**First reversal agent for apixaban, rivaroxaban**

**BY CATHERINE HACKETT**

**MDEDGE NEWS**

Andexanet alfa, the first agent shown to reverse the anticoagulant effects of rivaroxaban and apixaban, has been approved by the Food and Drug Administration, according to a May 3 statement from Portola Pharmaceuticals.

It is approved for use in patients treated with these factor Xa inhibitors when reversal of anticoagulation is needed because of life-threatening or uncontrolled bleeding, according to the company.

Andexanet alfa (Andexxa, Portola) received both U.S. Orphan Drug and FDA Breakthrough Therapy designations and was approved under the

See FDA  page 5

**Drug-coated balloons: The future of hemodialysis access?**

**BY BRUCE JANCIN**

**MDEDGE NEWS**

**EXPERT ANALYSIS FROM THE NORTHWESTERN VASCULAR SYMPOSIUM**

CHICAGO – Drug-coated balloons show promise of being a long-sought major advance in the endovascular treatment of stenotic arteriovenous fistulae and grafts for hemodialysis access, Syed M. Hussain, MD, said at a symposium on vascular surgery sponsored by Northwestern University.

Something significantly better than today’s standard treatment options is needed, according to Dr. Hussain. Medicare pays out more than $50 billion annually for the treatment of patients with end-stage renal disease, and a hefty chunk of that money goes for oft-repeated procedures aimed at preserving the patency of the access sites.

“Primary patency rates leave much room for improvement,” observed Dr. Hussain, a vascular surgeon at the Christie Clinic in Champaign, Ill.
OPIOIDS AND US: Designed to fail

BY MALACHI SHEAHAN III, MD
DEPUTY MEDICAL EDITOR, VASCULAR SPECIALIST

OPIODS AND US: Designed to fail

.ids, the Vietnam War, whatever your preferred scale for measuring horrific events, the numbers from the opioid crisis are as grave or worse. And, once again, it is the young who are dying. How we got to this point is an unbelievable story of corporate greed, government incompetence, regulatory commission overreach, and, unfortunately, physician ignorance.

Every one of us has contributed to this tragedy, and most of us still do. There are some easy first steps surgeons can take, but first let’s review the mistakes made that drove our country into addiction.

In 1995, as their patent on MS Contin was set to expire, Purdue Pharma gained Food and Drug Administration approval for OxyContin (“contin” is pharma talk for continuous). At this time, opioids generally were considered to be dangerous and mainly prescribed for cancer or end-of-life patients. Purdue representatives began an aggressive marketing campaign to break out of this niche. They were aided in this pursuit by the FDA, which wrote in the package insert that iatrogenic addiction was rare and the delayed absorption of OxyContin “is believed to reduce the abuse liability of a drug.” These statements were made without the backing of any clinical trials. But with an on-label statement of reduced addiction risk, representatives could sell OxyContin based on a diminished potential for abuse.

In addition to oncologists, the drug was now marketed to rheumatologists, primary care physicians, and surgeons. OxyContin, therefore, broke through the cancer barrier and became one of the most widely prescribed painkillers in the United States. While generating billions in profits, OxyContin also would become one of the most abused drugs in history.

There were several issues with OxyContin that led to its widespread misuse. The preparation contained up to 160 mg of oxycodone per pill, 16 times more than the strongest Percocet formulation. The tablet also could easily be crushed, overcoming the delayed-release formulation. Because of the FDA’s request, sales representatives were free to report an addiction risk of less than 1%, which they did. Widely.

But what science backed this claim? The study referenced was not a study at all. The citation was a one-paragraph, five-sentence letter to the editor published by the New England Journal of Medicine in 1980. In it, the authors briefly described their experience with inpatient opioid therapy. No reference was made to outpatient opioid prescriptions. Still, this letter has been scientifically cited more than 600 times, with a spike starting in 1995, the year OxyContin was released. Even as thousands of Americans were dying each year from opioid use, the “study” continued to be offered as proof of a low risk of addiction. As recently as 2014, the letter was cited in the journal OncoTargets and Therapy to support the statement, “In reality, medical opioid addiction is very rare.”

Maybe if we knew our history we could avoid repeating it. Previously, the drug diacetylmorphine was introduced as a safe, nonaddictive substitute for morphine by Bayer Pharmaceutical in the late 1890s. Diacetylmorphine is better known by its trademarked name, Heroin.

In 1996, the American Pain Society and the American Academy of Pain Medicine formed a committee to issue a joint statement that advocated opioid use for chronic pain and again stating a low risk of addiction. The committee was chaired by J. David Haddox, DDS, MD, a paid speaker (and later executive) for Purdue Pharma. The American Pain Society also launched a campaign to treat pain more aggressively. “Pain is the fifth vital sign” became a far-reaching strategy, which was adopted by the Department of Veterans Affairs and, ultimately, nearly every hospital in the country. The campaign was so successful that, in 2001, the Joint Commission required hospitals to:

- Assess pain in every patient.
- Record the results.
- Provide treatment for the pain.
- Reassess the effectiveness of the treatment.
- Teach staff how to manage pain.

The Joint Commission is not alone in creating opioid-friendly regulations. The Hospital Consumer Assessment of Healthcare Providers and Systems surveys patients after hospital stays. Several of the questions include pain management. One asks the patient whether the hospital staff did “everything they could” to assist with the patient’s pain. The satisfaction scores from these surveys are directly tied to hospital payments.
In 1998, the Federation of State Medical Boards published a statement reassuring doctors that they would not be punished for prescribing even large amounts of opioids if it were in the course of medical treatment. In 2004, the FSMB went further, stating that medical boards should consider “under-treatment of pain” to be a “departure from an acceptable standard of practice,” suggesting that state medical boards should sanction doctors who undertreated pain. According to a report by Catan et al. in the Wall Street Journal, this policy was drawn up with help from Dr. Haddox, who is now a senior executive with Purdue. The FSMB also would later disclose nearly $2 million in funding from opioid manufacturers.

These regulatory groups created widespread legal and financial pressure for doctors to diagnose and quickly treat pain in every patient. But what resources did we have to do this swiftly and effectively? Opioid prescriptions soared. There were 116 million opioid prescriptions issued in 1999; by 2013, it was 207 million. Annually, there are now more opioid prescriptions filled in the United States than there are people. Overdose deaths rose 300% between 1999 and 2016. Last year, there were more than 42,000 opioid-related mortalities in the United States. Like an untended fire, the crisis now spreads unabated.

What about vascular surgeons? Few of us prescribe OxyContin. Surely the 30 Percocets we give out after surgery are safe? In reality, Percocet contains oxycodone, the same opioid found in OxyContin, and therefore, carries a high risk of addiction. Norco, Vicodin, and Lortab all contain the opioid hydrocodone. Some studies have shown a higher risk of addiction with oxycodone, but all opioids carry a significant danger of abuse and dependence. As surgeons, we came into this crisis with little or no training. This made us susceptible to bad science, bad-faith marketing, and bad ideas from regulatory commissions. Most of us learned how to prescribe postop opioids during the “hidden curriculum” of our third and fourth years of medical school. In other words, the residents taught us. Much like learning sex education on the streets, your mileage may vary. It is no wonder that a 2016 JAMA Internal Medicine news release found that simply having surgery was a risk factor for developing an opioid addiction. Surgeons don’t have an evidence-based plan to treat postoperative pain with opioids. About 6.5% of patients are still taking “postop” opioids 3-6 months after minor surgery; the numbers are about the same for major surgery (3.9%). Therefore, it is unlikely that pain is driving this chronic use.

Richard J. Barth Jr., MD, of Dartmouth-Hitchcock Medical Center in Lebanon, N.H., has studied opioid use following surgery extensively. He found there is a wide variety in surgeons’ opioid-prescribing habits and most of us overprescribe. In one study, 72% of the prescribed pills after surgery were not taken. He recommends the following guideline for opioid prescriptions after inpatient surgical procedures: If the patient took no opioids the day before discharge, no script is needed. For patients taking 1-3 pills the day before discharge, 15 pills are given; and for those taking 4 or more pills, a script for 30 is given.

As vascular surgeons, we must break out of our bubble and address our contributions to this crisis. It is past time to look at our own habits. Over-prescribing is dangerous; the excess pills often are found by abusers, sold, or used recreationally by others in the household. Some patients take all of the pills simply because that is what the doctor prescribed; to the patient, he or she is merely following the doctor’s orders, and therefore not engaging in a risky behavior.

As vascular surgeons, there are several steps we can take immediately to reduce our contributions to the opioid epidemic and protect our patients:

• Always use the lowest effective dose of opioids and dramatically reduce the number of pills in your postop scripts. Fewer than 15 pills will cover most surgeries we perform.
• New data show that acetaminophen combined with ibuprofen works better for acute pain than acetaminophen combined with an opioid. Increase your use of nonnarcotic pain medications.
• Counsel your patients on the risk of addiction. If you plan to issue a script with only a few pills or nonnarcotics, let them know why in advance.
• Use caution when prescribing opioids to patients with anxiety or depression. The risk of addiction is much higher in these patients because of the anxiolytic and antidepressant qualities that opioids have.
• Avoid opioids in patients taking benzodiazepines, which can exacerbate the risk of respiratory depression and death.
• Help patients safely dispose of unused opioids.
• Use drug-monitoring programs whenever available.
• Use opioids for acute pain only. We do not have the training to manage long-term use.

Meanwhile, OxyContin still is available and sold exclusively by Purdue Pharma. Before its patent expired, Purdue altered the formulation to make it harder to abuse when crushing the tablets. They then lobbied the FDA to block generic production of the original formula because it was “unsafe.” Though Purdue (under Mundipharma) now markets this original version in South America, Europe, and Asia.

Many lawsuits have been brought against Purdue. Even with such high-profile lawyers as Rudy Giuliani and Eric Holder, Purdue has paid more than $600 million in fines and pleaded guilty to marketing OxyContin with “the intent to defraud or mislead.” Three Purdue executives have pleaded guilty to criminal misdemeanor charges. In 2015, the FDA approved marketing OxyContin to children as young as age 11 years.

To address their role in the opioid crisis, the Joint Commission issued a statement on April 18, 2016. It was not a master class in self-awareness; the statement claimed that it is a “misconception” that Joint Commission standards pushed doctors to prescribe opioids. Yet, according to a Class Action complaint (Kenova v. JCAHO), in a 2001 monograph published by the Joint Commission (and funded by Purdue Pharma), they wrote “Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance, and risk of death. This attitude prevails despite the fact that there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”

In 2016, the AMA passed a resolution to drop pain as a vital sign. They also urged the Joint Commission to stop requiring hospitals to ask patients about the quality of their pain care. The American College of Surgeons has started an education initiative to help surgeons and patients learn about opioids and surgery (funded by Pacira Pharmaceuticals, makers of EXPAREL, an injectable long-lasting local anesthetic). In a March 2016 statement in the New England Journal of Medicine, Centers for Disease Control and Prevention representatives said of opioids “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.” As vascular surgeons, we are long overdue for a self-assessment. It is now time to change our practices and habits to help end this national addiction.

Resources
5. www.jointcommission.org/joint_commission_statement_on_pain_management
Hemodialysis

Balloons from page 1

Indeed, the 50% primary patency rate at 6 months that was optimistically declared a ‘reasonable goal’ in the 2006 Kidney Disease Outcomes Quality Initiative is actually far-fetched using the conventional tools.

“That 50% patency at 6 months would be a tall order to try to meet. Anybody in this room that does fistulography and angioplasty knows the numbers are actually a lot lower than 50%,” said Dr. Hussain.

Plain old balloon angioplasty, the standard first-line intervention for stenotic hemodialysis access sites, has a 6-month patency rate of about 30%. Bare-metal stents push the rate up to about 39%. Covered stent grafts are the most effective of the conventional treatment modalities, with a 6-month patency of 51%-53%; however, they are widely considered too expensive for routine use.

The key thing to remember is that we have to look at patency in periods of months. We can’t look at years because it’s pretty unusual to see a fistula stay open that long.

Drug-coated balloons (DCBs) have been available for close to 3 years for treatment of lower-extremity peripheral artery disease, where they have achieved considerable success. The Food and Drug Administration has approved three commercially available DCBs for this purpose: Bard’s Lutonix 035 AV, Medtronic’s IN.PACT Admiral, and most recently the Stellarex DCB.

In addition, the Lutonix DCB is approved for treatment of dysfunctional or stenotic arteriovenous (AV) fistulae on the strength of the positive results of the first prospective randomized multicenter trial of a DCB versus balloon angioplasty for AV access stenosis as reported at a conference in Leipzig, Germany, in 2017 and summarized by Dr. Hussain.

The pathophysiology of arterial atherosclerotic stenosis is very different from the stenosis that plagues AV access for dialysis. Arterial atherosclerotic stenosis is due to neointimal hyperplasia caused by inflammation and barotrauma secondary to angioplasty. In contrast, the neointimal hyperplasia in AV access stenosis is due to smooth muscle cell proliferation in response to nonphysiologic blood flow dynamics and shear forces between a high-pressure arterial system and the low-pressure venous system to which it has been connected, with resultant stenosis at the venous outflow anastomosis and often at the cephalic arch, Dr. Hussain explained.

Other contributors to the high rate of early stenosis in AV fistulae and grafts include traumatic balloon dilation, uremia, and repetitive traumatic needle insertion.

The breakthrough for DCBs as a potential game changer in dialysis access stenosis came with the discovery that venous smooth muscle cells are much more sensitive to paclitaxel and other antiproliferative drugs than are arterial smooth muscle cells. All three commercially available DCBs utilize paclitaxel as their active agent.

Multiple small single-center studies involving off-label use of the DCBs for dialysis access stenosis strongly suggested 6-month patency rates were higher than with balloon angioplasty. Then came the core lab- adjudicated Lutonix multicenter trial, in which 285 hemodialysis patients at 23 sites were randomized to the DCB or balloon angioplasty. Participants had to have a target lesion less than 10 cm long and had to undergo successful predilatation with high-pressure balloon angioplasty.

“The key thing to remember when we talk about dialysis grafts or fistulae is that we have to look at patency in periods of months. We can’t look at years because it’s pretty unusual to see a fistula stay open that long. So most of the time we’re trying to achieve extra months on these types of circuits,” noted Dr. Hussain.

That being said, the 8-month target lesion primary patency rate was 61.6% in the Lutonix DCB group, compared with 49.4% for percutaneous angioplasty, a statistically significant and clinically meaningful difference. Moreover, 66 interventions were required to maintain target lesion patency during that time frame in the DCB group, versus 94 in the angioplasty group; that translated to a 30% reduction in repeat interventions.

“This clearly has the potential to save a lot of money for the health care system,” he said.

The two forms of treatment were equally safe.

The expanded indication for the Lutonix DCB that resulted from this large randomized trial has triggered considerable research interest in DCBs for AV access stenosis around the world. Major ongoing randomized trials include the PAVE trial in the United Kingdom, the Spanish FIBOL trial, the APERTO trial in the Netherlands, and an Israeli randomized trial restricted to patients with cephalic arch stenosis.

Dr. Hussain is particularly excited about the ongoing 330-patient, prospective, multicenter, single-blinded clinical trial of the IN.PACT Admiral DCB versus plain balloon angioplasty. The Medtronic DCB employs a higher dosage of paclitaxel: 3.5 mcg/mm², compared with 2.0 mcg/mm² for the Lutonix DCB. Also, due to differences in the excipients used in the two DCBs, the paclitaxel from the IN.PACT device stays in the media of blood vessels for up to 180 days, compared with 60 days following drug delivery with the Lutonix balloon. Whether this longer period of close range antiproliferative activity will translate into a higher patency rate remains to be seen.

Dr. Hussain reported having no financial conflicts of interest regarding his presentation.
Anticoagulation reversal

FDA from page 1

FDA’s Accelerated Approval pathway. “Today’s approval represents a significant step forward in patient care and one that the medical community has been eagerly anticipating,” said Stuart J. Connolly, MD, professor of medicine and an electrophysiologist at McMaster University in Hamilton, Ont., who is chair of the ANNEXA-4 executive committee. “Andexxa’s rapid reversal of the anticoagulating effects of rivaroxaban and apixaban will help clinicians treat life-threatening bleeds, where every minute counts,” he added in the statement.

The approval was supported by two phase 3 trials in the ANNEXA series, which showed acceptable change from baseline in anti-Factor Xa activity in healthy volunteers. But the strongest data came from interim results from ANNEXA-4, a single-arm cohort study with 227 patients who were receiving a factor Xa inhibitor and were experiencing an acute major bleeding event.

Clinicians administered andexanet alfa as a bolus followed by a 2-hour continuous infusion, with hemostatic efficacy assessed 12 hours after the start of treatment. The results showed that factor Xa inhibition fell by a median 90% for rivaroxaban and 93% for apixaban.

Andexanet alfa is a factor Xa “decoy” molecule that acts by latching onto the inhibitor molecules and thereby preventing them from interacting with actual factor Xa, but andexanet also has a short half-life and hence the effect quickly reduces once treatment stops, Dr. Connelly reported at the American College of Cardiology annual meeting in March when presenting ANNEXA-4.

He noted at the time the results placed andexanet in the same ballpark for efficacy and safety as idarucizumab (Praxbind) approved in 2015 for reversing the anticoagulant dabigatran (Pradaxa). “The expansion of available reversal agents for people prescribed newer oral anticoagulant therapies is crucial,” Randy Fenninger, CEO of the National Blood Clot Alliance, said in the Portola statement. “The availability now of a reversal agent specific to rivaroxaban and apixaban expands choice and enables patients and providers to consider these treatment options with greater confidence.”

The prescribing information for andexanet states that treated patients should be monitored for signs and symptoms of arterial and venous thromboembolic events, ischemic events, and cardiac arrest. Further, anticoagulant therapy should be resumed as soon as medically appropriate following andexanet treatment to reduce thromboembolic risk.

The most common adverse reactions, occurring in at least 5% of patients, were urinary tract infections and pneumonia.

Portola intends to bring Andexxa to limited markets in early June; a broader commercial launch is anticipated in early 2019.

The FDA is requiring a postmarketing clinical trial that randomizes patients to either andexanet or usual care. The study is scheduled to begin in 2019 and report outcomes in 2023. #chackett@mdedge.com

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VENOUS DISEASE

Early endovenous ablation speeds venous ulcer healing

BY BIANCA NOGRADY

FROM THE NEW ENGLAND JOURNAL OF MEDICINE

Intervening early with endovenous ablation in patients with venous leg ulcers could significantly improve ulcer healing times and delay their recurrence, new research has found.

A randomized study presented at the International Charing Cross Symposium and published simultaneously in the April 24 issue of the New England Journal of Medicine compared the effects of early endovenous ablation with those of deferred ablation in 450 patients with venous leg ulcers, all of whom also received compression therapy.

The study showed that patients who received endovenous ablation within 2 weeks of randomization had significantly shorter healing times, compared with patients whose ablation was deferred for 6 months or until after the ulcer healed.

With early-treatment, the median time to healing was 56 days vs. 82 days when deferred.

In the early-treatment group, the median time to ulcer healing was 56 days, while in the deferred-treatment group, it was 82 days. By 12 months, 93.8% of the early-intervention group had healed ulcers, compared with 85.8% in the deferred-intervention group.

Even after adjustment for factors such as patient age, ulcer size, ulcer duration, and recruitment center, patients who received early endovenous ablation were 38% more likely to have healed by 12 months, compared with the deferred-intervention group.

Researchers also saw significantly higher healing rates at 12 weeks in the early-intervention group, compared with the deferred-intervention group (63.5% vs. 51.6%, respectively).

“Observational studies have suggested that endovenous treatment of varicose veins – a treatment that may be particularly appropriate for the elderly population with venous leg ulcers – may improve ulcer healing,” wrote Manjit S. Gohel, MD, from the Cambridge (England) University Hospitals NHS Foundation Trust and from Imperial College London and his coauthors. “In the current trial, we found that faster ulcer healing can be attained if an endovenous intervention is performed promptly.”

Early endovenous ablation also was associated with a delay in the recurrence of ulcers. The rate of recurrence was 11.4% among patients in the early-intervention group whose ulcers had healed and 16.5% among those in the delayed-intervention group whose ulcers had healed.

Patients who received the early endovenous ablation had a median ulcer-free time of 306 days, compared with 278 days in the delayed-intervention group, a significant difference.

The authors noted that all patients in the study also received high-quality compression therapy, which may account for the good healing rates seen in both groups that might not otherwise be observed in a real-world clinical setting.

“Accordingly, the improvement in ulcer healing with early endovenous intervention is likely to be greater in clinical practice than was observed in this trial,” the authors wrote. “Because endovenous intervention is usually performed as a single procedure, the clinical benefits are likely to be less dependent on ongoing patient adherence than they would be with compression therapy.”

The most common method for endovenous ablation used in this multicenter study was ultrasound-guided foam sclerotherapy, a minimally-invasive procedure the authors said had versatility and acceptability.

However, they commented that while previous, large randomized trials have suggested that the rates of complete venous occlusion are lower with foam sclerotherapy than with thermal ablation.

The main complications seen with endovenous ablation were pain and deep vein thrombosis.

The authors pointed out that two limitations of their trial were that patients with a leg ulcer that had been present for more than 6 months were excluded from patient selection and that the 450 patients enrolled had been selected from a larger group of around 6,500.

The study was supported by a grant from the National Institute for Health Research Health Technology Assessment Program. One author declared grants from a pharmaceutical company outside the submitted work, and seven declared funding from the NIHR as part of the conduct of the study. No other conflicts of interest were declared.


Does this RCT settle the issue? Maybe yes?

Finally: A randomized controlled trial (RCT) that proves what we all kind of expected but which until now was unsupported by available literature. That is that endovenous ablation (EVA) in the presence of a concomitant venous ulcer not only decreases ulcer recurrence rates and increases ulcer-free time, it also significantly hastens ulcer healing times.

I don’t know about you, but it always made sense to me that treatment of an incompetent saphenous vein, a known cause of ulceration, could be a factor in the time to ulcer healing. But that’s what a whole host of retrospective and/or nonrandomized studies seemed to suggest: garbage in, garbage out. Enter the RCT – Issue resolved? Yes, with some caveats, and maybe no.

First, as the authors readily admit, the compression therapy applied to patients in both arms of the study was of “high quality” and would not likely be reproduced in real-world practice. The authors also suggest that, in a real-world, clinical practice, the benefits of early EVA may prove to be even more pronounced because of poor patient compliance with compression. Not sure about that. In fact, if – in a real-world setting – the rate of compliance with compression in both groups turned out to be less than optimal, particularly in the patients who had EVA, the benefits of early ablation with respect to ulcer healing times might disappear.

In other words, we do not know from this study whether there would be the same advantages to early saphenous vein intervention without the addition of compression as compared with compression alone. This might explain why shorter ulcer healing times of EVA have been difficult to prove in non-RCT, more real-world studies. Perhaps a randomized trial comparing ulcer healing times with early EVA without compression versus compression therapy only? Hmmm.

Also, would the outcomes of the current study be similar on this side of the pond? Only 31.7% of limbs were treated with endothermal ablation only, by far the most common form of ablation performed in the United States. Almost 65% of limbs in the study were ablated with either foamed sclerotherapy alone or in conjunction with endothermal or mechanical modalities – not a common form of treatment here in the colonies. Inexplicably, the authors do not indicate whether outcomes were in any way influenced by the type of ablation performed. I am going to assume for now that it did not.

In summary, this study does not answer all the questions related to the use of EVA for the treatment of venous ulcers, but it comes pretty close. My takeaway is that there is no downside (or none that I can think of) to the use of EVA early on in the treatment of venous ulcers but a whole lot of potential upside for the patient. Now I, and probably you, have proof that what we were already doing really does have some increased benefit. Finally!
Endovascular interventions associated with large benefits in peripheral artery disease

BY TED BOSWORTH
MDEDGE NEWS
REPORTING FROM CRT 2018

WASHINGTON – An all-comer observational study associated endovascular treatment of lower-limb peripheral artery disease (PAD) with low event rates and substantial improvements in quality of life at 18 months, even in Rutherford stage 6 patients.

Although the proportion of patients with Rutherford stage 6 PAD was relatively small, the study results showed that peripheral vascular intervention “can be successful in this patient population as evidenced by a high freedom from major amputation,” reported William Gray, MD, system chief of the division of cardiovascular disease at the Lankenau Heart Group, Wynnewood, Pa., at CRT 2018, sponsored by the Cardiovascular Research Institute at Washington Hospital Center.

After 18 months of follow-up in the LIBERTY 360 study, 82% of patients with Rutherford stage 6 disease, which is the most severe stage of PAD, were free from major amputation. The figure for a combined endpoint of freedom from amputation and death was 64%. The mortality at 18 months in the Rutherford stage 6 patients, reflective of a very high-risk population, was 24%.

“Many of the patients in this trial, particularly the Rutherford 6 patients, would never be included in the pivotal trial for endovascular devices,” Dr. Gray said. He called this “a unique study” in that it had almost no exclusions.

The study enrolled 1,204 patients with peripheral artery disease at 51 participating sites. After 18 months, follow-up data were available on 793 patients. These were divided by Rutherford classifications into three groups: 374 patients in the combined Rutherford 2 and 3 classifications (R2/3); 371 in the combined Rutherford 4 and 5 classifications (R4/5); and 48 in the Rutherford 6 classification (R6). Patients treated with any Food and Drug Administration–approved technology for treatment of claudication and critical limb ischemia for PAD were eligible.

The endpoints considered at 18 months included procedural and lesion success, major adverse events, and quality of life. Four core laboratories were responsible for an independent analysis of outcomes. A follow-up of 5 years is planned and will include an economic analysis.

The procedural success rates were 84.4% for the R2/3 group, 76.9% for the R4/5 group, and 70.2% for the R6 group. Almost all of those in the R2/3 and R4/5 groups were discharged immediately after treatment. In the R6 group, approximately 25% of patients were held for complications or additional care.

At 18 months of follow-up, freedom from major adverse events – defined as death, major amputation, or a target vessel revascularization – was achieved by 76.9% of those in the R2/3 group, 68.2% of those in the R4/5 group, and 52.8% of those in the R6 group. The analysis also looked at specific events: The rates for freedom from amputation were 99.3%, 93.3%, and 81.7% in the R2/3, R4/5, and R6 groups, respectively; the freedom from death was 93.9%, 85.5%, and 76.2%; and the freedom from target vessel revascularization was 77.5%, 70.6%, and 65.7%.

Those in R2/3 maintained the improvement in Rutherford classification observed at 30 days for the subsequent 12 months. Those in R2/3 and R4/5 showed continued improvement in Rutherford classification. For example, R4 represented approximately 90% of the patients in R3/4 classification at baseline but less than 20% of this group at 18 months.

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DVT AND PULMONARY EMBOLISM

Many VTE patients live in fear of the next event

BY DOUG BRUNK
MDEdge NEWS
REPORTING FROM THSNA 2018

SAN DIEGO – An estimated 41% of patients who experienced a venous thromboembolism (VTE) fear another clot often or almost all the time. In addition, about 25% report abnormal levels of anxiety, and 12% have abnormal depression scores.

Those are key findings from a large survey that set out to estimate the number of bleeding harms and emotional harms experienced by a U.S. population of adults who have experienced a VTE.

“There is emerging research in Europe that shows high levels of stress and anxiety in people who have a thrombosis event,” lead study author Michael Feehan, PhD, said in an interview at the biennial summit of the Thrombosis & Hemostasis Societies of North America. “We interviewed people around the country and found that a lot of them were living with fear, anxiety, and distress. We did a projective exercise and asked, ‘If VTE was an animal, what would it be?’ Many responded with snakes and bears, hostile things. Snakes came up a lot. Snakes can be dormant, and then they can suddenly come out and bite you. That was the kind of language they were using.”

In what he said is the largest study of its kind, Dr. Feehan, a psychologist in the College of Pharmacy at the University of Utah, Salt Lake City, and his associates conducted an online survey of 907 patients aged 18 and older who had experienced a VTE event in the previous 24 months.

The survey was administered in May 2016 and excluded patients with cancer-related VTE. It took about 30 minutes to complete and included questions about the bleeding harms that have occurred since their VTE diagnosis, such as nosebleeds or a cut difficult to control, excessive bruising, vomiting blood, bloody urine, and blood in stools. It also included

VTE continued on page 9

Interventions from page 7

The change in Rutherford classification was reflected in quality of life (QOL) analyses. As far as total QOL scores, the R6 group, which had lower scores at baseline, was no longer significantly different at 18 months from the R4/5 group. On the pain subdomain QOL score, which was incrementally worse at baseline for increased PAD severity, there were no differences at 18 months after improvements in all groups.

Overall, the LIBERTY 360 study “supports aggressive management” with endovascular procedures in symptomatic patients with PAD. This is important because PAD often is inadequately treated or left untreated, according to Dr. Gray. He cited data suggesting that up to 50% of patients who undergo amputation because of lower limb claudication never even undergo a vascular evaluation.

Although there was no control group to evaluate outcomes in patients not treated or treated with another intervention, such as surgery, Dr. Gray suggested that there are encouraging results in a study that was conducted to enroll patients “with as many confounders as possible.”

Dr. Gray reported financial relationships with Abbott Vascular, Cordis, Medtronic, WL Gore, and a number of other device manufacturers.

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DVT AND PULMONARY EMBOLISM

Few acutely ill hospitalized patients receive VTE prophylaxis

BY DOUG BRUNK
MDEDGE NEWS
REPORTING FROM THSNA 2018

SAN DIEGO – Among patients hospitalized for acute medical illnesses, the risk of venous thromboembolism (VTE) remained elevated 30-40 days after discharge, results from a large analysis of national data showed.

Moreover, only 7% of at-risk patients received VTE prophylaxis in both the inpatient and outpatient setting.

“The results of this real-world study imply that there is a significantly unmet medical need for effective VTE prophylaxis in both the inpatient and outpatient continuum of care among patients hospitalized for acute medical illnesses,” researchers led by Alpesh Amin, MD, wrote in a poster presented at the biennial summit of the Thrombosis & Hemostasis Societies of North America.

 According to Dr. Amin, who chairs the department of medicine at the University of California, Irvine, hospitalized patients with acute medical illnesses face an increased risk for VTE during hospital discharge, mainly within 40 days following hospital admission. However, the treatment patterns of VTE prophylaxis in this patient population have not been well studied in the “real-world” setting. In an effort to improve this area of clinical practice, the researchers used the Marketscan database between Jan. 1, 2012, and June 30, 2015, to identify acutely ill hospitalized patients, such as those with heart failure, respiratory diseases, ischemic stroke, cancer, infectious diseases, and rheumatic diseases.

The key outcomes of interest were the proportion of patients receiving inpatient and outpatient VTE prophylaxis and the proportion of patients with VTE events during and after the index hospitalization. They used Kaplan-Meier analysis to examine the risk for VTE events after the index inpatient admission.

The mean age of the 17,895 patients was 58 years, 55% were female, and most (77%) were from the Southern area of the United States. Their mean Charlson Comorbidity Index score prior to hospitalization was 2.2. Nearly all hospitals (87%) were urban based, nonteaching (95%), and large, with 68% having at least 300 beds. Nearly three-quarters of patients (72%) were hospitalized for infectious and respiratory diseases, and the mean length of stay was 5 days.

Dr. Amin and his associates found that 59% of hospitalized patients did not receive any VTE prophylaxis, while only 7% received prophylaxis in both the inpatient and outpatient continuum of care. At the same time, cumulative VTE rates within 40 days of index admission were highest among patients hospitalized for infectious diseases and cancer (3.4% each), followed by those with heart failure (3.1%), respiratory diseases (2%), ischemic stroke (1.5%), and rheumatic diseases (1.3%). The cumulative VTE event rate for the overall study population within 40 days from index hospitalization was nearly 3%, with 60% of VTE events having occurred within 40 days.

The study was funded by Portola Pharmaceuticals. Dr. Amin reported having no financial disclosures.

SOURCE: Amin A et al. THSNA 2018, Poster 75.

VTE continued from page 8

Exciting Updates Based on Your Feedback:

Physician Wellness — We’ll address the very real issue of burnout and discuss ideas for stress relief and self-care.

Tips & Tricks and Ask the Experts — These interactive sessions offer the chance to engage with the experts.

Online Planner Integrated with New Mobile App — Design a personalized program, then navigate VAM on our new mobile app.

Something for Everyone — Sessions include scientific programs to practical sessions with tips to put in practice, to plenty of chances to interact.

CME for PAs — PAs get an afternoon of programming and also can earn up to 28 AAPA Category 1 CME credits for VAM.

VAM on Demand — Revisit sessions at your own pace, or see those you missed. Only $99 with registration, now through VAM.
PAs Have Own Programming at VAM

Up to 28 AAPA Credits Possible

Physician assistants want to showcase how important PAs are to the vascular team, and learn more about vascular disease and medical management at the same time.

That’s the intent of the afternoon of programming from 1 to 5 p.m. Thursday, June 21, at the Vascular Annual Meeting. “It’s for PAs, by PAs,” said Erin Hanlon, who, with Ricardo Morales co-leads the new PA section of the Society for Vascular Surgery. The section was created in late 2017, and more than 135 PAs have applied to join it.

The PA program theme, “Teamwork & Collaboration,” complements the overall VAM theme of “Home of the Vascular Team – Partners in Patient Care.” The PA programming will include many of the elements of the overall meeting, with panel sessions, abstract presentations and research, said Hanlon. “We told PAs, ‘We want to know what you’re doing, we want to know how other PAs operate,’” she said.

The afternoon includes six sessions:
- Introduction, including the importance of PAs in a vascular surgery practice
- PA Research and Case Presentations
- PAD
- Carotid Artery Disease
- Aortic Disease
- Closing Remarks

The PAD, carotid and aortic sections all include similar elements: medical and surgical management, care coordination and interesting cases, all ending with panel discussions.

Hanlon cited several particular presentations as being of interest, including treating thoracic outlet syndrome, implementing a multidisciplinary team approach for hemodialysis access, innovations in surgical management of vascular surgery (to be led by Sean Gage who is clinical liaison for a biotechnology company) and taking a multidisciplinary team approach to palliative care for the vascular patient.

“We think this is a great refresher course, particularly on medical and surgical management, and a great learning opportunity,” Hanlon said.

The program also offers the chance to meet with others in the field and “build a solid professional network,” she said. “People will be able to see what others are doing and what they may be able to implement in their own practices.”

PAs may receive up to 28 Continuing Medical Education credits from the AAPA for their participation in VAM.

YOUR SVS: June Membership Application Deadline Near

For the first time, prospective members may apply by June 1 to become part of the world’s premier vascular care organization.

The Society for Vascular Surgery switched to a quarterly application system this year, with deadlines on March 1, June 1, Sept. 1 and Dec. 1. Application materials and more information are available at vsweb.org/JoinSVS. Send questions to membership@vascularsociety.org.

SVS includes a new section for physician assistants and also is the management home for the Society for Vascular Nursing. SVN welcomes nurses and nurse practitioners in the vascular setting at many levels and ranges of expertise.

For more information, visit svnet.org.
VASCULAR ANNUAL MEETING:

See You in Beantown!

Boston is my hometown and I can’t wait to show it off at our Vascular Annual Meeting. Come join me there June 20-23 for the preeminent educational and social networking event of the year in vascular surgery. Scientific sessions will be June 21-23 and the Exhibit Hall will be open June 21-22.

All scientific meetings, educational sessions, and exhibits will be at the Hynes Convention Center. Committee meetings, the SVS Board of Directors meeting, and alumni and committee receptions will be held at the Sheraton Boston Hotel, the VAM headquarters hotel. Other hotel options are available. (See vsweb.org/hotels18.) Special room rates were to end May 22, so it’s possible you may need to make your own housing arrangements.

This year’s VAM is all about the vascular team. In fact, that’s the theme: “Home of the Vascular Team – Partners in Patient Care.” There are sessions for the whole team – surgeons, nurses, nurse practitioners, technologists, and physician assistants. We have special programming for PAs on Thursday afternoon, and the Vascular Quality Initiative and the Society for Vascular Nursing are holding their annual initiatives and the Society for Vascular Nursing are holding their annual events for international members, to SVS members, a $300 value – is a mainstay of the Vascular Annual Meeting.

The big question: ‘Who would want to go into vascular surgery today with the uncertainties of tomorrow and how can those already committed remain dominant?’ Dr. Ernst wrote.

Dr. Crawford felt the SVS needed to take a leadership role in this and other questions; he believed the SVS and its members were eminently Crawford continued on page 13

VASCULAR ANNUAL MEETING:

Crawford Forum Celebrates 25 Years

The E. Stanley Crawford Critical Issues Forum – marking 25 years under that name this year – is a mainstay of the Vascular Annual Meeting. But who was E. Stanley Crawford? He was a “cardiovascular surgeon extraordinaire,” according to the late Calvin Ernst, MD, writing after Dr. Crawford’s death in late 1992. Dr. Crawford developed new techniques for treating AAA; was a coinventor of the Baylor (College of Medicine, where he worked from 1956 until his death) Rapid Autologus Transfusion System, a machine that recycles a patient’s red blood cells during surgery; and wrote more than 300 peer-reviewed publications and book chapters. With his son, Dr. John Lloyd Crawford II, he wrote the “Diseases of the Aorta” textbook, which Dr. Ernst called “a standard reference text on aortic surgery.”

Dr. Crawford also helped develop the SVS Forum on Critical Issues, convening the first session during the 1988 VAM. It was decided the forum should address socioeconomic and research issues, as they impact vascular surgery, and be led by that year’s president-elect.

Dr. Ernst said Dr. Crawford believed the vascular surgery specialty had become “increasingly vague, its mission ill-defined, and its future membership uncertain. The big question: ‘Who would want to go into vascular surgery today with the uncertainties of tomorrow and how can those already committed remain dominant?’” Dr. Ernst wrote.

Crawford continued on page 13
With Collaboration the Norm, Fitting For Nurses, Surgeons to Have Meetings in Tandem

It seems fitting, said Tiffany Street, President of the Society for Vascular Nursing, that SVN and SVS have their conferences in the same location and with overlapping times. “It parallels what we do every day in clinical practice,” she said. Recently, we have focused our attention on the emphasis of the clinical vascular care team. Physicians and nurses collaborate daily on the care of vascular patients so collaboration in the learning environment is imperative.

SVN’s 36th Annual Conference, SVN@SVS, will be held June 20 to 21, coinciding with the opening two days of VAM. The SVN conference registration fee permits entrance to VAM, as well.

Both organizations are emphasizing the team approach to vascular care this year, with SVN also stressing vascular education and the holistic approach to vascular patient care, Ms. Street said. An abstract session Thursday will focus on “The Vascular Team Connections,” with two abstract presentations plus a panel discussion on “How Collaboration Changes a Patient.” Speakers include surgeon and SVS President R. Clement Darling III, MD; a physician assistant, Erin Hanlon, PA-PAC; and two nurses, Marie Rossi, BS, RN, and Karen Fitzgerald, MSN, RN, NP.

The team approach is vitally important, Ms. Street said. “Vascular nursing is responsible for the care of the patient across the continuum in collaboration with the surgeon,” she said. Undergoing a surgical procedure affects not only the patient but also the patient’s family, she pointed out. “Because the family support system is vital to good postoperative outcomes, vascular nurses support the family as well.” Nurses cover with the patient and family what they all might expect during the patient’s recovery, helping them think through the various issues and how best to manage them, she said. “It’s all part of the team approach.”

Abstract sessions at SVN@SVS will focus on CLI, AAA, carotid artery, PAD, venous and arterial compression, and vascular team connections. Concurrent sessions will target both the novice and experienced nurse, plus include other emphases, as well. Several SVS members will be presenters at SVN sessions.

The keynote address will cover the care of patients from the Boston Marathon bombing in 2013. Jonathan Gates, MD, who was Medical Director of Trauma Services at Brigham and Women’s Hospital at the time of the bombing and operated on bombing victims that day, will present the address.

Other sessions at the Vascular Annual Meeting also stress the vascular team and patient benefits, including “Team Forum: Improving Metrics in Clinical Practice,” from 1:30 to 3 p.m. Friday. Nurses are sure to find topics of interest at VAM, said Dr. Darling. “I find the team approach integral to optimal patient outcomes,” he said. “I could not be happier at including all members of the team at this year’s VAM, from the special programming for physician assistants on Thursday afternoon to SVN@SVS.

“When we work together,” he said, “everyone benefits, especially the patient.”

Visit vsweb.org/SVN18conference or the VAM Planner (vsweb.org/VAMPlanner) for the complete schedule and more information. vc

Dear VESS Members and Attendees: Welcome to Spring Meeting

On the advent of this year’s Society for Vascular Surgery’s (SVS) Vascular Annual Meeting (VAM), I would like to welcome you to the 2018 annual spring meeting for VESS, which convenes in conjunction with VAM on June 20 at the Hynes Convention Center in Boston. Our Wednesday program looks very diverse and outstanding, covering key topics in aortic and branch aortic, cerebrovascular, lower extremity, venous disease, hemodialysis, physician wellness/burnout, academic issues, and the medical management of vascular disease. Thank you to Matthew Smeds and the rest of the program committee for putting together such an engaging lineup for this year’s spring meeting! I would also encourage you to visit our industry sponsors for this event; exhibits will be available for perusal June 21-22 within the convention center. Finally, we will be cosponsoring an event Thursday, June 21, at 7 p.m. in the Independence West Room of the Sheraton Hotel as a Networking Reception for Women, Diversity, and Young Surgeons. All residents and students are invited to attend this networking reception hosted by SVS and VESS. Thanks also to the SVS for hosting this meeting and for the ongoing collaboration we have enjoyed between our societies.

VESS members and leadership have continued to elevate the practice of vascular surgery and the research that has defined it. The more than 40-year history of this society is well outlined by Dr. Vik Kashyap in J Vasc Surg 2014;60(4):1123-4. VESS remains focused on engaging vascular trainees and vascular surgeons within a framework of collegial academic excellence. We continue to support research through grant funding at both the trainee and young investigator levels, and our presenters at both the spring VESS/VAM and Winter Annual Meetings enjoy a very high acceptance rate for publication of their findings. For more information about VESS, just visit vsurgery.org. The leadership for this society is proud of what it stands for. We are committed to exploring relevant and educational topics in vascular surgery. We hope this year’s spring meeting enhances your understanding and practice of vascular surgery. See you June 20th! vc

Jon Elason, MD
VESS President
### 2018 Vascular Annual Meeting Exhibitors

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### VAM 2018 – B9: Ways All Practices Can Incorporate Research

**What?** By? How? What if ...? Whether considering the prevention, diagnosis, or treatment of vascular disease, vascular surgeons across practice settings are well acquainted with a wealth of unanswered questions.

**A session at the Vascular Annual Meeting can help busy surgeons, even in settings not devoted primarily to research, find ways to incorporate research into their practice and help answer these critical questions.**

Attendees can explore the possibilities at “Research for the Busy Clinician in the Modern Era – Participation, Contribution, Collaboration,” set for 8 a.m. Saturday. Moderators from the SVS Research and Education Committee, Edith Tzeng, MD, and Karen Ho, MD, will lead the session focusing on how busy clinical vascular surgeons can contribute to research even without serving as a principal investigator – by collaborating with basic scientists and engineers, being a source of patient and human tissues and by conducting clinical trials.

**Research Benefits When Clinicians Participate**

Vascular research benefits when clinicians get involved, said Dr. Tzeng. In fact, some investigations can’t get off the ground without assistance from vascular surgeons outside the research community.

“Researchers who perform investigations into human disease don’t always have access to patients or patient tissues or even a clear understanding of how clinicians treat the disease,” said Dr. Tzeng. “This session targets clinicians who have interest in being involved in research but lack formal research experience.”

**Research continued on page 14**

### Three Event Favorites Have Been Moved to Saturday

**F**rom the opening postgraduate courses on Wednesday morning to the RPVI exam review course and the Championship Round of the Poster Competition on Saturday afternoon, the 2018 Vascular Annual Meeting is chock-full of interesting and informative sessions.

To answer members’ requests to spread sessions out through all four days, three events that formerly were held Thursday will take place Saturday morning instead:

- **The John Homans Lecture**, 9:30 to 10 a.m., given by Hazim Safi, MD.
- **The Awards Ceremony**, including the SVS Lifetime Achievement Award Ceremony, naming this year’s award recipient, 10 to 10:15 a.m.

Who will it be? Come to the ceremony to find out.

- **The Roy Greenberg Distinguished Lecturer**, 10:15 to 10:45 a.m., presented by Kenneth Ouriel, MD. He will discuss “Imaging in Two, Three and Four Dimensions: A Common Trait of the Successful Medical Device Innovator.”
- **The Crawford Forum**, continued from page 11

**Crawford continued from page 11**

Qualified to do so successfully.

After his death, the SVS Executive Council unanimously agreed to rename the Critical Issues Forum for Dr. Crawford. The first such named forum was held 25 years ago, at the 1993 VAM.

This year’s Crawford Forum will focus on the vascular surgery workforce, addressing challenges and solutions. President-Elect Michel S. Makaroun, MD, who spearheaded a survey of SVS members on workforce data in late December 2017, will moderate. **vc**
Wednesday Workshops Address Variety of Important Issues

The first day of the 2018 Vascular Annual Meeting is jam-packed from beginning to end with a wide variety of educational opportunities. Among them are workshops, 90-minute sessions designed to impart practical information on important issues facing vascular surgeons and other care providers of patients with vascular diseases.

Workshops are $100 each, over and above the VAM fee. Workshops are non-CME events. Tickets are available via online registration or at the on-site registration counter.

VAM 2018 will offer nine workshops on a wide variety of topics, in three time periods.

8 to 9:30 a.m.
• W1: ZFEN Sizing: Best Practices
• W2: Mastering Pedal Access. Short case presentations will be followed by small-group sessions in which leaders in the field will review tips and tricks for successful pedal access.

10:30 a.m. to 12 p.m.
• W4: Technical Skills for TEVAR in Type B Dissections, covering key points; topics will include appropriate sizing, use of IVUS, centerline imaging and managing difficult landing zones. Participants will be able to use hands-on simulators.
• W5: TransCarotid Artery Revascularization. This is an introduction to the TCAR procedure, including the physiologic rationale for it, instruction on proper procedural technique and hands-on utilization of the treatment device. The workshop will also include discussion on practice development and financial aspects of the procedure.
• W6: Hemodialysis Access Declot: Open and Percutaneous Techniques, reviewing methods for both open and percutaneous access declotting, with step-by-step instructions. Interesting cases will be presented, as will the troubleshooting of difficult ones.

1:30 to 3 p.m.
• W7: Treatment Options to Revolve Type II Endoleaks, designed to familiarize attendees with the approach and embolization materials currently available. The selection of best options for particular anatomy will be presented.
• W8: Mastering the Art of Crossing Tibial CTO, concentrating on methods and techniques for recanalization of tibial occlusions. The workshop will cover interesting cases, treatment options, and troubleshooting complications.
• W9: How to Do a Complete Venous Ultrasound Exam, covering goals, indications, imaging, diagnostic criteria, and ultrasound-guided treatments. Visit the VAM Planner site (vsweb.org/VAMPlanner) to obtain more information on the agendas, presenters and moderators. VC

Sean Roddy, MD, will discuss coding and billing in a workshop during the 2018 Vascular Annual Meeting.

Research

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training or do not have protected time to invest in research effort. They may be asking ‘How can I contribute without having to put in a big effort or have training as a researcher?’”

Session presenters are all surgeon-scientists with extensive teaching, research, and clinical experience. They will share their viewpoints on opportunities to engage in research, followed by open discussion and an opportunity to network with colleagues.

• Omaida Velazquez, MD, Chair of the Department of Surgery at the University of Miami, and Surgeon-in-Chief for the University’s health system, will speak on “Building and Maintaining a Passion for Research as a Busy Clinician.”
• C. Keith Ozaki, MD, Director of Vascular Surgery Research at Brigham and Women’s Hospital, and Professor of Surgery at Harvard Medical School, will address “Developing and Sustaining Collaborations with Basic Science Researchers.”
• Michael P. Murphy, MD, Associate Professor of Surgery at Indiana University School of Medicine, will share his views on “Supporting Translation by Initiating and Participating in Clinical Trials.”

Contributing to Better Patient Care

Ultimately, Dr. Tzeng explained, the session aims to harness vascular surgeons’ collective interest in medical science to advance patient care. “Everybody’s curious,” she said. “Knowing how to channel that curiosity is something else. Everybody has an interest in helping our patients, and if they are given the opportunity to contribute to helping to understand disease and develop treatments, they will. It’s about contributing.” VC
VAM 2018 – B8: New Drug Therapies Available

A recently published research findings attest, drug therapies for medically managed vascular patients are changing quickly, and for the better. Clinical care team members attending next month’s Vascular Annual Meeting will have an opportunity to go beyond journal articles and hear directly from some of the top experts responsible for these advances.

The session, “DOACs, PCSK9 Inhibitors and New Anti-Platelet Agents: What Every Vascular Surgeon Needs to Know,” is sponsored jointly by SVS and the Society for Vascular Medicine (SVM). It will be a primer on new options for medical management of common vascular conditions. Participants at the Friday 6:30 a.m. breakfast session will learn about new evidence-based protocols and how to implement them in daily clinical practice.

Sharing Clinical Experience That Is Grounded in Research

Session moderators are two clinician scientists at the University of Michigan, Ann Arbor, an institution known for its commitment to integrated medicine. Representing SVM is James Froehlich, MD, MPH, an SVM Past President and Clinical Professor of Cardiovascular Medicine at the university. He is widely known for his research on anticoagulants. Representing SVS is Katherine Gallagher, MD, an Associate Professor of Vascular Surgery at the University of Michigan whose research focuses on diabetic wound-healing and PAD. Both moderators maintain busy clinical practices.

“Medical management of vascular disease has continued to evolve, vascular surgery and cardiology have become more integrated, especially here at Michigan,” Dr. Gallagher said. “From a patient-care perspective, having both groups involved significantly improves the quality of care. There’s no doubt that current trends and current literature support integrated medical management for patients with vascular disease.”

Panelists, too, reflect both cardiology and vascular surgery specialties as well as the translational perspective of hands-on clinician scientists who are advancing medical management therapies for patients with vascular and cardiac disease.

• Dr. Froehlich will share emerging protocols for “Peri-Procedural Anticoagulation (Bridging) and Emergency Reversal of DOACs.”

• Marc Bonaca, MD, MPH, of Brigham and Women’s Hospital in Boston and Assistant Professor at Harvard Medical School, will speak on “State-of-the-Art Lipid Management for the Cardiovascular Patient – What a Vascular Surgeon Needs to Know.”

• Andrea Obi, MD, Assistant Professor of Vascular Surgery at the University of Michigan, will address “DOACs in the Vascular Patient Population and Their Effect on Graft/Stent Patency.”

Dr. Gallagher said panelists will emphasize practical considerations important for anyone who cares for vascular patients.

“There’s been a shift over the last 5-10 years in medical management,” she said. “This session will offer an update on what is the current standard of care. … I think it will be very important information, whether you’re in an academic institution, a hospital setting, or in a solo private practice. Everybody is running into the same questions.”

VQI@VAM Builds on Past Success

The SVS Vascular Quality Initiative’s third Annual Meeting continues to build upon the successes of the past 2 years.

VQI@VAM, held in conjunction with the SVS Vascular Annual Meeting, will be all day Wednesday, June 20, and the morning of Thursday, June 21, with educational opportunities spanning the breadth of the VQI registries. A separate registration fee of $250 is required.

“It’s getting better and better. All the changes we make from year to year are based directly on participant feedback,” said Jens Eldrup-Jorgensen, MD, SVM VQI’s Medical Director.

The Annual Meeting is designed for physicians, nurses, data managers, quality improvement professionals and administrators. It will continue to focus on providing practical information, in the form of case studies and best practices, to help VQI members utilize their registry data to initiate quality improvement projects. “The projects, in turn, can drive better patient outcomes,” said Dr. Eldrup-Jorgensen.

New for 2018 are:

• Concurrent sessions Thursday morning, to focus on abstraction issues, based on recent Inter-Rater Reliability audit findings
• Abstraction-specific sessions to start each morning
• Quality Initiative networking for the last 30 minutes of the Poster Session and Networking Reception, to share experiences on the QI process
• The opportunity to meet with the VQI’s director of analytics, to discuss your site’s VQI reports
• “Ask the Expert” roundtables on Thursday morning, focusing on hemodialysis access, open AAA, varicose veins/inferior vena cava, and TCAR

Overall, the meeting aims to present information that helps vascular team members better extract data for registries and then understand and analyze that data to implement quality improvement initiatives, said Dr. Eldrup-Jorgensen. Presenters will also highlight new and innovative ways data are being used in research and quality improvement.

“We’ll be building on several new sessions that were introduced in 2017: expanding sessions specifically dealing with case abstraction for our hospital data managers,” he said. While frequently nurses do the abstraction of data, physicians also abstract data or must write operative notes to aid in that data abstraction.

Wednesday morning’s sessions will focus on how the care team can analyze VQI data to initiate quality improvement projects. Afternoon sessions will cover case studies, programmatic updates, and research presentations derived from VQI datasets. The Poster Session and Networking Reception – added last year and a big hit – end the day.

Thursday’s sessions (8 a.m. to 12 p.m.) will focus on case abstraction for difficult cases, using information derived from Inter-Rater Reliability audits conducted earlier this year and the “experts” roundtables.

Other sessions of note include:

• An update on the Vascular Ultrasound Registry Pilot Project, 1 to 1:15 p.m. Wednesday
• “Coordination of SVS Clinical Practice Guidelines and VQI, 2:30 to 3 p.m. Wednesday, presented by Thomas Forbes, MD, and Larry Kraiss, MD
• The SVS VQI TransCarotid Revascularization Project, 3 to 3:30 p.m. Wednesday

For more information, visit vsweb.org/VQI18.
Earn CME, MOC Credits at VAM
PAs, Nurse Practitioners and Nurses Also Can Earn Credits

Beyond learning what’s new in the world of vascular surgery, physician registrants can get a big boost in collecting required credits, by earning both Continuing Medical Education credits and Maintenance of Certification Part 2 Lifelong Learning and Self-Assessment credits.

The Society for Vascular Surgery is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SVS has designated the 2018 Vascular Annual Meeting for a maximum of 31.75 AMA PRA Category 1 Credits™. Physicians should claim only the credits commensurate with the extent of their participation in the activity. Full credit cannot be issued for attendance at two sessions occurring simultaneously. Of the 31.75 credits, 12.75 AMA PRA Category 1 credits™ meet the requirements for American Board of Surgery MOC Part 2 self-assessment. To claim MOC credits, physicians must attend a session and then complete the appropriate self-assessment exam with a passing score of at least 75 percent. Participants will be able to claim credits and access the MOC exams via the VAM mobile app and a link on the SVS and VAM planner websites.

Participants can claim credits beginning Wednesday, June 20. Credits must be claimed by Dec. 31, 2018. Separate certificates are issued for postgraduate courses, the Registered Physician Vascular Interpretation exam course and for VAM itself, depending on session participation. The accompanying chart provides information on which sessions offer what credits.

PAs, Nurses Can Also Get Credits
Physician Assistants: The Vascular Annual Meeting has been reviewed and is approved for a maximum of 28 American Academy of Physician Assistants Category 1 CME credits by the AAPA Review Panel. PAs should claim only those credits for time spent participating in the CME activity. This activity was planned in accordance with AAPA CME Standards for Live Programs and for Commercial Support of Life Programs. PAs who attend Thursday’s afternoon of programming can earn an additional 3.75 credits.

Physicians: SVS has designated the 2018 Vascular Annual Meeting for a maximum of 28 American Academy of Physician Assistants Category 1 CME credits by the AAPA Review Panel. Physicians should claim only the credits commensurate with the extent of their participation in the activity. Full credit cannot be issued for attendance at two sessions occurring simultaneously. Of the 31.75 credits, 12.75 AMA PRA Category 1 Credits™ meet the requirements for American Board of Surgery MOC Part 2 self-assessment. To claim MOC credits, physicians must attend a session and then complete the appropriate self-assessment exam with a passing score of at least 75 percent. Participants will be able to claim credits and access the MOC exams via the VAM mobile app and a link on the SVS and VAM planner websites.

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VAM on Demand: Take VAM Home For a Year
Throughout the Vascular Annual Meeting, attendees face tough choices: Attend the postgraduate course on managing the diabetic foot or treating acute pulmonary embolism and developing a PERT – Pulmonary Embolism Response Team? Nine workshops beckon Wednesday, but each is held simultaneously with two others.

On Thursday, will it be a scientific session, or a chance to talk with expert Daniel Clair, MD, about aortic care for occlusive disease? There’s even a third option at that time: "Lifelong Learning: MOC for the Vascular Surgeon in the 21st Century."

This situation is repeated throughout VAM. There’s simply no way for any one participant to be able to view every session he or she would like to.

VAM on Demand is the solution to the problem of too many sessions and not enough time. This electronic reference includes audio and slide presentations of hundreds of VAM sessions, with videos of a select few. It lets people perform the trick of being in two places at one time.

People can watch the sessions they missed but wanted to see. Or they can watch one again. It lets you relive and review VAM at your own pace,” SVS President R. Clement Darling III, MD, said. This invaluable tool is just $99 through the close of VAM. Purchase it while registering (those who have already registered can revise their registration to add it) or at the Registration Counter, Level 2, Exhibit Hall C, Foyer, at the Hynes Convention Center during the meeting itself. After VAM closes, the price jumps to $199 for attendees and $499 for nonattendees. VAM on Demand provides no education credits.

VAM on Demand: Extend your learning – and take VAM home with you. vc
NEWS FROM SVS

IN JVS:
National Trends in AAA Repair

Open AAA repairs fell almost 80 percent from 2003 to 2013, indicating that the technique is performed too infrequently to be used to assess, properly, hospital and surgeon quality in cardiovascular repair. The trends analysis is published in the June Journal of Vascular Surgery. Researchers concluded that surgical training will need to “… ensure that surgeons and interventionists can safely perform these high-risk surgical procedures.” The story is available free through July 31 at vsweb.org/JVS-Trends.

SPOTLIGHT ON LEADERSHIP:
Interview with Dr. Vivian Gahtan

BY MELISSA KIRKWOOD, MD
ON BEHALF OF THE LEADERSHIP DEVELOPMENT AND DIVERSITY COMMITTEE

Encouraging the heart: Why communication skills and professionalism are such critical skills to learn early in a career.

I had the privilege of interviewing Dr. Vivian Gahtan, professor and chief of vascular surgery at SUNY (the State University of New York) Upstate Medical University College of Medicine in New York. Dr. Gahtan is a leader in the field of vascular surgery and role model to many, as she is the first woman to preside as Chair of the Vascular Surgery Board of the American Board of Surgery and serve as President of the Eastern Vascular Society. Despite all of these accomplishments she manages a NIH ROI-funded research laboratory focused on the role of the thrombospondins in intimal hyperplasia. Dr. Gahtan has been awarded 23 research grants and has mentored 18 trainee grant awards. She has co-authored 85 peer-reviewed journal articles and over 35 book chapters and reviews. In addition to her successful research career she is recognized as a stellar clinician and has participated in several clinical trials, including serving as co-investigator for the BEST-CLI trial. Dr. Gahtan is an inspiration to me as well as to many others, and it was a true pleasure to be able to interview her.

Q: What are some of the most important attributes a leader should possess?
A good leader is fair and inclusive. It is important to provide an avenue for others to have an opportunity to get involved so that the entire group is represented, not just your close circle of colleagues. That is why as Chair of the Vascular Surgery Board, the process of requesting volunteers to participate in question-writing and review for the certifying exam was promoted in 2016. This was a great success and we continue on following page

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- Completion of an accredited residency program
- Board certification/eligibility in Vascular Surgery

About Penn State Health St. Joseph
Penn State Health St. Joseph is a two-campus health system located in Berks County, PA, with our acute care hospital in Bern Township on Route 183 and our Downtown Reading campus at 6th and Walnut Streets. We have outpatient locations and physician offices throughout Berks County and beyond.

St. Joseph physicians and staff have worked hard to earn recognition for innovation and high quality of care in various specialties, including our Heart Institute and Chest Pain Center, as well as our thriving Cancer Center which partnered with Penn State Hershey Cancer Institute in 2010. In 2015, St. Joseph became Penn State Health’s first member of the not-for-profit health enterprise.

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Greg Emerick, DASPR, Physician Recruiter
Email: gemerick@pennstatehealth.psu.edu
Phone: 717-531-4725

Penn State Health St. Joseph is committed to affirmative action, equal opportunity and the diversity of its workforce. Equal Opportunity Employer - Minorities/Women/Protected Veterans/Disabled
Leadership
continued from previous page

had more than 100 vascular-surgeon volunteer. This allowed us to involve diplomates who might not otherwise have gotten involved. In addition, a strong leader should exude a calm confidence and have passion for what he or she leads. A strong leader must lead by example and be viewed as part of the team.

Q: Do you have any leadership pearls for up-and-coming vascular surgeons?

It is always important to maintain respectful relationships with everyone you work with even if you do not consider them a friend, because it is the right thing and you never know what the future holds. You never want to lose an opportunity because someone objects to your involvement down the road. Along the same lines if your career path takes you in a different direction, always focus on exiting your current position with grace so no one has a negative memory of you, and you build a positive reputation.

Q: Which leadership skills have been the most difficult to acquire?

Effective communication and listening skills. Listening to all sides of a conflict prior to reacting allows you to really learn what the issues are and it helps you see the conflict from everyone’s perspective. This enables you to effectively diffuse a situation and reach a solution more quickly.

Realizing when to delegate tasks. Tasks that do not require your complete personal attention can often be delegated to other people you trust so that your focus can be on leading your group. This is a difficult skill to learn since, as vascular surgeons, we are often a micromanaging type. A personality group. I know this was a challenging concept for me to embrace.

Consensus building vs. definitive decision-making. A great leader is able to read situations well, remain calm and adaptable and make decisions that are best for the group instead of the individual.

Q: For those on the learning path of leadership, are there one to two practical pieces of advice you can provide that may save them time and discomfort?

Whatever you decide to be involved in, become engaged, stay passionate and contribute greatly to that mission. If you know you don’t have time to fully participate, it is better to say no than to commit and perform poorly.

Apply for key committee opportunities that are in line with your goals, i.e., hospital committees for quality or medical school committees for education. Be viewed as a team player and take opportunities to meet leaders of the institution, particularly outside of your division/department. Don’t be afraid to take risks. Leaving Yale and coming to SUNY Upstate was a risk for me. At the time I was recruited as Division Chief but there were no other faculty in the division and the infrastructure did not exist. I was responsible for building the program and had the support and active participation of my partners. Looking back, I am glad I took that risk because our practice is thriving, we have a group of seven faculty and provide vascular coverage for four hospitals.

Q: As a female leader in the Society for Vascular Surgery what advice do you have for junior female faculty and trainees?

I think my comments apply to both men and women. Determine the direction of your career – education, administration, research, clinical excellence – and start planning early. Have mentors from within your division, department and institution and from the outside – different purposes, different time points. Engage strategically in institutional activities to make sure as an individual you are valued, but not spread too thin. Don’t be afraid to apply for opportunities or to reach out and try to network. Make sure you maintain your commitments. Having the reputation of delivering can take you far in the long run.

Know the rules. Understand the culture of your group so that you can be successful in it. Academically, understand from the beginning institutional policies on promotion and, if relevant, tenure. Based on the goal, over time choose activities that will fulfill those requirements and gain relevant experiences to get to the next step.

DIABETES AND RELATED CONDITIONS
CVD risk high in individuals who once had metabolically healthy obesity

BY ANDREW D. BOWSER
MEDGE NEWS
FROM THE JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Any individuals with metabolically healthy obesity (MHO) will progress to metabolic syndrome over time, putting them at increased risk of cardiovascular disease (CVD), according to results published in the Journal of the American College of Cardiology.

The results provide new evidence that MHO alone is not a stable or reliable characterization of lower CVD risk, according to Morgana Mongraw-Chaffin, PhD, of the department of epidemiology and prevention at Wake Forest University, Winston-Salem, N.C., and her coauthors.

Instead, MHO signals an opportunity for weight reduction, and prevention and management of existing metabolic syndrome components should be prioritized,” Dr. Mongraw-Chaffin and her colleagues wrote.

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Obesity

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Individuals with MHO, defined in this study as a body mass index of 30 kg/m² or greater without metabolic syndrome, have a relatively favorable metabolic profile. However, their precise level of CVD risk remains contentious, the investigators noted.

“Although the accumulating evidence is leaning toward the consensus that MHO is not a low-risk state compared with metabolically healthy normal weight, many questions remain about the risk stratification for this group and what causes the heterogeneity seen in the literature,” they wrote.

In this study, 501 out of 1,051 individuals with MHO at baseline (48%) developed metabolic syndrome over a median follow-up of 12.2 years. Moreover, they then had increased odds of CVD (odds ratio, 1.60; 95% confidence interval, 1.14-2.25), compared with individuals who had stable MHO or normal weight. Duration of metabolic syndrome was linearly associated with CVD risk, with an odds ratio of 0.41 for those with metabolic syndrome at one out of five study visits, 2.19 for metabolic syndrome at two or three visits, and 2.50 for metabolic syndrome at four or five visits, the researchers said.

Those with MHO may experience a lag in risk while they progress to metabolic syndrome and develop the resultant cardiometabolic risk.

The results of this study may explain why some previous meta-analyses found individuals with MHO had increased risk, but only with longer duration of follow-up. “Both transition to metabolic syndrome and longer duration of metabolic syndrome were associated with CVD, indicating that those with MHO may experience a lag in risk while they progress to metabolic syndrome and develop the resultant cardiometabolic risk,” Dr. Mongraw-Chaffin and her colleagues wrote.

The results mean that MHO represents an opportunity for primary prevention of CVD, they added. “Prevention of incident metabolic syndrome and resulting CVD at the population level will necessitate the prevention of obesity,” they explained in a discussion of the results.

Dr. Mongraw-Chaffin and her associates reported that they had no relevant relationships to disclose.


Metabolically healthy obesity not so healthy after all

While obesity has inherent adverse effects on cardiometabolic parameters and cardiovascular disease (CVD) risk factors, metabolically healthy obesity (MHO) has emerged as a categorization of obese individuals who may not be at increased CVD risk because of relatively normal levels of lipids, blood pressure, and glucose.

An increasing body of research, however, including the present study by Dr. Mongraw-Chaffin and colleagues, highlights “dangers and long-term outcomes” of the MHO phenotype, Prakash Deedwania, MD, and Carl J. Lavie, MD, wrote in an editorial.

The analysis of 6,809 individuals in the Multi-Ethic Study of Atherosclerosis found that MHO is not a stable condition, as almost one-half of individuals developed metabolic syndrome over 12.2 years of follow-up, they noted.

Moreover, CVD risk was indeed elevated in these individuals with metabolically unhealthy obesity. “Such population-wide healthy interventions are the only hope of preventing the oncoming tsunami of metabolic syndrome, diabetes, and CVD,” the editorial authors concluded.

PERSPECTIVE by Prakash Deedwania, MD

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