Vascular Study Group of New England (VSGNE)

June 7, 2019
10:00 AM – 4:00 PM
Dartmouth-Hitchcock Medical Center
Agenda - Morning

10:00 -10:10 Welcome by Dr. Philip Goodney and Dartmouth Hitchcock Medical Center

10:10am – 11:10am National Committee Updates:
- Regional Reports Review – P Goodney / J Jorgensen (45 min)
- LTFU Update – J Jorgensen (10 min)
- VQI National Research Advisory Council Update – P Goodney (5 min)

11:10am-11:50am VSGNE Quality Improvement Projects
- Brian Nolan/Andres Schanzer - Improving Care for Patients Undergoing Transcarotid Artery Revascularization Using a Novel Preoperative Risk Assessment Tool
- Douglas Jones – Reducing Postoperative Hospital Utilization through Improved Discharge Planning After Lower Extremity Revascularization
- Cassius Iyad Ochoa Chaar – A pilot study of a comprehensive multidisciplinary inpatient-based approach to smoking cessation for patients with vascular disease
- Aaron Barnes - Anticoagulation and Antiplatelet Treatment Plan Communication and Documentation Improvement Project
- Panel Discussion (Nolan/Jones/Chaar/Barnes): What should we do with our findings from the QIPs?

11:50am-12:45pm Lunch Break (Data Managers’ Meeting and Lunch – Fuller Boardroom – 3rd Floor)
Agenda - Afternoon

12:50pm-1:00pm National Committee Updates II:
• Arterial Quality Council Update – Jessica Simons (5 min)
• Venous Quality Council Update – Phil Goodney (5 min)
• Governing Council Update – Jens Jorgensen (10 min)

1:10pm-1:40pm: Ruptured AAA Survey and CAS Survey - Brian Nolan) (30 min)
1:40pm – 1:55pm Data Managers Update – Patricia Bozeman (15 min)
1:55pm – 2:05pm RAPID/SPEED Update – Daniel Bertges (10 min)
2:05pm – 2:15pm Paclitaxel Working Group Update (Jens Jorgensen/Daniel Bertges) (10 min)

Break (10 min)

2:25pm - 3:45pm VSGNE RAC Update and Research Progress Reports (J Siracuse)
• Cassius Lyad Ochoa Chaar, Yale New Haven: A Vascular Quality Initiative database comparison of atherectomy and other endovascular modalities for lower extremity revascularization; A Vascular Quality Initiative database study of the effects of laterality on the performance of arteriovenous grafts
• Scott Levin, BMC: AV access in IV drug use patients; Shunting practices after acute stroke; Changes in AAA screening (15 min)
• Nkiruka Arinze, BMC: Effect of BMI on outcomes after CEA (5 min)
• Thomas Cheng, BMC: EVAR with obligate ICU use (5 min)
• Livia de Guerre, BIDMC: The impact of the degree of oversizing in aortic aneurysm repair
• Mathijs Carvalho, BIDMC: Investigating the Optimal Age for Endovascular and Open Aortic Aneurysm Repair
• Kirsten Dansey, BIDMC: Carotid intervention laterality - association with perioperative complications
• Chun Li, BIDMC, Preoperative statin use and survival following thoracic endovascular aortic repair.

3:45pm-4:00pm Meeting Evaluation, and Planning/Fall Meeting
Welcome and Introductions

Backus Hospital
Baystate Medical Center
Berkshire Medical Center
Beth Israel Deaconess Medical Center
Boston Medical Center
Brigham and Women's Hospital
Cape Cod Hospital
Catholic Medical Center; CTSA NH
Central Maine Medical Center
Charlton Memorial Hospital
Concord Hospital
Danbury Hospital
Dartmouth Hitchcock Medical Center
Diagnostic Imaging of Milford
Elliot Health System
Hartford Hospital
Hoenig Vascular Center
Lahey Hospital and Medical Center
Lakes Region General Hospital
Maine Medical Center
MaineGeneral Medical Center
Massachusetts General Hospital
Middlesex Hospital
Northern Light Eastern Maine Medical Center
Portsmouth Regional Hospital
Rhode Island Hospital
Saint Francis Hospital
St. Elizabeth Medical Center
St. Luke's Hospital
Steward Good Samaritan Medical Center, Inc.
Steward St. Anne's Hospital Corporation
The Hospital Of Central Connecticut
The Miriam Hospital
Tufts Medical Center
U Mass Memorial
University of Vermont Medical Center
Yale-New Haven Hospital
Regional Reports:

Philip Goodney, MD

1) In all reports, regional data are not shown if the region does not have at least 3 centers with at least 10 cases meeting inclusion criteria for each outcome in the applicable registry.
2) In “by Center” bar charts, unless noted, data are not shown for centers with <10 cases and for regions with <3 centers.
3) In all graphics, “*” indicates a p-value <.05.
4) This report includes all data that had been entered into the VQI as of Jan. 31, 2019.
The table below summarizes your center’s results as presented in each of the subsequent reports and provides regional and national benchmarks for comparison. In the “Your Center” column, percentages represent the rate of cases with the noted outcome. Numbers in parentheses are the number of cases with the outcome/the total number of cases meeting the inclusion criteria (see the full report for details). In the “Your Region” and “VQI Overall” columns, the numbers represent the 25th, 50th (median) and 75th percentiles for centers in your region and across all centers in the VQI. Percentiles are ordered so that a higher percentile always indicates better performance.

Your center’s results are highlighted in green if your center is at or above the 75th percentile nationally, in yellow if your center is among the middle 50% of centers, and in red if at or below the 25th percentile.

Unless otherwise noted, the timeframe for all outcomes is January 1-December 31, 2018. For more details about each outcome, click on the name of report in the table of contents at left.
| Registry                        | Outcome                        | Your Center % (n/N) | Your Region [25p|50p|75p] | VQI Overall [25p|50p|75p] |
|--------------------------------|--------------------------------|---------------------|-----------------------------|-----------------------------|
| All                            | Total Procedure Volume         | [52 | 172 | 385]           | [37 | 125 | 315]           |
| Multiple (Jan-Dec 2016)        | Long-Term Follow-Up            | [60 | 78 | 87%]          | [50 | 78 | 89%]          |
| Multiple                       | Discharge Medications          | [82 | 87 | 92%]          | [75 | 84 | 92%]          |
| AVACCESS                       | Primary AVF vs. Graft          | [82 | 87 | 91%]          | [77 | 85 | 93%]          |
| CAS                            | In-Hospital Stroke/Death       | [4 | 0 | 0%]           | [2 | 0 | 0%]           |
| CEA                            | In-Hospital Stroke/Death       | [2 | 0 | 0%]           | [1 | 0 | 0%]           |
| CEA                            | LOS>1 Day                      | [37 | 25 | 16%]          | [31 | 22 | 13%]          |
| EVAR                           | LOS>2 Days                     | [15 | 10 | 0%]           | [17 | 10 | 4%]           |
| EVAR (Jan-Dec 2016)            | Sac Diameter at LTFU           | [40 | 62 | 74%]          | [36 | 60 | 75%]          |
| INFRA                          | Major Complications            | [3 | 0 | 0%]           | [6 | 0 | 0%]           |
| IVCF (July 2017-June 2018)     | Filter Retrieval               | NA (<3 centers)   | [0 | 17 | 39%]          |
| LEAMP                          | Postop Complications           | [23 | 19 | 17%]          | [17 | 11 | 4%]          |
| OAAA                           | In-Hospital Mortality          | [0 | 0 | 0%]           | [0 | 0 | 0%]           |
| PVI                            | ABI/TBI Reported               | [70 | 79 | 90%]          | [65 | 82 | 92%]          |
| SUPRA                          | Postop Complications           | [0 | 0 | 0%]           | [0 | 0 | 0%]           |
| TEVAR (Jan-Dec 2016)           | Sac Diameter at LTFU           | [9 | 36 | 50%]          | [21 | 40 | 62%]          |
| EVAR                           | Sac Size Guideline             | [54 | 65 | 74%]          | [50 | 58 | 71%]          |
| EVAR                           | Iliac Inflow Guideline         | [98 | 100 | 100%]        | [99 | 100 | 100%]        |
| OAAA                           | Cell-Saver Guideline           | [100 | 100 | 100%]        | [93 | 100 | 100%]        |
| OAAA                           | Iliac Inflow Guideline         | [100 | 100 | 100%]        | [100 | 100 | 100%]        |
## Total Procedure Volume, All Years

Includes all procedures entered in VQI as of Jan. 31, 2019

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Your Center (N)</th>
<th>Your Region (N)</th>
<th>VQI Overall (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVACCESS</td>
<td>4424</td>
<td>43147</td>
<td></td>
</tr>
<tr>
<td>CAS</td>
<td>3168</td>
<td>25969</td>
<td></td>
</tr>
<tr>
<td>CEA</td>
<td>22657</td>
<td>112906</td>
<td></td>
</tr>
<tr>
<td>EVAR</td>
<td>7432</td>
<td>44323</td>
<td></td>
</tr>
<tr>
<td>INFRA</td>
<td>12631</td>
<td>48823</td>
<td></td>
</tr>
<tr>
<td>IVCF</td>
<td>NA (&lt;3 centers)</td>
<td>11105</td>
<td></td>
</tr>
<tr>
<td>LEAMP</td>
<td>1238</td>
<td>12896</td>
<td></td>
</tr>
<tr>
<td>OAAA</td>
<td>3628</td>
<td>11436</td>
<td></td>
</tr>
<tr>
<td>PVI</td>
<td>26370</td>
<td>168342</td>
<td></td>
</tr>
<tr>
<td>SUPRA</td>
<td>3526</td>
<td>16146</td>
<td></td>
</tr>
<tr>
<td>TEVAR</td>
<td>1503</td>
<td>12579</td>
<td></td>
</tr>
<tr>
<td>Varicose Veins</td>
<td>NA (&lt;3 centers)</td>
<td></td>
<td>25610</td>
</tr>
<tr>
<td>Overall</td>
<td>87066</td>
<td></td>
<td>533282</td>
</tr>
</tbody>
</table>
Procedure Volume by Center in Your Region (Jan-Dec 2018)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

Procedure Volume Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)
Physician Specialties Across VQI (as of Jan. 31, 2019, N=4183 Physicians)
Physician Specialties Across Your Region (as of Jan. 31, 2019, N=309 Physicians)
### Percentage of Procedures with 9 Months or Greater Follow-Up

Procedures performed between Jan. 1 and Dec. 31, 2016

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2016, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of procedures in the VQI, and the percentage of those procedures with long-term follow-up.

<table>
<thead>
<tr>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVACCESS</td>
<td>492 (85%)</td>
<td>6977 (71%)</td>
</tr>
<tr>
<td>CAS</td>
<td>361 (62%)</td>
<td>3709 (67%)</td>
</tr>
<tr>
<td>CEA</td>
<td>1861 (73%)</td>
<td>16217 (73%)</td>
</tr>
<tr>
<td>EVAR</td>
<td>645 (73%)</td>
<td>6202 (75%)</td>
</tr>
<tr>
<td>INFRA</td>
<td>1008 (75%)</td>
<td>6726 (77%)</td>
</tr>
<tr>
<td>IVCF</td>
<td>NA (&lt;3 centers)</td>
<td>1906 (66%)</td>
</tr>
<tr>
<td>LEAMP</td>
<td>208 (75%)</td>
<td>2037 (74%)</td>
</tr>
<tr>
<td>OAAA</td>
<td>212 (67%)</td>
<td>1164 (73%)</td>
</tr>
<tr>
<td>PVI</td>
<td>3046 (78%)</td>
<td>24524 (76%)</td>
</tr>
<tr>
<td>SUPRA</td>
<td>351 (72%)</td>
<td>2208 (74%)</td>
</tr>
<tr>
<td>TEVAR</td>
<td>183 (68%)</td>
<td>2017 (70%)</td>
</tr>
<tr>
<td>2016 Overall</td>
<td>8381 (75%)</td>
<td>73687 (74%)</td>
</tr>
<tr>
<td>2015 Overall</td>
<td>9053 (70%)</td>
<td>70365 (75%)</td>
</tr>
</tbody>
</table>
Percentage With Long-Term Follow-Up by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Long-Term Follow-Up by Center in Your Region (Jan-Dec 2016)

Centers (centers with <10 cases not shown)

“**” indicates center’s rate differs significantly from the regional rate.

1. Central Maine Medical Center
2. Saint Francis Hospital
3. Hoenig Vascular Center
4. Yale-New Haven Hospital
5. University of Vermont Medical Center
6. Brigham and Women’s Hospital
7. U Mass Memorial
8. Berkshire Medical Center
9. Concord Hospital
10. Boston Medical Center
11. Beth Israel Deaconess Medical Center
12. Maine Medical Center
13. Baystate Medical Center
14. Eastern Maine Medical Center
15. Hartford Hospital
16. Maine General Medical Center
17. Tufts Medical Center
18. Elliot Health System
19. The Miriam Hospital
20. St. Elizabeth Medical Center
21. Rhode Island Hospital
22. Danbury Hospital
23. Dartmouth Hitchcock Medical Center
24. Massachusetts General Hospital
25. Charlton Memorial Hospital
26. Catholic Medical Center; CTSA NH
27. Lakes Region General Hospital
Long-Term Follow-Up by Region Across VQI (Jan-Dec 2016)

Regions (regions with <3 centers with at least 10 cases not shown)

“Others” indicates centers that do not belong to a regional group. “*” indicates region’s rate differs significantly from the VQI rate.
**Discharge Medications Procedures performed between Jan 1, 2018 and Dec 31, 2018 and entered by Jan 31, 2019**

Excludes patients who died in hospital and patients who were not treated for medical reason or non-compliant. “Antiplatelet” is defined as ASA or P2Y12 inhibitor.

<table>
<thead>
<tr>
<th>Number of Procedures at Your Center</th>
<th>Antiplatelet+Statin</th>
<th>Antiplatelet Only</th>
<th>Statin Only</th>
<th>Neither</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Region Overall</td>
<td>7564</td>
<td>86%</td>
<td>9%</td>
<td>3%</td>
</tr>
<tr>
<td>VQI Overall</td>
<td>73585</td>
<td>82%</td>
<td>11%</td>
<td>4%</td>
</tr>
</tbody>
</table>
Percentage Receiving Discharge Antiplatelet+Statin by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Discharge Antiplatelet+Statin Rate by Center in Your Region (Jan-Dec 2018)

Other centers in your region
Your center

Centers (centers with <10 cases not shown)

*** indicates center’s rate differs significantly from the regional rate.

Discharge Antiplatelet+Statin Rate by Region Across VQI (Jan-Dec 2018)


Regions (regions with <3 centers with at least 10 cases not shown)

*** indicates region’s rate differs significantly from the VQI rate.
Hemodialysis Access: Percentage of Primary AVF vs. Graft

Procedures performed between Jan. 1 and Dec. 31, 2018

Excludes patients with previous access procedure in the same arm.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of access procedures meeting the inclusion criteria in the VQI, and the percentage of those cases that were AVF vs. graft.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of access procedures meeting inclusion criteria</td>
<td></td>
<td>361</td>
<td>5323</td>
</tr>
<tr>
<td>Percentage with primary AVF</td>
<td></td>
<td>87%</td>
<td>83%</td>
</tr>
</tbody>
</table>
Rate of Primary AVF Access by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of Primary AVF Access in Your Region (Jan-Dec 2018)

Centers (centers with <10 cases not shown)

**” indicates center’s rate differs significantly from the regional rate.

Rate of Primary AVF Access by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

**” indicates region’s rate differs significantly from the VQI rate.
**Carotid Artery Stent: Stroke or Death in Hospital**

Procedures performed between Jan. 1 and Dec. 31, 2018

Elective procedures, excluding prior ipsilateral CAS, CAS for intracranial treatment and dissection, trauma and “other” lesion types

The table below shows the number of CAS procedures meeting the inclusion criteria that were in the VQI as of Jan. 31, 2019, and the observed and expected rates of in-hospital stroke or death for those cases.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CAS procedures meeting inclusion criteria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among procedures meeting inclusion criteria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>361</td>
<td>4483</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among cases with complete data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected rate of stroke or death among cases with complete data*</td>
<td>1.8%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0.16</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*"Expected rate" is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of In-Hospital Stroke or Death After CAS by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of In-Hospital Stroke or Death After CAS in Your Region (Jan-Dec 2018)

Centers (centers with <10 cases not shown)

**” indicates center’s observed rate differs significantly from its expected rate.

Rate of In-Hospital Stroke or Death After CAS by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

**” indicates region’s observed rate differs significantly from its expected rate.
Carotid Endarterectomy: Stroke or Death in Hospital

Procedures performed between Jan. 1 and Dec. 31, 2018

Elective procedures, excluding prior ipsilateral CEA and concomitant CABG, endovascular or other arterial procedure

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of CEA procedures meeting the inclusion criteria in the VQI, and the observed and expected rates of in-hospital stroke or death for those cases.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CEA procedures meeting inclusion criteria</td>
<td>1239</td>
<td>14325</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among procedures meeting inclusion criteria</td>
<td>1%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>1195</td>
<td>13641</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among cases with complete data</td>
<td>1%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of stroke or death among cases with complete data*</td>
<td>1.1%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>1</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of In-Hospital Stroke or Death After CEA by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Carotid Endarterectomy: Percentage of Patients with LOS>1 Day

Procedures performed between Jan. 1 and Dec. 31, 2018

Elective procedures, excluding prior ipsilateral CEA, concomitant CABG, proximal endovascular or other arterial operation, in-hospital death with LOS≤1 day, procedures done on weekends or not done on admission day. LOS is based on the midnight rule used for hospital billing.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of CEA procedures meeting inclusion criteria in the VQI, and the observed and expected rates of those cases with LOS>1 Day.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CEA procedures meeting inclusion criteria</td>
<td>1125</td>
<td>12806</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;1 day among procedures meeting inclusion criteria</td>
<td>26%</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>1084</td>
<td>12294</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;1 among cases with complete data</td>
<td>26%</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of LOS&gt;1 among cases with complete data*</td>
<td>23%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0.01</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*"Expected rate" is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. "Cases with complete data" include patients who have data on all of those factors.
Rate of CEA Patients With LOS>1 Day by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of CEA Patients With LOS>1 Day in Your Region (Jan-Dec 2018)

“***” indicates center’s observed rate differs significantly from its expected rate.

Rate of CEA Patients With LOS>1 Day by Region Across VQI (Jan-Dec 2018)

“***” indicates region’s observed rate differs significantly from its expected rate.
Endovascular AAA Repair: Percentage of Patients with LOS>2 Days

Procedures performed between Jan. 1 and Dec. 31, 2018

Excludes ruptured aneurysms and in-hospital deaths with LOS≤2 days, patients with prior aortic surgery, procedures not done on day of admission and weekend procedures. LOS is based on the midnight rule used for hospital billing.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of EVAR procedures meeting the inclusion criteria and the observed and expected rates of those cases with LOS>2 Days.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of EVAR procedures meeting inclusion criteria</td>
<td>444</td>
<td>5133</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;2 days among procedures meeting inclusion criteria</td>
<td>11%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>421</td>
<td>4806</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;2 among cases with complete data</td>
<td>11%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of LOS&gt;2 among cases with complete data*</td>
<td>12%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0.65</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of EVAR Patients With LOS>2 Days by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of EVAR Patients With LOS>2 Days in Your Region (Jan-Dec 2018)

Centers (centers with <10 cases not shown)

"*" indicates center's observed rate differs significantly from its expected rate.

Rate of EVAR Patients With LOS>2 Days by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)
EVAR: Rate of Sac Diameter Reporting at Long-Term Follow-Up

Procedures performed between Jan. 1 and Dec. 31, 2016

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2016, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of EVAR procedures in the VQI, and the percentage of those cases in which the patient had a follow-up visit between 9 and 21 months post-surgery at which a sac diameter was recorded.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of EVAR procedures</td>
<td></td>
<td>645</td>
<td>6202</td>
</tr>
<tr>
<td>Percentage with sac diameter recorded at follow-up</td>
<td></td>
<td>55%</td>
<td>56%</td>
</tr>
</tbody>
</table>
Rate of LTFU Sac Diameter Reporting by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of LTFU Sac Diameter Reporting in Your Region (Jan-Dec 2016)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

**"** indicates center’s rate differs significantly from the regional rate.

Rate of LTFU Sac Diameter Reporting by Region Across VQI (Jan-Dec 2016)

- Virginia
- Michigan
- Great Lakes
- New York
- Southeast
- Southern California
- New England
- Pacific NW
- VQI
- Northern California
- Rocky Mountains
- Mid-America
- Midwest
- Carolinas
- SOVONET
- Mid-Atlantic
- Upper Midwest

Regions (regions with <3 centers with at least 10 cases not shown)

**""** indicates region’s rate differs significantly from the VQI rate.
Infrainguinal Bypass: Rate of Major Complications

Procedures performed between Jan. 1 and Dec. 31, 2018

Includes only patients with indication of rest pain or tissue loss. Major complications are defined as in-hospital death, ipsilateral BK or AK amputation or graft occlusion.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of INFRA cases with indication of rest pain or tissue loss in the VQI, and the percentage of those cases that resulted in in-hospital death, ipsilateral amputation or graft occlusion.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of INFRA procedures meeting inclusion criteria</td>
<td>511</td>
<td>4033</td>
<td></td>
</tr>
<tr>
<td>Percentage with major complications after INFRA</td>
<td>1.8%</td>
<td>3.8%</td>
<td></td>
</tr>
</tbody>
</table>
Rate of Major Complications After INFRA by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of Major Complications After INFRA in Your Region (Jan-Dec 2018)

Other centers in your region  Your center

Centers (centers with <10 cases not shown)

*** indicates center's rate differs significantly from the regional rate.

Rate of Major Complications After INFRA by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

*** indicates region's rate differs significantly from the VQI rate.
IVCF: Percentage of Temporary Filters With Retrieval or Attempt at Retrieval

Procedures performed between July 1, 2017 and June 30, 2018

Excludes patients with permanent filters and patients who have died since discharge.

Data for this report include all cases with surgery date between July 1, 2017 and June 30, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of IVCF procedures meeting the inclusion criteria in the VQI, and the percentage of those cases in which the filter was retrieved, or an attempt was made to retrieve it, at any time post-procedure.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of procedures meeting inclusion criteria</td>
<td>NA (&lt;3 centers)</td>
<td>1376</td>
<td></td>
</tr>
<tr>
<td>Percentage with filter retrieval, or attempt at retrieval</td>
<td></td>
<td></td>
<td>38%</td>
</tr>
<tr>
<td>Percentage not retrieved because not clinically indicated</td>
<td></td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>Percentage not retrieved because patient declined</td>
<td></td>
<td></td>
<td>1%</td>
</tr>
</tbody>
</table>

Rate of IVCF Retrieval by Region Across VQI (July 2017-June 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

**” indicates region's rate differs significantly from the VQI rate.**
Lower-Extremity Amputation: Rate of Postop Complications

Procedures performed between Jan. 1 and Dec. 31, 2018

Complications are defined as myocardial infarction, dysrhythmia, congestive heart failure, surgical site infection, renal and/or respiratory complication.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of LEAMP cases in the VQI, and the percentage of those cases that resulted in complication.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of amputation procedures</td>
<td></td>
<td>286</td>
<td>3109</td>
</tr>
<tr>
<td>Percentage with complications after LEAMP</td>
<td></td>
<td>19%</td>
<td>12%</td>
</tr>
</tbody>
</table>
Rate of Complications After LEAMP by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of Complications After LEAMP in Your Region (Jan-Dec 2018)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

*** indicates center’s rate differs significantly from the regional rate.

Rate of Complications After LEAMP by Region Across VQI (Jan-Dec 2018)

- Southeast
- Up. Midwest
- Carolinas
- VQI
- New York
- Virginias
- Mid-America
- New England*

Regions (regions with <3 centers with at least 10 cases not shown)

*** indicates region’s rate differs significantly from the VQI rate.
Non-Ruptured Open AAA: In-Hospital Mortality

Procedures performed between Jan. 1 and Dec. 31, 2018
Excludes ruptured aneurysms.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of OAAA procedures meeting the inclusion criteria in the VQI, and the observed and expected rates of in-hospital death for those cases.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of OAAA procedures meeting inclusion criteria</td>
<td>170</td>
<td>986</td>
<td></td>
</tr>
<tr>
<td>Observed rate of in-hospital death among procedures meeting inclusion criteria</td>
<td>2.9%</td>
<td>4.1%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>150</td>
<td>891</td>
<td></td>
</tr>
<tr>
<td>Observed rate of in-hospital death among cases with complete data</td>
<td>3.3%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of in-hospital death among cases with complete data*</td>
<td>3.7%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>1</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Observed rate of in-hospital death among procedures with infrarenal proximal clamp</td>
<td>2.5%</td>
<td>3.6%</td>
<td></td>
</tr>
<tr>
<td>Observed rate of in-hospital death among procedures with suprarenal proximal clamp</td>
<td>3.4%</td>
<td>4.5%</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of In-Hospital Death After OAAA by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of In-Hospital Death After OAAA in Your Region (Jan-Dec 2018)

Centers (centers with <10 cases not shown)

"***" indicates center's observed rate differs significantly from its expected rate.

Rate of In-Hospital Death After OAAA by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

"***" indicates region's observed rate differs significantly from its expected rate.
PVI: Percentage of Claudicants with ABI/Toe Pressure Reported Before Procedure

Procedures performed between Jan. 1 and Dec. 31, 2018

“ABI or toe pressure reported” indicates at least one measure was recorded for the side of the operation, or on both sides for bilateral and aortic procedures.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of PVI procedures with indication of claudication in the VQI, and the percentage of those cases in which ABI or toe pressure was recorded.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PVI procedures with indication of claudication</td>
<td>1241</td>
<td></td>
<td>12822</td>
</tr>
<tr>
<td>Percentage with ABI/toe pressure recorded before procedure</td>
<td>76%</td>
<td></td>
<td>77%</td>
</tr>
<tr>
<td>Percentage who were current smokers</td>
<td>32%</td>
<td></td>
<td>39%</td>
</tr>
</tbody>
</table>
Rate of ABI/TBI Assessment Before PVI by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of ABI/TBI Assessment Before PVI in Your Region (Jan-Dec 2018)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

*** indicates center's rate differs significantly from the regional rate.

Rate of ABI/TBI Assessment Before PVI by Region Across VQI (Jan-Dec 2018)

- Southeast*
- Nor. Cal.*
- New York*
- Rocky Mtns.*
- Midwest
- Pacific NW
- Up-Midwest
- Canada
- New England
- MidSouth
- VQI
- Carolinas
- Mid-Atlantic
- Virginias*
- So. Cal.
- Mid-America
- Michigan*
- G. Lakes*
- SOVONET*

Regions (regions with <3 centers with at least 10 cases not shown)

*** indicates region's rate differs significantly from the VQI rate.
Suprainguinal Bypass: Rate of Major Complications

Procedures performed between Jan. 1 and Dec. 31, 2018

Includes only patients with indication of rest pain or tissue loss. Major complications are defined as in-hospital death, ipsilateral BK or AK amputation or graft occlusion.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of SUPRA cases in the VQI, and the percentage of those cases that resulted in complication.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of SUPRA procedures</td>
<td></td>
<td>124</td>
<td>793</td>
</tr>
<tr>
<td>Percentage with major complications after SUPRA</td>
<td></td>
<td>4%</td>
<td>5%</td>
</tr>
</tbody>
</table>
Rate of Major Complications After SUPRA by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of Major Complications After SUPRA in Your Region (Jan-Dec 2018)

Centers (centers with <10 cases not shown)

"**" indicates center's rate differs significantly from the regional rate.

Rate of Major Complications After SUPRA by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

"**" indicates region's rate differs significantly from the VQI rate.
TEVAR: Rate of Sac Diameter Reporting at Long-Term Follow-Up

Procedures performed between Jan. 1 and Dec. 31, 2016

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2016, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of TEVAR procedures in the VQI, and the percentage of those cases in which the patient had a follow-up visit between 9 and 21 months post-surgery at which a sac diameter was recorded.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of TEVAR procedures</td>
<td>183</td>
<td></td>
<td>2017</td>
</tr>
<tr>
<td>Percentage with sac diameter recorded at follow-up</td>
<td>46%</td>
<td></td>
<td>43%</td>
</tr>
</tbody>
</table>
Rate of LTFU Sac Diameter Reporting by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
New SVS Guideline Reports Using VQI Data!!
EVAR: Percentage of Elective Patients with AAA Diameter Within SVS Guideline (≥5.5cm for Men; ≥5 cm for Women)

Procedures performed between Jan. 1 and Dec. 31, 2018

Excludes non-elective procedures.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of elective EVAR procedures in the VQI, and the percentage of those cases meeting the SVS sac size guideline.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of elective EVAR procedures</td>
<td></td>
<td>468</td>
<td>5445</td>
</tr>
<tr>
<td>Percentage meeting SVS sac size guideline</td>
<td>61%</td>
<td></td>
<td>60%</td>
</tr>
</tbody>
</table>
Rate of EVAR Cases Meeting Sac Size Guideline by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of EVAR Cases Meeting Sac Size Guideline in Your Region (Jan-Dec 2018)

Other centers in your region • Your center

Centers (centers with <10 cases not shown)

*** indicates center’s rate differs significantly from the regional rate.

Rate of EVAR Cases Meeting Sac Size Guideline by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

*** indicates region’s rate differs significantly from the VQI rate.
Preserve flow to at least one Internal Iliac Artery
– Univariate analysis

• Open AAA – worse SSI, in-patient mortality and 1 year mortality
Preserve flow to at least one Internal Iliac Artery

Multivariable analysis

- Open AAA – worse 1 year mortality
OAAA: Percentage of Patients Meeting SVS Cell Saver Guideline (Cell Salvage or Ultrafiltration Device Used if EBL>500 ml)

Procedures performed between Jan. 1 and Dec. 31, 2018
Excludes patients with EBL≤500 ml.

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2018, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of OAAA procedures with EBL>500 ml in the VQI, and the percentage of those cases meeting the SVS cell-saver guideline.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of OAAA procedures meeting inclusion criteria</td>
<td>153</td>
<td></td>
<td>1003</td>
</tr>
<tr>
<td>Percentage meeting cell-saver guideline</td>
<td>99%</td>
<td></td>
<td>94%</td>
</tr>
</tbody>
</table>
Rate of OAAA Cases Meeting Cell-Saver Guideline by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of OAAA Cases Meeting Cell-Saver Guideline in Your Region (Jan-Dec 2018)

Centers (centers with <10 cases not shown)

"**" indicates center's rate differs significantly from the regional rate.

Rate of OAAA Cases Meeting Cell-Saver Guideline by Region Across VQI (Jan-Dec 2018)

Regions (regions with <3 centers with at least 10 cases not shown)

"**" indicates region's rate differs significantly from the VQI rate.
Autotransfusion during open AAA – 30-100%

OAAA: Compliance with Cell Salvage Guideline by Center

Room for Improvement

Focus for QI efforts
Use of Autotransfusion during open AAA –

• Inhospital Mortality – 9% vs 18%
• One year Mortality – 14% vs 25%
• Adherence to use of cell saver had decreased inpatient and one year mortality following open AAA repair
National VQI Update:  
Jens Jorgensen, MD
565 VQI Centers
565 centers in North America
1 center in Singapore
18 Regional Quality Groups

- Canadian Vascular Quality Initiative
- Upper Midwest Vascular Network
- Pacific NW Vascular Study Group
- Northern California Vascular Study Group
- Southern California Vascular Outcomes Improvement Collaborative
- Rocky Mountain Vascular Quality Initiative
- Southern Vascular Outcomes Network
- Mid-America Vascular Study Group
- Southeastern Vascular Study Group
- MidSouth Vascular Study Group
- Carolinas Vascular Quality Group
- Virginia Vascular Study Group
- Great Lakes Vascular Study Group
- Midwest Vascular Collaborative
- Mid-Atlantic Vascular Study Group
- Vascular Study Group of Greater New York
- Vascular Study Group of New England
- Michigan Vascular Study Group
Total Procedure Volume tab reflects net procedures added to the registry for the month

<table>
<thead>
<tr>
<th>Total Procedures Captured (as of 5/1/2019)</th>
<th>585,440</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>186,722</td>
</tr>
<tr>
<td>Carotid Endarterectomy</td>
<td>120,105</td>
</tr>
<tr>
<td>Infra-I nguinal Bypass</td>
<td>52,717</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>48,470</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>47,434</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>29,762</td>
</tr>
<tr>
<td>Varicose Vein</td>
<td>29,574</td>
</tr>
<tr>
<td>Supra-I nguinal Bypass</td>
<td>17,563</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>14,464</td>
</tr>
<tr>
<td>Lower Extremity Amputations</td>
<td>14,179</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>12,280</td>
</tr>
<tr>
<td>IVC Filter</td>
<td>12,170</td>
</tr>
</tbody>
</table>

VQI Total Procedure Volume

Total Procedure Volume tab reflects net procedures added to the registry for the month.
Major update to VQI website

- Redesign of Home page to provide better navigation
- Highlights on Home page for featured QI and News, as well as the Latest Articles
- Greater focus on regions, QI and data analysis in new sections
- Clearer Resources section, including Reporting and Registry Updates and a Directory in Contact Us
- [www.vqi.org](http://www.vqi.org)
- For feedback, contact Nancy Heatley, [nheatley@svspso.org](mailto:nheatley@svspso.org)
Making our Data Better: Audits!

Data audits via Pathways have begun and will continue throughout the year, with a new audit scheduled for each month. The focus this year is on out of range data entries. So far:

- Dec/Jan -- AVACCESS: ~900 out of range data points audited across 9 data fields. Centers fixed/verified ~300 entries. The rest will be set to NULL.
- Feb -- CEA: ~1400 out of range entries audited across 20 data fields. After 3 weeks, 76% of those points had been fixed or verified.
- March – CAS out of range and stroke audit
- April – Varicose Vein out of range
- May – EVAR out of range and hours symp to repair
- June – OAAA out of range and transfusion
- July – IVCF

The PSO has finalized an agreement with Q-Centrix (abstraction company) to begin doing third party audits. Details to be shared shortly.
2019 Reports:

• Quarter 1:
  – Spring Regional Reports,
  – QI Update: EVAR LTFU Imaging Update/Risk Calculator
  – Performance Awards

• Quarter 2:
  – QI Initiative Updates – DC meds and EVAR LTFU imaging
  – Center and System Dashboards

• Quarter 3:
  – Fall Regional Reports
  – QI Initiative Updates – DC meds and EVAR LTFU imaging
  – Center and System Dashboards

• Quarter 4:
  – QI Initiative Updates – DC meds and EVAR LTFU imaging
VQI Quality Initiative Report

Follow-Up Imaging With AAA Diameter Reported After EVAR (2016 Procedures)

Excludes patients who died within 21 months of surgery. "Imaging" includes CT, CTA, MR, MRA, duplex, and/or angiogram imaging between 9 and 21 months post-surgery, with sac diameter recorded. Time from surgery to imaging=Date of follow-up visit where imaging was recorded - surgery date.

Long-term imaging after EVAR has been an SVS PSO National Quality Initiative for three years, but rates have remained stubbornly low: From 2013 to 2016, respectively, only 54%, 60%, 59% and 60% of EVAR patients received follow-up imaging between 9 and 21 months postop. The goal is for 100% of EVAR patients to have imaging at one year. Increased compliance with EVAR LTFU imaging is associated with reduced risk of rupture and improved patient survival.

Many VQI centers are beginning to identify best practices and conduct studies on EVAR LTFU imaging. To help all centers improve their imaging rates, this report identifies factors associated with loss to follow-up imaging and offers a patient screening tool that might be useful in planning follow-up care.

The table below shows your center’s imaging rate for 2016 cases and compares it with your region’s rate, the overall VQI rate, and your center’s 2015 rate.

Results

| Number of 2016 procedures at your center meeting inclusion criteria | 36 |
| Number imaged (your center’s imaging rate) | 32 (89%) |
| 75th percentile for 2016 cases among all VQI centers | 79% |
| Your region’s rate for 2016 cases | 58% |
| P-value for comparison of your center’s rate to your region’s rate | <.01 |
| Overall VQI rate for 2016 cases | 60% |
| P-value for comparison of your center’s rate to the overall VQI rate | <.01 |
| Your center’s follow-up imaging rate for 2015 cases | 76% |
| P-value for comparison of your center’s 2016 rate to its 2015 rate | 0.16 |

The graphic below shows the variation in the rate of follow-up imaging after EVAR among VQI centers. Such variation offers an enormous opportunity for improvement.
## Lost to EVAR LTFU Imaging Risk Score

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age&lt;70 or &gt;79</td>
<td>1</td>
</tr>
<tr>
<td>Non-white race</td>
<td>1</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>2</td>
</tr>
<tr>
<td>BMI&lt;24</td>
<td>2</td>
</tr>
<tr>
<td>Not discharged home</td>
<td>6</td>
</tr>
<tr>
<td>Transfer patient (any admission status)</td>
<td>5</td>
</tr>
<tr>
<td>Non-elective admission, not transferred</td>
<td>2</td>
</tr>
<tr>
<td>Smoker</td>
<td>3</td>
</tr>
<tr>
<td>Creatinine &gt;1.8 mg/dL or on dialysis</td>
<td>3</td>
</tr>
<tr>
<td>Not living at home</td>
<td>3</td>
</tr>
<tr>
<td>No family history of AAA</td>
<td>1</td>
</tr>
<tr>
<td>No completion endoleak</td>
<td>1</td>
</tr>
<tr>
<td>Lives &gt;100 miles from hospital</td>
<td>5</td>
</tr>
<tr>
<td>Surgeon has &lt;16 years’ experience</td>
<td>1</td>
</tr>
<tr>
<td>Score &gt;2 on Frailty Index*</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Total Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0-3</td>
</tr>
<tr>
<td>Medium</td>
<td>4-7</td>
</tr>
<tr>
<td>High</td>
<td>8+</td>
</tr>
</tbody>
</table>

*The “Frailty index” is a 0-9 score based on results from “Interaction Between Frailty and Sex on Mortality after Elective Abdominal Aortic Aneurysm Repair,” a manuscript under development by Sarah Barbey, Salvatore Scali and other VQI researchers.

**To calculate a patient’s Frailty Index,** add 1 point each if the patient has any of the following conditions preop: hypertension, compromised functional status, diabetes, chronic obstructive pulmonary disease, congestive heart failure, history of myocardial infarction or unstable angina, cardiac disease (prior percutaneous coronary intervention, cardiac surgery or stable angina), peripheral vascular disease (prior non-cardiac revascularization or major lower extremity amputation), cognitive impairment. Scores >2 are significantly associated with not receiving LTFU imaging.
<table>
<thead>
<tr>
<th>Risk factors for loss to LTFU imaging after EVAR</th>
<th>% with risk factor, 2018 procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds ratio</td>
</tr>
<tr>
<td>Age &lt;70 or &gt;79</td>
<td>1.1</td>
</tr>
<tr>
<td>Non-white race</td>
<td>1.1</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>1.3</td>
</tr>
<tr>
<td>BMI&lt;24</td>
<td>1.2</td>
</tr>
<tr>
<td>Not discharged home</td>
<td>1.7</td>
</tr>
<tr>
<td>Any status, transferred (vs. elective, not trans.)</td>
<td>1.7</td>
</tr>
<tr>
<td>Non-elective, not trans. (vs. elective, not trans.)</td>
<td>1.2</td>
</tr>
<tr>
<td>Current smoker</td>
<td>1.3</td>
</tr>
<tr>
<td>Creatinine&gt;1.8 mg/dL or on dialysis</td>
<td>1.3</td>
</tr>
<tr>
<td>Not living at home</td>
<td>1.3</td>
</tr>
<tr>
<td>No family history of AAA</td>
<td>1.1</td>
</tr>
<tr>
<td>No completion endoleak</td>
<td>1.1</td>
</tr>
<tr>
<td>Lives &gt;100 miles from home to hospital</td>
<td>1.6</td>
</tr>
<tr>
<td>Surgeon has &lt;16 years' experience (vs. 16+ years)</td>
<td>1.1</td>
</tr>
<tr>
<td>Frailty index*=&gt;2</td>
<td>1.2</td>
</tr>
</tbody>
</table>
January: PVI Basic Form
February: LTFU Calculation Revisions
Close to release (TBD):
  Varicose Vein Registry Changes
  New Venous Stent Registry
  Hemodialysis Registry Changes
  New Medicine Registry
Quality Improvement Webinars:

- **2019 Quarterly Webinars**
  - February 2019 “Starting a QI project”
  - May 2019
    - Educational – Methodology, QI tools
    - Case studies from participants
  - September 2019
    - Educational – Methodology, QI tools
    - Case studies from participants
  - November 2019
    - Wrapping up a QI project, 2020 Participation Award information
Recap of 2018 QI Projects

Putting Data into Action

• Fifty five participating sites
• Four categories – D/C Meds, LTFU, Clinical, and Documentation
• Success reported from those sites

See what your colleagues are doing re QI
# Quality Improvement Details: Charter Information

<table>
<thead>
<tr>
<th>Activity</th>
<th>Documentation</th>
</tr>
</thead>
</table>
| 1. QI Project Initiation | Attestation to include:  
  - QI Project Title  
  - Problem Statement  
  - Project Leader  
  - Clinical Sponsor  
  - Expected start date  
  
  Form can be accessed at https://www.vqi.org/vqi-resource-library/quality-improvement/  
  - Project charters should be emailed to QI@SVSPSO.ORG |
|                        | 2 points -  
  * Due on or before 3/15/2019 |

- Will accept charters at any time during the year
- "Soft" due date of March 15th was set to:
  - Organize new charters into categories  
    - LTFU  
    - D/C Meds  
    - Clinical  
    - Documentation  
  - Give Cheryl a chance to review and provide suggestions to make your charter stronger  
  - Start new charter focused group calls  
    - Automatically included when charter submitted. Cheryl will reach out to you with information,  
    - New calls will start in late May  
- Will meet charter participants during the poster networking session at VQI@VAM
Charters

- Focused group calls
  - Interactive discussion sharing barriers and successes
  - Sharing of charters
  - Networking
  - Checking in – where are you in the process
  - Celebrating success

One on one calls, if requested.
Newsletters

- The VQI News
  - Distributed every other month
  - Provides updates on regulatory issues, technical updates, and crossover news from the SVS

- VQI Quality Improvement Newsletter
  - Distributed every other month
  - Focusing on QI processes, tools, and definitions
New Project

• SVS PSO work group to address national opioid epidemic with a focus on vascular patients. To develop recommendations based on work from National Academy of Medicine, Prescription Drug Monitoring Program (PDMP) and evidence-based practice.

• Led by Dr. Peter Henke - University of Michigan

• Meet at VAM. June 12-15, 2019 Gaylord Convention Center, National Harbor, MD (Washington, DC)
Participation Awards: 2018

• 50 sites earned 3 stars, 92 sites earned 2 stars and 54 earned 1 star (383 eligible sites)

• Overall median LTFU increased to 74% from 70% in the prior year

• 55 Charters were submitted as part of the new quality domain

• 119 centers qualified for a bonus point for Discharge Medications and 62 centers for EVAR LFTU, based on maintaining their standing in the top quartile or by achieving statistically significant improvement in these areas
Participation Awards:

• Awards were distributed in March

• 3 Star recipient to receive Certificates at Regional and National Meeting

• 1 & 2 Star centers will be sent a PDF of their Certificate

• Standardized Press Release was created for Star Awards.
Participation Award Results!!

Dartmouth Hitchcock Medical Center
University of Vermont Medical Center

Concord Hospital
Central Maine Medical Center
Elliot Health System
Berkshire Medical Center

Baystate Medical Center
Brigham and Women's Hospital
Hartford Hospital
Hoenig Vascular Center

Maine Medical Center
U Mass Memorial
Boston Medical Center

Saint Francis Hospital
Yale-New Haven Hospital
Beth Israel Deaconess Medical Center

Congratulations to all Star Awards Winners
For general inquiries about the Participation Awards, please contact Cheryl Jackson at CJACKSON@SVSPSO.ORG or Jim Wadzinski at JWADZINSKI@SVSPSO.ORG.

Submit Project Charters and supporting documentation for presentations and posters to QI@SVSPSO.ORG.

Visit the VQI Members Only Website for webinars and presentations on VQI Quality Improvement Projects.
VQI@VAM: June 11-12, 2019

• **Tuesday 6/11 12:00 – 4:30pm:**
  Registry case abstractions.

• **Tuesday 6/11 5:00-6:30pm:**
  Poster/Networking

• **Wednesday 6/12 8:00am – 5:00pm:**
  – **AM** - QI activities-Podium presentations - abstract/poster submissions.
  – Update on VQI’s audit activities.
  – **PM** - Updates on National QI initiatives and Opioid Workgroup.
  – RAC research projects.
LTFU Update
Jens Jorgensen, MD
What do these athletes have in common?

- Magic Johnson
- Jim Brown
- Julius Erving (the other Dr J)
- Sandy Koufax
- Franco Harris
- Shaquille O’Neal
- OJ Simpson
What do these athletes have in common?

- Magic Johnson
- Jim Brown
- Julius Erving (the other Dr J)
- Sandy Koufax
- Franco Harris
- Shaquille O’Neal
- OJ Simpson
VSGNE - 32

- VSGNE started in 2003 and we have been collecting follow up since then
- 32 biannual meetings
- 32 times LTFU on agenda
- 32 times (the other) Dr J has presented
VSGNE
LTFU

• Longitudinal Care - Improves Care
• Monitors outcomes – EVAR, graft patency
• Secondary prevention – Antiplatelets, statin, tobacco cessation
• Incidental findings – aneurysm, TIA, chest pain
Percentage of Procedures with 9 Months or Greater Follow-Up

Procedures performed between Jan. 1 and Dec. 31, 2016

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2016, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of procedures in the VQI, and the percentage of those procedures with long-term follow-up.

<table>
<thead>
<tr>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVACCESS</td>
<td>492 (85%)</td>
<td>6977 (71%)</td>
</tr>
<tr>
<td>CAS</td>
<td>361 (62%)</td>
<td>3709 (67%)</td>
</tr>
<tr>
<td>CEA</td>
<td>1861 (73%)</td>
<td>16217 (73%)</td>
</tr>
<tr>
<td>EVAR</td>
<td>645 (73%)</td>
<td>6202 (75%)</td>
</tr>
<tr>
<td>INFRA</td>
<td>1008 (75%)</td>
<td>6726 (77%)</td>
</tr>
<tr>
<td>IVCF</td>
<td>NA (&lt;3 centers)</td>
<td>1906 (66%)</td>
</tr>
<tr>
<td>LEAMP</td>
<td>208 (75%)</td>
<td>2037 (74%)</td>
</tr>
<tr>
<td>OAAA</td>
<td>212 (67%)</td>
<td>1164 (73%)</td>
</tr>
<tr>
<td>PVI</td>
<td>3046 (78%)</td>
<td>24524 (76%)</td>
</tr>
<tr>
<td>SUPRA</td>
<td>351 (72%)</td>
<td>2208 (74%)</td>
</tr>
<tr>
<td>TEVAR</td>
<td>183 (68%)</td>
<td>2017 (70%)</td>
</tr>
<tr>
<td>2016 Overall</td>
<td>8381 (75%)</td>
<td>73687 (74%)</td>
</tr>
<tr>
<td>2015 Overall</td>
<td>9053 (70%)</td>
<td>70365 (75%)</td>
</tr>
</tbody>
</table>

60-80%
Long-Term Follow-Up by Center in Your Region (Jan-Dec 2016)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

"**" indicates center's rate differs significantly from the regional rate.

1. Central Maine Medical Center
2. Saint Francis Hospital
3. Hoenig Vascular Center
4. Yale-New Haven Hospital
5. University of Vermont Medical Center
6. Brigham and Women's Hospital
7. U Mass Memorial
8. Berkshire Medical Center
9. Concord Hospital
10. Boston Medical Center
11. Beth Israel Deaconess Medical Center
12. Maine Medical Center
13. Baystate Medical Center
14. Eastern Maine Medical Center
15. Hartford Hospital
16. MaineGeneral Medical Center
17. Tufts Medical Center
18. Elliot Health System
19. The Miriam Hospital
20. St. Elizabeth Medical Center
21. Rhode Island Hospital
22. Danbury Hospital
23. Dartmouth Hitchcock Medical Center
24. Massachusetts General Hospital
25. Charlton Memorial Hospital
26. Catholic Medical Center; CTSA NH
27. Lakes Region General Hospital

> 80%
Long-Term Follow-Up by Region Across VQI (Jan-Dec 2016)

Regions (regions with <3 centers with at least 10 cases not shown)

"Others" indicates centers that do not belong to a regional group. "*" indicates region’s rate differs significantly from the VQI rate.
Percentage With Long-Term Follow-Up by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
### One year follow up

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR</td>
<td>645 (73%)</td>
</tr>
<tr>
<td>INFRA</td>
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<tr>
<td>IVCF</td>
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<td>LEAMP</td>
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<tr>
<td>OAAA</td>
<td>212 (67%)</td>
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One year follow up

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</table>
One year follow up

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<td>73%</td>
</tr>
</tbody>
</table>

We need better follow up for TCAR
EVAR: Rate of Sac Diameter Reporting at Long-Term Follow-Up

Procedures performed between Jan. 1 and Dec. 31, 2016

Data for this report include all cases with surgery date between Jan. 1 and Dec. 31, 2016, that had been entered into the VQI as of Jan. 31, 2019. The table below shows the number of EVAR procedures in the VQI, and the percentage of those cases in which the patient had a follow-up visit between 9 and 21 months post-surgery at which a sac diameter was recorded.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of EVAR procedures</td>
<td></td>
<td>645</td>
<td>6202</td>
</tr>
<tr>
<td>Percentage with sac diameter recorded at follow-up</td>
<td></td>
<td>55%</td>
<td>56%</td>
</tr>
</tbody>
</table>
Our goal

>90%

Rate of LTFU Sac Diameter Reporting by Year

Regional data are not shown for the region with <3 centers with at least 10 cases.
Rate of LTFU Sac Diameter Reporting in Your Region (Jan-Dec 2016)

- Other centers in your region
- Your center

**“*”** indicates center’s rate differs significantly from the regional rate.

Rate of LTFU Sac Diameter Reporting by Region Across VQI (Jan-Dec 2016)

- Virginia
- Michigan
- G. Lakes
- New York
- Southeast
- So. Cal.
- New England
- Pacific NW
- VQI
- Nor. Cal.
- Rocky Mtns.
- Mid-America
- Midwest
- Carolinas
- SOVONET
- Mid-Atlantic
- Up. Midwest

**“*”** indicates region’s rate differs significantly from the VQI rate.
The Race for Quality has no finish line

So technically it’s more like a death march.
RAC Update
Phil Goodney, MD
RAC Update

• No Restriction of data release based on similar projects; collaboration is encouraged
• Only 1 refresh of data within 24 months of initial approval
• Industry related projects need to collaborate with the steering committee/s (i.e. TCAR)
  – Review policy and industry charters on the web
• Device Identification Policy: review on the web before submitting proposal
VSGNE Quality Improvement Projects
Philip Goodney, MD
Moderator
VSGNE Quality Improvement Projects
Nathan Aranson, MD and Brian Nolan, MD
Improving Care for Patients Undergoing Transcarotid Artery Revascularization Using a Novel Preoperative Risk Assessment Tool
Improving Care for Patients Undergoing Transcarotid Artery Revascularization Using a Novel Preoperative Risk Assessment Tool

VSGNE QIP
Nathan J Aranson, MD RPVI FACS
June 07, 2019
Background

- TCAR being performed with increased prevalence
- Post-stenting hypotension incidence 10-40%
- Post-op hypotension associated with:
  - Increased neurologic events
  - MACE

| Table 2. Hypotension related postoperative complications |
|-----------------------------------------------|-----------------|-----------------|
| Stroke/TIA                              | Card Cx          | LOS>1-d         |
| No Hypotension                          | 2.6%             | 2.1%            | 28%             |
| Hypotension                             | 7.3%             | 9.6%            | 65%             |
| p-value                                 | 0.001            | 0.001           | 0.001           |
## Risk Stratification

### Table 1. Hypotension risk score

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>NL score*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atherosclerotic lesion (v. restenosis)</td>
<td>6.7</td>
<td>0.001</td>
</tr>
<tr>
<td>Female gender</td>
<td>2.3</td>
<td>0.001</td>
</tr>
<tr>
<td>Positive stress test</td>
<td>2.0</td>
<td>0.001</td>
</tr>
<tr>
<td>Age &gt; 80</td>
<td>1.9</td>
<td>0.001</td>
</tr>
<tr>
<td>History of MI or angina</td>
<td>1.9</td>
<td>0.001</td>
</tr>
<tr>
<td>Age 70 to 79</td>
<td>1.5</td>
<td>0.002</td>
</tr>
<tr>
<td>Urgent (v. elective) procedure</td>
<td>1.0</td>
<td>0.009</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>-1.1</td>
<td>0.022</td>
</tr>
</tbody>
</table>

* Normalized risk score
Approach

- **Pre-op**
  - Risk stratify all patients
  - Decide which medications to hold

- **Intra-op**
  - Glycopyrrolate vs. Atropine vs. None

- **Post-op**
  - Neosynephrine vs. Midodrine vs. Pseudoephedrine
### Figure 2. Draft of Risk Assessment Tool

<table>
<thead>
<tr>
<th>Medication</th>
<th>Start date &gt;14-days</th>
<th>Dose day of procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Statin</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Antihypertensives</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vitals</th>
<th>Admission</th>
<th>30-min post Admit</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR</td>
<td>65</td>
<td>60</td>
</tr>
<tr>
<td>BP</td>
<td>140/80</td>
<td>120/80</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk calculator</th>
<th>Score</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No prior CEA</td>
<td>6.7</td>
<td>X</td>
</tr>
<tr>
<td>Female gender</td>
<td>2.3</td>
<td>X</td>
</tr>
<tr>
<td>Age &gt; 80</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>Age 70-79</td>
<td>1.5</td>
<td>X</td>
</tr>
<tr>
<td>Positive stress test</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Prior MI or angina</td>
<td>1.9</td>
<td></td>
</tr>
<tr>
<td>Urgent procedure</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Prior hypertension</td>
<td>-1.1</td>
<td>X</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>9.4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Category</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt; 4</td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>4 to 7</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>&gt;7</td>
<td>X</td>
</tr>
</tbody>
</table>
Goals

• Accurately identify patients at risk
• Treat early
• Minimize adverse events
• Decreased length of stay
Question #1

What % of all carotid interventions are TCAR?

a. <25%
b. 25-50%
c. 50-75%
d. >75%
Question #2

• What BP medications do you hold pre-op?
  a. ACE/ARB
  b. Diuretic
  c. CCB
  d. B Blocker
  e. None
Question #4

• Do you have a protocol for management intra op hypotension?
  a. Yes
  b. No
Question #5

• Do you have a protocol for management post op hypotension?
  
  a. Yes
  
  b. No
Question #6

• How soon will you start oral BP augmentation post op?
  a. <1 hour
  b. 1-4 hours
  c. 4-12 hours
  d. >12 hours
  e. Variable
  f. Do not prescribe oral BP meds
Question #7

• Do you have a protocol for discharge on oral BP augmentation meds?
  a. Yes
  b. No
VSGNE Quality Improvement Projects

Douglas Jones, MD

Reducing Postoperative Hospital Utilization through Improved Discharge Planning After Lower Extremity Revascularization
VSGNE Quality Improvement Projects
Cassius Iyad Chaar, MD
A pilot study of a comprehensive multidisciplinary inpatient-based approach to smoking cessation for patients with vascular disease
Update on Research Project from YNHH

Cassius Iyad Ochoa Chaar MD, MS, FACS
Associate Professor of Surgery
Division of Vascular Surgery
Yale School of Medicine
VSGNE Meeting – June 7th, 2019
Project 1:
Effect of Laterality in Dialysis Access on patency
Left-silled and right-sided central veins are different in humans

Left brachiocephalic vein is longer and has to cross over brachiocephalic artery and aorta, while the right does not

Salik et al., Journal of Vascular and Interventional Radiology, 2007

Left IJ catheters make several curves before reaching SVC
Right-sided IJV dialysis catheters perform better in humans (93.9%) inserted into the right internal jugular vein functioned adequately compared with seven of 13 catheters (53.8%) inserted into the left internal jugular vein ($P = 0.006$). All 11 catheters
Dardik lab pig data:
Left-sided AV grafts showed reduced patency

88% patent on the right, 40% patent on the left
References (human studies)

- **Left IJV temporary dialysis catheters have reduced patency compared to catheters placed in the right IJV**

- **Left sided catheters are associated with increased infection and need for later access ligation due to central venous occlusion**

- **KDOQI guidelines cite reduced rates of blood flow and greater rates of stenosis and thrombosis on the left side**
Project 2: Atherectomy and other endovascular modalities of treatment
One-Year Results of the LIBERTY 360 Study: Evaluation of Acute and Midterm Clinical Outcomes of Peripheral Endovascular Device Interventions

Jihad Mustapha, MD\textsuperscript{1,2}\textsuperscript{id}, William Gray, MD\textsuperscript{3,4}, Brad J. Martinsen, PhD\textsuperscript{5}, Ryan W. Bolduan, BA\textsuperscript{5}, George L. Adams, MD, MHS, MBA\textsuperscript{6}, Gary Ansel, MD\textsuperscript{7}\textsuperscript{id}, and Michael R. Jaff, DO\textsuperscript{8,9} on behalf of the LIBERTY Investigators
# Liberty Trial

<table>
<thead>
<tr>
<th>Atherectomy devices</th>
<th>Baseline RC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RC2.3 (n=605)</td>
<td>RC4.5 (n=775)</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Balloons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angioplasty</td>
<td>494/597 (82.7)</td>
<td>635/766 (82.9)</td>
</tr>
<tr>
<td>DCB</td>
<td>74/597 (12.4)</td>
<td>54/766 (7.0)</td>
</tr>
<tr>
<td>Cutting</td>
<td>42/597 (7.0)</td>
<td>58/766 (7.6)</td>
</tr>
<tr>
<td>Focal Force</td>
<td>73/597 (12.2)</td>
<td>97/766 (12.7)</td>
</tr>
<tr>
<td>Scoring</td>
<td>3/597 (0.5)</td>
<td>7/766 (0.9)</td>
</tr>
<tr>
<td>Atherectomy devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diamondback, Stealth</td>
<td>274/437 (45.9)</td>
<td>347/494 (45.3)</td>
</tr>
<tr>
<td>Jetstream</td>
<td>19/437 (3.2)</td>
<td>12/494 (1.6)</td>
</tr>
<tr>
<td>Excimer laser</td>
<td>35/437 (5.9)</td>
<td>39/494 (5.1)</td>
</tr>
<tr>
<td>Rotablator</td>
<td>7/437 (1.2)</td>
<td>7/494 (0.9)</td>
</tr>
<tr>
<td>Turbohawk, Silverhawk, Hawk One</td>
<td>87/437 (14.6)</td>
<td>82/494 (10.7)</td>
</tr>
<tr>
<td>Phoenix</td>
<td>6/437 (1.0)</td>
<td>14/494 (1.8)</td>
</tr>
<tr>
<td>Crosser</td>
<td>14/437 (2.3)</td>
<td>8/494 (1.0)</td>
</tr>
<tr>
<td>Stents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DES</td>
<td>34/120 (5.7)</td>
<td>37/111 (4.8)</td>
</tr>
<tr>
<td>BMS</td>
<td>88/120 (14.7)</td>
<td>72/111 (9.4)</td>
</tr>
<tr>
<td>Covered</td>
<td>5/120 (0.8)</td>
<td>6/111 (0.8)</td>
</tr>
</tbody>
</table>
RC6, respectively. **Conclusion:** The results indicate that peripheral endovascular intervention is a viable treatment option for RC2,3, RC4,5, and RC6 patients as evidenced by the high freedom from major amputation, as well as the improvement in QoL and the RC at 12 months. Furthermore, primary unplanned amputation is often not necessary in RC6.
Concerns over outcomes specially in Claudicants

Table 3. Femoral–Popliteal and Tibial–Peroneal Atherectomy Downstream Utilization Within 18 Months of Incident Procedure (OB: N = 262, HB: N = 662).\textsuperscript{a}

<table>
<thead>
<tr>
<th>Service</th>
<th>1 Month</th>
<th>6 Months</th>
<th>12 Months</th>
<th>18 Months</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral–popliteal atherectomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular endovascular intervention (any)</td>
<td>23 (8.8)</td>
<td>24 (3.6)</td>
<td>86 (32.8)</td>
<td>148 (22.4)</td>
<td>105 (40.1)</td>
</tr>
<tr>
<td>Peripheral vascular bypass</td>
<td>1 (0.4)</td>
<td>3 (0.5)</td>
<td>4 (1.5)</td>
<td>17 (2.6)</td>
<td>7 (2.7)</td>
</tr>
<tr>
<td>Any amputation</td>
<td>1 (0.4)</td>
<td>8 (1.2)</td>
<td>6 (2.3)</td>
<td>26 (3.9)</td>
<td>7 (2.7)</td>
</tr>
<tr>
<td>Major amputation</td>
<td>1 (0.4)</td>
<td>4 (0.6)</td>
<td>4 (1.5)</td>
<td>13 (2.0)</td>
<td>5 (1.9)</td>
</tr>
<tr>
<td>Tibial–peroneal atherectomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular endovascular intervention (any)</td>
<td>18 (8.9)</td>
<td>13 (5.9)</td>
<td>72 (35.6)</td>
<td>59 (26.7)</td>
<td>90 (44.6)</td>
</tr>
<tr>
<td>Peripheral vascular bypass</td>
<td>0 (0.0)</td>
<td>1 (0.5)</td>
<td>3 (1.5)</td>
<td>4 (1.8)</td>
<td>4 (2.0)</td>
</tr>
<tr>
<td>Any amputation</td>
<td>2 (1.0)</td>
<td>5 (2.3)</td>
<td>6 (3.0)</td>
<td>16 (7.2)</td>
<td>9 (4.4)</td>
</tr>
<tr>
<td>Major amputation</td>
<td>2 (1.0)</td>
<td>2 (0.9)</td>
<td>4 (2.0)</td>
<td>9 (4.1)</td>
<td>6 (3.0)</td>
</tr>
</tbody>
</table>

Abbreviations: HB, hospital outpatient-based setting; OB, office-based laboratory.

\textsuperscript{a}Data are presented as n (%) per column (OB vs HB).
Thank you
VSGNE Quality Improvement Projects
Aaron Barnes, MD
Anticoagulation and Antiplatelet Treatment Plan
Communication and Documentation Improvement Project
Anticoagulation and Antiplatelet Treatment Plan Communication and Documentation Improvement Project

J. Aaron Barnes, MD
Philip P. Goodney, MD, MS
Kayla O. Moore, MPH
Background

- There is significant variation in the use of anticoagulant & antiplatelet medications within vascular surgery
Background

• Indications for these medications may be clear to vascular surgery practitioners, but their role may be less clear to practitioners in other fields
Background

• Indications for these medications may be clear to vascular surgery practitioners, but their role may be less clear to practitioners in other fields.

• Intended duration of therapy and ability to be paused may also be unclear.
Background

• Indications for these medications may be clear to vascular surgery practitioners, but their role may be less clear to practitioners in other fields.

• Intended duration of therapy and ability to be paused may also be unclear.

• Documentation may be incomplete or inaccessible.
The Challenge

Unfamiliarity

Variation

Documentation

Poor communication & disjointed patient care
The Goal

• To improve how vascular surgery, and eventually all services, at Dartmouth-Hitchcock (DH) documents and communicates anticoagulant and antiplatelet treatment plans
Aims & Approach

**Aim 1:** Vascular surgery anticoagulant/antiplatelet discharge documentation

- Discharge template creation
- Template review
- Implementation
- Internal compliance monitoring
Aims & Approach

**Aim 1:** Vascular surgery anticoagulant/antiplatelet discharge documentation

- Discharge template creation → Template review → Implementation → Internal compliance monitoring

**Aim 2:** Vascular surgery anticoagulant/antiplatelet outpatient documentation

- Outpatient template creation → Template review → Implementation → Internal compliance monitoring
Aims & Approach

**Aim 1:** Vascular surgery anticoagulant/antiplatelet discharge documentation

- Discharge template creation → Template review → Implementation → Internal compliance monitoring

**Aim 2:** Vascular surgery anticoagulant/antiplatelet outpatient documentation

- Outpatient template creation → Template review → Implementation → Internal compliance monitoring

**Aim 3:** EMR-embedded anticoagulant/antiplatelet treatment plan tool

- Multidisciplinary tool creation → Tool review and approval → Implementation → System utilization monitoring
Monitoring

• Aims 1 & 2
  • Internal compliance with template utilizations
  • Internal surveys assessing communication efficacy

• Aim 3
  • EMR system utilization monitoring
  • System-wide surveys assessing communication efficacy
<table>
<thead>
<tr>
<th>Aim 1&amp;2: creation &amp; implementation</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim 1&amp;2: monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aim 3: design, build, implementation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aim 3: monitoring</td>
<td></td>
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</tr>
</tbody>
</table>
Deliverables

• Characterization and reporting on overall QI process

• Implementation analysis of each aim and characteristics of EMR tool utilization

• Survey analysis of efficacy of communication
Challenges & Limitations

• Stakeholder buy-in and commitment to participate in template and tool implementation

• Complexities of EMR-embedded tool creation and implementation
References

Thank you
VSGNE Quality Improvement Projects

Panel Discussion

What should we do with our findings from the QIPs?
Lunch Break: 11:50am – 12:45pm

Lunch in Auditorium G, 4th Floor
Lunch for Data Managers: Fuller Board Room, 3rd Floor
National Update II
AQC Update
Jessica Simons, MD
• Harmonizing similar help text
• Updating all help text by the end of 2019 (using audit results to inform changes)
• IDE device clean up (Please do not enter an IDE as “other”)
• Other device clean up (Need more details, manufacturer, device name, product #)
• General Registry Updates (Infra, Supra and OAAA on deck for 2019)
VQC Update
Phil Goodney, MD
• Varicose Vein Registry:
  – revisions to decrease data entry only for “treated leg”
  – Early follow up requirement changing to < 30 days to capture early complications

• IVC Filter: feedback on temporary filter removal reminders?

• Venous Stent Registry: to be released soon!
Governing Council Update
Jens Jorgensen, MD
Governing Council Update

- Vice Chairs elected:
  Randy DeMartino (AQC)
  Mark Passman (VQC)
- SSN Workgroup:
  Whitepaper being published to outline value for full SSN (Medicare claims and SSDI matching)
- New Guideline reports
- Cerner Abstraction Pilot
- Participation at Regional Meetings
Ruptured AAA Survey and CAS Survey
Kimberly Malka, MD, and Brian Nolan, MD
Improving the Outcomes of Ruptured Aortic Aneurysms with an Aortic Emergency Pathway

Kimberly T. Malka, MD, PhD
June 7, 2019
VSGNE
SVS Recommendations for Care in Patients with rAAA

- Establishing a protocol for management of rAAA.
- Placement of 2 large bore peripheral IVs
- Permissive hypotension
- Door to intervention time of less than 90 minutes
- EVAR first strategy
Background

- Development of an EVAR first protocol to treat rAAA as been associated with lower mortality (Moore et. al. 2007)
- Initiation of an aortic emergency pathway has been shown to increase volume of acute aortic cases and decrease time to definitive care in multiple single center studies. (Davies et. al. 2010; Shin et. al. 2016)
- The effect on morbidity and mortality in these studies ranges from no change to improved.
- A regional rapid transport system can help with the transfer of patients, but there are predictors of increased mortality using this system (Manzur et. al. 2016)
- No multi-center studies have been done to show differences in outcomes in centers with an aortic emergency pathway compared to those without such a pathway.
Research Question

- In our own institution, was there a difference in outcomes after implementation of an aortic emergency pathway?
- Is there a difference in outcomes of emergent aortic cases in centers who have an aortic emergency pathway in place compared to those who do not?
Questions

1. Do you perform ruptured AAA repairs (rAAA) at your hospital?
   - YES
   - NO
2. Does your center have an aortic emergency pathway for rAAA?
   – YES
   – NO
3. Does the pathway include mass activation of resources from a central source (i.e. “Code Rupture”)?
   - YES
   - NO
4. Do you have a dedicated vascular team available in the OR 24/7?
   • YES
   • NO
5. Do you practice an EVAR first approach to rAAA?
   – YES
   – NO
6. Do you have standardized pick sheets for open and EVAR rAAA?
   - YES
   - NO
7. Do you have a specific protocol for permissive hypotension?
   – YES
   – NO
8. Would you like to be part of an initiative to develop a standardized rAAA pathway?
   
   – YES
   – NO
9. Would you like to be part of a study comparing centers with and without a pathway?
   • YES
   • NO
Data Managers’ Update
Patricia Bozeman, RN
RAPID/SPEED Update
Daniel Bertges, MD and
Jens Jorgensen, MD
Registry Assessment of Peripheral Interventional Devices (RAPID)

Daniel Bertges, MD
VSGNE Meeting
June 7, 2019
• NEST (National Evaluation System for health Technology) demonstration project
• Mission improve national system for peripheral device evaluation throughout the total product lifecycle
RAPID Leadership

Founding Chairs
• Jack Cronenwett, MD, Society of Vascular Surgery VQI
• Pablo Morales, MD, United States Food and Drug Administration
• Robert Thatcher, MBA, 4C Medical Technologies

MDEpiNet Key Advisors
• Mitch Krucoff, MD, Duke Clinical Research Institute
• Danica Marinac-Dabic, MD, PhD, MMSC, US FDA

Leadership team
• Daniel Bertges, MD; SVS VQI PVI Registry Chairman
• Misty Malone, United States Food and Drug Administration
• Melanie Raska, Boston Scientific

Contributors
• Roseann White, PhD
• Jens Jorgensen, MD; SVS VQI Medical Director

Project Managers at DCRI
• Mina Baqai
• Cara Abram
• Sarah Palmer
• Rebecca Wilgus

http://mdepinet.org/rapid/
RAPID – Public Private Partnership

Society for Vascular Surgery (SVS) | Vascular Quality Initiative (VQI)
Value of Device Lifecycle and Evaluation
Joint JVS-Circulation publication of RAPID PAD-specific core data elements
SFA-Popliteal Evidence Development

http://aicdheart.com/patient_education/heart_HTML_scaleable/heart/fempop.htm
http://www.yoursurgery.com/ProcedureDetails.cfm?BR=5&Proc=33
Objective Performance Goals (OPG)

• To determine the minimum acceptable success rate to aid in device comparative effectiveness

• To determine the minimum acceptable success rate for a device based for clinical trial populations
Why SPEED?

- Mature space, but new drug-coated and other technologies in pipeline
- Many devices are being used off-label, for patients and disease severity not tested in trials
  - Difficult for patients/physicians to chose wisely
- Current objective performance goals for SFA-POP devices are out of date
  - Do not reflect contemporary practice
VIVA OPGs for femoral-popliteal PTA/stent

Performance Goals and Endpoint Assessments for Clinical Trials of Femoropopliteal Bare Nitinol Stents in Patients With Symptomatic Peripheral Arterial Disease

Krishna J. Rocha-Singh, MD, FACC, Michael R. Jaff, DO, FACC, Tami R. Crabtree, MS, Daniel A. Bloch, PhD, and Gary Ansel, MD, FACC, on behalf of VIVA Physicians, Inc.

Objective: This analysis proposes safety and performance goals for prospective single-arm trials of bare nitinol stents to treat patients with debilitating claudication associated with femoropopliteal (FPA) atherosclerotic lesions. Background: To date there have been no analyses of clinical data from prospective studies of new bare nitinol stents in the treatment of symptomatic arterial disease. While prospective randomized clinical trials have been reluctant to sponsor studies of new devices, the FDA has recently recognized that such trials are appropriate. Our aim was to review the medical literature (1990-2006) for similar trials and analyze these data in order to identify 116 patients with claudication and femoropopliteal lesions who had undergone percutaneous transluminal angioplasty and/or stenting. These data were supplemented by an analysis of medical literature on the natural history of symptomatic peripheral arterial disease. Methods: Based on the natural history of femoropopliteal lesions and the medical literature, an expected vessel patency of 28% at 12 months was calculated. Additional information is provided on safety and other reporting standards and stent integrity evaluation for bare metal stents.

116 patients

PTA patency 33%

Stent patency 66%

Key words: nitinol stents; stenting; femoropopliteal artery; percutaneous transluminal angioplasty; intermittent claudication; peripheral arterial disease
Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

Michael S. Clowes, MD, David S. Sloan, MPH, Stuart R. Lipkin, MD, MPH, and Anton N. Skandalakis, MD
Aurora, Colorado

Objective: To develop a set of objective performance goals (OPGs) for evaluating new catheter-based treatments in critical limb ischemia (CLI), based on evidence from historical controls.

Methods: Randomized, controlled trials of surgical, endovascular, and pharmacologic/biologic treatments for CLI were reviewed according to specified criteria regarding study population and data quality. Line-item data were obtained for each endpoint and summarized and compared against the OPGs.

Table Va. Summary of safety outcomes for overall CLI cohort

<table>
<thead>
<tr>
<th>Outcome</th>
<th>30 day events (%; 95% CI)</th>
<th>Maximum allowable events (trial N = 392)</th>
<th>Safety OPG</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>6.2% (4.7-8.1)</td>
<td>20 (5.1, 3.1-7.8%)</td>
<td>8%</td>
</tr>
<tr>
<td>• Death</td>
<td>2.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• MI</td>
<td>3.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• CVA</td>
<td>1.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALE</td>
<td>6.1% (4.6-7.9)</td>
<td>18 (4.6%, 2.7-7.2)</td>
<td>8%</td>
</tr>
<tr>
<td>Amputation</td>
<td>1.9% (1.1-3.1)</td>
<td>5 (1.3%, 0.4-3.0)</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table Vb. Summary of efficacy outcomes (one year) for overall CLI cohort and suggested OPG for each endpoint

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Point (95% CI)</th>
<th>Efficacy OPG</th>
</tr>
</thead>
<tbody>
<tr>
<td>MALE + POD</td>
<td>76.9% (74.0-79.9)</td>
<td>71%</td>
</tr>
<tr>
<td>AFS</td>
<td>76.5% (73.7-79.5)</td>
<td>71%</td>
</tr>
<tr>
<td>RAS</td>
<td>46.5% (42.3-51.2)</td>
<td>39%</td>
</tr>
<tr>
<td>RAO</td>
<td>61.3% (58.0-64.9)</td>
<td>55%</td>
</tr>
<tr>
<td>Limb salvage</td>
<td>88.9% (86.7-91.1)</td>
<td>84%</td>
</tr>
<tr>
<td>Survival</td>
<td>85.7% (83.3-88.1)</td>
<td>80%</td>
</tr>
</tbody>
</table>

838 patients from bypass trials
CLI OPGs only
Rapid Phase II/III Combination Project
SFA-Popliteal EvidencE Development (SPEED)

• Expected clinical utility for comparative effectiveness of devices
• OPGs serve as framework for design of prospective device trials nested in a coordinated registry network
  – Set appropriate comparators
  – Benchmarks for non-inferiority and superiority endpoints
RAPID Phase II/III Combination Project
SFA-Popliteal Evidence Development (SPEED)

• Three OPGs:
  mortality at one and four-years
  major amputation at one-year
  target lesion revascularization at one-year
• OPGs stratified by artery: SFA versus popliteal
• OPGs further stratified by treatment
  1. Plain balloon angioplasty
  2. Self expanding stent
  3. Atherectomy
  4. “practice of medicine” = all treatments combined
• N= 21,377 procedures
• Next steps
Prospective device trials within a coordinated registry network

Use RAPID collaborative to analyze mortality after paclitaxel PVI
Paclitaxel Working Group Update
Jens Jorgensen, MD, and
Daniel Bertges, MD
Katsanos – Meta-analysis of RCT paclitaxel-coated balloons and stents in the femoropopliteal artery

• All-cause mortality increased at 2 years
  (7.2% vs 3.8%, risk ratio 1.68)
  number –needed-to-harm, 29 patients

• All-cause mortality increased at 5 years
  (14.7% vs 8.1%, risk ratio 1.93)
  number –needed-to-harm, 14 patients
Katsanos – context

- Cardiology – similar signal with paclitaxel 10 years ago “Firestorm” – no causation identified

- Chemotherapeutic agent – used for breast Ca in 2nd or 3rd trimester (X10,000 dose weekly X 12)
Katsanos – response

- FDA

- UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers
Katsanos – International response

- SwedePAD – stopped enrollment of Paclitaxel, subsequently reinstated
- BASIL-3 – stopped enrollment
- UK MHRA – Do not use for claudication
  Individualize for CLI
Katsanos – response

• JAMA Cardiology – Secemsky et al. CMS 16000 pts 600 days. No increased mortality

• JACC – Schneider et al. Industry trials 1800 pts up to 5 years. Paclitaxel safe and effective
Katsanos – response

- VIVA analysis
- Society Coalition – KR
- Industry coalition
- RAPID/VQI
- SVS – PSTF
The SVS Paclitaxel Safety Task Force

- Kim J Hodgson, MD  PSTF Chair & SVS President
- Jens Eldrup-Jorgensen, MD  SVS-PSO Medical Director
- Larry Kraiss, MD  Chair, SVS Quality Council
- Daniel Bertges, MD  Chair, SVS-PSO PVI Registry
- Michael Conte, MD  Co-Editor, Global Vascular Guidelines
- Alik Farber, MD  Co-PI; BEST CLI Trial
- Fred Weaver, MD  Chair, SVS PSO
- Thomas Forbes, MD  SVS Document Oversight Committee
The SVS Vascular Quality Initiative
Data Granularity in the SVS-VQI

- SVS-VQI uses the FDA’s GUDID system (Global Unique Device Identification) for accurate device-specific data entry
- GUDID allows device specific linkage to CMS, FDA, SSDI and other databases
FDA panel – mid June

- ACC, VIVA, etc
- Industry
- RAPID/VQI
- SVS – PSTF (VQI)
The Paclitaxel Safety Signal and the SVS-PSO-VQI Vision for a Pathway Forward

Kim J Hodgson, MD
President, Society for Vascular Surgery
Chair, SVS Paclitaxel Safety Task Force
Professor & Chairman of Vascular & Endovascular Surgery
Southern Illinois University

Daniel J Bertges, MD
Chair, SVS-PSO PVI Registry
Associate Professor of Surgery
University of Vermont Medical College
Mortality after Paclitaxel Coated Balloon Angioplasty and Stenting of the Superficial Femoral and Popliteal Artery in the Vascular Quality Initiative

Daniel J Bertges, MD; Tainyi Sun; Mohammad H Eslami, MD; Marc Schermerhorn, MD; Philip P Goodney, MD; Adam Beck, MD; Jack L Cronenwett, MD; Art Sedrakyan, MD, PhD; Jens Eldrup-Jorgensen, MD

On behalf of the Society for Vascular Surgery Vascular Quality Initiative
Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Spirooulas, MD, PhD; Panagiotis Kitrou, MD, PhD; Miltiadis Krokides, MD, PhD; Dimitrios Kamakitis, MD, PhD

Background—Several randomized controlled trials (RCTs) have already shown that paclitaxel-coated balloons and stents significantly reduce the rates of vessel restenosis and target lesion revascularization after lower extremity interventions.

Methods and Results—A systematic review and meta-analysis of RCTs investigating paclitaxel-coated devices in the femoral and/or popliteal arteries was performed. The primary safety measure was all-cause patient death. Risk ratios and risk differences were pooled with a random effects model. In all, 28 RCTs with 4663 patients (89% intermittent claudication) were analyzed. All-cause patient death at 1 year (28 RCTs with 4432 cases) was similar between paclitaxel-coated devices and control arms (2.3% versus 2.3% crude risk of death; risk ratio, 1.08; 95% CI, 0.72–1.61). All-cause death at 2 years (12 RCTs with 2316 cases) was significantly increased in the case of paclitaxel versus control (7.2% versus 3.8% crude risk of death; risk ratio, 1.68; 95% CI, 1.15–2.47; —number-needed-to-harm, 29 patients [95% CI, 19–59]). All-cause death up to 5 years (3 RCTs with 863 cases) increased further in the case of paclitaxel (14.7% versus 8.1% crude risk of death; risk ratio, 1.93; 95% CI, 1.27–2.93; —number-needed-to-harm, 14 patients [95% CI, 9–32]). Meta-regression showed a significant relationship between exposure to paclitaxel (dose–time product) and absolute risk of death (0.4±0.1% excess risk of death per paclitaxel mg-year; P<0.001). Trial sequential analysis excluded false-positive findings with 99% certainty (2-sided α, 1%).

Conclusions—There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted.

Clinical Trial Registration—URL: www.crd.york.ac.uk/PROSPERO. Unique identifier: CRD42018099447. (J Am Heart Assoc. 2018;7:e011245. DOI: 10.1161/JAHA.118.011245.)

Key Words: balloon angioplasty • paclitaxel • paclitaxel-coated balloon • paclitaxel-eluting stent
Background

Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers

January 17, 2019

Dear Peripheral Interventionalists and Vascular Medicine Physicians:

We are writing to inform you that the FDA is evaluating recent information regarding the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents to treat peripheral arterial disease (PAD) in the femoropopliteal artery.

A recent meta-analysis (https://www.ahajournals.org/doi/10.1161/JAHA.119.011245) of randomized trials published in the Journal of the American Heart Association (JAMA) suggests a possible increased mortality rate after two years in PAD patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents compared to patients treated with control devices (non-coated balloons or bare metal stents). The specific cause for this observation is yet to be determined.

BACKGROUND

Paclitaxel-coated balloons and paclitaxel-eluting stents are intended to treat de novo or restenotic lesions in the femoropopliteal artery. The balloon and stent work to mechanically open the obstructed vessel. Paclitaxel is released from the balloon or stent to prevent scar tissue formation in the blood vessel that can re-obstruct the artery (restenosis).

In the U.S., paclitaxel-coated balloons are also marketed for the treatment of stenotic lesions in dysfunctional native arteriovenous dialysis fistulae. While paclitaxel-coated stents have been approved for use in the treatment of coronary artery disease, no paclitaxel-coated balloons or paclitaxel-eluting stents are currently marketed for this use.

RECOMMENDATIONS

The FDA recommends that health care providers:

- Continue surveillance of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents per the current standard of care.
- In clinical decision-making, discuss the risks and benefits of all available treatment options for PAD with your patients.
Background

UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers

March 15, 2019

Several weeks ago, we notified health care providers about the potential for increased long-term mortality associated with the use of paclitaxel-coated balloons and paclitaxel-eluting stents. Here are some key points to consider:

- When making treatment recommendations and as part of the informed consent process, consider that there may be an increased rate of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents.
- Discuss the risks and benefits of all available PAD treatment options with your patients. For most patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents should generally be used until additional analysis of the safety signal has been performed.
- For some individual patients at particularly high risk for restenosis, clinicians may determine that the benefits of using a paclitaxel-coated product may outweigh the risks.

These data should be interpreted with caution for several reasons. First, there is large variability in the risk estimate of mortality due to the limited amount of long-term data. Second, these studies were not originally designed to be pooled, introducing greater uncertainty in the results. Third, the specific cause and mechanism of the increased mortality is unknown.

Paclitaxel-coated balloons and stents are known to improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels. However, because of this concerning safety signal, we believe alternative treatment options should generally be used for most patients while we continue to further evaluate the increased long-term mortality signal and its impact on the overall benefit-risk profile of these devices. The FDA intends to conduct additional analyses to determine whether the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use. The FDA will also evaluate whether these analyses impact the safety of patients treated with these devices for other indications, such as treatment of arteriovenous access stenosis or critical limb ischemia.
Methods

• Retrospective propensity matched analysis
• VQI Peripheral Vascular Intervention Registry October 2016 to December 2017
• Device capture within registry
• Global Universal Device Identifier (GUDID)
Methods

Comparators

1. Paclitaxel eluting stent (DES) vs. bare metal self expanding stents (B-SES)
2. Paclitaxel coated balloons (DCB) vs. plain balloon angioplasty (PTA)
3. Any paclitaxel device vs non-drug device
Methods

- Outcome: Mortality stratified by claudication vs. critical limb ischemia (CLI)
- Linkage to Social Security Death Index (SSDI)
- Mean follow up X months
- Kaplan-Meier survival analysis

Stay tuned for Results at VAM
A Pathway Forward: Leveraging Real World Evidence through MDEpiNet, RAPID, VISION and the SVS VQI

Daniel J Bertges, MD
SVS VQI PVI Registry Chair
RAPID Co-chair

On behalf of SVS VQI and the Registry Assessment of Peripheral Devices (RAPID)
Pathways forward

1. Retrospective analysis VQI PVI with linkage to Medicare claims 2012-2017 with VISION: Vascular Implant Surveillance and Interventional Outcomes Network

2. Prospective real-time tracking of mortality in VQI PVI using DELTA: Data Extraction and Longitudinal Trend Analysis
Collaboration

Society for Vascular Surgery VQI
SVS Paclitaxel Task Force
MDEpiNet and RAPID VISION
SVS Paclitaxel Task Force

- Kim Hodgson, MD; Task Force Chair, SVS President elect
- Daniel Bertges, MD; Chair SVS VQI PVI Registry
- Michael Conte, MD
- Alek Farber, MD; Co-chair BEST CLI
- Thomas Forbes, MD
- Jens Jorgensen, MD; SVS PSO Medical Director
- Larry Kraiss, MD; SVS VQI
- Michel Makaroun, MD; SVS President
- Ken Ouriel, MD, MBA; SYNTACTX
- Ken Slaw, PhD; SVS Executive Director
- Jim Wadzinki; SVS PSO Senior Director
- Fred Weaver, MD; Chair SVS PSO Governing Council
VISION

Vascular Implant Surveillance and Interventional Outcomes Network

• Art Sedrakayn, MD, PhD; principle investigator
• Phil Goodney, MD; Dartmouth Institute
• Collaboration between FDA’s MDEpiNet, Weill Cornell Medicine Science and Infrastructure Center and the VQI
• links Medicare claims data to SVS VQI registry

http://mdepinet.org/vision-in-usa/
Retrospective analysis 2012-2018

- VQI PVI Registry data source
- Linkage to Medicare claims with VISION 2012 to 2018
- Identify additional paclitaxel devices through ICD 9/10 diagnosis and procedural codes
- 6-year survival for DES
- 4-year survival for DCB
Prospective real-time tracking

SVS VQI and DELTA

• Data Extraction and Longitudinal Trend Analysis
• Near real time, risk adjusted tracking of mortality within the VQI Registry
• In collaboration with Dr. Fred Resnik and the Lahey Clinic and Hospital
Pathways forward

1. Retrospective analysis of VQI PVI with linkage to Medicare claims 2012-2017 with VISION

2. Prospective real-time tracking of mortality in the VQI PVI using DELTA
VSGNE RAC Update
Jeff Siracuse, MD
(Moderator)
Cassius Iyad Ochoa Chaar, MD
Yale New Haven Hospital

A Vascular Quality Initiative database comparison of atherectomy and other endovascular modalities for lower extremity revascularization; A Vascular Quality Initiative database study of the effects of laterality on the performance of arteriovenous grafts
Scott Levin, MD
Boston Medical Center

AV access in IV drug use patients;
Shunting practices after acute stroke;
Changes in AAA screening
Nkiruka Arinze, MD
Boston Medical Center

Effect of BMI on outcomes after CEA
Thomas Cheng, MD
Boston Medical Center
EVAR with obligate ICU use
Livia de Guerre
BIDMC
The impact of the degree of oversizing in aortic aneurysm repair
Mathijs Carvalho
BIDMC

Investigating the Optimal Age for Endovascular and Open Aortic Aneurysm Repair
Kirsten Dansey
BIDMC

Carotid intervention laterality - association with perioperative complications
Chun Li
BIDMC

*Preoperative statin use and survival following thoracic endovascular aortic repair*
Meeting Evaluation:

- What did you like about this meeting?
- What can we do better?
- Next meeting location: