SVS | Society for Vascular Surgery

6
Dr. Sheahan addresses paclitaxel chaos.

8
Dr. Siracuse muses on his role in the unique clinical trial.

10 News From SVS
Collaboration is key at this year's Vascular Annual Meeting near Washington, D.C.

Vascular Specialist
VOL. 15 • NO. 4 • APRIL 2019
SVS | Society for Vascular Surgery | Official Publication

FDA Ups Ante on Paclitaxel For PAD

BY MARK S. LESNEY
MDEDGE NEWS

"Alternative treatment options should generally be used for most patients," rather than paclitaxel-coated balloons and stents for peripheral arterial disease (PAD), pending an ongoing safety review, according to the Food and Drug Administration.

The FDA conducted a preliminary analysis of long-term follow-up data (up to 5 years in some studies) of the pivotal premarket randomized trials for paclitaxel-coated products indicated for peripheral arterial disease. In a Letter to Healthcare providers issued March 15, the

See **FDA** · page 14

Dmitrii Kotin/Thinkstock

What Makes Women Leave Surgical Training?

BY SARA FREEMAN
MDEDGE NEWS
FROM A LAUNCH EVENT HELD BY THE LANCET

LONDON – Being unable to take leave and experiencing poor mental health are just two of the reasons uncovered that may help explain why some women choose not to complete their surgical training, despite having wanted to be a surgeon for many years, a study of women in surgical training has found. The results were presented at a press briefing and published in a special edition of the Lancet.

These factors are in addition to some previously identified, such as the long working hours, fatigue and sleep deprivation, unpredictable lifestyle and its effects on maintaining personal relationships, and the ability to both start and maintain a family life. Then there are the more serious issues of sexism and discrimination, bullying, and sexual harassment and assault that women face in a still male-dominated field that have been noted in prior studies.

See **Women** · page 14

NEWS Briefs

Starting a Training Program is Easier

Requirements for starting a vascular surgery training program have been lightened. Having a general surgery residency at your institution is no longer a requirement for starting either a vascular fellowship or integrated residency. Faculty requirements are being reviewed as well. The SVS has set up a task force to encourage and assist with the formation of new vas-

Column Continued on page 7

Vascular Specialist
10255 W Higgins Road,
Suite 280
Rosemont, IL 60018

Presorted Standard
U.S. Postage
PAID
Permit No. 384
Lebanon Jct. KY

CHANGE SERVICE REQUESTED

FROM THE EDITOR

The Paclitaxel Paradox

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

As medical editor of Vascular Specialist, it has always been my hope to use our excellent reporters and rapid production schedule to keep readers abreast of the latest news in vascular surgery. While my colleagues at the Journal of Vascular Surgery publish studies that will drive treatment, my goal is to drive discussion.

With topics like burnout, workforce shortages, and electronic medical records, I feel we have been successful. The downside of staying current is we sometimes find ourselves publishing contradictory stories. This has been the case with paclitaxel. Let's take a break from the fray and review where we are, and where we might go from here.

In 2012, the Zilver PTX became the first drug-eluting stent (DES) to gain Food and Drug Administration approval for the treatment of peripheral vascular disease. Two years later, the FDA approved the Lutonix 035 as the first drug-coated balloon (DCB) for use in the femoral-popliteal arteries. The Lutonix would also gain a second indication for failing dialysis fistulas. Medtronic and Spectranetics received authorizations for their DCBs in 2015 and 2017, respectively.

While the safety of paclitaxel-coated devices in the coronary system had previously been called into question, the drug was generally considered safe and effective in the peripheral arterial system. The controversy began in December 2018, when Katsanos et al.[1] published a meta-analysis of 28 randomized, controlled trials (RCTs) investigating paclitaxel-coated devices in the femoral-popliteal arteries. While all-cause patient mortality was similar at 1 year between paclitaxel-coated devices and controls (2.3% in each), at 2 years the risk of death was significantly higher in those treated with paclitaxel (7.2% vs. 3.8%). The 5-year data were available for three trials where there was a continued significantly increased risk of mortality with paclitaxel (14.7% vs. 8.1%)

Dr. Sheahan is the Claude C. Craighead Jr., Professor and Chair, division of vascular and endovascular Surgery, Louisiana State University Health Sciences Center, New Orleans, and the medical editor of Vascular Specialist.

Opposition to these findings was prompt from both physicians and industry. Weaknesses of the analysis, both perceived and real, were hammered. The meta-analysis did not include individual patient data, and the actual cause of death was unknown in most of the included trials. The study was not adequately powered to eliminate the risk of type 1 error when comparing mortality after 2 years. Individuals assigned to the control group may have received paclitaxel treatment at some point in their follow-up. The DCB and DES treatment groups were combined. The methods employed by the authors, however, stood up reasonably well to scrutiny.

On Jan. 17, 2019, the FDA issued their first response stating, "the FDA believes that the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use."[2]

Later that month, Peter Schneider, MD, and associates published a patient-level meta-analysis in the Journal of the American College of Cardiology.[3] The study included 1,980 patients and found no statistically significant difference in all-cause mortality between DCB (9.3%) and percutaneous transluminal angioplasty (PTA) (11.2%) through 5 years. Shortly after that, however, a correction was issued.

On Feb. 15, 2019, Medtronic reported an error in the 2- and 3-year follow-up periods for the IN-.PACT Global postmarket study. The company stated, "Due to a programming error, mortality data were inadvertently omitted from the summary tables included in the statistical analysis." The mortality in the DCB cohort was corrected from 9.30% to 15.12%. The authors stated that this new mortality rate was still not significantly higher than the PTA group ($P = .09$).[4]

Less than 1 week later, another device company issued a correction. And once again, the error had been made in favor of the paclitaxel-treated group. In 2016, the 5-year data from Cook Medical's Zilver PTX trial were published in Circulation. The study reported a mortality of 10.2% in the DES group and 16.9% in the PTA cohort. Regrettably, these numbers were reversed and significantly higher in the paclitaxel-treated group (16.9% vs. 10.2%, $P = .03$).[5]

On Feb. 12, 2019, another response to the Katsanos meta-analysis was published in JAMA Cardiology.[6] In this study, Secemsky et al. analyzed patient-level data from a Medicare database. The authors reported finding no evidence of paclitaxel-related deaths in 16,560 patients. Unfortunately,

Paradox continued on next page

SVS Society for Vascular Surgery Vascular Specialist

FRONTLINE MEDICAL COMMUNICATIONS

VASCULAR SPECIALIST Medical Editor Malachi Sheahan III, MD
Associate Medical Editors Bernadette Aulivola, MD, O. William Brown, MD, Elliot L. Chaikof, MD, PhD, Carlo Dall'Olmo, MD, Alan M. Dietzek, MD, RPVI, FACS, Professor Hans-Henning Eckstein, MD, John F. Eidt, MD, Robert Fitridge, MD, Dennis R. Gable, MD, Linda Harris, MD, Krishna Jain, MD, Larry Kraiss, MD, Joann Lohr, MD, James McKinsey, MD, Joseph Mills, MD, Erica L. Mitchell, MD, MEd, FACS, Leila Mureebe, MD, Frank Pomposelli, MD, David Rigberg, MD, Clifford Sales, MD, Bhagwan Satiani, MD., Larry Scher, MD, Marc Schermerhorn, MD, Murray L. Shames, MD, Niten Singh, MD, Frank J. Veith, MD, Robert Eugene Zierler, MD
Resident/Fellow Editor Laura Drudi, MD.
Executive Director SVS Kenneth M. Slaw, PhD.
Interim Director of Membership, Marketing and Communications Angela Taylor
Managing Editor SVS Beth Bales

POSTMASTER Send changes of address (with old mailing label) to Vascular Specialist, Subscription Services, 10255 W. Higgins Road, Suite 280, Rosemont, IL 60018-9914.
RECIPIENT: To change your address, contact Subscription Services at 1-800-430-5450. For paid subscriptions, single issue purchases, and missing issue claims, call Customer Service at 1-833-836-2705 or e-mail custsvc.vasc@fulcoinc.com.
The Society for Vascular Surgery headquarters is located at 9400 W. Higgins Road, Suite 315, Rosemont, IL 60018.
Vascular Specialist (ISSN 1558-0148) is published monthly for the Society for Vascular Surgery by Frontline Medical Communications Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Phone 973-206-3434, fax 973-206-9378
Subscription price is $230.00 per year.

National Account Manager Valerie Bednarz, 973-206-8954, cell 973-907-0230, vbednarz@mdedge.com
Digital Account Manager Amanda Smith, (973) 206-2321, asmith@mdedge.com
Classified Sales Representative Drew Endy, 215-657-2319, cell 267-481-0133, dendy@mdedge.com
Senior Director of Classified Sales Tim LePella, 484-921-5001, cell 610-506-3474, tlapella@mdedge.com
Advertising Offices 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609 973-206-3434, fax 973-206-9378

Vascular Specialist is the official newspaper of the Society for Vascular Surgery and provides the vascular specialist with timely and relevant news and commentary about clinical developments and about the impact of health care policy. Content for Vascular Specialist is provided by Frontline Medical Communications Inc. Content for the News From the Society is provided by the Society for Vascular Surgery.

BPA WORLDWIDE

Scan this QR Code to visit vascularspecialistonline.com

FRONTLINE MEDICAL COMMUNICATIONS SOCIETY PARTNERS
Director, FMC Society Partners Mark Branca
Editor in Chief Mary Jo M. Dales
Executive Editors Denise Fulton, Kathy Scarbeck
Managing Editor Mark S. Lesney
Creative Director Louise A. Koenig
Director, Production/Manufacturing Rebecca Slebodnik

Letters to the Editor: VascularSpecialist@vascularsociety.org
Editorial Offices: 2275 Research Blvd, Suite 400, Rockville, MD 20850, 240-221-2400, fax 240-221-2548

FRONTLINE MEDICAL COMMUNICATIONS

Corporate
President/CEO Alan J. Imhoff
CFO Douglas E. Grose
SVP, Finance Steven J. Resnick
VP, Operations Jim Chicca
VP, Sales Mike Guire
VP, Society Partners Mark Branca
VP, Editor in Chief Mary Jo M. Dales
VP, Editorial Director, Clinical Content Karen Clemments
Chief Digital Officer Lee Schweizer
VP, Digital Content & Strategy Amy Pfeiffer
President, Custom Solutions JoAnn Wahl
VP, Custom Solutions Wendy Raupers
VP, Marketing & Customer Advocacy Jim McDonough
VP, Human Resources & Facility Operations Carolyn Caccavelli
Data Management Director Mike Fritz
Circulation Director Jared Sonners
Corporate Director, Research & Comms. Lori Raskin
Director, Custom Programs Patrick Finnegan

In affiliation with Global Academy for Medical Education, LLC
President David J. Small, MBA

NEWS Briefs

Continued from page 1

cular surgery training programs. If you are interested, we can help you. Please contact the SVS at *vascular@vascularsociety.org*.

Audible Bleeding Podcast

Audible Bleeding is a podcast produced by the Vascular Surgery Fellowship Program at New York Presbyterian – Cornell / Columbia. Episodes have featured Frank Veith, Thomas Forbes, and Vascular Specialist Medical Editor Malachi G. Sheahan III. Available through Apple, Spotify, and Google. *www.audiblebleeding.com*.

Upcoming Meetings

The 37th Annual Southern California Vascular Surgical Society Annual Meeting

The meeting will be held May 3-5, 2019, at the Omni Rancho Las Palmas Resort and Spa,, Rancho Mirage, Calif. This CME-accredited meeting is a highlight of the year for our membership of vascular surgeons, and residents who will compete for the Robert J. Hye Best Trainee Competition. Cash prizes will be awarded for 1st, 2nd, and 3rd place.

The Upper Midwest Vascular Society Annual Meeting

The meeting will be held May 3-4, 2019, at the JW Marriott, Mall of America, in Minneapolis, and will be held jointly with the Vascular Quality Initiative / Upper Midwest Network meeting.

The Program for Advanced Limb Preservation (PALP)

The meeting will be held in New York City, May 17-18, 2019, at the Sheraton New York Times Square Hotel. The meeting is an educational event for physicians and health care professionals devoted to the care of patients suffering from the ravages of critical limb-threatening ischemia and diabetic foot conditions. PALP offers an inclusive, balanced, and provocative program covering the latest controversies and approaches to limb revascularization and amputation prevention. *www.palpnyc.org/program.*

The Pacific Northwest Endovascular Conference (PNEC)

The meeting will be held May 24, 2019, at The Conference Center at Convention Place, Seattle. With its interactive learning format, world-class faculty, focused breakout sessions, and opportunities for physicians in training, PNEC has emerged as a regional powerhouse with national recognition, according to the organizers. *http://pnec-seattle.org/*.

CORRECTION

SAVS Annual Meeting

At the 2019 Annual Meeting of the Southern Association for Vascular Surgery, Gilbert Upchurch, Jr., MD, was chosen as President-Elect of the society, not current President as stated in the March issue of Vascular Specialist. He will follow current President W. Charles Sternbergh III, MD, of the Ochsner Clinic, New Orleans.

Paradox

continued from previous page

the mean follow-up time was only 389 days, which may have been insufficient to detect the late mortality reported in the Katsanos meta-analysis.

On March 15, 2019, the FDA issued a second statement, this time with a much stronger tone.[7] The agency reported an ongoing analysis of the long-term survival data from the pivotal randomized trials. In the three studies with 5-year data available, each showed a significantly higher mortality in the paclitaxel group (see cover story).

When pooled, there were 975 patients, and the risk of death was 20.1% in the paclitaxel group versus 13.4 % in the controls. The FDA recommended discussing the increased risk of mortality with all patients receiving paclitaxel therapy as part of the informed consent process. They also stated that for most patients alternative options should generally be used until additional analysis of the mortality risk is performed.

Industry bristled at this new, strongly worded statement. Becton Dickinson, makers of the Lutonix balloon, asserted that the FDA recommendation was based on "a limited review of data from less than 1,000 patients."[8] The company noted that its LEVANT 2 trial did not see a signal of increased mortality at 5 years. Although they did acknowledge that, among the randomized patients, there was a significantly higher mortality at 5 years for those treated with paclitaxel.

How do we make sense of this? Paclitaxel is a cytotoxic drug. Its pharmacokinetics vary significantly based on the preparation and administration. The FDA label for the injectable form (Taxol) warns of anaphylaxis and severe hypersensitivity reactions, but there is no mention of long-term mortality. In the coronary vessels, paclitaxel-coated devices have been associated with myocardial infarction and death. Obviously it is easy to comprehend how local vessel effects in the coronary system can lead to increased mortality. The pathway is less clear with femoral-popliteal interventions. If the association of paclitaxel with death is truly causation there must be some systemic effects. The dose delivered with femoral-popliteal interventions is much higher than that seen with coronary devices.

The mortality may be associated with the platform used or even the formulation (crystalline formularies have a longer half-life). Could it be something more benign? Paclitaxel-treated patients see less recurrence of their femoral-popliteal disease. Are the control group patients with more recurrences seeing their interventionalist more often and therefore receiving more frequent reminders to comply with medical therapy?

At this point, we have few answers. After an all-day town hall at the recent Cardiovascular Research Technologies conference,[9] one moderator said, "I came in with uncertainty and now I'm going away with uncertainty, but we made tremendous progress." His comoderator added, "I know I don't know." Well then, glad we cleared that up!

In any event, changes are coming. The BASIL-3 trial has suspended recruitment. Physicians using paclitaxel-coated devices are now advised by the FDA to inform patients of the increased risk of death and to use alternatives in most cases. Therefore, if you employ these devices routinely in the femoral-popliteal vessels you are seemingly doing so in opposition to the recommendations of the FDA. Legal peril may follow.

The time for nitpicking the Katsanos analysis has ended. Our industry partners must be compelled to supply the data and finances needed to settle this issue. The signal seems real and it is time to find answers. Research initiatives are underway through the SVS, the VIVA group, the UK Medicines and Healthcare Products Regulatory Agency, and the FDA.

Going forward, the SVS has formed a Paclitaxel Safety Task Force under the leadership of President-elect Kim Hodgson. Their mission is to facilitate the performance and interpretation of an Individual Patient Data meta-analysis using patient-level RCT data from industry partners. The task force states: "We remain troubled by the recent reports of reanalysis of existing datasets, pooled analyses of RCTs, and other 'series', as we believe that the findings of these statistically inferior analyses bring no additional clarity, cannot be relied upon for guidance, and distract us from the analysis that needs to be performed." ■

References

1. J Am Heart Assoc. 2018 Dec 18;7(24):e011245.
2. www.fda.gov/medicaldevices/safety/letterstohealthcareproviders/ucm629589.htm.
3. J Am Coll Cardiol. Jan 2019. doi: 10.1016/j.jacc.2019.01.013.
4. Circulation. 2019;139:e42.
5. https://evtoday.com/2019/02/20/zilver-ptx-trial-5-year-mortality-data-corrected-in-circulation.
6. JAMA Cardiol. 2019 Feb 12. doi:10.1001/jamacardio.2019.0325.
7. www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm633614.htm.
8. www.med-technews.com/news/bud-defends-safety-of-drug-coated-device-following-fda-warnin/.
9. www.crtonline.org/news-detail/paclitaxel-device-safety-thoroughly-discussed-at-c.

LETTER TO THE EDITOR

EHR and Burnout

Responding to "EHR stress predicts burnout" in Vascular Specialist, March 2019, p.4.

With this publication of a Rode Island physician survey, Dr. Gardiner and her colleagues have shown what many of us are experiencing every day: The electronic health record (EHR) is one of the root causes of the burnout epidemic amongst practitioners today.

Her study showed that 26% of respondents were suffering from burnout, and 70% reported at least one symptom of health information technology (HIT) related stress. Less than half of the physicians felt that the EHR improved medical care, while >50% reported insufficient time for EHR documentation. Of those that reported HIT-related stress, the odds of burnout were between 1.9 and 2.8, depending on which HIT related stress symptom was reported. Physicians without an EHR had half the rate of burnout as compared to those with an EHR.

What this shows is that the EHR is a primary component of physician burnout, and until the EHR is made more user friendly, it will be impossible to cure the epidemic of burnout currently hindering our medical profession. Promoting solutions for the individual practitioner, while possibly helpful, implies that the problem lies with the individual physician.

It has become clear that the problem is systematic. If they are to be successful, solutions to the EHR problem must be aimed at fixing these products, which are optimized for billing rather than patient care. ■

Kellie R. Brown, MD, Professor of Surgery
Division Chief, Zablocki VA Medical Center
Division of Vascular and Endovascular Surgery
The Medical College of Wisconsin, Milwaukee

FROM THE VASCULAR COMMUNITY

Experiences With the Best CLI Trial

As the BEST-CLI trial enters its last phase of new patient enrollment, I thought it was important to reflect on what this trial has meant for both the Vascular Surgery field and for me personally. This trial has been closely examining one of the most commonly treated conditions that we take care of – critical limb ischemia (more recently better described as chronic limb-threatening ischemia (CLTI). BEST-CLI (ClinicalTrials.gov Identifier: NCT02060630) has the potential to be one of the most meaningful and impactful trials in the history of our profession, and that of our colleagues who also treat CLTI.

Unlike many of the industry-sponsored endovascular device trials, vascular surgeons are at the table and are key leaders and enrollers. The results will be quoted for decades and there will be many questions answered that we have not been able to answer before– including questions that were not even on people's minds when the trial began – such as paclitaxel-related outcomes. This trial will also provide the long-term follow-up that has limited the impact of many other peripheral arterial disease trials.

From a personal point of view, I feel like the BEST trial has always been closely connected to my practice. I have been fortunate to be partners with one of the national principal investigators, Alik Farber, MD. We enrolled the first patient in the trial in my second month as an attending in August of 2014. Since then, I have been able to operate on 30 patients that were randomized into the trial. It not only allowed me, as a junior attending, to get involved in a major trial, but also forced me to further develop both my open and endovascular skills so that I could provide the best care to each patient as needed.

This trial has also moved me to see things more objectively; I am now more aware of my personal treatment biases and try more consciously to suspend them when I have equipoise between treatment options. I also continue to follow patients that I enrolled and treated over 4 years ago.

This trial will challenge many wide-spread beliefs, anecdotes, and urban legends in the field of peripheral arterial disease. The results will be scrutinized and analyzed and the results will be debated – particularly by some who do not find their preconceived biases confirmed.

A trial of this magnitude looking at limb-threatening ischemia will most likely never happen again in this country. This is the one time for us as a group of professionals who care for patients with CLTI to do this correctly, rather than rely solely on data from single-arm studies, often industry sponsored, that are typically focused on device approvals.

It is key, as we get close to the finish line, that we suspend our preconceived notions and finish enrollment. We need to ensure this trial has adequate power to give us the answers we need the most – how to best take care of the most vulnerable and ill patients that we treat; they will greatly benefit from a clear answer as to how best we should address their limb- and life-threatening problems. ■

Jeffrey J. Siracuse, MD, Associate Professor of Surgery
Division of Vascular and Endovascular Surgery
Boston University, School of Medicine
Boston Medical Center

DKD, Retinopathy Associated With PAD in Foot Ulcer Patients

BY MARK S. LESNEY

MDEDGE NEWS
FROM DIABETES & METABOLIC SYNDROME: CLINICAL RESEARCH & REVIEWS

Patients with diabetic foot ulcers have a high incidence of associated chronic vascular disease, including diabetic kidney disease (DKD), retinopathy, and peripheral artery disease (PAD). In addition, there was statistically significant association between both diabetic retinopathy and DKD and PAD, according to a study reported by Magdy H. Megallaa, MD, and colleagues.

Their cross-sectional study, published in Diabetes & Metabolic Syndrome: Clinical Research and Reviews, comprised 180 type 2 diabetic patients (aged 30-70 years) with diabetic foot ulcers (DFUs).

The prevalence of DKD and diabetic retinopathy was 86.1% and 90.0%, respectively, with 86.7% of patients having neuropathic DFUs, 11.1% having ischemic DFUs, and 2.2% having neuroischemic DFUs. The prevalence of peripheral neuropathy and PAD was 82% and 20%, respectively.

Using albuminuria as a measure of DKD, the researchers found that 86.1% of the patients had albuminuria and that there was a statistically significant association between albuminuria and the patient's vibration perception threshold (VPT), a measure of diabetic neuropathy (*P* less than .001), and the ankle brachial index (ABI), a measure of PAD (*P* less than .031). In addition, there was a statistically significant association between diabetic retinopathy and VPT (*P* less than .008) and between diabetic retinopathy and ABI (*P* less than .001). "Albuminuria, diabetic retinopathy and peripheral neuropathy are very common among those patients and strongly associated with risk factors of diabetic foot ulceration," the researchers concluded. They reported having no conflicts. ■

mlesney@mdedge.com

SOURCE: Megallaa MH et al. Diabetes Metab Syndr. 2019 Mar-Apr;13(2):1287-92.

MADE FOR *TCAR*

Restenosis after prior CEA is a challenge. TCAR is your option.

With thousands of real world patients studied, TCAR has shown to be a safe and clinically effective alternative to CEA.

SILKROAD MEDICAL®

Other patients who could benefit from carotid revascularization through robust reverse flow include:*

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

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

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

AP233 - A

Vascular Research: VRIC Brings Cutting-Edge Science to Boston's Back Bay

Make travel plans now to attend Vascular Research Initiatives Conference (VRIC) – the Society for Vascular Surgery's essential meeting for translational vascular science and interdisciplinary research. This year VRIC will be held on Monday, May 13, in Boston.

Sometimes dubbed "the SVS annual meeting for basic and translational research," VRIC focuses on emerging vascular science and biology. "With more excellent abstracts than ever submitted in prior years, the program committee expanded the scientific program for 2019 to include a QuickShot Poster Session," said Luke Brewster, MD, PhD, chair of the SVS Research and Education Committee.

The posters will be displayed for viewing during lunch, and authors will present their research in a competition format led by Mohamed Zayed, MD, PhD, during the VRIC reception.

This year's theme is "Hard Science: Calcification and Vascular Solutions." Abstracts will cover four topic areas crucial to the understanding of vascular disease progression and potential treatments: 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.

Four VRIC scholarship winners will be recognized:

- Edmund B. Chen, who will present on "Microbial Colonization Restores Neointimal Hyperplasia Development after Arterial Injury in Germ-Free Mice;"
- Peter Kip, "Periprocedural Hydrogen Sulfide Therapy Impairs Vascular Remodeling and Improves Vein Graft Patency;"
- Constance J. Mietus, "Microvascular Pathology Influences Walking Performance in Patients with Peripheral Artery Disease;"
- Thomas A. Sorrentino, "Circulating Exosomes in PAD Patients: Disease Severity Correlates with Effects on Vascular Cell Migration and miRNA Content."

Dr. Brewster also noted that two of last year's four scholarship recipients, Drs. Catherine Go and Karim Salem, will return this year to present updates on their work. "VRIC is a great opportunity for our younger members just beginning their research careers," he said. "It is a privilege for me to see these young people develop and to see how their effort in the laboratory leads to successes in improving our understanding and treatment of vascular disease."

Other VRIC highlights include:

The Alexander W. Clowes Distinguished Lecture, presented by Cecilia Giachelli, PhD, the W. Hunter and Dorothy Simpson Professor and Endowed Chair of Bioengineering at the University of Washington. She will discuss "New Concepts in Regulation and Bioengineered Therapies for Vascular and Valvular Calcification."

The **Translational Panel** discussing "Hard Science: Calcification and Vascular Solutions," featuring Raul Guzman, MD, Beth Israel Deaconess Medical Center, Boston; Elena Aikawa, MD, PhD, Brigham and Women's Hospital, Boston; and Dwight Towlers, MD, PhD, of University of Texas Southwestern Medical Center.

Recognition of the work of Dr. Frank LoGerfo, William V. McDermott Distinguished Professor of Surgery, Beth Israel Deaconess Medical Center and Harvard Medical School.

For more information, visit **vsweb.org/VRIC19**. ■

Boston Researchers: VRIC is in Your Back Yard

Boston is home to a large number of vascular research labs and researchers. "We encourage all our fellow surgeon-scientists to spend their day May 13 with us, to see what's new and relevant in the world of vascular disease," said Dr. Brewster.

"You never know what will be the spark that leads to a greater understanding of it, and to potential treatments."

VAM: Working Together Enhances Education

The Vascular Annual Meeting flourishes with the collaboration and participation of many other organizations.

Six societies and associations are collaborating with SVS this year, adding their members' voices, experiences and expertise. "We collaborate to improve the care of the vascular patient," said Vikram Kashyap, MD. He chairs the SVS Postgraduate Education Committee, which oversees VAM programming for the breakfast, concurrent and Ask the Expert sessions, as well as workshops and postgraduate courses.

For example, the SVS has long worked with the American Podiatric Medical Association in caring for vascular patients' feet. The APMA and SVS will jointly present postgraduate session 5, "Multidisciplinary Teams and Techniques for Limb Preservation."

"Our podiatric colleagues are indispensable partners in allowing us to save legs," said Dr. Kashyap. "This session highlights our collaborative efforts to do all we can to prevent limb loss and procure prolonged limb salvage."

The partnership is several years old and is a good one, said Dyane Tower, DPM, a session moderator. Both sides learn from each other, particularly about issues that affect their common patients. For example, she said, "Perhaps one of our diabetic patients gets an ulcer that doesn't heal, and so then discovers he or she has poor blood flow." Joint sessions help APMA members educate their patients as to what to expect when they see a vascular specialist and how that will help heal the ulcer, she said.

Postgraduate course No. 3 is a collaboration with the American Venous Forum. "Venous Disease: Ensuring the Appropriate Venous Care in 2019" will focus on ensuring appropriate venous care for patients. "There has been a lot of controversy — and it's reaching national levels — on who should get venous interventions. The conversation has to do with both superficial and deep venous disease, and at this session, both organizations will present information on which patient should receive which operation and at what point should they, as medical professionals, perform a procedure," said Dr. Kashyap.

Dr. Kashyap also highlighted Breakfast Session 9, presented in collaboration with the Outpatient Endovascular and Interventional Society: "Complications in Office-Based Vascular Procedures: Their Prevention and Management." He said that, as vascular procedures become more minimally invasive, doing such procedures in an outpatient surgical suite is gaining momentum throughout the country.

In fact, the SVS has a new member section: Section on Outpatient and Office Vascular Care. "Participants will learn how to set up the office, set up the surgical suite, how to do the procedures and do them safely without complications," said Dr. Kashyap.

Besides the AVF, APMA and OEIS, other organizations presenting sessions in collaboration with the SVS are the Society for Vascular Medicine, the Society for Vascular Ultrasound and The Society of Thoracic Surgeons. The Vascular and Endovascular Surgery Society also holds two abstract-based sessions at VAM. ■

MILOSLUZ/GETTY IMAGES

Explore National Harbor and Washington, D.C.

The setting for the 2019 Vascular Annual Meeting provides plenty of opportunities for fun before and after the meeting for attendees, and during VAM, for family members.

VAM takes place in National Harbor, Md., near Alexandria, Va., and Washington, D.C.

National Harbor itself, comprised of 350 acres along the Potomac River, includes spectacular views, 160-plus shops and restaurants, a marina, the Capital Wheel Ferris wheel, which soars 180 feet above the ground, and an Americana-themed 36-foot carousel.

For those who prefer not to drive, National Harbor's water taxis service Washington, D.C., Georgetown and Alexandria. The latter is known for its history and 18th- and 19th Century architecture and boasts the Old Town Alexandria neighborhood dating to the mid-1700s. The national historic district has cobblestone streets and red brick sidewalks, restaurants, boutiques, museums and nine historic sites.

SEAN PAVONE/THINKSTOCK

And let's not forget nearby Washington, D.C., the country's power center. Visitors can immerse themselves in U.S. history, visiting dozens of monuments and historic sites, such as the National Mall; Washington Monument; the U.S. Capitol; the Lincoln, Jefferson and FDR Memorials; Arlington National Cemetery; memorials to the Korean and Vietnam wars and World War II; the Martin Luther King, Jr., Memorial; the National Air and Space Museum and the 11 museums — and National Zoo — that comprise the Smithsonian Institution.

For baseball fans, the Washington Nationals will be home June 13 to 23. ■

VAM19 Registration Fees

Register today for the Society for Vascular Surgery's 2019 Vascular Annual Meeting.

Fees are:

SVS Member: $753
SVS Candidate Member: $522
SVS Candidate Member in-training (including Candidate Resident, Candidate Student, Vascular Fellows and incoming Fellows), Non-member vascular surgery and general surgery residents (with letter from Chief of Service), medical student and Society for Vascular Nursing student (with letter from university): . . . . . all $331
Non-member physician: $978
International physician: $405
SVS allied health professional member: $607
Allied health professional non-member (including non-MD registration, PhD and researchers): $634
SVN Member: $607
SVN Non-Member: $634

All fees are in U.S. dollars. SVS members in all member categories may attend the Wednesday postgraduate courses for no additional charge (a $300 value). Tickets are required.

VAM will be held June 12 to 15 at the Gaylord National Resort & Convention Center in National Harbor, Md., just outside Washington, D.C. Postgraduate sessions and many international events are among the offerings for June 12. Scientific sessions are June 13 to 15 and exhibits are June 13 to 14. Attendees may reserve rooms at four National Harbor hotels through MCI USA, the official housing agency.

To register and secure hotel room reservations, visit **vsweb.org/VAM19**.

VAM will celebrate vascular surgery and vascular surgeons with the "Vascular Spectacular" gala, set for 6:30 p.m. Friday, June 14, and benefiting the SVS Foundation. The evening includes cocktails and dinner, entertainment and both live and silent auctions. Tickets (which are limited) are $250 each, $150 of which is considered a tax-deductible contribution to the SVS Foundation. Purchase tickets — and contribute auction items — at **vam19gala.givesmart.com**. ■

SVN Adds Simulation Session to 37th Annual Conference

Learn by doing. In response to feedback and member requests, the Society for Vascular Nursing is embracing that learning model with a clinical surgical simulation session at its 37th Annual Conference.

SVN@VAM, June 12 to 13, is being held in concert with the 2019 SVS Vascular Annual Meeting.

"Members want more hands-on training, particularly on wound care, and discussions that include assessments," said Chris Owen, MSN, ACNP-BC, RNFA and SVN board member. She is a nurse practitioner in acute care and assists in the surgical operating room for both endovascular and open surgeries at the University of Maryland Baltimore Washington Medical Center.

"The Team Approach to Limb Salvage," from 1:30 to 3:30 p.m. Thursday, June 13, will feature a hands-on collaborative experience with multiple scenarios on venous and arterial wounds.

This session also incorporates the conference theme of teamwork. Keynote speaker Virginia R. Beeson, BSN, MSN, NEA-BC, a retired captain in the United States Navy Nurse Corps, will highlight that theme as well as resilience in her opening address, "Teamwork: It's All About Teamwork!"

The simulation session is aimed at both bedside and clinic nurse and Advanced Nurse Practitioners. Elements include a review of the diagnostic studies – to include CAT scans and angiograms – necessary for wound diagnosis. "We'll talk about a team approach to these complex patients: What do you see, how to speak to the physician about what you see. Let's make an assessment and provide a diagnosis," said Owen.

Task trainers with a variety of wounds specific to either arterial or venous disease will be available, and an industry representative will explain how specific wound care products are used in different settings. There also may be time for a debridement session.

SVN members are enthusiastic about the upcoming session. "It's something new, different and exciting," said Owen. For more information about the SVN conference, visit **vsweb.org/svnconference19**. ■

Organizers of the new clinical simulation session are looking for SVS members to help facilitate. If interested, please contact Joanna Bronson, SVS director of inter-society relations, at **JBronson@vascularsociety.org**.

Looking Ahead to 'Going Once, Going Twice ...'

Auction items continue to come in for the SVS Foundation's Vascular Spectacular gala, one of the highlights of the Vascular Annual Meeting in June. Proceeds will benefit the SVS Foundation.

Winning bidders could spend two nights at the storied Greenbrier, a National Historic Landmark and a top resort in West Virginia. Those who enjoy skiing or mountain climbing, or perhaps world-class fishing and hiking might find the one-week stay at a condo near downtown Breckenridge, Colo., tickles their fancy.

Also available are a fashionable alligator clutch bag, a pair of Maui Jim sunglasses and the chance to take a trip back to the days of early America with admission tickets to Old Sturbridge Village in Massachusetts.

These and more will be available at either the live (on-site only) or silent auctions. Gala co-chairs Drs. Cynthia Shortell and Ben Starnes expect spirited bidding at both.

KRBLOKHIN / ISTOCK EDITORIAL / GETTY IMAGES PLUS

The Vascular Spectacular begins at 6:30 p.m. Friday, June 14, at the riverfront ballroom at the Gaylord National Resort & Convention Center. With VAM still two months away, plenty of time remains to contribute auction offerings, said Drs. Starnes and Shortell, urging members to consider what they can donate. Suggestions include tickets, vacation destinations, restaurant gift certificates, gift cards, products. "Everything, big or small, is welcome, and the sky is the limit," said Dr. Starnes.

Not only are all SVS members and their friends and colleagues encouraged to donate to the auction, they also can make bids, from the Gaylord or from the screened-in porch at home, in the case of the silent auction. Electronic bidding of all silent auction items will begin in late May, closing during the Spectacular itself. Bidders can set up alerts for their items of interest and even see precisely just who is after the same item or items.

The gala also will include cocktails, dinner and entertainment. Tickets are limited (nearly 400 already have been sold) and are $250 each, of which $150 is a tax-deductible donation to the SVS Foundation.

To donate or purchase tickets, visit **VAM19gala.givesmart.com**. To learn more about the gala itself, visit **vsweb.org/Gala19**. ■

'Ask the Experts' Expanded to 7 Sessions at VAM

Members: Bring Experts Your Own Cases

"Ask the Experts" is back for 2019, with additional presentations scheduled and audience participation not only added but encouraged.

The seven topics for 2019 are "Complications of IVC Filters: Managing Complex IVC Filter Problems;" "Infected Aortic Grafts: Treatment Options for Challenging Cases;" "Thoracic Outlet Syndrome;" "Spine Exposure;" "Complex Open Aortic Surgery: Tips and Tricks for Exposure;" "Endovascular and Hybrid Interventions for Mesenteric Occlusive Disease;" and "Techniques for Open Tibial, Pedal, Plantar Exposure and Bypass."

"We selected these topics based on member feedback and suggestions. Members want and need up-to-date information on these subjects from the experts in the fields," said Vikram Kashyap, MD, chair of the SVS Postgraduate Education Committee, which oversees the sessions.

Members enthusiastically participated in these small-group sessions in 2018. This year, organizers want attendees to bring their own cases to show the experts. "Every surgeon and vascular care professional has cases with complications, cases where they'd wanted help," he said.

Attendees can participate by loading their case images and information on a thumb drive, which can be plugged in for discussion at the sessions.

For session dates and times, visit the SVS VAM19 Interactive Planner, at **vsweb.org/OnlinePlanner**. ■

EDUCATION: SVS Coding Course Moves to Rosemont for 2019

With the SVS' move to Rosemont, the location and timing for the 2019 SVS Coding Course – a must-attend for those who want to stay up-to-date on coding and all-important reimbursement issues – have been changed.

This year's course will be Sept. 20 to 21 at the Hyatt Rosemont, near the new SVS Rosemont headquarters office and just minutes from O'Hare International Airport.

The SVS course teaches how to do coding the right way the first time, to avoid an audit. Dr. Sean Roddy, who has led the course, has somewhat of a mantra for coding: "Maximize your appropriate reimbursement, limit your risk of audit and avoid red tape."

Registration for the 1 ½-day course, as well as the optional half-day Evaluation and Management Coding course, will open in mid-summer. ■

Join the Party; Get *Connected*

The SVS*Connect* online community and its mobile app are generating some rave reviews.

On SVS*Connect*, members can post discussion topics, such as on difficult cases or coding issues, as well as offer their own thoughts. They can share resources, become informed of upcoming events and seek out colleagues.

"It is very enriching to read about others' experiences and different strategies, or interventions used to attain a goal. ... SVS*Connect* highlights solidarity, selflessness and compassion found amongst those who represent the Society for Vascular Surgery." – Therese Massri, SVS medical student member.

"One of the best things the SVS has ever done. ... *Connect* is especially important to me in solo practice, in a small-town hospital with no other vascular colleagues." – Dr. Daniel McGraw, SVS active member.

Get started today at **vsweb.org/SVS-Connect** and see what the buzz is all about. Those who run into sign-in difficulties may email communications@vascularsociety.org or call 312-334-2300. ■

FROM OUR JOURNALS:

Open-source Articles through June 30

Journal of Vascular Surgery: A study in May's JVS evaluating outcomes and fenestrated and branched endovascular aneurysm repair (F-BEVAR) in high-risk patients is associated with favorable outcomes. Researchers concluded that surgeons should consider reported risk factors associated with early and late mortality when selecting patients. See **vsweb.org/JVS-Complex**.

JVS-Venous & Lymphatic Disorders: Researchers studied the relationship between influenza A and venous thromboembolism events to evaluate initiating an empirical systemic anticoagulation protocol for patients suffering severe acute respiratory distress syndrome (ARDS). For such patients, the system "significantly reduced VTE incidence without increased hemorrhagic complications. Visit **vsweb.org/JVSVL-H1N1**. ■

PAD Tied to Higher Prevalence of LV Diastolic Dysfunction

BY MARK S. LESNEY
MDEDGE NEWS
FROM THE JOURNAL OF CARDIOLOGY

Patients with peripheral artery disease (PAD) were also more likely to have left ventricular diastolic dysfunction, according to a study published in the Journal of Cardiology.

The study enrolled 1,121 patients with preserved left ventricular (LV) systolic function. The mean age was 68 years and 56% of patients were men. A total of 200 patients (17.8%) had PAD; 33.0% of these had no symptoms, 54.5% had intermittent symptoms, and 12.5% had critical ischemia, according to Koji Yanaka, MD, and colleagues at the Hyogo College of Medicine, Nishinomiya, Japan.

Multivariate logistic regression analysis showed that PAD was an independent predictor of LV diastolic dysfunction (adjusted odds ratio, 1.77; $P = .01$).

"The prevalence of LV diastolic dysfunction was higher in patients with PAD than those without PAD. These findings suggest that patients with PAD should be evaluated not only for LV systolic but also diastolic function in echocardiography," the researchers concluded.

The authors reported that they had no disclosures. ■

mlesney@mdedge.com

SOURCE: Yanaka K et al. J Cardiol. 2019 Feb 18. doi: 10.1016/j.jjcc.2019.01.011.

Paclitaxel Devices

FDA from page 1

FDA reported that their preliminary review of these data found "a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products, compared to patients treated with uncoated devices."

> The FDA also announced that it is planning on convening an Advisory Committee meeting of the Circulatory System Devices Panel to address this issue.

The three trials (totaling 975 patients) that had 5-year follow-up data demonstrated an approximately 50% increased risk of mortality in subjects treated with paclitaxel-coated devices vs. those treated with control devices (20.1% vs. 13.4% crude risk of death at 5 years), according to the agency.

The FDA indicated that these data "should be interpreted with caution for several reasons."

They cited a large variability in the risk estimate of mortality because of the limited amount of long-term data and pointed out that the studies were not designed to be pooled. In addition, the specific cause and mechanism of the increased mortality was unknown.

The FDA also announced that it is planning on convening an Advisory Committee meeting of the Circulatory System Devices Panel to address this issue, including plausible mechanisms for this mortality effect, a re-examination of the benefit-risk profile, modifications of current and future clinical trials regarding these devices, and guidance to any regulatory action, as needed. The timing of this meeting is to be announced within the upcoming weeks.

The FDA letter further stated that the agency intends to conduct additional analyses "to determine whether the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use." ■

mlesney@mdedge.com

SOURCE: Food and Drug Administration Letter to Healthcare Providers. 2019 Mar 15.

Surgical Training

Women from page 1

"Women are underrepresented in surgery and leave training in higher proportions than men," study lead Rhea Liang, MBChB, and coauthors wrote (Lancet. 2019;393:541-9). Previous attempts to understand why this is the case "have been confounded by not fully understanding the problem," they suggested in the briefing. Their research took a more qualitative and feminist approach than other studies, consulting women who had chosen to leave rather than those who continued their surgical training.

Dr. Liang is a consultant general and breast surgeon based at the Gold Coast Hospital and Health Service in Robina, Australia, who personally interviewed women who had decided to leave their surgical training, some as early as 6 months and others up to 4 years after initiation, for reasons other than underperformance.

A "snowball approach" was used to recruit women whereby women who had agreed to participate were asked to refer others. Although only 12 women were interviewed, it's quality over quantity, Dr. Liang said in a response to a Twitter comment on the study size. "The study is carried out in Australia where about 300 training places are offered across all the specialties annually. About 30% are women; 20% of those women choose to leave. So, if you do the maths, you'll see that we actually recruited quite well," she said at the briefing.

According to The Royal College of Practitioners, women made up a very small percentage of consultant surgeons in England in 2016 (11.1%), which didn't change much by 2018 (12.2%). This is despite a high percentage (58%) of women being accepted onto university courses in medicine and dentistry (58% in 2016). So why so do so few women end up as surgeons?

"Training is a 'pinch point' at which women leave surgery," Tim Dornan, PhD, noted at the launch of the special edition of the Lancet in which the findings appear. Dr. Dornan is professor of medical and interprofessional education at Queen's University Belfast (Northern Ireland) and one of the coauthors of the research.

This choice to leave surgery deprives society of able surgeons-to-be," Dr. Dornan said, noting that there was evidence to suggest that women make as good, if not better, surgeons than men. The decision to leave also deprives women of career opportunities and potentially deprives patients of receiving the best surgical care.

"Something very striking about this research is that women who left within an average of 6-18 months after starting surgical training might have wanted to be surgeons from their teenage years, so it seems something happens at that pinch point which makes women to choose to leave."

> "Women who left within an average of 6-18 months after starting surgical training might have wanted to be surgeons from their teenage years, so it seems something happens at that pinch point."

Qualitative research is a good way to understand causality in complex social systems, Dr. Dornan explained. Furthermore, "it's equitable. If you use an open exploratory method, it's entirely up to the participants to frame the research, it's not done a priori, and it has the potential for great policy impact."

Dr. Liang and team found that multi-

Women Leaving Surgical Training: The Leaning Tower

This provocative article in The Lancet written by two women surgeons (Rhea Liang, MD, and Debra Nestel, MD) detailed a study conducted in Australia and New Zealand, following 12 women who chose to leave surgical training programs over a 4-year period. Women, they report, are under–represented in surgery and leave training in higher proportions than men. While there have been previous articles written on the topic, many were not through a feminist lens nor did they evaluate the complexity of the problem with more than quantitative analyses.

There have been many ways surgical specialties have attempted to attract and retain women with a less than satisfactory understanding of the problem. In 2006, I was a young vascular surgery program director with a 2-year-old daughter, asked to be on an Association of Program Directors in Vascular Surgery (APDVS) panel about why women weren't choosing vascular surgery as a career path. Jeb Hallet, MD,'s wife, Linda, Austin, MD – author of "What's Holding You Back? 8 Critical Choices for Women's Success" – was the highlight of the panel.

Though I was supposed to be coming up with answers for fellow program directors on how to recruit and interest women to go into our field, I was more intrigued by Dr Austin's comments. Despite its being the 21st century, women still liked to be 'asked,' she said. Apparently, no one had ever asked her to be a surgeon – despite her uncle being a well-known vascular surgeon in Cincinnati – and thus she never entertained the idea, though she might have liked to. As a panelist, I highlighted several gender-neutral ideas to be considered for recruitment of women, but I was not about to commit career suicide and offer anything female related. Suffice to say, I don't think I helped anyone very much that day.

Previous quantitative methods in this area of study have come away with lists such as insufficient role models, gender discrimination / harassment, adverse interactions with those more senior, pregnancy, and childrearing. While many lists can be generated, prior studies have not adequately examined why or how the problem exists. There have been some qualitative studies published showing that women pretend to enjoy sexualized banter in the operating room to give them credibility in a male-dominated world and that they demonstrate masculine traits to become a legitimate woman surgeon. It is disappointing to think that must be the case for women to do well in surgery.

The authors discuss that we are all guided by habitus – the deeply ingrained habits, skills, and dispositions that develop through life experiences. An appropriate surgical habitus at one institution might be an assertive manner, a tendency toward direct and immediate decisions and communication, and an ability to take part in robust discussions with those more senior. Habitus, it is reported, is often mistaken for natural ability, however, it is culturally developed. Thus, there can be an unconscious bias against those who may not fit the perceived "required" habitus of our surgical dispositions. The authors go on to say that feminist theory maintains that institutions like surgery, which have been created by men and traditionally dominated by men, are defined by the absence of embedded roles for women. Female roles cannot simply be added to an existing institutional structure. Faced with the absence of a gender-congruent role, women in surgery must choose to either identify as a woman and remain outside the traditional structures of surgery or identify as a surgeon in the customary masculine terms. This binary choice seems rigid to me, though again concerning if this is what trainees think of us.

Some factors previously published why women leave surgery included long hours, fatigue, unpredictable lifestyle, bullying, impact on relationships, insufficient role models, and sexual harassment, as well as impact on child raising. New factors identified in these 12 women who chose to leave training in Australia and New Zealand included poor mental health, fear of repercussion, and – perhaps most disappointing to me – absence of interactions with women on the surgical faculty. For most of these trainees, the factors were additive – a tower of blocks – with the final block to topple the tower relatively small. Could not a small intervention have reversed their decision?

Dr. Reed is professor and chief of Vascular and Endovascular Surgery at the University of Minnesota, Minneapolis, and president of the Association of Program Directors in Vascular Surgery.

Women reportedly have more of these blocks to deal with than men in the real-world construct of surgical training and are more likely to have three or four blocks already stacked and leaning in their tower. The authors suggest that a factor that causes additional stress to a man in training is more likely to be the final block that tips the tower and results in a woman leaving. Efforts to improve retention of women in surgical training should focus on multiple factors – not just those focusing unduly on gender. Long hours, unpredictable lifestyle, childrearing impact women and men in surgery.

As one of less than 300 board-certified women in vascular surgery in the United States, it is sobering for me to read this – particularly as I reflect on my own training, my own career, and my own tower of blocks in both my professional and personal life. I remember when I was a senior resident at the Brigham and the annual vascular meeting included a women's breakfast. There were four of us in attendance. Many years later when I had the honor and pleasure of serving as chair of the Society for Vascular Surgery Women's Committee, we graduated to a cocktail party. More recently, the Women's Committee was absorbed into another SVS committee with the thought that we didn't need that anymore – the women of vascular surgery were just fine, thank you very much. Perhaps we put that aside a bit too hastily.

I believe there remains ample opportunity, need, and reason to meet at any of our gatherings – APDVS, the SVS, the SCVS, our regional societies and beyond. A social gathering of like-minded women vascular surgeons helps trainees and faculty share thoughts, concerns, and ideas. This doesn't necessarily mean another committee or exclusion of men – rather just another reason to gather for a meal, camaraderie, and sharing the highs and lows of our careers and life. Let us not be the block that topples the tower, but the intervention that shows the way forward into vascular surgery careers.

ple factors played a role in the decision to leave surgical training, which on their own might be seemingly small, but when stacked on top of each other formed a tower, which was in danger of toppling after a threshold of three or four factors was reached.

To exhaustion and lack of opportunity to learn, for example, could be added bullying, and then being denied leave while it is granted for a male colleague for a similar requested reason. The cumulative impact of these factors may all add up to create the impetus to leave.

"Just as a tower of blocks can rebalanced with small adjustments, out study indicates that relatively small interventions (e.g., a cup of tea or a supportive chat) could have been effective in preventing them choosing to leave," she said.

However, they advocate targeting interventions at all trainees and not just women, to reduce gender differences as focusing on women would be more likely to exaggerate the "otherness" of women further and alienate male trainees. They suggest: "Women might be best helped by interventions that are alert to the possibility of unplanned negative effects, do not unduly focus on gender, and address multiple factors."

"If you really want to benefit women you should benefit everybody and address the root problem, which is the harsh conditions of training," Dr. Dornan said. "The prediction would be that, if you do that, then you will actually retain men as well as women."

The research appears in a special edition of the Lancet that promotes advancing women in science, medicine, and global health. ■

SOURCE: Liang R et al. Lancet. 2019;393:541-9.

Endovascular Device Sustains Blood Pressure Control After 3 Years

BY TED BOSWORTH
MDEDGE NEWS
REPORTING FROM CRT 2019

WASHINGTON – As a result of remarkably sustained antihypertensive effect, interest is intensifying in the potential for a pivotal trial to associate a novel endovascular device with unprecedented blood pressure control in patients with treatment-resistant hypertension, according to an update presented at CRT 2019, sponsored by MedStar Heart & Vascular Institute.

With up to 3 years of follow-up, "systolic blood pressures have remained persistently reduced by as much as 24 mm Hg," reported John P. Reilly, MD, an interventional cardiologist in Southampton, N.Y., who presented follow-up data for some of those enrolled in the first-in-human study of this device.

When the stent-like device is placed in the carotid artery, it alters its geometric shape, which increases pulsatile wall strain. The increase on wall strain alters an afferent signaling loop controlled by carotid baroreceptors that inhibits sympathetic outflow to lower blood pressure.

> The large reductions in blood pressure previously reported at 6 months have been sustained. Follow-up is approximately 3 years in most patients and the reductions previously reported have persisted.

In the proof-of-principle, first-in-human CALM study, 47 patients were implanted with the device (MobiusHD, Vascular Dynamics). The initial study enrolled 30 subjects in Europe and 17 in the United States. Initial findings in the cohort of European patients, which included a mean 21–mm Hg reduction in systolic blood pressure and a 12–mm Hg reduction in diastolic blood pressure measured by ambulatory monitoring at 6 months, were published in the Lancet (2017 Dec 16;390[10113]:2655-61).

The patients enrolled in the proof-of-principle CALM trial were required to have highly-treatment-resistant hypertension, defined as a systolic blood pressure greater than or equal to 160 mm Hg despite at least three antihypertensive medications. The average number of medications was 4.4, according to Dr. Reilly. The mean blood pressure at entry was 165/98 mm Hg. Nearly 20% had previously undergone renal denervation.

The device was successfully deployed in all of the patients who participated in the open-label CALM study. Most of the 10 serious adverse events were related to hypotension, according to Dr. Reilly. Others included a wound infection and a case of intermittent claudication. Two instances of neurologic complaints, such as numbness and weakness, experienced within a day of device placement were considered potential transient ischemic attacks, but these resolved completely and no defects were observed on imaging.

In an update on CALM, Dr. Reilly reported that the large reductions in blood pressure previously reported at 6 months have been sustained. Follow-up is approximately 3 years in most patients, and the reductions previously reported have persisted in responders. When a clinically significant response is defined as a 10–mm Hg or more reduction in office blood pressure or 5–mm Hg or more reduction in ambulatory blood pressure, 75% of patients enrolled are still responding, but the more important point is that there has been no substantial reduction in blood pressure control over time in responders, according to Dr. Reilly.

When patients were stratified by a pulse pressure of greater or less than 70 mm Hg at study entry, response rates have been similar, he added.

The long-term responses are significant because there was concern about tachyphylaxis. In fact, coronary stents also produce a reduction in blood pressure immediately after placement that is likely caused by the same effect, but that effect "peters out in a day or 2," noted Dr. Reilly. As opposed to the round shape of coronary stents, the rectangular shape of the novel device produces "an increase in the perceived strain on the carotid body" that does not appear to diminish over time.

CALM-2, which is designed to be a pivotal trial to support regulatory approval of the device, began enrolling in September 2018. An enrollment of 300 patients with treatment-resistant hypertension is planned. Participants will be randomized to receive the device or a sham procedure consisting of a carotid artery angiogram, according to Dr. Reilly. Although the initial CALM trial was small, open label, and conducted without a control, the persistent benefit over extended follow-up is driving excitement about the potential of this device.

"These are some of the greatest sustained reductions in ambulatory blood pressure we have ever seen," according to Vasilios Papademetriou, MD, PhD, a professor of medicine at Georgetown University, Washington. Impressed by undiminished blood pressure control observed so far, he characterized the promise of this device as "very compelling."

Dr. Reilly disclosed that he was a stockholder in Johnson & Johnson. ■

PERSPECTIVE by David Rigberg, MD

CALMing Down the Hype?

Dr. Rigberg is a clinical professor of surgery and program director, University of California, Los Angeles, Division of Vascular Surgery, and an associate medical editor for Vascular Specialist.

CALM-2 (Controlling and lowering blood pressure with MobiusHD) is a prospective, randomized double-blinded study designed as a pivotal trial for evaluation of the MobiusHD device. This device is a carotid stent with a rectangular shape. It was engineered to stimulate the carotid bulb baroreceptors in a sustained fashion by increasing pulsatile wall strain, and designed as a potential therapy for treatment-resistant hypertension. The sustainability of the impact on blood pressure has been an issue, as previously observed drops in blood pressure after both carotid and coronary artery stenting have been short-lived.

Data presented at the recent CRT (Cardiovascular Research Technologies) 2019 meeting suggest the device can achieve prolonged drops in blood pressure. As part of the initial proof of principle CALM study, John P. Reilly, MD, an interventional cardiologist, reported that blood pressure drops up to 24 mm Hg were maintained at 3-year follow-up. As follow up to this study, CALM-2 is looking to enroll up to 300 patients.

It is important to note that, despite the blood pressure impact in the initial CALM trial, there were complications in 10/30 patients, even if most were related to hypotension. Although the device may show promise, it is important to keep in mind the potential for devastating complications when intervening on the carotid artery. It is also not clear what the longer term follow-up may reveal about placing these devices in an otherwise healthy carotid artery. Finally, it is not clear what impact the presence of carotid pathology will have on their effectiveness – for example, even calcification in the absence of significant stenosis may preclude the desired impact on the baroreceptors.

As of now, the MobiusHD device has received European CE Mark approval for treating hypertension, while there is no commercial availability in the United States. The results of the CALM-2 trial should help to answer some questions about this device and its use for therapy, and it will be important to establish both the safety and effectiveness of the device. It is also useful to remember that there are therapies that do not require placing a device within the carotid artery, and the risks attendant with intra-carotid therapies will need to be weighed against further successes with these non-intra-arterial devices.

Registry Supports Efficacy of Coated Balloon

BY TED BOSWORTH
MDEDGE NEWS
REPORTING FROM CRT 2019

WASHINGTON – After patients with symptomatic peripheral arterial disease (PAD) were treated with a paclitaxel-coated balloon for 1 year, 89.5% remain free of target lesion restenosis (TLR), according to real-world registry data presented as a late-breaker at CRT 2019 sponsored by MedStar Heart & Vascular Institute.

Freedom from TLR is the primary endpoint of this registry, which will continue to accrue data for 2 more years, according to Nicolas W. Shammas, MD, medical director of Midwest Cardiovascular Research Foundation, Davenport, Iowa.

The nearly 90% rate of freedom from TLR at 1 year was achieved "despite the fact that over 50% of the patients had diabetes, 29% had severe calcification, 35% had critical limb ischemia, and 25% had complete total occlusions," said Dr. Shammas, an interventional cardiologist.

> Since some patients might have had restenosis but no second procedure, TLR at 1 year is not equivalent to patency.

The registry, called SAFE-DCB, was created to evaluate long-term outcomes after treatment with the Lutonix (Bard Medical) paclitaxel-coated balloon catheter, which is employed in percutaneous angioplasty to treat stenotic lesions in the peripheral vasculature. Over an 18-month period, 1,005 patients were enrolled at 74 treatment centers. Dr. Shammas presented data on 766 of these patients, who have completed 12 months of follow-up. There are 835 patients enrolled in the ongoing study.

In a review of characteristics prior to treatment, Dr. Shammas reported that the average target lesion stenosis was 86.7% and the average target lesion length was 75 mm. Endovascular treatments prior to angioplasty were permitted in the registry protocol. Half of the patients underwent directional atherectomy.

After treatment, the residual stenosis was 11.54%. Even though the recommended protocol called for balloon inflations of 30 seconds each at a pressure of 7 atmospheres, the mean balloon inflation times were 35 seconds at 8 atmospheres. The mean total time for balloon inflations per patient was 152 seconds against the protocol recommendation of 140 seconds.

The primary safety endpoint was freedom from periprocedural mortality, limb amputation, and TLR at 30

Balloon continued on following page

Higher Blood Pressure After Thrombectomy Links With Bad Stroke Outcomes

BY MITCHEL L. ZOLER
MDEDGE NEWS
REPORTING FROM ISC 2019

HONOLULU – Acute ischemic stroke patients who underwent endovascular thrombectomy and then had a peak systolic blood pressure of greater than 158 mm Hg during the next 24 hours had worse 90-day outcomes than did patients whose peak systolic pressure remained at or below 158 mm Hg in a prospective, multicenter, observational study with 485 patients.

The results hint that maintaining a lower systolic blood pressure after thrombectomy in acute ischemic stroke patients may improve outcomes, but because the current study was observational, the hypothesis that patients benefit when treatment keeps their systolic pressure at or below 158 mm Hg must undergo testing in a prospective, randomized trial, Eva A. Mistry, MBBS, said at the International Stroke Conference, sponsored by the American Heart Association.

The finding from this study that 158 mm Hg provided the best dichotomous division between systolic blood pressures linked with good or bad outcomes is a first step toward trying to devise a more systematic and evidence-based approach to blood pressure management in acute ischemic stroke patients following endovascular thrombectomy, said Dr. Mistry, a neurologist at Vanderbilt University in Nashville, Tenn.

Neither Vanderbilt nor any of the other 11 major U.S. stroke centers that participated in the study currently have an established protocol for blood pressure management after thrombectomy, Dr. Mistry said in an interview.

"We usually treat to reduce blood pressure, but we don't have a [broadly agreed on] threshold" to trigger treatment. "It depends on a collective decision" by the various medical specialists who care for an individual acute stroke patient. In addition, no consensus yet exists for the best treatment strategy for blood pressure lowering in acute ischemic stroke patients. Intravenous nicardipine is often the top choice because it is fast-acting and easy to administer and control as an intravenous agent. Those same properties make the beta-blocker labetalol a frequently used second drug, she said.

The BEST (Blood Pressure After Endovascular Stroke Therapy) study ran at 12 U.S. centers and enrolled 485 patients who underwent endovascular thrombectomy to treat an acute ischemic stroke. The patients averaged 69 years old, and 48% also underwent thrombolytic treatment. The study's primary outcome was the percentage of patients with a modified Rankin Scale score of 0-2 at 90 days after their stroke, an outcome reached by 39% of all patients in the study.

Statistical analysis of the collected data showed that a peak systolic blood pressure of 158 mm Hg reached during the 24 hours following thrombectomy best divided patients with good 90-day outcomes from those with worse outcomes. Patients with a postthrombectomy peak systolic pressure above 158 mm Hg had a 2.2-fold increased rate of having a modified Rankin Scale score of 3 or higher after 90 days, a statistically significant relationship, Dr. Mistry reported. However, in an analysis that also adjusted for age, baseline stroke severity, glucose level, time to reperfusion, ASPECTS score, history of hypertension, and recanalization status, the elevated risk for a bad outcome linked with higher systolic pressure dropped to 39% greater than that for patients with systolic pressures that did not rise above 158 mm Hg, a difference that was not statistically significant. This suggests that these adjustments were unable to account for all confounders and further highlighted the need for a prospective, randomized trial to test the value of controlling blood pressure following thrombectomy, Dr. Mistry said. The unadjusted results confirmed a prior report from Dr. Mistry and her associates that found a link between higher blood pressure after stroke thrombectomy and worse outcomes (J Am Heart Assoc. 2017 May 18. doi: 10.1161/JAHA.117.006167).

The analysis also showed that patients who were successfully recanalized by thrombectomy, achieving a thrombolysis in cerebral infarction (TICI) score of 2b or 3, had lower peak systolic blood pressures than did patients who failed to get this level of restored cerebral blood flow from thrombectomy.

BEST received no commercial funding. Dr. Mistry had no disclosures. ■

mzoler@mdedge.com

SOURCE: Mistry EA et al. Stroke. 2019 Feb;50(Suppl_1): Abstract 94.

Balloon

continued previous page

days, which was achieved in 98.2% of patients.

Mortality at 1 year was 7.1%. Cardiovascular deaths, such as those due to myocardial infarction, were the most common, but there were noncardiovascular deaths, including those due to sepsis, respiratory failure, and kidney disease.

Women represented 43% of the study population. When compared with men, women achieved the primary outcome at a numerically lower rate, but the difference was not statistically significant.

Dr. Shammas reported similar findings for those without complete total occlusions relative to those with complete total occlusions and those treated within the study protocol relative to those who were not. In each case, the differences in the proportion that achieved the primary outcome did not reach statistical significance.

Following his presentation, Dr. Shammas was asked to respond to the criticism that TLR is a soft endpoint. Since some proportion of patients might have had a return of symptoms due to restenosis but elected not to have a second procedure, TLR at 1 year is not equivalent to patency at 1 year.

While acknowledging the accuracy of this criticism, Dr. Shammas reported that TLR was a practical surrogate in the absence of imaging or another objective method of target lesion assessment. Noting that this endpoint has been employed before for long-term follow-up in trials of percutaneous therapies, he said that the TLR rates in this SAFE-DCB registry "are well within previously reported data" for 1-year outcomes with other treatments of symptomatic PAD. ■

SOURCE: Shammas N. CRT 2019 Mar 5.

Carotid Endarterectomy and Stenting Similarly Effective

BY ERIK GREB
MDEDGE NEWS
REPORTING FROM ISC 2019

HONOLULU – Carotid endarterectomy and carotid artery stenting with embolic protection have comparable efficacy and safety for asymptomatic patients with severe carotid artery stenosis, according to a pooled analysis presented at the International Stroke Conference. The treatments have similar rates of procedural complications and 4-year ipsilateral stroke, said Jon S. Matsumura, MD, chairman of the division of vascular surgery at the University of Wisconsin in Madison.

Two of the five most recent large, randomized trials – CREST and ACT I – compared carotid stenting with endarterectomy in asymptomatic patients. Dr. Matsumura and his colleagues conducted a pooled analysis of these two trials to help inform the choice of treatment.

The investigators analyzed data from the CREST and ACT I studies, which had many similarities. The researchers in these trials carefully selected the surgeons and the interventionalists who participated in them. Each trial used single carotid stent systems, and both trials used routine, distally placed embolic protection. The trials had independent neurologic assessment, routine cardiac enzyme screening, and central clinical and adjudication committees.

Dr. Matsumura and his colleagues decided to conduct a patient-level pooled analysis using a primary endpoint of a composite of death,

Carotid continued on following page

Compression Doesn't Prevent DVT in the Very Ill

BY JIM KLING
MDEDGE NEWS
REPORTING FROM CCC48

SAN DIEGO – In critically ill patients receiving pharmacologic thromboprophylaxis, adjunct intermittent pneumatic compression (IPC) had no effect on the rates of lower-limb deep vein thrombosis (DVT), according to a new trial.

"I was surprised. My hypothesis was that it would work," said lead author Yaseen M. Arabi, MD, chairman of the intensive care department at King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia.

Many physicians routinely carry out the practice on the assumption that IPC should lead to better blood flow and further cut DVT risk. The procedure carries few risks, aside from patient discomfort. "The main issue is that it's not needed. It might be useful in patients who are not receiving heparin or low-molecular-weight heparin," said Dr. Arabi, who presented the results of the study at the Critical Care Congress sponsored by the Society of Critical Care Medicine. The study was simultaneously published online in the New England Journal of Medicine.

Unfractionated or low-molecular-weight heparin reduces the risk of DVT by about 50%, but about 5%-20% of critically ill patients will develop DVT in spite of treatment, and mechanical thromboprophylaxis reduces DVT risk, compared with no prophylaxis.

Some researchers have attempted to address whether adjunct intermittent pneumatic compression could further reduce DVT risk, but their studies were marked by a lack of controls, unoptimized pharmacologic regimens, and other limitations.

The trial included 2,003 adults from 20 sites in Saudi Arabia, Canada, Australia, and India, who were expected to have an intensive care unit stay of at least 72 hours. They were randomized to receive IPC combined with pharmacologic thromboprophylaxis (pneumatic compression group) or pharmacologic thromboprophylaxis alone (control).

The proportion of patients receiving unfractionated heparin versus low-molecular-weight heparin was similar between the two groups, with about 58% treated with unfractionated heparin.

A total of 3.9% of patients in the pneumatic compression group experienced incident proximal DVT, compared with 4.2% of controls (relative risk, 0.93; $P = .74$). A total of 3.4% experienced prevalent proximal DVT, compared with 2.7% of controls (RR, 1.29; 95% confidence interval, 0.78-2.12). There was no significant difference in the incidence of any lower-limb DVT (9.6% vs. 8.4%; RR, 1.14; 95% CI, 0.86-1.51).

There was no difference between the two groups in a composite outcome that included pulmonary embolism or all prevalent and incident lower-limb DVT (RR, 1.11; 95% CI, 0.85-1.44), and there were no between-group differences with respect to lower-limb skin injury or ischemia.

The results should change practice among those who still provide adjunct intermittent pneumatic compression, however surprising physicians may find these new results to be, according to Dr. Arabi: "People believed strongly that (adjunct IPC) should work, but you need to be evidence based, and here it showed no difference. But that's why we do studies, right?"

The study was funded by King Abdulaziz City for Science and Technology and King Abdullah International Medical Research Center. Dr. Arabi has no relevant financial conflicts. ■

SOURCE: Arabi Y et al. CCC48, Abstract 142. N Engl J Med Feb 18. doi: 10.1056/NEJMoa1816150.

Carotid

continued from previous page

stroke, and myocardial infarction in the periprocedural period and any ipsilateral stroke within 4 years of randomization. They included in all randomized, asymptomatic patients who were younger than 80 years.

The analysis comprised 2,544 patients, 1,637 of whom were randomized to stenting, and 907 of whom were randomized to endarterectomy. The population included more than 1,000 patients with 3-year follow-up and more than 500 with 4-year follow-up.

Patients randomized to stenting were slightly younger, but the percentage of patients older than age 65 was similar between groups. Current cigarette smoking was slightly more common among patients randomized to stenting. The groups were well balanced by sex, race, and risk factors such as hypertension, hyperlipidemia, and diabetes.

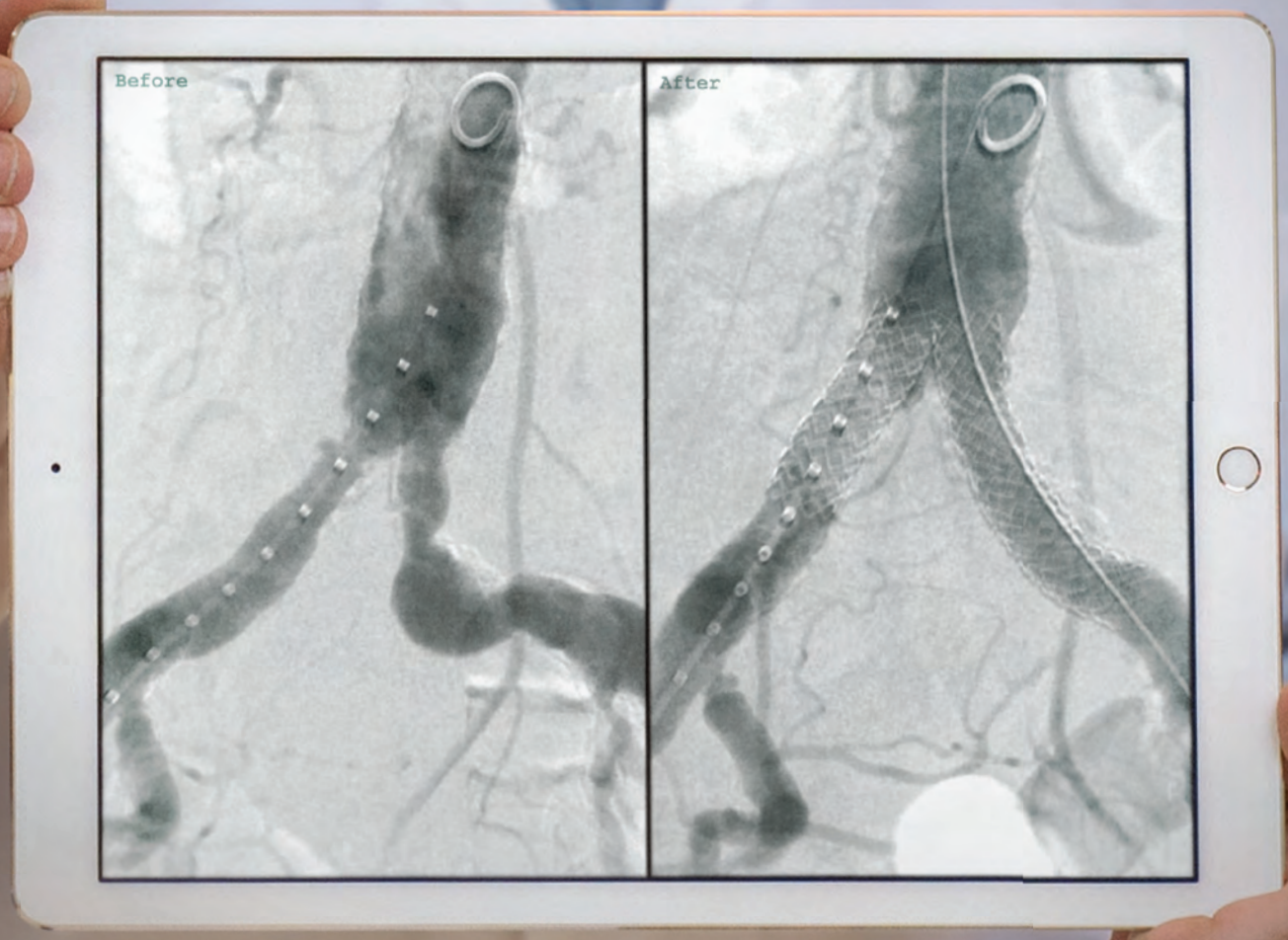
The rate of primary endpoint events was 5.3% in the stenting arm and 5.1% in the endarterectomy arm (hazard ratio with stenting, 1.02; 95% confidence interval, 0.7-1.5; $P = .91$). The rate of periprocedural stroke was 2.7% in the stenting arm and 1.5% in the endarterectomy arm ($P = .07$). The rate of periprocedural myocardial infarction was 0.6% in the stenting arm and 1.7% in the endarterectomy arm ($P = .01$). The rate of periprocedural stroke and death was 2.7% in the stenting arm and 1.6% in the endarterectomy arm ($P = .07$). The rate of 4-year ipsilateral stroke was 2.3% in the stenting arm and 2.2% in the endarterectomy arm ($P = .97$).

A secondary analysis indicated that the cumulative, 4-year rate of stroke-free survival was 93.2% in the stenting arm and 95.1% in the endarterectomy arm ($P = .10$). "Almost all this difference is the initial periprocedural hazard difference," said Dr. Matsumura. The rate of cumulative 4-year survival was 91% in the stenting arm and 90.2% in the endarterectomy arm.

The results of the pooled analysis do not support the perception that stenting entails an increased risk of periprocedural stroke. "The majority of trials have been in symptomatic patients," said Dr. Matsumura. "We're studying asymptomatic patients. We're also studying them in the context of second-generation devices." The results may reflect the amount of device-related training that the researchers undertook, as well as the decision to use single-stent dedicated carotid systems, he added. ■

egreb@mdedge.com

SOURCE: Hanlon B et al. ISC 2019, Abstract LB13.



CASE STUDY
Achieving conformability and durable results in **tortuous anatomy.**[1]

Expands to **every demand**

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

Flexible strength and proven clinical success in complex iliac occlusive disease cases, including:[1]

- Tortuous vessels
- Aortic bifurcation lesions
- TASC II C & D lesions
- Severely calcified lesions
- Total occlusions

View the complete case study at **goremedical.com/vbx/conformability**

W. L. Gore & Associates, Inc. | Flagstaff, AZ 86004 | goremedical.com

1. Bismuth J, 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.

Please see accompanying prescribing information in this journal.

GORE
Creative Technologies Worldwide