Tracking 90-day vascular surgery outcomes: The coming new normal?

BY MARK S. LESNEY
MDEdGE NEWS
FROM SURGERY

The Centers for Medicare & Medicaid Services is testing a new quality measurement model that pushes hospital readmissions measures out from 30 to 90 days.

Previous research has identified vascular surgery as having twice as high rates of 90-day readmissions, compared with 30-day readmissions (Am J Manag Care. 2014;20(9):e432-e438), and this could prove problematic in light of the CMS pilot project currently underway, according to Donald E. Fry, MD, of MPA Healthcare Solutions.

Vascular programs without NIVL curriculum leave trainees wanting

BY KARI OAKES
MDEdGE NEWS
REPORTING FROM MIDWESTERN VASCULAR 2018

St. Louis – Many vascular surgery trainees felt unprepared to take the Registered Physician in Vascular Interpretation (RPVI) exam, according to a recent survey. However, trainees in a program without a structured noninvasive vascular laboratory (NIVL) curriculum felt particularly unprepared, said Daisy Chou, MD.

“There is wide variation in NIVL experience amongst vascular surgery training programs,” noted Dr. Chou, a vascular surgery fellow at the Ohio State University, Columbus. She presented survey results at the annual meeting of the Midwestern Vascular Surgical Society.

The survey constructed by Dr. Chou and her colleagues went out to trainees in both 0+5 and 5+2 vascular surgery training programs in September 2017, in 114 unique programs. Eventually, trainees from just over half of the programs responded (n = 61 programs, 53.5%), said Dr. Chou.

Vascular Nurses Get SVS Affiliate Member Discount

Vascular Nurses Week was Sept. 9-15. SVS is inviting Society for Vascular Nursing members to join the SVS as affiliate members. Applicants will receive a 50% discount through Dec. 1. Email CVs and the completed membership form (available at https://vascular.org) to membership@vascularsociety.org.

Column Continued on page 7
ELIQUIS is indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE following initial therapy.

**IMPORTANT SAFETY INFORMATION**

**WARNING:** (A) PREMATURE DISCONTINUATION OF ELIQUIS INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

(A) Premature discontinuation of any oral anticoagulant, including ELIQUIS, increases the risk of thrombotic events. If anticoagulation with ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

(B) Epidural or spinal hematomas may occur in patients treated with ELIQUIS who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- a history of traumatic or repeated epidural or spinal punctures
- a history of spinal deformity or spinal surgery
- optimal timing between the administration of ELIQUIS and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated.

**CONTRAINDICATIONS**

- Active pathological bleeding
- Severe hypersensitivity reaction to ELIQUIS (e.g., anaphylactic reactions)

**WARNINGS AND PRECAUTIONS**

- Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including ELIQUIS, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from ELIQUIS to warfarin in clinical trials in atrial fibrillation patients. If ELIQUIS is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

- Bleeding Risk: ELIQUIS increases the risk of bleeding and can cause serious, potentially fatal, bleeding.
  - Concomitant use of drugs affecting hemostasis increases the risk of bleeding, including aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, and NSAIDs.
  - Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue ELIQUIS in patients with active pathological hemorrhage.
  - The anticoagulant effect of apixaban can be expected to persist for at least 24 hours after the last dose (i.e., about two half-lives). An agent to reverse the anti-factor Xa activity of apixaban is available. Please visit www.andexxa.com for more information on availability of a reversal agent.

- Spinal/Epidural Anesthesia or Puncture: Patients treated with ELIQUIS undergoing spinal/epidural anesthesia or puncture may develop an epidural or spinal hematoma which can result in long-term or permanent paralysis. The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of ELIQUIS.

**INDICATIONS**

ELIQUIS is indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE following initial therapy.

**For appropriate patients with DVT/PE**

Choose ELIQUIS from the START

DVT: deep vein thrombosis; PE: pulmonary embolism.
ELIQUIS for initial DVT/PE treatment*—

And for appropriate patients, continue on a low dose† to reduce the risk of recurrent DVT/PE following initial therapy†.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont’d)

The next dose of ELIQUIS should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of ELIQUIS for 48 hours.

Monitor patients frequently and if neurological compromise is noted, urgent diagnosis and treatment is necessary. Physicians should consider the potential benefit versus the risk of neuraxial intervention in ELIQUIS patients.

• Prosthetic Heart Valves: The safety and efficacy of ELIQUIS have not been studied in patients with prosthetic heart valves and is not recommended in these patients.

• Acute PE in Hemodynamically Unstable Patients or Patients who Require Thrombolyis or Pulmonary Embolectomy: Initiation of ELIQUIS is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

• The most common and most serious adverse reactions reported with ELIQUIS were related to bleeding.

TEMPORARY INTERRUPTION FOR SURGERY AND OTHER INTERVENTIONS

• ELIQUIS should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. ELIQUIS should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be noncritical in location and easily controlled. Bridging anticoagulation during the 24 to 48 hours after stopping ELIQUIS and prior to the intervention is not generally required. ELIQUIS should be restarted after the surgical or other procedures as soon as adequate hemostasis has been established.

DRUG INTERACTIONS

• Combined P-gp and Strong CYP3A4 Inhibitors: Inhibitors of P-glycoprotein (P-gp) and cytochrome P450 3A4 (CYP3A4) increase exposure to apixaban and increase the risk of bleeding. For patients receiving ELIQUIS doses of 5 mg or 10 mg twice daily, reduce the dose of ELIQUIS by 50% when ELIQUIS is coadministered with drugs that are combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, or ritonavir). In patients already taking 2.5 mg twice daily, avoid coadministration of ELIQUIS with combined P-gp and strong CYP3A4 inhibitors.

Clarithromycin

Although clarithromycin is a combined P-gp and strong CYP3A4 inhibitor, pharmacokinetic data suggest that no dose adjustment is necessary with concomitant administration with ELIQUIS.

• Combined P-gp and Strong CYP3A4 Inducers: Avoid concomitant use of ELIQUIS with combined P-gp and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John’s wort) because such drugs will decrease exposure to apixaban.

• Anticoagulants and Antiplatelet Agents: Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. APPRAISE-2, a placebo-controlled clinical trial of apixaban in high-risk post-acute coronary syndrome patients treated with aspirin or the combination of aspirin and clopidogrel, was terminated early due to a higher rate of bleeding with apixaban compared to placebo.

PREGNANCY CATEGORY B

There are no adequate and well-controlled studies of ELIQUIS in pregnant women. Treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. ELIQUIS should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.


Please see Brief Summary of Full Prescribing Information, including Boxed WARNINGS, on adjacent pages.

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WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation

Premature discontinuation of any oral anticoagulant, including ELIQUIS, increases the risk of thrombotic events. An increased rate of stroke was observed during the ADVANCE-1 trial in patients with nonvalvular atrial fibrillation who prematurely discontinued ELIQUIS compared to those who continued on ELIQUIS. The discontinuation rate in this trial was 2.6% at 30 months in patients who discontinued ELIQUIS. In the ARISTOTLE trial, the rate of stroke was 3.6% in patients who prematurely discontinued ELIQUIS.

The increased risk of stroke was 4.7% in patients who prematurely discontinued ELIQUIS and 2.8% in patients who completed treatment with ELIQUIS. The risk of stroke increased in a time-dependent manner, with a hazard ratio of 1.66 (95% CI 1.41, 1.95) at 30 months in patients who prematurely discontinued ELIQUIS. The increased risk of stroke in patients who prematurely discontinued ELIQUIS was observed across all subgroups, including in patients with a history of diabetes, hypertension, or prior stroke.

Patients should be educated about the risk of stroke and encouraged to continue treatment with ELIQUIS as prescribed. If treatment must be discontinued, it should be done by the original prescriber.

Patients should be advised to report any symptoms of neurological impairment promptly. If any symptoms develop, the patient should be advised to seek immediate medical attention. The patient should be advised to contact their prescriber if they develop any symptoms of neurological impairment.

Blind-ending study

ADVANCE-3 Table 2: show the number of patients experiencing major bleeding during the treatment period and the bleeding rate (percentage of subjects with at least one bleeding event per 100 patient-years in ADVANCE-3).

<table>
<thead>
<tr>
<th></th>
<th>ELIQUIS (n=2798)</th>
<th>Warfarin (n=2730)</th>
<th>Hazard Ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding</td>
<td>10 (0.03%)</td>
<td>37 (0.16%)</td>
<td>0.06 (0.02, 0.16)</td>
<td>-</td>
</tr>
<tr>
<td>Intracranial</td>
<td>1 (0.00%)</td>
<td>3 (0.02%)</td>
<td>0.33 (0.05, 2.07)</td>
<td>-</td>
</tr>
<tr>
<td>Hemorrhagic stroke</td>
<td>1 (0.00%)</td>
<td>5 (0.06%)</td>
<td>0.08 (0.00, 0.84)</td>
<td>-</td>
</tr>
<tr>
<td>Non-infratranial</td>
<td>0 (0.00%)</td>
<td>22 (0.20%)</td>
<td>0.04 (0.00, 0.56)</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 3: Bleeding During the Treatment Period in Patients Undergoing Elective Hip or Knee Replacement Surgery

<table>
<thead>
<tr>
<th></th>
<th>ADVANCE-3 Hip Replacement Surgery</th>
<th>ADVANCE-2 Knee Replacement Surgery</th>
<th>ADVANCE-1 Knee Replacement Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First dose (days post surgery)</td>
<td>Second dose (days post surgery)</td>
<td>First dose (days post surgery)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major bleeding</td>
<td>19 (5.5%)</td>
<td>18 (5.3%)</td>
<td>16 (5.0%)</td>
</tr>
<tr>
<td>Bleeding rate</td>
<td>1.1% (0.7, 1.6)</td>
<td>0.9% (0.6, 1.3)</td>
<td>0.9% (0.6, 1.3)</td>
</tr>
</tbody>
</table>

Other Adverse Reactions

Hemorrhagic events include GI bleeding (upper or lower), intracranial hemorrhage, and retroperitoneal hemorrhage. These events were observed in the clinical trials of ELIQUIS and are consistent with events observed in clinical trials of other oral anticoagulants.

Other adverse events reported in clinical trials of ELIQUIS included hypertension, fluid retention, peripheral edema, and respiratory tract infections.

In the ADVANCE-3 trial, 11% of patients treated with ELIQUIS 2.5 mg twice daily or placebo experienced major bleeding. The bleeding rate was 0.06% in patients treated with ELIQUIS 2.5 mg twice daily or placebo. The bleeding rate was 0.16% in patients treated with warfarin 3 mg twice daily.

In the ARISTOTLE trial, 3.7% of patients treated with ELIQUIS 1.5 mg twice daily experienced major bleeding. The bleeding rate was 3.4% in patients treated with aspirin 75 mg daily and 2.3% in patients treated with warfarin 2 mg twice daily. The bleeding rate was 1.3% in patients treated with warfarin 3 mg twice daily.

In the ADVANCE-3 trial, 1.1% of patients treated with ELIQUIS 2.5 mg twice daily or placebo experienced major bleeding. The bleeding rate was 0.5% in patients treated with ELIQUIS 2.5 mg twice daily or placebo.

In the ARISTOTLE trial, 1.3% of patients treated with ELIQUIS 1.5 mg twice daily experienced major bleeding. The bleeding rate was 3.4% in patients treated with aspirin 100 mg daily and 2.3% in patients treated with warfarin 3 mg twice daily.

In the ADVANCE-3 trial, 1.1% of patients treated with ELIQUIS 2.5 mg twice daily or placebo experienced major bleeding. The bleeding rate was 0.5% in patients treated with ELIQUIS 2.5 mg twice daily or placebo.

In the ARISTOTLE trial, 1.3% of patients treated with ELIQUIS 1.5 mg twice daily experienced major bleeding. The bleeding rate was 3.4% in patients treated with aspirin 100 mg daily and 2.3% in patients treated with warfarin 3 mg twice daily.

In the ADVANCE-3 trial, 1.1% of patients treated with ELIQUIS 2.5 mg twice daily or placebo experienced major bleeding. The bleeding rate was 0.5% in patients treated with ELIQUIS 2.5 mg twice daily or placebo.

In the ARISTOTLE trial, 1.3% of patients treated with ELIQUIS 1.5 mg twice daily experienced major bleeding. The bleeding rate was 3.4% in patients treated with aspirin 100 mg daily and 2.3% in patients treated with warfarin 3 mg twice daily.
Table 7: Bleeding Results in the AMPLIFY-EXT Study

<table>
<thead>
<tr>
<th></th>
<th>ELIQUIS (apixaban)</th>
<th>Enoxaparin/Warfarin</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.5 mg bid</strong></td>
<td>n=2689</td>
<td>n=811</td>
<td>n=811</td>
</tr>
<tr>
<td>Major</td>
<td>0.8%</td>
<td>0.9%</td>
<td>0%</td>
</tr>
<tr>
<td>CRNM*</td>
<td>4.3%</td>
<td>3.6%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Major + CRNM</td>
<td>5.1%</td>
<td>4.5%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Minor</td>
<td>14.5%</td>
<td>14.2%</td>
<td>14.6%</td>
</tr>
<tr>
<td>All</td>
<td>15.9%</td>
<td>15.6%</td>
<td>15.6%</td>
</tr>
</tbody>
</table>

* CRNM = clinically relevant nonmajor bleeding.

Table 8: Adverse Reactions Occurring in ≥1% of Patients Undergoing Extending Treatment for DVT and PE in the AMPLIFY-EXT Study

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation</td>
<td>2.6%</td>
<td>2.4%</td>
<td>2.3%</td>
</tr>
<tr>
<td><strong>Menorrhagia</strong></td>
<td>3.8%</td>
<td>3.3%</td>
<td>3.1%</td>
</tr>
<tr>
<td><strong>Hematuria</strong></td>
<td>1.4%</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td><strong>Anemia</strong></td>
<td>1.2%</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>**Postprocedural hemorrhage **</td>
<td>1.0%</td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
<tr>
<td><strong>Renal and urinary disorders</strong></td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

**Note:** Atrial fibrillation is a laboratory abnormality.

Table 9: Bleeding Results in the AMPLIFY Study

<table>
<thead>
<tr>
<th></th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td>0.6%</td>
<td>0.7%</td>
<td>1.1%</td>
</tr>
<tr>
<td>CRNM*</td>
<td>3.7%</td>
<td>3.3%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Major + CRNM</td>
<td>4.4%</td>
<td>4.0%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Minor</td>
<td>12.5%</td>
<td>12.3%</td>
<td>11.9%</td>
</tr>
<tr>
<td>All</td>
<td>13.6%</td>
<td>13.3%</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

* CRNM = clinically relevant nonmajor bleeding.

Table 10: Adverse Reactions Occurring in ≥1% of Patients in the AMPLIFY Study

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Epistaxis</strong></td>
<td>0.8%</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Contusion</strong></td>
<td>0.4%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Hematuria</strong></td>
<td>0.6%</td>
<td>0.5%</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Hemoptysis</strong></td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Gingival bleeding</strong></td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

**Note:** Atrial fibrillation is a laboratory abnormality.

Table 11: Bleeding Results in the AMPLIFY Study

<table>
<thead>
<tr>
<th></th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td>0.2%</td>
<td>0.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>CRNM</td>
<td>0.9%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Major + CRNM</td>
<td>1.1%</td>
<td>1.1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Minor</td>
<td>2.0%</td>
<td>2.0%</td>
<td>2.0%</td>
</tr>
<tr>
<td>All</td>
<td>2.3%</td>
<td>2.3%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

* CRNM = clinically relevant nonmajor bleeding.

Table 12: Drug Interactions

<table>
<thead>
<tr>
<th>Drug Interaction</th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug A</strong></td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>Drug B</strong></td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

**Note:** Atrial fibrillation is a laboratory abnormality.

Table 13: Anticoagulants and Antiplatelet Agents

<table>
<thead>
<tr>
<th>Antiplatelet Agent</th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aspirin</strong></td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>Clopidogrel</strong></td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

**Note:** Atrial fibrillation is a laboratory abnormality.

Table 14: Adverse Reactions Occurring in ≥1% of Patients in the AMPLIFY Study

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bleeding</strong></td>
<td>3.7%</td>
<td>3.3%</td>
<td>3.6%</td>
</tr>
<tr>
<td><strong>Menorrhagia</strong></td>
<td>1.4%</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td><strong>Hematuria</strong></td>
<td>1.4%</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td><strong>Anemia</strong></td>
<td>0.8%</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Postprocedural hemorrhage</strong></td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Renal and urinary disorders</strong></td>
<td>0.4%</td>
<td>0.4%</td>
<td>0.4%</td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td>0.4%</td>
<td>0.4%</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

**Note:** Atrial fibrillation is a laboratory abnormality.

Table 15: Bleeding Results in the AMPLIFY Study

<table>
<thead>
<tr>
<th></th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td>0.6%</td>
<td>0.7%</td>
<td>1.1%</td>
</tr>
<tr>
<td>CRNM*</td>
<td>3.7%</td>
<td>3.3%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Major + CRNM</td>
<td>4.4%</td>
<td>4.0%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Minor</td>
<td>12.5%</td>
<td>12.3%</td>
<td>11.9%</td>
</tr>
<tr>
<td>All</td>
<td>13.6%</td>
<td>13.3%</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

* CRNM = clinically relevant nonmajor bleeding.

Table 16: Adverse Reactions Occurring in ≥1% of Patients Treated for DVT and PE in the AMPLIFY Study

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Epistaxis</strong></td>
<td>0.8%</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Contusion</strong></td>
<td>0.4%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Hematuria</strong></td>
<td>0.6%</td>
<td>0.5%</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Hemoptysis</strong></td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Gingival bleeding</strong></td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

**Note:** Atrial fibrillation is a laboratory abnormality.

Table 17: Bleeding Results in the AMPLIFY Study

<table>
<thead>
<tr>
<th></th>
<th>ELIQUIS n (%)</th>
<th>Enoxaparin/Warfarin n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td>2.6%</td>
<td>2.0%</td>
<td>2.0%</td>
</tr>
<tr>
<td>CRNM*</td>
<td>3.8%</td>
<td>3.2%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Major + CRNM</td>
<td>7.2%</td>
<td>5.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Minor</td>
<td>7.3%</td>
<td>6.3%</td>
<td>6.4%</td>
</tr>
<tr>
<td>All</td>
<td>9.4%</td>
<td>7.7%</td>
<td>8.4%</td>
</tr>
</tbody>
</table>

* CRNM = clinically relevant nonmajor bleeding.

Events associated with each endpoint were counted once per subject, but subjects may have contributed events to multiple endpoints.

Adverse reactions occurring in ≥1% of patients in the AMPLIFY study are summarized in Table 2.

Bleeding results from the AMPLIFY study are summarized in Table 7.
GUEST EDITORIAL: We need to reassess our primitive understanding of the venous system

BY JEAN BISMUTH, MD

If one includes the entire spectrum of venous disease, it is a more common pathology than peripheral arterial disease. The financial impact of venous disease is substantial. Why, then, has it taken so long to generate enthusiasm for venous disease of the femorocaval and subclaviocaval segments? For years, the endovascular management of venous disease used technology and techniques borrowed from the arterial space; although results were encouraging, it is clear that they varied widely and continue to do so. Management of these vascular beds is very reminiscent of the barrage of devices we have thrown at the superficial femoral artery.

In peripheral arterial disease, there have been much education and research focused on understanding atherosclerosis and its interaction with arterial devices. However, the paucity of investigation and enlightenment in the venous domain is evident when a literature search is performed. Certainly there are data from Comerota et al. showing an increased amount of collagen in the walls of chronically diseased veins. While this is a reasonable start, there are not sufficient data on which to build an entire treatment paradigm. Just like peripheral arterial disease, venous pathology presents in a continuum. Without an in-depth appreciation of the variability of those presentations, it is difficult to envision targeted therapies.

Although vendors have recently engaged in the development of venous-specific devices, it is in great part grounded in expert opinion rather than in hard data. The Medicare Evidence Development & Coverage Advisory Committee has made it known that we need more evidence on the efficacy of all venous procedures. Peter Gloviczki, MD, former president of the Society for Vascular Surgery, put it succinctly in an issue of Venous News: “We need to focus on venous research and never forget that whoever owns research owns the disease. We must continue innovation and collaboration, with other venous specialties and with industry.” Truth be told, there doesn’t seem to be much fascination with comprehension of the disease, but there appears to be an enormous drive from a variety of specialties to do procedures.

In July 2015, Gerard O’Sullivan, MD, wrote of a multidisciplinary group in Europe established to develop some standardization in venous stenting guidelines. He describes a “need for consistent guidelines for preoperative imaging, follow-up, anticoagulation duration and type, stent diameter, length into the inferior vena cava and lower end in relation to the internal iliac vein/external iliac vein.” I concur, that this would be utopic. I have not come across such guidelines to date.

Current basic science research focuses on pathologic considerations of venous thrombosis, including the consequences related to mechanical behavior of the venous wall in those conditions. In our group’s opinion, these considerations are elemental in determining the next steps in the research paradigm. What determines the remodeling of a vein, with or without intervention? How does a stent influence remodeling? Not surprisingly there are numerous questions that remain unanswered.

Translational investigation has provided insight into innovative ways to use computed tomography and magnetic resonance imaging. The ability to stage venous disease noninvasively could have a profound impact on how and why we manage the pathology. Additionally, knowing what the pathology looks like and potentially behaves like has the potential to promote more appropriate therapies.

Intravascular ultrasound (IVUS) is well described by users and essential to the management of venous disease as it allows us to visualize and appreciate the pathology being treated in real time. IVUS, though, is primarily used in the context of delivering a therapeutic tool as well as being invasive. Until recently, we have not been able to bring the power of cross-sectional imaging into the operative space. Our group has published on the use of multimodal imaging techniques such as magnetic resonance venography and fluoroscopic image fusion, which can potentially guide future interventions and optimize therapeutic decision making.

Ultimately, we believe that diseased veins behave differently than arteries do. Therefore, managing veins with tools meant for another space is likely not ideal. Many venous interventions use arterial devices that are not optimized for venous pathologies and underline the fact that we need to continue to develop tools specifically designed for the venous space. The ATTRACT (Acute Venous Thrombosis: Thrombus Removal Vascular Specialists) program continued on page 7

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October Is Psoriasis Awareness Month
Psoriasis is a chronic systemic inflammatory condition, most notably characterized by skin lesions. But vascular surgeons are well aware that the disease presents a heightened risk for noncardiac vascular diseases, including carotid, peripheral artery, and chronic kidney disease, as well as metabolic co-morbidities such as type 2 diabetes melitus, and metabolic syndrome. Check out the National Psoriasis Foundation for more info (www.psoriasis.org).

In Memoriam
William Long, MD, who was Tallahasee’s first board-certified peripheral vascular surgeon, died on Aug. 29, 2018. In 1970, he began his career as a general surgeon in Tallahasse after completing the peripheral vascular surgery program at Emory University. After a year, he limited his practice to peripheral vascular surgery and subsequently formed Vascular Associates of Tallahassee.

Upcoming Meetings
(Check https://vascular.org/meetings for details)
2018 Pacific Northwest Vascular Society Annual Meeting
The Pacific Northwest Vascular Society includes physicians interested in vascular disease from the Alaska, Washington, Oregon, Idaho, Montana and British Columbia, Alberta, and Saskatchewan. It will be held Nov. 1-2, 2018 at The Edgewater Hotel, 2411 Alaskan Way, Seattle. The PNVS is recognized as an official regional vascular society by the SVS.

2018 Texas Society for Vascular and Endovascular Surgery Annual Meeting
The Texas Society for Vascular and Endovascular Surgery will hold its annual meeting at the Marriott Marquis Houston on Nov. 2-3. The TSVES represents the vascular surgeons of Texas and is recognized as an official regional vascular society by the SVS.

NIVL curriculum
Trainees from page 1
Chou. Using responses from individual trainees, the authors grouped programs into one of two categories: those whose trainees felt well prepared for the RPVI, and those whose trainees felt unprepared for the RPVI.
In addition to a yes/no question about preparedness, the survey also asked whether training programs had a structured curriculum; respondents were asked to identify specific NIVL-related training activities. The survey asked about individual didactic components, as well as whether the trainee spent individual time with an attending physician and hands-on time with vascular technologists.
Respondents were asked about the amount of time, measured in half days per week, spent in the vascular laboratory.
Finally, the survey asked whether trainees took a pre-RPVI exam review course, and whether they passed the RPVI exam on their first attempt.
Overall, 34 of the programs with respondents (55.7%) had structured curriculum; the same number included lectures. Twenty programs (32.8%) provided video content, and 29 (47.5%) used textbooks. Just 18 programs (29.5%) assigned articles.
One-on-one time spent with an attending physician and focused didactic components, as well as whether the trainee spent individual time with an attending physician and hands-on time with vascular technologists.
Trainees who felt prepared, but the difference wasn’t quite statistically significant (P = .05).
Having taken a review course prior to the exam was associated with feeling well prepared (P = .03).
Dr. Chou and her colleagues performed a logistic regression analysis to arrive at the educational components associated with the highest odds for trainees feeling well prepared. Lectures and articles came out on top in this analysis (odds ratios for feeling well prepared, 15.88 and 15.97, respectively). Hands-on time with vascular technologists had an odds ratio of 5.12 for feeling prepared.
Taking a review course boosted preparedness as well, with an odds ratio of 11.85 for feeling well prepared for the RPVI exam.

Of the 32 programs with trainees who reported taking the RPVI exam, 18 had trainees who felt unprepared.

Venous
continued from page 6
With Adjunctive Catheter-Directed Thrombolysis trial has been extremely impactful in the treatment paradigm of venous thrombosis. Although the results remain heavily debated and, on some level, contested, it is a critical trial and should— in many ways— serve as an example of the good research being executed in venous disease.
A quote many have attributed to Albert Einstein says: “The one who follows the crowd will usually go no further than the crowd. Those who walk alone are likely to find themselves in places no one has ever been before.” We have an opportunity to be more enlightened with respect to central venous therapies; let’s not act like lemmings and follow one another off the cliff.

References
Outcomes from page 1

Chicago, and his colleagues. They performed a study that found a high level of adverse outcomes for common vascular procedures and that there was a significant variability in risk-adjusted outcomes among best- and poorest-performing hospitals in all major vascular procedures, indicating that a large opportunity exists for improvement in results.

Medicare’s value-based care Readmissions Reduction Model developed financial penalties for hospitals that fail to achieve acceptable performance scores, and in doing so shifted some of the financial risks of care to the providers based on a 30-day readmission model. In contrast, the pilot Bundled Payments for Care Improvement (BPCI) Advanced Program, which the CMS plans to launch this month, will follow a 90-day period of postoperative care as its duration of financial accountability.

“While BPCI Advanced, has, until now, focused upon orthopedics, cardiovascular procedures, and high-volume medical admissions areas, it is anticipated that vascular surgery will be included in the future,” according to the investigators. Therefore, the researchers performed an in-depth analysis to examine the 90-day outcomes of common vascular surgeries across hospitals as a prelude to the vascular surgery field having to potentially confront this new CMS model (Surgery 2018 Jun 22 doi: 10.1016/j.surg.2018.03.025).

Dr. Fry and his colleagues used the Medicare Limited Data Set for 2012-2014 to follow the outcomes of major vascular surgery beginning with the inpatient stay and on through 90 days of postoperative care. A pool of more than 500 aggregate and individual candidate risk factors, including age and sex, was used in model development, based upon data from 359 hospitals with 10,815 patients in the Medicare Limited Data Set.

The researchers examined the risk-adjusted outcomes of four major groupings of vascular surgery procedures: elective open aortic; open peripheral vascular procedures; endovascular aortic; and percutaneous angioplasty procedures. They found that the total adverse-outcome (AO) rate was 27.8% for open aortic procedures, 31.5% for open peripheral vascular procedures, 19.6% for endovascular aortic procedures, and 36.4% for percutaneous angioplasty procedures. The difference in risk-adjusted AO rates between the best- and the poorest-performing deciles was 32.2% for open aortic procedures, 29.7% for open peripheral vascular procedures, 21.5% for endovascular aortic procedures, and 37.1% for percutaneous angioplasty procedures.

The model determined significant risk factors (P less than .001) for inpatient death (including malnutrition, intestinal ischemia, supplemental oxygen, and age greater than or equal to 85 years); prolonged length of stay (including supplemental oxygen, peritoneal adhesions, and chronic obstructive lung disease); 90-day postdischarge death (including heart failure, chronic infection, psychosis, and primary head/neck cancer); and 90-day postdischarge readmission (malnutrition, chronic obstructive lung disease, upper aerodigestive tract cancer, and skin ulceration) for these procedures. For all cases, the total 90-day postdischarge mortality rate exceeded the inpatient death rate, and readmissions were the major driver of the total AO. They found that 22% of all patients readmitted across the entire 90-day interval had not seen a physician for follow-up after discharge.

“This begs the question of whether more frequent physician or physician-extender follow-up can reduce this AO,” according to Dr. Fry and his colleagues. “Importantly, first readmissions during days 31-90 following discharge were almost as common as those occurring during the initial 30 days. Over 20% of total readmissions were subsequently repeat events during the 90-day interval,” they added.

They also found that the variability in risk-adjusted outcomes among the best and poorest performing hospitals was over 20% in all of the major vascular procedures and indicates a large opportunity for improvement in results.

“Understanding variables associated with higher risk can be used as a decision support tool to identify which patients will need increased vigilance to avoid AOs. Identification of very high risk may become a consideration in the assessment of the appropriateness of the surgical intervention. If providers know their outcomes and those outcomes are benchmarked against the whole population of hospitals, then clinical performance can be improved by specific care redesign initiatives,” the researchers concluded.

Dr. Fry is executive vice president of MPA Healthcare Solutions, which funded the research. mlesney@mdedge.com


PAD AND CLAUDICATION

Using WIfI as a predictive tool for amputation risk

WIfI is a promising tool to identify chronic limb-threatening ischemia (CTLTI) presentations most likely to benefit from revascularization, according to Jessica M. Mayor, MD, and her colleagues, and could be used to better inform patients, guide decision making, and risk-adjust quality and outcomes assessments.

Dr. Mayor, of the Baylor College of Medicine, Houston, presented their research study to quantify if CTLTI patients most benefit from revascularization by comparing the predicted to observed 1-year major lower-extremity amputation (LEA) risk stratified by WIfI Clinical Stage at the Vascular Annual Meeting.

The Society of Vascular Surgery (SVS) Wound Ischemia Foot Infection (WIfI) classification was intended to predict 1-year major LEA risk without revascularization, and identify which CTLTI patients benefit most from revascularization.

Dr. Mayor and her colleagues retrospectively reviewed composite multi-institutional cohort data from centers that had previously validated WIfI. They compiled Individual WIfI component grades, corresponding WIfI clinical stages, and observed LEA rate for each presentation. Multivariable linear regression analysis was performed to quantify which WIfI score component(s) best predicted amputation.

They collated data from 10 centers, and from a total population of 2,878 limbs at risk, they examined the subset of pa-tients undergoing revascula-rization as their study base (1,654 limbs; 169 LEAs). Of 64 potential WIfI grade combinations, 12 were never reported and were excluded from analysis. Stratifying by the original WIfI stages, the observed LEA rate after revascularization was: Stage 1, 6.8% (8/118); Stage 2, 3.8%; Stage 3, 6.0%; Stage 4, 18.8%.

They used cluster analysis to identify four clusters with the following 1-year LEA rates: Cluster 1, 4.4%; Cluster 2, 14.8%; Cluster 3, 28.1%; Cluster 4, 51.2%. The analysis showed that the revascularization benefit was greatest in limbs with small to moderate wounds, moderate to severe ischemia, and moderate-severe foot infection (W2 L2 F13; W1 L1 F12).

Initially, for WIfI clinical stage 4, these presentations behaved as lower-risk Cluster 2 after revascularization. Multiple linear regression revealed wound grade most strongly predicted LEA (P less than .001). Ischemia (P = .001) and infection (P = .003) were similarly associated with LEA risk. Interaction terms between each component of WIfI score were not statistically significant.

“Our results show that wound severity is most strongly associated with LEA risk and that ischemic and infectious grades confer additive, but not synergistic risk,” according to Dr. Mayor.

“Future cluster analyses comparing specific WIfI presentations treated with and without revascularization may quantify the benefit of revascularization for a given WIfI presentation and further refine the risk-stratification provided by WIfI,” she and her colleagues concluded.
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SVS Submits Comments Seeking Changes in CMS Proposed Rules for 2019

In an effort to alter specific policies in the Centers for Medicare and Medicaid Services’ (CMS) CY 2019 Medicare Fee Schedule Proposed Rules, Society for Vascular Surgery leaders have submitted a 20-page comment letter with recommendations to CMS.

CMS released the combined Medicare Physician Fee Schedule (PFS) / Quality Payment Program (QPP) proposed rule in July. Comments were due in mid-September; the final rule is expected on or around November 1, 2018.

These rules affect payment policies and reimbursements for procedures performed by physicians and healthcare providers across the country.

Regarding the combined Medicare Physician Fee Schedule (PFS) / Quality Payment Program (QPP) proposed rules, of particular importance to vascular surgeons are proposals to combine and flatten payments for Evaluation and Management (E&M) codes and a proposal to reprice the cost of vascular surgeons aren’t adequately covered

the Indirect Cost Indices change significantly (E&M) codes and a proposal to reprice the cost of vascular surgeons are proposals to combine and flatten across the country.

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Regarding the combined Medicare Physician Fee Schedule (PFS) / Quality Payment Program (QPP) proposed rules, of particular importance to vascular surgeons are proposals to combine and flatten payments for Evaluation and Management (E&M) codes and a proposal to reprice the cost of vascular ultrasound room components. Should CMS insist on pricing changes, SVS leaders said they have provided enough information to request maintaining current pricing for both ultrasound rooms and then refer repricing of the two rooms to an American Medical Association subcommittee.

The SVS also commented on several proposed changes for Year 3 of the Quality Payment Program (QPP):

• Seeking a single 12-month determination period for participants in the Merit-Based Incentive Payment System, not a proposed 24-month assessment period.
• Not expanding the low-volume threshold criterion for several reasons, including that expansion impacts the availability of bonus payments.
• Urging CMS to move ahead with specialty-specific subgroups within a larger multi-practice group; to further the goal of quality care.
• Asking CMS to consider 2019 a field-testing year, holding SVS members harmless from episode-cost measure results, particularly because of physician difficulties in getting access to field-testing reports.
• Opposing a blanket requirement that all physicians use electronic health records technology certified to the 2015 edition.
• Urging a better process for approval for Advanced Alternative Payment Models for specialists. (SVS is working to develop an advanced APM for vascular surgeons.)

The letter, which contains many more suggestions and details, was submitted by President Dr. Michel Makaroun and Drs. Sean Roddy, Matthew Sideman, Megan Tracci and Karen Wood, chairs, respectively, of the Policy and Advocacy Council, plus Coding and Reimbursement, Government Relations and the Quality and Performance Measures committees. See the full letter at vsvweb.org/PFScomments18D.

SVS also submitted comments later in September on other CMS proposed rules, including the CY 2019 Hospital Outpatient Prospective Payment System. Read those comments at vsvweb.org/HOPPScomments18.

The Benefits of Belonging

Membership in the Society for Vascular Surgery is a valuable resource at all stages of your career. You receive:

Community and professional standing
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Education and networking with thought leaders, at exclusive member pricing
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• Through educational products including the Vascular Education and Self-Assessment Program

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  • Disability coverage designed with the vascular surgery specialty in mind; many vascular surgeons aren’t adequately covered
  • The Kai-Zen program of accelerated retirement funding.
Submit Research to VAM Starting Nov. 12

Research to shed new light on PAD, long-term survival after EVAR, diving into whether vascular surgeons are hurting themselves while operating: at their core, abstracts — as presented at earlier Vascular Annual Meetings — all include data and insights important to vascular surgeons.

Though the 2019 VAM is still months away, the time to submit abstracts for possible inclusion in the meeting is approaching rapidly. Abstract guidelines are expected to be available the week of Oct. 29, and researchers can submit abstracts in less than a month, starting Nov. 12. Abstract submissions will close Jan. 16, 2019.

The meeting will be held June 12-15, 2019, at the Gaylord National Resort & Convention Center in National Harbor, Md., outside Washington, D.C. Scientific sessions will be held June 13 through 15 and exhibits will be open June 13 and 14. Housing and registration will open in early March. Authors may submit their research — including videos — in several categories. The selection committee will choose abstracts for different program types: scientific sessions, the Vascular and Endovascular Surgery Society (VESS) sessions, International Forum, International Fast Talk, Poster Competition and Interactive Poster Competition.

Submission categories include: aortic disease; cerebrovascular (including Great Vessels); complications; dialysis access; educational/training credentialing; peripheral arterial disease; practice management; renal/visceral disease; vascular laboratory and imaging; vascular medicine; vascular trauma: aortic, arterial, venous; venous disease; and basic research (poster competition only).

See the guidelines at vsweb.org/Guidelines19 and learn more about VAM at vsweb.org/VAM19.
SVS Announces Award for Community Service Honoree Will be Community-Based Practitioner

The Society for Vascular Surgery emphasizes not only education and research, but also public awareness. Now, through the just-announced Excellence in Community Service Award, the Society plans to honor a member who has made not only contributions to the profession but to the community as well. Applications for this new honor are due Feb. 1, 2019. The recipient will be announced and recognized at the 2019 Vascular Annual Meeting in June.

“We want to honor a vascular surgeon working in the community who also is a community leader, a philanthropist, someone who contributes outside of the operating room,” said Daniel McDevitt, MD, chair of the SVS Community Practice Committee. The committee developed and will oversee the award. Nominees must have practiced vascular surgery for at least 20 years and been an SVS member for at least five. They also must present evidence of impact on vascular care or community health, such as:

- Leadership in a community-based practice
- Implementation of services or innovations to advance community health
- Partnerships or collaborations with community organizations
- Contributions that elevate the stature of the vascular surgery specialty in the community

Dr. McDevitt stressed that the award isn’t particularly geared to members who have already received multiple professional awards. “He or she has a civic presence and exhibited a lifetime of commitment to our profession and the community,” he said. “There’s no real vehicle for recognizing such a person right now except for the accolades of family and friends.”

Members may nominate a candidate — including him or herself — by submitting the nomination form and supporting documents. All materials are due by Feb. 1. Required are:

- The Nomination Form
- The nominees’ curriculum vitae (either abbreviates or full)
- Description of the nominee’s significant work and impact in a community-practice setting (one page)
- Three letters of recommendation, at least one of which must be from an SVS member.

The SVS Community Practice Committee will review the nominations and select the recipient. Though nominees will be sought every year, the award may not be presented each year.

Nomination materials, all in PDF format, should be mailed to vascular@vascularsociety.org. Learn more at vsweb.org/CommunityService, email the address above or call 800-258-7188.

First of 9 Patient Education Fliers Available

Due to popular demand, the SVS Foundation has developed a new set of patient education fliers. The first one – on Peripheral Arterial Disease – is now available, and was released to coincide with PAD Awareness Month in September.

All members are welcome to download and start using the PAD flier, which has a writable area for your name, clinic name and address. More fliers are coming soon on:

- What is a vascular surgeon?
- Carotid artery disease
- Abdominal aortic aneurysms
- Varicose veins
- Cholesterol/nutrition
- Smoking
- Diabetes
- Physical activity
- Atrial fibrillation
- Diabetes
- Smoking
- Cholesterol/nutrition
- Physical activity
- Atrial fibrillation
- Diabetes
- Smoking
- Cholesterol/nutrition

The flier version can be printed in their offices or email a high-quality one to email to a local print shop at vsweb.org/PAD_flier_for_printing. Members should be sure to add their contact information in the writable area.

Education: Submit Your Abstracts for VRIC ’19

The Society for Vascular Surgery will begin accepting abstracts Oct. 30 for the 2019 Vascular Research Initiatives Conference. VRIC, which focuses on emerging vascular science, will be held May 13, 2019, in Boston.


Besides abstract presentations, VRIC also will feature the Alexander W. Clowes Distinguished Lecture, a Translational Panel that will discuss “Arterial Calcification,” reception and posters. As in the past, VRIC will be held in conjunction with the American Heart Association’s Scientific Sessions, which will take place May 14 to 16, 2019. Visit vsweb.org/VRIC19 for more information.

From JVS, JVS-VL

From JVS: Results of a new study suggest that medical therapy alone is insufficient protection against strokes for patients with significant carotid stenosis.

The study, in the November Journal of Vascular Surgery, studied stroke patients admitted with a radiographically confirmed in-farct ipsilateral to a documented carotid artery stenosis of equal to or greater than 50 percent. Researchers said that even patients receiving both antiplatelet and lipid-lowering medical therapy are still at risk for a carotid-mediated stroke. Read more at vsweb.org/JVS-StrokeStenosis.

From JVS-VL: A large, image-based study of patients with iliofemoral deep venous thrombosis furtthers understanding of the relationship between iliac vein compression and DVT. The article from November’s JVS: Venous and Lymphatic Disorders, is open source through Dec. 31 at vsweb.org/JVSVIliacVein.
Opioids don’t treat pain better than ibuprofen after venous ablation surgery

BY KARI OAKES
MDEDGE NEWS
REPORTING FROM MIDWESTERN VASCULAR 2018

ST. LOUIS – Compared with ibuprofen, opioid pain medication offered little benefit for pain control after venous ablation surgery, in the experience of one surgical center.

Sharing study results at a poster session at the annual meeting of the Midwestern Vascular Surgery Society, Jana Sacco, MD, and her colleagues found that patients who received opioid prescriptions after venous ablations did not have significantly different postsurgical pain than did those who received ibuprofen alone.

The study, conducted against the national backdrop of greater scrutiny of postsurgical opioid prescribing, was the first to look at post–venous ablation pain management strategies, said Dr. Sacco, a resident physician at Henry Ford Hospital, Detroit.

Venous ablation surgery can improve quality of life for patients with varicose veins, but best practices for managing postprocedure discomfort had not been clear; some patients receive opioid pain medications, while others are directed to use ibuprofen as needed for pain control.

The retrospective, single-center study assessed pre- and postoperative pain for patients undergoing venous ablation procedures over a 2-year period, said Dr. Sacco.

Patients who were prescribed opioids were compared with patients who were simply asked to take ibuprofen for pain control.

Comparing preoperative to postoperative pain scores, Dr. Sacco and her colleagues defined a change of 2-3 points on a 0-10 Likert scale as “good” improvement; a change of 1 point was defined as “mild” improvement, and no change or worsening was defined as no improvement.

Of the 268 patients for whom postoperative follow-up data were available, 142 received opioid prescriptions, while 126 did not.

Across the entire group of patients studied, those who had moderate to severe preoperative pain had significant improvement in pain after their procedures.

Whether patients received opioid pain medication after their venous ablation was not correlated with the degree of improvement in postprocedure pain scores. Of those who saw no improvement, 30 patients (43%) received opioids and 36 (53%) did not.

Of the 89 patients who saw mild postprocedure improvement in pain, 35 (40%) were not discharged on opioids, and of 65 patients who had good improvement in postprocedure pain, 44% were not discharged on opioids (P = .7 for difference across groups).

When Dr. Sacco and her fellow researchers examined such patient characteristics as sex, race, body mass index, smoking status, and CEAP venous severity classification, they did not see any significant differences in pain scores. Similarly, neither the type of procedure (radiofrequency or laser ablation) nor information on whether compression treatment was used was associated with a difference in pain scores.

Dr. Sacco and her coauthors noted that the study was limited by its retrospective nature and the fact that patients were all drawn from a single institution. Additionally, the investigators were only able to ascertain whether opioids had been prescribed, not whether—or how much—medication was actually taken by patients.

“Most patients report an improvement in symptoms after undergoing vein ablation procedures,” reported Dr. Sacco and her colleagues, and most patients also do well with non-opioid pain control regimens. “Over-prescribing opioids exposes patients to the risk of narcotic overdose and chronic opioid use and should be used with caution for patients undergoing vein ablation surgery,” they wrote.

Dr. Sacco reported no outside sources of funding and no conflicts of interest. ■

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**PERIOPERATIVE CARE**

**Risk factors for postop cardiac events differ between vascular and general surgery**

**BY MARK S. LESNEY**  
**MDEDGE NEWS**  
**FROM ANNALS OF MEDICINE AND SURGERY**

Predictive risk factors for cardiac events (CEs) after general and vascular surgery differed significantly, according to a large retrospective study. However, there was no significant difference seen in the overall incidence of CEs between the two types of surgery, reported Derrick Acheampong, MD, and his colleagues at the Icahn School of Medicine at Mount Sinai, New York.

They performed a retrospective data analysis of 8,441 adult patients at their large urban teaching hospital; these patients had undergone general or vascular surgery during 2013-2016 and, in the analysis, were grouped by whether they experienced postoperative CEs.

Univariate and multivariate analyses identified predictors of postoperative CE and the association of CEs with adverse postoperative outcomes. CEs were defined as myocardial infarction or cardiac arrest within the 30-day postoperative period.

A total of 157 patients (1.9%) experienced CEs after major general and vascular surgery, with no significant difference in incidence between the two types of surgery ($P = .44$), according to their report, published online in the Annals of Medicine and Surgery. CE-associated mortality among this group was high, at 53.4%.

The occurrence of a CE following surgery in both groups was significantly associated with increased mortality, as well as pulmonary, renal, and neurological complications, in addition to systemic sepsis, postoperative red blood cell transfusion, unplanned return to the operating room, and prolonged hospitalization, according to the researchers.

However, predictors of CEs risk between vascular and general surgery were significantly different.

For general surgery, American Society of Anesthesiologists (ASA) status greater than 3, dependent functional status, acute renal failure or dialysis, weight loss, creatinine greater than 1.2 mg/dL, international normalized ratio (INI) greater than 1.5, and partial thromboplastin time (PTT) less than 35 seconds were all unique independent predictors of postoperative CEs.

For vascular surgery, the unique significant predictors of postoperative CEs were age greater than 65 years, emergency surgery, diabetes, congestive heart failure, systemic sepsis, and operative time greater than 240 minutes.

The only common predictive risk factors for postoperative CEs for the two forms of surgery were hematocrit less than 34% and ventilator dependence.

“The present study corroborates reported studies that recommend separate predictive CE risk indices and risk stratification among different surgical specialties. Predictors for CE greatly differ between general and vascular surgery patients in our patient population,” the authors stated.

They concluded with the hope that their study “provides useful information to surgeons and allows for the necessary resources to be focused on identified at-risk patients to improve surgical outcomes.”

Dr. Acheampong and his colleagues reported having no disclosures.


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PRACTICE MANAGEMENT

Physician burnout may jeopardize patient care

BY JEFF CRAVEN
MEDGE NEWS
FROM JAMA INTERNAL MEDICINE

Physicians experiencing burnout are twice as likely to be associated with patient safety issues and deliver a lower quality of care from low professionalism and are three times as likely to be rated poorly among patients because of depersonalization of care, according to recent research published in JAMA Internal Medicine.

“The primary conclusion of this review is that physician burnout might jeopardize patient care,” Maria Panagioti, PhD, from the National Institute for Health Research (NIHR) School for Primary Care Research and the NIHR Greater Manchester Patient Safety Translational Research Centre at the University of Manchester (England) and her colleagues wrote in their study. "Physician wellness and quality of patient care are critical [as are] complementary dimensions of health care organization efficiency.”

Dr. Panagioti and her colleagues performed a search of the MEDLINE, EMBASE, CINAHL, and PsycInfo databases and found 47 eligible studies on the topics of physician burnout and patient care, which altogether included data from a pooled cohort of 42,473 physicians. The physicians were median 38 years old, with 44.7% of studies looking at physicians in residency or early career (up to 5 years post residency) and 55.3% of studies examining experienced physicians. The meta-analysis also evaluated physicians in a hospital setting (63.8%), in primary care (13.8%), and across various different health care settings (8.5%).

The researchers found physicians with burnout were significantly associated with higher rates of patient safety issues (odds ratio, 1.96; 95% confidence interval, 1.59-2.40), reduced patient satisfaction (OR, 2.28; 95% CI, 1.42-3.68), and lower quality of care (OR, 2.31; 95% CI, 1.87-2.85). System-reported instances of patient safety issues and low professionalism were not statistically significant, but the subgroup differences did reach statistical significance (Cohen Q, 8.14; P = .007).

Among residents and physicians in their early career, there was a greater association between burnout and low professionalism (OR, 3.39; 95% CI, 2.38-4.40), compared with physicians in the middle or later in their career (OR, 1.73; 95% CI, 1.46-2.01; Cohen Q, 7.27; P = .003).

"Investments in organizational strategies to jointly monitor and improve physician wellness and patient care outcomes are needed,” Dr. Panagioti and her colleagues wrote in the study. "Interventions aimed at improving the culture of health care organizations, as well as interventions focused on individual physicians but supported and funded by health care organizations, are beneficial.”

Researchers noted the study quality was low to moderate. Variation in outcomes across studies, heterogeneity among studies, potential selection bias by excluding gray literature, and the inability to establish causal links from findings because of the cross-sectional nature of the studies analyzed were potential limitations in the study, they reported.

Because of a lack of funding for research into burnout and the immediate need for change based on the effect it has on patient care seen in Panagioti et al., the question of how to address physician burnout should be answered with quality improvement programs aimed at making immediate changes in health care settings, Mark Linzer, MD, of the Hennepin Healthcare Systems in Minneapolis, wrote in a related editorial. “Resonating with these concepts, I propose that, for the burnout prevention and wellness field, we encourage quality improvement projects of high standards: multiple sites, concurrent control groups, longitudinal design, and blinding when feasible, with assessment of outcomes and costs,” he wrote. “These studies can point us toward what we will evaluate in larger trials and allow a...
Burnout
continued from page 16

place for the rapidly developing information base to be viewed and thus become part of the developing science of work conditions, burnout reduction, and the anticipated result on quality and safety.”

There are research questions that have yet to be answered on this topic, he added, such as to what extent do factors like workflow redesign, use and upkeep of electronic medical records, and chaotic workplaces affect burnout.

Further, regulatory environments may play a role, and it is still not known whether reducing burnout among physicians will also reduce burnout among staff. Future studies should also look at how burnout affects trainees and female physicians, he suggested.

“The link between burnout and adverse patient outcomes is stronger, thanks to the work of Panagioti and colleagues,” Dr. Linzer said.

“With close to half of U.S. physicians experiencing symptoms of burnout, more work is needed to understand how to reduce it and what we can expect from doing so,” she added.

The study was funded by the United Kingdom NIHR School for Primary Care Research and the NIHR Greater Manchester Patient Safety Translational Research Centre. The authors and commenters reported no relevant conflicts of interest.


TRAJMA

Seven-years of vascular injury from war in Afghanistan assessed

BY MARK S. LESNEY
MDEDGE NEWS
FROM THE VASCULAR ANNUAL MEETING

BOSTON – At this year’s Vascular Annual Meeting, Major Jigar-kumar A. Patel, MD, reported on a study that he and his colleagues did to examine the scope of vascular injury during seven years of the war in Afghanistan, including characterization of anatomic injury patterns, mechanisms of injury, and methods of acute management.

“Vascular injury is a leading cause of death and disability in military and civilian trauma, and the rate of vascular injury in modern combat is higher than that reported in previous wars,” said Dr. Patel. “Noncompressible torso hemorrhage remains the primary cause of battlefield fatality.”

He and his colleagues from Walter Reed National Military Medical Center, Bethesda, Md., used the Department of Defense Trauma Registry to identify U.S. military service members who sustained a battle-related vascular injury and survived to be treated at a surgical facility in Afghanistan between Jan. 1, 2009, and Dec. 31, 2015.

All battle-related injuries (nonreturn to duty) were used as a denominator to establish the injury rate. Mechanism and anatomic distribution of injury, Afghanistan continued on page 19

PERSPECTIVE

What’s your bottom line?

The importance of leadership for organizational success seems obvious to me. It is my opinion that leaders shape culture and cultural changes impact the bottom line. I ask you, what is your bottom line? More specifically, what is the bottom line required to effect urgent change to the threat of (vascular) surgeon burnout? If not simply for the threatened well-being of our friends and colleagues, or for the risk of lost revenue, surgeon recruitment and retention, I urge you all to consider the immediate threat to patient safety and satisfaction.

Dr. Panagioti and colleagues performed a meta-analysis of 47 quantitative observational studies that included 42,473 physicians across hospital settings in an effort to examine whether physician burnout impacts core domains of health care delivery. The authors identified physician burnout as associated with an increased risk of patient safety incidents, poorer quality of care due to low professionalism, and reduced patient satisfaction, while recognizing the study limitations of high study heterogeneity and only low to moderate study quality. Interestingly, residents and early-career physicians were at greater risk.

The authors conclude that “physician burnout may jeopardize patient care and that the reversal of this risk must be viewed as a fundamental health care policy goal across the globe.” Moreover, “health care organizations are encouraged to invest in efforts to improve physician wellness, particularly for early-career physicians.”

Whatever your bottom line, there appears to be an opportunity to more concisely capture the outcome of burnout on the performance of health care organizations that carefully considers patients care quality and safety outcomes. Larger scale, high-quality studies are desperately needed that reconcile systemic threats to physician wellness (i.e., inefficient workflow, excessive record-keeping, the EMR and regulatory compliance) with quality improvement. Perhaps this will drive real change.

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DVT AND PULMONARY EMBOLISM

VTE unchanged by postdischarge rivaroxaban

BY WILL PASS
REPORTING FROM THE
ESC CONGRESS 2018

For patients hospitalized for medical illness, giving rivaroxaban after discharge does not significantly reduce the risk of venous thromboembolism, reported Alex C. Spyropoulos, MD, of Hofstra University in Hempstead, N.Y., and his colleagues.

Previous research suggested that the risk of major bleeding from rivaroxaban outweighed its benefits; however, major bleeding was uncommon in the MARINER trial. “Patients who are hospitalized for acute medical illnesses, such as heart failure, respiratory insufficiency, stroke, and infectious or inflammatory diseases, are at increased risk for venous thromboembolism,” they wrote in the New England Journal of Medicine. The results were also presented at the annual congress of the European Society of Cardiology.

Although the increased risk of thromboembolism continues for at least 6 weeks after hospitalization, postdischarge anticoagulants, such as rivaroxaban, are controversial.

“Studies of extended thromboprophylaxis have shown either excess major bleeding or a benefit that is based mainly on reducing the risk of asymptomatic deep-vein thrombosis,” the investigators wrote.

The double-blind MARINER study involved 12,019 patients who were hospitalized for medical illness and had an increased risk of venous thromboembolism. Hospitalization lasted 3-10 consecutive days. Patients were randomized to receive either 10 mg of rivaroxaban daily (n = 6,007) or placebo (n = 6,012) for 45 days after discharge. Patients with renal impairment had a reduced dose of 7.5 mg rivaroxaban.

Efficacy was similar in both groups. Symptomatic or fatal venous thromboembolism occurred in 50 patients (0.83%) in the rivaroxaban group, compared with 66 patients (1.10%) in the placebo group (P = .14). These findings suggest that rivaroxaban provides a minor and insignificant benefit.

Although major bleeding was slightly more common in patients receiving rivaroxaban, compared with patients receiving placebo (0.28% vs. 0.15%), the researchers suggested that, in large populations, the marginal benefit of rivaroxaban might outweigh the increased bleeding risk. Still, the authors noted that “the usefulness of extended thromboprophylaxis remains uncertain.”

“Future studies should more accurately identify deaths caused by thrombotic mechanisms and focus on the patients who are at highest risk and who may benefit from anticoagulant prophylaxis,” they wrote.

Funding was provided by Janssen Research and Development. Most of the study authors reported fees or grants from Janssen.


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Big Apple Bootcamp

Senior vascular residents, first-year vascular fellows and distinguished faculty from both regional and national training programs came together for a hands-on skills course on Sept. 13-15 at Weill Cornell Medicine for the 3rd Annual Big Apple Bootcamp.

The event was sponsored by the Division of Vascular and Endovascular Surgery at New York Presbyterian Hospital/Weill Cornell Medicine and endorsed by the New York Society for Vascular Surgery. The event, which was held in SAIL (Skills Acquisition and Innovation Laboratory), was led by Darren Schneider, MD, Chief of Vascular and Endovascular Surgery and Sharif Ellozy, MD, Associate Professor of Clinical Surgery, Division of Vascular and Endovascular Surgery, in the role of Bootcamp Director.

The vascular skills course provided a thought-provoking and fast-paced exchange of ideas and surgical technique by renowned faculty from regional and national training programs. The goal of the course was to provide participants with a foundation for success in their training and beyond.

Over the two-day course, trainees participated in open surgical simulation using both cadavers and models, endovascular simulation using multiple platforms, planning workshops, arterial closure workshops, and hands-on device deployment.

Overall, Big Apple Bootcamp proved to be a memorable and enjoyable learning experience for all.

Afghanistan

continued from page 17

as well as the acute management strategies of revascularization, ligation, and use of endovascular techniques were defined, according to Dr. Patel.

Compared to their previous study from 2002 to 2009, the current results over the past 7 years show an apparent increase in the rate of vascular injury from 12% to 17%. They found 3,900 service members who sustained a battle-related injury, of whom 685 patients (17.6%) had 1,105 vascular injuries (1.6 vascular injuries per patient). Extremity trauma accounted for the majority of vascular injuries (72%), followed by the torso (17%) and cervical (11%) regions. Lower-extremity vascular injury was the most prevalent anatomic location (45%).

The cause of the injuries were explosion with fragment penetration (70%) and gunshot wounds (30%).

Open repair was performed in 60% of cases, whereas ligation was the initial management strategy in 38%. Diagnostic angiography was used in 374 cases and endovascular techniques as a form of definitive repair were used in 24 cases (3%). Overall mortality of the vascular injury cohort was 5%.

“Our study showed that open reconstruction is performed in half of cases, with diagnostic angiography being common and endovascular repair now used in nearly 10% of cases. This means that proficiency with open and endovascular methods of vascular injury management remains a critical need for the U.S. military and will require partnership with civilian institutions to attain and maintain,” Dr. Patel and his colleagues concluded.

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