Upping the game of surgical researchers

BY RICHARD MARK KIRKNER
MDEDGE NEWS
EXPERT ANALYSIS FROM JAMA SURGERY

Many are submitted, but few are chosen. Concerned about the quality of submitted research papers based on large surgical databases that are not accepted for publication, the editorial board of JAMA Surgery has taken the initiative by giving some pointers to would-be authors, especially with regard to the use of databases in their research.

The journal editors have published a 10-point checklist of dos and don’ts to address commonly seen problems with submitted manuscripts. In addition, JAMA Surgery collaborated with the Surgical Outcomes Club to commission a series of practical

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Femoral artery endarterectomy still ‘gold standard’

BY BRUCE JANCIN
MDEDGE NEWS
EXPERT ANALYSIS FROM THE NORTHWESTERN VASCULAR SYMPOSIUM

CHICAGO – Additional higher-quality supporting evidence is needed before endovascular therapies can legitimately be placed on equal footing as an alternative to open surgery in patients with symptomatic common femoral artery stenosis, Jeffrey J. Siracuse, MD, FACS, asserted at a symposium on vascular surgery sponsored by Northwestern University.

“Open surgery in the CFA [common femoral artery] is probably still the gold standard in most cases,” said Dr. Siracuse, a vascular surgeon at Boston University.

He was quick to note that others would disagree. Stenting and other endovascular interventions in the CFA are booming in popularity, particularly among cardiologists, interventional radiologists, and the patients to whom the clinicians present the option in a favorable light. But this enthusiasm is based almost entirely on

See Endarterectomy page 3
CHANGE AND THE PRACTICE OF VASCULAR SURGERY: A never-ending learning curve

BY CARLO A. DALL’OLMO, MD

A s one who entered a vascular practice in Flint, Mich., as the third member of Vascular Surgery Associates in 1975, I would like to take this opportunity to address what has been a passion of mine – incorporating change into the practice of vascular surgery as a never-ending learning curve. I will reflect on aspects that have had both a positive – and at times, a negative – impact on the evolution of my group at the Michigan Vascular Center, now in its 54th year of existence. I have divided my experience into three parts – the insights learned in the early years, those learned in the middle years, and finally, our responsibility to community. I omit the final years because, by then, it is time to remain productive and gracefully step aside, supporting others dedicated to the evolution of the practice.

My hope is that these insights may be helpful to those entering practice, building a practice, or charged with maintaining and expanding an existing practice or department. While my entire career has been spent in the private practice arena, I see the principles involved in developing and running a successful practice as universal, applying to both the private practitioner and the employed physician.

Whatever the form of practice, there are several critical issues that ultimately must be addressed, factors that may not be readily apparent in the beginning but factors that, when eventually defined, will determine the scope, breadth, and success of the practice and one’s career. These factors relate to defining the practice’s ideology and its vision – essentially determining a practice’s culture and future. I will use our group’s experience as an example.

The early years
For a young surgeon entering practice, factors such as compensation, benefits, vacation time, partnership track, and the like are important because we often arrive with a heavy debt load. While a practice ideology may be discussed, it is less important than a steady income and the exhilarating experience of doing his/her initial cases. Some practices may not have a defined ideology. Certainly, the practice I joined did not. However, I was fortunate to have joined two other vascular surgeons, Albert Macksoon, MD, the founder, and Rick Sherrin, MD, who, like me, were products of training by Emerick Szylagyi, MD, at Detroit’s Henry Ford Hospital. With this common background, we brought with us Dr. Szylagyi’s rigorous and intellectually honest idealistic approach to the treatment of the patient with vascular disease.

We had two goals: Take good care of the patient and “cover the waterfront,” meaning add surgeons as the workload increased because there was power in numbers. There was one defining characteristic about the practice that I appreciated – we did not have our own private patients, rather we shared patients; we were a team, and thus, I was incorporated seamlessly. We respected each other’s skills and judgment such that I would see a patient in the office and schedule a procedure for a partner to do. This was the only way to have a life, since we covered an entire community with three hospitals, three emergency rooms, and our office. Patients accepted this approach. While we did not have a defined ideology, being a product of Dr. Szylagyi’s teaching program endowed us with a common philosophical approach to the patient. We were in sync, and the efficiency with which the practice ran was a testament to this.

I never fully appreciated how significant having a common background in patient care would be until we started hiring new physicians with different philosophical approaches and different levels of “soft skills,” meaning the ability to communicate clearly, to take initiative, to problem solve, and to get along with coworkers. These skills are difficult to decipher in an interview or letter of recommendation.

The middle years
As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates. As time passed, our workload expanded as did our workforce, adding employees and physician associates.

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other reservations as well. The CFA has traditionally been considered a “no-stent zone” because of the unique biomechanical stresses the artery is subjected to as a result of torsion, flexion, and extension at the hip joint. These forces render the area particularly vulnerable to neointimal hyperplasia, acute thrombosis, and stent fracture.

In addition, he noted, CFA endarterectomy for atherosclerotic lesions is a mature, well-established operation with an excellent track record for safety and durability. Dr. Siracuse’s review of procedural safety in 1,513 patients in the American College of Surgeons National Surgical Quality Improvement Project database during 2007-2010 showed a 30-day mortality of 1.5% and a 7.9% rate of major or minor complications (Vasc Endovascular Surg. 2014 Jan;48[1]:27-33).

In contrast, his review of 1,014 patients who underwent nonemergent endovascular CFA interventions for CFA stenosis without acute limb ischemia in the Vascular Quality Initiative registry demonstrated a 1-year patency rate of 85.3%, significantly lower than historically observed patency rates for endarterectomy.

The 30-day mortality rate of 1.6% associated with endovascular interventions was essentially the same as in his earlier analysis of endarterectomy in the ACS NSQIP database, and the average 1.5-day hospital length of stay was shorter than with open surgery. Of considerable concern, however, stent implantation, which was performed in 35% of the endovascular interventions, was an independent predictor of amputation or death, with an associated 19% increased risk (J Vasc Surg. 2017 Apr;65[4]:1039-46).

The travails of TECCO

The 17-center French TECCO study randomized 117 patients with de novo CFA atherosclerotic lesions to treatment via self-expanding stents or open surgery. A total of 98 participants were Rutherford stage 3, making TECCO primarily a study of claudicants. The primary outcome – the 30-day combined rate of morbidity and mortality – occurred in 26% of the surgical patients, a significantly higher rate than the 12.5% in the stent population. After a median follow-up of 24 months, the rates of primary patency, target lesion and extremity revascularization, and sustained clinical improvement were similar in the two groups (JACC Cardiovasc Interv. 2017 Jul 10;10[13]:1344-54).

The TECCO findings were hailed by endovascular therapy partisans as a big win. However, closer examination tells a different story, according to Dr. Siracuse.

There was no 30-day mortality in this rather small study. All 16 morbidity events occurring in the open-surgery group within 30 days were relatively minor: 10 cases of delayed wound healing, 4 cases of postoperative paresthesia requiring medication, and 2 cases of lymphorrhoea lasting longer than 3 days. In contrast, the seven morbidity events in the stent group included a complication requiring urgent open surgical repair at the time of stenting, one stent fracture, and a major amputation.

“Although I thought it was a little alarming because you should not have a major amputation with CFA interventions for claudicants,” the vascular surgeon commented, “Really, do people care about a lymphatic leak or do they care about amputation? I think more needs to be fleshed out about what really happened in that case.”

He was also puzzled by the hospital lengths of stay: a mean of 3.2 days in the stent group and 6.3 days in the open-surgery group. “I think those lengths of stay are astounding,” he observed.

Dr. Siracuse predicted that much-needed high-quality data comparing treatments of the CFA will be provided by the BEST-CLI trial (Best Endovascular versus Surgical Treatment for Critical Limb Ischemia), which has been updated to include both open and endovascular interventions.

He reported having no financial conflicts of interest regarding his presentation.
Each article includes a bulleted list of the data set’s attributes, an explanation of its limitations, a history of the data set, an explanation of how the data are collected and what is unique about the set’s features, and statistical considerations researchers should take into account when analyzing the data.

The series concludes with tips from the statistical editors of JAMA Surgery – Amy H. Kaji, MD, PhD, of Harbor–University of California Los Angeles Medical Center in Torrance; Alfred W. Rademaker, PhD, of Northwestern University Chicago; and Terry Hyslop, PhD, of Duke University, Durham, N.C. – for performing statistical analysis of large data sets: “With bigger data, random signals may denote statistical significance, and precision may be incorrectly inferred because of narrow confidence intervals,” the statistical editors noted.

“While many principles apply to all studies, the importance of these methodological issues is amplified in large, complex data sets.” However, they noted that large data sets are prone to bias and measurement errors. “It is important to respect and acknowledge the limitations of the data,” the statistical team wrote. They also reprise the introductory editorial’s call for a clear hypothesis and take-home message. “The challenge with Big Data is that it requires a carefully thought-out research question and a transparent analytic strategy,” the statistical editors said.

Dr. Bilimoria, a coauthor of the introductory editorial, said in an interview that the JAMA Surgery editorial team felt that key insights from “end users” could be valuable to share. Journal reviewers may also be interested in these insights and common pitfalls and the examples of good uses of the data sets.

And there are pitfalls. Dr. Bilimoria noted, “We shouldn’t let the database define our research. We should instead be asking interesting questions and then seeking out a database that fits best to answer the question.” He said one particular problem that comes up often for reviewers is trying to discern how researchers arrived at the population of interest in a study. A lot of inclusion and exclusion criteria are applied, and unless the reviewer can see the decisions that were made in the process, some fairly important biases can be introduced unintentionally. We as reviewers would like to be able to follow that exclusion pathway.

He said, “A problem we frequently see is that these databases change the variable definitions over time – in fact, change the variables over time. So if researchers aren’t checking to see if that variable was reported the same every year of the study and in the same way, they will get spurious results. Similarly, the number of hospitals reporting is important as well since hospitals come in and out of these data sets.”

In their introductory editorial, the JAMA Surgery team noted that the checklist, practical guides, and statistical tips are a three-pronged approach that authors should consult before submitting their manuscripts. “We hope that, by following these simple guides, authors can benefit from the collective wisdom of so many colleagues who have successfully completed similar analyses in the past,” they wrote. Dr. Bilimoria sees great strengths in database research, such as giving researchers a population-level view of how care is being delivered, insights into the outcomes of care, indications of the effects of policy decisions, and data on rare diseases and operations.

Big Data of all kinds will be increasingly available for researchers. Dr. Kibbe commented that, “In the future, having a comprehensive (not sampling) country- or worldwide electronic medical record that will allow for robust inclusion of all medical data at the individual as well as cohort level will greatly contribute to the era of personalized medicine.”

“In my opinion, this would be a real-time inclusive medical database that would allow for individual as well as population-based prospective studies.”

Dr. Haider receives support from the Henry M. Jackson Foundation of the Department of Defense, the Orthopaedic Research and Education Foundation, and the National Institutes of Health, and nonfederal research support the Centers for Medicare & Medicaid Services Office of Minority Health. Dr. Bilimoria was the president of the Surgical Outcomes Club from 2016 to 2017.

Using the SVS VQI

The Vascular Quality Initiative (VQI) consists of data sets relevant to 12 common vascular procedures and was developed in 2011 by the Society of Vascular Surgery. As part of the series of data set summaries published in JAMA Surgery for the benefit of researchers (see accompanying story “Upping the game of surgical researchers” on p. 1), it was described in detail by Sapan S. Desai, MD, and his colleagues from Northwest Community Hospital, Arlington, Ill., in an online report published in JAMA Surgery [doi: 10.1001/jamasurg.2018.0498].

The current VQI registries comprise the following vascular procedures:
- carotid artery stenting
- carotid endarterectomy
- endovascular abdominal aortic aneurysm repair
- hemodialysis access
- infrainguinal bypass
- inferior vena cava filter
- lower-extremity amputations
- open abdominal aortic aneurysm repair
- peripheral vascular interventions
- suprainguinal bypass
- thoracic and complex endovascular abdominal aortic aneurysm repair
- varicose vein treatment.

As of July 2017, 390,270 procedures were captured from 431 participating institutions representing more than 1,200 physicians throughout the United States and Canada, including 18 regional quality improvement groups.

The breakdown of participating institutions shows 40% community, 29% teaching, and 31% academic hospitals.

A significant factor in expanding the usefulness of the SVS VQI derives from its operation within the structure of a patient safety organization, which, according to Dr. Desai and his colleagues, protects the quality improvement activities as patient safety work product and thus provides a degree of privilege and confidentiality for the data.

In addition, because the VQI is a member of the Society for Vascular Surgery patient safety organization, comparisons with regional and national institutions can be performed, Dr. Desai and his colleagues added.

In line with all of the other data sets described for researcher use, Dr. Desai and his colleagues provided five best practices for using the VQI:
1. Use a flow diagram to demonstrate how the target population was selected.
2. Clearly delineate sample sizes, statistical techniques to mitigate selection bias, and the efficacy of the predictive model.
3. Emphasize practical clinical findings instead of incidental statistically significant results.
4. Include a power calculation.
5. Ensure clear methods to permit reproduction of results.

“The VQI is a robust database that provides detailed data of common vascular procedures. The large sample size of the procedures within the registry, inclusion of pertinent independent variables, and participation from a significant number of institutions allows a variety of outcomes analyses to be completed,” wrote Dr. Desai and his colleagues.

They warned that, as typical for the use of any large database, “care must be taken in the statistical methods, and the results must be clearly presented such that the reader is able to reproduce the findings of any article.”

Dr. Desai and his colleagues reported having no disclosures.

For more information, visit the SVS VQI web site: www.vqi.org.
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DVT AND PULMONARY EMBOLISM

Did design limitations compromise DVT trial?

BY TED BOSWORTH
MDEdge NEWS
EXPERT ANALYSIS FROM THE 2018 CRT MEETING

WASHINGTON – On the basis of a large randomized trial called ATTRACT, many clinicians have concluded that pharmacomechanical intervention is ineffective for preventing postthrombotic syndrome (PTS) in patients with deep venous thrombosis (DVT). But weaknesses in the study design challenge this conclusion, according to several experts in a DVT symposium at the 2018 Cardiovascular Research Technologies (CRT) meeting.

“The diagnosis and evaluation of DVT must be performed with IVUS [intravascular ultrasound], not with venography,” said Peter A. Soukas, MD, director of vascular medicine at Miriam Hospital in Providence, R.I. “You cannot know whether you successfully treated the clot if you cannot see it.”

The ATTRACT (Acute Venous Thrombosis: Thrombus Removal With Adjunctive Catheter-Directed Thrombolysis) trial was a recently published phase 3 multicenter trial that randomized 692 patients with acute proximal DVT to pharmacomechanical thrombolysis or anticoagulation alone (Vedantham S et al. N Engl J Med. 2017 Dec 7;377(23):2240-52). The results of the trial, sponsored by the National Heart, Lung, and Blood Institute, were negative for the primary outcome of a difference in the rate of PTS within 24 months of follow-up, but Dr. Soukas said the study does not resolve the issue.

“There were lots of limitations to that study. Here are some,” said Dr. Soukas, who then listed on a list of several considerations, including the fact that venograms – rather than IVUS, which Dr. Soukas labeled the “current gold standard” – were taken to evaluate procedure success. Another was that only half of patients had a moderate to severe DVT based on a Villalta score.

“If you look at the subgroup with a Villalta score of 10 or greater, the benefit [of pharmacomechanical intervention] was statistically significant,” he said. In addition, the study enrolled a substantial number of patients with femoral-popliteal DVTs even though iliofemoral DVTs pose the greatest risk of postthrombotic syndrome. Dr. Soukas suggested these would have been a more appropriate focus of a study exploring the benefits of an intervention.

The limitations of the ATTRACT trial, which was conceived more than 5 years ago, have arisen primarily from advances in the field rather than problems with the design, Dr. Soukas explained. IVUS was not the preferred method for deep vein thrombosis evaluation then as it is now, and there have been several advances in current models of pharmacomechanical devices, which involve catheter-directed delivery of fibrinolytic therapy into the thrombus along with mechanical destruction of the clot.

Although further steps beyond clot lysis, such as stenting, were encouraged in ATTRACT to maintain venous patency, Dr. Soukas questioned whether these were employed sufficiently. For example, the rate of stenting in the experimental arm was 28%, a rate that “is not what we currently do” for patients at high risk of PTS, Dr. Soukas said.

In ATTRACT, major bleeding events were significantly higher in the experimental group (1.7% vs. 0.3%; P = .049). The authors cited this finding when they concluded that the experimental intervention was ineffective. Dr. Soukas acknowledged that bleeding risk is an important factor to consider, but he also emphasized the serious risks for failing to treat patients at high risk for PTS.

“PTS is devastating for patients, both functionally and economically,” Dr. Soukas said. He called the morbidity of deep vein thrombosis “staggering,” with in-hospital mortality in some series exceeding 10% and a risk of late development of postthrombotic syndrome persisting for up to 5 years. For those with proximal iliofemoral DVT, the PTS rate can reach 90%, about 15% of which can develop claudication with ulcerations.

A large trial that was published in a prominent journal, ATTRACT has the potential to dissuade clinicians from considering pharmacomechanical intervention in high-risk patients who could benefit, Dr. Soukas said. Others speaking during the same symposium about advances in this field, such as John Fritz Angle, MD, director of the division of vascular and interventional radiology at the University of Virginia, Charlottesville, agreed with this assessment. Although other studies underway will reexamine this issue, there was consensus from several speakers at the CRT symposium that the results of ATTRACT should not preclude intervention in patients at high risk of PTS.

“I believe there is a role for DVT intervention for symptomatic patients with an extensive [proximal iliofemoral] clot provided they have a low bleeding risk,” Dr. Soukas said.

Dr. Soukas reported no conflicts of interest.

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Surgical specialists turn out to be top earners

BY RICHARD FRANKI
MDEdge NEWS

The five top-earning surgical specialties in 2017 also happened to be the five top-earning specialties, according to a survey by the medical social network Doximity.

Neurosurgery was first among all specialties with an average compensation of $663,000, followed by thoracic surgery ($560,000), and orthopedic surgery ($538,000). Vascular surgery ($476,000) held the fourth place position, followed by plastic surgery ($473,212).

Cardiology was just behind plastic surgery at $473,184, which made it the highest-earning nonsurgical specialty, Doximity said in its 2018 Physician Compensation Report. The report was based on data from surveys that were completed by more than 65,000 physicians who practice at least 40 hours a week.

In the next positions, gastroenterologists took in $456,000 and oncologists earned an average of $404,000.

Other surgical specialties among the 20 highest-earning specialties were otolaryngology at $431,000, which was 11th highest overall, general surgery at $382,000 (16th), and colon and rectal surgery at $380,000 (17th), Doximity reported.

Note: Compensation surveys were completed by more than 65,000 full-time U.S. physicians. Source: Doximity
**Bad kidneys not a factor in dabigatran reversal**

**BY MITCHEL L. ZOLER**
**MDEdge News**
**Reporting from ACC 18**

**ORLANDO** – Idarucizumab, the reversal agent for the anticoagulant dabigatran, appeared as effective in quickly reversing dabigatran’s effects in patients with severe renal dysfunction as in patients with normally working kidneys, in a post hoc analysis of data collected in the drug’s pivotal trial.

A standard dose of idarucizumab “works just as well in patients with bad kidney function as it does in patients with preserved kidney function,” John W. Eikelboom, MD, said at the annual meeting of the American College of Cardiology. “The time to cessation of bleeding and the degree of normal hemostasis achieved was consistent” across the entire range of renal function examined, from severe renal dysfunction, with a creatinine clearance rate of less than 30 mL/min, to normal function, with an estimated rate of 80 mL/min or greater.

The ability of idarucizumab (Praxbind), conditionally approved by the Food and Drug Administration in 2015 and then fully approved in April 2018, to work in patients with impaired renal function has been an open question and concern because dabigatran (Pradaxa) is excreted renally, because this has been a fear of clinicians,” explained Dr. Eikelboom, a hematologist at McMaster University in Hamilton, Ont.

To examine whether idarucizumab’s activity varied by renal function, he used data from the patients enrolled in the RE-VERSE AD (Reversal Effects of Idarucizumab on Active Dabigatran) study, the pivotal dataset that led to idarucizumab’s U.S. approval. The new, post hoc analysis divided patients into four subgroups based on their kidney function, and focused on the 489 patients for whom renal data were available out of the 503 patients in the study (N Engl J Med. 2017 Aug 3;377[5]:431-41).

The subgroups included 91 patients with severe dysfunction with a creatinine clearance rate of less than 30 mL/min; 127 with moderate dysfunction and a clearance rate of 30-49 mL/min; 163 with mild dysfunction and a clearance rate of 50-79 mL/min; and 108 with normal function and a creatinine clearance of at least 80 mL/min.

Patients in the subgroup with severe renal dysfunction had the worst clinical profile overall, and as predicted, had a markedly elevated average plasma level of dabigatran, 231 ng/mL, nearly five times higher than the 47-ng/mL average level in patients with normal renal function.

The ability of a single, standard dose of idarucizumab to reverse the anticoagulant effects of dabigatran were essentially identical across the four strata of renal activity, with 98% of patients in both the severely impaired subgroup and the normal subgroup having 100% reversal within 4 hours of treatment, Dr. Eikelboom reported. Every patient included in the analysis had more than 50% reversal.

The study followed patients to 12-24 hours after they received idarucizumab, and 55% of patients with severe renal dysfunction showed a plasma dabigatran level that crept back toward a clinically meaningful level and so might need a second idarucizumab dose. In contrast, this happened in 8% of patients with normal renal function.

In patients with severe renal dysfunction given idarucizumab, “be alert for a recurrent bleed,” which could require a second dose of idarucizumab, Dr. Eikelboom suggested.

**SOURCE:** Eikelboom JW et al. ACC 18, Abstract 231M-11.

**Balloon angioplasty for CTEPH improves symptoms**

**BY TED BOSWORTH**
**MDEdge News**
**Reporting from CRT 2018**

**WASHINGTON** – Balloon pulmonary angioplasty provides meaningful improvements in functional capacity for patients with chronic thromboembolic pulmonary hypertension (CTEPH) who are not candidates for surgical pulmonary thromboendarterectomy, according to a single-center experience with 15 consecutive patients that was presented at CRT 2018 sponsored by the Cardiovascular Research Institute at Washington Hospital Center.

The treatment of choice for CTEPH is pulmonary thromboendarterectomy (PTE), but “a huge percentage of the population with CTEPH is not eligible or does not undergo surgical treatment, which was the impetus to initiate this intervention, reported Riyaz Bashir, MD, director of vascular and endovascular medicine at Temple University Hospital and professor of medicine at Temple University, Philadelphia.

Much of the experience with balloon pulmonary angioplasty (BPA) for CTEPH comes from outside the United States, particularly Japan, where this procedure has been associated with improved survival, compared with historical untreated controls, according to Dr. Bashir. He cited registry data showing that more than 80% of CTEPH patients are not surgical candidates and up to 40% of those who are candidates still fail to undergo PTE for other reasons.

There have now been 15 CTEPH patients treated with BPA by Dr. Bashir and her team at Temple University. He reported 6-month outcome data on the first 13 patients, all of whom had a history of pulmonary embolism. Three of the patients had a prior PTE.

The primary outcome of interest in this series was functional improvement. Unlike PTE, immediate improvement in hemodynamics is not typically observed immediately after the procedure, but these measures do improve incrementally over time, Dr. Bashir reported. This is reflected in progressive improvements in the 6-minute walk test and in New York Heart Association (NYHA) functional class.

Of the 13 patients treated so far, 6 (46%) were in NYHA class IV and only 2 (15%) were in NYHA class II prior to BPA. Six months after BPA, the proportions had reversed. At that point, seven patients (54%) were in class II and two (15%) in class IV.

The remaining patients at both time points were in NYHA class III. Similar improvements were seen in the 6-minute walk test, which typically tracks with NYHA class.

Describing their first case, Dr. Bashir explained that a tight stenosis in the right lower pulmonary artery of a 44-year-old woman was reached with a multipurpose guiding catheter through femoral access. A 5-mm balloon was used to dilate the stenosis and create a pulsatile flow.

“The goal is not to raise the mean arterial pressure above 35 mm Hg, because this has been associated with significant peripheral edema,” Dr. Bashir explained.

In this patient, progressive improvements in pulmonary pressure, cardiac index, and other hemodynamics were associated with progressive shrinking of the right ventricle over 6 months of follow-up. The walk test improved from 216 m prior to BPA to 421 m at her most recent evaluation.

The average age in the 13 patients treated so far was 55 years, and 75% are males. The mean left ventricular ejection fraction (LVEF) was 59%. According to Dr. Bashir, most patients required at least two treatment sessions and some have required up to four.

There have been two complications—one patient developed hemoptysis that required a brief intubation and the other involved perfusion edema—and no deaths in this series so far, he said.

The outcomes so far, which Dr. Bashir characterized as “an early experience,” provide evidence that BPA is “safe and feasible” for patients with CTEPH who are not surgical candidates. At Dr. Bashir’s institution, where PTE is commonly performed in patients with CTEPH (Dr. Bashir reported that 134 cases were performed over the period of time in patients in which these 15 cases of BPA were performed), there is a plan to compare functional outcomes in CTEPH patients managed with these two different approaches.

Dr. Bashir reported no disclosures.

**SOURCE:** Bashir R. CRT 2018
RESIDENT FORUM

How real is resident burnout?

By Richard Mark Kirkner

MeDedge News
At the Annual Academic Surgical Congress

Jacksonville, Fla. — Burnout is commonly ascribed to surgical residents, but reliable estimates of the numbers involved and a clear, comparable definition of burnout remain elusive.

A large study of general surgery residents has found that almost one in four have at least one symptom of burnout daily and more than two in five report poor psychiatric well-being, according to results of a survey reported at the Association for Academic Surgery/Society of University Surgeons Academic Surgical Congress.

“Twenty-two percent of general surgery residents report at least one symptom of burnout daily,” said Daniel “Brock” Hewitt, MD, a research fellow in the Surgical Outcomes and Quality Improvement Center in the department of surgery, Feinberg School of Medicine, Northwestern University, Chicago.

“Poor resident wellness is associated with more duty-hour violations, feeling unprepared for residency, and an increase in self-reported medical errors. However, burnout is not associated with worse surgical outcomes.”

But to measure burnout, the researchers had to first define it. The instrument Dr. Hewitt and coauthors used is the Maslach Burnout Inventory, named for University of California at Berkeley psychology professor Christina Maslach, PhD. It quantifies three different factors for burnout: emotional exhaustion; depersonalization or cynicism; and a low sense of personal accomplishment.

This study defined “burnout” as having feelings of both emotional exhaustion and depersonalization, and dismissed the third measure of burnout because physicians rarely possess a low sense of personal accomplishment.

Overall, 22.3% reported one sign or symptom of burnout daily, and 56.5% did so on a weekly basis, Dr. Hewitt said.

However, Dr. Hewitt noted, burnout measurement thresholds can vary “because burnout itself is not an actual diagnosis.” Studies have calculated the burnout rate among surgeons at 28%-69% (J Am Coll Surg. 2016;222:1230-9). A recent systematic review found up to eight different cutoffs used to define “high burnout” (Cogent Med. 2016 7 Oct; doi.org/10.1080/2331205X.2016.1237605; J Am Coll Surg. 2016;223:440-51).

How studies of physician burnout establish cutoffs and which Maslach Burnout Inventory subscales they measure has an impact on the rates of burnout they report, Dr. Hewitt said. For this study, the researchers used the Maslach scores in the top quartile in both emotional exhaustion and depersonalization to define burnout.

“Burnout is probably best defined as a continuum from engagement on the one end and burnout on the other, so there’s some combination of the (Maslach) subscales that lead to burnout,” he said.

Among survey respondents, 19.5% reported high Maslach scores for emotional exhaustion and 9% of depersonalization on a daily basis (6.2% reported both); 22.3% reported at least one daily. On a weekly basis, 54.2% reported high scores for emotional exhaustion and 25.6% high scores for depersonalization, with 56.5% reporting at least one and 22.4% reporting both.

To evaluate residents’ sense of psychiatric well-being, the study used the General Health Questionnaire (Psychol Med. 1998;28:915-21). Among survey respondents, 43% met criteria for poor psychiatric well-being.

Burnout rates among men and women were identical, but a significantly higher percentage of women had poor psychiatric well-being: 48.4% to 39.7% of men.

Burnout and psychiatric well-being scores also varied depending on postgraduate year. Second-
and third-year residents were significantly more likely to report burnout, compared to first-year residents, Dr. Hewitt said. Rates of poor psychiatric well-being were lowest for fourth- and fifth-year residents.

Most pronounced was the impact of 80-hour duty-week violations had on residents’ sense of burnout and poor psychiatric well-being. Burnout rates were 8.4% for those who reported no monthly duty-hour violations, but doubled and quadrupled with more frequent monthly duty-hour violations: 16.1% for those who reported one to four violations a month; and 35% for those who reported five or more a month, Dr. Hewitt said.

Another factor that contributed to burnout and poor psychiatric well-being was a sense of unpreparedness for residency, Dr. Hewitt said. Burnout rates for those who felt prepared were 8.9% vs. 19.1% for those who didn’t feel prepared. The disparity was less drastic, but nonetheless significant, for poor psychiatric well-being: 37.5% for those who felt prepared and 52.1% for those who didn’t.

With regard to outcomes, Dr. Hewitt said, “Residents in the highest quartile of burnout and the highest quartile of poor psychiatric well-being were significantly more likely to report a near miss or harmful medical error.”

Among the burnout group, highest quartile rates were 39.3% for a near miss and 14.4% for a harmful medical error vs. 11.1% and 2.4%, respectively, for the lowest quartile. Among surgical residents who reported poor psychiatric well-being, highest quartile rates were 31.9% for a near miss and 13.2% for a harmful medical error vs. 12.5% and 2.1%, respectively, for those in the lowest quartile.

The study also analyzed outcomes for 134,877 surgical patients and found no association of overall morbidity and death or serious morbidity with resident wellness.

“However,” Dr. Hewitt said, “when we look at mortality and failure to rescue, we can see an association with burnout, specifically in programs that have high levels of burnout; these patients have significantly lower odds of mortality and failure to rescue.” Each has an adjusted odds ratios of 0.81.

Among the study limitations Dr. Hewitt noted were its cross-sectional nature that led to inferences of association, not identification of causation; residents completing the survey after the ABSITE may have influenced their answers; and the fact it did not account for certain intermediate factors such as physician or nursing burnout or institutional quality measures.

The American Board of Surgery, Accreditation of Graduate Medical Education, American College of Surgeons and Agency for Healthcare Research and Quality provided grants to support the research.

**Source:** Hewitt B et al. Surgical Congress Abstract 21.01
Andexanet alfa reverses factor Xa inhibitors

BY MITCHEL L. ZOLER MD
MDEDE NEWS
REPORTING FROM ACC 18

ORLANDO – Andexanet alfa, a new agent that reverses the anticoagulant effect of direct factor Xa inhibitors, showed an acceptable level of efficacy and safety in 227 patients who received the drug in the agent’s pivotal trial.

These results, which placed andexanet in the same ballpark for efficacy and safety as idarucizumab (Praxbind), approved in 2015 for reversing the anticoagulant dabigatran (Pradaxa), suggest that andexanet is likely on track for its own Food and Drug Administration marketing approval, Stuart Connolly, MD, said at the annual meeting of the American College of Cardiology.

Portola Pharmaceuticals, the company developing andexanet alfa (AndexXa) previously announced that it expected Food and Drug Administration marketing approval in May 2018.

Andexanet reversal “has similar efficacy and safety as seen with other reversal agents” for other types of anticoagulants, said Dr. Connolly, a professor of medicine and an electrophysiologist at McMaster University in Hamilton, Ont. In the trial results he reported, andexanet treatment of patients who were bleeding while on treatment with a direct factor Xa inhibitor had an 83% rate of hemostatic efficacy and an 11% rate of thrombotic events. By comparison, idarucizumab, the FDA-approved reversal agent for the anticoagulant dabigatran, produced a 68% hemostatic efficacy and a 6% rate of thrombotic events in the idarucizumab pivotal trial, RE-VERSE AD (N Engl J Med. 2015 Aug 6;373[6]:311-20).

“[T]he anticoagulants in high-risk PCI [percutaneous coronary intervention] patients with atrial fibrillation, and I expect to use more direct factor Xa inhibitor anticoagulants in light of the COMPASS findings, so having an agent that works for reversal – and these are very promising results – will be very important in our armamentarium. It will give us a safety net,” commented Ajay J. Kirtane, MD, director of the cardiac catheterization laboratory at Columbia University Medical Center in New York. (The COMPASS results, also presented at ACC 18, showed that peripheral artery disease patients on rivaroxaban plus aspirin had significantly fewer adverse peripheral vascular outcomes.)

Andexanet alfa will boost factor Xa–inhibitor use

T
reatment with andexanet alfa produced good or excellent hemostasis in 83% of patients in the ANNEXA-4 study, which is what matters when patients are bleeding. Clinicians want to know that you can restore coagulation to a level where you can stop bleeding, and that’s what the results show.

The lack of a reversal agent until now for direct-acting factor Xa–inhibitor drugs has probably been a modest but real obstacle to widespread adoption of these agents. We can look at the example of another new oral anticoagulant, dabigatran (Pradaxa), which works by a different mechanism, specifically by inhibiting thrombin. After a reversal agent for dabigatran, idarucizumab (Praxbind) received Food and Drug Administration approval and became available in late 2015, an uptick in dabigatran prescriptions occurred. That experience shows that patients and providers want the safety net of a reversal agent. They want to know that, if there is bleeding or need for urgent surgery, there is a way to facilitate restoration of hemostasis.

It’s the same with direct factor Xa inhibitors:

Some patients are concerned about the lack of a reversal agent, and having such an agent may help increase access to these agents for such patients. I think that, once andexanet becomes available for routine U.S. practice, we’ll see an uptick in prescribing of direct factor Xa inhibitors. Also, some patients who have opted for treatment with warfarin will switch to a safer class of drugs, the direct factor Xa inhibitors. A myth exists that reversal agents can easily negate the anticoagulant effect of warfarin. The reality is that, despite having treatments that reverse warfarin’s effect, this is often not an easy process in actual practice.

On the safety side, there was no indication in the ANNEXA-4 results of rebound thrombosis with andexanet alfa treatment. Patients receiving a direct factor Xa inhibitor are prothrombotic – that’s why they are on an anticoagulant – so their risk for a thrombotic event is always there, especially when they are not fully anticoagulated, such as when a reversal agent is administered. We need to look to restarting treatment with an anticoagulant because these patients have a high thrombotic risk.

The Prospective, Open-Label Study of Andexanet Alfa in Patients Receiving a Factor Xa Inhibitor Who Have Acute Major Bleeding (ANNEXA-4) enrolled 227 patients at any of 60 centers, with efficacy data available from 132 of the patients. About 60% of the patients had an intracranial bleed, and about 30% had a gastrointestinal bleed, and their average age was 77 years. Roughly three-quarters of patients were on an anticoagulant for atrial fibrillation, with the rest treated for venous thromboembolism, with 4% having both conditions. The most commonly used direct factor Xa inhibitors in these patients were apixaban (Eliquis) in 105 and rivaroxaban (Xarelto) in 75. The ANNEXA-4 study has not enrolled patients treated with a direct factor Xa inhibitor anticoagulant and undergoing surgery, a setting that will be the subject of a future study, Dr. Connolly said.

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 about 75%-90% within minutes of starting the bolus and remained depressed at that level during the infusion but then began recovering by 2 hours after the stop of infusion. Andexanet 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.

“There is no doubt that andexanet rapidly decreases anti-factor Xa activity,” he said.

Adjudicated efficacy results were available for 132 patients and showed good or excellent hemostasis achieved on andexanet in 109 patients (83%), Dr. Connolly reported. The effect on hemostasis was consistent regardless of patient age, sex, bleeding site, type of anticoagulant, and dosage tested.

Thrombotic events during the 30 days following treatment occurred in 24 of 227 patients (11%) who received andexanet and were evaluable for safety. Notably, no clustering of thrombotic events occurred early, even among the 129 patients who restarted on an anticoagulant during the 30 days after treatment. Among the 129 patients who restarted on an anticoagulant, 97% had a thrombotic event during the 30-day follow-up, compared with 15 events among 98 patients (15%) who did not restart on an anticoagulant.

Dr. Connolly acknowledged that a limitation of the ANNEXA-4 study is the absence of a control group, but he added that he and his associates believed randomizing patients with a serious bleed to placebo control would not have been “practical, feasible, or ethical.”

ANNEXA-4 is sponsored by Portola Pharmaceuticals, the company developing andexanet alfa (AndexXa). Dr. Connolly has been a consultant to Portola, and also to Bayer, Boehringer-Ingelheim, Bristol-Myers Squibb, and Sanofi-Aventis. Dr. Kirtane has received research support from several device manufacturers.


PERSPECTIVE by Gregory Piazza, MD

Gregory Piazza, MD, is a cardiologist at Brigham and Women’s Hospital in Boston. He has been an adviser to Portola Pharmaceuticals, the company developing andexanet alfa, as well as to Bayer and Pfizer, and he has received research funding from Bristol-Myers Squibb, Janssen, and Daiichi Sankyo. He made these comments in an interview.

mzoler@mdedge.com
The silence was deafening, but the message was very clear – a new era was dawning: Change or perish!

Noninvasive diagnostic testing was now the norm, and endovascular stent therapy was being practiced by some. However, our group, like many others, continued to focus on open surgery. All that began to change with a meeting held by Frank Veith, MD at the Waldorf Astoria in November 1992. When Juan Carlos Parodi, MD, presented a video in which interventional techniques were used to treat an aortic aneurysm using a homemade endograft created in conjunction with his friend, Julio Palmaz, MD. There were about 300 vascular surgeons in attendance. You could have heard a pin drop on the plush carpet in the room. The mood was somber; the silence was deafening, but the message was very clear – a new era was dawning: Change or perish!

Realizing we were already behind, our race to learn the new skills we began. We took courses wherever we might and networked as best we could.

The prize then was to be invited to be involved in AAA endograft clinical trials because it was the only way to get the necessary exposure to the new treatment modalities and thus craft a novel endovascular identity. However, for almost 2 years, our attempts to become a clinical trial site were thwarted because the directors of the sponsoring organizations, nonphysicians, wanted to enroll only academic centers. Fortuitously, Victor Bernhard, MD, well known in these circles, became the new medical director of EndoVascular Technologies (EVT), and we had hired Robert Molnar, MD, who was familiar with the EVT system. After my discussion with Dr. Bernhard, he selected us as a trial site for the EVT Aortic Endograft trial in December 1997. We had overcome a major hurdle, and change became the new norm.

As if this set of challenges for our group was not enough, carotid stents were being placed without cerebral protection devices at the University of Alabama at Birmingham by cardiologist Gary Roubin, MD. Remarkably, there were few strokes. It was apparent another treatment modality was about to come of age and had to be learned, but the question became where.” Cardiologists were not inclined to take vascular surgeons under their wings for training.

The vascular world was rapidly being transformed by other specialties with skills sets that few vascular surgeons had or were prepared for. The call for change was unmistakable.

Along with these external challenges, our group was also confronted with a number of internal challenges such as incorporating new physicians with different philosophical backgrounds in patient care. We continued to face challenges with getting appropriate training in the new technologies and with creating a public identity commensurate with our emerging endo-treatment skills. We had to find a way to better define us as vascular surgeons and differentiate us from other specialties.

Did our group’s name – Vascular Surgery Associates – convey to the public all the diagnostic and therapeutic options we offered? Did the word “surgery” limit the public’s understanding of our services? Having added a number of associates with differing philosophies, who were we as a group and what was the group’s purpose and vision? Where were we headed and how were we going to get there to grow and maintain our grasp on the vascular referral market? While we had spent many hours talking about the potential of our group as a destination vascular center, we had no road map and no support from the three area hospital networks.

After reading several books listed in the references, I realized we needed a set of core values, a core purpose, and a system to integrate these values and purpose. Core values define a company by what it stands for and are its enduring tenets. Good exam-
The staying power of an organization depends on its ability to withstand, adapt, and foster the endless internal and external forces of change.

The most comprehensive, innovative, and best possible vascular care based on sound principles of treatment.

Our core values are defined as follows:

1. We are a professional organization – a team – working equally in a common cause: to provide the best possible vascular care for the physicians, patients, and institutions of our community.
2. We share a commitment to excellence in the vascular care of patients through the pursuit of knowledge, communications, innovation, and research.
3. We value our employees and incorporate them into our team.
4. We commit to each other to honor and pursue these values.

Our responsibility to community

These principles defined our relationship with our employees, and with the public. They defined our commitment to change and innovation, making certain we did all we could to create, maintain, and perpetuate a group with the highest standards and quality while reaching out to the public to educate and serve them.

They established our culture and became our GPS for the future. Our commitment to these principles caused us to look into the future and decide what and where we wanted to be – a destination vascular center – and plan on how we would get there. This led to a cascade of decisions intended to fulfill our purpose of improving the quality of life for the patient with vascular disease.

Over the years, we have expanded what most would consider a basic vascular practice to include a self-funded, independent Michigan Vascular Research Center that has been involved in more than 70 different clinical trials. By having several members of our group travel all over the world, we have gained significant experience in carotid stenting and have entered more than 700 patients into various carotid stent trials.

We have been able to incorporate several freestanding outpatient centers to better serve venous pathology outpatients. In 2005, we established our first Michigan Vascular Access Center in Flint to improve life for patients on dialysis. We also have opened, in 2010, our first prosthetics center (Michigan Vascular Mobility Center) with our own prosthetist, to improve the rehabilitation of our amputees.

We have embarked on an aggressive branding and marketing strategy, including free vascular screenings, lectures to the public, and a blood pressure awareness program given for middle school students.

In 2014, we established a vascular fellowship that offers two 2-year positions, each filled as they become vacant.

We also changed the name our practice to be more representative of the diagnostic and consultative services we offer. Since we are now more than just “surgery,” we found the name of Vascular Surgery Associates to be restrictive. We instead became the Michigan Vascular Center, thus connoting a range of vascular services to the public and to referring physicians.

To try to constantly refresh ourselves in the mind of the public and referring physicians, we publish the Vascular Voice, an informational brochure, every few months.

This serves several purposes: Since many doctors are hospital employees who work in an office only and no longer make rounds, we rarely see them, so this is an opportunity for our group to keep in contact. Similarly, it is our introduction to physicians new to the community.

Finally, it serves as a vehicle to disseminate information to everyone about what we are up to. We write about our clinical trials, our newest group members, and new developments in the vascular field. Our mailing list goes to about 4,000 physicians and businesses.

As W. Edward Deming, PhD, mentions in his books, everyone in the organization must be on board to fulfill our group’s purpose.

To this end, we proudly post our Mission Statement and Core Values throughout our office and exam rooms to crystallize the defining culture for all to see and understand – employees, physicians, patients, and the community. These serve to offer guidance and inspiration to people inside the company and influence their behavior to be consistent with the ideology. Patients, too, have a better understanding of the philosophical approach, attitude, and culture of those in the practice who will be treating them.

In fact, every new patient gets an informational booklet in which we clearly state our values and services. In essence, there is alignment of all involved: employees, departments, physicians, and patients within the culture that we have established.

The staying power of an organization depends on its ability to withstand, adapt, and foster the endless internal and external forces of change. Your organization’s ideology will serve as a compass for your success.

The values will serve as a guide for the future direction of your group, its dynamics, its hiring practices, and its employees. They will force you to treat your practice, your department, and your position as an ongoing concern – one that was here before you, one that will be here after you, and most importantly, one that will be better because of you.

At Team Vascular, we are laying the groundwork not only for the next generation but also for the next 50 years, confident that our core values will help in the selection of new physicians the group now needs, confident they will continue to stimulate change to better achieve our purpose of improving the quality of life of our patients and will stimulate us to perpetuate the group’s culture of maintaining the highest standards of patient care. It is change as a norm, change as a never-ending learning curve. It is the Michigan Vascular Way.

References


The values will serve as a guide for the future direction of your group, its dynamics, its hiring practices, and its employees. They will force you to treat your practice, your department, and your position as an ongoing concern – one that was here before you, one that will be here after you, and most importantly, one that will be better because of you.
Guideline for Follow-up Imaging Unveiled

The Society for Vascular Surgery now has a clinical practice guideline devoted solely to imaging following vascular surgery interventions.


Six sections cover carotid artery procedures, thoracic and abdominal aortic repairs, mesenteric and renal artery repairs, and lower extremity arterial revascularization. The recommendations emphasize vascular laboratory testing and vascular imaging for both open and endovascular interventions.

“It is essential that vascular laboratory testing be performed by qualified personnel using appropriate instrumentation, as demonstrated by individual credentialing and facility accreditation,” the guideline says.

“The overall aim is to provide the best outcome from the initial procedure,” said Dr. Zierler, who headed the guideline writing group. “All arterial procedures have modes of failure,” he said, and “to make the arterial intervention as durable as possible, we have to understand these modes, how to detect them, and when to re-intervene.”

The main focus was to determine what kind of imaging would be most appropriate and, importantly, how often it should be done. When possible, issues involving diagnostic criteria and thresholds for re-intervention were also addressed.

“Despite the writing group’s work, the guideline is not the final word,” he said. Unlike other SVS clinical practice guidelines, none of the recommendations could be based on high-quality evidence (i.e. Grade A). “Our group’s review of the available evidence clearly shows a need for more clinical research on testing methods, surveillance protocols, indications for re-intervention, and outcomes,” he said.

For example, the first carotid recommendation is that: “Following CEA or CAS, we recommend surveillance with DUS (duplex ultrasound scanning) at baseline and every 6 months for 2 years and annually thereafter until stable … The first or baseline DUS should occur soon after the procedure, preferably within 3 months, with the goal to establish a post-treatment baseline. Considering the small risk of delayed restenosis or ISR, some interval of regular surveillance (e.g. every 2 years) should be maintained for the life of the patient.”

The strength of the recommendation is “strong” and the quality of the evidence “moderate” (1B recommendation).

“Evidence is somewhat scarce for many of the endovascular techniques because they change so quickly, unlike the more established open procedures,” Dr. Zierler noted. “Endovascular procedures are developing rapidly and devices are changing frequently. The life cycle of a certain device or intervention may be quite short.”

Whatever the quality of the current evidence, Dr. Zierler noted that vascular surgeons must create a follow-up plan for each patient that is most likely to provide the best possible outcome while minimizing costs and risks. “These guidelines should serve as a starting point for creating that plan,” he said.

“We decided early on … our overriding philosophy would be to err on the side of caution and image more frequently.”
- R. Eugene Zierler, MD, RPVI

YOUR SVS: Visit SVS Booth in Exhibit Hall at VAM

Booth at VAM

SVS members who are attending the Vascular Annual Meeting can get in-person help with any application issues or, indeed, any membership services concerns. The SVS Booth, #1015, in the Exhibit Hall will be staffed both Thursday and Friday, June 21-22. SVS staff members will be able to provide information on a wide range of topics, including:

- Member services, including
  - The benefits of belonging
  - Dues
  - Membership applications
  - Log-in issues
  - Contact information updates – don’t fall off the contacts list
- The Affinity Program of expanded benefits
- Educational products, including the fourth edition of the Vascular Education Self-Assessment Program (VESAP), the SVS Coding Course, Oct. 19-20 in Chicago, the SVS Vascular Research Initiatives Conference and the Rutherford’s Vascular Surgery book
- The Journal of Vascular Surgery publications (offering JVS socks!)
- The SVS Patient Safety Organization Vascular Quality Initiative
- Quality and clinical practice guideline initiatives (including printed copies of four of the latest SVS guidelines)
- The Mobile App or VAM Planner
- The SVS Foundation and the SVS Political Action Committee; members can make a donation to either or both

Visitors may also scan the QR code as part of the Exhibit Hall Scavenger Hunt.

Enter to win a prize: Those who drop by can be entered into a drawing for three prizes: an SVS Membership waiver for next year, free VAM 2019 registration and VAM on Demand from the 2018 meeting. In addition, while supplies last, visitors also can pick up a memento of their visit plus a DVD of a visit to the DeBakey Library and Museum in Houston.

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, visitsvnnet.org.
**NEWS FROM SVS**

**VAM Session: Physician, Heal Thyself**

**B5: Promoting Physician Wellness: Achieving Quadruple Aim**

Friday, 6:30 – 8:00 a.m.

HCC, Room 304/306

Between billing, coding, keeping electronic medical records up to date and ... oh yes, ... actual surgery, vascular surgeons increasingly report feeling overwhelmed and burned out.

In fact, vascular surgeons and trauma surgeons occupy some of the top rungs among the surgical subspecialties at risk for burnout, according to a 2009 study on the topic.

The Society for Vascular Surgery has created a Wellness Task Force to address causes, concerns, and possible solutions to the issue. The group, co-led by Drs. Dawn Coleman and Malachi Sheahan, has already distributed one detailed survey (to which approximately 800 people responded) and is in the process of readying another.

Burnout will also be addressed at a breakfast session at the Vascular Annual Meeting. “Promoting Physician Wellness: Achieving Quadruple Aim” will be held from 6:30 – 8 a.m. Friday in Room 304/306 of HCC. Tickets are required and may be obtained at a registration counter.

The first survey, preliminary results of which may be presented during the session, sought data on symptoms, if burnout were affecting work and contributing factors that are creating burnout. It also included questions on work schedules, including on-call shifts, how much work respondents were bringing home and electronic medical records.

The second survey, said Dr. Sheahan, hopes to delve deeper into other factors, such as physical stressors and wear and tear on a vascular surgeon’s body.

He noted that he wrote his first column on burnout for “Vascular Specialist” more than a year ago, when he did not yet know the issue’s prevalence. “The articles I’d seen were more than 10 years old,” he said. “I got a lot of feedback which told me there was something definitely there.”

Together, he and Dr. Coleman wrote a series of three articles on burnout. Positive reaction led to creation of the Task Force and then to the upcoming VAM presentation.

Topics include changes in medical and surgical practice in the 21st century, the hidden costs of burnout for both physician and patient, interventions to enhance surgeons’ personal well-being, what burnout is and why it occurs, strategies to combat it, and a “Societal Call to Action: Can We Improve Physician Wellness?”

Dr. Sheahan said he hopes to uncover more facts and feedback. For example, do researchers report the same level of burnout as surgeons in private practice? Do surgeons in rural settings have different, or more, stressors than those in urban environments?

He — and others who have written about physician burnout — believes electronic medical records play a big part. “I’m almost positive it’s going to prove a major factor,” he said. “It takes so much more time — time we don’t have.” At least five different medical record systems that don’t talk to each other exist, he said. “How did we develop that?” he asked. “It’s a very aggravating problem.”

Possible solutions also will be explored. Dr. Sheahan advocates that these solutions focus less on personal resilience and more on institutional change. “I believe that if we, on a large scale, tie the problem into our own productivity, health, and our own patient safety, they’ll have no choice but to change,” he said. One example would be to hold software engineers and hospital administrators accountable and get them to fix the lack of integration in EMR systems. A “rewards program” has possibilities as well. Credits, such as meals delivered for a week, are given for tasks over and above the norm. Stanford University has used this and it shows promise, Dr. Sheahan said.

Some experts have suggested resilience training, Dr. Sheahan disagrees. “Doctors are resilient by nature. Those who aren’t get weeded out a long time ago.” And teaching people to “deal with” stress isn’t the answer, he added. “We have to try to remove the stressors.

Just let us do what we’re good at. Physicians are happiest, safest, and most productive when doing what we were trained to do,” he said. “We now have so many things that take us away from patient care. It is these distractors that I believe lead to burnout.”

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**VAM: Many International Events Slated for Wednesday**


No matter the language, our international attendees are here in Boston to take advantage of the educational offerings provided at the Vascular Annual Meeting. Over the years, Wednesday has become a kind of “International Day” at VAM, with a large number of sessions aimed at this constituency.

This year is no exception and, in fact, a few new sessions have been added to the lineup: an International Poster Competition and an International Relations Forum. The traditional debate between SVS and the European Society for Vascular Surgery (set for Thursday) has been updated into a forum discussing differences in devices and health care deliver, among other topics.

**International events include:**

**Wednesday**

- International Forum, 8:00 – 11:30 a.m., HCC, Room 309
  - This is an abstract-based session.
- International Relations Forum: Scholarship Award Retrospective, 10:45 – 11:30 a.m. HCC, Room 309
  - This special session takes a look at the effects of the international scholarship program on awardees’ careers. In addition, short vignettes will play throughout the day, showcasing the stories of awardees unable to attend in person, but whose careers also have been impacted by the program.

Continued on following page
VAM: Learn About Affinity Program at SVS Booth

Popular Offerings Include Disability Insurance, Retirement Programs

What would happen if you suddenly couldn’t work, due to illness or injury? Would your current disability policy provide adequate coverage for your needs?

While at the Vascular Annual Meeting, find the answer to those questions and learn about other benefits offered through the Society for Vascular Surgery’s Affinity Program of expanded benefits.

These benefits for members and, in many cases, their families, help with refinancing of student loans, disability insurance, medical malpractice insurance, merchant solutions, such as payment processing and help with payroll and workers’ compensation issues.

From JVS and JVS-VL

From JVS-VL: Public Funding of EVA Reduces Costs

Publicly funded endovenous ablation has reduced the rates of high ligation and stripping, which in turn has reduced costs to the Canadian health system by approximately $42,000 a year.

And great saphenous vein intervention rates have not increased, according to an article in the July issue of the Journal of Vascular Surgery: Venous and Lymphatic Disorders. The article, “Economic Implications of Endovenous Great Saphenous Ablation in a Public Health Care System” is from the Canadian Society for Vascular Surgery and is open-source through July 31-Aug. 30.

Researchers retrospectively reviewed cases of HL/S between 2003 to 2014 and cases of EVA between 2007 — when it was introduced into the public system in Saskatchewan, Canada — and 2014. While the rates for great saphenous vein intervention were similar for both time periods, case costs of HL/S were higher than those of endovenous laser treatment. The total annual costs of great saphenous vein intervention decreased 154 percent after EVA was introduced.

Researchers have identified predictors of embolic filter debris load during carotid artery stenting in asymptomatic patients. The study is from the Vascular and Endovascular Surgery Society and is published in the July issue of the Society of Vascular Surgery. It is available, free, through Aug. 30 at vsweb.org/JVS-Debris.

Researchers performed a quantitative analysis of all patients with asymptomatic carotid stenosis of more than 70 percent undergoing CAS between 2008 and 2016. The authors concluded that the majority of asymptomatic carotid stenoses treated with CAS have detectable embolic debris in the protecting filter. Factors of being older than 75, a preexisting ipsilateral cerebral ischemic lesion, hypoechogenic plaque and plaque larger than 15 mm should be considered independent predictors of clinically relevant embolic debris during the procedure.

Friday

• SVS/ESVS Transatlantic Forum, 3:30 to 5 p.m.

Thursday

• SVS/ESVS Transatlantic Forum, 3:30 to 5 p.m.

HCC, Ballroom A/B

◊ The annual joint-presentation between the two societies has previously taken the form of a lively debate. It’s been turned into a forum for 2018, covering three issues as they are handled on either side of the Atlantic: teaching of open surgical skills, new technology and different regulatory environments, and the components of the vascular team.

Continued from previous page


• International Fast Talk, 2:30 – 4:15 p.m., HCC, Room 309

◊ This is an abstract-based session, during which the winners of the Young Surgeons Competition will be announced.

• International Poster Session, 4:30 – 6:15 p.m., HCC, Room 310

• International Guest Reception, 6:15 – 7:15 p.m., HCC, Room 310 (ticket required; available at Registration)

The Kai-Zen program, meanwhile, acts to accelerate contributions to retirement, helping participants maintain their lifestyles after they stop working.

As with nearly everything related to financial products, details matter. Blocker will be able to explain various products in detail and confer with members about their particular situations. He will be available for one-on-one consultations, by appointment. Members might want to consider bringing additional policies with them for review, he suggested.

Visit the SVS Booth for more information and to make an appointment.

Announcing a New Supplemental Retirement Opportunity

FOR SVS MEMBER PHYSICIANS

In collaboration with NIW Companies, SVS is offering access to a financial strategy that uses leverage to provide up to 60% more protection in the event of chronic or terminal illness and up to 60% more supplemental retirement income.

Contact Mark Blocker at nationalaffinityservices@nasd.com to learn more and get a quote.
Check out the latest news online at www.mdedge.com/vascularspecialistonline

Follow us on Twitter @VascularTweets
**NEWS FROM SVS**

**VAM: Learn to Navigate a Changing Fiscal Landscape**

Billing and coding. MACRA and MIPS. Payment methods and compensation levels. Stay autonomous or be part of a group? All are part of today’s fiscal landscape, and these challenges and realities can be difficult for vascular surgeons to navigate. Postgraduate course 6 (P6), “How to Succeed in a Challenging and Evolving Fiscal Landscape,” aims to make sense of it all. It will be held from 1:30 – 4:30 p.m. Wednesday. A separate fee and ticket are required.

The course will cover two broad concepts, said session moderator Vikram Kashyap, MD: How vascular surgeons can navigate the current fiscal landscape and whether surgeons should stay autonomous, compete against others, or somehow integrate.

Multiple health care providers are eyeing a particular population, he said, raising pointed questions. “Do we fight over the pie?” he asked. “Or do we grow the pie?” Should a surgeon become part of a group and/or a regional center to which patients travel for vascular care? “That’s where collaboration comes in. And maybe that will actually lead to better fiscal results as well as better patient outcomes,” he said.

Vascular surgeons could work with cardiologists, vascular medicine specialists, and/or cardiothoracic surgeons; those who don’t do procedures nonetheless could be excellent at diagnosing problems, evaluating and optimizing risk factors for best outcomes, and preparing patients for surgery, he said. “Of course, the devil is in the details” of compensation, allocation of resources, and other specifics, he said.

Participants will learn the specifics of a cardiovascular service line (CVSL), a patient-centric group of providers, and how to integrate vascular medicine into a CVSL. Besides surgeons, the group could include radiologists, vascular interventionists, nurse practitioners, extenders and others, Dr. Kashyap said. “A service line breaks down the traditional separations in many academic health centers. Incorporating physicians who are expert at imaging, at evaluation, at endovascular treatment and in open surgery often involves specialists with different training and requires changes to the organization-al structure.”

Such a group, he said, “requires collaboration among groups that have not traditionally been aligned.”

The session also will highlight coding processes surgeons need to know this year and discuss the lessons learned from year 1 of MACRA and MIPS that will make it easier for both academic and community physicians to comply in year 2.

Employment models are on the agenda as well and are tied into billing. Many SVS members are currently in private practices, operating as an LLC, billing and collecting fees for the procedures they do. A hospital or institutional setting is a different model, where surgeons provide services within a framework. “Even though the financial aspects of practice may be remote to a salaried employee, understanding how both the professional and technical revenue are generated and the margins calculated for your group are powerful when negotiating with the leadership of your institution,” he said.

The course offering follows the mission of SVS, to offer education for member needs, Dr. Kashyap said. “Many of our members may not be aware of the evolving fiscal landscape,” he said. “We need to be proactive. And this helps our members stay prepared as further challenges will undoubtedly be forthcoming.”

This is a ticketed session and requires an additional fee for non-SVS members. Register at a registration counter at VAM or online at vsweb.org/VAM18. 

P6: How to Succeed in a Challenging and Evolving Fiscal Landscape  
HCC, Room 304  
Wednesday, 1:30 – 4:30 p.m.

**VAM: Get Up-to-Date With Guidelines Updates**

Given the importance of clinical practice guidelines to SVS members, it’s not surprising to find more than one session on them at the Vascular Annual Meeting. This year’s presentations include:

- An update Thursday on Aortic Abdominal Aneurysm guidelines during the first scientific session, the William J. von Liebig Forum. A 12-minute presentation by Elliot Chaikof, MD, will begin at 9:46 a.m.
- Concurrent Session 6, “Update on Society for Vascular Surgery Clinical Practice Guidelines,” 1:30 – 3 p.m. Friday, HCC, Room 312. Topics include:
  - Overview and update of SVS process for development of clinical practice guidelines and reporting standards
  - Clinical practice guidelines for thoracic endovascular aneurysm repair for thoracic aortic aneurysms, including acute aortic syndromes and trauma
  - Guidelines for the care of patients with chronic mesenteric ischemia
  - Reporting standards for endovascular repair of complex aortic aneurysms using fenestrated and branched stent-grafts
  - Clinical practice guidelines for endovascular repair of complex aortic aneurysms involving the paravisceral aorta
  - Panel discussion
- A Saturday update on a new, far-reaching global guideline on the management of chronic limb-threatening ischemia (CLTI), a joint project of the SVS, the European Society for Vascular Surgery and the World Federation of Vascular Societies. The update will be held in the final 15 minutes (9:15 – 9:30 a.m.) of Scientific Session 6, 8 – 9:30 a.m. Michael Conte, MD, will present the update on the guideline, including an overview of the new GVG™ Global Limb Anatomical Staging System (GLASS).
- For members attending VQI@VAM, the annual meeting for the Vascular Quality Initiative, SVS members Thomas Forbes, MD, and Larry Kraiss, MD, will address “Coordination of SVS Clinical Practice Guidelines and VQI,” from 2:30 – 3 p.m. Wednesday, HCC, Room 312. Please note that admission to the VQI meeting carries an additional fee of $250.

For more information on these and all VAM sessions, see the VAM Planner at vsweb.org/VAM-Planner.

**Printed Guidelines to be distributed at SVS Booth**

Want quick access to printed versions of recent SVS guidelines? Look no further than the SVS Booth, No. 1015, in the Exhibit Hall.

We will be distributing printed “Pocket Guides” of the new abdominal aortic aneurysm guidelines, listing all 112 recommendations, plus tables with helpful evaluation and risk-scoring schemes as well as treatment algorithms.

Also available will be Pocket Guides for three other recent guidelines: Management of Diabetic Foot, Peripheral Arterial Disease and Venous Leg Ulcers. These printed publications — created with Guidelines Central — normally cost between $9.95 to $13.95, depending on the guideline. The guides will be available while supplies last.

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*FOR MEMBERS ONLY*  
Use Print Guidelines to your advantage for patient education and certification.  
Printed guidelines include a comprehensive list of recommendations, rationales, supporting data and references.  
Printed guidelines are a powerful tool to support patient education and are required for most fellowship accreditation programs.  

Printed Guidelines to be distributed at SVS Booth  
HCC, Room 304  
Wednesday, 1:30 – 4:30 p.m.
CAROTID DISEASE AND STROKE

Retinal infarctions get missed as stroke harbingers

BY MITCHEL L. ZOLER
MDEdge News
REPORTING FROM ISC 2018

LOS ANGELES – Retinal infarctions are often going missed as important red flags for future ischemic strokes.

Among U.S. Medicare beneficiaries older than 67 years who had a retinal infarction (RI), “only one-third underwent adequate stroke risk factor evaluation,” Alexander E. Merkler, MD, reported in a poster presented at the International Stroke Conference sponsored by the American Heart Association. And fewer than 10% underwent assessment by a neurologist, based on a review of 5,688 of these older Medicare beneficiaries who had an RI sometime during 2009-2015.

The high-risk profile of these patients was affirmed by a 1% ischemic stroke incidence during the 90 days following their RI diagnosis, a rate roughly fourfold higher than in similar patients without a recent RI.

“A lot of people don’t recognize that a retinal infarction is a type of stroke,” Dr. Merkler said in a video interview available online (www.vascularspecialistsonline.com). To test this hypothesis, Dr. Merkler and his associates examined the follow-up run on elderly Medicare beneficiaries following an RI diagnosis.

“The guidelines recommend evaluating why these patients had a stroke [a retinal infarction] and treating risk factors to reduce the risk of a future stroke,” said Dr. Merkler, a neurologist at Weill Cornell Medicine in New York.

The review showed that 34% of the RI patients underwent cervical carotid imaging, 29% had heart rhythm monitoring, 23% underwent echocardiography, and 8% had assessment by a neurologist.

Dr. Merkler had no disclosures.


Canagliflozin improved renal outcomes in type 2 diabetes

BY AMY KARON
MDEdge News
REPORTING FROM SCM 18

AUSTIN, TEX. – Canagliflozin can improve renal outcomes in patients with type 2 diabetes, even when they have mild or moderate kidney disease, new data from the CANVAS program suggested, according to Brendon L. Neuen, MBBS, of University of New South Wales, Sydney, and his associates. Baseline renal function also did not appear to affect the safety of canagliflozin, they added.

The multicenter, double-blind, placebo-controlled CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants with Type 2 Diabetes Mellitus) trials included more than 10,000 adults with type 2 diabetes and high cardiovascular risk.

In the primary analysis, canagliflozin significantly reduced the risk of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke, compared with placebo (N Engl J Med. 2017 Aug 17;377[7]:464-57).

Among patients with preserved function at baseline, canagliflozin was associated with a statistically significant 47% decrease in risk of renal death, end-stage kidney disease, or a 40% or greater drop in estimated glomerular filtration rate (hazard ratio, 0.53).

Canagliflozin has a black box warning for amputation risk. There was no indication that early renal function further increased this risk, the researchers reported.

Janssen funded the CANVAS and CANVAS-R trials. Disclosures were not provided.
CAROTID DISEASE AND STROKE

EAGLES: Smoking cessation therapy did not up cardiovascular risk

BY AMY KARON
MDEDGE NEWS
FROM JAMA INTERNAL MEDICINE

Smoking cessation treatment with transdermal nicotine replacement therapy (NRT), bupropion hydrochloride, or varenicline did not increase the risk of cardiovascular events among stable adult smokers with up to 1 year of follow-up.

“In what we believe to be the largest smoking cessation clinical trial and the only trial comparing NRT, bupropion, and varenicline with placebo, we found no signal that smoking cessation pharmacotherapy increases the risk of serious cardiovascular disease or cardiovascular adverse events in a general population of smokers,” concluded Neal L. Benowitz, MD, of the University of California, San Francisco, and his associates. “While the number of events was small, the incidence of serious cardiovascular events was low, suggesting that any absolute increase in risk that we might have missed would be low and not clinically meaningful.” The findings were reported online in JAMA Internal Medicine.

In this double-blind, multicenter, triple-dummy EAGLES trial, Dr. Benowitz and his associates randomly assigned 8,098 adult smokers, who did not have acute or unstable cardiovascular disease, to receive bupropion (150 mg twice daily), varenicline (1 mg twice daily), NRT (21-mg/day patch with tapering), or placebo for 12 weeks, followed by 12 weeks of follow-up. A total of 4,595 patients agreed to be followed for another 28 weeks during an extension phase of the trial. More than half of the patients were women and the average age of a participant was 47 years. The primary endpoint was time to major adverse cardiovascular event (MACE), including cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. The researchers selected time to MACE as their primary endpoint to better detect differences among groups. One of the secondary endpoints was the occurrence of MACEs over the same three time intervals. Additionally, cardiovascular deaths, nonfatal MI, and nonfatal stroke (the components of MACE) were evaluated individually, as were hospitalizations for congestive heart failure and serious arrhythmias.

Differences in time to onset of MACE among all four patient groups, were not significant. The overall incidence of MACEs was less than 0.5% during all observation periods.

There were also no significant differences in rates of the individual types of MACE, coronary revascularization, hospitalization for unstable angina, or new or worsening peripheral vascular disease requiring treatment among groups.

Changes in body weight, blood pressure, and heart rate also were similar across patients.

There were five cardiovascular deaths, including one in the varenicline group, two in the bupropion group and two in the placebo group, according to the researchers. Overall, the trial results “are consistent with and support previously published findings from meta-analyses and small clinical trials in smokers with known [cardiovascular disease],” they wrote.

GlaxoSmithKline and Pfizer, who make and market smoking cessation therapies, sponsored the study. Dr. Benowitz disclosed a consulting relationship with Pfizer and other pharmaceutical companies. He also has been a paid expert witness in litigation against tobacco companies.

Eight coinvestigators disclosed ties to Pfizer, GlaxoSmithKline, and other companies.


Psoriasis duration reflects cardiovascular event risk

BY BRUCE JANCIN
MDEDGE NEWS
EXPERT ANALYSIS FROM SDEF HAWAII DERMATOLOGY SEMINAR

KAUAI, HAWAII – The recent report that the risk of a major adverse cardiovascular event increases by 1% more than in the general population for each additional year of psoriasis duration is sobering news for physicians who treat pediatric psoriasis.

“If I have a 16-year-old who has a 5-year history of psoriasis, what does that mean for when she’s 30 or 40? And should we be intervening more aggressively?” Lawrence F. Eichenfield, MD, asked at the Hawaii Dermatology Seminar provided by the Global Academy for Medical Education/Skin Disease Education Foundation.

The question was rhetorical. As lead author of the first-ever pediatric psoriasis comorbidity screening guidelines, he is an advocate for a proactive approach. The published screening guidelines (JAMA Dermatol. 2017 Jul 1;153[7]:698-704), largely based upon expert consensus, were a joint project of the Pediatric Dermatology Research Alliance and the National Psoriasis Foundation.

“Even though there’s not a great deal of evidence, there’s some evidence to rationalize early screening in psoriasis,” according to Dr. Eichenfield, chief of pediatric and adolescent dermatology at Rady Children’s Hospital–San Diego and professor of dermatology and pediatrics at the University of California, San Diego.

Psoriasis develops during childhood in almost one-third of patients

The pediatric psoriasis screening guidelines describe a simple routine screening program and timeline for early identification of overweight or obesity, type 2 diabetes, hypertension, nonalcoholic fatty liver disease, anxiety, depression, substance abuse, inflammatory bowel disease, and quality of life issues, all of which are encountered with increased frequency in pediatric psoriasis patients.

A fasting lipid panel is recommended in children aged 9-11 years with psoriasis and again at age 17-21 years.

“Don’t forget arthritis. For a kid with psoriasis, at every office visit, I ask about morning stiffness or limp. Those are probably the two most sensitive questions in screening for psoriatic arthritis,” according to Dr. Eichenfield.

It has been clear for some time that the skin is not the only organ affected by psoriatic inflammation. The study that quantified the relationship between psoriasis duration and cardiovascular risk – a 1% increase for each year of psoriasis – was a collaboration between investigators at the University of Copenhagen and the University of Pennsylvania.

The two-part project included aortic imaging of 190 psoriasis patients using fludeoxyglucose F 18 PET/CT scan, which showed a strong relationship between duration of psoriasis and the degree of vascular inflammation. This was bolstered by a population-based study using Danish national registry data on 87,161 psoriasis patients and 4.2 million controls from the general Danish population (J Am Acad Dermatol. 2017 Oct;77[4]:650-56.e3).

Dr. Eichenfield reported serving as a consultant to and/or recipient of research grants from more than a dozen pharmaceutical companies.

SDEF/GlaxoSmithKline provided funding for the two-part project.

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Dr. Lawrence Eichenfield

BRIAN G. JONES/MDEDGE NEWS

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