FDA responds to data on increased PAD device mortality risk

BY JEFF CRAVEN
MDEdge News

The Food and Drug Administration has issued a letter alerting health care providers that it is aware of and examining recent data on an increase in long-term mortality rates for patients receiving paclitaxel-coated balloons and paclitaxel-eluting stents for treatment of peripheral artery disease.

“Currently, the FDA believes that the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use,” William Maisel, MD, MPH, chief medical officer of the Center for Devices and Radiological Health at the FDA, wrote in a letter to

See FDA page 7

Newly released criteria aim to advise clinicians about the most appropriate interventions for managing peripheral artery disease.

The report, published in the Journal of the American College of Cardiology, drew on the expertise of a broad panel of experts, including representatives from the American Heart Association, the Society for Cardiovascular Angiography and Interventions, the Society of Interventional Radiology, the Society for Vascular Medicine, and the Society for Vascular Surgery.

“Improvements in the diagnosis of peripheral artery disease (PAD) have led to an increasing number of treatment and revascularization methods, especially endovascular interventions,” wrote Steven R. Bailey, MD, who headed the multidisciplinary writing committee.

“As new and increasingly sophisticated devices are developed,” Bailey wrote, “the need for evidence on which to base treatment recommendations becomes even more urgent.”

See PAD page 8

Gilbert Upchurch Jr., MD, elected SAVS President

Dr. Upchurch, of the University of Florida Heart Health and Vascular Hospital, Gainesville, was elected 2019 president of the Southern Association for Vascular Surgery at their 43rd Annual Meeting held in Boca Raton, Fla., Jan 23-26, succeeding Matthew S. Edwards, MD, of Wake Forest Baptist Health, Winston-Salem, N.C.

Column Continued on page 19
FROM THE EDITOR:
Vascular groups issue call for change

BY MALACHI G. SHEAHAN III, MD
MEDICAL EDITOR, VASCULAR SPECIALIST

Through the 21st-Century Cures Act, Congress directed the Department of Health & Human Services (HHS) to establish a goal, develop a strategy, and provide recommendations to reduce EHR-related burdens that affect care delivery. HHS has now submitted a draft titled “Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.” A call for comments from the public and medical community was issued. The response from the Society for Vascular Surgery is documented at right. The work of the SVS Wellness Task Force shaped the content of this letter. Your remarks and responses to the surveys and focus groups have been heard and are now directing action. At press, the presidents of the Association of Program Directors in Vascular Surgery, the Society for Clinical Vascular Surgery, the Vascular and Endovascular Surgical Society, and all five major regional vascular societies have endorsed the letter.

This document represents a clear and definitive specialty-wide call for change.

SPECIAL COMMUNICATION
SVS groups send comment letter to HHS

January 25, 2019

Seema Verma, Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services

Don Rucker, MD, National Coordinator for Health Information Technology Office of the National Coordinator for Health Information Technology U.S. Department of Health & Human Services

On behalf of the undersigned organizations, we would like to thank you for the efforts of the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) to address the burden regarding the use of health IT and EHRs in a physician’s practice. However, there is still much work to be done, and the Society for Vascular Surgery (SVS) in concert with eight of our fellow societies have developed a set of recommendations regarding future steps that CMS and ONC could take to further address the regulatory and administrative burden of health IT and EHRs. Together, our organizations represent the majority of vascular surgeons in the United States. Today, we take this opportunity to reach out to you with one voice, on these recommendations to address this significant disruption throughout our specialty.

While systems of medical records have been in place for a very long time, only recently have they become the source of widespread physician dissatisfaction. This phenomenon coincides with the mass integration of electronic-based health records over the past decade. Paper-based charts could be completed almost passively, usually during interactions with the patient. Computer-based systems often require the physician to literally turn their back on the patient to complete the documentation in real time. Many physicians eschew this practice in favor of performing the record keeping at some later point in time, after completion of the patient encounter. Multiple studies have confirmed the increased documentation burdens placed on physicians via Electronic Health Record (EHR) integration. This additional time often occurs after regular work hours and comes at the expense of time spent with families, time spent on leisure activities, and even sleep. The result is emotional exhaustion, an essential component of physician burnout.

In 2018, active SVS members were surveyed anonymously using a validated burnout assessment embedded in a questionnaire that also captured demographic and practice-related characteristics. The survey was personalized for the specialty and did allow for free-text. We specifically analyzed emotional exhaustion, a critical dimension of burnout. Responses from 872 practicing vascular surgeons were analyzed. Overall, 30% of respondents met criteria for burnout, 37% screened positive for symptoms of depression in the past month.
An increased mortality risk with paclitaxel DCB, DES?

Dr Schneider is Chief Medical Officer for Intact Vascular; has received modest royalties from Cook Medical; and has served as a noncompensated advisor for Medtronic, Abbott Vascular, and Cardinal. He has published articles regarding the IN.PACT SFA trial 2 and has an upcoming article in discussing this topic further, which will be reported on in next month’s Vascular Specialist.

A recently published meta-analysis concluded that “There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs.”1 The study was an analysis of summary-level data from 28 published or presented trials (4,663 patients) that evaluated the use of drug-coated balloons (DCB) or drug-eluting stents (DES) for the treatment of femoral-popliteal occlusive disease. Mortality was similar at 1 year but was significantly increased at 2 years for paclitaxel versus control (7.2% versus 3.8%), and there was an even larger differential at 5 years (14.7% versus 8.1%). On face value, this is worrisome.

The use of summary-level data to perform meta-analysis is a legitimate form of scientific inquiry. However, this method is typically used to generate hypotheses, which must be subsequently confirmed and is not intended to be used as a definitive answer.

The advantages of summary-level data are clear; it is readily available and it permits use of larger patient cohorts than would otherwise be possible, which may identify a signal that is not otherwise apparent. There are some disadvantages of using summary-level data that can result in bias and possibly incorrect conclusions.

Assumptions have to be made: that the analyzed trials are similar enough to each other to be comparable; that the delivery of paclitaxel was uniform; that censored patients were handled in a certain way in all the studies. The actual dose of paclitaxel cannot be calculated. Missing data must be imputed, since some studies report percentages, rather than numbers of events.

Is it scientifically valid to include studies of DCB and DES in the same meta-analysis, given the dramatic difference in the mechanism of paclitaxel delivery? Is it reasonable to make the assumption that paclitaxel remains present for the length of patient’s follow-up after a single time balloon inflation many years before? These trials were powered to evaluate 1-year parity, not longer-term mortality. We have to take the data for what they are; a signal that we have work to do to better understand if there is any increased risk to our patients.

The conclusion of the meta-analysis focuses on the long-term mortality risk. Only three studies extend to five years; 2 DCB studies and one DES study.2-4 In all three of these studies, longer-term mortality was higher for paclitaxel devices than control. Is this finding a coincidence or a missed safety signal? Because there are only three studies, idiosyncratic features of any of these trials will have an outsized effect on the results of the meta-analysis. Among the DCB trials for example, the IN.PACT SFA Trial randomized DCB to PTA in a 2:1 manner (104 patients in the PTA group), and the subsequent mortality rate for the PTA group in the first three years was the lowest ever reported in a trial of peripheral vascular patients (0%, 0.9%, and 1.9%, respectively).2 The Thunder Trial only randomized 54 patients to PTA and the initial design was for a two-year follow up. When the patients were subsequently followed up at five years, 48% of the PTA group was lost to follow-up.5 No one could have anticipated that these seemingly small things could weigh a meta-analysis in a particular direction many years later. In studies that fully evaluated the causes of mortality, there does not appear to be any clustering of the deaths as to any particular cause. Mortality rates for all of the DCB and DES trials are within the range of that demonstrated in other vascular device trials. No particular mechanistic relationship between paclitaxel and mortality has been proposed. DCB and DES have resulted in a substantial improvement in patency for patients that require femor-popliteal revascularization and have appeared until now to possess an acceptable safety profile.

Beneficial results have been confirmed in numerous trials performed by a myriad of investigators, using a variety of devices over a broad geography. The benefits are substantial, but if there is a safety signal with paclitaxel, we need to understand its magnitude urgently.

Because this is an important issue for our patients and because of a deep desire to do no harm, it cannot be summarily rejected and we owe it aggressive due diligence. Is this a statistical aberration or an important safety signal that must guide subsequent clinical practice? In my opinion, it is not appropriate to draw a firm conclusion at this time.

The mortality risk will be better understood when we have a patient-level data with calculated drug doses and adjudicated mortality from a variety of trials.

References

PAD from page 1

oped, the medical community needs to understand how best to incorporate these technologies into daily clinical decision making and care, and how to choose between new and more established methods. This project was initiated to respond to this need and to ensure the effective use of peripheral artery revascularization.

The document is not intended to cover every possible clinical scenario that could employ these interventions, wrote Dr. Bailey, who is the Janey Britscoe Distinguished Chair in Cardiology at the University of Texas, San Antonio, and his coauthors. “Rather, the goal is to provide generalized guidance into the use of these devices and techniques, while understanding that each clinical situation is unique, with physicians using their best judgment and the available evidence base to craft the most beneficial approach for the patient. In all cases, it is assumed that guideline-directed medical therapy should be applied first.”

The panel identified 45 scenarios in key clinical areas in which PAD interventions – either surgical or endovascular procedures – might be employed as first-line therapy. These included renal artery stenosis, lower extremity disease, critical limb ischemia, and asymptomatic artery disease. The report also discussed options for endovascular interventions, and secondary treatment options for lower extremity disease. The panel graded the value of interventions as appropriate, may be appropriate, or rarely appropriate.

“The scenarios in this document are arranged according to the clinical decision points confronting vascular practitioners in everyday clinical practice.”

Lower extremity disease

Recommendations for lower extremity revascularization in patients with claudication are based largely on the 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease. For patients with PAD and intermittent claudication, medical therapy and exercise are the first-line treatments. Revascularization should be considered only when this option fails. The appropriateness of intervention depends on the location and length of the lesion.

Intensification of medical therapy or endovascular treatment are appropriate for patients with aortoiliac, superficial femoral artery, and popliteal artery lesions; surgery also may be appropriate here. Medical therapy is appropriate for lesions located below the knee, as well; endovascular approaches also may be appropriate. Surgery for these lesions is rarely appropriate.

Critical limb ischemia

Medical therapy is generally not considered for these patients. But regardless of the lesion location, the panel found either endovascular or surgical treatment appropriate. Indeed, revascularization is the only viable treatment for these patients.

“Revascularization, whether endovascular or surgical, is critical for the reduction of high morbidity and mortality rates associated with limb loss. Mortality rates have been reported to be as high as 20% within 6 months of diagnosis and exceeding 50% after 5 years in patients left untreated. Furthermore, this degree of PAD is commonly associated with excessive cardiovascular events, often surpassing mortality rates associated with even symptomatic coronary artery disease.”

Asymptomatic artery disease

The recommendations in this category address the need to gain arterial access for potentially life-saving cardiovascular procedures. There are no published data in this area, so the recommendations are all based on expert opinion.

To gain access for coronary interventions, endovascular treatment and surgery are both appropriate. For hemodynamic support and large vascular or valvular interventions, endovascular approaches are appropriate, and surgical approaches may be appropriate.

Options for endovascular treatment when deemed appropriate or may be appropriate

Since there is no standardized treatment when an intervention is deemed appropriate, the potential procedures are organized by general lesion location (above or below the inguinal ligament and below the knee), and by lesion length. The recommendations cover the most commonly used endovascular treatment modalities.

“Of note, the use of atherectomy in the iliac artery has been rated Rarely Appropriate in all clinical scenarios,” the team noted. “This rating derives from an absence of data supporting the use of this technology, compared with balloon angioplasty and stenting. Similarly, the use of atherectomy in the superficial femoral and popliteal arteries and below-the-knee vessels also received a lower score, again because of the lack of comparative data relative to technologies with prospectively collected data. The evidence base to judge intervention below the knees is not as developed as other lower-extremity locations, which results in more frequent use of the May Be Appropriate category. The rating panel felt that below-the-knee atherectomy once again lacked comparative evidence to support general use.”

There are some exceptions, “favoring atherectomy include severe calcification and undilatable lesions; however, other technologies had a better evidence base for routine revascularization in most settings.”

Secondary treatment options

This section addresses options for very specific situations, including in-stent restenosis, venous bypass graft failure, and prosthetic bypass graft failure.

“It is recognized that the need for revascularization of a failing conduit, graft, or stent is a marker of adverse outcomes for all of the reparative modalities employed,” the panel wrote. “Literature comparing treatment modalities for in-stent stenosis, venous graft failures, and arterial graft failures is very limited. Therefore, the recommendations primarily reflect consensus based upon current clinical practice.”

The modality choice should probably depend more upon surgeon preference and clinical experience, rather than a blanket recommendation. In general, the panel felt that surgical revascularizations are rarely appropriate for in-stent stenosis, especially if the patient is asymptomatic.

The panel felt that endovascular approaches are generally appropriate for focal stenoses in patients with prior surgical grafts and bioprosthetic material, but in patients with diffused stenosis or thrombosed grafts, both endovascular and surgical approaches were graded as may be appropriate.

“The specific type of therapy [de- vice or surgical procedure] is at the discretion of the clinician, dictated by the clinical scenario plus physician and facility experience.”

Dr. Bailey had no financial disclosures; however, some members of the panel did disclose relationships with device manufacturers and pharmaceutical companies.


Check out the latest vascular news at MDedge.com/VascularSpecialistOnline
Osteomyelitis amputation tied to comorbidities

BY M. ALEXANDER OTTO
MDEDGE NEWS
REPORTING FROM THE 2018 ACS CLINICAL CONGRESS

BOSTON – The higher the comorbidity burden, the greater the likelihood that osteomyelitis will lead to amputation within 2 years, according to a review of 1,186 patients at the University of Michigan, Ann Arbor.

The limb amputation incidence was 7.2% over 2 years in patients with no comorbidities, 21.4% among patients with heart failure, 36.1% in patients with diabetes, and 36.7% among those with peripheral vascular disease (PVD).

The 2-year incidence marched steadily upward with combined comorbidities to 47.4% in patients with diabetes and heart failure; 64.5% in patients with diabetes and PVD; and 75.0% in patients with diabetes, heart failure, and PVD.

“What this means is that looking at diabetes versus no diabetes alone is not sufficient to gauge the risk of amputation. We have to look at the patient’s comorbidity profile as a whole,” said lead investigator Toby Keeney-Bonthrone, a medical student.

“The question is if some patients would benefit from [an earlier,] more prophylactic amputation,” he said at the annual clinical congress of the American College of Surgeons.

“We often find ourselves reacting to osteomyelitis as it progresses. I think patients deserve a better deal than that. They deserve for us to think one or two steps ahead,” he added.

The team reviewed adult patients from 2004 to 2015 who were followed for at least 2 years after diagnosis; 610 had diabetes, a known risk factor for osteomyelitis and amputation, and 576 did not.

Comorbidities were considerably more common in the diabetes group, including PVD and heart failure, but also chronic obstructive pulmonary disease, previous heart attack, prior amputation, and especially renal disease. The 2-year amputation incidence was also higher in the diabetes group (43.1% vs. 12.3%), as was 2-year mortality (22.3% vs. 15.5%).

Odds ratios for lower limb amputation climbed in a stepwise fashion on multivariate analysis, from almost a 100% increase in men and in black patients to a 158% increase among patients with past amputations; a 206% increase with PVD; a 256% increase in patients with type 2 diabetes, and a 349% increase among patients with type 1 diabetes.

The work was funded by the NIH.

Physician burnout: It’s good to complain

COMMENTARY

BY DONALD L. ZIMMERMAN, PHD

Burnout among vascular surgeons and other physicians is a serious national epidemic that needs immediate attention by senior policy makers and health care leaders. Not only is maintaining an appropriate supply of fully qualified surgeons important to the medical demands of our country, the underlying causes of physician burnout clearly point to increased personal pain and suffering within the physician community.

While it is quite clear that a serious response to physician burnout requires immediate action, the most pressing and urgent question for senior leadership is exactly what can be done to best address the causes of this epidemic.

This commentary reflects an approach and strategy for building an effective response to physician burnout deeply rooted in the broad discipline of health care management theory and research. Our understanding of the problem starts with the simple and common observation that our thoughts about our job are deeply embedded in the conditions and “lived reality” of doing our job. We can see this link in everyday conversations when they quickly turn to detailed complaints about all things work related.

Listening to people complain about their jobs can sometimes sound like unfounded “whining.” But if we dig deeper into such complaints, we can start to see some common elements giving credence to such grievances. For example, if we step back a little from our current preoccupations and look at the history of work over the last 100 years or so, we can see the outline of a long and generally progressive arc of change aimed at improving the conditions for making a living.

This arc of change has allowed us to stop complaining so much about the risk of losing life and limb from industrial accidents because those complaints helped to create new laws that imposed strict regulations, making the conditions of working with big machines much safer. From the 40-hour week, paid vacations, and tenure to workplace discrimination, harassment, and abuse, there are many examples of how complaining about the conditions of one’s job has led to major changes in how people work together in an organization.

Coming back to the present, the big, clamoring machines that caused many to complain years ago have now been replaced by the clicking and hum of computers used by knowledge-based workers. But while the tools, physical environment, workforce, and other key characteristics of what people do for a living change over time, serious complaints about job conditions remain important sources of information about how to make those conditions job safer and healthier.

The importance of complaining

One of the primary goals of every health care organization should be to consciously create safe and healthy working conditions for physicians and everyone else involved in the daily production of health care services.

At present, there is considerable interest in developing new programs for addressing physician burnout by using therapeutic interventions. This approach is focused on mediating the severity of an unhealthy workplace by helping physicians better cope with personal frustrations and other psychological difficulties related to their job.

Personal counseling, yoga at noon, and other tools for building personal resilience can certainly improve coping skills but fundamentally miss the point of addressing the underlying causes for burnout.

The problem here is that a reliance on therapeutic interventions alone can mask and reflect the cause of the problem from their source in the conditions of the workplace back onto the physicians who must do their job under those conditions. This is roughly equivalent to providing therapeutic counseling to a factory worker who loses an arm to a machine in an industrial accident with no mention or effort to fix the dangerous machine that workers were loudly complaining about before the accident.

In order to develop an effective response to burnout, attention needs to be given to the specific content of what physicians are complaining about as existential threats to their personal health and safety in the environment in which they do their work as physicians.

A clear-eyed assessment of the real-life structures and processes that define how the work of physicians is routinely carried out every day is needed in every modern health care organization. Such an assessment is not a call for simply “whining” about everyday annoyances and bothers that are encountered as part of most people’s jobs. Rather, a thoughtful cataloging of what physicians are complaining about is required.

This examination needs to carefully listen to complaints to better understand two highly related factors. First: What do vascular surgeons and other physicians “want to do” in order to be personally “satisfied” with their job? And second: How does the organization (structure) and established “flow” (processes) of their given work environment encourage, help, hinder, or prevent them from being satisfied as a regular part of being a physician?

Such an assessment of complaints will not be easy. Important methodological considerations will need to be made to make conceptual and measurable distinctions between complaints about major threats to physician health that are part of the current work environment and ongoing and rapid changes affecting the overall profession of medicine. For example, new and ongoing developments in medical technology, health informatics, generational shifts in the attributes of the workforce, evolution of state and federal policy, shifting patient and epidemiological profiles, and other major trends will continue to affect the workplace of physicians. Such changes are part of the current dynamics of the workplace of physicians and may be major components of the conditions of work that are generating complaints and contributing to burnout.

Viewing physician complaints as important tools for improving the working conditions of physician does not mean that such changes can be stopped. More directly, it means that physician complaints can become a critical part in the policy debate and management discussion about what changes in the physician workplace need to change to eliminate burnout.

From a health care management perspective, physicians should take the lead and keep complaining. It is an essential window for senior leadership to see exactly what needs to be done to create a safer and healthier workplace for physicians to be physicians.
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PUSHING BOUNDARIES
and 8% reported thoughts of taking their own life during the last 12 months. Factors significantly associated with burnout included clinical work hours, on-call frequency, electronic medical record (EMR)/documentation requirements, perceived conflict between work and personal responsibilities, and physical pain. What was more compelling, perhaps, was that nearly 80% of the free text comments expanded on frustrations of the EHR.

Similarly, Wellness Focus Groups were conducted at the 2018 Vascular Annual Meeting of the Society for Vascular Surgery. Participants identified several themes that produced additional stress and negatively impacted quality of life. Again, the EHR was identified as one of the most significant stressors. Simply put, we are a specialty in crisis and negatively impacted quality of life. Again, the integration of EHR has significantly, and perhaps principally, contributed to these issues.

The proprietary EHR vendors helped to defeat the Stark bill (HR 6898) and pass the Health Information Technology for Economic and Clinical Health Act (HITECH). HITECH essentially mandated EHR implementation. The vendors then marketed themselves to hospital administrators, often based on billing efficacy. Usability remained unmeasured. If EHRs had been designed to maintain or improve the physician experience, this would have been a priority. To this day, there have been no standards placed on the “usability” of EHR platforms. While proprietary EHR vendors have generated billions in profits, there is little evidence of any significant investment in finding methods to reduce the burden they place on physicians, much less improving the work life of doctors, a vital component of the Quadruple Aim system to improve health care.

While we agree with many of the principles advanced by the 21st-Century Cures Act, we feel there must be a greater sense of urgency. The effects of EHR implementation have created a public health crisis. As a surgical subspecialty, vascular surgery is facing a dire workforce shortage. According to reports prepared for the Association of American Medical Colleges, there are no current projections under which the demand for vascular surgeons can be met by 2030. EHR burdens are producing widespread burnout in our existing workforce, leading to decreased productivity, substance abuse, and early retirement. Urgent reform is needed. The major EHR vendors have shown little interest in addressing the impact their technology has had on physician burnout. As such we need actionable goals and strict deadlines for implementation. It is time to hold the major EHR vendors accountable for their contributions to the deficiencies of our current system.

1. Usability of EHR systems remains unmeasured. Metrics, measures, and standards must be developed immediately to improve the physician experience and decrease time spent on EHR documentation. These actions must be performed with full physician collaboration including vascular surgeons who remain at particular risk to EMR-related emotional exhaustion.

2. To better integrate EHRs, all systems should be required to have a standardized import/export function.

3. Prescription Monitoring Programs should be integrated into all EHRs.

4. Vascular surgeons should be able to document patient encounters according to their practice. The focused history, problem list, review of systems, physical exam should be specialty specific. These guidelines and requirements should be set in coordination with the Society for Vascular Surgery.

5. Each EHR vendor should be required to continuously consult clinicians from all essential medical and surgical specialties. This could be achieved by either submitting to each major clinical society or by nationally (or each state/region) developing a team of clinicians with representatives from each specialty to review new EHRs. This team should include not only practicing physicians but also residents, physician assistants and nurse practitioners who also regularly interact with the EHR.

6. Health insurance agencies should be required to facilitate automatic authorization through communication with EHRs.

7. Effective and efficient physician training and support for EHR use must become standard and related to the specific “support package” purchased by the health care organization.

8. Quality measures must be universal across all payers.

Thank you for your review, we enthusiastically offer our assistance in any manner required.
Vascular Annual Meeting Program Taking Shape

Session by session, time slot by time slot, the 2019 Vascular Annual Meeting is coming together.

“Dr. (Vik) Kashyap and his Postgraduate Education Committee have finished selecting breakfast sessions and postgraduate courses, and the members are well on the way to finalizing workshops and concurrent sessions,” said Dr. Matthew Eagleton. He chairs the Program Committee, which oversees all the programming of the Vascular Annual Meeting.

Also selected, said Dr. Eagleton, are topics for most of the “Ask the Expert” sessions. These debuted in 2018 and were so popular that in some instances hopeful participants had to be turned away; additional sessions are slated for this year. “Attendees continue to tell us that they like the small-group setting and the chance to talk with the presenters,” Dr. Eagleton said.

“Particularly with the non-research-related events, we can respond both to feedback from the previous year and the suggestions and proposals for the current year in selecting subjects,” said Dr. Eagleton. “That helps us build a VAM program of interest to a wide range of participants.”

For example, the “Advanced Tools for Vascular Surgeon Wellness” breakfast session will tackle surgeon wellness and avoiding burnout. Those topics are so relevant and significant that SVS has a task force addressing them, said Dr. Eagleton.

Other requests for 2019 include:
- Scheduling workshops throughout VAM. This year’s workshops will on Thursday and Friday afternoons, instead of holding them all on Wednesday.
- The latest on issues vascular surgeons face frequently. “There’s a great demand for information on hemodialysis, for example, this year and every year,” said Dr. Eagleton.

“We’re responding with a breakfast session and other programming,” said Dr. Eagleton.

- Programming specifically for fellows.
- Career setting-specific gatherings.
- “The needs of our academic and hospital-based surgeons are different from those in private practice, and surgeons at the beginning of their careers face different challenges than those established practitioners face,” Dr. Eagleton said. “We need to, and will, meet a host of different needs, including career paths, practice management, even exit strategies.”

As for research, abstracts and videos were to be selected by the end of February for podium presentations: scientific sessions, the two VESS sessions, International Forum and International Fast Talk, plus the Poster Competition and the Interactive Poster Session.

“With each additional component identified and slotted, all of us involved with creating this year’s meeting are getting more excited,” said Dr. Eagleton. “It’s going to be a great, informative meeting. No matter what stage of career, from trainee to seasoned veteran, we’ll offer sessions of interest and value.

“Don’t miss it.”

Young Researcher Dr. Catherine Go Relishes Presenting Her Work

Encourages Other Young Surgeon-Scientists to Attend VRIC

Dr. Catherine Go had the opportunity last year to present her research at VRIC, answer questions about her work and talk collaboratively with others during the conference.

After her positive experience, she encourages other young researchers to attend this year’s Vascular Research Initiatives Conference with an eye toward submitting an abstract in 2020. (Abstract submissions are closed for this year’s VRIC, May 13, in Boston.)

Dr. Go, an integrated vascular surgery resident at the University of Pittsburgh Medical Center, was awarded an SVS Foundation VRIC Trainee Travel Scholarship to present at 2018 VRIC. She also received the SVS Foundation’s Student Research Fellowship in 2013. Her VRIC presentation was on “Retrograde Hemorrhage and Ischemic Injury after REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta) in a Porcine Model of Uncontrolled Aortic Injury.”

She found that by “occluding the aorta, endovascular balloons lead to spinal cord ischemia and organ malperfusion.” This was a smaller part of a larger project to compare the REBOA balloon to a retrievable self-expanding “rescue” stent that she and her fellow researchers envisioned using in aortic trauma patients.

“This was one of my first experiences as a presenting author,” said Dr. Go. Mentor Dr. Bryan Tillman was invaluable to her success, she said.

“He’s been very supportive, but also gives me the independence and confidence to answer discussion questions myself up at the podium, and that is very exciting.”

Catherine Go

When: Monday, May 13, at the Marriott Copley Square Hotel in Boston. VRIC is held the day before and in the same location as the American Heart Association’s Vascular Discoveries sessions.
Cost: Member, $275; nonmember, $300; resident/student/candidate (both member and nonmember): $150.
Highlights: Cecilia Giachelli, PhD, Professor and Chair, Department of Bioengineering at the University of Washington, will present the 2019 Alexander W. Clowes Distinguished Lecture, “New Concepts in Regulation and Biologically Engineered Therapies for Vascular and Valvular Calcification.” This year’s Translational Session is “Hard Science: Calcification and Vascular Solutions.”
Abstract sessions: Aortopathies and novel vascular devices; vascular regeneration, stem cells and wound healing; mechanisms and advanced therapies for venous disease; atherosclerosis, arterial injury and diabetes.

NEWS FROM SVS
Prepare for a ‘Spectacular’ Evening at VAM Gala

PURCHASE tickets today for “Vascular Spectacular,” the elegant evening planned for Friday, June 14, at the Vascular Annual Meeting to benefit the SVS Foundation. The ticket/donation website (vam19gala.givesmart.com) is now open. Members and friends may purchase their tickets there for the gala and, later, not only arrange to donate items for the Live Auction and Silent Auction but also peruse the listings to see if anything tickles their fancy. Bidding is expected to open sometime in May.

Attendees will enjoy cocktails and dinner, headliner entertainment, both Live and Silent auctions and an evening of conversation and fun with friends and colleagues. All proceeds will benefit the SVS Foundation and the community initiatives, research, scholarships, grants and disaster relief it helps fund. Tickets to the Vascular Spectacular are $250, $150 of which is a tax-deductible donation to the SVS Foundation.

Anyone can register to participate in the Silent Auction via the website, vam19gala.givesmart.com. When bidding opens, bids will be updated in real time and high bidders will be notified when their bids are topped. “This lets all of our members, colleagues and friends be part of the excitement of ‘Vascular Spectacular,’” said Cynthia Shortell, MD, gala co-chair with Benjamin Starnes, MD. “While we at VAM will be on the East Coast, anyone – on the West Coast or anywhere in the United States – can still participate in the Silent Auction.”

Silent Auction bidding will end during the evening. Because of the rapid pace of live auctions, only those present can participate in that. “But anyone who wants to can view the items ahead of time, and arrange bidding with a friend,” Dr. Shortell advised. “You might come away with something remarkable.”

Both co-chairs are excited about the evening. “It will bring people together on the final evening of VAM to not only have a wonderful time but also to showcase and benefit the important work of the SVS Foundation,” said Dr. Shortell. “It’s going to be spectacular.”

YOUR SVS: New Member Urges Others to Take Advantage of SVS Opportunities

Young Erben, MD, has fully embraced SVS membership, joining an SVS committee and actively taking advantage of the benefits SVS offers.

March 1 is the first quarterly membership application for 2019. Dr. Erben urges all who are eligible to apply and enjoy the boost that membership can provide a career. For example:

“The most important thing is the fact that we get to see and interact with a lot of colleagues,” said Dr. Erben, who became an Active member in 2018. “We recognize each other; we’re constantly communicating with each other. It helps to know there are fellow members, who are devoted to the field and are part of the community.”

The ability to encourage younger people and get them engaged: Dr. Erben is a member of the Resident and Student Outreach Committee, which participates in the student/resident/fellowship activities during the Vascular Annual Meeting. Committee members assist with the simulation activities and in the forums that help coach students on interviewing and other career development necessities.

“This work is important, she said. “We’re encouraging young people, helping to disseminate information and get them engaged early on.”

Mentorship and applications: Most members would cite mentorship as an important factor in going into the field of vascular surgery, she said. “It’s crucial. The right mentorship attracts students and gets them to be engaged, active members of the community, and that’s what keeps our Society running and advancing the science in vascular care,” she said.

Her mentors all are SVS members, she said. “They encourage their residents to go into vascular surgery,” she said. “As a resident, you want to emulate these members – you know your mentors are good people and excellent members developing guidelines for the care of our patients. You WANT to become a member and be a positive contributor to the field.”

Scholarships, plus leadership and training opportunities: such as the Women’s Leadership Training Grant: Dr. Erben applied last summer for and received an SVS Foundation Research Career Development Travel Award. “The beauty of being a member is that you get all of these opportunities to improve yourself and get better,” she said. Being a practicing vascular surgeon means constant continuing education. “These opportunities are available to all members,” said Dr. Erben. “It’s silly not to take advantage of them.”

She’s considering the Women’s Leadership Training Grant, believing it important not only to encourage women to go into vascular surgery and also take on leadership roles. “If a woman sees only males, they think, ‘This is not for me.’ They don’t see role models they can relate to,” she said. “SVS is actively encouraging our women to take on leadership roles.

“It’s an amazing opportunity,” she added.

Take advantage of all SVS has to offer. Visit vsweb.org/join for more information. Deadlines for 2019 are March 1, June 1, Sept. 1 and Dec. 1.
Other patients who could benefit from carotid revascularization through robust reverse flow include:*

- AGE ≥75
- CONGESTIVE HEART FAILURE
- ≥2 DISEASED CORONARIES WITH ≥70% STENOSIS
- SEVERE PULMONARY DISEASE
- SURGICALLY INACCESSIBLE LESION
- PRIOR HEAD/NECK SURGERY
- RESTENOSIS POST CEA
- IRRADIATED NECK
- CONTRALATERAL OCCLUSION
- BILATERAL STENOSIS REQUIRING TREATMENT
- SEVERE TANDEM LESIONS

*Reimbursement eligible criteria for the TCAR Procedure per the Medicare National Coverage Determination (20.7) on PTA including CAS

Please visit SilkRoadMed.com for instructions for use and to learn more about TCAR

AP234 - A
Welcome to Our New SVS Members

The Society for Vascular Surgery welcomes the following new members, who joined in 2018.

**Active Members**

Jessica Secor, MD; Dunlap, IL
Michael Madigan, MD; Pittsburgh, PA
Daniel Altermann, MD, RPVI; Muskegon, MI
Luis Antonio Lopez Galarza, MD; Manati, PR
William B. Harris, DO; Fort Sam Houston, TX
Charles Bailey, MD; Brandon, FL
Kevin Brown, MD; Bethesda, MD
Christopher Busken, MD; San Antonio, TX
Jonathan Cardella, MD; New Haven, CT
Sherry Cavanagh, MD, RPVI; Flint, MI
Jason Chapman, MD; Macon, GA
Allan Conway, MD; New York, NY
Ayaj Dhadwal, MBBS; Jersey City, NJ
Young Erben, MD; New Haven, CT
Edgar Galinanes, MD; Miami, FL
Matthew Goldman, MD; Winston-Salem, NC
Claire Griffin, MD; Salt Lake City, UT
Angela Gucwa, MD; Lanham, MD
George Hipp, MD; Vestavia, AL
Kamran Jafree, MD; Dayton, OH
Milu Ja, MD, MS; Allentown, PA
Vijay Kamath, MD; Brown Mills, NJ
Sarah Koch, MD; Tacoma, WA
Jared Ray, DO; Cedar Rapids, IA
Lidie Lajoie, MD, MPH; Dalton, GA
Megan March, MD; Daytona Beach, FL
Katherine McGinigle, MD, MPH; Chapel Hill, NC
R Michael Patton, MD; Wilmington, NC
Jennifer Czarniak, PA-C, MHP; Maspeth, NY
Rachel Dresher Gurr, PA-C; Murray, UT
Sarah Finke-Fyffe, PA-C; Northfield, IL
Daniel Forsberg, PA-C, MPH; Roslyn, NY
Shardul Nagre, MD; Kingsport, TN
Zachary Osborne, MD; Urbana, IL
Eugene Palchik, MD; Syracuse, NY
Karen Quirk, MD; Oxnard, CA
Elena Rinehardt, MD; Bellevue, WA
Adam Ring, MD; Saint Louis, MO
Melanie Rose, MD; Mobile, AL
Michael Rosenbaum, MD; Cleveland, OH
Hossain Said-Mahmoudian, MD; Salisbury, MD
Noah Scherrer, MD; Louisville, KY
Mark Song, MD; Brooklyn, NY
Emily Spangler, MD; Birmingham, AL
Michael Stephen Williams, Jr., MD; St. Louis, MO
Jordan Stern, MD; Mountain View, CA
Joseph Stinson, MD; Tupelo, MS
Scott Sundick, MD; Springfield, NJ
Pedro Teixeira, MD; Austin, TX
Axel Thors, DO, RPVI; Overland Park, KS
Ellis Tinsley, MD, Wilmington, NC
Samuel Tyagi, MD; Lexington, KY
Joshua Unger, MD; Miami Beach, FL
Matthew W. Lawrence DO, Philadelphia, PA
Douglas W Jones, MD; Boston, MA
Marlin Wayne Causey, MD; San Francisco, CA
Jonathan Wilson, DO; North Kansas City, MO

**Affiliate Members, PA Section**

Lauren Altot, PA-C; Clackamas, OR
Jo Ann Eisinger, PA; Lake Success, NY
Eric Barth, PA-C; St. Paul, MN
Ashley Bays PA-C; Kalama, WA
Bryon Brown, PA-C; Charleston, SC
Chrystal Buchanan, PA-C; Tacoma, WA
Jennifer Czarniak, PA-C, MHP; Maspeth, NY
Rachel Dresher Gurr, PA-C; Murray, UT
Sarah Finke-Fyffe, PA-C; Northfield, IL
Daniel Forsberg, PA-C, MPH; Roslyn, NY
Shardul Nagre, MD; Kingsport, TN
Zachary Osborne, MD; Urbana, IL
Eugene Palchik, MD; Syracuse, NY
Karen Quirk, MD; Oxnard, CA
Elena Rinehardt, MD; Bellevue, WA
Adam Ring, MD; Saint Louis, MO
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Douglas W Jones, MD; Boston, MA
Marlin Wayne Causey, MD; San Francisco, CA
Jonathan Wilson, DO; North Kansas City, MO

**International Members**

Alexandre Bueno Silva, MD; Rio Grande do Sul, Brazil
Manuel Doblas, MD; Toledo, Spain
Dale Maharaj, MD; Port of Spain, Trinidad
Juan Paolini, MD; Buenos Aires, Argentina
Juan Pardo, MD; Buenos Aires, Argentina
Felipe Trajano de Barao, PhD; São Paulo, Brazil
Kak Khee Yeung, MD, PhD; Memphis, TN
Rachel Dresher Gurr, PA-C; Murray, UT
Benjamin Phillip, PA-C; Bronx, NY
Madeleina Pimentel, PA-C; Salt Lake City, UT
Ruth Pinkerton, PA-C; Dallas, TX
Laura Prince, PA-C; Salt Lake City, UT
Steven Savoy, PA-C; Tupelo, MS
Angel Segura, PA; Walnut Creek, CA
Anita Singur, PA-C; Tacoma, WA
Robert Skasko, PA-C; Wilkes-Barre, PA
Kimberly Skinner, PA-C; Charlotte, NC
Illiana Suero, PA-C; Salt Lake City, UT
Iris Swiderski, PA-C; Middletown, NY

**Nominate an SVS Honoree**

Apply by March 1 for SVS, SVS Foundation Awards

SVS is accepting nominations and applications through March 1 for its three highest honors, to be recognized at the 2019 Vascular Annual Meeting in June.

The **SVS Lifetime Achievement Award** recognizes an individual’s outstanding and sustained contributions to the profession and SVS as well as exemplary professional practice and leadership.

The **Distinguished Fellow Designation** recognizes members who have provided sustained contributions to vascular surgery through research, teaching, clinical and/or creative accomplishments.

A number of SVS and SVS Foundation awards also carry March 1 application dates. They are: the SVS Women’s Leadership Training Grant and the SVS Foundation Community Awareness and Prevention Project Grant, E.J. Wylie Traveling Fellowship and Clinical Research Seed Grant. Visit vsweb.org/Awards for more award information.
NEWS FROM SVS

From Our Journals

From JVS: Researchers believe metformin, a commonly used prescribed oral hypoglycemic agent, may limit enlargement of abdominal aortic aneurysms, after analyzing patients of diabetic patients who are being treated in the U.S. Department of Veterans Affairs. The findings, outlined in an open-source article in the March Journal of Vascular Surgery, support holding clinical trials to test the drug’s effectiveness in limiting progression of early AAA disease. Read more through April 30 at vsweb.org/JVSVL-EVToveruse.

From JVS-VL: A recent retrospective study showed that vascular surgeons accounted for 22.6 percent of specialists performing endovascular therapy among Medicare patients from 2012-14. However, the largest percentage of providers (29.7 percent) was comprised of non-surgical specialties or specialists not generally associated with vascular procedures. The study, according to the article in the March JVS-Vascular and Lymphatic Disorders, “raises the question of financially driven, potentially inappropriate utilization of EVT.” Read more free through April 30 at vsweb.org/JVS-Metformin.

YOUR SVS: In Memoriam

Michael Daniel Sulkin, 79, Dec. 20, 2018. Dr. Sulkin founded one of the largest vascular surgery practices in Maryland and enjoyed a distinguished medical career in surgery that spanned 40-plus years. He was a constant advocate of innovative procedures and techniques to enhance patient care.

Do you know of an SVS member who has passed away? Please let us know at communications@vascularsociety.org.

YOUR SVS: Expanded Benefits Program Covers Multitude of Needs

The SVS’ Affinity Program of expanded benefits can help members protect their businesses, practices, families and future.

SVS launched the portfolio of financial and practice surgeons two years ago, providing members pre-vetted products and services. Members get a special discount on nearly every one of them.

Most SVS members tend to concentrate on three particular offerings: medical malpractice insurance, disability insurance and the retirement accelerator program.

Medical Malpractice Insurance: The Affinity Program offers professional liability insurance with a 5% discount through MedPro; the company said its claims team wins 90 percent of all physician malpractice trials. In addition, MedPro will not settle any case without the physician’s consent, offers free tail coverage for physicians at retirement.

Benefits continued on page 18

VRIC 2019

Hard Science: Calcification & Vascular Solutions

May 13, 2019—Boston

Join Us for a Day of Emerging Vascular Science

• Abstracts | Posters | Distinguished Speakers | Experts Panel
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REGISTER TODAY!

vsweb.org/VRIC19
Benefits
continued from page 17

after just one year of insurance and is addressing emerging issues such as cyber liability and optional coverage for billing errors and omissions.

Disability Insurance: More than one disability income protection program is available. Critical factors to consider include: whether benefits are tax-exempt or not, recognition of medical specialties and subspecialties, plan portability and renewability and whether rates are locked in at enrollment. The tax-exempt benefits have no offsets from other income and enrollees are protected as a vascular surgeon. Discounts apply for members.

Retirement Protection: Kai-Zen essentially accelerates retirement income, with participant funding complete in five years. The unique product combines financing and life insurance, with funds growing tax-deferred. The policy repays the loan at the end of 15 years and is the ONLY collateral for the loan. The plan uses a life policy which has a zero percent floor, meaning contributions are protected, and it is portable unlike a 457 plan. The plan has money available for long-term care and death benefits.

Other products address needs across the spectrum. For individuals, offerings include high net-worth life insurance, identity theft protection insurance, dental and vision care discounts, international medical insurance, student loan consolidation and high-limit disability income protection.

Offerings for practices include help with payroll, 401K programs and workers’ compensation insurance; payment processing; business overhead expense insurance; guarantee issue life and disability insurance for employees; business cybercrime protection; simplified issue life insurance; guarantee issue to group practices; and employee dental and vision care discounts.

For more information, visit vsweb.org/AffinityProgram, call 312-291-4472 or email Mark Blocker, SVS program representative, at mark@nationalaffinity.net

We’re Changing Our Address

By the end of this month, the Society for Vascular Surgery will be working out of its new headquarters in Rosemont, Ill., just minutes from O’Hare International Airport. The SVS Foundation and the SVS Patient Safety Organization share SVS’ workspace. The Society also provides management services for the Association of Program Directors in Vascular Surgery, the Society for Vascular Nursing and the Delaware Vascular Society.

The new space is nearly twice the size of the current main office in Chicago. It has room for expansion and additional programming to meet the future needs of vascular surgeons, including ongoing training. Its location near O’Hare is convenient for meeting attendees and will eliminate the need to rent meeting room space near the airport, as has been routine for many years.

The new headquarters also includes access to a surgical simulation center where surgeons can hone their skills on the latest endovascular procedures and maintain their open surgery skills.

SVS will show off its new headquarters in photos in the March Vascular Specialist, as well as in Pulse and on the SVS website. Be sure to check out our new look! We’re proud of our new space and can’t wait for members to see it as well.

Note Our New Address, as of Feb. 22
9400 W. Higgins Road
Suite 315
Rosemont, Ill., 60018

Benefits of membership

Are you ‘Connected’ Yet?

C


SVS | CONNECT


insurance company issues and many practice-oriented questions, such as those on imaging.

To be part of SVSConnect, visit vsweb.org/SVSConnect.

Coming soon to SVSConnect

The SVSConnect mobile app, bringing SVSConnect to phones and tablets

“Mentor Match” capability

Additional discussion groups

NEWS FROM SVS

Are you ‘Connected’ Yet?

Connected that is, via SVSConnect, the Society for Vascular Surgery’s new online members-only community. There, members can post discussions, respond to others’ questions, collaborate and expand their professional networks.

SVSConnect opened in December and has enjoyed many robust conversations since then, on topics ranging from burnout, electronic health records, to...
CAROTID DISEASE AND STROKE

Healthier lifestyle in midlife women reduces subclinical carotid atherosclerosis

BY BIANCA NOGRADY
MDEDGE NEWS
FROM JAHA: JOURNAL OF THE AMERICAN HEART ASSOCIATION

Women who have a healthier lifestyle during the menopausal transition could significantly reduce their risk of cardiovascular disease, new research suggests.

Because women experience a steeper increase in CVD risk during and after the menopausal transition, researchers analyzed data from the Study of Women’s Health Across the Nation (SWAN), a prospective longitudinal cohort study of 1,143 women aged 42-52 years. The report is in JAHA: Journal of the American Heart Association.

The analysis revealed that women with the highest average Healthy Lifestyle Score – a composite score of dietary quality, levels of physical activity, and smoking – over 10 years of follow-up had a 0.024-mm smaller common carotid artery intima-media thickness and 0.16-mm smaller adventitial diameter, compared to those with the lowest average score. This was after adjustment for confounders and physiological risk factors such as ethnicity, age, menopausal status, body mass index, and cholesterol levels.

“Smoking, unhealthy diet, and lack of physical activity are three well-known modifiable behavioral risk factors for CVD,” wrote Dongqing Wang of the University of Michigan, Ann Arbor, and his coauthors. “Even after adjusting for the lifestyle-related physiological risk factors, the adherence to a healthy lifestyle composed of abstinence from smoking, healthy diet, and regular engagement in physical activity is inversely associated with atherosclerosis in midlife women.”

Women with higher average health lifestyle score also had lower levels of carotid plaque after adjustment for confounding factors, but this was no longer significant after adjustment for physiological risk factors.

The authors analyzed the three components of the healthy lifestyle score separately, and found that not smoking was strongly and significantly associated with lower scores for all three measures of subclinical atherosclerosis. Women who never smoked across the duration of the study had a 49% lower odds of having a high carotid plaque index compared with women who smoked at some point during the follow-up period.

The analysis showed an inverse association between average Alternate Healthy Eating Index score – a measure of diet quality – and smaller common carotid artery adventitial diameter, although after adjustment for BMI this association was no longer statistically significant. Likewise, the association between dietary quality and intima-media thickness was only marginally significant and lost that significance after adjustment for BMI.

Long-term physical activity was only marginally significantly associated with common carotid artery intima-media thickness, but this was not significant after adjustment for physiological risk factors. No association was found between physical activity and common carotid artery adventitial diameter or carotid plaque.

The authors said that 1.7% of the study population managed to stay in the top category for all three components of healthy lifestyle at all three follow-up time points in the study.

“The low prevalence of a healthy lifestyle in midlife women highlights the potential for lifestyle interventions aimed at this vulnerable population,” they wrote.

In particular, they highlighted abstinence from smoking as having the strongest impact on all three measures of subclinical atherosclerosis, which is known to affect women more than men. However, the outcomes from diet and physical activity weren’t so strong: The authors suggested that BMI could partly mediate the effects of healthier diet and greater levels of physical activity.

One strength of the study was its ethnically diverse population, which included African American, Chinese, and Hispanic women in addition to non-Hispanic white women. However, the study was not powered to examine the impacts ethnicity may have had on outcomes, the researchers wrote.

The Study of Women’s Health Across the Nation is supported by the National Institutes of Health. No conflicts of interest were declared.


Audible Bleeding Podcast

Upcoming Meetings
Charing Cross Symposium
The Charing Cross Symposium will be held Apr. 15-18, 2019, in London. The symposium assembles a world-class faculty to address key issues in vascular and endovascular treatment and to challenge the available evidence in order to reach a consensus after discussion with an expert audience.

International Vein Congress
The Congress is being held at the Lowes Miami Beach hotel, Miami Beach, Fla., on Apr. 25-27, 2019. This CME event covers the treatment of superficial and deep venous disease, including topics from sclerotherapy optimization to managing thrombophilies and discussing clot bursting strategies.

Physicians are achieving durable outcomes across the elbow with fewer reinterventions in rapidly failing AV access circuits.

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