



13 Leadership
Building out teams on
strengths and weaknesses
of members

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Regulatory unity can help drive medical device adoption globally, FDA official says

BY JOCELYN HUDSON

LAS VEGAS—Efforts at international collaboration across borders can drive harmony among disparate regulatory requirements and lead to greater global cooperation at the medical device level, a senior member of the Food and Drug Administration (FDA) told the opening session of the 2019 Vascular Interventional Advances (VIVA) conference (Nov. 4–7).

Global groups like the International Medical Device Regulators Forum (IMDRF) exemplify the kind of work regulators across the globe are undertaking to spark unity, explained Misti Malone, assistant director of the FDA's peripheral interventional devices team. "This is a voluntary effort among medical device

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Dramatic decline in open AAA repair training stokes strong concern over future surgical competence

BY BRYAN KAY

NEW YORK—The dramatic shift away from open surgery toward an endovascular approach has landed vascular practice at a stark crossroads, attendees at the VEITHsymposium (Nov. 19–23, 2019) heard during a lecture whose title bore a clear message: "How to teach competent open surgery in the endovascular era."

The presentation, delivered by R. Clement Darling III, MD, chief vascular surgeon in the division of surgery

at Albany Medical Center Hospital, Albany, New York, comes in the wake of a study published by the *Journal of Vascular Surgery* that found nearly half of senior trainees from 2010–2014 had performed less than five open abdominal aortic aneurysm (AAA) procedures.

Darling drew attention to numbers that demonstrate an open AAA training vacuum at many medical schools: "If you look at the data, there are 10 programs that didn't even have their fellows graduate with any open aortic experiments, which is a little bit shocking,

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Am I my brother’s keeper? A skeptic’s call for peer support in vascular surgery

BY MALACHI SHEAHAN III, MD



Malachi Sheahan III is the Claude C. Craighead Jr. professor and chair in the division of vascular and endovascular surgery at Louisiana State University Health Sciences Center in New Orleans. He is the medical editor of *Vascular Specialist*.

In the classic 1991 movie, “New Jack City,” drug dealer Nino Brown rhetorically asks his gang (the Cash Money Brothers), “Am I my brother’s keeper?” Nino’s subsequent murder spree suggests he was not. This well-known phrase first appeared in the Bible, though not in the context with which we are familiar. God approached Cain and inquired about the whereabouts of Abel. Cain, having recently killed his brother Abel, responds, “Am I my brother’s keeper?” Cain, it seems, was a bit of a tool. Despite its morally nebulous connotation in religion and popular culture, this idiom has taken on a different meaning: an expression of support for our peers.

Surgeons around the U.S. are suffering from mental exhaustion, substance abuse, burnout and suicide. Treatment to date has been sporadic, inconsistent and mostly ineffective. So now it is time for surgeons to ask ourselves, “Are we our siblings’ keepers?”

Why are surgeons suffering? We are exposed to sickness, disability, pain, trauma and death on a near-daily basis. That comes with the job. But how do we deal with this? What defenses do we deploy? Which defenses are helpful? Most importantly, which are harmful to either ourselves or our patients? As one might expect from a profession as singular as surgery, our responses to stress are fairly unique as well.

Defense mechanisms are often characterized by how primitive they are. The most primitive are learned in childhood and are sometimes retained because of their short-term efficacy. The trouble with primitive defenses is that, in the long term, they are ineffective and often harmful. As surgeons, our defense mechanisms are a mixed bag. Denial, altruism, depersonalization and humor are the most

commonly employed. Without these defenses, we would succumb to guilt, fear and despair. It is a difficult balance.

The very techniques that save us can quickly become destructive, even fatal. Altruism taken too far can lead to martyrdom. Martyrdom is a self-destructive condition in which the surgeon ignores their own well-being and that of their family. Depersonalization is an essential tool for surgeons. But when the disconnect is taken too far, burnout will ensue. Denial is one of the most primitive reflexes, a refusal to accept reality. Denial is highly effective in the short term—and highly destructive over time. Sublimation is one of the more mature defenses and is commonly expressed by surgeons as humor. Humor allows the channeling of unacceptable feelings into the acceptable.

Darker impulses

Of course, there are darker defense mechanisms that some surgeons deploy. Acting out is the hallmark of the disruptive surgeon: extreme behavior as a form of self-expression. Finally, substance abuse and even suicide are other means of defense surgeons employ disproportionately.

Surgeons must learn to balance empathy and

emotional dissociation to make our jobs possible. Learning this duality may be more effective when done with a peer group. For most physicians, our experience with peer group interactions occurs early in medical school in an unusual place: the gross anatomy lab.

Through the early 1900s, cadaver dissection was illegal in many parts of the U.S. Wealthier medical students traveled to Europe to learn anatomy. The less fortunate had to deal with grave robbers or, worse, become one.

Objections to cadaver training were also rooted in the theory that students would become hardened by the process, learning that the human body was simply an object to study. The students themselves, however, clearly valued the experience. The scarcity of cadavers in the U.S. meant that students had to perform anatomic dissection as a team. A new method of learning resulted—group hands-on study.

Looking through medical school photographs from the early 20th century, the most popular manner for a student to pose was with their anatomy group in the cadaver lab. Medical students viewed this activity as the ideal setting to portray their experience. Through the dissections and their peer groups, students were learning the “scientific” and “affective” aspects of medicine. Even though the anatomy groups formed out of necessity, it appears that medical students thrived as a consequence. In retrospect, it was our first evidence of the efficacy of peer support for physicians facing depersonalization.

Some of the photos of the cadaver groups from the early 1900s show the body posed as if alive. While distasteful by today’s standards, this does demonstrate the employment of sublimation to confront the conflicting feelings that human dissection engenders. Recently, facing new pressure

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EVAR

Meta-analysis: Translumbar embolization is superior to transarterial procedure in treatment of post-EVAR type II endoleaks

BY BRYAN KAY

Translumbar embolization had a greater technical efficacy than its transarterial equivalent in the treatment of type II endoleaks after endovascular aneurysm repair (EVAR), according to a systematic review and meta-analysis published in the *Journal of Vascular Surgery*.

As a result, lead author Qiang Guo, MD, of West China Hospital, Sichuan University, China, wrote, that the translumbar technique might be the better option in the treatment of patients who require reintervention.

Guo and his research team sought to compare clinical outcomes between the transarterial and translumbar (direct aneurysm sac puncture) approaches in the case of persistent type II endoleaks after patients had undergone EVAR procedures for an abdominal aortic aneurysm (AAA).

Type II endoleaks are caused by the backflow of collateral arteries into the aneurysm sac, the investigators explained, and are the most common complication of EVAR “with an occurrence rate of 22%.”

They continued, “Although most of the initially identified [type II] cases seal spontaneously, persistent [type II endoleaks are] associated with an increased incidence of adverse outcomes, including aneurysm sac growth and rupture.”

That’s why a consensus was reached that type II leaks persisting beyond six months with an increasing aneurysm size (>5mm) need reintervention, the authors added.

The investigators trawled multiple electronic databases up to Oct. 31, 2018, for eligible trials that included patients with type II endoleaks after EVAR and evaluated the outcomes of translumbar versus transarterial embolization.

They determined the primary outcome of the study as clinical success—meaning absence of an endoleak after a final examination—with secondary outcomes of technical success and complication rate.

Odds ratios (ORs) with 95% confidence intervals (CIs) were estimated, the authors wrote, and among the 904 studies screened, nine spanning 354 participants were included in their review.

“None of the studies reported rupture or mortality,” they explained. “The translumbar group had a relatively higher clinical success rate than the transarterial group, but this difference was not statistically significant (OR: 2.29; 95% CI, 1.00–5.25; p=0.05).

“The technical success rate was significantly higher in the translumbar group than in the transarterial group (OR: 13.32; 95% CI, 3.41–52.07; p=0.0002). No significant difference was found in the complication rate of the two groups (OR: 1.15; 95% CI, 0.26–4.96; p=0.85).”

In discussion, the authors observed that guidelines recommend imaging surveillance of one month after an EVAR procedure, then annually thereafter.

“However, a standardized treatment algorithm for the surgical management of persistent [type II leaks] with sac growth does not exist yet,” they wrote. “Rahimi *et al* concluded that in treating patients with persistent [type II leaks] in the setting of sac enlargement, if two endovascular procedures fail to obtain control of the endoleak,

repeated endovascular procedures are not recommended.

“They explained that a failed first attempt at the endovascular repair of persistent [type II leaks] is a strong predictor of future failure of endovascular interventions. Based on the results of this study, we suggest translumbar percutaneous sac puncture embolization as first-line treatment of persistent [type II leaks], and transarterial or transcaval embolization could be considered alternatively.”

In summary, the authors wrote: “Both translumbar and transarterial techniques are generally safe, causing rare postoperative morbidity and no mortality. However, translumbar technique had a superior technical efficacy over transarterial technique. Based on the current evidence, we suggest that the translumbar approach might be a better choice for patients with [type II endoleaks] that require intervention. Once repeated endovascular approaches have failed, open repair should be performed.”

SOURCE: DOI.ORG/10.1016/J.JVS.2019.05.074

AAA diameter could have crucial implications for patient outcomes

BY BRYAN KAY

The diameter of an abdominal aortic aneurysm (AAA) may have an important clinical impact on patient outcomes, according to a study of cases contained in the Vascular Quality Initiative (VQI) database.

The discovery, published in the *Journal of Vascular Surgery*, was made by Douglas W. Jones, MD, of the division of vascular and endovascular surgery at Boston Medical Center, Boston, and colleagues, who had sought to examine differences in patient selection, operative outcomes and survival after elective endovascular aneurysm repair (EVAR) based on AAA diameter thresholds.

In their rationale, the research team outlined the study backdrop: randomized trials have shown no benefit for repair of small AAAs, they explained, even though it is widely practiced. It has also been suggested that repair of large-diameter AAAs may incur worse outcomes, the researchers added.

In prior studies, EVAR for small AAAs was common, “indicating that many practitioners repair small AAAs on the basis of the presumed, unproven benefit of ‘early repair’ or that practitioners have developed individualized approaches to patient selection that take into account other patient-specific factors thought to modify rupture risk, such as rate of AAA growth, aneurysm morphology, family history of AAA, or gender,” they wrote.

The Society for Vascular Surgery recommends elective

AAA repair when the maximum diameter is equal to or greater than 5.5cm in men and 5cm in women.

To carry out their research, the team accessed the VQI database for all EVARs performed from 2003–2017, with 22,975 patients undergoing elective EVAR for AAA. The investigators found that 41% were for small, 47% for medium and 12% for large AAAs.

Only patients undergoing elective EVAR for infrarenal AAAs were studied, the authors noted. In explaining their findings, the investigators wrote: “Patients with small AAAs were younger and had fewer comorbidities. Consequently, patients with small AAAs were more likely to have low predicted operative mortality risk and five-year mortality risk based on risk models (p<0.001 for both).

“For operative outcomes, 30-day mortality was significantly different across diameter categories (small, 0.4%; medium, 0.9%; large, 1.6%; p<0.001). EVAR for large AAAs had the highest rates of multiple medical complications, including myocardial infarction (p<0.001), respiratory complications (p=0.001), and renal complications (p<0.001). In contrast, EVAR for small AAAs had the lowest rates of type I endoleak at completion and reoperation during index hospitalization, shortest operative times, and shortest hospital length of stay (p<0.001 for all).”

Aneurysm diameter was associated with differential one-year, reintervention-free survival (92% small vs. 89% medium vs. 82% large; p<0.001) and five-year overall survival (88% small vs. 81% medium vs. 75% large; p<0.001), the team went on.

Multivariable models further demonstrated that, compared with medium AAAs, small AAAs had an independent protective effect against one-year reintervention or death (HR: 0.82; p=0.003) and five-year mortality (HR: 0.78; p=0.001).

“Conversely, compared with medium AAAs, large AAAs carried an independent increased risk of one-year reintervention or death (HR: 1.75; p<0.001) and five-year mortality (HR: 1.50; p<0.001),” the researchers added. Asked about these findings, Jones emphasized that “survival rates for patients undergoing EVAR for small AAAs in the VQI are comparable to those seen in the surveillance arms of randomized controlled trials examining the utility of EVAR for small AAAs. Although these data illustrate that long-term survival is associated with AAA diameter at the time of EVAR, they should not be misinterpreted as supportive of EVAR for small AAAs over surveillance.”

“Small AAAs account for more than 40% of EVAR procedures in the VQI,” the researchers concluded. “Patients with small AAAs selected for repair are younger and have fewer comorbidities and consequently lower risk of operative and five-year mortality. Conversely, large AAA EVAR is associated with the worst operative and five-year mortality. Aneurysm diameter is independently associated with reinterventions and mortality after EVAR, suggesting that AAA diameter may have an important clinical effect on outcomes.”

SOURCE: DOI.ORG/10.1016/J.JVS.2019.02.053



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Open training

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especially if you're trying to give them credentials down the line," he said. "It's going to be hard to do that, especially for open surgery."

His warning finds fertile ground in the recent research. The study—"The decline of open abdominal aortic aneurysm surgery among individual training programs and vascular surgery trainees"—finds intensifying concern over the proficiency of future surgeons.

"The variable and diminishing [open AAA repair] exposure among vascular surgery training programs highlights growing concerns surrounding competence in complex open repairs and suggest that only a small proportion of current trainees have ample opportunity to develop confidence and proficiency in this high-risk operation," wrote a research team led by Margaret E. Smith, MD, of the department of surgery at the University of Michigan, Ann Arbor, Michigan.

For Darling, a snapshot of practice at his institution illustrates the point: "We're in a 3-1, 4-1 endo[vascular] versus open group but we still do a fair amount of aortic surgery and open distal surgery as well as carotid surgery," he explained.

"So the problem we are presented with is decreasing volume—and any of the volume that we are doing is more complex or redo from some of the interventional failures. Everything we do we fail at one point or another. Patients tend to be sicker and older, with less time to learn and fewer patients to learn from. And we have a higher scrutiny of what we do throughout the country."

Problem of declining volume

Darling then posed the burning question that underscores the difference between the training received by previous generations of vascular surgeons and the current one: How do you teach when volume is declining?

"One thing we have tried to emphasize to our fellows is they don't have to do to learn, and so many times when we're doing an open aneurysm or an open aortobifemoral bypass we can actually bring multiple residents in there to show them the anatomy, show them the techniques so it will be a group learning instead of a single learning," he said.

Darling emphasized the very different profile of the emerging generation of surgeons: their approach to work-life balance, their expectations—and their varying approaches to learning. There are those who learn intellectually, those who absorb through repetition, Darling continued. "But mostly, especially the millennial generation, people learn from positive reinforcement and being able to guide them through the learning."

Continuing on the theme of overcoming the open surgery chasm, Darling returned to how he and his team approach training in Albany.

"I would argue, especially with aortic surgery, it's more like flight training now," he said. "We have a meeting before where we have the fellows present to us exactly how the technical aspects of the operation went [...] We anticipate all the problems and then at the end with the nurses and the fellows, we go through a technical debriefing of what happened and how we can improve the situation."



R. CLEMENT DARLING III

Students are exposed to a number of techniques, Darling continued: "We use simulation for open and endo[vascular]; a lot of video preparation, [which] allows them to see the anatomy because I think the most important thing is to have the anatomy in your mind's eye; and team simulation and observation.

"So our approach is we sit in the morning and discuss every case, discuss every approach, discuss how we do it and the technical aspects of it. We make them visualize as well as verbalize exactly what we do and understand the potential pitfalls as we do it. We have a series of plans that are already arranged so no one does any thinking in the OR [operating room]; you do your thinking before you get to the OR, and answer all the questions then. And know what your endpoints in every operation are going to be."

Darling reiterated the importance of group learning "especially in these days of low volumes," adding: "All of us are smarter than one of us. As Napoleon said, amateurs discuss tactics and the professionals discuss [logistics]. Because it's all about the logistics and the set-up of these operations: it has to be intellectual as well as tactile, and you've

"One thing we have tried to emphasize to our fellows is they don't have to do to learn, and so many times when we're doing an open aneurysm or an open aortobifemoral bypass we can actually bring multiple residents in there to show them the anatomy, show them the techniques so it will be a group learning instead of a single learning."

got to figure out exactly how you can adapt these younger students to a learning process."

At the moment, Darling argued, students aren't being trained well enough in open surgery owing to the field's failure to adjust to the current generation's particular needs and modes of learning. He prescribed the development of centers of excellence in order to create volume exposure as well as simulation, videos and active preparation to maximize the education of trainees as potential remedies.

Decade of dramatic change

For Smith *et al*, the investigators behind the recent study, the spur to action came in light of alarm over what they described as an inadequate level of open aortic repair exposure among trainees, leaving vascular surgery's emerging practitioners unable "to develop the necessary confidence and competence to perform this high-risk procedure independently."

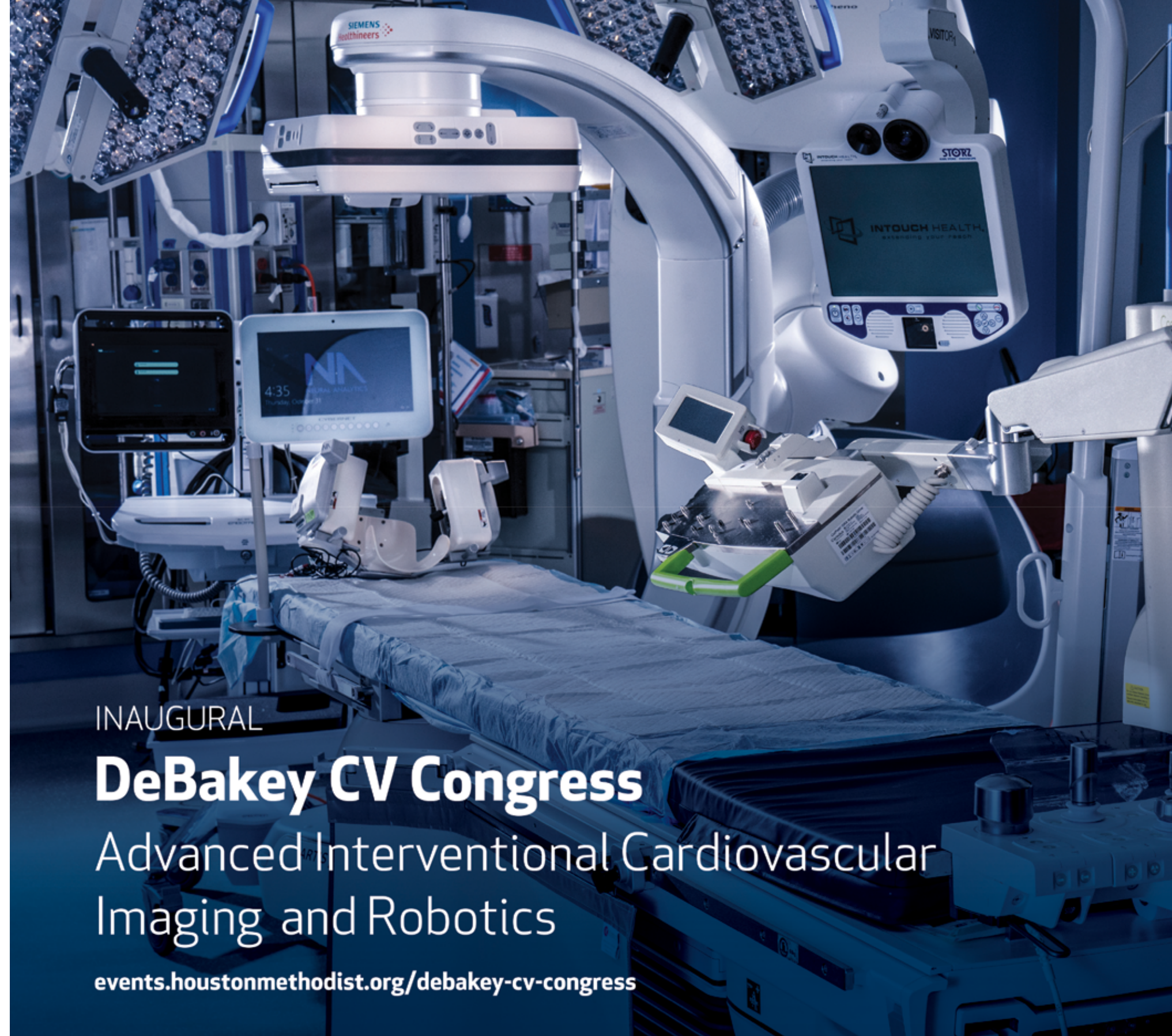
The research team wrote: "The evolution in surgical management of abdominal aortic aneurysm (AAA) from open AAA repair to endovascular aneurysm repair (EVAR) has been accompanied with apprehension regarding vascular surgery trainees' exposure to [open AAA repair]. The use of EVAR increased rapidly after its approval in 1999 with the proportion of AAA treated endovascularly increasing from 5% in 2000 to 74% in 2010; only 15% of AAA in Medicare beneficiaries were treated with [open AAA repair] in 2014."

The team sought to better understand variation in open repair training among vascular surgery trainees across the U.S. They studied Medicare beneficiaries undergoing EVAR or open AAA repair at accredited vascular surgery training intuitions between 2010 and 2014. "We aimed to understand AAA repair trends within individual programs as well as to evaluate individual trainees' opportunity for [open AAA repair] exposure," they wrote.

In a retrospective review of prospectively acquired data from the Centers for Medicare and Medicaid Services, the researchers identified accredited vascular surgery training program hospitals, with open repair and EVAR volume aggregated at the program level. The number of senior vascular surgery trainees per year at each program was then captured. "The training program all-payer total AAA repair volume was calculated based on the national proportion of patients undergoing AAA covered by Medicare in the Vascular Quality Initiative," they explained. "Temporal trends in program and vascular surgery trainee [open AAA repair] and EVAR volume were calculated."

A total of 119,408 (77%) EVAR and 35,042 (23%) open repair cases were identified in the Medicare database over the five-year period studied, the authors explained. "Of these, 21% were performed among the 111 training programs, including 22,227 (73%) EVAR and 8,416 (27%) [open AAA repair]. The total [open repair] volume among training programs decreased by 38% during the study period, from a median of 29.1 to 18.2 [open repair]. In 2014, 25% of programs performed fewer than 10 [open repairs] annually. Among senior vascular surgery trainees, the median number of [open repairs] decreased from 10 in 2010 to 6.4 in 2014 and approximately one-half of senior trainees had

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Open training

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exposure to fewer than five [open repairs] in 2014.”

Since its approval 20 years ago, EVAR has steadily replaced open repair as the go-to procedure. Only a year afterwards, the investigators observed, open repair volume decreased from 88% in 1998 to 77% in 2000. Two years later, the surgical community started to speak out about operative training in open repairs for future surgeons, they wrote. “Over the past 20 years, workforce concern for future surgeons’ competence in performing [open surgery] has exponentially grown.”

Shifting institutional policy might demand change in the current dynamic, the authors continue. “The 2018 Leapfrog Group volume standards state that hospitals should perform a minimum of 15 [open aortic repairs] annually and surgeons should perform a minimum of 10 [open repairs] annually to be credentialed. Although the usefulness

of [open repair] volume as a quality metric is questioned, many healthcare systems are implementing these standards and barring surgeons who do not perform a minimum of 10 [open repairs] per year. Our results demonstrate that a significant proportion of senior vascular surgery trainees will perform fewer than 10 [open repairs] in their training and may be ill-equipped to safely meet these credentialing standards.”

Doubt cast over remedy

Smith *et al* note that exposure to open repair varies across the country with nearly half of all learners performing fewer than 10 in their final years of training. Prior suggestions put forth to address the shortfall are “untested or may have unintended consequences,” they wrote in conclusion.

By way of example, the research team referenced simulation-based open repair training, which they described as “low fidelity and unlikely to provide nuanced skills necessary for proficiency.”

The authors continued:

“Regionalization of [open repair] to specific centers, as suggested in previous studies, may result in few trainees exposed to this procedure, thus failing to address the declining number of surgeons with [open repair] expertise.” This remedy may exaggerate healthcare disparities among vulnerable populations, they argue.

The investigators outline their own prescription amid a rapidly changing clinical training experience for AAA management. They cite clear technical standards, redefined volume and case-mix thresholds, systematic performance measurement of trainees, and the leverage of quality collaborative efforts such as the Vascular Quality Initiative in order to track the clinical outcomes of junior surgeons.

This, the authors write, “may be necessary to ensure trainees are ready for independent aortic practice when entering the workforce.”

Furthermore, the researchers zeroed in on the shifting sands of EVAR’s long-term benefits and cost-

effectiveness. As this process plays out, they add, a growing population of patients may elect open repair “and healthcare policies may preclude continued widespread use of EVAR as is currently proposed in the United Kingdom’s National Institute for Health and Care Excellence guidelines, which significantly restrict the use of EVAR.

“Although EVAR will likely remain the most common approach for AAA in the U.S., both institutional and specialty-wide initiatives must be studied to ensure future vascular surgeons are provided the expertise needed to perform high-risk [open repair] when necessary.”

Back at the VEITHsymposium in New York, meanwhile, Darling left his audience with another simple message: “I think Charles Darwin was correct when he said the stronger of species survive,” he told those gathered. “It’s not the most intelligent; it’s the one most adaptable to change.”

SOURCE: DOI.ORG/10.1016/J.JVS.2019.06.204

Peer support

Continued from page 2

to shorten or eliminate anatomy courses, defenders have cited the benefit of cadaver dissection as the first step toward learning medical professionalism.

Our struggle to balance empathy and emotional distance only begins in medical school. In 2000, Albert Wu published the landmark article “Medical error: The second victim.” Suddenly, this secret was exposed. Doctors who appear uncaring or detached after an adverse event are actually trying to cope with their own suffering. Researchers have attempted to characterize the stages of physiological and psychological responses physicians exhibit after an untoward patient outcome.

Surgeon-patient relationship

Surgeons, however, demonstrate a pattern of behavior unique from other physicians. This is likely due to the intimacy surgery imparts on the doctor-patient relationship. Surgeons generally follow a four-stage response to major complications. Stage one, “the kick,” is characterized by anxiety, physiologic stress and feelings of failure.

In stage two, “the fall,” surgeons become wrapped in feelings of loss of control. This occurs concurrently with a desperation to right the ship. Stage two is a pivotal point, and the surgeon’s personal and professional life can become consumed. As the surgeon reaches stage three, “the recovery,” they begin to deploy their coping mechanisms.

At this point, most surgeons are open to discussing the event, especially with peers. Based on the result of stage three, a broad range of outcomes are possible in the final stage: “long-term impact.” Here, the cumulative effects of these events are brought to bear on the surgeon’s sense of self.

Some surgeons learn and take positivity from the experience. Others become riddled with doubt.

While the surgeon goes through this process, what is the institution’s response to a major adverse event? First, steps are taken to care for the patient—“the first victim”—and their family. Hospitals will also look at the root cause analysis and provide reports to the appropriate agencies. What’s clear is that in most cases, little is done to address the physician’s pain.

Elusive wellness

Yet, if you look around, physician wellness initiatives are popping up everywhere. What has caused this sudden surge in institutional benefaction? Recent data show that when a physician succumbs to burnout, their organization is faced with more than \$2 million in lost profit. This fact has been well circulated in hospital administration literature. Coincidence?

Nevertheless, every hospital CEO knows that physician wellness programs are at least a financial priority. But, much like we have seen with the Heart and Vascular Centers™, there is little evidence of their efficacy. So we get window dressing treatments like meditation, mindfulness training and yoga retreats.

To see what works, we should look to other professions that routinely face trauma. Military personnel, firefighters, police and EMTs have been using peer support for years with great success. Why doesn’t it work as well in hospitals? Surgeons are loathe to jeopardize their leadership role in the healthcare team.

In psychological treatment, certified peer specialists are persons who have already received mental health therapy and can use their recovery as a resource for others. The best peer support appears to come from someone who has a shared experience. The same message is conveyed by

research into the support physicians receive from their spouses. The best support appears to be found in dual physician marriages.

What are the two most common reasons surgeons would seek support? Medical errors and malpractice issues. For most of us, this type of support is not available in our homes or hospitals. There are many barriers to building a network of peer support in vascular surgery. We are a small specialty that is geographically diverse. We have little time to spare in our lives. I have come to believe, however, that we have little choice but to try. And we are dangerously late to the game.

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AORTIC INTERVENTION

‘Alarming rate’ of severe cerebrospinal fluid drain complications discovered in first-stage TEVAR and F-BEVAR of aortic aneurysm procedures

BY BRYAN KAY

Severe complications from placement of cerebrospinal fluid drains (CSFD) during first-stage thoracic endovascular aortic repair (TEVAR) and fenestrated-branched endovascular repair (F-BEVAR) of pararenal and thoracoabdominal aortic aneurysms (TAAAs) were found to occur at an “alarming rate” in a prospective, nonrandomized study published by the *Journal of Vascular Surgery*—so much so the investigators behind the research changed their practice.

Conducted by a team led by Gustavo S. Oderich, MD, and Jussi M. Kärkkäinen, MD, the researchers established that the risk of major CSFD-related complications “is not negligible and should be carefully weighed against its potential benefits,” despite the procedure being widely used to prevent ischemic spinal cord injury during complex aortic repair.

“One-third of spinal cord injuries were caused by CSFD placement,” wrote Kärkkäinen, at the time of the study a visiting research fellow at the Mayo Clinic in Rochester, Minnesota, *et al*. The most worrisome finding was the rate of spinal hematoma, but intracranial hemorrhage also occurred. “The use of fluoroscopic guidance may decrease the risk of CSFD-related complications.”

The research team had set out to determine the rates and risk factors of complications related to CSFD during the two endovascular procedures.

The study cohort included patients with pararenal and TAAAs enrolled between November 2013 and October 2018. “The presence of substantial degenerative lumbar disease [DLD], thought to make drain placement difficult (such as spinal canal stenosis), was identified based on review of preoperative computed tomography [CT] scan or CT angiography radiology reports or history of lower-back surgery,” the authors noted.

Of the 293 consecutive patients enrolled in the trial, 106 were treated without CSFD and excluded, which included three patients who underwent staged repair and 103 patients who had single-stage F-BEVAR. Included in the study were 187 patients treated for 20 pararenal



GUSTAVO S. ODERICH

and 167 TAAAs. With a mean age of 73, 70% of them male, they received CSFD in 240 procedures, including 51 first-stage TEVARs, 184 index F-BEVARs, and five completion temporary aneurysm sac perfusion (TASP) procedures.

The results showed that 19 patients (10%) had 22 CSFD-related complications after 21 aortic procedures (9%). Complications were graded as severe to moderate in 17 patients (9%), the investigators found. There were 12 patients (6%) with intracranial hypotension, including three (2%) who had intracranial hemorrhage, and nine (5%) with post-dural puncture headache, which required blood patches in six. Another six patients (3%) developed spinal hematomas resulting in paraplegia in two (1%) and transient paraparesis in two (1%). One patient had CSF leakage from the puncture site with no intervention required.

“Four patients had bleeding during attempted drain placement, which required postponement of F-BEVAR,” the researchers continued. “Technical difficulties were experienced in 57 drain insertions (24%), more often in patients with DLD than in those without DLD (35/113 [31%] vs. 22/121 [18%]; p=0.03). Fluoroscopic

guidance was used in 44 drain placements (18%) with a lower rate of technical difficulties compared with the blind approach (9% vs. 28%; p=0.01).

“There was a statistically nonsignificant trend toward more complications in patients with technical challenges (14% vs. 7%; p=0.10).”

Of 13 study patients who developed spinal cord injuries during aortic procedures, four (31%) were attributed to CSFD, the authors added.

Noting the study’s 9% rate of CSFD-related complications during endovascular procedures for pararenal and TAAAs, the authors reported their findings “nearly identical to the 10% rate” found in a systematic review by Lisa Q. Rong, MD, *et al*, of Weill Cornell Medical College, New York, published in the *British Journal of Anaesthesia*. “The complication risk was similar in first-stage TEVAR and F-BEVAR procedures,” they explained.

“An alarming 4% of the study patients had severe, potentially life-threatening spinal drain complications, which possibly contributed to the death of two patients (1%). In comparison, the rates of severe complications and death in the previous systematic review were essentially the same, at 2.7% and 0.3%, respectively. The incidence of ICH [intracranial hemorrhage] in our series was also comparable, but the incidence of spinal hematomas (3.0%) was higher in our study compared with the systematic review (0.8%).”

Explaining the rationale behind the change in their practice, the authors continued: “Because of the high rate of spinal hematomas, we no longer recommend CSFD during first-stage TEVARs or for patients with pararenal or extent IV TAAAs who require shorter segments of supraceliac coverage. In addition, CSFD is individualized for patients

with extent III TAAAs and used routinely for extent I and II TAAAs. Among patients who undergo F-BEVAR without a drain, CSFD is indicated only if the patient develops irreversible changes in intraoperative neuromonitoring or postoperative neurologic symptoms of SCI.”

In terms of the study’s shortcomings, the investigators pointed to what they described as its most major limitation: the retrospective nature of collecting CSFD-related data.

“Although the note template for spinal drain insertion procedure was fairly well-structured in our electronic medical record, there is a possibility of variation in reporting between neuroradiologist and anesthesiologist because these specialists used different note templates,” they wrote.

“The association between CSFD and ICH is often obscure, and causality can be difficult to establish; the authors agreed on the etiology of two ICHs and one remained inconclusive.”

CT scans, the researchers went on, are often reported in a standardized fashion by the radiologists but “DLD was not well-defined in this retrospective study because it mostly relied on the radiology report, and it is very common in middle aged to older individuals.”

“This is the first study to analyze CSFD-related complications in first-stage TEVAR and F-BEVAR of pararenal and TAAAs in a comprehensive and systematic way,” the authors wrote in conclusion. “It demonstrated an alarming rate of severe complications which has led to changes in practice in our hospital. Although CSFD is widely used to prevent ischemic SCI [spinal cord injury] during complex aortic repair, the risk of major CSFD-related complications is not negligible and should be carefully weighed against its potential benefits. Use of fluoroscopic guidance may reduce the risk of CSFD complications.”

Of the organizations noted by the authors as conflicts of interest, none had any involvement in the research, they reported.

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Global vascular guidelines for CLTI are gaining traction but work remains to raise awareness and delivery of care

BY RICHARD F. NEVILLE, MD

The application of new global vascular guidelines for chronic limb-threatening ischemia (CLTI) provides an opportune and worthwhile window to revisit the concept of critical limb ischemia (CLI) along with its implications as a worldwide healthcare issue.

Peripheral arterial disease (PAD) leading to CLI is a growing problem around the world. More than nine million Americans have PAD, including 30% aged 70 and over, with many patients believing that significant leg pain is just a part of getting old. CLI itself is also on the rise worldwide, particularly in light of the explosion in diabetes. It is estimated that by the year 2040, more than 640 million patients across the globe will be suffering from the condition. This includes a significant increase outside of North America, particularly in the Asia-Pacific region. There are more patients worldwide with PAD than those with other well-recognized disease entities, including heart failure, Alzheimer's disease, cancer, HIV/AIDS and those related to the opioid addiction problem. This virtual epidemic will increase the cost of the disease globally to well over \$600 billion. Additionally, the rate of women with PAD has now crept up on the rate among men.

In 1982, at an international vascular symposium, CLI gained attention as a condition in patients without diabetes who have chronic ischemia as a major threat to a limb. Symptoms—rest pain and tissue loss—and the physical examination (pulse exam) have always been important in the diagnosis and evaluation of CLI, but



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physiologic criteria were also included in the analysis. These criteria have included an ankle-brachial index of less than 0.3, an absolute systolic blood pressure less than 15mmHg at the ankle, an absolute systolic blood pressure less than 30mmHg at the toe, and a decrease in PVR (pulse volume recording) waveforms (<5mm) and PPG (photoplethysmogram) waveforms (<4mm).

In the 1980s and 1990s, the Rutherford and Fontaine classifications gained popularity. These classification systems included categories consistent with CLI. In the Rutherford system, categories 4–6—and Fontaine's stages 3 and 4—are consistent with CLI. The Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) II document from 2008 added to the classification of CLI with a focus on arterial anatomy as well as ischemic symptoms, and objectively proven PAD. This classification system was adopted by the American Heart Association and American College of Cardiology in 2016.

The Society for Vascular Surgery (SVS) has been an advocate of the Wound, Ischemia and foot Infection (WIFI) classification system, which incorporates a classification of the

wound, degree of ischemia and extent of infection. Most recently, several vascular societies—including the SVS, the European Society for Vascular Surgery and the World Foundation of Vascular Surgery—have issued global vascular guidelines, renaming the disease CLTI.

The guidelines state that the term CLI is outdated and fails to encompass the full spectrum of the disease as well as moderate practice. CLTI is proposed as a broader category in order to decrease delays in therapy and avoid amputation. The authors of these guidelines feel that previous classification systems did not capture the full range of neuro-ischemic compromise involved with these patients and felt that a specific hemodynamic threshold for CLI may not be appropriate. But they did advocate for certain hemodynamic criteria based on the patient's clinical presentation. The authors supported the use of the WIFI system proposed by the SVS.

Despite the refinement in definition and management guidelines, much work remains to be done in terms of awareness and delivery of care. The public and healthcare policy advocates do not fully understand this disease process or its implications in terms of care and cost to our healthcare system. TASC II pointed out that after one year of CLI therapy, only 25% of patients were alive with the resolution of their symptoms. Lower extremity amputation and an underappreciated mortality rate continue to impact patients with CLI. An incident diagnosis of CLI has a higher five-year mortality than most diseases with the exception of lung cancer, with a 46% survival rate at five years among

Medicare beneficiaries who have no prior diagnosis of CLI. The impact of a major amputation is profound.

Meanwhile, it is also increasingly recognized that there is a disparity in the delivery of care based on angiography and socioeconomic status: availability of care for patients with CLI and amputation rates appear to correlate nationally, although this does not impart causation. There are also racial and ethnic disparities.

Therefore, there is fertile ground for progress to be made in the delivery of care for the growing number of patients with CLI/CLTI related to PAD. As vascular specialists, we must continue to raise awareness among patients, nonvascular physicians and healthcare policymakers on this important issue. As vascular specialists, we must help impact and alleviate the disparity of care delivered based on both geography and socioeconomic status. As vascular specialists, we must focus on reduction of amputation and the progress that has been made in this regard as well as prosthetic development to maintain the ambulatory status and health of our patients.

Finally, as vascular specialists, we must make use of this opportunity. We have to make certain that these patients are on appropriate adjunct medical therapy in the form of statins, antiplatelet agents and other medical regimens in order to decrease the mortality associated with this condition. Although this may seem a daunting task, much progress has been made. The future appears ripe for a major impact to be made on a significant healthcare problem.

When world vascular societies combined to produce new global guidelines for chronic limb-threatening ischemia

BY BRYAN KAY

Four years ago, vascular experts from around the world were tasked with a quest to get all surgeons and providers to agree on the best ways to treat this common and debilitating illness: chronic limb-threatening ischemia (CLTI). The goal came to fruition with the publication of the new global guidelines, produced by the European Society for Vascular Surgery (ESVS), the Society for Vascular Surgery (SVS) and the World

Federation of Vascular Societies (WFVS) and published in the ESVS' *European Journal of Vascular and Endovascular Surgery* as well as in the SVS' *Journal of Vascular Surgery*.

CLTI is the end-stage of peripheral vascular disease, which carries with it the risk of amputation or even death from the effects of vascular disease.

The co-editors were Michael Conte from the SVS, Philippe Kohl from the ESVS and Andrew Bradbury from the WFVS. Nearly 60 additional

authors worked on the project. Participants spanned six continents and represented all specialties that treat CLTI.

The collaboration between expert vascular specialists from around the world has created a unique practice guideline, reflecting the spectrum of the disease and approaches seen worldwide, said Conte. An extensive evidence review was undertaken, directed by a methodologist, to support the writing group's work.

CLTI continued on page 9

PAD

CLTI

Continued from page 8

"This guideline provides a new foundation for describing and treating CLTI, an escalating public health problem around the world that involves a broad array of health professionals," Conte said. "By improving the staging of CLTI, we believe that optimal care pathways can be defined and based on more accurate clinical and epidemiologic evidence going forward."

Conte noted with pride that the multispecialty, international group of vascular experts emphasized the importance of a patient- and limb-centric approach to the care of CLTI.

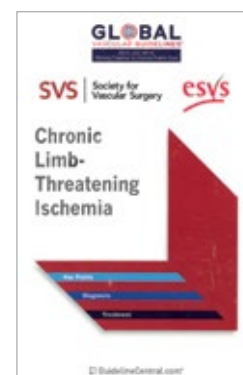
"With the continuous evolution of vascular technology, we must remain focused on the primary goals of treatment, in contradistinction to a lesion-centric emphasis on technical success," he said.

On the part of the ESVS, Florian Dick, of the University of Bern in Bern, Switzerland, spoke of a central message that approaches the patient in a holistic way—with a planned scheme. Speaking at the 2017 iteration of the ESVS meeting in Lyon, France, he went on: "Only then you can decide on how to treat the patients, as you have a basic matrix to predict risks and outcomes. Then you put in your differential treatments and you assess again. You have the chance to follow the patient in a very structured way, and make sure (i.e. measure) that what you are doing leads to improvement. If it does not, you change your treatment approach."

Among the major changes that came with the new guidelines was to the name itself. The term "critical limb ischemia (CLI)" was "outdated" and failed to encompass the full spectrum of patients evaluated and treated for limb-threatening ischemia, the authors said.

Conte attributes the success of the diverse, international group to a process of consensus development. "A key aspect of our success was broad agreement on the importance

of creating a new set point for CLTI around the world. CLTI is one of the most common conditions treated by vascular specialists, and often the most challenging.



We also recognized that where evidence is limited the recommendations must be carefully considered to encompass the scope of practice," he said.

Major recommendations cover the need for comprehensive assessments in patients with suspected CLTI; optimal medical therapy, including a variety of treatments for patients with CLTI; and prompt and effective revascularization for patients with advanced ischemia and limb threat. The document also outlines the importance of an individualized approach to improve patient care and reduce limb loss.

The guideline also endorses the SVS Threatened Limb Classification System based on grading Wound, Ischemia and foot Infection (WIFI) in the affected limb. And it introduces the Global Limb Anatomic Staging System (GLASS) to stratify the patterns of arterial occlusive disease in the affected limb. GLASS integrates the complexity of disease along a selected target artery path from groin to foot. GLASS stages (1–3) are designed to correlate with immediate technical success and 12-month limb-based patency following peripheral vascular intervention.

The GLASS classification, explained Dick, "really relates to the arterial path down the limb. After the step back to see the holistic scheme which integrates the person and the problem (wound, perfusion and infection), you need to go into more detail for the anatomic scheme of the arterial path. With GLASS, we have a matrix that assesses the two levels (fem-pop and tibial) regarding arterial vascularization options with the aim of restoring one path to the foot. Essentially, GLASS looks at the distribution and the severity of the different lesions along the whole limb, and grades them against the chances of success with endovascular treatment."

Conte highlighted the guideline's "structured approach to decision-making regarding revascularization based on patient risk, limb severity and anatomic complexity (PLAN), in that order of priority," adding that it "seeks to provide a new foundation for practice but also for data collection to support evidence-based revascularization in CLTI."

Beyond improving patient care, identifying key research priorities is an important secondary goal for the guideline. Thus, each section includes such priorities, where efforts and resources should be focused to improve patient care and advance the science.

Spotlight

K. CRAIG KENT, MD, has been named executive vice president for health affairs at the University of Virginia. He will oversee UVA Health and its clinical enterprise. He currently is dean of Ohio State University's College of Medicine.

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PEARLS: A mnemonic to help handle adversity

BY JOHN F. EIDT, MD, AND GABRIELA VELAZQUEZ, MD

There is accumulating evidence that adverse clinical outcomes have a negative impact on the clinician. As vascular surgeons, we are particularly vulnerable to feelings of guilt, shame and self-doubt when we are confronted by a complication related to our actions. It hurts when a patient suffers as a consequence of our care. How we respond to adverse outcomes is critical to our ability to deliver compassionate, effective surgical care.

And yet, most of us have not had any training or preparation for dealing with adversity in a positive and constructive way. We are all too familiar with the statistics of burnout, depression, substance abuse and suicide prevalent in our specialty. How can we as surgical specialists learn to care for ourselves and our colleagues in the face of the inevitable adverse outcomes that are unfortunately common in our specialty?

Over the last two years, we have asked a number of leaders in surgery for their advice in dealing with adversity. After reviewing their responses, we identified six common themes and developed the mnemonic PEARLS to help us remember them. P is for patient. Our highest priority must be to assure that the patient—if alive—continues to receive appropriate care.

The second priority is emotional support not only for the patient and family, but also the surgeon.



JOHN F. EIDT



GABRIELA VELAZQUEZ

Usually this means being an active, sympathetic listener. You don't need to—nor should you—try to provide answers or false reassurances. These are difficult situations that may lead to a variety of unpleasant consequences (lawsuits, disciplinary actions, etc.), and giving false hope is not really helpful, potentially hindering recovery.

The next priority is apology/disclosure. It is usually appropriate to have a frank discussion with the patient and/or family about the facts of the case. It may be appropriate to include a colleague or hospital representative during these conversations. One surgery chairman said that he accompanies his faculty during these sometimes challenging conversations.

The following step is review. In some cases, it may be appropriate to provide a “competent critique” of the care rendered. We all have a desire to improve

our surgical skills. Having an opportunity to review the facts of a case and consider strategies to avoid future complications may be needed. The morbidity and mortality (M&M) conference may have an important therapeutic effect by allowing the surgeon to share the facts of a case in an environment that is nonjudgmental and protected from discovery.

Then we consider the legal implications of the case. Appropriate consultation with risk management and legal counsel may be indicated.

Finally, we consider the safety of the surgeon. It is important to consider the potential for self-harm, including substance abuse and suicide. If there are any indications that the surgeon may be a danger to him or herself, early referral to professional counseling may be required.

Vascular surgery is a fantastic specialty. Hopefully, you will throw more touchdowns than interceptions. But when you are victimized by a pick-six, you need to have the support system in place that will get you back on top of your game.

John F. Eidt is a vascular surgeon at Baylor Scott & White Heart and Vascular Hospital in Dallas. Gabriela Velazquez, also a vascular surgeon, is an assistant professor of vascular and endovascular surgery at Wake Forest University School of Medicine in Winston-Salem, North Carolina.

Leadership: Strengths and weaknesses of team members

BY CHERRIE ABRAHAM, MD

Audra Duncan, MD, is professor of surgery at the University of Western Ontario in London, Ontario, Canada, and vascular surgery division chair since 2016. Prior to being named chair, she was on the faculty at the Mayo Clinic in Rochester, Minnesota. Duncan has led multiple educational and research committees, including as program director of the Mayo Vascular Surgery Residency and Fellowship; chair, Institutional Review Board; and chair of the American Board of Surgery Vascular Surgery In-Training Examination Committee.

This discussion continues our interviews with prominent vascular surgery leaders based on topics from “The Heart of Change,” by John P. Kotter and Dan S. Cohen. We specifically address topics in chapter three and the theme of “Building the team: How to evaluate team members’ strengths and weaknesses.”

When the team is not a team

“A common problem is that those who should be driving change are not doing their job.”

Q. What advice can you give potential leaders who encounter these kinds of individuals? Is there a right or wrong approach?

A. I’ve found the best approach is to first figure out “why.” In many cases, especially with young individuals who are charged with complex projects, they may not realize the time required, the impact on their practice or their family/life balance. Rather than accusing, it’s best to start with trying to understand the root problem for a team member not doing his or her job.

Putting together an effective team

Q. What advice can you give early-to mid-career leaders to help them best determine their team members’ strengths and weaknesses?

A. Communicate as frequently as reasonable. I check-in with extended team members (OR [operating room] staff, nurses, trainees, other faculty) weekly. This allows me to understand how my core team of staff is performing, and what members’ strengths and weaknesses are. Just by keeping my ear to the ground and being approachable have allowed me to learn so much about the people I work with in order to understand



AUDRA DUNCAN



CHERRIE ABRAHAM

what I can do to direct the team.

Q. Is there value in partnering team members with obvious strengths with team members with obvious weaknesses, or is that counterproductive?

A. In vascular surgery, generally the core faculty is such a small group that I haven’t used this technique *per se*. However, I would advocate for that process if I had concerns about a weak team member.

Q. What is your approach to improving team members’ weaknesses and how do you handle difficult conversations, especially with younger, more impressionable faculty?

A. I am usually fairly straightforward, because everyone is short of time these days. I typically find there is a reason for the weakness (i.e., a drop in clinical productivity may be due to a difficult family situation), so I first try to address that. In many cases just offering an opportunity to discuss life stresses can result in positive change.

Q. What are the most common weaknesses you have observed in younger faculty?

A. Difficulty managing time challenges. Our hours are as long as ever, but work-life balance has a different priority than in the past. Younger faculty have a hard time saying no to anyone and it results in work overload, stress and decreased wellness.

Q. Do you actively implement a strategy or program to improve a glaring weakness? What kind of timeline to demonstrable improvement is appropriate?

A. I start with a focused meeting, discuss the problem and outline the plan. Then I write up a follow-up email to confirm our discussion and reiterate the expectations. No matter what the issue is, I would check in again about progress in two to

three weeks, because allowing too much time to pass often diminishes attention to the problem.

Q. What are the main characteristics you like to see or help develop in a valuable team member?

A. Approachability and empathy. I think it is impossible to be a good team member unless you can communicate well with your team and you can see others’ points of view.

The mechanics of meetings

“Teamwork, and the underlying feelings of trust and emotional commitment to others, can be undercut by many factors. Individuals who aren’t team members or who aren’t trustworthy can destroy a group.”

Q. What is your best advice on how to deal with an individual who is not a team member and is causing strife between team members?

A. Addressing the root cause is a first step. I advocate for a direct approach, being straightforward but not judgmental or accusing in a one-

on-one meeting. Giving the team member a focused task that allows him or her to work alone can also be helpful to add value to the team without disrupting other members.

Q. What is the most effective meeting format? Free discussion with team members voicing different opinions, or approaches? Sticking to a premade agenda?

A. I don’t like meetings without an agenda! However, depending on the group size, I think it’s important to allow members to speak freely as long as we stay on time and on topic. I also think it is important to adhere to start and stop times for meetings, out of respect for everyone’s busy schedule.

Cherrie Abraham is director of the aortic program at the Knight Cardiovascular Institute, Oregon Health and Sciences University (OHSU), Portland, Oregon, and associate professor of surgery in the division of vascular surgery at OHSU. This interview was conducted on behalf of the SVS Leadership Development and Diversity Committee.

FDA

Continued from page 1

regulators to harmonise various regulatory requirements across their jurisdictions,” she said.

The FDA considers the IMDRF as part of its “strategic priority” to put in place the foundations for creating a Medical Device Single Review Program, Malone reported, with the eventual goal that some authorizations be adopted across national boundaries once granted in a single market.

Malone’s presentation focused on updates concerning the regulatory landscape and various recent changes.

“I hope you do not consider the FDA the most challenging and controversial aspect in clinical care,” she began, adding, “We are here to interact and be collaborative with you, and we appreciate the hard work that you are doing.”

Regulatory pathways are evolving across the world, Malone continued. She drew attention to the FDA 510k pathway—required for most Class II, medium-risk devices, including guidewires, introducers, balloon catheters and peripheral atherectomy instruments. This pathway requires demonstration of “substantial

equivalence” to a legally-marketed predicate device, meaning that the device design, performance and intended use must be similar to a Class II device that is currently on the market, she said.

On Sept. 20, 2019, the FDA released new guidance regarding an alternative 510k process called the Safety and Performance-based Pathway (SPP). While this is based on the predicate device equivalence benchmark that underlies the current pathway, there must also be performance testing that involves FDA-specified methods and criteria that may be based on recognised standards and historical performance of comparable devices rather than side-by-side testing with specific marketed devices.

Malone said “it is not our goal to reduce innovation [but] to help support it by allowing the process to move as efficiently as possible” in what is a complex and evolving cardiovascular device technology marketplace.

“One of the goals of this new pathway is that it will be more similar to regulatory paradigms in other countries,” she added.

Malone referenced third-party certification in Japan that relies on performance criteria set by the Japanese government but includes



Misti Malone speaks at VIVA 2019

few cardiovascular devices. “This may be a pathway that will be valuable for some of our simpler devices in which we can set these performance criteria,” she said.

Malone also reported on continued discussion around the adoption of the Medical Devices Regulation (MDR) in the European Union (EU) that is likely to take effect in May. She said one goal of this update is to reinforce provisions for clinical evidence so that evaluation will be required premarket for some devices, continuing in the post-market with regular updates, surveillance and analyses. “The EU hopes that this will provide more information to support clinical and

patient decision-making.”

According to Malone, devices that are most likely to require clinical investigation under the MDR are those that are implants and high-risk devices; devices that may be Class II or lower where the technology has little or no experience; or a device for which the intended purpose is being extended or if there is a new indication for use. For Class III and implantable devices, she detailed that a post-market clinical follow-up report “may be required.”

At the close of her presentation, Malone urged delegates: “Please consider global strategies when appropriate.”

PASSPORT NEEDED FOR VAM 2020!



2020

VASCULAR ANNUAL MEETING

TORONTO

All U.S. residents entering Canada will be required to travel with a valid passport. Your passport expiration date may not be within six months of your travel dates. For additional information (including passport requirements for international travelers), visit the Canada Border Services Agency’s website at vsweb.org/CanadaDocuments.

U.S. members, start your passport process at vsweb.org/USPassports.



Advocacy: Coding and Reimbursement Committee experiences lead to greater sense of awareness

BY JEFFREY SIRACUSE, MD



JEFFREY SIRACUSE

As a member of the Society for Vascular Surgery's Coding and Reimbursement Committee (two years), I have been able to attend both CPT and RUC meetings in conjunction with the American Medical Association (AMA).

When I began, I had known CPT stood for Current Procedural Terminology, relating to defining the codes that exist for patient encounters, but I had not heard of RUC. A simple Google search revealed that the R stands not for a word but rather another acronym; RUC is the RVS Update Committee or the "relative value scale" Update Committee. This scale relates to the relative value units (RVUs) that value every operation and professional encounter we perform.

Like many physicians, I had no formal training in the coding or reimbursement process. Everything I knew was second-hand, through informal meetings, trial and error, and by being inquisitive of those who seemed to be "in the know." As surgeons, we like to be in control and understand how things fundamentally work. However, even as a trainee, I realized that I, plus likely many of my colleagues, had little knowledge of this whole process. I did know it was something I both

Vascular surgery often partners with general surgery, cardiology and interventional radiology. It is clear societies all benefit from working together.

wanted and needed to know more about. It wasn't necessarily to get "paid more money." Rather, it was clear to me that these metrics are often used as a gauge of your value to your department and institution. These often

seem to correlate to resource distribution, and overall support to the surgeon, the practice and the patients.

RUC meetings are important tri-annual gatherings of all the medical specialty societies. The RUC evaluates new codes created at CPT meetings and re-evaluates older codes to determine the appropriate work and direct practice expense for procedures. Each society sends its representatives to the AMA RUC panel to present their data, often consisting of surveys from members and details of the service in question. Factors as small as how many alcohol wipes or pairs of gloves are needed are considered.

While many of us are territorial about our expertise and specialty, the RUC is a great example of collaboration between overlapping fields. Vascular surgery often partners with general surgery, cardiology and interventional radiology. It is clear societies all benefit more from working together here. These panel recommendations are forwarded to the Centers for Medicare and Medicaid Services and can affect the value of a code for years to come.

It is important SVS members and all physicians understand what happens at these meetings, for greater understanding and improved participation.

It becomes clear why it is important to fill out those long and sometimes tedious RUC code surveys we all receive—RVU assignment is often anchored on these survey results. Completing them requires a thoughtful response about how long it really takes to accomplish the task in question—including preparation time, planning and all aspects of relevant post-evaluation/intervention care. Accurate comparisons to other procedures we are familiar with is essential. It's also important to be thoughtful about what codes are to be re-evaluated. Re-evaluating an old code may increase reimbursement, especially if there have been changes in practice. However, this reassessment may be detrimental as not only the code in question may lose value but so might other associated codes if they are determined to be potentially misvalued.

Overall, my experience on the committee has allowed me to be more aware, helping me appreciate the larger issues at stake in medicine and being able to get involved at a higher level. Though many see these issues as nuisances, they influence our daily lives. Small decreases in information asymmetry can exponentially increase one's understanding of the process.

Jeffrey Siracuse is an attending surgeon of the Boston Medical Center, Boston, and assistant professor of surgery and radiology for Boston University School of Medicine. He has been an Active member of the SVS since 2016. Siracuse also has been involved with the Quality Council, the Coding and Young Surgeons Advisory committees and with committees associated with the Vascular Quality Initiative. He currently chairs the Appropriateness Committee.

Countdown: VESAP4 set to expire in six months

With the expiration of the fourth edition of the Vascular Educational Self-Assessment Program (VESAP4) on July 31, owners have a bit more than six months to complete all modules and claim credits.

Those who want to purchase the educational product similarly should be aware of this expiration date; content and exams will not be available as of Aug. 1.

The online program contains 10 modules and more than 500 questions and is designed to meet Maintenance of Certification (MOC) requirements of the Vascular Surgery Board of the American Board of Surgery for continuing medical education and

MOC self-assessment credits.

VESAP4 is intended primarily for vascular surgeons preparing for qualifying, certification and recertification examinations in vascular surgery and to remain current in the specialty. Residents and fellows have found it useful for studying for their ABS In-Training and Vascular Surgery In-Training examinations.

Major structural changes are ahead for the recertification process and the MOC program. Thus, VESAP5 similarly will be an entirely new product. It is expected to debut by August 2020.

For more information, visit vsweb.org/VESAP.

Learn all about coding updates at Jan. 22 webinar

Because the Centers for Medicare and Medicaid Services (CMS) updates healthcare billing codes annually, vascular surgeons need to have updates as well. It is important they have the knowledge and understanding required to correctly apply these billing codes to receive reimbursement for their services to their patients.

The SVS Community Practice Committee will host a coding webinar from 7–8 p.m. (Central Standard Time) Wednesday, Jan. 22. All members are encouraged to join in to learn coding and billing basics, pitfalls in claims submissions and working effectively with private payers.

Fran Aiello, MD, Ravi Hasanadka, MD, and Sunita Srivastava, MD, of the Coding Committee will explore these topics in more detail. They include CMS' National Correct Coding Initiative edits, site of service selection, timely filing, appropriate documentations, delayed payment issues, differences between private payers and Medicare/Medicaid rules, pre-authorizations, and post-care denials, including services that are pre-authorized.

Participants will be able to ask questions during the webinar. To register, visit vsweb.org/CodingWebinar0120.

Vital importance of funding for pair of separate needs

BY JOHN A. CURCI, MD, AND MICHAEL C. DALSSING, MD



JOHN A. CURCI



MICHAEL C. DALSSING

The Society for Vascular Surgery (SVS) has two dedicated member-supported service organizations fulfilling very distinct needs: the SVS Foundation and the SVS Political Action Committee.

Both are vitally important to the future of the vascular specialty and our lives as surgeons. Both are dependent upon direct financial support of the SVS membership.

The SVS Foundation funds basic and clinical research, community outreach, public education, and prevention and awareness. SVS expanded the Foundation's mission in 2017 to include awarding research grants to further disease prevention as well as patient awareness and education.

The SVS Foundation touches every SVS member, from our researchers searching for solutions to circulatory disease to our surgeons in private practice, saving patients' lives and limbs and enhancing health and healthcare. Your contributions to the Foundation may be tax-deductible.

The SVS Foundation's five funds support a wide array of projects:

- Greatest Need (annual) Fund: this unrestricted fund supports programs where needs arise.
- Awareness and Prevention (community health initiatives) Fund: supports the work in disease prevention, patient education and public awareness with outreach such as community health projects, screenings and patient education fliers.
- Research Grants Fund: supports awards to

vascular surgeons at all career levels for research in critical areas of vascular disease.

(Visit vsweb.org/Awards.)

- Disaster Relief Fund: supports programs that provide short-term emergency assistance and longer-term aid for vascular surgery practices and patients in communities devastated by disasters.
- Alexander W. Clowes Distinguished Lecture Fund: supports the lecture named for our late colleague and mentor, Alec Clowes, given annually at the Vascular Research Initiatives Conference.

The SVS Political Action Committee seeks to impact patient care in an entirely different way, by protecting vascular surgeons' ability to do their jobs well, in terms of legal issues and reimbursement. SVS has had, for more than a decade, a presence in Washington, D.C., with staff dedicated to representing the interests of vascular surgeons and vascular surgery.

Now, with health laws, payment models and reimbursement issues undergoing a seismic shift, this presence is more important than ever. We

must be informed of pending bills and regulations that affect our patients and their access to care. We must actively advocate for them and our specialty and be able to provide expert opinions when asked. Contributions to the SVS PAC help support those lawmakers who, we believe, will be receptive to our concerns.

If we want a say in how the legislative process works—and that is an absolute necessity—supporting our PAC is vital. If we are "not at the table," then our opinions will not be heard. The SVS PAC provides the avenue to put us in the discussion. Your contributions to the SVS PAC are not tax-deductible.

Through completely different activities, both of these SVS entities have, at their heart, the same end goal: to effect change that will lead to improved patient care.

Some of that will occur through public awareness projects, patient education efforts and through research funded by SVS Foundation projects. Some will occur with the election of members of Congress who share our aims, understand our goals and work to bring change via legislation, which we can influence by developing a relationship of mutual trust.

With so much at stake in both realms, we humbly ask for your help and your donations. To donate, visit vsweb.org/GIVE (Foundation) or vsweb.org/PAC (PAC).

John A. Curci is the SVS Foundation Development Committee chair. Michael C. Dalsing is the SVS PAC chair.

SVS launches key valuation study

The Society for Vascular Surgery (SVS) is undertaking a new study to take an objective, qualitative and quantitative approach when assessing the importance and financial impact of vascular services to health systems.

SVS members have said that the lack of identity for vascular services as a leading service line represents a fundamental threat to the specialty. In many markets, health system administrators are unaware of the importance of vascular surgery, its impact on patient safety and the value of the support it provides to many other service lines within an organization.

"Our goal is to develop materials to educate hospital and healthcare system leaders on the infrastructure and programmatic scope of services required to deliver high-value vascular care. We want to inform administrators of all the elements—visible and invisible—that are part of the service line," said SVS President Kim J. Hodgson, MD.

The SVS is partnering with Sg2,

a nationally recognized healthcare strategy and analytics company. Sg2 will utilize its data assets, analytics and experience to complete the project. SVS members have been asked to supply information for various study components, including a survey distributed in December.

This valuation study complements the SVS branding initiative now in progress, said Hodgson. "The branding initiative explains who we are and what we do—what sets us apart from other medical professionals. And the valuation project quantifies our value to our institutions.

"Our hope is that if we can illustrate our concrete, real worth to a hospital or institution with reliable data, it could help increase our voice, impact and compensation," he said. "It could help solidify our identity and standing to the general public and help stave off competition from other physicians."

The SVS Valuation Work Group will update members as the study progresses.

Registration open for VRIC



Register today for the 2020 Vascular Research Initiatives Conference, to be held Monday, May 4, in Chicago.

The conference emphasizes emerging vascular science and encourages interactive participation of all attendees. VRIC Chicago 2020: "From Discovery to Translation" takes place at the Hilton Chicago Hotel, the same venue for the American Heart Association's Vascular Discovery Scientific Sessions (May 5–7).

The VRIC program includes four abstract sessions, a

translational panel, poster presentations and the Alexander W. Clowes Distinguished Lecture, presented this year by Philip S. Tsao, PhD, of Stanford University School of Medicine and the Veterans Administration Palo Alto Epidemiology Research and Information Center for Genomics. His talk is entitled "Molecular mechanisms of AAA disease."

Registration is \$275 for members, \$300 for nonmembers and \$150 for residents, students and candidates. Learn more and access the registration link at vsweb.org/VRIC19.

Save the date for 2020 SVS Foundation Gala

Attendees had a “spectacular” evening at the 2019 SVS Foundation Gala, and organizers urge all members attending the 2020 Vascular Annual Meeting (VAM) in June to keep that Friday evening clear for this year’s event.

The 2020 SVS Foundation Gala will be held Friday, June 19, at the recently renovated Fairmont Royal York in Toronto, the VAM headquarters hotel. SVS members had the chance during the 2019 gala to bid on a stay at the Fairmont.

Benjamin Starnes, MD, and Cynthia Shortell, MD, enjoyed their roles as co-chairs of the planning committee last year, and are reprising them this year to lead the effort once again.

“The first gala was a huge success,” said Shortell, urging members to attend the 2020 gathering. “We greatly exceeded everyone’s expectations and sold out weeks ahead of the event.”

The funds raised helped advance the important work of the SVS Foundation, improving the public’s vascular health through funding basic and clinical research, community



Attendees enjoy the opening reception at the 2019 SVS Foundation ‘Vascular Spectacular’ Gala. This year’s event will be the evening of Friday, June 19

outreach and prevention, and awareness via patient education.

There’s another goal—simple but important—beyond continuing the Foundation’s work: celebrating the specialty and enjoying the company of fellow SVS members. “The event brought us all together in a way that allowed us to interact socially, not just professionally, and to have a lot of fun,” said Shortell. “We want to do

that again this year.”

Tickets are expected to go on sale in early February. For more information visit vsweb.org/2020Gala.

(Note: Were you high bidder for any of 2019’s offerings, including vacations, wines, lunches or any other items, and would be willing to share your experiences? Please email: bbales@vascularsociety.org.)

Awards deadlines

February SVS

- Excellence in Community Service Award (Feb. 1)
- SVS/ACS Health Policy Scholarship (Feb. 3)

SVS Foundation

- Student Research Fellowship (Feb. 1)

March 1 deadlines

SVS

- Lifetime Achievement Award
- Medal for Innovation in Vascular Surgery
- Distinguished Fellow

SVS Foundation

- Community Awareness and Prevention Project Grant
- E.J. Wylie Traveling Fellowship
- Clinical Research Seed Grants

Membership Deadline is March 1.

Apply today at vsweb.org/Join

Burned out on burnout? Changing course with peer support

BY DAVID RIGBERG, MD, AND KRISTYN MANNOIA, MD

Imagine a conversation with a (nonvascular surgeon) colleague about aortic dissections. “Renal malperfusion,” he says, “is just part of the natural history of the condition. Nothing you can really do about it.” You, of course, take issue with this and explain the possible interventions and the robust supporting data that have essentially changed the way we approach management of complicated aortic dissections. Perhaps you are a surgeon only a year out of fellowship, and you have never encountered this old dogma before. You have seen during training what a difference early intervention can make. And yet this doctrine is new enough that there are people in practice who are unaware of—or discount—the significant advances made in the treatment of complicated dissections.

This month the SVS Member Support Group topic is burnout. Yes, again. But the point our community is trying to drive home is that burnout is another condition we can treat.

We know that more than 50% of physicians report being burned out. Our Society for Vascular Surgery member survey found that 41% of SVS members meet criteria for burnout. And the natural history, so to speak, is well studied. In physicians who experience emotional exhaustion, depersonalization or diminished sense of personal success—the main measures of burnout—there is an increased risk of motor vehicle accidents, depression, substance abuse and suicidal ideation.

Professionally, burnout can contribute to suboptimal care, disruptive behavior, malpractice lawsuits and reduced patient satisfaction with the surgeon. In a broader context, major medical error and premature departure from a job are significantly more common in physicians who report symptoms of burnout.

This is part of a natural history we do not need to accept; it is a clinical certainty we can challenge. Being a vascular surgeon does not need to lead to burnout at such high rates. Residents and fellows entering

vascular surgery can start with a new paradigm of practice just as we did with aortic dissection. And once there are warning signs, we now know there are interventions we can undertake to change the course of this condition.

So why is the practice of vascular surgery so often a set-up for burnout? Part of the problem is the gravity of the consequences that accompany our “failures”—stroke, amputation, paralysis and death at the most serious. And even the stress of patient dissatisfaction with seemingly “minor” problems can overwhelm any conscientious surgeon. Add to this the urgent nature of much of our work, and it is no mystery why we are particularly susceptible to burnout as a specialty. But recognizing that we are all working in these conditions provides an opportunity for coping with these situations in a healthier way.

Most obvious opportunities for change are focused on systems that create environments conducive to burnout. The SVS provides excellent resources for organizational improvement: go to SVSCONnect for

tips on maximizing on electronic medical record templates or the SVS website (vascular.org) for credentialing resources, among other things.

For many vascular surgeons, though, expecting large organizational change is unrealistic. What we do have, though, is potent if we can take advantage of it: a body of surgeons with a deep well of experience and wisdom.

From medico-legal advice, to business guidance, to emotional support, please visit SVSCONnect (vsweb.org/SVSCONnect). We can support each other as peers and empower a change in the natural history of burnout in our community.

David Rigberg is director of the UCLA Medical Center program and associate professor of surgery at UCLA, Santa Monica, California. He is past president of the Southern California Vascular Surgical Society. At SVS, he chairs the Resident and Student Outreach Committee and is a member of the Education Council. Kristyn Mannoia is a vascular surgeon with the Loma Linda University Medical Center in Loma Linda, California. She is a graduate candidate member of the SVS.

MAKE AN IMPACT... APPLY FOR SVS & SVS FOUNDATION AWARDS

Deadlines for many SVS and SVS Foundation Awards are below. Apply now!

SVS | Foundation

FEBRUARY 2020

- Excellence in Community Service Award
- SVS/ACS Health Policy Scholarship
- General Surgery Resident/ Medical Student VAM Travel Scholarship
- Diversity Medical Student VAM Travel Scholarship

MARCH 1, 2020

- Lifetime Achievement Award
- Medal for Innovation in Vascular Surgery

For a complete list of SVS and SVS Foundation awards, visit vsweb.org/Awards

SVS | Society for Vascular Surgery

NIH/AHRQ MULTIPLE DEADLINES

- Mentored Research Career Development Awards (K Awards)

JANUARY 2020

- Resident Research Award
- Vascular Research Initiatives Conference Trainee Award

FEBRUARY 1, 2020

- Student Research Fellowship

MARCH 1, 2020

- Clinical Research Seed Grant
- Community Awareness and Prevention Project Grant
- E.J. Wylie Traveling Fellowship

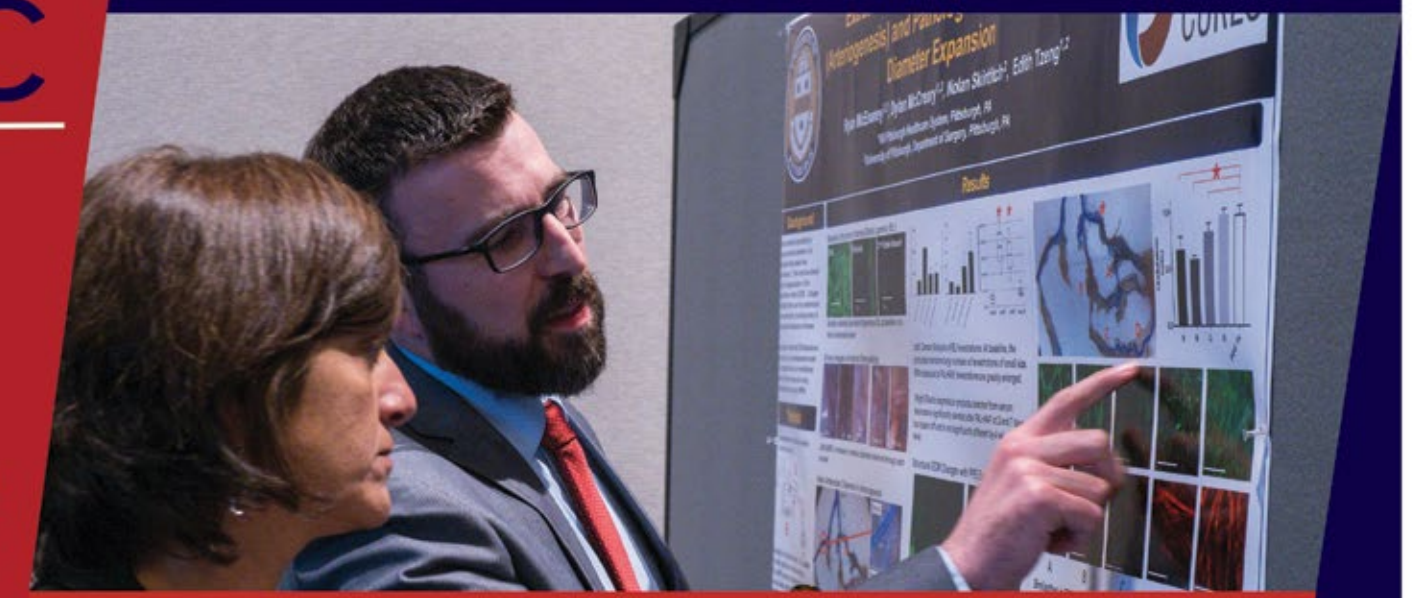
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Fogarty gives roadmap to future of innovation

BY BRYAN KAY

HOUSTON—World-renowned innovator and inventor of the balloon catheter Thomas Fogarty, MD, delivered a robust pitch against the singular pursuit of financial gain during the process of innovation before a gathering of surgical colleagues at the inaugural International Society of Endovascular Specialists (ISEVS) Symposium.

Too much of a focus on economic reward can often cloud the core mission of innovation, Fogarty told his audience during the keynote lecture at the three-day meeting in Houston, Sept. 16, 2019.

“Sometimes people want to make so much money, they lose sight of what they’re here for,” he said of his experiences as both an innovator and an investor. “We all like to make money but if that’s all you’re focused on I don’t want to be around [people like that].”

The remarks came in answer to a question posed by Alan Lumsden, MD, medical director of Houston Methodist DeBakey Heart & Vascular Center, that sought to establish the most common mistakes young surgeon-innovators make when attempting to follow in the footsteps of people like him. Fogarty, founder and director of the Fogarty Institute for Innovation, Mountain View, California, answered by talking about his experience with a venture capital company, which he helped found.

“Do you know what a venture capitalist is?” he said. “Well, I was one of those once. The fact that I co-founded [one]. I think it was 18 months later that they kicked me out. Why? Venture capitalists are nothing but vultures. I call them vulture capitalists. That’s a very appropriate name ... you can’t work with people who have the wrong motives.”

Fogarty pointed out another innovation hazard among emerging inventors: “If they’re very young, they think they know so much, and they’re so focused on being important by knowing so much,” he said.

“Some of the biggest deterrents you don’t recognize until you’ve experienced one of those deterrents. The thing I’ve learned is that very brilliant people from very prestigious institutions with all kinds of awards are easy to like but many of them are full of it. And that can cost you.”

Fogarty, whose inventions include the balloon catheter and the AneuRx stent graft, required little introduction owing to his stature in the cardiovascular surgery world. But Lumsden, ISEVS president and host of the symposium, kicked off proceedings by briefly telling the story of the Fogarty catheter’s genesis in the inventor’s passion for fishing: the tale of how Fogarty came up with the idea and produced a prototype by tying the fingertip of a latex glove to a hollow tube with a piece of fishing line. “To this day, it moves clot unlike anything else,” said Lumsden.

Rod White, MD, medical director of vascular surgery at Long Beach MemorialCare Heart and Vascular Institute, Long Beach, California, then kicked off the lecture in a formal introduction, setting a mirthful tone that was to run through the lecture: “If you look at this whole list of things [that Tom’s achieved], he started off as a boxer—so that explains some of the stuff that’s going on.”



THOMAS FOGARTY

More seriously, White also referred to an important lesson he learned while working with Fogarty: “Be the first one to know when a technology is not going to work.”

Mentees and mentors

The address, entitled “What’s Innovation?”, saw Fogarty open by proclaiming: “Some of my best mentees are now my best mentors. I’m very proud of that. A lot of guys are now teaching me that I was a mentor for.”

He continued: “If you innovate, that technology can be used by other physicians. That’s rewarding because you multiply what a surgeon does. It’s a really interesting cycle that we go through, the process of learning. I’m still innovating and I do so in a private environment, a private hospital.”

At his institute, Fogarty said, they do so with the primary purpose of reducing healthcare costs. As an example, he spoke about its work on the portable wound vac. “It costs less, it does the same job [as the wound vac], it very significantly reduces costs and we can afford to have it in nursing homes. This was something I never thought of but it came to us at the institute to help in the process. The product is completed.” Investment in the portable device should see it commercialized in the next year, Fogarty added.

He highlighted another example: “Does anyone know Chris Zarins?” he asked the audience.

“He was the first company that we took into the institute. He and an engineer developed the technology called HeartFlow, a major, major change in the way we are going to treat cardiac disease, primarily coronary disease. It can diagnose coronary disease without an angiogram.”

The result: Reduced costs, Fogarty added.

“It’s very interesting how innovation in many different fields can bring better technology but at reduced cost,” Fogarty said. “That is something that we have to do. Everybody knows medicine costs

“Sometimes people want to make so much money, they lose sight of what they’re here for.”

too much. Now, we can’t get rid of all the doctors. They’re expensive. But we’re kind of heading in that direction. Watch out for socialism!

“So the implications of what innovation can do for our patients, and how we can innovate: at the same time provide better care with better technology but at a reduced cost.”

Another question from the audience queried Fogarty on the importance of persistence in innovation, referring to his work on an atrial fibrillation intervention with nuclear devices that initially received little support, an advance 14 years in the making. “Part of the problem was the concept was so outlandish, everybody said it wouldn’t work,” he said. “A lot of innovators have that same problem. The concept is so outlandish you can’t get anyone to invest in it. It’s the biggest problem we have in raising money. Far-out ideas are the most valuable to human kind—our patients. But they cost a whole lot. It takes a long time. It takes a lot of personnel. It’s very expensive. But if you stick with it, you overcome those obstacles; you’ll finally get there.”

On a question addressing protecting an idea, Fogarty recalled his journey with the balloon catheter. “I had no money,” he explained. “My mentor, Jack Cranley, Cincinnati, Ohio, a vascular surgeon, told me, ‘You’ve got to patent this, Tom.’ Well, I found an attorney. He said, ‘That’s ok, pay me when you can.’ An attorney!”

He added: “You’ve just got to keep at it. Know what the obstacles are.”

The queries continued: How might an inventor manage the risk that follows innovation, Fogarty was asked. “Well, follow the rules,” he answered. “That’s number one. Pay attention to the FDA [the Food and Drug Administration]. If you don’t you’ll be in deep ... Because they’ll get you. Think of all the entities that could get you into trouble, and all of the regulations that you have to follow.”

Balancing act

What does Fogarty see for the future? “Innovation in the field of medicine is going to be even more critically important. Because there are many problems in many different areas. I think if we handle our innovations right, we’ll end up reducing cost.”

As the lecture was drawing to a close, Fogarty was asked how surgeons might balance promising ideas with maintaining patient care. He answered by referencing the importance of conducive environments. He circled back to his time at Stanford University.

“At Stanford, I was hired and re-fired two different times because I was interested in commercialization,” he said. “Academia feels very often that those who relate to commercial entities are evil. Industry and the representatives of industry are often there only to contaminate the academic mission. That’s why they don’t like salespeople getting into hospitals. At Stanford they were so adamant about salespeople... they used to give you pencils or pens that the dean required them to put in a large basket outside his office because they were contaminating by bribery with a pencil. That’s one reason I left Stanford the first time.”

Persistently high-cost Medicare patients are more likely to be younger, come from an ethnic minority group

BY BRYAN KAY

Persistently high-cost patients are younger, more likely to be members of racial or ethnic minority groups, eligible for Medicare based on having end-stage renal disease and dually eligible for Medicaid compared to their transiently and never high-cost counterparts, a study of more than 5.5 million Medicare beneficiaries published in *Health Affairs* found.

A research team led by José F. Figueroa, MD, an instructor of medicine at Harvard Medical School in Boston, established that 28.1% of patients who were high cost in 2012 remained persistently high cost over the subsequent two years.

“Persistently high-cost patients had greater relative spending on outpatient care and medications, while very little of their spending was related to preventable hospitalizations,” they wrote. “Healthcare systems and policymakers can use this information to better target spending reductions and care improvements over time.”

The authors set out to answer three main questions: What proportion of Medicare patients who are high cost in one year remain persistently high cost over three years? What are the key characteristics of persistently high-cost patients that differentiate them from transiently or never high-cost patients? And what are the differences in underlying spending patterns of persistently high-cost patients compared to transiently or never high-cost patients?

The investigators conducted their study against a backdrop of rising healthcare costs, noting moves by U.S. policymakers to invest in new approaches to reduce spending and improve health outcomes.

“Over half of spending for the Medicare population in any given year is concentrated among approximately 10% of the patients,” the investigators continued. “What is less clear is how often these Medicare patients remain persistently high cost over time. If health systems are to intervene with these patients, understanding the degree to which high costs persist over time and which patients are likely to remain high cost is critical.”

The researchers used a 20% sample of Medicare administrative claims data from 2012–2014, excluding

A VASCULAR PERSPECTIVE

The study bears some important implications for the vascular space, says Thomas O’Donnell, MD, professor of surgery at the Tufts University School of Medicine, Boston, and a former hospital CEO.

“It is interesting that the three risk factors identified in this study for persistent high costs in Medicare patients were ethnicity, i.e., if you’re African American or Hispanic; as well as dually eligible for Medicaid, i.e., younger patients,” observed O’Donnell. “And that latter factor highlights, if you will, a vascular problem and a major risk factor, end-stage renal disease. If you have end-stage renal disease [ESRD] in the U.S. you qualify for a special program under Medicaid. That greatly affects the allocation of where the money was spent.”

O’Donnell zeroed in on a central point from both an arterial and venous point of view. “What I thought was most interesting in the persistently costly versus the transiently costly group is the allocation of expenditures, where in the persistently group outpatient cost was greater than inpatient,” he said. “And that’s not what we usually see in the people with some form of arterial disease. The inpatient costs drive the total expenditures.”

“For example in the transient group, the inpatient cost, when calculated in a standard way—per patient per year expenditure—was around \$7,500 versus almost \$13,000 for the persistently. But the outpatient cost for the transient group was one half of the inpatient cost, \$4,000.

By contrast, for the persistently outpatient cost was the higher area of expenditure at \$16,000.

“How does this relate to peripheral arterial disease [PAD]? If you look at an older landmark paper published in *Vascular Medicine* in 2008, written by the late Alan Hirsch, they identified \$4.37 billion on PAD-related treatments. But the most important part of that study was that 88% of the expenditures were for inpatient care. That was 2008 so you know that’s increased, but that gives you a magnitude to compare to this.”



THOMAS O'DONNELL

With vascular disease, O’Donnell explained, both the volume of procedures and the procedural costs are dually important factors when considering Medicare expenditures.

“If you look at aneurysm surgery volume in the U.S. from 2003 to 2013, there’s been a 36% decrease overall in aneurysm surgery,” he said. “That includes both the open approach and EVAR [endovascular aneurysm repair]. If you then move to carotid disease: there has been a 54% decrease in CMS [the Centers for Medicare and Medicaid Services] carotid procedures from 1999 to 2015.

“So you’ve got two arterial procedures that have seen volume decreases.”

How are such costs controlled? This current study, said O’Donnell, demonstrated “a tremendous increase in costs. It’s not sustainable if we have to expend this much.” He continued, “What has been proposed for controlling Medicare costs starting with the [Barack] Obama administration is the Alternative Payment Model, or value-based programs.”

This involves the use of Accountable Care Organizations (ACOs), in which costs are calculated on a population basis rather than a disease-specific basis. O’Donnell pointed out success achieved by a specialty-oriented ACO for ESRD, which focuses specifically on access to dialysis. “The importance of this approach is that there are some data now that show how you can control ESRD by adopting a disease-specific ACO type of structure. With this they have seen a 4% decrease in hospitalizations and a reduction—just in the first phase—of \$68 million, or 2%, in spending by Medicare.”

Yet, it remains an elusive method to control costs for the vascular space at present, O’Donnell explained. “My assessment is none of the therapies for vascular disease currently would satisfy either the volume requirements or the cost requirements to do a specialized ACO or bundled payments.”

patients for attributes such as lack of a valid beneficiary identification number or sex designation and those who died during the period from which the data were drawn.

Of the 5,507,218 patients in the sample who were continuously enrolled in Medicare, 2.8% remained persistently high cost for three years, while 7.2% were transiently high cost. “Of the top decile of patients by costs in 2012 (n=550,722), 28.1% remained consistently high cost for three years, while 71.9% were transiently high cost,” the authors wrote.

Regarding age, the high-cost patients were younger than the transiently high cost, the investigators found: a mean age of 66.4-years-old to 73.3. Similarly, persistently high-cost patients were also more likely to be black (20.1%) and Hispanic (4%) than their transiently high-cost counterparts (9.2% and 1.8%).

In their findings, the investigators laid out the impact in dollar terms. “On average, in the first year persistently high-cost patients spent \$64,434, compared to \$45,560 for transiently high-cost patients and \$4,538 for never high-cost patients,” they continued. “In subsequent years persistently high-cost patients spent slightly more per year than in the index year, while the transiently high-cost patients, by definition, spent substantially less in subsequent years. Persistently high-cost patients spent more across all categories of spending, with the most spending occurring in the outpatient and inpatient settings and for drugs.”

In conclusion, the investigators wrote: “We found a modest degree of persistence of high costs in the Medicare fee-for-service population. Patients who were persistently high cost were younger, more chronically complex, and more likely to be a member of a racial or ethnic minority group, compared to transiently and never high-cost patients. The greatest differences in spending between persistently high-cost patients and the other two groups were for outpatient services and drugs, with a smaller difference in spending for preventable acute care use. Policymakers and clinical leaders should consider these issues when developing programs to improve care for high-need, high-cost patients.”

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