SVS | Society for Vascular Surgery

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Vascular Specialist

SVS | Society for Vascular Surgery | Official Publication

FDA Panel: Continue Paclitaxel-Eluting PAD Device Use With Care

BY MARK S. LESNEY
MDEDGE NEWS
REPORTING FROM AN FDA PANEL MEETING

GAITHERSBURG, MD. – There was sufficient evidence of a late mortality signal seen at 2-5 years post procedure for paclitaxel-eluting stents and coated balloons used for peripheral artery disease (PAD) to warrant a label change for the devices, the Food and Drug Administration's Circulatory System Devices Panel unanimously agreed after 2 days of deliberation.

That signal was brought to light in

See **FDA**· page 8

CRAWFORD CRITICAL ISSUES FORUM

'Good Outcomes Not Good Enough'

NATIONWIDE PHOTOGRAPHERS

BY MARK S. LESNEY
MDEDGE NEWS
REPORTING FROM THE VASCULAR ANNNUAL MEETING

NATIONAL HARBOR, MD. – A tradition at the Vascular Annual Meeting, the E. Stanley Crawford Critical Issues Forum is organized by the incoming SVS President and devotes itself to discussing particular challenges currently facing the society. This year's Forum focused on how to use evidence-based medicine to improve outcomes, reduce costs, and ensure appropriate utilization of resources.

Session moderator and organizer Kim J. Hodgson, MD, new SVS President and chair of the division of vascular surgery at Southern Illinois University School of Medicine, outlined the problem in his introductory presentation "Why Good Outcomes Are No Longer Good Enough."

He pointed out how there are several driving forces influencing the inappropriate use of medical procedures, resulting in diminished quality of outcomes and increased costs of health care: These comprise incorrect evaluation, incorrect treatment and planning, and improper

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2019 VASCULAR ANNUAL MEETING
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PRESIDENTIAL ADDRESS

Change Doesn't Come Easy! But It Is Needed

In selecting the subject of his presidential address, SVS President Michel Makaroun, MD, decided to focus on the inadequacy of vascular manpower to meet the demands and needs of the public.

He quoted a favorite saying from Mark Twain that gave him the topic of his address, "I am in favor of progress; it's change I don't like." He then proceeded to outline why changes are necessary and what the Society for Vascular Surgery is doing to help implement them.

"You are all familiar with the highlights of the problem: It is in our numbers! A problem with multiple facets, including unfilled jobs, increasing demand, maldistribution, and a demographic cliff of our membership," Dr. Makaroun said.

The manifestations of this shortage are multiple. The number of advertised jobs far exceeds the number of graduates. There is also a significant maldistribution of the workforce. "We are concentrated in the northeast, and many populous states including Texas, Florida, and California are well below average," he said.

Additionally, many community hospitals, in both suburban areas or small towns completely lack any access to vascular surgical care, even in states with seemingly adequate numbers.

The shortage problem in vascular surgery will get worse before it gets better, he added, saying "Our pipeline is simply not large enough to overcome an older retiring generation of vascular surgeons, with nearly half retiring before 65."

Nationwide Photographers

Dr. Michel Makaroun

"Change does not come easy!" Dr. Makaroun warned.

"We cannot ignore in the discussion of workforce issues, the major shifts, change, and uncertainty we are experiencing in health care delivery, education, and the generational change of our newest members," he said.

More than 10% of vascular surgeons now practice primarily if not exclusively in ambulatory facilities. This direction is gathering steam and reduces the pool of vascular surgeons available to accept hospital practices and cover emergencies, particularly in underserved communities. "The most pressing concern is the inability of our specialty to provide vascular surgery services to the multitude of hospitals located in smaller communities.

"The SVS established a task force to study our manpower issues last fall. The taskforce was divided into three workgroups to focus on different areas of the problem," he said.

The first workgroup, under the leadership of Malachi Sheehan III, MD, and Jeffrey Jim, MD, focused on the obvious solution: a campaign to increase training programs and available positions. Unfortunately, this is only aspirational, since reality fails the SVS in this effort. The pool of general surgery graduates is finite, with competition from several specialties that are more analogous to modern general surgery than vascular surgery.

Increasing the number of integrated programs is less efficient because of a 5- to 6-year lag between initiation of a new program and graduation, but it can tap into an almost unlimited pool of applicants from medical school, and more recently some very qualified international medical graduates. This makes it potentially a far more effective solution for the long term, Dr. Makaroun said.

The workgroup attempted to contact all hospitals with a general surgery program and no associated vascular fellowship. Help in navigating the process of securing financing and applying for a new program was offered. A session was conducted at VAM for interested potential sites to start discussing the process, and representatives from 27 hospitals were there expressing interest.

The second workgroup, under the leadership of Rick Powell, MD, and Andy Schanzer, MD, was tasked with analyzing the entire spectrum of surgeons' clinical activities and producing a valuation study that illustrates the economic and vital impact of vascular surgery for hospitals and patients. "The work of this group is essential to promote a healthier relationship between our specialty and our institutions, making vascular surgery more attractive for future recruits," he said.

The third workgroup under the leadership of Will Jordan, MD, and Tim Sarac, MD, had the toughest job, said Dr. Makaroun. It was tasked with thinking outside the box and suggesting methods to address the most glaring need: the community hospitals, where most of the advertised jobs are, jobs that are being shunned by graduates of current training programs.

Dr. Makaroun cited the difficulties of recruitment of vascular surgeons to community hospital systems in

Address continued on following page

SVS | Society for Vascular Surgery **Vascular Specialist**

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Address

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small towns and rural areas, and he reminded people that recent general surgery graduates continue to offer vascular surgery services in such communities. Unfortunately, this is without any additional vascular training and most hospitals grant privileges without a VSB certificate when the need is demonstrated. "You all appreciate that recent graduates of general surgery programs do not have the breadth or depth of exposure to modern vascular surgery that an older generation did," he added.

The workgroup explored many options to provide relief to community hospitals. But probably the most efficient, according to Dr. Makaroun, is to consider strategies that tap into new constituencies. One consideration to be explored is to offer a 3-year vascular surgery training opportunity to the dozens of qualified candidates in preliminary surgical positions unable to locate a categorical spot to finish their training. This process will lead to VSB certification, but will take some time to establish through the ACGME structure.

The workgroup developed an outline of a proposal for a community vascular surgery training program, as a first step. It has been sketched and will be part of the task force report submitted for review by the Executive Board of the Society.

The goals of the new pathway would be to improve local vascular care in underserved communities, while increasing the referral of appropriate cases to vascular centers. It would provide stress relief to isolated vascular surgeons, and where none exist, plant the seeds of a better work environment for vascular surgery graduates to reconsider this currently undesirable career choice.

The program is designed to offer an additional year of vascular surgery training to general surgery graduates already committed to a community practice, many of whom are already planning to offer vascular services anyway. The program will individualize training but focus only on low-complexity procedures, both open and endovascular, and more importantly the clinical situations that dictate referral, said Dr. Makaroun.

To maintain quality, the program will mandate the availability of mentorship, support, and real-time advice after completion of the program, through a regional "sponsoring vascular surgery service." This service will also be responsible for retrospective peer review and root cause analysis of complications. In addition, the association with a sponsoring institution will facilitate and increase referrals of appropriate patients to higher level of care at a vascular surgery center.

"The suggested program graduates will not be board certified and will be performing mostly general surgery and low-complexity vascular cases part time in smaller communities. They will also require supervision by the board-certified graduates of the current training pathways, working in a regional vascular center, typically in a larger urban center. Instead of competing, they will actually complement our current trainees and provide an extension of their reach." he stated.

"We must find a way to fill the vacuum now before the reality on the ground permanently excludes our specialty from this primary level of vascular care," Dr. Makaroun said. "It is time for another bold step to preserve the legacy of our specialty in meeting the needs of our patients and the public.

"Progress is made through change even if we don't like it!" Dr. Makaroun concluded.

DES and DCB

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a meta-analysis published last December by Konstantinos Katsanos, MD, of Patras University Hospital, Rion, Greece, and colleagues (J Am Heart Assoc. 2018;7:e011245). Although there were concerns about the quality of the industry data used in the study, the caliber of the analysis itself and the subsequent data presented by the FDA to the panel were deemed sufficient to recommend a warning of concern to patients and providers.

Much of the new data from industry and large database registries presented to the panel, which was chaired by Richard A. Lange, MD, indicated a lessening of to no evidence of the mortality effect. But this evidence was deemed insufficient to counter the evidence of the randomized controlled trials individually and collectively as presented in the Katsanos meta-analysis and subsequent information presented by the FDA that examined various parameters in a variety of sensitivity analyses that confirmed the late mortality signal. There was also concern that the industry and the registry analyses presented were not peer reviewed.

However, the panel also determined that it would be inappropriate to pull the devices from the market and from general use for several reasons.

One key reason was that, according to the panel, there was no mechanistic cause apparent for the late mortality. In addition, no convincing dose-response data could be teased from the preclinical and clinical trials studied because of their variability of devices, application methods, and lack of appropriate tissue analysis across studies.

Finally, the industry data used to create the meta-analysis were considered to be fundamentally flawed: in blinding, in the relatively small numbers of patients, and in the large percentage of patients lost to follow-up. The latter could have dramatically influenced the perceived results, especially as the studies were not powered or designed to follow mortality over such a period of time, according to the panel.

These limitations to the signal were especially important to the panel because of the obvious benefits with regard to quality of life provided to patients from these devices, which were attested to during the 2-day meeting by numerous presenters from industry, medical organizations – including societies and nonprofits – and providers.

In responding to FDA requests on a variety of concerns, the panel reiterated that there was a credible mortality signal, but that they could not be confident about the magnitude and whether it was caused by the paclitaxel treatment or some factor in the design or conduct of the studies. In addition, the panel members felt that they could neither confirm nor eliminate a class effect, given the fact that the information was based on a meta-analysis and thus none of the included devices could safely be removed from consideration.

They suggested that further safety information should be obtained, potentially by assessing and perhaps altering data collection in 29 ongoing studies over the next 5 years or so in more than 10,000 patients.

In addition, several of the panel members felt that additional animal studies might be performed including the use of older rat models; and using animal models that mimicked the kind of comorbidities present in the treated population, such as diabetes and atherosclerosis. They suggested cross-company industry cooperation with the FDA on these models, including looking at drug interactions and mimicking the dose application of stents/balloons.

Both the FDA representative and the panel were especially concerned with the benefit/risk profile.

The recommendation to still market the devices with a label warning was warranted, according to many members of the panel. They pointed to the clear benefits in quality of life and the lowered need for revascularization despite the evidence of the mortality signal, which, while statistically significant, could not be pinned town with regard to mechanisms or specific causes of death.

Overall, there was a concern that there should be a dialogue between patients and their doctors to discuss clear short-term benefits with unknown long-term risk, and that the label should support this by clearly mentioning the mortality signal that was found, although there was no attempt to develop exact wording.

Panel member Joaquin E. Cigarroa, MD, head of cardiovascular medicine at Oregon Health & Science University, Portland, suggested with regard to labeling that a statement "that 'there may be' – not 'there is' – a late mortality signal, should be included."

Panel member John C. Somberg, MD, program director of clinical research and bioinformatics at Rush University in Lake Bluff, Ill., stated: "The label should say something like, 'when looking at a meta-analysis that combined all studies with stents and balloons that carried paclitaxel, there may be a late mortality, which must be balanced against an early and sustained benefit in terms of pain on walking and potential loss of circulation to your extremity.' "

Other panel members thought that the meta-analysis should not be privileged and that somehow the totality of the evidence should somehow be distilled down into the label, including the evidence against the signal.

"We're meeting because of a signal, of a concern – an honest, well-meaning concern – of increased mortality. And my opinion is that the patients need to be informed of it," said Dr. Lange, president, Texas Tech University, El Paso.

Some members of the panel felt that it may not be justifiable to use these devices in patients with low intrinsic risk and low recurrence risk, and the whole spectrum of patients may need to be considered in further studies to figure out the subgroups that have more benefits and more

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Improving Quality

Crawford from page 1

motivation. The first two factors can be improved through education and development and promulgation of evidence-based medical practices, but the last is correctable only through enforced regulation and peer-review. This has become increasingly more difficult as procedures move from the hospital to outpatient centers, where the profit motive for performing inappropriate procedures, and the means to satisfy it, are increasingly more tempting.

He emphasized how SVS has tools such as the Vascular Quality Initiative and its registries to provide evidence-based input on the appropriateness of procedures and whether an institution is matching up to its peers in providing appropriate patient care. The importance of the VQI was also stressed by the majority of the Crawford Forum speakers.

"Unfortunately, like it or not, the reality is that some degree of regulation is inevitable, and if we don't step up and regulate ourselves, there are plenty of other people willing to do it for us. I would say that we let the bureaucrats develop our EHRs, and you know how that worked out. So, I think it is incumbent upon us to be able to regulate ourselves."

Arlene Seid, MD, MPH, of the quality assurance office within the Pennsylvania Department of Health, then presented "The Government's Perspective on When & Where Endovascular Interventions Should Be Performed," which detailed how her department recently became concerned about an increase in the volume of endovascular procedures, and complications thereof, mainly in outpatient settings. The department also raised questions about the procedures and discussed whether reimbursement via programs such as Medicaid should be ceased.

She pointed out how federal regulations from the Centers for Medicare & Medicaid Services (CMS) only regulate through payments and their choice of procedures to be reimbursed, the vast majority of other regulations are established at the state level and vary widely from state to state. And at the state level, such as hers, there was great difficulty finding trustworthy expert opinion, and she added how organizations like the SVS could be of tremendous use in providing guidance in developing regulations.

DR. HODGSON

As an example she used Ambulatory Surgical Centers, which are defined differently from state to state and vary widely in their requirements for licensing. The state's job is made much simpler, and more effective, when expert organizations like the SVS can provide certification programs as a firm foundation for basing such licensing efforts.

She also said that if individuals have problems with state regulations, they must become knowledgeable as to what level of state organization is involved, and ideally enlist the help of groups such as SVS to provide justification for change.

Anton Sidawy, MD, MPH, FACS, professor and chair of the Department of Surgery at the George Washington University Medical Center, discussed how SVS is working with the American College of Surgeons to develop certification for vascular surgery centers. He addressed the need for organizations such as SVS to take the initiative in defining quality and value for the field, in no small part because payment models are shifting from the rewarding of volume to the rewarding of value.

Defining value may come from many sources: government, private insurers, and the public. Unless SVS has a strong voice in defining value, it may find itself not pleased with the results, according to Dr. Sidawy.

Then Fred A. Weaver, MD, chair of the SVS Patient Safety Organization and professor of surgery and chief of the vascular surgery division at Keck School of Medicine of University of Southern California, described the current state of the Vascular Quality Initiative. This is an SVS database whose 12 registries have gathered demographic, clinical, procedural and outcomes data from more than 500,000 vascular procedures performed in North America in 18 regional quality groups.

Currently, the VQI is comprised of 571 centers in the United States and Canada, with one in Singapore. Of particular importance, the makeup of the practitioners involved in the VQI is very diverse in specialty training, with only 41% of the membership being vascular surgeons.

In the near future, three more VQI registries are coming, according to Dr. Weaver: An ultrasound registry (in concert with the Society of Vascular Ultrasound); Venous Stenting; and Vascular Medicine (in concert with the American Heart Association).

Dr. Weaver emphasized how tracking outcomes is crucial for both vascular surgeons and certified vascular surgery centers to assess and improve their performance and how the VQI is critical to these endeavors.

Finally, Larry Kraiss, MD, chair of the SVS Quality Council and professor and chief of the vascular surgery division at the University of Utah, presented the goals of the new SVS council and described how the council is expanding the quality mission to include appropriate use criteria in addition to the long-standing clinical practice guidelines the SVS produces.

He elaborated how Appropriate Use Criteria (AUC) perform a substantially different role than that of Clinical Practice Guidelines (CPG).

Since 2006, SVS has developed 13 active guidelines, with more on the way. Guidelines provide positive yes/no statements with regard to treatment decision-making. However, many patients fall outside the guidelines, and appropriate use criteria are vital in these cases to evaluate where on a spectrum the patient fits with regard to performing an operation or the use of a device.

Appropriate use criteria can be developed through the use of risk assessment to determine where on the spectrum of safety and effectiveness a particular patient falls with regard to a particular procedure or device. A major role of the new SVS Quality Council is to develop appropriate use criteria using outcome tools such as VQI and to provide recommendations as to how individuals and institutions could improve their performance by taking into account risk factors and assess infrastructural needs.

"The SVS board has authorized development of AUC in particular areas," said Dr. Kraiss. "This process with be closely tied with updating the CPG. The first commissioned AUC will be to address intermittent claudication. But I invite the membership to participate in this process, especially on the panels, which can have up to 17 members, and we envision AUC coming out in carotid intervention, AAA management, and venous disease," he added.

FDA

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risks, and also to consider how to mitigate risks in patients who receive the device, whether through medical therapy or lifestyle modification.

In particular, Frank W. LoGerfo, MD, the William V. McDermott Distinguished Professor of Surgery at Harvard Medical School, Boston, stated: "Interventions for claudication should be extremely rare. It rarely progresses, and the pain should be worked through by exercise with low risk of limb loss." He added that intervention with these devices "takes away options. Trading life for something that is not limb threatening is something we should not be considering."

There was no firm consensus on whether new randomized trials should be done, although they were of course the ideal solution. Kevin E. Kip, PhD, Distinguished USF Health Professor at the University of South Florida, Tampa, and others argued that, whether new trials were necessary or not, to deal with the safety question in a timely fashion, existing trials have to capture as much of the missing data as possible, and carry out follow-up out further.

FDA representative Bram Zuckerman, MD, director of the Office of Cardiovascular Devices at the Center for Devices and Radiological Health, indicated that those things might not be easily be accomplished because of regulatory constraints and the financial costs, and that to do so there would be need for community effort among stakeholders, including collaborative efforts with existing prospective registries such as that run by the Vascular Quality Initiative.

One overall conclusion by both the FDA and panel members was that the quality of these and other such studies going forward must improve, by standardizing definitions and data forms to make studies more uniform across the industry. They reemphasized the need to work with the registries to get common data included, and to incorporate of insurance provider and Social Security death data as much as possible to help alleviate the lost follow-up problem.

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SOURCE: Webcasts of the complete 2 days of the FDA panel meeting are available online.

COMMENTARY

FDA Convened Panel on DCB and DES: There Is More Work To Do

BY PETER A. SCHNEIDER, MD, AND DANIEL CLAIR, MD

The FDA panel on paclitaxel-delivering drug-coated balloons and drug-eluting stents took place outside Washington, DC on June 19 and 20, 2019. This advisory panel was convened as the FDA sought advice on 12 questions related primarily to the safety of paclitaxel-delivering devices for peripheral arterial disease and recommendations regarding potential steps forward with respect to how these devices should be further evaluated and used in clinical practice.

There was substantial new information presented to the panel, including additional new follow up data in the randomized control trial patients, analysis of dose-response as pertaining to mortality, re-analysis of causes of mortality, an individual patient-level meta-analysis of the RCT patients by the FDA and another one by VIVA, along with several new large data-base analyses (VQI, private insurance, CMS). The FDA is very likely to issue a statement in the near future on its position regarding the issue, but no timeline for this has been established.

This panel was held in response to concerns of long-term mortality in patients treated with paclitaxel delivering devices raised by a summary level meta-analysis published in December 2018 suggesting that the hazard ratio for 5-year mortality was 1.93 for paclitaxel devices.(1)

The panel conclusions included the following key points.

The signal of increased mortality in the paclitaxel groups was present in the combined patient-level meta-analysis performed by the FDA and the patient-level meta-analysis performed by VIVA, although the magnitude of the signal varied. Important caveats are as follows. None of the separate RCTs showed a significant mortality signal; it was only present when meta-analyses were performed. The data were inconclusive and are evolving. For example, as more follow-up data have been obtained, the differences in mortality between paclitaxel and non-paclitaxel groups have become smaller. The magnitude and confidence limits of the relative risk associated with paclitaxel are different in each study, and the overall magnitude is not clear. The relative risk in the FDA meta-analysis was 1.72 at five years, and in the VIVA meta-analysis was 1.38. (2,3) All of the RCTs were powered for 1-year patency and none were powered or designed to assess long-term mortality. The FDA postulated that a well-designed randomized control trial to answer the mortality issue definitively could require up to 40,000 subjects.

When asked whether the mortality risk was a "class effect" implicating potentially all these devices despite differences in dose and characteristics of the devices, and carrier of the drug, the panel concluded this was likely a class effect if the signal is, in fact, a real increased risk. Panel members did note that this could potentially be differentiated between devices, but with available evidence to date, one has to conclude that this is a class effect if proven to be a real risk to patients. Panel members also concluded there was no evidence of a subgroup that is potentially at higher risk, and there were no clustered events or deaths that were identified.

Dr. Schneider is Professor of Surgery, Division of Vascular & Endovascular Surgery, University of California, San Francisco. He presented Medtronic's "IN.PACT DCB Effectiveness Analysis" at the FDA panel meeting. He disclosed that he was on the Scientific Advisory Board of Boston Scientific and Medtronic and serves as an adviser for Surmodics, as well as being on the board of VIVA, a 501c3 nonprofit. Dr. Clair is the chair, Department of Surgery, University of South Carolina, Palmetto Health-USC Medical Group. He gave "The PAD Patient and the Impact of Paclitaxel Device Therapy – Pan-Industry Presentation" and was part of the "Combined Manufacturer Presentation" at the FDA panel meeting. He disclosed that he was adviser to Medtronic and Boston Scientific and a consultant and Data Safety and Monitoring member for BD/Bard, with compensation paid to the Palmetto Health Medical Group.

No apparent dose response was identified. There was no evidence in the FDA analysis that there was an increasing risk of mortality with increasing dose, as was asserted by the JAHA meta-analysis. This is important for identifying whether there is causation between paclitaxel and mortality, or whether it is simply an association, which could be explained by trial design, various types of bias or a myriad of other factors, such as differences in follow-up or in medical management. Because there were small numbers of patients in certain dose ranges, the panel also acknowledged that the presence of a dose response could not be completely ruled out.

No plausible mechanism has been identified as to how paclitaxel could cause an increase in long-term mortality. The panel supported the continued use of paclitaxel-coated devices in clinical practice, and the benefits of paclitaxel-coated devices were acknowledged. However, the condition under which these devices should be used has yet to be determined. There was broad support on the panel for the continuation of existing paclitaxel device trials and an emphasis on the need for complete, long-term follow-up of these patients and a high level of data integrity. Industry presentations highlighted the volume of data which will be available for evaluation over the next few years. There are currently 29 studies with over 10,000 patients being evaluated for outcomes with treatment using paclitaxel-coated devices. These studies should provide significant data for analysis in the coming years.

The panel agreed that the benefits of paclitaxel-coated devices are significant, well-documented, and should be considered when balancing risk/benefit ratio. Patients should be made aware of the risks with the totality of data in mind. Patient advocates stressed the need to give patients the ability to choose paclitaxel treatment. In addition, quality of life was acknowledged to be as important as quantity of life – patient choice. The FDA was urged by several speakers to consider revising its letter to practitioners of March 15, 2019, especially since the result of the letter has been to make these devices unavailable in many practices.

In addition to the data discussed above, new information published since December 2018 or presented at the FDA panel include the following:

- 5-year results on IN.PACT IDE study (4);
- Patient-level meta-analysis of 1980 patients in the IN.PACT DCB program (5);
- A patient-level meta-analysis from Illumenate DCB program (6);
- Population-based study of CMS patients with DES or bare metal stents (7);
- Population-based study of CMS patients with paclitaxel or non-paclitaxel lower extremity revascularizations (8);
- Population-based study of CMS Medicare risk patients (9);
- Population-based study of large insurance carrier in US (10);
- VQI database (11).

There was broad support for the continuation of existing paclitaxel device trials and an emphasis on the need for complete, long-term follow up of these patients and a high level of data integrity.

None of these studies detected a mortality signal in paclitaxel patients and several of the large observational studies showed higher mortality in the non-paclitaxel cohorts.

Together, these studies are composed of more than 200,000 patients and show no mortality signal, as compared with 4,663 patients that were included in the original meta-analysis that did demonstrate a mortality concern. This is important because ultimately the FDA and physicians will

Commentary continued on following page

Scenes From The Vascular Annual Meeting

Dr. Misty D. Humphries receives the Mentored Patient-Oriented Research Career Development Award (left); Dr. Douglas W. Jones (center) receives the E.J. Wylie Traveling Fellowship and Dr. Wei Zhou receives the Bridge Grant. All awards are from the SVS Foundation.

Recipients of 2019 Presidential Citations include: Drs. Dawn Coleman (second from right; front) and Malachi Sheahan (front left), for their dedication to improving the well-being of SVS members and all vascular surgeons; Michael Conte (right front), John White (back left) and Joe Mills (second from left; front), for their dedicated effort to complete the Global Vascular Guidelines Project; and Sean Roddy (right back) and Matthew Sideman (center back), for their tireless work in advocating for and protecting the interests of the specialty.

Poster Competition: Ten finalists competed in the championship round of the Poster Competition at VAM. The three top finishers, seated in the front row with their awards, are (from left) Jesse Columbo, third place; Alexander King, first place; and Arash Fereydooni, second place.

Young Surgeon Competition: Francesco Squizzato, MD, received the 2019 Frank J. Veith Award, as winner of the International Young Surgeons Competition during VAM. He is pictured with John Blebea, MD, of the International Relations Committee.

PHOTOS MARTIN ALLRED/NATIONWIDE PHOTOGRAPHERS

Commentary

continued from previous page

likely base decisions about the use of these devices on the totality of data, given that each dataset has its particular challenges.

The issue is not yet settled, and there is more work to do and we must remain vigilant and persistent in collecting and analyzing available data and exploring all possibilities to protect our patients. Nevertheless, none of the developments in the 6 months since publication of the JAHA meta-analysis have shown that the danger concern is real or that there is a causal biological mechanism, a dose response or a clustering of deaths as to a certain cause.

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VRIC 2019 a Big Success; Scientists Look Forward to 2020 in Chicago

With a record number of attendees, abstracts submitted, and abstracts presented, not to mention outstanding research presentations and high enthusiasm throughout, the 2019 SVS Vascular Research Initiatives Conference (VRIC) has been dubbed a big success.

VRIC, with the theme "Hard Science: Calcification and Vascular Solutions," was held May 13 in Boston.

"This year, we challenged ourselves to meet three goals while maintaining the quality of the work presented: increase the number of abstracts submitted, increase attendance, and increase visibility," said Luke Brewster, MD, PhD, chair of the SVS Research and Education Committee.

"Thanks to the hard work of the R&E Committee, our SVS support and the SVS leadership (Drs. Edith Tzeng, Michel Makaroun and Clem Darling), we accomplished them all, and we are looking forward to next year."

Four abstract sessions highlighted advancements in vascular remodeling, thrombosis, and discovery science for venous disease; vascular regeneration, stem cells and wound healing; aortopathies and novel vascular devices; and atherosclerosis, arterial injury and diabetes. Translational presentations included mechanistic insights on vessel remodeling insights; wound healing mechanistic insights on AAA and cutting-edge theragnostics for PAD.

Drs. Karen Woo and Mohamed Zayed (MD, PhD), 2017 recipients of the SVS Foundation Mentored Clinical Scientist Research Career Development Award, presented "amazing talks" detailing their progress on their K awards, said Dr. Brewster. Dr. Woo is examining causes of disparity in dialysis access, and Dr. Zayed has discovered a unique mechanism in lipid metabolism that is disrupted in diabetic PAD patients.

SVS member Dr. Frank LoGerfo, mentor to many vascular surgeon-scientists, was honored for his dedication to mentoring so many on translational and impactful research in the field of vascular diseases. He also shared pearls for the audience on how to maintain a presence as a vascular surgeon while directing a successful research laboratory.

Cecilia Giachelli, PhD, of the University of Washington's Department of Bioengineering gave the Alexander W. Clowes Distinguished Lecture on "New Concepts in Regulation and Bioengineered Therapies for Vascular and Valvular Calcification." And the Translational Panel, said Dr. Brewster, "provided key insights into recent scientific inroads as they relate to developing solutions for vascular calcification."

> For surgeons and surgeon-scientists, "VRIC is a great place to meet up with friends and hear, learn and contribute to the direction of next-generation therapeutics for vascular disease."

Finally, this year, all poster presenters were able to discuss their work as "Quick-Shot" presentations organized by Dr. Zayed during the cocktail reception. Winners were recognized at the session. "This addition was a big hit, and we are grateful to Dr. Zayed for initiating this inaugural event," said Dr. Brewster. The entire day resonated with a high level of interest and energy. "The enthusiasm for the presentations, the abstracts, the discussions, everything, was palpable," Dr. Brewster added.

The day also brought home to attendees that, in terms of research and researchers, the SVS has a pipeline that's as robust as it's ever been, he said. "I think the future is exceptionally bright. The amount and breadth of talent certainly makes our committee look good, but in reality, it is the dedication and hard work of so many surgeon-scientists, coupled with support from SVS leadership, that makes VRIC so special year in and year out."

Planning already is underway for VRIC 2020, set for May 4, 2020, in Chicago. "The location is a big attraction, not only because Chicago (like Boston) has so many excellent research institutions but also because of Chicago's proximity to Medical College of Wisconsin and the Universities of Wisconsin, Indiana, Southern Illinois and Iowa," Dr. Brewster said. "It is likely we can build on the 'local' attendance in much the same way as we did in Boston, thanks to the program directors, motivated trainees and vascular researchers from the local area."

Why should SVS members attend VRIC? Dr. Brewster said, "All surgeons (and cardiovascular specialists) will find the conference valuable because the work presented is intended to be link clinical insights and solutions with translational discoveries that provide the pipeline for next generation therapies for vascular patients in the years to come."

Then he offered a two-part answer to two different groups:

For surgeons and surgeon-scientists, "VRIC is a great place to meet up with friends and hear, learn and contribute to the direction of next-generation therapeutics for vascular disease," he said.

For the cradle-to-grave investigators, "VRIC is a great place to enlighten the relevant community on their work and develop collaborations and future collaborative goals that can change the health of vascular patients for the better."

View more VRIC photos at **vsweb.org/VRIC19Photos**.

SAVE THE DATE!

2019 SVS Coding & Reimbursement Workshop

SEPT. 20–21, 2019

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(Near O'Hare Airport)

SVS | Society for Vascular Surgery

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Registration today for the workshop, Sept. 20 to 21, plus the optional half-day Evaluation and Management Coding course. The workshop will be held at the Hyatt Rosemont, just minutes from O'Hare International Airport and near the new SVS headquarters office (944 W. Higgins Road, Rosemont, Ill.).

Course Chair, Sean Roddy, MD, stresses the workshop's value to vascular surgeons and/or their office staff. "You learn to be paid fairly for your work," he said. "You learn how to do appropriate billing to maximize your reimbursement – and how not to make yourself a target for an audit."

It's vital a surgeon in a solo practice has a coder, he said. In a group practice, at least one person needs to be knowledgeable.

Learn more and register at **vsweb.org/Coding19**.

Innovtion Medal: Honoring 'Pioneer of Venous Surgery'

Groundbreaking. Innovative. Pioneer. "Father of Modern Venous Surgery." A man who "truly changed the world with respect to treatment of venous disease." All of the above – and more – describe Dr. Robert Kistner, recipient of the SVS Medal for Innovation in Vascular Surgery, presented at the 2019 Vascular Annual Meeting. He was the first awardee in six years.

Dr. Kistner influenced venous practice in three fundamental ways, said Dr. Thomas Wakefield. Dr. Kistner:

- Invented several new techniques to correct reflux.
- Has been a fundamental contributor to the development of the CEAP classification system, used "today to be able to speak a common language regarding our venous patients."
- Was instrumental in starting the Pacific Venous Symposia. These meetings are one reason why the National Institutes of Health now supports venous research, said Dr. Wakefield.

Martin Allred/Nationwide Photographers

Robert Kistner, MD, (left) is presented the SVS Medal for Innovation in Vascular Surgery by Michel Makaroun, MD.

"While there are many who had invented or advanced some aspect of vascular surgery, few can match the breadth and depth of his works. Few in our midst had such an influence in sparking the birth and growth of an entire major branch of vascular disease. … ,' " wrote several SVS members in nominating Dr. Kistner.

His list of important contributions started in his residency in the late 1950s, when a professor challenged residents to determine a way to clean secretions from tracheotomy tubes. In addition to people "drowning" in their own secretions, the tubes also caused trauma to surrounding tissue and prevented people from speaking.

Working over many months, Dr. Kistner helped invent the tracheostomy valve, which stopped the flow out and forced secretions up and out through the mouth. "A byproduct was that it allowed them to talk," he said.

With what others call his characteristic humility, Dr. Kistner pointed out dryly, "It didn't (work) so well that they're using it anymore."

His career has included a number of new surgical techniques and other contributions, including performing an open repair of a leaky femoral valve with direct suturing, a technique now known as "internal valvuloplasty." "It was taboo – touching the vein," he said of that time, 1968. "You don't touch the vein and if you do, it's very gentle. This is quite the opposite of that."

He had some misgivings about the procedures, "but it seemed reasonable." After all, surgeons had been working with arteries for quite a long time. "One doesn't do something radically different," he said, "without …. thinking it will work."

This "signal procedure" not only opened the door to direct venous surgery but also helped develop the whole field of venous disease, surgeons said.

Dr. Kistner also was first to outline the principles of grading reflex severity, the foundation for the current system, now adopted worldwide. He was also one of the founders (and president) of American Venous Forum, and he and his colleagues in Honolulu began the Pacific Symposia, attracting venous leaders from around the world.

"These seem like standard tools to us today," said Immediate Past President Michel Makaroun. "Back then they revolutionized our ability to diagnose and treat disease."

Now 90, Dr. Kistner has officially retired, doing, he jokes, "whatever my wife (Adelaide) tells me to do." But, as others point out, "retired" is "relative." He and Dr. Fedor Lurie are analyzing the mountain of data Dr. Kistner has collected over the years and he still travels worldwide to venous meetings. "So the retirement is 'official' but his Venous Mission unofficially continues," surgeons said.

He looks back on his career and life with deep satisfaction. "I've enjoyed the practice of medicine. Always did, always will," he said. "The thing I've loved the most is taking care of people," said Dr. Kistner. "I got a lot of joy in treating people and solving problems. It's been very fulfilling and fun to do."

Compassion's other name: Dr. William Pearce

It may have come as no surprise to his colleagues, mentees and patients at Northwestern University that Dr. William Pearce, Charles and Violet Baldwin Professor of Surgery Emeritus, was named the 2019 Lifetime Achievement awardee by the Society for Vascular Surgery at its annual meeting in June.

At Northwestern he has been an accomplished leader of one of the strongest vascular surgical departments in the nation. He mentored countless professionals, not just fellows, residents and students, but also nurses and faculty.

The Lifetime award is just one of many that have honored this extraordinary surgeon. In 2007, he earned the Surgery Mentoring Award from the American Heart Association's Council on Cardiovascular Surgery and Anesthesia, then was named Faculty Mentor of the Year by Northwestern's Feinberg School of Medicine in 2008 and was named Mentor of the Year by the school in 2010. In 2014, he was named to the Feinberg's Teaching Hall of Fame and Mecklenberg Distinguished Physician Awards. Over 37 years, many of his proteges have gone on to outstanding careers and leadership positions in academics. He was chief of the Feinberg's Division of Vascular Surgery from 1998 to 2010.

Among his many attributes, his extraordinary personality of caring and compassion was mentioned at length by every one of his nominators.

"He is constantly stopped (in the hallways) by appreciative employees or patients," wrote one of his mentees, Dr. Melina Kibbe. "His compassion for people is extraordinary. For example, when one of the cafeteria workers was sick, he sent her flowers. He often gives out his home number and has spent hours on the phone with patients explaining their disease, treatment options, and simply providing comfort and support. His children have recounted numerous stories of how Dr. Pearce has made personal house calls to patients who do not have the means to travel to the clinic for outpatient visits. He is keenly aware of their financial struggles and has waived his own reimbursement when patients are not able to pay."

MARTIN ALLRED/NATIONWIDE PHOTOGRAPHERS

William Pearce, MD, (left) was presented the 2019 Lifetime Achievement Award by Michel Makaroun, MD.

He is an internationally known clinical vascular surgeon with interests in PAD, venous problems, and aortic aneurysms, and he is a recognized researcher with expertise in the pathophysiology of aortic aneurysms. He has been the principal investigator or co-PI on grants totaling nearly $62 million dollars. He has written more than 250 scholarly articles, has edited 42 books and written 122 book chapters.

In the midst of all these achievements, he also had a busy clinical practice and has volunteered at Walter Reed Army Medical Center and Landstuhl Medical Center in Germany during the Iraq and Afghanistan conflicts. He went on medical missions to Guatemala in 2009 and 2012. In addition to providing medical care, he has volunteered several times to build housing on Native American reservations and serving in a local soup kitchen. In 2013, he was awarded the Martin Luther King Jr. Humanitarian Award from Northwestern Memorial Hospital.

While Dr. Pearce taught his fellows and residents how to become accomplished surgeons, said one of his nominees, Dr. Mark Eskandari, "his greatest impact during his 30-year career at Northwestern has been exemplifying the essentials of compassionate care. He personally connects with each patient and recalls everyone he has ever treated."

He also has insisted that his staff make time for their own families despite their demanding schedules. "A saying of his with which we are all familiar," Dr. Kibbe said, "was 'family comes first.'"

His extraordinary compassion had some unanticipated side effects, however. "Because of his inability to say no to door-to-door sales people," Dr. Kibbe noted, his children have told her, "they had so many magazine subscriptions that they didn't know what to do with them."

A snapshot of achievements

The contributions and recognition of Dr. William Pearce could fill a book. Here are just a few:

- Professor Emeritus Northwestern University (2018)
- Charles and Violet Baldwin Professor of Surgery (1990-present)
- Chief of the Division of Vascular Surgery Northwestern Feinberg School of Medicine (FSM) Alpha Omega Alpha (AOA) Counselor Northwestern FSM Chapter
- Author: 259 peer-reviewed papers and 122 book chapters; Editor: 42 books
- Visiting professor/invited speaker: 43 occasions
- Director, basic science laboratory at Northwestern since 1984; more than 60 grants
- NIH grant to fund the Vascular Surgery Scientist Training program at Northwestern University
- 1992 NIH academic award to develop a novel, integrated, multidisciplinary faculty approach to patient care, which has since become a standard of care
- NIH grant reviewer 1994-1999, 2010-2015
- 36 course directorships, 1991-2018
- 238 course faculty/lecturer
- Member, 34 societies
- Editorial board member, 15 surgical journals/publications
- Volunteer with Walter Reed, Landstuhl Medical Center, Faith in Practice medical missions to Guatemala
- 2001 President, American Association of Vascular Surgeons (formerly the International Society of Cardiovascular Surgery-North American Chapter, ISCVS)
- Recorder ISCVS (American Association of Vascular Surgeons) 1997-2001
- SVS Committees: Ad Hoc Education, Program, SVS/ISCVS Joint Council, Standardized Reporting Practices; Lifeline Foundation (SVS Foundation)

SVS Foundation-Sponsored Screening Uncovers 2 Aneurysms: Will Help Screen Vets in July

A recent free AAA and PAD screening was well worth the time for two patients diagnosed with aneurysms.

The SVS Foundation was a sponsor of the early June screening in Washington, D.C., partnered by AAAneurysm Outreach and George Washington University Medical Faculty Associates. Other sponsors were the Society for Vascular Nursing and the Society for Vascular Ultrasound. W.L. Gore & Associates provided funding and American Heart Association volunteers provided blood pressure checks.

Those patients who were found to have vascular issues were able to talk immediately with SVS member Dr. Robyn Macsata, who was on site.

The SVS Foundation next will participate in the AAAneurysm Outreach screenings July 20-22 at the Veterans of Foreign Wars convention in Orlando. This is the third straight year the SVS Foundation has participated in this annual screening, which typically draws hundreds of people. Last year 11 people of more than 600 screened discovered they needed medical attention for an AAA.

LEADERSHIP: Spotlight on Michael Conte, MD

BY BRYAN W. TILLMAN, MD, PHD
ON BEHALF OF THE LEADERSHIP DEVELOPMENT AND DIVERSITY COMMITTEE

I had the privilege of interviewing Dr. Michael S. Conte, Professor and Chief of the Division of Vascular & Endovascular Surgery at the University of California, San Francisco. We focused on the themes of the chapter: "Challenge Is the Crucible for Greatness," from "The Truth About Leadership," by Kouzes and Posner.

Q: Over your lifetime, who have been some of your role models for leadership and what are the most important lessons you learned from them?

A: I guess like most people I've had multiple mentors for different aspects of my professional career. Two surgical chairs at the Brigham (and Women's Hospital in Boston), Mike Zinner and John Mannick, were both role models in uniquely different ways. Mike, because he was such an effective leader in a complex academic health system. Very insightful, engaging, always available and a strong advocate for his people. Someone who would make you feel like part of his team and invest the time and energy to make you successful. I found Mike to be transparent, accountable and very honest about where things stood, i.e., someone to trust. I always appreciated his ability to get everybody behind one vision in a large department. John Mannick was just the consummate academic vascular surgeon. He had NIH funding for his entire career, was doing high-end complex vascular surgery, was an effective administrator, and yet was done by 6:30 p.m. every day. His intellectual prowess and amazing efficiency were daunting to try to duplicate, but very inspiring. As a surgeon-scientist, Alec Clowes was a tremendous role model. As my career went on I got to know him more and more. It was incredibly rewarding, as Alec was a brilliant, insightful scientist. Always available, always intellectually curious and very rigorous, and a great sounding board for a million things. I got to work with him on the Prevent III trial, but then over time our relationship deepened.


DR. CONTE

He was a terrific role model, staying true to his mission of being a surgeon scientist. Alec's premature death was a tremendous loss for vascular surgery. Maybe most importantly, as an outstanding surgeon, Mike Belkin at the Brigham, my dear friend and long-term mentor, really personifies for me the complete vascular surgeon in terms of patient care. Mike always puts the patient first. He always does the right thing, and always does it well. If you ever want to know what the right thing to do is, you go to Mike. It's not necessarily going to be a shortcut, but it's going to work. His integrity and loyalty to his patients – and his people – are exemplary. Those are all the people who have, in different ways, inspired me.

Q: Are there particular experiences or challenges that have forged some of your leadership skills?

A: I think one of the big ones, in terms of both opportunity and challenge, was running the Prevent III trial. I was relatively junior at the time. It was an innovative trial of a genetic therapy for vein grafts. I was in the right place at the right time, and already had done some research in that arena. But it was huge undertaking, and I'd never been exposed to running a large-scale clinical trial. It was a 5- or 6-year ride, a lot of work, a great opportunity and a great learning experience. The disappointment and the challenge were that the treatment didn't work. The trial was run by a small company which partnered with a bigger company, but the resources disappeared almost the minute the trial was negative. So the challenge was how to pivot to make sure that we got the most information out of the trial, because there was not going to be any more analytic support provided. It was very disappointing that the molecular construct didn't work, so I spent a lot of time thinking about why. I became much more interested in inflammation as a pathway of vein graft disease, and it pushed me into the next R01. After many years of working on that, it was challenging to make a transition and pick up the pieces. I think we were successful at getting a lot of knowledge out of that trial. What I learned from that is the importance of having a leadership team that was very engaged and collaborative. We made sure everyone had something important to do, that they could lead some questions coming out of the trial. Together, we found a way to marshal the resources to get some good contributions done. I think it was important to be inclusive, and to share the data with a group of people who were interested in following through on the ancillary questions.

Q: What are common challenges for young faculty in your division where you are able to provide guidance?

A: Common challenges are learning what you are good at, building your own community in your area of interest and finding that village in your institution, while balancing all your commitments. At the end, it is about how you deal with failure. Because there is no success without lots of failure. Typically, we don't like to fail, particularly as surgeons. But we know as surgeons that we do fail – and you have to get up and keep going. The most important things are to stay true to your values and be honest with yourself. If you know there is an area where you need help, get the help whether inside or outside the operating room, don't be a hero. Use your colleagues, because vascular and academic surgery are fundamentally team sports. My door is always open, and I find that there's a way to be a good mentee and a way to be a good mentor. I ask people to think of potential obstacles ahead of time. Part of my job is to foresee where the obstacles are, but it is hard to be in everyone's shoes. It's a lot about not trying to over-extend yourself, but I know I am not always the best example! Learn and use the resources around you. If something doesn't work, put it down for a little while, think about it from a different side and get some different opinions. Don't keep burrowing into your own rabbit hole, which we all tend to do. Part of the purpose of coming to national meetings is to get out of that rabbit hole so you can see what other people are doing. Each journey depends on where someone's passion is. It's really important to match the person with the job, otherwise the struggles are harder to fix later.

Q: Clearly the paradigm for leaders has changed since your training. What do you see as new transitions that leaders will need to become accustomed to?

A: I think one of the biggest challenges on both an institutional and on a national level is defining what our value is. One of the biggest reasons people in academic surgery may not be happy at times is that they feel undervalued, or they feel their efforts are not being appropriately measured by the "system." We are a relatively small group, so we need to … as they say "punch above our weight." I think we have to define our value really well, in every one of these settings in our department, in our hospital, in our health system, and on the national stage. There are a lot of people who do work in our arena, so how are we distinguished? At the end of the day our value should be defined by what we do for our patients. These discussions should be driven by the quality of our argument with data, not by how loud we are. I also think it's is a really important skill to learn how to build consensus. You can't just argue for what you want. You have to listen to what everyone is trying to get at, help to sharpen the vision, define common ground, and still move forward. Especially in an academic health environment where there are lots of competing interests. Our field is very complicated and the public, at large, does not really understand what we do. I think this is the No. 1 challenge for us: clarifying what we contribute and what we do for our patients. Leading multidisciplinary teams to improve vascular care requires that we are open, collaborative, and accountable – and not insular. I worry sometimes that as we try to move our priorities forward we may appear too inward-looking. Our leaders will need to maintain a broad perspective to meet these challenges.

SPOTLIGHT

Spotlight highlights significant honors and achievements our members receive, medical and otherwise. Send information to communications@vascularsociety.org.

Robert Zwolak, MD, PhD, has been appointed chief of surgical services for a planned Ambulatory Surgical Center for the Manchester (New Hampshire) Veterans Affairs Medical Center. Development of an ASC was approved to address the emerging needs of New Hampshire veterans.

More Scenes From The Vascular Annual Meeting

Passing the Gavel: Past President Michel Makaroun (right) passes the gavel – and leadership of the Society for Vascular Surgery – on to 2019-20 President Kim Hodgson.

Prevention Award: Soma Brahmanandam, MD, and Uwe Fischer, MD, PhD, are two of the three recipients of the 2019 SVS Foundation Community Awareness and Prevention Project Grants.

Women Leadership Training Grants: Drs. Lori Pounds (left) and Jessica Simons receive two of the three 2019 Women's Leadership Training Grants.

Four awards: SVS Foundation award recipients include: Drs. Efthymios Avgerinos (from left) and Sikandar Khan, Clinical Research Seed Grant; Young Erben, Research Career Development Travel Award; and Frank M. Davis, Resident Research Award. Dr. Avgerinos competed at VAM for his grant, during a special grant challenge involving three runners-up for the award.

JVS Awards: Two SVS members honored by the Journal of Vascular Surgery are: Michael J. Rohrer, MD, (left) for the Best Reviewer Award, and Matthew Eagleton, MD, for the Most Highly Cited Article Award.

PHOTOS MARTIN ALLRED/NATIONWIDE PHOTOGRAPHERS

Risk Factors for Foot Ulcers Differ for Type 1 and Type 2 Diabetes

BY RANDY DOTINGA
MDEDGE NEWS
FROM DIABETES RESEARCH AND CLINICAL PRACTICE

Danish researchers have linked multiple factors to higher risk of first-time diabetic foot ulcers (DFUs) in patients with type 1 and type 2 diabetes, although some of the factors – older age, smoking, history of cardiovascular disease, and longer duration of diabetes – seem to indicate increased risk only in type 1 disease, according to the new study findings.

The authors suggest that, since clinical information gathered from patients during routine follow-up visits often includes mention of the risk factors for first-time DFU, it could form the basis of a risk stratification process for first-time DFU that can be integrated into the electronic record system and easily incorporated into routine care.

DFU is a significant complication for both type 1 and type 2 diabetes,

Foot Ulcers continued on page 18

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CHA is recruiting a Vascular Surgeon to join our existing department consisting of over 20 general and fellowship trained subspecialized surgeons.

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We are an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability status, protected veteran status, or any other characteristic protected by law.

LOYOLA MEDICINE

Loyola Medicine and Loyola University Chicago (LUC) Stritch School of Medicine are currently recruiting vascular physicians in the following specialties:

- Vascular Surgery
- Endovascular Surgical Neuroradiology (fellowship trained)

Successful candidates will be a board certified or board eligible and licensed to practice in the state of Illinois at the time of hire.

Candidates interested in learning more about either of these opportunities should contact Colleen Chenevey, Physician Recruitment Office, at **Colleen.Chenevey@lumc.edu** as well as apply online at **www.careers.luc.edu**

USF Health

USF Health's mission is to envision and implement the future of health. It is the partnership of the University of South Florida Morsani College of Medicine, the College of Nursing, the College of Public Health, the College of Pharmacy, the School of Biomedical Sciences and the School of Physical Therapy and Rehabilitation Sciences; and the USF Physician's Group. USF is a global research university ranked 34th in federal research expenditures for public universities.

For information regarding the USF Health, please visit our website at **https://health.usf.edu/care/surgery**

Open Rank Academic Vascular Surgery

The Department of Surgery at USF is seeking an experienced academic vascular surgeon to join the Division of Vascular Surgery. The ideal candidate should have 7 plus years clinical experience, as well as a commitment to resident education and research.

The successful candidate must be BC/BE Vascular Surgeon, be eligible for medical licensure in the State of Florida and eligible to work in the United States.

This is a full-time 12-month salaried faculty appointment at the rank of Associate Professor/Professor and carries with it attending staff privileges at Tampa General Hospital (TGH) and affiliated hospitals. TGH is a level 1 trauma center that serves as a tertiary care facility serving south central and west Florida.

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Job # 20640. Inquiries may be directed to Dr. Murray Shames, Division Chief, via Megan Etue at **metue@health.usf.edu**

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Von Liebig: TCAR Showed Improved In-Hospital Outcomes Compared to CEA

BY MARK S. LESNEY
MDEDGE NEWS

Transcarotid artery revascularization (TCAR) with dynamic flow reversal was designed to offer a potentially less invasive option to carotid endarterectomy (CEA) in high-risk patients.

The Society for Vascular Surgery Vascular Quality Initiative TCAR Surveillance Project (SVS-VQI-TSP) was designed in collaboration with the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration to evaluate the safety and effectiveness of TCAR in real-world practice, according to Mahmoud B. Malas, MD, of the University of California San Diego, San Diego.

In the Von Liebig Research Forum at the 2019 Vascular Annual Meeting, Dr. Malas presented an analysis that he and his colleagues performed assessing the outcomes of patients who underwent TCAR compared with CEA between 2015 and 2018. They included 3,435 TCAR and 62,032 CEA patients who underwent their treatment without concomitant procedures, while excluding tandem, traumatic, or dissection lesions

Patients in the two treatment groups were matched using propensity scoring to the nearest neighbor based on several baseline difference including age, symptomatic status, a variety of comorbidities, and prior interventions, as well as contralateral occlusion, degree of ipsilateral stenosis, and anesthesia and protamine use, according to Dr. Malas. He and his colleagues evaluated 1-year outcomes using Kaplan-Meier and Cox regression analysis.

They found that patients undergoing TCAR were significantly older and had more medical comorbidities versus those undergoing CEA. Univariable analysis showed

TCAR had significantly higher rates of bleeding requiring intervention (1.5% vs 1.0%). In contrast, patients undergoing CEA had higher rates of cranial nerve injury (2.7% vs 0.4%) and were more likely to stay in the hospital for more than 1 day (31.5% vs 29.1%) both significant differences. Overall, no difference was noted in terms of in in-hospital mortality, stroke, transient ischemic attack, stroke/death and stroke/death/myocardial infarction (MI).

However, after propensity score matching, TCAR was associated with lower odds of stroke/death/MI (odd ratio [OR] 0.63), cranial nerve injury (OR, 0.13), postprocedural hypertension (OR, 0.63), and higher odds of postoperative hypotension (OR, 1.47) compared with CEA (all values within their 95% confidence intervals).

Patients undergoing TCAR were also significantly less likely to stay in the hospital for more than 1 day (OR, 0.71). The association between TCAR and outcomes did not differ significantly with respect to symptomatic status, and at 1 year, the matched cohort showed no differences in mortality, stroke, and stroke/death between TCAR and CEA.

"In this real-world analysis of 3435 high-risk patients in the TSP, TCAR was associated with a significant reduction in the odds of inhospital stroke/death/MI, cranial nerve injury, and postprocedural hypertension compared with CEA.

At 1 year, there were no differences in outcomes between the procedures. Better follow-up and a larger sample size are needed to further validate these findings and guide clinical decision-making," Dr. Malas concluded.

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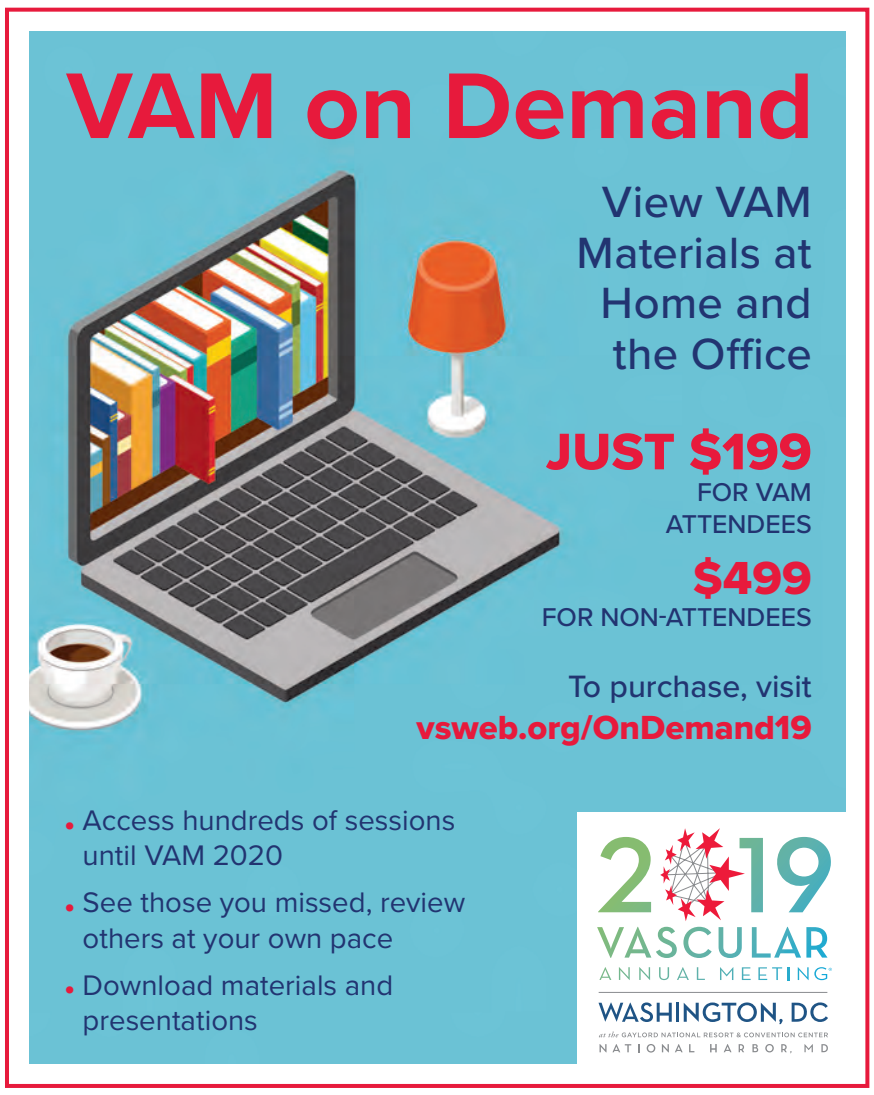

Foot Ulcers

continued from page 16

but no previous research has stratified the risk factors for first-time DFUs by type of diabetes, emphasized the study authors, led by Sine Hangaard, MSc, of Steno Diabetes Center Copenhagen.

For the new study, the researchers tracked 5,588 patients with type 1 diabetes and 7,113 with type 2, all of whom were treated at a hospital clinic in Denmark between 2001 and 2015. The authors noted that the patients with type 2 disease who were treated at the center were clinically more complicated and had a longer disease duration than average type 2 patients, whereas the patients with type 1 diabetes did not differ from average type 1 patients.

Several factors boosted the risk of first-time DFU in both types of disease, including high or low levels of albumin excretion, advanced diabetic retinopathy, limited or nonexistent vibration sense, symptoms of neuropathy, and absence of foot pulses per univariable regression (all *P* less than .01). The researchers linked the neuropathy and absences of foot pulses to especially high spikes in risk.

Female gender was protective for type 1 and type 2 disease (hazard ratios, 0.7 and 0.5, respectively; *P* = .0000). Various body mass index levels seemed to have no impact on risk.

Three factors that posed a higher risk for first-time DFU in type 1 disease, but not type 2, were smoking (HR, 1.4 vs. no smoking, *P* = .0220), age of 60-79 years (HR, 1.7 vs. age 40-59; *P* = .0000), cardiovascular disease (HR, 2.2 vs. no cardiovascular disease; *P* = .0000), and diabetes duration of between 5 and 20 years (HR, 2.2 vs. less than 5 years; *P* = .0027) or 20 years or more (HR, 5.2 vs. less than 5 years; *P* = .0000).

The authors noted that "25% of all patients with diabetes develop DFU during their lifetime, and DFUs precede 80% of all lower leg amputations in patients with diabetes."

In addition, DFU often occurs in feet already compromised by neuropathy or peripheral vascular disease, and is therefore associated with greater risk for infection, poorer outcomes, recurrent ulceration, amputation, and increased mortality. These risks underscore the need for the earliest-possible identification of first-time DFU and timely adoption of effective, preventative strategies, they wrote.

The study was not funded. Several of the authors reported that they own shares in Novo Nordisk.

SOURCE: Hangaard S et al. Diabetes Res Clin Pract. 2019 Apr 18;151:177-86.

Rivaroxaban: More GI Bleeds Than Other NOACs

BY DOUG BRUNK
MDEDGE NEWS
REPORTING FROM DDW 2019

SAN DIEGO – Patients on rivaroxaban had significantly higher rates of GI bleeding, compared with those taking apixaban or dabigatran, results from a large population-based study showed.

"This may be due to the fact that rivaroxaban is administered as a single daily dose as opposed to the other two non–vitamin K anticoagulants [NOACs], which are given twice daily," lead study author Arnar B. Ingason said at the annual Digestive Disease Week. "This may lead to a greater variance in plasma drug concentration, making these patients more susceptible to bleeding."

Mr. Ingason, a medical student at the University of Iceland, Reykjavik, and his associates performed a nationwide, population-based study during March 2014–January 2018 to compare the GI bleeding risk of patients receiving rivaroxaban to that of a combined pool of patients receiving either apixaban or dabigatran. They drew from the Icelandic Medicine Registry linked to the personal identification numbers of patients in the Landspitali University diagnoses registry, which includes more than 90% of all patients hospitalized for GI bleeding. They used 1:1 nearest neighbor propensity score for matching and Kaplan-Meier survival estimates and Cox regression to compare rates of GI bleeding.

Mr. Ingason reported that the baseline characteristics were similar between the rivaroxaban group and the apixaban/dabigatran group. They matched for several variables, including age, sex, Charlson score, the proportion being anticoagulant naive, moderate to severe renal disease, moderate to severe liver disease, any prior bleeding, and any prior thrombotic events.

During the study period, 3,473 patients received rivaroxaban, 1,901 received apixaban, and 1,086 received dabigatran. After propensity score matching, the researchers compared 2,635 patients who received rivaroxaban with 2,365 patients who received either apixaban or dabigatran. They found that patients in the rivaroxaban group had significantly higher rates of GI bleeding, compared with the apixaban/dabigatran group (1.2 and. 0.6 events per 100 patient-years, respectively). This yielded a hazard ratio of 2.02, "which means that patients receiving rivaroxaban are twice as likely to get GI bleeding compared to patients on apixaban or dabigatran," Mr. Ingason said. When the researchers examined the entire unmatched cohort of patients, the rivaroxaban group also had significantly higher rates of GI bleeding, compared with the apixaban/dabigatran group (1.0 and 0.6 events per 100 patient-years; HR, 1.75).

Mr. Ingason and his colleagues observed that patients in the rivaroxaban group had higher rates of GI bleeding, compared with the apixaban/dabigatran group, during the entire follow-up period. At the end of year 4, the rivaroxaban group had a 4% cumulative event rate of GI bleeding, compared with 1.8% for the apixaban/dabigatran group, a highly significant difference at $P = .0057$).

The researchers reported having no disclosures.

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Revascularization Plus Exercise Is Most Effective for Intermittent Claudication

BY CALEB RANS
MDEDGE NEWS
FROM JACC: CARDIOVASCULAR INTERVENTIONS

Alongside best medical therapy, percutaneous transluminal angioplasty (PTA) plus supervised treadmill exercise therapy (SET) could be the most beneficial first-line treatment option for intermittent claudication, according to a systematic review and network meta-analysis of 37 randomized clinical trials.

The meta-analysis "has shown that in addition to best medical therapy, angioplasty combined with supervised exercise appears to be the optimal initial treatment strategy for patients presenting with claudication," wrote Athanasios Saratzis, PhD, of Guy's and St Thomas' Hospital in London, and colleagues.

They searched major databases for studies that compared all potential treatment options for patients with intermittent claudication. After applying the search criteria, the team found 37 clinical studies that included a total of 5 multi-arm randomized trials. The primary outcome measure used was the improvement in Maximum Walking Distance. The secondary outcome included in the analysis was patient-reported Quality of Life (QoL).

Overall, four different treatment options for peripheral arterial disease (PAD) with intermittent claudication were compared: SET alone, PTA alone, PTA plus SET, or best medication therapy (lacking SET or PTA). In all, 2,983 patients with intermittent claudication were included.

After analysis, the researchers found that PTA plus SET was associated with a larger improvement in maximal treadmill walking distance (MWD), compared with best medication therapy alone, with an increase of 290 meters (95% confidence interval, 180-390 meters; P less than .001).

With respect to quality of life, PTA plus SET was associated with better improvement in quality of life versus best medical therapy.

The researchers acknowledged that a key limitation of the study was the lack of patient level data.

No funding sources were reported. Dr. Saratzis reported financial affiliations Amgen, Medyria Medical AG, and Regeneron.

SOURCE: Saratzis A et al. JACC Cardiovasc Interv. 2019 May 29. doi: 10.1016/j.jcin.2019.02.018.

PERSPECTIVE by Dr. Mary M. McDermott

Important Questions Remain, Commentators Report

One question that remains from the current study is whether revascularization plus exercise changes the rates of adverse events seen among patients with intermittent claudication.

While results of the network meta-analysis showed benefit for combination percutaneous transluminal angioplasty and supervised treadmill exercise therapy in terms of efficacy, no data on adverse events were reported. Other studies have revealed that exercise therapy does not increase rates of adverse events in patients with peripheral arterial disease, but this may not be the case with PTA.

A recent study showed the rates of serious adverse events, such as adverse limb events, myocardial infarction, stroke, or death, in a group of patients with intermittent claudication who underwent PTA. While the event rates were low, the follow-up period was short (30 days). Further studies have also shown that responses to PTA alone may not be long lasting.

In a similar manner, the long-term efficacy and safety of PTA plus SET remains unknown. In addition, questions surrounding the statistical significance of quality of life measures from the network meta-analysis also remain.

Rather than encouraging more PTA procedures, results of this network meta-analysis should encourage increased participation in SET by patients with PAD.

Mary M. McDermott, MD, professor of medicine at Northwestern University in Chicago, made these comments in an editorial. She reported financial affiliations with the National Heart, Lung, and Blood Institute, the National Institute on Aging, and Regeneron (JACC Cardiovasc Interv. 2019 May 29. doi: 10.1016/j.jcin.2019.03.017).

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1. Bismuth Gray BH, Holden A, Metzger C, Panneton J; VBX FLEX Study Investigators. Pivotal study of a next-generation balloon-expandable stent-graft for treatment of iliac occlusive disease. *Journal of Endovascular Therapy* 2017;24(5):629-637.

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