The case for rivaroxaban & aspirin for PAD gets stronger

BY MITCHEL L. ZOLER
FRONTLINE MEDICAL NEWS
REPORTING FROM ACC 18

ORLANDO – Combination treatment with aspirin and a low dosage of the anticoagulant rivaroxaban had a broader benefit for reducing adverse events in patients with peripheral artery disease than initially reported from the COMPASS trial, which included more than 7,000 patients whose primary diagnosis at study entry was stable PAD.

Secondary analysis of data from the PAD patients enrolled in the COMPASS (Rivaroxaban for the Prevention of Major Cardiovascular Events in Coronary or Peripheral Artery Disease) trial showed that, compared with aspirin alone, treatment with 100 mg aspirin daily plus a low dosage of the anticoagulant rivaroxaban (2.5 mg b.i.d.) resulted in a statistically significant, 24% relative See PAD · page 12

Dabigatran effective for myocardial injury after noncardiac surgery

BY MITCHEL L. ZOLER
FRONTLINE MEDICAL NEWS
REPORTING FROM ACC 18

ORLANDO – Treating patients who developed myocardial injury after noncardiac surgery with the anticoagulant dabigatran significantly cut the rate of subsequent major vascular complications in a randomized, multicenter trial with 1,754 patients, a result that gives surgeons and physicians the first evidence-based intervention for treating a common postsurgical condition.

"Because we have not systematically followed noncardiac surgery patients, it's easy to presume that everyone is okay, but all the epidemiology data show that these patients [who develop myocardial injury after noncardiac surgery] don't do okay. We need to be aggressive with secondary prophylaxis," P.J. Devereaux, MD, said at the annual meeting of the American College of Cardiology. "The unfortunate thing is that right now, we don't do much for these patients," said Dr. Devereaux, professor of medicine and director of cardiology at McMaster

See Dabigatran · page 14
FROM THE EDITOR

Veith’s Views and yours too?

BY RUSSELL H. SAMSON, MD
MEDICAL EDITOR, VASCULAR SPECIALIST

I

n this month’s Vascular Specialist, Frank Veith, MD, uses a pithy catchphrase to opine that ambition may subvert “aspiring” leaders’ ability to serve our Society for Vascular Surgery. Dr. Veith is respected for his enormous contributions to vascular surgery. He is also renowned for his willingness to go out on a limb in expressing his views on where our specialty should be heading. This Veith’s Views (see page 3) is accordingly all the more disconcerting.

In essence, his premise is the evolution of vascular surgery has been hampered by a nominating process that elects leaders of the SVS based on their academic achievements and previous leadership positions rather than on their stated goals and aspirations for the Society. While there is no question that these activities should be rewarded, the implication is that the system does not reveal potential candidates’ agendas nor their opinions on substantive matters. There is, therefore, no accountability.

At the outset, however, it is essential that we recognize that the vast majority of our past leaders have been exemplary in their guidance of our Society. Despite that fact that there are some paid positions in the SVS, for example, the editors of the JVS and even my role as Medical Editor of this news magazine, all prior members of the Executive have been pure volunteers. They have worked tirelessly, attending multiple meetings often on weekends and late at night. They suffered financial repercussions when they had to take time away from their practices. In many instances, they had to pay their own expenses. Furthermore, most had made significant contributions to the science of vascular surgery and had concurrently educated many current members. All had diligently served on multiple committees over the previous years and had proven devotion to the SVS. Some have succumbed on occasion to personal interest, but surely most attempted to promote what they thought was best for the SVS, its members, and the patients we serve. Further, as Frank correctly states, vascular surgeons who achieve leadership in areas outside of vascular surgery increase the stature of our specialty. Therefore it would be incorrect to interpret his comments as suggesting that such outstanding vascular surgeons be limited in any way or maligning those who achieve a Chair of Surgery.

However, inherent in Frank’s opinion piece is the implication that the current election format is not optimized to ensure a vibrant future for our specialty. I suggest it is not so much because “aspiring” leaders will subvert our interests but rather because our leadership currently acts in an information vacuum. How can they avoid personal bias if they do not know the desires of the majority of members? After all, do the members want a separate American Board of Vascular Surgery or are they satisfied with the status quo? Do they desire a separate Vascular Residency Review committee under the auspices of the ACCME? Does the membership want to fund primary research or use some of those financial resources to promote what we do as vascular surgeons? In fact, it has been many years since a general membership referendum was held on a vital issue such that our leaders could make an informed determination.

However, the outcome of that vote to determine whether there should be a separate American Board of Vascular Surgery was overthrown by the leadership at the time. Perhaps some were the “aspiring” leaders to whom Frank refers. Others probably believed that it was not an opportune time to split from general surgery. Heated emotions on both sides almost destroyed our Society. Even now disparate viewpoints threaten to polarize members. This is a disruptive consequence that we can ill afford. It is imperative that we remain united since we face competitive forces, not only from general surgeons but more so from other physicians who are increasingly becoming involved in treating patients with vascular disease.

What then could be another take away from Frank’s thought-provoking opinion piece? First, it is imperative that we remain united since we face competitive forces from other physicians who are increasingly becoming involved in treating patients with vascular disease.

Russell H. Samson, MD, is a physician in the practice of Sarasota Vascular Specialists and clinical professor of surgery, Florida State University, Tallahassee. He is also the medical editor of Vascular Specialist.
Aspiring vascular surgeons and their impact on vascular surgery

BY FRANK J. VEITH, MD

Vascular surgeons generally provide excellent care for their patients. They often also have leadership abilities. These are typically expressed in positions of administrative responsibility within the specialty as Chief of a vascular surgery service or division within an institution.

However, some vascular surgeons with administrative or leadership talents have ambitions beyond vascular surgery. These vascular surgeons aspire to positions beyond and often above vascular surgery. They are “aspiring” vascular surgeons, and they seek positions as leaders outside and often administratively superior to vascular surgery. Such positions include being a Chair of a department of surgery, Dean of a medical school, President and CEO of a hospital or even a health care system.

The term “aspiring” vascular surgeon can also be applied to those who seek and accept an appointment within the leadership of the American Board of Surgery, the Residency Review Committee in Surgery, as well as important positions within the American Surgical Association and the American College of Surgeons. All these entities exert some control over vascular surgical activities, reimbursement, training, or status within institutions beyond the body of American Medicine.

To have vascular surgeons chosen for these esteemed positions and appointments greatly increases their stature. It also enhances the prestige of the specialty of vascular surgery and reflects its importance in the medical world. Moreover, it may be helpful to the interests of our specialty. Thus, these “aspiring” vascular surgeons provide clear benefit to all vascular surgeons.

However, there is a dark side to the impact these “aspiring” vascular surgeons may have on our specialty which launched them into these prestigious positions and appointments. Clearly “aspiring” vascular surgeons are ambitious. This ambition prompts them to want to ascend ever higher in the food chain of medicine – to seek positions of greater responsibility and appointments with greater power and control. Furthermore, because of their talents, stature, and recognition, such individuals are often elected to leadership positions in our vascular surgical societies – the entities which are charged with furthering the interests of vascular surgery and protecting its status in the medical hierarchy.

An inherent conflict of interest can exist when “aspiring” vascular surgeons occupy leadership positions in our vascular surgical organizations at the same time that they are seeking to advance in the hierarchy of entities beyond vascular surgery. This creates a conflict of interest for those whose interests or specialties may not coincide with the interests of vascular surgery. In such an instance the “aspiring” vascular surgeon will have to choose which interest to support: those of his or her original specialty or those of the organizations in which he or she wishes to rise further.

Conflicts like this have often resulted in actions that are not in the interest of vascular surgery. One example is the poor reimbursement vascular surgeons receive for many of their procedures relative to other specialties. Another effect of such conflicts is the failure of vascular surgery to attain status as an independent American Board of Medical Specialties (ABMS)–approved specialty in 2007. This failure occurred despite the fact that vascular surgery met all the ABMS requirements for such separate specialty status.

So what can be done about the issue of vascular surgery aspiring vascular surgeons and their conflict of interests? The best solution, as Frank suggests, lies in the development and publication of a code of ethics for vascular surgeons. This code will establish a set of rules and guidelines for vascular surgeons to follow when faced with conflicts of interest.

A leadership position in a vascular surgical society is more than an honor or a position of power. It carries responsibility to fulfill the mission of the organization and to protect and promote the interests of the underlying specialty.

From the Editor continued from page 2

The nominating committee must maintain an impartial and objective stance when nominating candidates. The committee should consider each candidate's qualifications and experience, as well as their potential to contribute to the Society's mission and goals.

The nominating committee should also ensure that candidates have a clear understanding of their responsibilities and the time commitment required for their positions. This includes attending meetings, participating in ongoing projects, and serving on committees.

In conclusion, the nominating committee plays a crucial role in selecting the best candidates for leadership positions within the Society. Their efforts help ensure a strong and effective leadership structure that benefits the Society and the specialty as a whole.

APRIL 2018

VASCULARSPECIALISTSONLINE.COM • 3
NEWS FROM SVS

EDUCATION: New Global Guideline on CLTI Ready For Review

After three years of work, research, and study, vascular experts from around the world have released a new, far-reaching global guideline on the management of chronic limb-threatening ischemia (CLTI), formerly known as critical limb ischemia. SVS members soon will be urged to review the guideline and submit comments.

The lengthy guideline includes just more than 100 specific recommendations. It was developed by members of the Society for Vascular Surgery, the European Society for Vascular Surgery, and the World Federation of Vascular Societies, with a co-editor from each association and 57 additional authors.

Its primary goal is to improve the quality of care for patients with CLTI and those at risk for it. Identifying key research priorities is an important secondary goal.

Major recommendations cover the need for comprehensive assessments in patients with suspected CLTI, optimal medical therapy, including a variety of treatments for patients with CLTI, and prompt and effective revascularization for patients with advanced ischemia and limb threat.

"The optimal initial revascularization strategy in CLTI depends on patient risk and life expectancy, severity of limb threat and anatomic complexity," the guideline states.

A major change is the name itself. The term "critical limb ischemia (CLI)" is "outdated and fails to encompass the full spectrum" of patients evaluated and treated for limb-threatening ischemia, the authors said. CLTI "acknowledges the broad range of ischemia, neuropathy, and limb threat that are evaluated and managed by vascular specialists around the globe," said Michael Conte, MD, SVS co-editor. Other co-editors are Andrew Bradbury, MD, World Federation, and Philippe Kolh, MD, ESVS.

Dr. Conte outlined other major changes:

- Staging Anatomy: GLASS Added
  Besides endorsing the SVS Threatened Limb Classification System based on grading wound, ischemia and foot infection (WIFH) in the affected limb, the guideline introduces the Global Limb Anatomic Staging System (GLASS). GLASS incorporates the integrated complexity of disease along a selected target artery path (TAP) from groin to foot. GLASS relates disease pattern to anticipated immediate technical success and 12-month limb-based patency (LBP) following intervention.

- Decision-Making: Have a PLAN
  "Perhaps most notably, the guideline supports a structured approach to decision-making regarding revascularization based on Patient risk, Limb severity and ANatomic complexity (PLAN), in that order of priority," said Dr. Conte. "The guideline seeks to provide a new foundation for practice and for data collection to support Evidenced-Based Revascularization in CLTI."

The document includes key research priorities in each section, where efforts and resources should be focused to improve patient care and advance the science in this area. The collaboration between expert vascular specialists from around the world has created a unique practice guideline, reflecting the spectrum of the disease and approaches seen worldwide, said Dr. Conte. Participants, meanwhile, spanned six continents and all specialties treating CLTI: vascular surgery, interventional cardiology, interventional radiology, vascular medicine, and podiatry.

The guideline will be available for review and comment soon.

VAM 2018 By the Numbers

Nearly 400 abstracts. Six postgraduate courses. Six SVS breakfast sessions. Ten concurrent sessions. Eight scientific sessions. Eight chances to learn tips and tricks and to ask the experts. Nine workshops. One each:


Fine-tuning continues for the 2018 Vascular Annual Meeting, set for June 20 to 23 in Boston. A full day of postgraduate courses, workshops and the VQI and SVN meetings take place Wednesday. Scientific sessions are Thursday through Saturday and the Exhibit Hall is open Thursday and Friday. Register today for the premier educational event of the year for vascular surgery. Bring yourself; bring the team to VAM 2018: Home of the Vascular Team – Partners in Patient Care. Register at vsweb.org/VAM18.

VAM18: Learn from "Ask the Experts" and "Tips and Tricks"

Get up close and personal with the experts and learn some potentially new tools of the trade with two additions to this year's Vascular Annual Meeting.

Both "Tips and Tricks" and "Ask the Experts" will occur daily, Wednesday through Saturday, and these small-group sessions will encourage questions and answers between presenters and attendees. For "Experts," in fact, participants may send in interesting cases and questions now for possible inclusion in June. These submissions will be turned into four, one-hour sessions coding, aortic issues, hemodialysis and PAD.

"They'll actually be helping plan the education at VAM," said Kellie Brown, MD, chair of the SVS Postgraduate Education Committee.

For submission information, email education@vascularsociety.org. This year's four "Tips and Tricks" sessions will focus on cases treated with open technique, which "aren't used as much, because of the increasing use of endovascular repairs," said Dr. Brown. "But they're procedures our surgeons really want to know about."

Adding the "Tips" and "Experts" sessions answers the call from members for "information that's applicable and relevant, that they can take home and implement in their daily practices," said Dr. Brown. "They want translational value, they want to be presented with a problem and to participate in dialogue with the experts for solutions."

Last year's "My Worst Complication: How It Was Managed and Lessons Learned" offered a similar format, and attendees loved it, she said.

Both new sessions also are expected to appeal to young surgeons who want to expand their knowledge base, Dr. Brown said.

No tickets are needed to attend the eight sessions, but space will be limited. "It's first come, first served," she said.
RESEARCH: VRIC-ATVB – Better Vascular Science, Better Care

The annual SVS Vascular Research Initiatives Conference (VRIC) is known as the must-attend gathering for vascular surgeon-scientist teams. In recent years, through SVS’ continued partnership with the American Heart Association Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) scientific sessions, VRIC has gained visibility in the broader vascular biology community.

“The overlap between heart disease and vascular disease is clear,” said Edith Tzeng, MD, chair of the SVS Research and Education Committee. “Having a common mission to treat the causes of cardio-vascular disease is in our best interests. The VRIC-ATVB relationship takes advantage of the fact that researchers in the SVS and the AHA focus on similar areas of investigation.”

The VRIC (May 9) and ATVB (May 10-12) meetings are collaborative from start to finish: co-scheduled and co-located; co-planned and co-moderated; their programs shaped and presented by leading investigators in vascular surgery and cardiology. This symbiosis owes to the work of the vascular surgeons make up the single biggest physician type. About 30 percent of the council members are vascular surgeons, and SVS is formally represented by Scott Damrauer, MD; Peter Henke, MD; and Joseph Mills, MD.

“I’ve learned that the PVD Council is focused on collaboration, not competition,” Dr. Henke said. He believes that the ATVB two ATVB sessions that emerged from the PVD Council are of particular interest to SVS members.

• A session on research priorities in thrombosis, which Dr. Henke jokingly calls, “What topic in arterial or venous thrombosis would you tackle if you had $10 million to spend as you wish?” Four prominent investigators will answer that question through four different lenses – basic science, arterial and venous; and clinical science, arterial and venous. This session is scheduled for 10 a.m., Friday, May 11. A crowd-sourced survey on these topics will be a focus for this session as well.

• “Translational Science of Vascular Medicine: Vascular Dysfunction” at 3:45 p.m. May 11. The program will feature Mary McDermott, MD, considered one of the world’s leading experts on claudication trials and medical therapy for peripheral arterial disease and Michael S. Conte, MD, an international expert on peripheral arterial disease, discussing specialized lipid mediators and resolution of vascular inflammation. The session will also showcase rapid-fire presentations by authors of the top 10 abstracts submitted for consideration.

Dr. Tzeng welcomes all SVS members to participate in VRIC-ATVB.

“Everybody is realizing the care of the patient goes beyond the surgeon and that team medicine is better. … The same goes for research. We can stay in our own teams investigating our own problems but the bigger problems get solved when you bring different types of expertise together.”

GIVING: Consider Making The SVS Foundation a Beneficiary of Your Estate

Remembering the SVS Foundation in your estate plan provides several benefits, including an increase in current income. Careful estate planning and planned giving – such as the SVS Foundation – can reduce or virtually eliminate certain tax obligations, such as capital gains taxes and/or inheritance taxes. The SVS Foundation mission has expanded to include not only funding research but also disease prevention, public education and awareness. That means there are plenty of reasons to fund the future. Your gift can even be restricted to your particular area of interest.

Some estate gift strategies to consider include:

• Will/Revocable Trust: Some people put off making a will or trust. But by having an estate plan, you take control and ensure your wishes are carried out to bestow the people and causes you care about. You are not leaving your estate to chance or decisions made by others.

• Charitable Gift Annuity: Such an annuity allows someone to make a gift that provides payments to him or herself for life, beginning as soon as the gift is established with a charity. The donor funds the annuity by transferring assets to the charitable organization, retaining fixed payment until death. It is an easy life-income gift that helps boost supplement retirement income.

• IRA Rollover: IRA transfers to qualified charities are exempt from federal income tax. Qualified IRA account holders can donate directly from an IRA to the SVS Foundation. Taxpayers 70½ or older may contribute up to $100,000 per year.

If you think a planned gift is right for you, seek advice first from your financial representative. Call 312-334-2339 to speak to a staff member about giving. Read more about the SVS Foundation at vsweb.org/Donate.
NEWS FROM SVS

Why Hospital Privileges Guidelines Matter and How You Can Help

SVS Updates 2008 Guidelines
A cardiology colleague once invited Keith Calligaro, MD, to speak at a cardiology conference. As he was about to take the podium, the moderator asked the audience, “Can you believe that Dr. Calligaro has questioned whether cardiologists should be allowed to perform peripheral vascular procedures?”

Today, Dr. Calligaro said, “I would point to our [new hospital privileges guidelines] and say, ‘I don’t think a cardiologist or a thoracic, general or vascular surgeon should be doing vascular procedures unless they meet the criteria in this document.’”


The new guidelines offer hospital administrators detailed parameters for sound decision-making that align with vascular surgery training requirements prescribed by the Accreditation Council for Graduate Medical Education and the Association of Program Directors for Vascular Surgery. For procedures supported by evidence-based research, the guidelines include minimum criteria for specific types of cases.

The 2018 guidelines are the third set issued by SVS, superseding those published in 2008. The biggest changes for 2018 are emphasizing the maintenance of certification, and documenting clinical results over time through a registry, such as the Vascular Quality Initiative database, launched in 2011.

Many vascular surgeons believe that only they should be allowed to perform vascular procedures. Dr. Calligaro said he learned it’s not that simple. Some cardiologists, he explained, have opted for a fourth year of training in peripheral vascular interventions, and want to put that training to use.

But many of these procedures, whether open or endovascular, are interventions that “vascular surgeons do best, and have the most training for and the most interest in,” he said. “And all vascular interventionalists should question if some of these vascular procedures are being done for wrong indications or if certain interventionalists are not getting good outcomes.”

“Still, vascular surgeons as a group cannot dictate to other specialties what they should be allowed to do. It’s hospital administrators who decide. That’s why our guidelines are so important because they serve as a reference.”

Dr. Calligaro hopes every vascular surgeon will encourage their hospital administrators to adopt the guidelines.

“Those who feel there are other specialists doing vascular procedures who may not have adequate training can refer to this manuscript for their hospital administrators,” he said. They can ask these administrators to “heed the recommendations of the experts in vascular surgery, who are vascular surgeons.”

To view the new guidelines—and share them with your hospital administrator—visit vsweb.org/Hospital.

Hospital Privileges Guidelines at a Glance
1. Physicians should meet minimum case volume criteria for open and endovascular cases during residency and fellowship, as set by the ACGME Residency Review Committee for Surgery recommendations.
2. New vascular privileges applicants should have completed an accredited vascular surgery residency or fellowship before 2020 and should obtain American Board of Surgery certification in vascular surgery or American Osteopathic Association certification within seven years of ending training.
3. Those applying for privileges renewal should be board certified in vascular, general or cardiothoracic surgery. They should participate in MOC programs and maintain board certification.
4. Surgeons performing open or endovascular procedures should use nationally validated outcomes tracking registries, such as the Vascular Quality Initiative.
5. For vascular lab exams, physicians should meet a minimum number of supervised interpreters, during postgraduate training, as suggested by the Intersectorial Accreditation Commission. Read the full hospital privileges guideline recommendations at vsweb.org/Hospital.

MEMBERSHIP: For First Time, SVS Membership Applications Accepted after March 1

It’s already April. In years past, that meant the SVS membership application process was closed for the year.

But for 2018, SVS has moved to a new system, with membership applications reviewed quarterly.

Yearly deadlines are March 1, June 1, Sept. 1 and Dec. 1—four chances a year to become a member of the world’s premier vascular care organization. The first group of applicants were informed of their status early in April.

“This is great news,” a prospective member wrote the SVS. “I’ve tried to apply for membership twice now, but missed the March 1 deadline both times. Now I have a chance in June—and this year I’m going to do it!”

Membership benefits include professional prestige, legislative advocacy, research opportunities and information, practice tools and resources, discounted registration for educational programs, free publications and events for networking with members from across the country and the globe.

Members also receive access to an expanded program of personal and practice benefits such as disability insurance.

Membership continued on page 11

In JVS and JVS-VL: Grip Strength And May-Thurner Syndrome

Two articles of interest from the May Journal of Vascular Surgery and JVS-Venous and Lymphatic Disorders are open source through June 30.

From JVS: Researchers studied grip strength and its association with frailty, comorbidity and cardiac risk among patients with vascular disease, for use with patients with walking impairment. Findings suggest that grip strength could be used as a simple risk screening tool that, among other advantages, would avoid the need for imaging. See vsweb.org/Grip.

From JVS-VL: A review and analysis of literature on May-Thurner Syndrome found that MTS is more common in women, women with MTS tend to present at a younger age and have increased risk of pulmonary embolism. See vsweb.org/MTS.
SVS Members Praise Affinity Program of Benefits

From disability insurance, to student loan refinancing, medical malpractice, retirement and more, vascular surgeons have a number of financial issues for which to plan, quite apart from the medical management of their patients.

The Society for Vascular Surgery began an Affinity Program of expanded benefits just more than a year ago to help simplify members’ lives and provide them with solutions to many of these problems. And since then, some of our members have purchased products that have improved their lives.

Robert Allen, MD, recently graduated from his vascular surgery fellowship. “I like many, was overwhelmed with finding appropriate insurance coverage to protect myself and my family in the future,” he wrote.

Affinity Program representative Mark Blocker helped Dr. Allen navigate options for disability and life insurance and with refinancing his medical school loans.

“Mark has an understanding of our lifestyle and sacrifices, and is easy to approach in making these tough decisions,” said Dr. Allen.

Nicolas. J. Mouawad, MD, said Blocker helped him decide on disability and malpractice insurance for himself and his group. “It can be daunting with so many selections, but the process was very smooth and seamless,” Dr. Mouawad said.

Blocker has noted several times that many vascular surgeons’ disability insurance plans have coverage gaps that could sharply reduce benefits if a surgeon becomes disabled.

“Our plans protect vascular surgeons’ most valuable assets – their income,” he said.

Drs. Allen and Mouawad both highly recommend obtaining plans through SVS. “These plans are tailored to us and created by professionals that have our best interest,” said Dr. Allen.

To view all SVS Affinity offerings, visit vsweb.org/AffinityProgram. Contact Blocker by calling 312-291-4472 or at mark@nationalaffinity.net.

Purchasing products through the Affinity Program benefits not only you and your practice, but also SVS itself.)

Membership continued from page 10
and retirement plans. Active members are also enrolled in the “Find A Specialist” online referral program for patients on vsweb.org.

Find application materials and more information at vsweb.org/JoinSVS. Send questions on membership or benefits to membership@vascularsociety.org.

SVS welcomes members of the vascular team, and now offers a new section specifically for physician assistants.

The SVS is also the management home for the Society for Vascular Nursing. SVN welcomes nurses and nurse practitioners in the vascular setting at many levels and ranges of expertise. For more information, visit svnnet.org. ■
Aspirin “plus”

PAD from page 1

cut in the combined rate of vascular interventions: acute or chronic limb ischemia, vascular amputations, peripheral vascular bypass or percutaneous intervention, and vascular hospitalizations, Sonia S. Anand, MD, said at the annual meeting of the American College of Cardiology.

This finding plus the results in a prior report from COMPASS that rivaroxaban plus aspirin cut major adverse limb events (MALE) by 33%, compared with aspirin alone (Lancet. 2018 Jan 20;391:219-9), together show that rivaroxaban plus aspirin represent a new, effective regimen for a majority of PAD patients (in addition to treating with a statin and an ACE inhibitor) to cut adverse outcomes in a high-risk but historically undertreated patient population, Dr. Anand said in a video interview.

Additional analysis that Dr. Anand reported in her talk showed that patients with PAD who had an index MALE during follow-up had a very high rate of subsequent events. Among the 128 PAD patients in COMPASS who had an index MALE (major vascular amputation or severe limb ischemia that resulted in an intervention) and, compared with the PAD patients who did not have a MALE, the rate of subsequent death was more than three times higher, the rate of hospitalization increased more than 7-fold, and the rate of amputation increased nearly 200-fold.

Concurrently with Dr. Anand’s report at the meeting the results appeared in an article online in the Journal of the American College of Cardiology.

“It’s marvelous [that this study] highlighted the role of limb events in outcomes. The most important message [from the study] is that patients with PAD who have limb events are at incredibly high risk for everything else,” commented Joshua A. Beckman, MD, professor of medicine and director of vascular medicine at Vanderbilt University in Nashville, Tenn.

The analysis of post-MALE outcomes, as well as the expanded vascular-outcomes analysis, focused on 6,391 of the COMPASS patients who had lower-extremity PAD and were randomized to either 100 mg aspirin daily or the low-dose rivaroxaban plus aspirin regimen. COMPASS also randomized patients to a higher-dose rivaroxaban-only regimen administered at 5 mg b.i.d., but this arm did not perform as well as the lower-dose regimen, with an efficacy that equaled aspirin only and with more bleeding. The primary efficacy and safety data from COMPASS for all 27,395 enrolled patients, which included many patients with stable coronary artery disease and without diagnosed PAD, appeared in 2017 (N Engl J Med. Oct 5;377(14):1319-30).

Dr. Anand also reported on a comparison of the clinical and demographic profiles of the 128 PAD patients who developed MALE during follow-up and the 6,263 who did not, a 2% incidence during almost 2 years. Multivariate analysis identified four significant factors that closely linked with MALE incidence: a history of peripheral surgery or angioplasty, prior limb amputation, baseline Fontaine classification of stage III or IV, and treatment in COMPASS with aspirin alone and not with rivaroxaban plus aspirin.

The new, additional analyses Dr. Anand reported also showed total peripheral vascular outcomes during follow-up in COMPASS in 8.0% of patients on aspirin only and 6.2% of patients on aspirin plus low-dose rivaroxaban, a 24% relative risk reduction, and vascular interventions in 7.1% of aspirin-only patients and in 5.5% of the combined-regimen patients, also a 24% relative risk reduction. MALE occurred in 2.6% of the aspirin-only patients and in 1.5% of patients on both drugs, a 33% relative risk reduction. All of these relative risk reductions were statistically significant, said Dr. Anand, a cardiologist and professor of medicine at McMaster University in Hamilton, Ont.

She estimated that about two-thirds of the PAD patients she sees in routine practice would qualify for treatment with aspirin plus low-dose rivaroxaban once the 2.5-mg formulation becomes approved by regulators. The companies that jointly market rivaroxaban (Xarelto) have an application pending with the Food and Drug Administration to market a 2.5-mg pill based on the COMPASS results. Patients with stable PAD who are not good candidates for the COMPASS regimen are those with a history of a major bleed, those who require full-dose anticoagulation for a comorbidity such as atrial fibrillation or a mechanical heart valve, and patients with newly diagnosed, stable PAD without concurrent coronary artery disease who might receive adequate protection from aspirin alone, Dr. Anand said.

COMPASS was sponsored by Bayer, the company that along with Janssen markets rivaroxaban. Dr. Anand has been a consultant to Bayer and Novartis. Dr. Beckman has been a consultant to Janssen and other pharmaceutical companies.


AORTIC DISEASE

Ustekinumab quells aortic inflammation in severe psoriasis

BY MICHELE G. SULLIVAN
FRONTLINE MEDICAL NEWS
REPORTING FROM AAD 2018

SAN DIEGO – A 12-week course of ustekinumab significantly reduced inflammation in the aorta—an effect on par with the benefit of statins—in patients with moderate to severe plaque psoriasis.

Whether or not the reduction in aortic inflammation will translate into a reduction in cardiovascular risk remains to be determined, but investigators are very encouraged by the results of the Vascular Inflammation in Psoriasis-Ustekinumab (VIP-U) study, Joel M. Gelfand, MD, said at the annual meeting of the American Academy of Dermatology.

“We know that psoriasis patients with a body surface area of more than 10% have an 80% increased risk of cardiovascular mortality, independent of any other risk factors,” said Dr. Gelfand, director of the Psoriasis and Phototherapy Treatment Center at the University of Pennsylvania, Philadelphia. “It confers a risk of major adverse cardiac event that is similar to that conferred by diabetes, and 30 times greater than their risk of melanoma.”

“The clinical links are clear when you look at the mortality curves. But the question is, how do we get from the psoriasis phenotype to the cardiovascular disease phenotype? And would treating psoriasis lower the risk of these future morbidities and help ustekinumab continued on page 14
Continued from Ustekinumab on page 12 people live longer, healthier lives?"

For the past decade, researchers have worked on the assumption that the chronic systemic inflammation of severe psoriasis overlaps with similar inflammatory pathways that drive atherosclerosis, plaques that rupture, and cardiovascular events.

Recently, they have employed fluorodeoxyglucose positron-emission tomography (FDG-PET) to confirm some of this. Studies in 2011, 2013, and 2017 confirm that patients with severe plaque psoriasis can develop diffuse vascular inflammation with increased noncalcified coronary artery plaques. These more fragile plaques are the type that are prone to rupture and cause cardiovascular events, Dr. Gelfand said.

"In these studies, the more imaging signal we saw in the aorta, the higher the risk of a future cardiovascular event. In fact, we determined that patients with severe psoriasis can have increased aortic inflammation equivalent to a decade of aging. As your PASI (Psoriasis Area and Severity Index) score goes up, so does the amount of aortic inflammation. The anatomic consequence is that people develop a high risk of atherosclerotic plaques, and a higher rate of noncalcified coronary plaques that are more likely to lead to these events."

The VIP-U study was conceived to examine whether calming psoriatic inflammation with ustekinumab (Stelara), an anti-interleukin-12 and -23 antibody, could also improve vascular inflammation as measured by FDG-PET. The small study comprised 43 patients, half of whom received placebo and half of whom received two injections of ustekinumab: 45 or 90 mg depending on weight, at baseline and at week 4. There was an imaging assessment at week 12, after which the placebo patients crossed over to open-label ustekinumab every 2 weeks. Everyone was followed out to 64 weeks.

Dr. Gelfand reported the 12-week data; the 64-week data will be forthcoming later this year, he said.

"The patients were typical for such a study, with a mean age of about 45 and a mean disease duration of 18 years. The mean body surface area was about 25%, and the mean PASI was 20. Most had been on prior therapy, including phototherapy, oral agents, and biologics."

Unsurprisingly, ustekinumab was significantly more effective than placebo in treating the psoriasis. At week 12, 10% of the placebo patients had achieved a PASI 75, compared with 77% of the ustekinumab patients. A Physicians Global Assessment (PGA) score of clear or almost clear occurred in 10% of those taking placebo and 64% of those taking the biologic.

However, the drug was also highly effective in reducing total aortic inflammation, Dr. Gelfand said. "In just 12 weeks, we saw a 6.6% reduction in total aortic inflammation among those taking ustekinumab, but a 12.1% increase in inflammation among those taking placebo. When you compare the delta, you see a highly statistically significant improvement in aortic inflammation in ustekinumab-treated patients, with the effect size similar to statin therapy."

The benefit may be a class-associated one. Two recent similar studies of adalimumab, a tumor necrosis factor-α inhibitor, failed to find any improvement in vascular inflammation, compared with placebo.

"We need more information about the longer-term effects of ustekinumab treatment, as well as cardiometabolic biomarkers, and these are currently underway," Dr. Gelfand said. "We also need additional trials to determine if this effect is due to the inhibition of IL-12, IL-23, or a combination. Cardiovascular studies will be necessary to fully determine the clinical implications of our findings."

To refer a patient into the VIP study, call 215-662-SKIN or email SKINVIP@upenn.edu.

The National Institutes of Health and University of Pennsylvania sponsored the study. Dr. Gelfand reported no financial disclosures. #

msullivan@frontlinemed.com


TIPS AND TRICKS: Closure of large hole percutaneous access

BY DENNIS R. GABLE, MD

As endovascular techniques and devices increase for various aortic pathologies, the use and desire for percutaneous treatment in these procedures has increased as well. Although there are certainly several methods one can use for vascular closure of percutaneous access points for devices using large 18-25 French (F) access, the procedure outlined below has worked well at our institution. To begin, ultrasound guidance has become a mainstay using a standard micropuncture Seldinger technique to gain wire access to the common femoral artery. A standard short J-wire is inserted through the micropuncture sheath and an 8 F dilator (without the sheath) is then passed over the wire (especially in patients with scarring from prior procedures or excessive fatty tissue overlying the vessel). This will facilitate the passage of the closure device.

A Perclose device (Abbott, Santa Clara, Calif.) is then inserted and deployed with the device angled at the 10 o’clock position. A second device is then inserted at the 12 o’clock position and a third device is inserted at the 2 o’clock position. Many operators will use only two devices oriented at the 10 and 2 o’clock positions, however, we have found that these devices add additional support and increases the chances for successful closure. Upon successful deployment of each device, a rubber shod is used to secure the suture ends however to allow the operator to maintain the order of placement of the devices, the first suture set will have two shod ends on the mosquito clamp, the second will have only one and the third will be just a mosquito clamp without a shod on the end. The purpose of maintaining this order is related to the exchanges of multiple large bore devices. As devices are exchanged, there is the chance that the closure suture may become entwined in the vessel and around the multiple closure sutures. If the last suture placed is secured first, it may allow the first closure suture placed to be “locked” without being able to pulled up and secured tightly.

Once the devices are placed as outlined above, the planned endovascular procedure is completed. When ready to close the access point, a stiff wire is maintained and closure is performed over the stiff wire. The wire through the dilator in place or the delivery device itself (if a tapered tip is present – depending on which treatment device is used) is slowly withdrawn while holding femoral pressure until the tapered portion of the tip of the device or sheath is one half of the way out of the access. The Perclose sutures are then secured and tightened around the access point sequentially in the order that they were placed. The device is then fully withdrawn but left on the wire (in the event that there is closure failure, the device can be easily re-inserted for hemostasis while open conversion is made). This is also the reason for leaving a stiff wire in place during the closure.

If there is minimal oozing noted around the wire, the wire is then removed at this time and the Perclose sutures are fully secured and locked in place. Heparin is reversed and pressure held until full hemostasis is achieved. The access point is then instilled with 0.8% bupivacaine hydrochloride and the site closed with either a subcuticular suture or a skin adhesive alone. If there is still unacceptable bleeding around the wire site prior to locking the sutures in place, an 8 F angioseal device (Terumo medical, Somerset, N.J.) placed over the stiff wire and deployed is usually successful in providing hemostasis. One must remember, however, when placing this device after a large hole access, gentle upward traction must be maintained during deployment to keep the closure plug external to the vessel and this must be weighed against not pulling too aggressively otherwise the intraluminal foot will be pulled outside the lumen. While holding the angioseal device upward, and prior to seating the plug, the Perclose sutures are locked in place and then the angioseal plug is seated as a final part of the closure. Again pressure is then held while the heparin anticoagulation is reversed. The access points are then closed as described above.

Dr. Gable is Chief of Vascular and Endovascular Surgery, The Heart Hospital Baylor Plano Plano, Tex., and an associate medical editor of Vascular Specialist.
Cardiac injury

Dabigatran from page 1

University in Hamilton, Ont.

Results from prior epidemiology studies have shown that, among the roughly 200 million people who undergo noncardiac surgery worldwide each year, 8% will develop MINS (myocardial injury after noncardiac surgery) (Anesthesiology. 2014 Mar;120(3):564-78). The myocardial injury that defines MINS is identified by either an overt MI that meets the universal definition, or an otherwise unexplained rise in serum troponin levels from baseline in the first couple of days after surgery. In the new study, Dr. Devereaux and his associates identified 80% of MINS by a troponin rise and 20% by a diagnosed MI.

The challenge in diagnosing MINS and then administering dabigatran will be implementation of this strategy into routine practice, commented Erin A. Bohula May, MD, a cardiologist at Brigham and Women’s Hospital in Boston. “The problem is, troponin is not routinely measured in postoperative patients. It will be hard to change practice,” she noted. Dr. Devereaux agreed that a significant barrier is convincing clinicians, especially surgeons, to routinely measure a patient’s troponin levels just before and immediately after surgery. “People are lulled into a false sense of security because patients [who develop MINS] usually don’t have chest pain,” he said in a video interview. “When we first showed that patients with MINS have bad outcomes, that convinced some [surgeons] to measure troponin after surgery. Showing we can do something about it” is another important step toward fostering more awareness of and interest in diagnosing and treating MINS.

The Management of Myocardial Injury After Noncardiac Surgery

Trial (MANAGE) enrolled 1,754 patients at 82 centers in 19 countries. Researchers randomized patients to treatment with either 110 mg dabigatran b.i.d. or placebo. A majority of patients in both arms also received aspirin and a statin, treatments that Dr. Devereaux should be used along with dabigatran in routine practice, based on observational findings, although the efficacy of these drugs for MINS patients has not been tested in randomized studies. The study’s primary endpoint was the incidence of major vascular complications, a composite that included vascular mortality, nonfatal MI, nonfatal and nonhemorrhagic stroke, peripheral arterial

PERSPECTIVE by Dennis R. Gable

Evaluate and consider

Myocardial injury after noncardiac surgery (MINS) has been described for over two decades with one of the earliest publications arising from Pasterнак et al. in 1989. In this study, 200 patients undergoing a peripheral vascular surgical procedure were monitored perioperatively. Two hundred patients were divided into two with 120 patients in group I (aortic and lower extremity procedures) and 80 patients in group II (carotid endarterectomy). In group I, there was evidence of “silent ischemia” (asymptomatic troponin T release) in 38% of patients intraoperatively and as high as 48% seen in patients in the immediate postoperative period. In group II, silent ischemia was seen in 41% intraoperatively and 54% in the postoperative period. Interestingly, ischemia was also seen in the immediate postoperative period in both groups at a rate of 40% and 38% respectively. Overall, 63% of the 200 patients demonstrated silent ischemia at some point in the perioperative time frame. Although no specific treatment recommendations were made and this study concentrated more on the time of ischemia and recognition of such, one of the main conclusions was that silent cardiac ischemic episodes occur frequently in patients undergoing peripheral vascular procedures and this does place these patients at a higher risk for acute cardiac events. There was an increase in postoperative myocardial infarction in these patients with an odds ratio of 4.76 to 5.2 (95% CI, 1.03-22).

Moving forward to 2009, Winkel et al. published a study evaluating 220 patients undergoing endovascular aneurysm repair with sampling of troponin T levels routinely on postoperative days 1, 3, and 7. Follow-up of these patients was done out to a median of 2.9 years. In follow-up, 20 out of 220 patients (9%) had asymptomatic troponin T release with silent ischemia and an additional 4 patients had symptomatic ischemia. Through the median of 2.9 years of follow-up, asymptomatic troponin T release was noted to have an increased risk for poor long-term survival and a 4.6 fold increase in risk (95% CI, 1.15-2.1) for death.

Now fast forward to 2018. The recent presentation of the MANAGE trial at the 2018 American College of Cardiology looked at patients with silent cardiac ischemia and the asymptomatic release of troponin T in the postoperative setting after noncardiac surgery. The use of dabigatran to try and reduce postoperative cardiac and vascular morbidity and mortality drew great interest. If you react as I did (admittedly defensive) to the remarks by Dr. Douglas, my initial response was that these patients are not that “hard to find.” In fact, just come by and see my (or any of my vascular surgery colleagues) operative schedule any day of the week and you can find a number of high-risk patients about to undergo a surgical procedure.

The idea that it would be “impractical” for the cardiologists for this patient population to play a role also seems far-fetched since most of these patients are going to have a cardiologist with whom they have a preoperative relationship. I also take issue with the concern she expressed that the surgeons may not be “incentivized” to identify these patients due to the “surgery that they (patients) just underwent.” In fact I would argue that, as a specialty, we are after the best possible outcomes for all of our patients following any procedure or service that we provide. After reviewing some of the data (old and new) prior to writing this commentary, despite my statements above, I do in fact agree that Dr. Devereaux and his colleagues deserve congratulations on a nicely done study. Although I don’t agree they identified a “new disease entity,” they did indeed bring back to the forefront a possible valid finding that as a specialty, and as an overall profession (all surgical specialties), we may admittedly not be giving enough attention. Multiple studies have shown that patients undergoing noncardiac surgery have similar reported rates of silent ischemia between 8% and 24%. These studies, as well as the recently presented MANGE study, also support comparable findings for the relatively short-term increased mortality seen in patients with MINS.

In the end I propose vascular specialists should at least evaluate the findings of the MANAGE study and older studies in more detail and perhaps consider the validity of their findings. If we can indeed achieve a postoperative risk reduction for morbidity/mortality in our patients that express an elevated postoperative troponin T by upward of 28% as is shown in this recent study, then it is certainly worth further investigation.

Even though the Manage study does offer some interesting data to consider, there are some weaknesses of the study. The study did not separate out the various types of vascular procedures. Are all of the listed vascular procedures at the same risk for MINS and/or do they carry the same chance for risk reduction? Additionally, would a lowered dose of dabigatran (i.e., 75 mg) offer a reduction in the post-operative bleeding risk but maintain the same reduction in morbidity and mortality? These questions and more need to be further evaluated before blind acceptance but I would thank Dr. Devereaux and his colleagues for his work in bringing forward this important complication and in offering a potential treatment path.

References
4. Anesthesiology. 2014;120(3):564-78.
thrombosis, amputation, or symptomatic venous thromboembolism. After an average follow-up of 16 months, the primary endpoint occurred in 11% of the dabigatran-treated patients and in 15% of controls, which represented a 28% risk reduction that was statistically significant. The study’s primary safety endpoint was a composite of life-threatening, major, and critical organ bleeds, which occurred in 3% of the dabigatran-treated patients and in 4% of controls, a nonsignificant difference.

The dabigatran-treated patients showed a significant excess of both minor bleeds—13% compared with 10% in controls—and “nonsignificant” lower gastrointestinal bleeds, 4% with dabigatran and 1% in the controls. The dabigatran-treated patients also had a significantly higher incidence of dyspepsia.

Pamela S. Douglas, MD, a cardiologist and professor of medicine at Duke University in Durham, N.C., commented on this presentation as a discussant for MANAGE and in an interview: “Dr. Devereaux and his associates are to be congratulated on identifying a new disease entity, MINS (myocardial injury after noncardiac surgery), and now giving us a way to treat it. MINS is extremely common and quite morbid, and there had never before been a trial that studied its treatment. Identifying patients with MINS is extremely important. These are very-high-risk patients, and they are very hard to find.

“The results from MANAGE give us a way to do something about MINS and an opportunity to improve patient outcomes. The etiology of MINS puts the responsibility primarily on surgeons to diagnose and treat MINS. I hope the message will reach surgeons about MINS and how it can be treated. It does not seem practical for cardiologists to play a role in most of these cases. I also have some concern that, while surgeons are the logical clinicians to diagnose and treat MINS, they also might feel some disincentive to identify patients who develop an initially asymptomatic complication because of the surgery they have undergone.”

MANAGE was funded by the Population Health Research Institute and had no commercial funding. Dr. Devereaux has received research support from Abbott Diagnostics, Boehringer Ingelheim, Philips Healthcare, and Roche Diagnostics. Dr. May has been a consultant to Daiichi Sankyo, Merck, and Servier and has received research funding from Eisai.

mzoller@frontlinemed.com

---

**SVS | VRIC VASCULAR RESEARCH INITIATIVES CONFERENCE**

**Register for VRIC Today**

May 9, 2018 | San Francisco, California

The Vascular Research Initiatives Conference brings together researchers to better understand the biology of vascular disease, with presentations and discussion of new research and possibilities.

**ACCOMMODATIONS:**
Hilton San Francisco Union Square

**REGISTRATION IS NOW OPEN**
For more information visit vsweb.org/VRIC18
MEDICOLEGAL ISSUES

CYBERLIABILITY INSURANCE: Should you purchase a policy?

BY ALICIA GALLEGOS
FRONLINE MEDICAL NEWS

As hackers become more sophisticated, these cybercriminals are finding novel ways to access protected health data, leaving health care providers to pick up the costly pieces of their crimes.

In 2017, there were at least 477 publicly reported health data breaches in the United States, affecting some 5.6 million patients, up from 450 health care breaches in 2016, according to Protenus, a health care cybersecurity vendor that tracks data breaches reported to the U.S. Department of Health & Human Services.

When medical files are stolen, physicians are on the hook for more than just a possible ransom request; they also face thousands of dollars in potential fines, fees, and legal costs, said Joshua R. Cohen, JD, a medical malpractice defense attorney based in New York. To mitigate the consequences, cybersecurity experts say physicians should consider purchasing cyberliability insurance, a relatively new coverage policy that protects against data breaches and subsequent lawsuits.

“A breach is very expensive,” said Mr. Cohen, chair for the New York City Bar Association Committee on Medical Malpractice. “You have the fine to the Office for Civil Rights, which can be in the millions of dollars, and you’re going to have to ameliorate the breach, which can be hundreds of dollars per person, let alone deal with lawsuits from the patients.”

Cyberliability: What’s the risk?
Cyberliability refers to legal dangers arising from data breaches, privacy law violations, and ransomware/cyberextortion threats, as well as data loss and business interruption from computer system failures.

Physicians ... also face thousands of dollars in potential fines, fees, and legal costs.

Of the 477 breaches in 2017 analyzed by Protenus, 37% were from hacking, 37% resulted from insider incidents, and 16% stemmed from data loss or theft. About 10% of cases resulted from unknown reasons, according to the report.

Data breaches caused by hackers and malware attacks are rising in the health care sector, said Katherine Keeffe, global head of breach response services for Beazley, a national cyberliability insurer and risk management company. Beazley handled 2,615 data breaches in 2017, more than half of which were health care–related, Ms. Keeffe said in an interview. The top three causes of health care breaches reported to Beazley in 2017 were accidental disclosure, hack or malware, and insider incidents, according to a recent report from that company.

Ms. Keeffe noted that Beazley has seen a recent surge of phishing emails, electronic attempts to gain sensitive information for malicious reasons by disguising the sender as a trusted source. The emails often request that employees click on a link and change a password in an effort to steal data or gain access to medical records.

“We see an awful lot of that,” Ms. Keeffe said. “There’s been a real surge in successful phishing emails and social engineering that enables criminals to identify medical practice leaders. It’s not hard to dress up an email to look like it’s coming from a specific individual. There are all kinds of increasingly sophisticated tactics to trick people into letting criminals into their systems or tricking people into forwarding money or valuable information.”

Hackers frequently use phishing emails to get employees to download a payload, the portion of malware that performs malicious actions, Mr. Cohen added. Once downloaded, payloads can do significant damage to a medical practice.

“Once you get hit with these payloads, not only do they start pulling information out of the computer system, they can also start doing things, such as turning on laptop cameras, reading emails, listening in on computer microphones,” he said. “All they need is one employee to click.”

Considering Cybercoverage
To protect themselves from potential breach expenses, more medical practices are purchasing cyberliability insurance policies. A 2017 survey of 270 insurance brokers and 125 underwriters found that health care has more first-time buyers of standalone cyberliability insurance than does any other industry.

However, Mr. Cohen advises that practices should do their research before buying and be aware of the different types of policies, coverage limits, and insurance options.

“Be careful about what it covers,” he said. “Are they going to pay for all the amelioration for all the patients affected? Some policies will cover repairing and disinfecting the system, but they will not likely cover all the [Office for Civil Rights] fines.”

The Doctors Company, a national medical liability insurer, provides $50,000 in cybersecurity coverage to all its insured physician members and the option to increase coverage by $1 million in additional protection, according to Crystal Brown, senior vice president of underwriting for the Doctors Company. The coverage protects against regulatory and liability claims arising from theft, loss, or accidental transmission of patient or financial information as well as the cost of data recovery.

Another policy offered protects against claims arising from administrative actions pertaining to utilization, licensing, credentialing, and misconduct.

“In health care, data breaches are not a matter of ‘if, but when.’” Ms. Brown said in an interview. “With the costs of breach response and potential HIPAA violations now reaching several hundred dollars per stolen medical record, we urge physicians to carefully evaluate their risks and make certain they are adequately protected.”

Meanwhile, national medical liability insurer ProAssurance offers health providers a basic cyberliability coverage endorsement in most states on its medical professional liability policy. The insurer also has a branded cyberprogram that allows cli-
with companies such as the Doctors Company to provide coverage and also works with state-run malpractice programs to offer a cyberliability component for a small, additional premium, she said.

Ms. Keefe stressed that cyberliability coverage can ensure that physician practices don’t run up a hefty bill in the event of a data breach by paying for separate specialists and damage control. “One of the reasons doctors should have cyberliability coverage are the costs associated with figuring out what to do if patient records are lost or stolen,” she said. “The cost of hiring a lawyer, hiring a forensics investigator to assess the situation, the cost of notifying the patients, and taking all the steps required by HIPAA can really add up. Most practices don’t have those costs built into their annual budgets. A cyberpolicy acts as a buffer against those expenses.”

Manage Risk Before a Breach
Of course, there is plenty that practices can do to prevent – and protect themselves from – a health data breach before it happens. Providing employee awareness training is an important step, said Craig Musgrave, chief information officer of the Doctors Company.

Institute a training program for staff at all levels and go over the basics, such as refraining from opening emails from senders they don’t know, Mr. Musgrave wrote in a recent column. Updating all software regularly and backing up data are also essential. And Mr. Musgrave emphasizes the importance of “whitelisting.”

“Health care systems are fragmented in their management of systems and data,” Mr. Musgrave wrote in his column. “Their ability to patch legacy systems and employ cybersecurity staff varies enormously. Therefore, application whitelisting is essential. Rather than blacklisting known malicious software, an application whitelist prevents the launching of any executable program (known or unknown) that does not have explicit authorization. This, in combination with strong firewalls and network segmentation tools like micro-segmentation, provides stronger security.”

In addition, consider implementing data security policies and incident response protocols as well as employee training on securing patient data, ProAssurance’s Ms. Tullos said.

“A breach can also occur within a third-party vendors system and infiltrate the physician’s records, so it is important to discuss cybersecurity with those vendors and all parties should purchase cyberliability insurance,” she said.

**PRACTICE MANAGEMENT**

Parental leave not available to all academic surgeons

BY RICHARD MARK KIRKENER
FRONTLINE MEDICAL NEWS
FROM THE JOURNAL OF SURGICAL RESEARCH

Paid parental leave policies have been unevenly adopted among academic medical centers, according to a study published in the Journal of Surgical Research. These policies, or their lack, may have important ramifications for recruiting and specialty selection by surgeons, and for women of child-bearing age in particular.

Parental leave for surgeons has been championed by the American College of Surgeons, among other professional societies, in formal statements and supportive policies in recent years.

The ACS supports maternity leave of no less than 6 weeks (vaginal delivery)/8 weeks (cesarean section) and paternity leave of not less than 6 weeks.

The American College of Obstetricians and Gynecologists endorses paid parental leave for all workers that includes maintenance of full benefits and 100% of pay for at least 6 weeks. The Association of Women Surgeons has issued a similar statement supporting paid parental leave.

Dina S. Itum, MD, a fifth-year resident in the department of surgery, University of Texas Southwestern Medical Center, Houston, and a research team looked into how widespread parental leave is for surgeons in U.S. medical centers.

Their sample was the 91 top-ranked academic medical centers identified by U.S. News & World Report in 2016. The method used by U.S. News & World Report for ranking medical centers is based on student selectivity, dean and residency directors’ peer assessment of national institutions, faculty to student ratio, and the dollar amount in NIH research grants received.

"Parental leave" was defined by the research team as any leave dedicated to new mothers, fathers, and/or primary caregivers after childbirth or adoption. "Paid leave" was defined as some protected leave with salary without mandated use of sick leave or vacation leave.

The study found that, among the top-ranked 91 institutions, 48 (53%) offered some form of paid parental leave to faculty surgeons. The higher the rating, the more likely the institution offered paid parental leave: 77% of those in the top third of rankings vs. 33% in the middle third and 29% in the bottom third. Private institutions were more likely to offer paid leave of 6 weeks or longer; 67% vs. 33% of public institutions.

The investigators posed a question: Did these institutions implement the policy to attract the top talent, or did the policy improve faculty morale and productivity leading to a higher ranking? The study does not answer the question, but the investigators consider it an important issue for further study.

The investigators also suggested that surgeons of child-bearing age use parental leave information their in their own employment negotiations.

"As physicians, we are aware of the health care benefits associated with parental leave, and as leaders within our communities, we should be at the forefront of supporting further advancement of this benefit," according to the investigators.

The investigators reported having no financial disclosures.

SGLT2 inhibitors cut cardiovascular outcomes

BY HEIDI Splete
FRONTLINE MEDICAL NEWS
REPORTING FROM ACC 18

ORLANDO — Data on cardiovascular outcomes from diabetes treatments in patients outside the United States and Europe are limited, said Mikhail Kosiborod, MD, of Saint Luke’s Mid-America Heart Institute and University of Missouri–Kansas City. In fact, most patients with type 2 diabetes reside in the Asia-Pacific and the Middle East, he said in a presentation at the annual meeting of the American College of Cardiology.

Dr. Kosiborod was involved in a previous large pharmaco-epidemiologic study known as the Comparative Effectiveness of Cardiovascular Outcomes in New Users of Sodium-Glucose Cotransporter-2 Inhibitors (CVD-REAL), that showed SGLT2 inhibitor effects in a broad population of type 2 diabetes patients, but that study included only patients from Europe and North America, and focused on just two outcomes: all-cause mortality and hospitalization for heart failure.

In this study, CVD-REAL 2, Dr. Kosiborod and his colleagues compared multiple outcomes data for patients treated with other glucose-lowering drugs (GLDs) and those treated with SGLT2 inhibitors in three world regions: the Middle East, Asia-Pacific, and North America.

The study population included adults aged 18 years and older diagnosed with type 2 diabetes; a total of 235,064 treated with SGLT2 inhibitors and 235,064 treated with other GLDs. The participants were selected from national databases in Australia, Canada, Israel, Japan, Singapore, and South Korea. Individuals with type 1 diabetes or gestational diabetes were excluded from the study.

Outcomes comparing SGLT2 inhibitors and other GLDs included all-cause death, all-cause death or hospitalization for heart failure, hospitalization for heart failure, myocardial infarction, and stroke. Baseline patient characteristics were similar between the two treatment groups. Exposure time for patients in the SGLT2-inhibitor group was highest by far for dapagliflozin (75%), followed by empagliflozin, ipragliflozin, canagliflozin, tofagliflozin, and luseogliflozin at 9%, 8%, 4%, 3%, and 1%, respectively. (Ipagliflozin, tofagliflozin, and luseogliflozin are approved only in Japan.)

The researchers identified 5,216 deaths from any cause. Overall, treatment with an SGLT2 inhibitor was associated with significantly lower risks of death (hazard ratio, 0.51), hospitalization for heart failure (HR, 0.64), death or hospitalization for heart failure (HR, 0.60), myocardial infarction (HR, 0.81), and stroke (HR, 0.68).

The findings remained consistent across countries and patient subgroups, and in patients with and without cardiovascular disease, Dr. Kosiborod noted.

The results suggest that the SGLT2 inhibitors’ impacts on cardiovascular outcomes persist across categories of ethnicity, geography, and cardiovascular disease.

AstraZeneca supported the study. Dr. Kosiborod disclosed relationships with multiple companies including AstraZeneca. The findings were simultaneously published online (J Am Coll Cardiol. 2018 Mar 11. doi: 10.1016/j.jacc.2018.03.009).
DVT AND PULMONARY EMBOLISM

Caval extension of iliofemoral DVT – better outcomes?

BY BRUCE JANCIN
FRONTLINE MEDICAL NEWS
REPORTING FROM
THE NORTHWESTERN VASCULAR SYMPOSIUM

CHICAGO – Caval extension of an acute iliolfemoral deep vein thrombosis paradoxically portends better treatment outcomes than does thrombolysis of a DVT without involvement of the inferior vena cava, according to Rabih A. Chaer, MD, professor of surgery at the University of Pittsburgh. This finding from a retrospective analysis of the University of Pittsburgh experience might seem counterintuitive. After all, caval extension clearly indicates a greater clot burden. One possible explanation: Clearing a thrombus from a large vessel, such as the inferior vena cava (IVC), provides an added protective effect. Also, since the caval segments don’t have valves – their flow is based upon negative pressure in the chest – they may not contribute as much to postthrombotic morbidity to the same extent as do thrombosed iliolfemoral segments, Dr. Chaer speculated at a symposium on vascular surgery sponsored by Northwestern University.

In addition, patients with caval extension were treated more aggressively: 98% of them underwent pharmacomechanical thrombolysis with the Angiojet or another device as an adjunct to catheter-directed thrombolysis, compared with 82% of noncaval patients.

The impetus for Dr. Chaer and co-investigators to review the Pittsburgh experience was a lack of clarity in the literature as to the effect IVC thrombosis has on thrombosis outcomes in patients with acute iliolfemoral DVT. Even though caval thrombus extension is present in up to 22% of patients with iliofemoral DVT, current guidelines issued by the American College of Chest Physicians, the American Heart Association, and the Society for Vascular Surgery don’t address the distinction between iliolfemoral DVT with and without IVC extension in regard to the occurrence of postthrombotic syndrome (PTS), the most common complication of DVT.

The incidence of PTS in patients whose iliofemoral DVT is treated by anticoagulation and compression alone is up to 50%. Mounting evidence indicates that catheter-directed thrombolysis and pharmacomechanical thrombolysis aimed at achieving early thrombus removal and symptom relief help maintain vascular competence and reduce the risk of PTS, the surgeon noted.

PTS is diagnosed using the validated Villalta scale, which incorporates clinical signs including pain on calf compression, skin edema and redness, and ulcers, as well as symptoms such as leg cramping, heaviness, itching, and paresthesia.

The Pittsburgh series included 102 consecutive patients treated with various combinations of catheter-directed or pharmacomechanical thrombolysis in 127 limbs with acute iliolfemoral thrombosis. In 46 patients, the thrombus extended into the IVC, all the way up to the renal veins in most cases.

The groups with and without caval extension were similar in terms of age and prevalence of malignancy, hypercoagulable state, and clot age. However, a history of previous DVT was significantly more common in the group with IVC thrombus. Also, more than 60% of patients with caval extension got an IVC filter, a rate more than 10-fold greater than that in patients without caval extension.

In this series, caval thrombosis had no effect on the technical success of thrombolysis. The technical success rate – defined as at least 50% clot lysis – was 89% in both groups. Rates of recurrent DVT within 30 days were similar in the two groups as well: 11% in the caval thrombosis group and 14% in the noncaval group.

At 2 years post-intervention, 77%-78% of patients in both groups remained free of DVT recurrence. The rate of PTS – defined by a Villalta score of 5 or more – at 2 years was 34% in the noncaval group, which was significantly higher than the 11% rate in patients with IVC thrombus extension. Ultrasound-identified valve reflux was present in 51% of the noncaval group at 2 years, compared with 51% of the noncaval group.

On multivariate analysis, incomplete clot lysis was associated with nearly a 23-fold increased risk of recurrent DVT and a 5.6-fold increased risk of PTS. Caval involvement was independently associated with a 78% reduction in PTS risk.

The Society for Vascular Surgery’s guidelines recommend pharmacomechanical thrombolysis over catheter-directed thrombolysis if the expertise is available. The Pittsburgh experience speaks to the worth of that recommendation.

“Pharmacomechanical techniques can be advantageous. They can expedite the lysis process by clearing most of the clot. In our series, 20 patients were treated with pharmacomechanical techniques in a single session,” Dr. Chaer noted.

The use of IVC filters in the setting of caval extension of iliolfemoral DVT is controversial, according to the surgeon: A thrombus that gets trapped in the filter is tough to remove, precluding successful recanalization.

“One-third of the patients in our series got a filter, but we’ve become more conservative nowadays. We don’t use filters anymore. But I think those patients who might benefit from an IVC filter are those who present with a PE [pulmonary embolism], because that’s telling you they might develop another PE, as well as those patients in whom pharmacomechanical thrombolysis is anticipated because we’ve seen that those patients are also more likely to develop a PE,” he said.


Dr. Chaer reported serving as a paid speaker for Boston Scientific. He is a consultant for Boston Scientific and Gore.


GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm – 13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation.

CONTRAINDICATIONS: Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to Instructions for Use at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events.®
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


Please see accompanying prescribing information in this journal.

Products listed may not be available in all markets.
GORE®, VIABAHN®, VBX, and designs are trademarks of W. L. Gore & Associates.
© 2018 W. L. Gore & Associates, Inc.  AX8235-EN1  FEBRUARY 2018