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

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,

See FDA page 12

See Open training page 4
Am I my brother’s keeper? A skeptic’s call for peer support in vascular surgery

BY MALACHI SHEHAN II, MD

Malachi Shehan II is the associate professor and chair in the Department of Vascular Surgery at the Medical College of Georgia at Augusta University. In this role, he is able to spend his time helping to improve the care of those with vascular disease. Dr. Shehan II is an active surgeon and an advocate for vascular disease patients. His goal is to make vascular disease care more efficient and effective.

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FROM THE EDITOR

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EVAR

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

BY BRIAN KAY

Transluminal embolization has been shown to be more effective than traditional surgical repair in the management of post-EVAR type II endoleaks, with an increased incidence of adverse outcomes and aortic growth and rupture.

The current study was a meta-analysis and review of the published data. A total of 317 patients were included in the review of 20 studies. The authors concluded that type II leaks persisting beyond six approximately 22%.

The technical success rate was significantly higher in the transluminal group compared to the transanatomic group. The investigators recommended that the transluminal technique be considered as initial treatment of post-EVAR type II endoleaks.

In summary, the authors concluded:

However, a tailored treatment algorithm for the surgical management of type II leaks has not been established. Further investigation of the indications and outcomes with endovascular interventions is recommended.

In conclusion, the authors recommended that the transluminal technique be considered as initial treatment of post-EVAR type II endoleaks.

AAA diameter could have crucial implications for patient outcomes

BY BRIAN KAY

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

The discovery, published in the Journal of Vascular Surgery, was made by Douglas W. Jones, MD, of Sichuan University, China, who wrote, that type II leaks persisting beyond six years have a lower occurrence rate of 22%.

Odds ratios (ORs) with 95% confidence intervals (CIs) were estimated, and among the 954 participants, 38% were included in this review.

In conclusion, the authors recommended that the transluminal technique be considered as initial treatment of post-EVAR type II endoleaks.

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Open training
Continued from page 1

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 intemesting 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 to 4:1 [endo/vascular] versus open group but we still do a fair amount of aortic surgery and open vascular surgery as well as cavital 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 decreasing 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 that we 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 that we’ll be a group learning instead of a single learning,” said Darling.

Darling emphasized the very different profile of the emerging generation of surgeons: “One 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 de-briefing of what happened and how we can improve the situation.”

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AORTIC INTERVENTION

BY BRYAN KAY

S evere complications from endovascular procedures, such as spinal cord ischemia, can occur in first-stage TEVAR and F-BEVAR procedures with high rates of technical difficulties compared with second-stage repair (front view vs. back view, p=0.01).

There was a statistically significant impact of more complications in patients with technical challenges (14% vs. 7%, p=0.05).

Of 13 study patients who developed severe complications from endovascular procedures, four (31%) were not provided F-BEVAR, the authors noted. Noting the study’s 9% rate of CSFD-related complications from first-stage TEVAR and F-BEVAR, they explained, an alarming 4% of study patients had severe, potentially life-threatening spinal drain complications, which possibly contributed to the death of two patients (1%).

The rates of severe complications led to changes in practice in our centers,” they wrote in conclusion. The incidence of SCI (1.2%) was lower than the rate of severe complications (2%), and death in the previous systematic review was 0%.

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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 opportunity and window of opportunity to remove the concept of critical limb ischemia (CLI), along with its implications as a worldwide emergency. 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 CLI is a normal part of getting old. CLI itself is also on the rise worldwide, particularly in light of more people surviving 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 many patients worldwide with PAD with those with other well-recognized disease entities, including heart failure, Alzheimer’s disease, cancer, HIV/AIDS and those related to the dialysis population. This 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 to 50%.

In 1982, at an international vascular symposium held in Edinburgh, Scotland, P.A. Herring proposed CLI as a condition in patients without diabetics who have chronic ischemia as a major threat to a limb. Symptoms included rest pain and tissue loss—and the world of medicine started to realize this would be a major threat to a limb. Symptoms—diabetes without CLI is the hallmark of PAD. Peripherally, CLI gained attention on the rate among men. Women with PAD has now crept up to 30% among women. The impact of CLI continues to increase outside of North America, particularly in the Asia-Pacific region. 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 many patients worldwide with PAD with those with other well-recognized disease entities, including heart failure, Alzheimer’s disease, cancer, HIV/AIDS and those related to the dialysis population. This 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 to 50%.

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Instruments. This pathway requires FDA 510k across the world, Malone continued. “You are doing.” She drew attention to the FDA 510k as part of its “strategic priority” as efficiently as possible” in what is a single market. Performance-based Pathway (SPP).

The second priority is emotional support not only for the clinician. As vascular surgeons, we are clinical outcomes have a negative impact on the patient and/or family about the facts of the case. Appropriate consultation with risk management and legal counsel may be indicated. It is important to consider the potential for self-harm, including substances 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, our workshops will help to encourage our conversations. One surgery chairman said that he accompanies his faculty during these sometimes challenging times.

The next priority is apology/disclosure. It is a difficult, but important step. Apologies are sometimes the best way to begin a conversation. As I mentioned earlier, it is important to acknowledge the patient’s feelings and the impact of the surgery.

Finally, we consider the safety of the surgeon. It is important to consider the surgeon’s physical and mental health. As vascular surgeons, we are particularly vulnerable to feelings of guilt, shame and self-doubt when we are confronted by a complication.

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Countdown: VESAP4 set to expire in six months

With the expiration of the fourth edition of the Vascular Educational Self-Assessment Program (VESAP), vascular surgeons, patients, and all components of the healthcare system need to adhere to the revised code sets for reporting surgical care. The VESAP4 edition, which was released in 2016, is expected to expire on Aug. 1, 2020. The program provides a comprehensive set of questions to assess knowledge and understanding required to correctly apply these billing codes to properly reimburse patients for their services to their patients.

The Vascular Society Community Practice will host a coding webinar from 7-8 p.m. (Central Standard Time) on Wednesday, July 22. All members are encouraged to attend the webinar and gain a full understanding of the updated coding rules.

Learn all about coding updates at Jan. 22 webinar

By JOHN A. CURIO, MD, and MICHAEL C. DALDING, MD

The Society for Vascular Surgery (SVS) will launch a national key valuation study on vascular surgery at all career levels for research funded by SVS Foundation projects. The study will assess the value of vascular surgery services in health systems. SVS members have shared a lack of identity for vascular services as a leading service line representing a fundamental threat to the specialty in many markets. The study objectives will be to understand the importance of vascular surgery services in health systems.

The valuation study complements the SVS branding initiative in the present and future, said Hodgson. “The branding initiative is designed to illustrate how we—what we do—what sets us apart from other medical professionals. And the valuation project quantifies our value to other service lines within 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 added. “And be able to provide expert opinions when asked. From a policy standpoint, we want to influence local, state and federal lawmakers who, we believe, will be receptive to our calls to action.

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 their opinions will not be heard. We need SVS PAC’s advisory and support to help advance legislative agendas. Our contributions to SVS PAC will provide the means to partner with policymakers as part of the SVS advocacy efforts.

Visit vsowh.org/Awards or contactsvs@vsowh.org for more information.

VESAP4 similarly will be an entirely new product. It is expected to debut in August 2020. The SVS Foundation funds basic and clinical research initiatives that are vital to advancing vascular surgery practices and patients in communities devastated by disasters.

John A. Curio is the SVS Foundation Development Chair. Michael C. Dalding is the SVS PAC chair.

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

Jeffrey Siracuse is an attending surgeon at the Boston Medical Center, Boston, and assistant professor of medicine at Boston University School of Medicine. He has an active voice in the SVS since 2016. Siracuse has been involved with the Quality Council, the Coding and Young Surgeons Advisory committees, and with committees associated with the SVS. He currently chairs the Appropriateness Committee.
A news item for the 2020 SVS Foundation Gala:

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 Starres, 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."

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More seriously, White also referred to an important lesson he learned while working with Fogarty: "Be the first to know when a technology is not going to work."
Flexible strength. Proven success.

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis
This advanced BX stent graft, an evolution of proven vascular solutions, provides precise delivery and positive outcomes that physicians can rely on for complex cases.

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