- Develop smart phone applications
  - VSGNE cardiac risk predictor
  - Outcome predictors (risk-adjusted)
  - Data input (especially procedure data)
ABCD2 | Risk of Stroke after TIA

Use this calculator to calculate the risk of stroke after TIA (transient ischemic attack) and guide urgency for workup and/or admission to hospital.

Age ≥60?  
No

BP ≥140/90 mm Hg at initial evaluation?  
No

Clinical Features:  
Unilateral Weakness

Duration of Symptoms  
<10 min

Diabetes  
No

Submit
Regional Clinical Trials

- To answer focused clinical questions
- Increase the “n” of patients while minimizing expense and bureaucracy
- Not meant to replace large randomized clinical trials or retrospective reviews
Regional cooperative effort

- NESVS Clinical Trials Committee – provides administration, oversight and funding
- VSGNE/M2S – facilitates data collection and storage
- Must be a member of NESVS and VSGNE to participate
- Open invitation to other sites to participate
NESVS ad hoc Clinical Trials Committee

- Jack Cronenwett, Chair
- Jens Jorgensen
- William Mackey
- Phil Goodney
- Bart Muhs
- Mark Schermerhorn
- Frank Pomposelli
Clinical Trials Committee

- Review and critique clinical trials
- Assist in study design
- Provide budget support
- Enhance patient and site recruitment
Clinical Trials Process

- Application form
- Reviewed by Clinical Trials Committee
- Approved by NESVS Executive Council
- Funding for up to $10,000 annually (max. 3 years)
Potential trials

- Routine vs no protamine after CEA or LEBPG
- Open vs endovascular repair of popliteal aneurysm
- Cadaver vein vs Propaten vs other for tibial bypass
- Atherectomy vs stent for infrainguinal disease
Research Advisory Committee
ByLaws

Analyses will be regularly performed by the VSGNE to provide feedback to member hospitals and physicians for purposes of quality improvement within the SVS PSO. These may yield useful information that could benefit the medical community at large, and warrant scientific publication or presentation. Proposals for specific research projects using shared regional data may be made by any VSGNE Member hospital or physician, and shall be considered by the Executive Committee. If approved by the Executive Committee such projects may proceed.
Research Advisory Committee

Mission:

To facilitate the conduct of quality improvement research by VSGNE members.
Research Advisory Committee

• **Planning** (novel hypothesis & in concert with VSGNE mission)
• **Design** (study design consultation)
• **Conduct** (assist with analytic conduct)
• **Interpretation** (of analytic output)
• **Presentation** (preparing of final materials)
• **Review** (transparent review process)
Analytic Memo Submitted

RAC reviews and evaluates proposal

MR sends RAC recommendations Exec

PI establishes working group

VSGNE members submit request to participate in project

MR sends proposal to VSGNE members to request wider participation

Perform study

Submit project for presentation/publication
Analysis Request for the Vascular Study Group of New England

The Research Advisory Committee of the Vascular Study Group of New England (VSGNE) provides assistance to researchers in the access, analysis, and interpretation of analytic datasets stemming from the collection and synthesis of data within the VSG PSO.

Instructions for completion and return to the Research Advisory Committee (RAC):
1. Please enter the requested information by clicking the appropriate check box, using the pull-down menus, and typing in the insertion boxes (these will expand as you add text). If you do not know the requested information or need input from the RAC regarding specifics, please complete the information to the best of your knowledge and we will work together to create the final analysis plan.

   If you have difficulty inserting any information, or would like to include mock tables, please attach them as a separate document. Margaret Russell Margaret.T.Russell@dartmouth.edu would be happy to help you fill in any information if need be.

2. Once complete, save the file using this naming convention:
   Request_<your last name>_mm-dd-yyyy.DOC

3. E-mail the completed data request, along with any supplemental materials to
   Margaret.T.Russell@dartmouth.edu

Requesting Investigator:
Project Name:
Funding Source:
Date of Request:
   Requested timeline for completion:
   □ Standard Queue
   □ Time Sensitive Request; if time sensitive needed by no later than

If this is a new project, with whom have you discussed this request? Jack Cronenwett

Background/ Overall Purpose (2-5 sentences):
Research Advisory Committee

• Meets once a month to review proposals
Research Advisory Committee
Members

Daniel Bertges
Philip Goodney
Donald Likosky
Brian Nolan
Margaret Russell
Andres Schanzer
YuanYuan Zhao
Smoking Cessation

- Summary of VSGNE data and variation
  - Andy Hoel

- How I Do It – Smoking Cessation Panel
  - Moderator: Phil Goodney
  - Panelists: Brian Nolan
    Andy Schanzer
    William Wilson
Variation in Smoking Cessation After Vascular Operations

Andrew W. Hoel, Brian W. Nolan, Philip P. Goodney, Yuanyuan Zhao, Andres Schanzer, Andrew C. Stanley, Jens Eldrup-Jorgensen and Jack L. Cronenwett

5.11.11
Smoking cessation in VSGNE

- Reviewed 12,866 patients in VSGNE of which 12,813 had smoking status documented.
Smoking cessation in VSGNE

- 7645 patients with follow-up smoking status.
- 2526 patients smoked at time of procedure.
- 1124 patients (45%), were non-smoking at follow-up.

![Smoking status post-procedure chart](chart.png)
Smoking Cessation in VSGNE

• Procedural variation in smoking cessation.

Stopped smoking by PROCEDURE (%)

- AAA: 51%
- EVAR: 50%
- LEB: 44%
- CEA: 42%
- CAS: 25%
Smoking Cessation in VSGNE

- Multivariate analysis of patient-level factors for smoking cessation.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
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<tr>
<td>Age&lt;50</td>
<td>Reference</td>
<td></td>
<td></td>
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<tr>
<td>Age 50-59</td>
<td>1.24</td>
<td>0.82 - 1.86</td>
<td>0.308</td>
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<tr>
<td>Age 60-69</td>
<td>1.51</td>
<td>1.01 - 2.24</td>
<td>0.042</td>
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<tr>
<td>Age 70+</td>
<td>1.92</td>
<td>1.29 - 2.87</td>
<td>0.001</td>
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<td><strong>Previous Vascular Procedure</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(Bypass, CEA, Aneurysm)</td>
<td>0.76</td>
<td>0.63 - 0.92</td>
<td>0.005</td>
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<tr>
<td>HTN</td>
<td>1.36</td>
<td>1.10 - 1.68</td>
<td>0.005</td>
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<tr>
<td>COPD</td>
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<td>0.66 - 0.92</td>
<td>0.003</td>
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<td><strong>Procedure Type</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>CEA</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LEB</td>
<td>1.22</td>
<td>1.00 - 1.49</td>
<td>0.050</td>
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<tr>
<td>EVAR</td>
<td>1.24</td>
<td>0.94 - 1.65</td>
<td>0.127</td>
</tr>
<tr>
<td>OPEN</td>
<td>1.33</td>
<td>1.05 - 1.68</td>
<td>0.018</td>
</tr>
<tr>
<td>CAS</td>
<td>0.50</td>
<td>0.27 - 0.91</td>
<td>0.023</td>
</tr>
</tbody>
</table>

AUC=0.59
Smoking Cessation in VSGNE

- Center-specific variation in smoking cessation.

![Bar chart showing smoking cessation rates by center](chart.png)
Smoking Cessation in VSGNE

- Center-specific variation in smoking cessation.
- Expected smoking cessation based on multivariate model.
Smoking Cessation in VSGNE

- Center-specific variation in smoking cessation.
- Expected smoking cessation based on multivariate model.
Reducing Complications in Diabetics

- **Summary of variation in VSGNE**
  - Brian Nolan
- **IV insulin protocol at FAMC**
  - Julie Adams
- **Glucose management service at DHMC**
  - Jessica Wallaert
Diabetes as a Risk Factor for Peripheral Vascular Surgery:
Data from the Vascular Surgery Study Group of New England
Post-Op Blood Glucose Control

• VSGNNE quality improvement effort began in 2008.

• Diabetes study group
  – Evaluate evidence surrounding post-op blood glucose protocols
  – Review outcomes of insulin and non-insulin dependent diabetics using VSGNNE data
  – Make recommendation regarding management of diabetic vascular patients.
Question

Does diabetes, and the type of diabetes, affect post-op complication rates?
Methods

• Sample: VSGNNE database (2003-2007)
  – 4125 CEA
  – 2145 LEB
  – 1849 AAA repairs (761 EVAR, 1088 open)

• Design: retrospective cohort
  – Non-diabetic, NIDDM, IDDM

• Univariate and multivariate logistic regression
  – NIDDM and IDDM as predictors of events
Methods

- **Primary outcome:** any major adverse event or death (M.A.E.)

<table>
<thead>
<tr>
<th></th>
<th>CEA</th>
<th>LEB</th>
<th>AAA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Death</td>
<td>Death</td>
<td>Death</td>
</tr>
<tr>
<td>Bleeding</td>
<td>Bleeding</td>
<td>Bleeding</td>
<td>Bleeding</td>
</tr>
<tr>
<td>MI</td>
<td>MI</td>
<td>MI</td>
<td></td>
</tr>
<tr>
<td>Dysrhythmia</td>
<td>Dysrhythmia</td>
<td>Dysrhythmia</td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>CHF</td>
<td>CHF</td>
<td></td>
</tr>
<tr>
<td>Wound infection</td>
<td>Wound infection</td>
<td>Wound infection</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>Renal</td>
<td>Renal</td>
<td>Renal</td>
</tr>
<tr>
<td></td>
<td>Respiratory</td>
<td>Respiratory</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Graft thrombosis</td>
<td>Bowel</td>
<td></td>
</tr>
</tbody>
</table>
Patient Demographics
All Operations (n=8,119)

- CRI: 9%
- CHF: 11%
- COPD: 29%
- CAD: 36%
- HTN: 85%
- Age>70: 53%
Conditions Associated with IDDM

- **CRI**: Lower risk
- **CHF**: Higher risk 3.6
- **HTN**: Higher risk 2.3
- **CAD**: Higher risk 1.9
- **Age > 70**: Lower risk 0.6
Prevalence of Diabetes

- CEA (n=4125):
  - NIDDM: 22%
  - IDDM: 8%

- LEB (n=2145):
  - NIDDM: 26%
  - IDDM: 25%

- Any AAA (n=1849):
  - NIDDM: 15%
  - IDDM: 1%
Post-Operative Complication Rates

<table>
<thead>
<tr>
<th>Procedure</th>
<th>None</th>
<th>NIDDM</th>
<th>IDDM</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEA</td>
<td>4.7%</td>
<td>4.7%</td>
<td>9.1%</td>
</tr>
<tr>
<td>LEB</td>
<td>24%</td>
<td>27%</td>
<td>36%</td>
</tr>
<tr>
<td>AAA repair</td>
<td>32%</td>
<td>29%</td>
<td>33%</td>
</tr>
</tbody>
</table>

* p<0.05
Multivariate Predictors of Post-Op M.A.E. Carotid Endarterectomy

O.R. 1.7 (95% C.I. 1.1-2.7)
Multivariate Predictors of Post-Op M.A.E.
Lower Extremity Bypass

O.R. 1.3 (95% C.I. 1.0-1.7)
Future Work

• Why are outcomes in IDDM worse?
  – Is it a more severe form of diabetes?
  – Can post-op insulin management affect the complication rate?

• Post-op blood glucose management and insulin protocols?
  – Fletcher-Allen, IV insulin drip protocol
  – DHMC, blood glucose management service
Diabetes and Insulin Dependence Increase the Risk of Complications Following Lower-Extremity Bypass

Associations between the extent of diabetes (defined by insulin dependence) and outcomes following LEB in critical limb ischemia (CLI) patients.
NESVS Abstract Submission

• Retrospective analysis of 2,245 LEBs done between 2003 and 2010 within the Vascular Study Group of New England.

• 40% of patients were non-diabetic, 28% were NIDD, and 32% were IDD.
% Non Diabetics

Non-Insulin Dependent Diabetics

Insulin-Dependent Diabetics

* p-values for test of trend across all 3 groups
Table. Multivariate model for post-operative complications following lower-extremity bypass surgery in patients with critical limb ischemia.

<table>
<thead>
<tr>
<th>Co-Variates</th>
<th>OR</th>
<th>95% CI</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>Age ≥80</td>
<td>1.4</td>
<td>1.08-1.82</td>
<td>0.011</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Diabetics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIDD</td>
<td>1.59</td>
<td>1.22 - 2.08</td>
<td>0.001</td>
</tr>
<tr>
<td>IDD</td>
<td>2.25</td>
<td>2.02 - 2.51</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Smoking</td>
<td>0.81</td>
<td>0.75 - 0.89</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>1.75</td>
<td>1.42 - 2.16</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

AUC 0.6347
Diabetes is a significant contributor to the risk of post-operative complications following LEB surgery, and insulin dependence increases this risk. Quality measures aimed at limiting complications following LEB in diabetics should focus on patients with IDD.
Use of a Postoperative Insulin Protocol Decreases the Wound Infection in Diabetics Undergoing Lower Extremity Bypass

Fuyuki Hirashima MD\textsuperscript{1}, Julie E. Adams MD\textsuperscript{1}, Peter Callas PhD\textsuperscript{2}, Daniel J. Bertges MD\textsuperscript{1}, Georg Steinthorsson MD\textsuperscript{1}, Janet McSorley RN\textsuperscript{1}, Andrew C. Stanley MD\textsuperscript{1}, Fletcher Allen Health Care\textsuperscript{1} University of Vermont\textsuperscript{2} Burlington, Vermont
Background

- Benefits seen with tight glucose control in ICU patients, and patients undergoing coronary artery bypass grafting (CABG)
- Preliminary data from pilot study using insulin drip after lower extremity bypass (LEB) surgery suggested benefit.
• Complex problem: does postop hyperglycemia or global effects of diabetes contribute to poor wound healing in postsurgical patients

• Consequences of hyperglycemia
  - Macrophage or neutrophil function is damaged.
  - Decrease synthesis of NO, with increased production of endothelin-1
• Hyperglycemia in ICU patients is a risk factor for developing infections in patients both with and without a history of diabetes

• Tight glucose control in ICU patients:
  - Decreased ICU LOS, blood stream infections, time on ventilator, and renal failure (Van den Berghe et al, 2001)

• Tight glucose control in CABG patients:
  - Decreased wound infections and pneumonia, lower incidence of atrial fibrillation, shorter LOS, and survival advantage during the initial 2 years (Lazar et al, 2004)

Methods - LEB patients

• Prospective pilot study FAHC studying 293 patients undergoing lower extremity bypass surgery
  – 104 patients had the insulin protocol instituted from January 2009 - December 2010.
  – 189 historic controls of patients from the preceding 2 years from 2006-2008

• Prospective data entry of demographic and comorbidity information into the Vascular Study Group of Northern New England

• Retrospective query
Methods

• Insulin Infusion Protocol implemented 2009
  - Begins postop and continues for 76 hours.

  I. Insulin Infusion (Circle A or B) (HISS P270)
  Note: Pharmacy will dispense regular insulin 1 unit/mL in NS IV infusion

  A. Initiate insulin infusion per Non-ICU Insulin Infusion Protocol
     1. Do not start insulin infusion until potassium is verified > 3.5 mEq/ml. Potassium =____
     2. Do not start insulin infusion until glucose is ≥120 mg/dl
     3. If glucose < 120 mg/dl, monitor glucose every 2 hours X 6 hours. If during this 6 hour period glucose is ≥120 mg/dl initiate insulin infusion. If after 6 hours, glucose is still < 120 mg/dl, begin AC and bedtime monitoring
     4. Begin an infusion of normal saline at 10 ml/hr with the insulin infusion

  - Goal glucose 80-120mg/dL
<table>
<thead>
<tr>
<th>Demographics</th>
<th>IV insulin</th>
<th>Standard Tx</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Gender</td>
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<td>83</td>
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<td>4.5</td>
<td>29.2</td>
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<tr>
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<tr>
<td>Oral meds</td>
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<td>13%</td>
<td>32</td>
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## Demographics

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<th>Standard Tx</th>
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<td>%</td>
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<td>%</td>
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<tr>
<td><strong>CABG/PTCA</strong></td>
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<td><strong>CHF</strong></td>
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<td>87</td>
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<td>162</td>
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<td>9%</td>
<td>9</td>
<td>5%</td>
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<td>7%</td>
<td>17</td>
<td>9%</td>
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<td>2</td>
<td>1%</td>
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<tr>
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<td>3</td>
<td>3%</td>
<td>4</td>
<td>2%</td>
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<tr>
<td><strong>Creatinine (umol)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (sd)</td>
<td>99.4</td>
<td>70.40</td>
<td>106.7</td>
<td>88.9</td>
<td>0.44</td>
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<td><strong>Pre-op ASA</strong></td>
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<tr>
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<td>97</td>
<td>95%</td>
<td>162</td>
<td>86%</td>
<td>0.02</td>
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<td>2</td>
<td>2%</td>
<td>8</td>
<td>4%</td>
<td>0.50</td>
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<tr>
<td><strong>Pre-op statin</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>82</td>
<td>81%</td>
<td>122</td>
<td>655</td>
<td>0.004</td>
</tr>
</tbody>
</table>
All patients: Complications after LEB

* p=0.047
Wound Infections and Diabetes

![Graph showing the comparison of IV insulin and Standard Tx between Diabetic and Non Diabetic patients](image)

- IV insulin: Diabetic % patients = 6, Non Diabetic % patients = 6
- Standard Tx:
  - Diabetic: % patients = 10
  - Non Diabetic: % patients = 12

Statistical significance:
- * p=0.03
- p=ns
Conclusions

• Diabetic patients who underwent LEB surgery who received the IV insulin protocol had significantly fewer wound infections compared to diabetic patients who did not receive the IV insulin protocol.
Conclusions

No Significant Differences found in:

- Graft Infection
- MI
- Transfusion Requirements
- Renal Complications
- Respiratory Complications
- CHF
- LOS
References


Testing the Impact of a Glucose Management Service on Outcomes Following Vascular Surgery

Jessica B. Wallaert, MD, Brian W. Nolan, MD, MS, Philip P. Goodney MD, MS, Richard Comi, MD, Sushela S Chaidarun, MD, PhD, Danielle Basta, APRN, MSN, Kathryn M King, APRN, MSN, Greg Ogrinc, MD, MPH
Motivation for Our Study: Variation in Rates of Complication

<table>
<thead>
<tr>
<th>Center</th>
<th>% LEB Cases with Post-Op Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20.6</td>
</tr>
<tr>
<td>2</td>
<td>21.7</td>
</tr>
<tr>
<td>3</td>
<td>38.6</td>
</tr>
<tr>
<td>4</td>
<td>30.7</td>
</tr>
<tr>
<td>5</td>
<td>27.7</td>
</tr>
<tr>
<td>6</td>
<td>21.4</td>
</tr>
<tr>
<td>7</td>
<td>14.2</td>
</tr>
<tr>
<td>8</td>
<td>11.8</td>
</tr>
<tr>
<td>9</td>
<td>14.7</td>
</tr>
<tr>
<td>10</td>
<td>12.9</td>
</tr>
<tr>
<td>11</td>
<td>21.1</td>
</tr>
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<td>12</td>
<td>7.1</td>
</tr>
<tr>
<td>13</td>
<td>14.3</td>
</tr>
<tr>
<td>14</td>
<td>33.3</td>
</tr>
</tbody>
</table>

Vascular Study Group of New England
Study Purpose

- To improve **glycemic variability** in diabetic patients following lower extremity revascularization procedures

- To **utilize a glucose management service (GMS)** to standardize diabetes management following surgery
Glucose Management Services (GMS)

- Improved glycemic control
- Reduced hypoglycemic episodes

Improving Glucose Management by Redesigning the Care of Diabetic Inpatients Using a Nurse Practitioner Service

Richard J. Comi, MD, Jeanne Jacoby, ARNP, Danielle Basta, ARNP, Mary Wood, RN, MS, and John Butterly, MD

INPATIENT MANAGEMENT OF HYPERGLYCEMIA: THE NORTHWESTERN EXPERIENCE

Anthony J. DeSantis, MD,1 Lowell R. Schmeltz, MD,1
Kathleen Schmidt, MSN, APRN-BC,1 Eileen O'Shea-Mahler, MSN, APRN-BC,1
Connie Rhee, MD,2 Angela Wells, PA-C, MMS,1 Stephen Brandt, MD,1
Sara Peterson, BA,1 and Mark E. Molitch, MD1
Study Design

- **Design**: Prospective longitudinal (‘before-after’) study:
  - 5 months baseline data
  - Intervention: early, routine involvement of GMS
  - 5 months post-intervention data

- **Outcomes**:
  - Primary: glycemic variability
  - Secondary: wound infection, mortality, MI, graft patency, transfer to a higher level of care, LOS and hypoglycemic episodes
# Glycemic Variability

Measured using Standard Deviation (SD)

![Standard Deviation Formula](image)

## Example

<table>
<thead>
<tr>
<th>Glucose</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>85</td>
<td></td>
</tr>
<tr>
<td>179</td>
<td>Mean 136.3</td>
</tr>
<tr>
<td>90</td>
<td>SD 47.29</td>
</tr>
<tr>
<td>160</td>
<td></td>
</tr>
<tr>
<td>110</td>
<td></td>
</tr>
<tr>
<td>194</td>
<td></td>
</tr>
</tbody>
</table>

## Example

<table>
<thead>
<tr>
<th>Glucose</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>110</td>
<td></td>
</tr>
<tr>
<td>122</td>
<td></td>
</tr>
<tr>
<td>130</td>
<td>Mean 137.2</td>
</tr>
<tr>
<td>146</td>
<td>SD 17.68</td>
</tr>
<tr>
<td>150</td>
<td></td>
</tr>
<tr>
<td>155</td>
<td></td>
</tr>
</tbody>
</table>
Next Steps

Pilot Study
- Powered to detect 50% improvement in glycemic variation
- Tests impact of GMS

Future VSG Study
- Powered to detect 20% reduction in post-operative complications, n=638.
- Tests impact of GMS and insulin administration protocol.
Topics For Discussion

- Are others surgeons interested in participating in a multi-center study?
- What resources are available in your center?
- Will this help?
Thank you
Quality Improvement Summaries

- Transfusion after infrainguinal bypass
  - Kevin Tan
- Risk-adjusted outcomes of CAS
  - Brian Nolan
- Gender differences in LEB outcomes
  - Fuyuki Hirashima
- Outcome of prosthetic BK LEB
  - Bjoern Suckow
Perioperative Blood Transfusion and Outcome after Lower Extremity Bypass

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

On behalf of the Vascular Study Group of New England
Background

- Red blood cell transfusion is common during operative course of surgical patients
  - acute blood loss
  - improves oxygen carrying capacity
- Inferior outcomes have been observed
  - critically ill patients  (Hebert PC, NEJM 1999;340:409-17)
  - acute coronary syndrome  (Rao SV, JAMA 2004;292:1555-1562)
  - cardiac surgery  (Murphy GJ, Circulation 2007;116:2544-2552)
  - orthopedic surgery  (Glance LG, Anesthesiology 2011;114:282-92)
Study Goal

- Evaluate the effect of perioperative blood transfusion on early and late outcomes following lower extremity bypass
Method

- Lower extremity bypass cohort

- Patients with lower extremity bypass categorized based on blood transfusion:
  - 0 units pRBC
  - 1-2 units pRBC
  - 3 or more units pRBC

- Transfusion groups were case matched:
  - age
  - coronary artery disease
  - diabetes
  - urgency of revascularization
Sample Selection

VSGNE 2003 to 2010
Consecutive LEB

Perioperative Blood Transfusion

Case Match:
Age, CAD, DM,
Urgency of procedure

Exclude:
Return to OR for infection
## Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>0 Unit (N=514)</th>
<th>1-2 Units (N=194)</th>
<th>3 + Units (N=108)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>354 (68.9%)</td>
<td>120 (61.9%)</td>
<td>69 (63.9%)</td>
<td>0.173064</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>504 (98.6%)</td>
<td>191 (100%)</td>
<td>106 (98.1%)</td>
<td>0.223491</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>73.4±10.7</td>
<td>73.3±11.1</td>
<td>74.6±10.8</td>
<td>0.52093</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>364 (70.8%)</td>
<td>142 (73.2%)</td>
<td>78 (72.2%)</td>
<td>0.811479</td>
</tr>
<tr>
<td>CAD, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>259 (50.4%)</td>
<td>96 (49.5%)</td>
<td>53 (49.1%)</td>
<td>0.956579</td>
</tr>
<tr>
<td>Dialysis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (9.3%)</td>
<td>20 (10.3%)</td>
<td>13 (12%)</td>
<td>0.680934</td>
</tr>
<tr>
<td>Characteristic</td>
<td>0 Unit (N=514)</td>
<td>1-2 Units (N=194)</td>
<td>3 + Units (N=108)</td>
<td>p-value</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------</td>
<td>-------------------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Indication, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Claudication</td>
<td>104 (20.2%)</td>
<td>18 (9.3%)</td>
<td>8 (7.4%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Rest Pain</td>
<td>119 (23.2%)</td>
<td>39 (20.1%)</td>
<td>23 (21.3%)</td>
<td></td>
</tr>
<tr>
<td>Tissue Loss</td>
<td>291 (56.6%)</td>
<td>137 (70.6%)</td>
<td>77 (71.3%)</td>
<td></td>
</tr>
<tr>
<td>Previous Bypass, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>150 (29.2%)</td>
<td>65 (33.5%)</td>
<td>43 (39.8%)</td>
<td>0.078653</td>
</tr>
<tr>
<td>Urgency, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>385 (74.9%)</td>
<td>146 (75.3%)</td>
<td>77 (71.3%)</td>
<td>0.709591</td>
</tr>
<tr>
<td>Urgent</td>
<td>129 (25.1%)</td>
<td>48 (24.7%)</td>
<td>31 (28.7%)</td>
<td></td>
</tr>
<tr>
<td>Estimated Blood Loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>213.6±182.6</td>
<td>338.6±261.1</td>
<td>736.8±807.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Characteristic</td>
<td>0 Unit (N=514)</td>
<td>1-2 Units (N=194)</td>
<td>3 + Units (N=108)</td>
<td>p-value</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>----------------</td>
<td>-----------------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Graft Origin, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Com Femoral</td>
<td>347 (67.8%)</td>
<td>136 (70.1%)</td>
<td>70 (64.8%)</td>
<td>0.895239</td>
</tr>
<tr>
<td>Profunda/SFA</td>
<td>110 (21.5%)</td>
<td>38 (19.6%)</td>
<td>24 (22.2%)</td>
<td></td>
</tr>
<tr>
<td>AK Pop/BK Pop/Pop/Tibial</td>
<td>55 (10.7%)</td>
<td>20 (10.3%)</td>
<td>14 (13%)</td>
<td></td>
</tr>
<tr>
<td><strong>Graft Recipient, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AK Pop/BK Pop</td>
<td>273 (53.1%)</td>
<td>83 (42.8%)</td>
<td>45 (41.7%)</td>
<td>0.061443</td>
</tr>
<tr>
<td>T-P Trunk/AT/PT/Peroneal</td>
<td>178 (34.6%)</td>
<td>80 (41.2%)</td>
<td>47 (43.5%)</td>
<td></td>
</tr>
<tr>
<td>DP Ankle/PT Ankle/Tarsal/Plantar</td>
<td>63 (12.3%)</td>
<td>31 (16%)</td>
<td>16 (14.8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Graft Type, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GSV</td>
<td>339 (66%)</td>
<td>121 (62.4%)</td>
<td>65 (60.2%)</td>
<td>0.355264</td>
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<tr>
<td>Prosthetic</td>
<td>140 (27.2%)</td>
<td>52 (26.8%)</td>
<td>33 (30.6%)</td>
<td>0.752956</td>
</tr>
</tbody>
</table>
# Perioperative Results

<table>
<thead>
<tr>
<th>30-day outcomes</th>
<th>0 Unit (N=514)</th>
<th>1-2 Units (N=194)</th>
<th>3 + Units (N=108)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Infection, n (%)</td>
<td>20 (3.9%)</td>
<td>15 (7.7%)</td>
<td>16 (14.8%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Graft Infection, n (%)</td>
<td>2 (0.4%)</td>
<td>0 (0.0%)</td>
<td>3 (2.8%)</td>
<td>0.007</td>
</tr>
<tr>
<td>MI, n (%)</td>
<td>20 (3.9%)</td>
<td>12 (6.2%)</td>
<td>21 (19.4%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Return to OR, n (%)</td>
<td>60 (11.7%)</td>
<td>34 (17.5%)</td>
<td>42 (38.9%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Discharge Patency, n (%)</td>
<td>487 (96.1%)</td>
<td>178 (91.8%)</td>
<td>89 (84%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
# One-Year Results

<table>
<thead>
<tr>
<th>1-year outcomes</th>
<th>0 Unit (N=514)</th>
<th>1-2 Units (N=194)</th>
<th>3 + Units (N=108)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-year Graft Patency, n (%)</td>
<td>232 (70.3%)</td>
<td>85 (72.6%)</td>
<td>32 (61.5%)</td>
<td>0.33704</td>
</tr>
<tr>
<td>1-year Mortality, n (%)</td>
<td>59 (14.5%)</td>
<td>28 (18.7%)</td>
<td>17 (23.3%)</td>
<td>0.123239</td>
</tr>
<tr>
<td>1-year Infection, n (%)</td>
<td>22 (7.9%)</td>
<td>14 (15.2%)</td>
<td>4 (10.3%)</td>
<td>0.120224</td>
</tr>
</tbody>
</table>
# Multivariate Analysis

Wound infection, $p=0.006$

<table>
<thead>
<tr>
<th></th>
<th>Adj. Odds Ratio</th>
<th>Lower Confidence Limit</th>
<th>Upper Confidence Limit</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 Units vs. 0 Units</td>
<td>1.9693</td>
<td>0.9769</td>
<td>3.9698</td>
<td>0.0581</td>
</tr>
<tr>
<td>3+ Units vs. 0 Units</td>
<td>4.2321</td>
<td>2.0692</td>
<td>8.6558</td>
<td>0.0001</td>
</tr>
<tr>
<td>3+ Units vs. 1-2 Units</td>
<td>2.1491</td>
<td>1.0069</td>
<td>4.5869</td>
<td>0.048</td>
</tr>
</tbody>
</table>
# Multivariate Analysis

Patency Failure at Discharge, $p < 0.0001$

<table>
<thead>
<tr>
<th></th>
<th>Adj. Odds Ratio</th>
<th>Lower Confidence Limit</th>
<th>Upper Confidence Limit</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 Units vs. 0 Units</td>
<td>2.3041</td>
<td>1.1468</td>
<td>4.6293</td>
<td>0.019</td>
</tr>
<tr>
<td>3+ Units vs. 0 Units</td>
<td>4.8206</td>
<td>2.3607</td>
<td>9.8437</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>3+ Units vs. 1-2 Units</td>
<td>2.0922</td>
<td>1.0049</td>
<td>4.3559</td>
<td>0.0485</td>
</tr>
</tbody>
</table>
Summary

Blood Transfusion is associated with:

1. Increased perioperative wound infection
2. Decreased graft patency at discharge
3. No long term consequences
Issues

• Unable to determine the exact timing of blood transfusion during the perioperative period

• Unable to assess the cause of blood transfusion

• Poor early data on hemoglobin (plan to collect and analyze recent data)
Outcomes Carotid Artery Stenting

Brian W. Nolan, MD, MS
Introduction

• Debate surrounding appropriate use of CAS
  – High medical risk (CHF, recent MI, severe COPD)
  – High anatomic risk (high bifurcation, previous CEA, contralateral ICA occlusion)

• Current FDA approval CAS
  – Symptomatic, ‘high risk’ patients

• Conflicting data from RCTs regarding stroke risk with CAS compared to CEA
Surgery on blocked neck arteries has long been considered the best procedure for preventing a stroke. Now a large North American study has found that a less invasive approach may be just as safe and effective, but other researchers are not so sure.

The findings, released Friday at a medical meeting in San Antonio, have the potential to make the less invasive procedure — inserting a small tube called a stent in the carotid artery — a more appealing option for many patients.

Yet just a day earlier, European investigators reported dismal results from another international trial (ICSS) involving carotid stents, published online Thursday by the British medical journal The Lancet.

In that study, patients treated with stents suffered almost double the rate of complications as those treated surgically, leading the British researchers to conclude that surgical treatment of carotid blockages, called endarterectomy, remains the treatment of choice.
Among the possible explanations offered for the disparities are that the European study included only symptomatic patients, who may have had more advanced disease, and that the North American trial carefully screened the doctors doing the stenting procedure, including only highly skilled physicians with a lot of experience.

Dr. Walter J. Koroshetz, deputy director of the institute that sponsored the North American trial, said the Crest trial was the first in which the results of stenting and surgery had been found to be equivalent — suggesting that the stent procedure had improved with time.

The most important message is that the overall death rate was extremely low, 0.6 percent, said one of the study’s principal investigators, Dr. Gary S. Roubin, the chairman of cardiovascular medicine at Lenox Hill Hospital in New York.

“What this trial has done overwhelmingly,” he said, “is shown that in North America, with the very skilled surgeons and physicians performing stenting, the outcomes were extremely safe.”
Question

• Within the VSGNE database, how do the outcomes of CAS compare to CEA?

Aims

• Stratified analysis to determine outcomes across asymptomatic, symptomatic and redo’s.
• Develop risk prediction model for stroke or death in patients undergoing CAS.
Sample

- VSGNE dataset, 2003-2010
- 7,649 CEA (excluded concomitant CABG)
  - 17 centers
  - 111 Vascular surgeons
- 430 CAS
  - 6 centers
  - 30 Vascular surgeons (perform both CEA & CAS)
  - 8 Interventionalists (perform only CAS)
<table>
<thead>
<tr>
<th>Feature</th>
<th>CEA (n=7,649)</th>
<th>CAS (n=460)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70</td>
<td>69</td>
<td>0.134</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td><strong>60%</strong></td>
<td><strong>66%</strong></td>
<td>0.019</td>
</tr>
<tr>
<td>Elective</td>
<td>89%</td>
<td>90%</td>
<td>0.509</td>
</tr>
<tr>
<td>Any symptoms</td>
<td>34%</td>
<td>36%</td>
<td>0.328</td>
</tr>
<tr>
<td>Cortical symptoms</td>
<td>24%</td>
<td>26%</td>
<td>0.279</td>
</tr>
<tr>
<td>Hypertension</td>
<td>88%</td>
<td>88%</td>
<td>0.730</td>
</tr>
<tr>
<td><strong>Any smoking history</strong></td>
<td><strong>80%</strong></td>
<td><strong>85%</strong></td>
<td>0.014</td>
</tr>
<tr>
<td><strong>Coronary artery disease</strong></td>
<td><strong>33%</strong></td>
<td><strong>45%</strong></td>
<td>0.001</td>
</tr>
<tr>
<td>Positive stress test</td>
<td>11%</td>
<td>13%</td>
<td>0.163</td>
</tr>
<tr>
<td><strong>CHF</strong></td>
<td><strong>8%</strong></td>
<td><strong>17%</strong></td>
<td>0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>31%</td>
<td>34%</td>
<td>0.203</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td><strong>23%</strong></td>
<td><strong>30%</strong></td>
<td>0.002</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>6%</td>
<td>8%</td>
<td>0.069</td>
</tr>
<tr>
<td><strong>Prior ipsilateral CEA</strong></td>
<td><strong>2%</strong></td>
<td><strong>33%</strong></td>
<td>0.001</td>
</tr>
<tr>
<td>Prior neck irradiation</td>
<td>1%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Antiplatelet therapy</strong></td>
<td><strong>90%</strong></td>
<td><strong>97%</strong></td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Current b-blocker therapy</strong></td>
<td><strong>81%</strong></td>
<td><strong>72%</strong></td>
<td>0.001</td>
</tr>
<tr>
<td>Current statin therapy</td>
<td>76%</td>
<td>78%</td>
<td>0.219</td>
</tr>
<tr>
<td>Non-white race</td>
<td>100%</td>
<td>100%</td>
<td>0.530</td>
</tr>
<tr>
<td>Procedural Characteristics</td>
<td>CEA</td>
<td>CAS</td>
<td>p-value</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-----</td>
<td>-----</td>
<td>---------</td>
</tr>
<tr>
<td>Preop Duplex</td>
<td>95%</td>
<td>91%</td>
<td>0.001</td>
</tr>
<tr>
<td>Preop CTA</td>
<td>28%</td>
<td>78%</td>
<td>0.001</td>
</tr>
<tr>
<td>Preop MRA</td>
<td>23%</td>
<td>24%</td>
<td>0.493</td>
</tr>
<tr>
<td>&gt; 1 Preop imaging study</td>
<td>43%</td>
<td>87%</td>
<td>0.001</td>
</tr>
<tr>
<td>Shunt</td>
<td>47%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patch</td>
<td>86%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General anesthesia</td>
<td>88%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completion duplex</td>
<td>31%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protamine</td>
<td>50%</td>
<td>38%</td>
<td>0.001</td>
</tr>
<tr>
<td>EPD</td>
<td></td>
<td>97%</td>
<td></td>
</tr>
<tr>
<td>Predilation</td>
<td></td>
<td>67%</td>
<td></td>
</tr>
<tr>
<td>Open cell stent</td>
<td></td>
<td>82%</td>
<td></td>
</tr>
</tbody>
</table>
## Primary Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Asymptomatic</th>
<th>Cortical Symptoms</th>
<th>Redo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stroke, death</td>
<td>Stroke, death</td>
<td>Stroke, death</td>
<td>Stroke, death</td>
</tr>
<tr>
<td><strong>CEA</strong></td>
<td>1.1%</td>
<td>4.1%</td>
<td>0.89%</td>
<td>3.6%</td>
</tr>
<tr>
<td><strong>CAS</strong></td>
<td>2.3%</td>
<td>2.8%</td>
<td>0.73%</td>
<td>1.1%</td>
</tr>
<tr>
<td><strong>p-value</strong></td>
<td>0.028</td>
<td>0.183</td>
<td>0.784</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>Stroke, death, CNI, MI</td>
<td>Stroke, death, CNI, MI</td>
<td>Stroke, death, CNI, MI</td>
<td>Stroke, death, CNI, MI</td>
</tr>
<tr>
<td></td>
<td>2.0%</td>
<td>5.5%</td>
<td>6.3%</td>
<td>7.2%</td>
</tr>
<tr>
<td></td>
<td>2.9%</td>
<td>8.0%</td>
<td>4.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td><strong>p-value</strong></td>
<td>0.003</td>
<td>0.452</td>
<td>0.543</td>
<td>0.441</td>
</tr>
</tbody>
</table>
## Unadjusted Overall Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>CAS (n=144)</th>
<th>CEA (n=172)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsilateral Stroke</td>
<td>1.6%</td>
<td>0.81%</td>
<td>0.073</td>
</tr>
<tr>
<td>Any Stroke</td>
<td><strong>2.3%</strong></td>
<td><strong>1.0%</strong></td>
<td><strong>0.010</strong></td>
</tr>
<tr>
<td>Major Stroke</td>
<td><strong>1.2%</strong></td>
<td><strong>0.42%</strong></td>
<td><strong>0.026</strong></td>
</tr>
<tr>
<td>Ipsilateral Stroke / Death</td>
<td>1.9%</td>
<td>0.97%</td>
<td>0.072</td>
</tr>
<tr>
<td>Any Stroke / Death</td>
<td><strong>2.3%</strong></td>
<td><strong>1.1%</strong></td>
<td><strong>0.028</strong></td>
</tr>
<tr>
<td>Major Stroke / Death</td>
<td>1.2%</td>
<td>0.58%</td>
<td>0.127</td>
</tr>
<tr>
<td>CNI</td>
<td><strong>0.0%</strong></td>
<td><strong>1.0%</strong></td>
<td><strong>0.039</strong></td>
</tr>
<tr>
<td>Stroke / Death / CNI</td>
<td>2.3%</td>
<td>2.7%</td>
<td>0.679</td>
</tr>
<tr>
<td>Major Stroke / Death / CNI</td>
<td>1.2%</td>
<td>1.5%</td>
<td>0.622</td>
</tr>
<tr>
<td>Stroke / Death / CNI / MI</td>
<td>2.8%</td>
<td>4.1%</td>
<td>0.183</td>
</tr>
</tbody>
</table>
# Stratified Outcomes

## Asymptomatic

<table>
<thead>
<tr>
<th>Event</th>
<th>CAS (n=144)</th>
<th>CEA (n=172)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsilateral Stroke</td>
<td>0.37%</td>
<td>0.63%</td>
<td>0.583</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>0.73%</td>
<td>0.81%</td>
<td>0.885</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.37%</td>
<td>0.32%</td>
<td>0.889</td>
</tr>
<tr>
<td>Minor Stroke / TIA</td>
<td>0.73%</td>
<td>0.99%</td>
<td>0.672</td>
</tr>
<tr>
<td>Post-op MI</td>
<td>0.73%</td>
<td>0.97%</td>
<td>0.693</td>
</tr>
<tr>
<td>Reperfusion</td>
<td>0.00%</td>
<td>0.18%</td>
<td>0.485</td>
</tr>
<tr>
<td>In-hospital Death</td>
<td>0.37%</td>
<td>0.16%</td>
<td>0.416</td>
</tr>
<tr>
<td>Ipsilateral Stroke / Death</td>
<td>0.37%</td>
<td>0.73%</td>
<td>0.483</td>
</tr>
<tr>
<td>Any Stroke / Death</td>
<td>0.73%</td>
<td>0.89%</td>
<td>0.784</td>
</tr>
<tr>
<td>Major Stroke / Death</td>
<td>0.37%</td>
<td>0.40%</td>
<td>0.938</td>
</tr>
<tr>
<td>CNI</td>
<td>0.00%</td>
<td>0.91%</td>
<td>0.113</td>
</tr>
<tr>
<td>Stroke / Death / CNI</td>
<td>0.73%</td>
<td>2.3%</td>
<td>0.095</td>
</tr>
<tr>
<td>Major Stroke / Death / CNI</td>
<td>0.00%</td>
<td>1.23%</td>
<td>0.102</td>
</tr>
<tr>
<td>Stroke / Death / CNI / MI</td>
<td><strong>1.1%</strong></td>
<td><strong>3.6%</strong></td>
<td><strong>0.027</strong></td>
</tr>
</tbody>
</table>
## Stratified Outcomes

### Cortical Symptoms

<table>
<thead>
<tr>
<th></th>
<th>CAS (n=111)</th>
<th>CEA (n=1800)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsilateral Stroke</td>
<td>4.5%</td>
<td>1.5%</td>
<td>0.017</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>6.3%</td>
<td>1.7%</td>
<td>0.001</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>2.7%</td>
<td>0.8%</td>
<td>0.036</td>
</tr>
<tr>
<td>Minor Stroke / TIA</td>
<td>3.6%</td>
<td>1.7%</td>
<td>0.151</td>
</tr>
<tr>
<td>Post-op MI</td>
<td>1.8%</td>
<td>1.3%</td>
<td>0.629</td>
</tr>
<tr>
<td>Reperfusion</td>
<td>1.8%</td>
<td>0.3%</td>
<td>0.020</td>
</tr>
<tr>
<td>Inhospital Death</td>
<td>1.8%</td>
<td>0.6%</td>
<td>0.139</td>
</tr>
<tr>
<td>Ipsilateral Stroke / Death</td>
<td>5.4%</td>
<td>1.8%</td>
<td>0.008</td>
</tr>
<tr>
<td>Any Stroke / Death</td>
<td>6.3%</td>
<td>2.0%</td>
<td>0.003</td>
</tr>
<tr>
<td>Major Stroke / Death</td>
<td>2.7%</td>
<td>1.2%</td>
<td>0.159</td>
</tr>
<tr>
<td>Permanent Cranial Nerve Injury</td>
<td>0.0%</td>
<td>1.2%</td>
<td>0.250</td>
</tr>
<tr>
<td>Stroke / Death / CNI</td>
<td>6.3%</td>
<td>4.0%</td>
<td>0.246</td>
</tr>
<tr>
<td>Major Stroke / Death / CNI</td>
<td>3.5%</td>
<td>2.4%</td>
<td>0.540</td>
</tr>
<tr>
<td>Stroke / Death / CNI / MI</td>
<td>7.2%</td>
<td>5.5%</td>
<td>0.452</td>
</tr>
</tbody>
</table>
## Stratified Outcomes

### Previous Ipsilateral CEA

<table>
<thead>
<tr>
<th>Event</th>
<th>CAS (n=144)</th>
<th>CEA (n=172)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsilateral Stroke</td>
<td>2.8%</td>
<td>1.7%</td>
<td>0.534</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>4.2%</td>
<td>2.9%</td>
<td>0.543</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>1.4%</td>
<td>1.2%</td>
<td>0.858</td>
</tr>
<tr>
<td>Minor Stroke / TIA</td>
<td>3.5%</td>
<td>2.3%</td>
<td>0.542</td>
</tr>
<tr>
<td>Post-op MI</td>
<td>2.8%</td>
<td>2.3%</td>
<td>0.799</td>
</tr>
<tr>
<td>Reperfusion</td>
<td>0.7%</td>
<td>0.0%</td>
<td>0.274</td>
</tr>
<tr>
<td>In-hospital Death</td>
<td>1.4%</td>
<td>1.2%</td>
<td>0.858</td>
</tr>
<tr>
<td>Ipsilateral Stroke / Death</td>
<td>3.5%</td>
<td>1.7%</td>
<td>0.330</td>
</tr>
<tr>
<td>Any Stroke / Death</td>
<td>4.2%</td>
<td>2.9%</td>
<td>0.543</td>
</tr>
<tr>
<td>Major Stroke / Death</td>
<td>1.4%</td>
<td>1.7%</td>
<td>0.801</td>
</tr>
<tr>
<td>CNI</td>
<td>0.0%</td>
<td>0.9%</td>
<td>0.256</td>
</tr>
<tr>
<td>Stroke / Death / CNI</td>
<td>4.2%</td>
<td>4.4%</td>
<td>0.919</td>
</tr>
<tr>
<td>Major Stroke / Death / CNI</td>
<td>0.9%</td>
<td>2.6%</td>
<td>0.313</td>
</tr>
<tr>
<td>Stroke / Death / CNI / MI</td>
<td>5.6%</td>
<td>8.0%</td>
<td>0.441</td>
</tr>
</tbody>
</table>
## Multivariate Risk Prediction

### Any Stroke or Death

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>O.R.</th>
<th>P</th>
<th>95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 70</td>
<td>5.3</td>
<td>0.042</td>
<td>1.1</td>
</tr>
<tr>
<td>History of CHF</td>
<td>3.9</td>
<td>0.051</td>
<td>1.0</td>
</tr>
<tr>
<td>Ipsilateral cortical symptoms</td>
<td>7.3</td>
<td>0.005</td>
<td>1.8</td>
</tr>
</tbody>
</table>

ROCK = 0.8167
Summary

• Overall higher stroke / death rate with CAS; no difference between CEA and CAS when accounting for MI and CNI
  – Due to increased risk of stroke / death in symptomatic patients
  – No difference in stroke / death in asymptomatic patients or patients with prior ipsilateral CEA

• Ipsilateral cortical symptoms, age>70 and history of CHF predictors of stroke or death in CAS
Conclusions

CAS may be best suited for asymptomatic, younger patients
The Influence of Gender on Outcomes of Lower Extremity Bypass: Analysis of the Vascular Study Group of New England

Reshma B. Patel MD¹, Peter W. Callas², Daniel J. Bertges MD¹, Andres Schanzer MD³, Andrew C. Stanley MD¹, Jack L. Cronenwett MD⁴, Jessica K. Andrews², Christopher T. Healey MD⁵, Julie E. Adams MD¹
Fletcher Allen Health Care¹, University of Vermont², University of Massachusetts³, Dartmouth-Hitchcock Medical Center⁴, Maine Surgical Care Group⁵
Introduction

- Women have lower primary-assisted graft patency
  - Prevent III
  - Dartmouth
- Secondary patency also lower in women, and women have reduced late survival
- Gender has not been previously identified as a risk factor for loss of independence after LEB

Methods

• **Study group**
  – All patients undergoing infrainguinal LEB from January 2003 to June 2010

• VSGNNE registry retrospectively reviewed
Methods

• Primary Endpoints
  - Ambulatory status on discharge
  - Disposition on discharge

• Secondary Outcomes
  - In-hospital reoperation for thrombosis or infection
  - Amputation
  - Mortality
Data Analysis

• Univariate Analysis
  – T-test for age
  – Chi-squared test for categorical variables

• Multivariate Modeling
  – Logistic regression to adjust for age
  – Stratified analysis used to look at ambulatory status and conduit as potential confounders
Patient Characteristics

- 3301 patients: 32.1% women, 67.9% men

No difference in number living at home preoperatively, 96% for both groups
Baseline characteristics

![Graph showing baseline characteristics]

- Smoking
- CAD
- HTN
- Statin
- Beta-blocker (periop)

P-values:

- Smoking: P=0.007
- CAD: P=0.005
- HTN: P<0.001
- Statin: P=0.006
- Beta-blocker (periop): P=0.05
Conduit Differences

Conduit type

All with P<0.001

Vein

Dacron

PTFE

Women

Men
Postop Complications

Return to OR - thrombosis
Return to OR - infection
Minor ipsilateral amputation

Women
Men

P<0.001
P=.02
P=0.10

(minor amp only significant after adjusting for age)
Other endpoints

- Graft patency did not differ between women and men
  - 94% and 95% primary patency at d/c
- Major amputation did not differ
  - 2% and 1% (p=ns)
- Death at discharge did not differ
  - 2% for both groups
At discharge…

![Bar chart](chart.png)

- **Return home**: P = 0.001
- **Ambulating independently**: P < 0.001
- **Statin**: P = 0.007

Legend:
- **Women**
- **Men**
Confounding?

• After adjusting for baseline characteristics, differences observed between women and men for return to OR for either infection or thrombosis, discharge to home and ambulation status remained significant
Conclusions

• Women had increased risk of returning to OR for either infection or thrombosis but clinical difference was small
Conclusions

• Females ambulatory prior to LEB were 43% less likely to be discharged home than were males who were ambulatory preoperatively. OR 0.57 (95% CI 0.47-0.67; P <0.001)
Conclusions

• Investigation into reasons why women are less likely to return home may help develop strategies for maintaining independence in the postoperative period.

• One year follow-up data will be useful in determining if the loss of independence is transient.
Real-World Use and Outcomes of Antithrombotic Therapy in Below-Knee Prosthetic Bypass Grafts

Bjoern Suckow, MD

Quality Improvement Topic
Vascular Study Group of New England
Background

- High-risk infrainguinal bypass grafts have higher occlusion rates

1-Year Occlusion Rate

<table>
<thead>
<tr>
<th></th>
<th>Above-knee</th>
<th>Below-knee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein</td>
<td>15%</td>
<td>45%</td>
</tr>
<tr>
<td>Prosthetic</td>
<td>20%</td>
<td>75%</td>
</tr>
</tbody>
</table>

- Antithrombotic therapy likely improves patency in across-knee prosthetic grafts
Background

- CASPAR Trial (2010)
  - Aspirin vs. Aspirin+Clopidogrel
  - Below-knee bypass grafts (vein & prosthetic)
  - Follow-up 2 years
  - Composite Endpoint
    - Occlusion
    - Reintervention
    - Amputation
    - Death
- In Prosthetic Grafts (n=253 patients)
  - Absolute Risk Reduction 35% (p=0.025)
Background

• Bandyk et al. (2007)
  – 121 patients with infrainguinal prosthetic bypass
  – Up to 4 years follow-up

• Warfarin use protective of patency (OR=8.4, p=0.003)

• Therapeutic warfarin dosing associated with absolute risk reduction of graft thrombosis of 34% (p<0.01)
Objective

• Evaluate the effect of “real-world” use of aspirin, clopidogrel and warfarin on outcomes in below-knee prosthetic bypass grafts

• Compare outcomes, by antithrombotic therapy, to a propensity-matched cohort with saphenous vein conduit
Methods

- VSGNE LEB Database 2003-2009
- Include
  - Only first LEB per patient
  - Above-knee origin
  - Below-knee target
  - PTFE/Dacron conduit
- Outcomes
  - Primary Patency
  - MALE (amputation, revision, thrombectomy/lysis)
  - Mortality
  - Bleeding Complications (return to OR for bleeding, transfusion > 2 PRBC)
Methods

• Comparison by antithrombotic regimen
  – Aspirin (ASA)
  – Aspirin + Clopidogrel (ASA+CLPG)
  – Aspirin + Warfarin (ASA+WAR)
  – Aspirin + Clopidogrel + Warfarin

• Comparison of outcomes with prosthetic conduit versus single-segment saphenous vein
  – Propensity-matched
## Patient Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>ASA</th>
<th>ASA+CLPG</th>
<th>ASA+WAR</th>
<th>ASA+CLPG+WAR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n=308)</td>
<td>106</td>
<td>45</td>
<td>119</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>68%</td>
<td>64%</td>
<td>59%</td>
<td>71%</td>
<td>0.41</td>
</tr>
<tr>
<td>White</td>
<td>97%</td>
<td>100%</td>
<td>99%</td>
<td>100%</td>
<td>0.72</td>
</tr>
<tr>
<td>Average Age</td>
<td>70 yrs</td>
<td>67 yrs</td>
<td>73 yrs</td>
<td>69 yrs</td>
<td>0.04</td>
</tr>
<tr>
<td>Smoking</td>
<td>91%</td>
<td>84%</td>
<td>74%</td>
<td>84%</td>
<td>0.02</td>
</tr>
<tr>
<td>Hypertension</td>
<td>85%</td>
<td>89%</td>
<td>87%</td>
<td>90%</td>
<td>0.86</td>
</tr>
<tr>
<td>Diabetes</td>
<td>45%</td>
<td>58%</td>
<td>45%</td>
<td>58%</td>
<td>0.29</td>
</tr>
<tr>
<td>Dialysis</td>
<td>6%</td>
<td>4%</td>
<td>6%</td>
<td>8%</td>
<td>0.94</td>
</tr>
<tr>
<td>Previous Bypass</td>
<td>43%</td>
<td>47%</td>
<td>49%</td>
<td>47%</td>
<td>0.82</td>
</tr>
<tr>
<td>Previous Angioplasty</td>
<td>14%</td>
<td>44%</td>
<td>28%</td>
<td>29%</td>
<td>0.001</td>
</tr>
<tr>
<td>Previous Amputation</td>
<td>3%</td>
<td>0</td>
<td>4%</td>
<td>8%</td>
<td>0.25</td>
</tr>
</tbody>
</table>
## Operative Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>ASA</th>
<th>ASA+CLPG</th>
<th>ASA+WAR</th>
<th>ASA+CLPG+WAR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n=308)</td>
<td>106</td>
<td>45</td>
<td>119</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>CLI</td>
<td>54%</td>
<td>58%</td>
<td>61%</td>
<td>71%</td>
<td>0.31</td>
</tr>
<tr>
<td>Right Side</td>
<td>46%</td>
<td>56%</td>
<td>51%</td>
<td>47%</td>
<td>0.72</td>
</tr>
<tr>
<td>Origin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- CFA</td>
<td>73%</td>
<td>71%</td>
<td>79%</td>
<td>97%</td>
<td>0.03</td>
</tr>
<tr>
<td>- SFA</td>
<td>14%</td>
<td>13%</td>
<td>9%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>- AK Pop</td>
<td>9%</td>
<td>7%</td>
<td>1%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Target</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- BK Pop</td>
<td>83%</td>
<td>89%</td>
<td>71%</td>
<td>52%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Tibial</td>
<td>17%</td>
<td>9%</td>
<td>24%</td>
<td>47%</td>
<td></td>
</tr>
</tbody>
</table>
Results

Primary Patency of Prosthetic Grafts by Therapy

\[ p = 0.33 \]
Results

Incidence of MALE in Prosthetic Grafts by Therapy

\[ p = 0.5 \]
# Secondary Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>ASA</th>
<th>ASA+CLPG</th>
<th>ASA+WAR</th>
<th>ASA+CLPG+WAR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Return to OR for bleeding</td>
<td>3/106 (3%)</td>
<td>4/45 (9%)</td>
<td>5/119 (4%)</td>
<td>4/38 (11%)</td>
<td>0.14</td>
</tr>
<tr>
<td>Transfusion &gt; 2 PRBC</td>
<td>5/106 (5%)</td>
<td>3/45 (7%)</td>
<td>11/119 (9%)</td>
<td>1/38 (3%)</td>
<td>0.45</td>
</tr>
<tr>
<td>1-Year Survival</td>
<td>65/74 (87%)</td>
<td>19/22 (86%)</td>
<td>76/90 (84%)</td>
<td>27/30 (90%)</td>
<td>0.45</td>
</tr>
</tbody>
</table>
# Prosthetic vs. Saphenous Vein

<table>
<thead>
<tr>
<th>Variable</th>
<th>Vein</th>
<th>Prosthetic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n=1,664)</td>
<td>1,356</td>
<td>308</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Coronary Disease</td>
<td>34%</td>
<td>49%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous Bypass</td>
<td>25%</td>
<td>46%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous Angioplasty/Stent</td>
<td>21%</td>
<td>26%</td>
<td>0.07</td>
</tr>
<tr>
<td>Origin - CFA</td>
<td>62%</td>
<td>78%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Origin - SFA</td>
<td>29%</td>
<td>11%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Target – BK Pop</td>
<td>52%</td>
<td>76%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Target - Tibial</td>
<td>40%</td>
<td>23%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Antithrombotic Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-ASA</td>
<td>59%</td>
<td>34%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- ASA+CLPG</td>
<td>20%</td>
<td>15%</td>
<td>0.04</td>
</tr>
<tr>
<td>- ASA+WAR</td>
<td>17%</td>
<td>39%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- ASA+CLPG+WAR</td>
<td>5%</td>
<td>12%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## Propensity-Matched

<table>
<thead>
<tr>
<th>Variable</th>
<th>Vein</th>
<th>Prosthetic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n=556)</td>
<td>278</td>
<td>278</td>
<td>0.87</td>
</tr>
<tr>
<td>Coronary Disease</td>
<td>49%</td>
<td>48%</td>
<td>0.87</td>
</tr>
<tr>
<td>Previous Bypass</td>
<td>46%</td>
<td>46%</td>
<td>1</td>
</tr>
<tr>
<td>Previous Angioplasty/Stent</td>
<td>22%</td>
<td>25%</td>
<td>0.55</td>
</tr>
<tr>
<td>Origin - CFA</td>
<td>78%</td>
<td>78%</td>
<td>0.92</td>
</tr>
<tr>
<td>Origin - SFA</td>
<td>9%</td>
<td>12%</td>
<td>0.32</td>
</tr>
<tr>
<td>Target – BK Pop</td>
<td>77%</td>
<td>75%</td>
<td>0.49</td>
</tr>
<tr>
<td>Target - Tibial</td>
<td>20%</td>
<td>23%</td>
<td>0.85</td>
</tr>
<tr>
<td>Antithrombotic Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-ASA</td>
<td>41%</td>
<td>37%</td>
<td>0.43</td>
</tr>
<tr>
<td>- ASA+CLPG</td>
<td>15%</td>
<td>16%</td>
<td>0.82</td>
</tr>
<tr>
<td>- ASA+WAR</td>
<td>33%</td>
<td>36%</td>
<td>0.53</td>
</tr>
<tr>
<td>- ASA+CLPG+WAR</td>
<td>11%</td>
<td>11%</td>
<td>1</td>
</tr>
</tbody>
</table>
Results

Primary Patency by Conduit

p = 0.44

Time (days)
Primary Patency at 1 Year

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Saphenous Vein</th>
<th>Prosthetic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>154/189 (81%)</td>
<td>133/167 (80%)</td>
<td>0.44</td>
</tr>
<tr>
<td>ASA</td>
<td>58/69 (84%)</td>
<td>49/60 (82%)</td>
<td>0.47</td>
</tr>
<tr>
<td>ASA+CLPG</td>
<td>21/29 (72%)</td>
<td>15/19 (79%)</td>
<td>0.42</td>
</tr>
<tr>
<td>ASA+WAR</td>
<td>57/65 (88%)</td>
<td>54/66 (82%)</td>
<td>0.2</td>
</tr>
<tr>
<td>ASA+CLPG+WAR</td>
<td>18/26 (69%)</td>
<td>15/22 (68%)</td>
<td>0.94</td>
</tr>
</tbody>
</table>
Results

Incidence of MALE by Conduit

Time (days)

Saphenous Vein Prosthetic

p=0.25
## MALE at 1 Year

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Saphenous Vein</th>
<th>Prosthetic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>31/182 (17%)</td>
<td>34/166 (20%)</td>
<td>0.25</td>
</tr>
<tr>
<td>ASA</td>
<td>9/69 (13%)</td>
<td>12/60 (20%)</td>
<td>0.27</td>
</tr>
<tr>
<td>ASA+CLPG</td>
<td>5/29 (17%)</td>
<td>5/20 (25%)</td>
<td>0.65</td>
</tr>
<tr>
<td>ASA+WAR</td>
<td>9/59 (15%)</td>
<td>13/64 (20%)</td>
<td>0.22</td>
</tr>
<tr>
<td>ASA+CLPG+WAR</td>
<td>8/25 (32%)</td>
<td>4/22 (18%)</td>
<td>0.89</td>
</tr>
</tbody>
</table>
## Secondary Outcomes

### Bleeding Complications

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Saphenous Vein</th>
<th>Prosthetic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>31/278 (11%)</td>
<td>29/278 (10%)</td>
<td>0.79</td>
</tr>
<tr>
<td>ASA</td>
<td>11/113 (10%)</td>
<td>8/104 (8%)</td>
<td>0.6</td>
</tr>
<tr>
<td>ASA+CLPG</td>
<td>4/42 (10%)</td>
<td>6/44 (14%)</td>
<td>0.55</td>
</tr>
<tr>
<td>ASA+WAR</td>
<td>12/92 (13%)</td>
<td>10/99 (10%)</td>
<td>0.52</td>
</tr>
<tr>
<td>ASA+CLPG+WAR</td>
<td>4/31 (13%)</td>
<td>5/31 (16%)</td>
<td>0.72</td>
</tr>
</tbody>
</table>

### 1-Year Survival

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Saphenous Vein</th>
<th>Prosthetic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>189/213 (89)</td>
<td>173/200 (87)</td>
<td>0.5</td>
</tr>
<tr>
<td>ASA</td>
<td>71/78 (91)</td>
<td>63/72 (88)</td>
<td>0.73</td>
</tr>
<tr>
<td>ASA+CLPG</td>
<td>30/30 (100)</td>
<td>19/22 (86)</td>
<td>0.13</td>
</tr>
<tr>
<td>ASA+WAR</td>
<td>61/77 (79)</td>
<td>69/81 (85)</td>
<td>0.58</td>
</tr>
<tr>
<td>ASA+CLPG+WAR</td>
<td>27/28 (96)</td>
<td>22/25 (88)</td>
<td>0.18</td>
</tr>
</tbody>
</table>
Conclusions

- In this cohort, one-year outcomes in below-knee prosthetic grafts are comparable to single-segment saphenous vein

- Selection of patients and antithrombotic regimen likely contribute to these findings
Discussion

• Limitation of sample size to assess contribution of differing antithrombotic regimens

• Inability to link choice of conduit with choice of antithrombotic therapy
Accountable Care Organizations

- How ACOs relate to the VSGNE
  - Phil Goodney
Accountable Care Organizations (ACOs): Potential Roles for Regional Collaboratives, Specialty Societies and Vascular Surgeons

Philip P. Goodney
Goals

- Explore the development of ACOs
- Review the structure of ACOs, and ways they will impact care
- Discuss how we can shape these efforts
Goals

• Explore the development of ACOs

• Review potential ways they will impact medical care

• Discuss how we can shape these efforts
Controlling Medicare Spending

- Affordable Care Act
  - Passed by Congress 9/17/2010
  - Signed by President Obama 12/14/10

- Key Element:
  - Accountable Care Organization (ACO)
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)
  - Implemented in 1997
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)
- Implemented in 1997
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)
- If Actual > Projected

Projected Medicare Expenditures

Actual Medicare Expenditures
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)
- “Update” is introduced…
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)

  “Update” is introduced

  The Update Will “Discount” services based on a predefined algorithm to limit spending growth

Future Medicare Expenditures

Actual Medicare Expenditures

Expenditures
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)

At least, in theory, balancing things out..
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)

What surgeons should know about...

What’s wrong with the SGR

by Cynthia A. Brown, Director, Division of Advocacy and Health Policy
Controlling Medicare Spending – Before?

- SGR (Sustainable Growth Rate)

- Disproportionately Penalized…
  - Physician Payments (Rather Than Hospitals)

- Office Procedures (Rather than Drugs)

by Cynthia A. Brown, Director, Division of Advocacy and Health Policy

OCTOBER 2004 BULLETIN OF THE AMERICAN COLLEGE OF SURGEONS
The Way Around the SGR - Volume

Figure 1

Cumulative growth in volume per beneficiary, by type of service, 1999-2002

Broad Dissatisfaction: Payers, Providers, Policymakers
The Next Step: Development of ACOs

Groups of Physicians, Hospitals or Care Systems

Responsible for Cost of Care for a Population

Responsible for Quality of Care for a Population

If Care Provided at Lower Cost
AND
High Quality

Portion of Savings Returned to Providers
IF QUALITY TARGETS ARE MET
<table>
<thead>
<tr>
<th>Care System Model</th>
<th>Era</th>
<th>Mechanism To Limit Expenditure</th>
<th>Excess Funds Go To</th>
<th>Incentive Provided to</th>
<th>Reason For Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit Access (Patient Level)</td>
<td>1990s</td>
<td>Co-Pays, Referral Requirements</td>
<td>Insurer</td>
<td>Patients to give up</td>
<td>Poor Public perception</td>
</tr>
</tbody>
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ACOs: 2010
Fixed Sum to Care for Population
Providers and Insurer Meet Quality Benchmarks and Provide Cost-Effective Care?
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</tr>
<tr>
<td>Capitation (Provider level)</td>
<td>1990s-2000s</td>
<td>Fixed Sum to Care for a Population</td>
<td>Providers and Insurer</td>
<td>Provider to Limit Care (No Quality Consideration)</td>
<td>Questions regarding rationing and incentives</td>
</tr>
</tbody>
</table>
## Is This Different Than Managed Care?

<table>
<thead>
<tr>
<th>Care System Model</th>
<th>Era</th>
<th>Mechanism To Limit Expenditure</th>
<th>Excess Funds Go To</th>
<th>Incentive Provided to</th>
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<tr>
<td>ACOs</td>
<td>2010</td>
<td>Fixed Sum to Care for Population</td>
<td>Providers and Insurer</td>
<td>Meet Quality Benchmarks and Provide Cost-Effective Care</td>
<td>?</td>
</tr>
</tbody>
</table>
## Is This Feasible?

<table>
<thead>
<tr>
<th>Project</th>
<th>Number of Hospitals</th>
<th>Number of Physicians</th>
<th>Number of Patients</th>
<th>Primary Payer</th>
<th>Examples of Quality Markers</th>
<th>Savings Returned to ACO Providers</th>
</tr>
</thead>
</table>
| Physician Group Project  | 10 large group practices | 5,000 physicians, ranging from 232-1291 per practice | 223,204           | Center For Medicare Services | • Beta Blocker Therapy for Post-MI patients  
• Documented Hypertension Plan of Care                                                     | $31.7 million distributed back to 5 sites that met quality goals |
## Is This Feasible?

<table>
<thead>
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<th>Project</th>
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• Documented Hypertension Plan of Care                                                     | $31.7 million distributed back to 5 sites that met quality goals |
| Advocate Physician Partners | 10 affiliated group and private practices | 3,500 physicians; 2,700 in group practice | ~1,000,000         | Blue Cross/Blue Shield      | • eICU capability for all ICU beds  
• Specified plan of blood sugar, cholesterol, blood pressure control                    | $38 million in incentive payments distributed to 3,700 physicians across 10 sites |
Goals

- Explore the development of ACOs
- Review the structure of ACOs, and ways they will impact care
- Discuss how we can shape these efforts
Goals

- Explore the development of ACOs
- Review the structure of ACOs, and ways they will impact care
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## Criteria for Designation as an Accountable Care Organization (ACO)

<table>
<thead>
<tr>
<th>Expression</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Express willingness to be accountable for quality, cost, and overall care of Medicare fee-for-service beneficiaries for a minimum of three years</td>
<td></td>
</tr>
<tr>
<td>Criteria for Designation as an Accountable Care Organization (ACO)</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Express willingness to be accountable for quality, cost, and overall care of Medicare fee-for-service beneficiaries for a minimum of three years</td>
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</tr>
<tr>
<td>Have a formal legal structure to receive and distribute shared savings</td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Have a formal legal structure to receive and distribute shared savings</td>
</tr>
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<td>Have at least 5,000 assigned beneficiaries with sufficient number of primary care ACO professionals.</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Report on quality, cost, and care coordination measures, and meet patient centeredness criteria set forth by the Health and Human Services (HHS) Secretary</td>
</tr>
</tbody>
</table>
# What Makes An Organization an ACO?

## Criteria for Designation as an Accountable Care Organization (ACO)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Express willingness to be accountable for quality, cost, and overall care of Medicare fee-for-service beneficiaries for a minimum of three years</td>
<td></td>
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<td></td>
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<td>Report on quality, cost, and care coordination measures, and meet patient centeredness criteria set forth by the Health and Human Services (HHS) Secretary</td>
<td></td>
</tr>
<tr>
<td>May initially focus on one-sided shared savings models.</td>
<td></td>
</tr>
</tbody>
</table>
## How Will They Be Structured?

<table>
<thead>
<tr>
<th>Type of ACO Structure</th>
<th>Complexity</th>
<th>Required Infrastructure</th>
<th>IF: Quality Targets are Achieved (Actual Spending &lt; Projected Spending)</th>
<th>Risk Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple Shared Savings</td>
<td>Simplest</td>
<td>Limited</td>
<td>Provider receives bonus</td>
<td>Risks reside primarily with payer</td>
</tr>
</tbody>
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<td>Simplest</td>
<td>Limited</td>
<td>Provider receives bonus</td>
<td>Risks reside primarily with payer</td>
</tr>
<tr>
<td>Symmetrical</td>
<td>Moderate</td>
<td>Complex regional cost tracking data required</td>
<td>Provider receives bonus if savings occur. However, provider liable for spending that exceeds projections</td>
<td>Shared risk between payer and providers.</td>
</tr>
</tbody>
</table>
## How Will They Be Structured?

<table>
<thead>
<tr>
<th>Type of ACO Structure</th>
<th>Complexity</th>
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<tr>
<td>Simple Shared Savings</td>
<td>Simplest</td>
<td>Limited</td>
<td>Provider receives bonus</td>
<td>Risks reside primarily with payer</td>
</tr>
<tr>
<td>Symmetrical</td>
<td>Moderate</td>
<td>Complex regional cost tracking data required</td>
<td>Provider receives bonus if savings occur. However, provider liable for spending that exceeds projections</td>
<td>Shared risk between payer and providers.</td>
</tr>
<tr>
<td>Partial Capitation</td>
<td>Complex</td>
<td>Cost tracking data required, Up-front payment per plan participants</td>
<td>Share of saving distributed back to providers. Larger potential to recover savings, but also greater risk if overspending occurs</td>
<td>Shared risk, early payment offers support for innovation</td>
</tr>
</tbody>
</table>
Challenges And Unknowns: General

How will these complex administrative structures be created, and who will pay for it?
Challenges And Unknowns: Surgeon-Specific

Will a busy surgeon be willing to limit his/her case volume for the promise of a quality-based incentive?

Need and Reimbursement for the Procedure

Quality Metrics Associated with the Procedure
Goals

- Explore the development of ACOs
- Review the structure of ACOs, and ways they will impact care
- Discuss how we can shape these efforts
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Need and Reimbursement for the Procedure

Quality Metrics Associated with the Procedure
Challenges And Unknowns: Surgeon-Specific

Vascular Surgeons and Regional Registries Are Ideally Positioned To Participate In Both of These Tasks !!!!

Need and Reimbursement for the Procedure

Quality Metrics Associated with the Procedure
Leveraging the Strengths of Registries

- VSGNE has nearly 10 years worth of:
  - **Regional rates of vascular procedures**
    - Can be used to justify population-based procedural rates
    - Extensive clinical detail
      - and therefore justification
  - These rates can be state, region, or ACO specific
Quality Metrics

- VSGNE has risk-adjusted quality metrics
  - Regional outcomes
  - Population-specific outcomes

- VSGNE is a quality leader in vascular surgery
  - Established track record in quality improvement
How Do We Move Forward?

- Regionally:
  - Continue prominent quality improvement work
  - Collaborate in “setting the bar” for vascular care

- Nationally:
  - Society-based endorsement of leadership role of vascular surgery in guiding vascular care in ACOs
<table>
<thead>
<tr>
<th>Conclusion: Take Home Points</th>
</tr>
</thead>
<tbody>
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<td><strong>ACOs are coming.</strong></td>
</tr>
<tr>
<td>Registries/SVS need to participate.</td>
</tr>
<tr>
<td><strong>ACOS will limit expenditures that are not evidence-based.</strong></td>
</tr>
<tr>
<td>Regional Registries Can Support Evidence-Based Provision of Vascular Care.</td>
</tr>
<tr>
<td><strong>ACOs need Quality Metrics.</strong></td>
</tr>
<tr>
<td>Regional Registries/SVS Should Design and Implement Vascular Quality Metrics.</td>
</tr>
</tbody>
</table>
Discussion:

- When do these efforts start?
- How to partner with decision-makers
- How to deal with tough decisions…
Next Meeting

- Date: Monday, November 7th
- Location: Maine Medical Center, Portland
- Time: 10 am – 4 pm