Peripheral Intervention Solutions
Need to Look Beyond White Males

For one week each May, the NCVH Annual Conference puts the focus on peripheral artery disease (PAD), critical limb ischemia and venous disease. While there are some common themes each year, new topics are also introduced into the agenda.

NCVH saved one of its headline topics for the last day—the new, highly anticipated session, “Gender and Racial Disparities in Peripheral Interventions,” on Friday, June 1.

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Woman are far more apt to die from myocardial infarction (MI) than men, perhaps because they present at an older age, with more diffuse disease. However, less than 20 percent of women consider heart disease to be their greatest risk, Dr. Walker said.

He also looked at demographic data related to AAAs. “A women’s aorta is normally much smaller at baseline, and small AAAs in women are three times more apt to rupture than in men,” he said. “And yet, we’re still using the same treatments that we do for men. We must question how we evaluate aneurysms and make a difference.”

Continued on page 7
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Peripheral Interventions: Essential for Every Patient and Hospital

Programs to treat PAD and venous disease are often not front of mind among hospital administrators. This was one of the reality checks offered during the day-long “The Business of Peripheral Interventions” session on May 29, 2018.

Now in its fourth year, this program has grown in size and scope as it supports the NCVH mission about raising awareness about PAD and lowering amputation rates.

“There is a great opportunity to save lives, save limbs, improve quality of life, lessen overall healthcare expenditures and have a successful business model,” said NCVH Chairman Craig Walker, MD.

Can a Complete Peripheral Vascular Program Improve a Community’s Health?

Dr. Walker cited the PARTNER trial, which showed that a minimum of 29 percent of patients over age 70, or ages 50 to 69 with diabetes or who were smokers, had PAD as defined by ankle-brachial index.

“It’s very apparent these people are not going to diagnose themselves,” he said, noting that only about 12.5 percent had typical PAD symptoms.

As the ABI falls, so does survival. Dr. Walker pointed out that a person with an index of less than 0.8 who is asymptomatic has a worse five-year prognosis than a woman with breast cancer.

Dr. Walker noted that PAD and CLI affect many parts of the body, “but you may get 100 treatments in the legs because we haven’t created a best-case diagnosis.”

“For some reason, it is considered conservative treatment to chop someone’s leg off and aggressive treatment to even do an angiogram,” he said.

“The problem is our definitions are upside down, backwards, they’re stupid. We need to inject some common sense.”

Dr. Walker believes no one should have an amputation without a team evaluation that includes a nurse coordinator, interventionists, open surgical revascularization specialists, infectious disease personnel, podiatry, diabetologists, wound-healing experts, and dialysis and smoking cessation professionals.

Economic Cost of Peripheral Artery Disease, Critical Limb Ischemia and Venous Disease: How Big is the Market?

Mary Yost, MBA, The Sage Group, co-chairman of “The Business of Peripheral Interventions,” cited figures from her group showing that PAD affects more people than cardiovascular disease, stroke and all cancer diagnoses combined.

PAD also accounts for $223 billion to $414 billion per year in inpatient and outpatient costs. Yost also pointed out that since 2003, CLI patients have become sicker. Only 54 percent of hospital admissions are due to primary CLI; the rest are due to diseases like hypertension and diabetes.

Which Patients Should Have Peripheral Vascular Screening and Why So Many Patients are Missed: The Lost Opportunity

“There are only about 50 to 80 physicians nationwide that are passionate about PAD. General practitioners must be engaged in prognosis and treatment of this disease,” said Osama Ibrahim, MD, co-chairman of NCVH Minneapolis.

PAD has similar characteristics to cancer—it’s progressive, asymptomatic, usually identified too late, and has significant morbidity and mortality, he said. It’s also extremely prevalent, with numbers on the rise. But PAD doesn’t have the same screening procedures as cancer.

“Every practitioner knows about pap smears, colonoscopy and mammograms, but you ask them about an ABI and they ask, ‘what is that?’” Dr. Ibrahim said. And yet, an ABI is a very fast, inexpensive and effective test—equivalent to an electrocardiogram for cardiovascular disease—and it’s in the guidelines.

Dr. Ibrahim discussed North Memorial Heart and Vascular Institute’s free PAD screening program, which focuses on diabetics and smokers. He said doctors convinced administrators to pay for the program by doing a pilot study showing that 40 percent of patients had positive PAD screenings.

The program has screened 1,000 patients over the past two years. Thirty percent had PAD, and most had unrecognized symptoms for years and were misdiagnosed.

The Cost Analysis of Amputation vs. Revascularization and the Impact of Treating Critical Limb Ischemia Patients: Benefits to Hospital

Larry Diaz-Sandoval, MD, discussed how to justify lengthy, complex and costly CLI procedures to hospital administration.

He said a Markov probabilistic model was used to simulate five-year survival of 100,000 hypothetical patients with diabetes, and found that primary prevention was at least 90 percent likely to provide cost savings.

Dr. Diaz-Sandoval also noted that PAD patients average 2.7 procedures per year, with a 13.2 percent profit margin. They create downstream revenue through cardiac and carotid workups, AAA screening, venous workups, AV fistula programs, recurrent interventions, wound care and follow-up programs. In addition, “satisfied patients are more likely to refer their friends and family to your facility,” he said.

“The elephant in the room” is physicians’ rejection of approaches and technologies due to a lack of awareness and understanding, Dr. Diaz-Sandoval said. Competition versus collaboration can also hinder an interdisciplinary team approach.

Why are you at NCVH?

“I first came to NCVH as a Fellow. Since then, I’ve developed a passion for PAD and limb salvage – I found my calling. I consider Dr. Walker my mentor.”

– Sohail Khan, MD

Congressman Says U.S. Healthcare System Provides ‘Perverse Incentives’ for Innovation and Outcomes

Healthcare has more government regulation than any other sector in our economy. And yet costs are rising and innovation and outcomes are not being rewarded, said Louisiana Congressman Garret Graves during “The Business of Peripheral Interventions” session on May 29, 2018.

“We’ve seen healthcare premiums in Louisiana increase 140 percent since Obamacare was enacted,” said Graves, a Republican who represents the south-central portion of the state. “We’re paying more and we’re getting less.”

Graves said voters showed in 2016 that they want to see government transformation, and that has occurred. As of May 30, President Trump had repealed 24 existing regulations for every new one enacted, and has also lowered tax rates to create more corporate competitiveness.

But third-party providers dis incent the innovation that results in better healthcare interventions, Graves said. In any other industry in our economy, if you develop a better widget, “you are absolutely going to score,” he said. That’s not the case with healthcare.

In fact, Graves believes the current U.S. healthcare system actually provides perverse incentives, and CMS is part of this problem.

“We have to move in the direction where we’ve moved in every other sector of the economy since this president has come in: deregulation,” he said. “This means incentivizing the right types of outcomes and paying doctors for better outcomes.”

“This doesn’t have to be a partisan fight, Graves noted. “Who doesn’t want better outcomes, more innovation, lower costs and lifesaving remedies?”

Why are you at NCVH?

“I get to interact with people on the cutting edge of vascular treatment. I can share my ideas and learn from others, and when I apply what I have learned it makes me a better physician and it is better for my patients.”

Frank Bunch, MD
NCVH Changes Surgeon’s Outlook, Saves Limbs

Every healthcare professional has one patient who has left a lasting mark—someone they will never forget.

NCVH Chairman Craig Walker, MD, has spoken about a patient who said he had purchased a gun and was planning to take his own life if there couldn’t be some resolution to his severe leg pain due to ischemia. Dr. Walker did treat him, and he lived 12 additional years.

For Claude Minor, MD, that patient is a 16-year-old girl. In 2003, he performed a bilateral above-the-knee amputation on her, due to complications from renal failure. Shortly after the surgery, depression set in, and she died six months later. Dr. Minor, a father of five, said this case still gets him choked up.

He told himself at that time, “There had to be a better way.” Shortly afterwards, he came across a flyer for a vascular conference in New Orleans, and thought he’d check it out. “I walked into NCVH and here was Dr. Walker talking about limb salvage, balloons and stents,” he said.

After hearing Dr. Walker discuss how endovascular procedures could be an option for nonsurgical candidates, Dr. Minor walked up to the NCVH chairman and said: “I have to learn how to do this.”

Dr. Minor then spent the better part of the next two years under the tutelage of Dr. Walker.

It may not be surprising to hear that Dr. Minor’s new skills were not well-received by other healthcare professionals in his hometown, who still saw amputation as the only option.

“I was criticized by other surgeons and radiologists,” he said. “I was told this wasn’t the way to do it. It [endovascular procedures] is now the standard of care.”

Prior to attending his first NCVH, Dr. Minor said he performed anywhere from four to 12 amputations a month. His patient population had high rates of diabetes and renal failure. Now, 95 percent of the time, he’s able to avoid amputation through revascularization.

“It was a godsend that I came to this conference,” he said. “It changed my practice and changed my outlook.”

Dr. Minor said patients now seek him out in the hope that an amputation can be avoided, which he understands because his family owned nursing homes during his childhood.

“Amputation changes the whole family dynamic,” he said. “Now someone has to stay home with mom, and she may eventually end up in a nursing home because her children can’t stay home from work to care for her.”

He hopes that by speaking about the impact of amputations in this way, it may cause a surgeon to hesitate before performing a major amputation.

Another challenge Dr. Minor has faced is when a patient has already had one amputation and is looking at losing the other limb due to disease progression. This sometimes happens just a few months after the first amputation.

Losing the second limb would make everyday tasks such as using the restroom or rolling over in bed nearly impossible to do without assistance.

“That one limb is so important,” he said. “It’s so worthwhile to save that limb.”

Dr. Minor hasn’t missed an NCVH since 2003, and this year, he brought his entire cath lab team with him.

“NCVH is always a great learning experience,” he said. “This is an ever-changing field.”

Navigating the Ins and Outs of Venous Disease

The prevalence of venous disease compares to PAD and CLI in both size and scope, with reports citing that nearly 175 million people have chronic venous disease, making it the most common chronic disease. NCVH continues to expand its focus on venous disease with both the NCVH Vein Forum and the “Insights on Venous Disease” session occurring on Friday, June 1.

“Chronic venous disease is underestimated, underdiagnosed and undertreated, making it look like PAD 20 years ago,” Mary Yost, MBA, said. A highlight of the session was the first presentation of new data from the ATTRACT Trial.

“Certainly it’s fair to say many of us were disappointed by the ATTRACT Trial results,” said Anthony Comerota, MD.

Among the results were that PCDT didn’t reduce mild PTS, according to the Villalta score, but PCDT reduced all PTS when evaluated with VCSS. PCDT also reduced overall severity of PTS, moderate-to-severe and severe PTS, pain and edema. PCDT improved disease-specific QOL and didn’t increase risk of major bleeding or the risk of recurrent VTE.

First Clinical Presentation of a Novel Clinical Imaging Modality for Venous Disease

During the NCVH Vein Forum, June 1, Ariel Sofer, MD, Fellow of the American College of Cardiology, pictured left, and David Wright, MD, Fellow of the Royal College of Surgeons, presented the novel imaging methodology, Mobile Infrared Thermography (MIT) and its successful use in reliably detecting superficial venous insufficiency.

Properly utilized, it is believed it could help millions of more people detect and ultimately treat circulatory diseases.
Craig Walker, MD, welcomed a record 130 Fellows to NCVH’s 8th Annual Fellows Course, Complex Strategies for Peripheral Interventions, on Tuesday, May 29. “Can I tell you how excited I am?” he asked. “You’re the ones who will shape the future of what we do. You are the future of PAD.”

Carlos Mena, MD, co-chairman of the Fellows Course along with Robert Beasley, MD, and Dr. Walker, attributed the record attendance this year in part to NCVH’s focus on building one of the country’s strongest fellow programs. “Fellows are the future,” said Dr. Mena. “Investing in them and preparing them to deal with the challenges ahead is key for the adequate management of patients with PAD.”

New Topics, Hands-On Workshops

While some of the core competencies remain the same, such as focuses on wire technology and devices, embolization is a new topic integrated into the course agenda. “We wanted to make the course more accessible to all the fellows in all the specialties and disciplines around the country that will eventually perform procedures related to PVD and treat patients with CLI,” said Dr. Beasley.

One reason new topics were added was to educate more specialties about these dangerous and deadly diseases. The majority of attendees at past fellows courses have represented the field of interventional cardiology. Adding new topics such as embolization creates opportunities for greater outreach among interventional radiology and vascular surgery fellows. This year’s course did accomplish that goal, with vascular surgery, interventional cardiology and interventional radiology fellows each comprising one-third of the course’s attendance.

Dr. Walker spoke about how NCVH’s education initiatives are working to reduce the trend to “cut off the leg first, think second” when treating PAD patients. “That’s still the case in some places, but it’s changing. Amputation rates are falling – our message is starting to resonate that we can improve patient care.”

He also pointed to advances in technology that are improving treatment outcomes, noting that “lesions we couldn’t have even dreamed of crossing are now commonplace.”

Dr. Walker implored the attendees to look for PAD, because otherwise they won’t find it. But he also warned that it’s not just about the lower extremities. Dr. Walker said one of the biggest obstacles for treating PAD and PVD is that many patients are asymptomatic, and therefore go undiagnosed. Diminished foot pulses may be the only signs of advanced disease.

“We’re missing an opportunity to start preventive care that can stop them from dying from a heart attack or stroke, or preventing progression to ischemia,” he said. “This is a massive healthcare problem, and one that we can leave a mark on.”
Podiatrists are Foot Soldiers in the Vascular Disease Battle

In many ways, podiatrists are the front line in dealing with PAD and CLI, said NCVH Chairman Craig Walker, MD, during the first in a series of sessions focused on podiatry and wound care.

And yet, said Vinay Satwah, DO, many patients tell him he’s the first practitioner who has actually touched their foot—even though that’s a key component in diagnosis of PAD and CLI.

Drs. Walker and Satwah were among the speakers who discussed how podiatrists can help diagnose and treat a variety of vascular disease issues that contribute to wounds, ulcers and amputation of feet and legs.

Session moderator Frank Tursi, DFM, gave an overview of PAD and CLI awareness, with a focus on wound healing. He said venous insufficiency is by far the biggest cause of lower-extremity ulceration, accounting for 35 to 75 percent of all cases. Arterial insufficiency is the cause of 10 to 30 percent of lower extremity ulcerations, followed by diabetes and neuropathy at 15 to 25 percent.

For wounds due to PAD, Dr. Tursi said treatment options include catheter-based techniques, with a relatively low-risk procedures. Ineligibility due to comorbidities is rare, and patients can usually ambulate within two to six hours after the procedure. Amputation is usually check out of the hospital the day after the procedure and attain pre-procedure activity levels within days.

Dr. Tursi said advanced percutaneous options for PAD include endovascular procedures such as percutaneous angioplasty, stenting, directional or laser atherectomy, and cutting-balloon or cryoplasty angioplasty devices.

Nadia Din, MD, said there are improved outcomes and a significant reduction in costs when podiatrists and vascular surgeons work together on PVD treatment and limb salvage. She detailed ways that podiatrists can accomplish this, including creating a fast-track referral system for area vascular surgeons and forming a wound care center.

Deepak Sudheendra, MD, said deep venous insufficiency and obstruction is an overlooked culprit in poor wound healing.

There are over 1 billion cases of venous disease worldwide, which is more than four times the rate of PAD. But few of those people get treated, Dr. Sudheendra said, because most people think of venous disease simply as cosmetic. However, the vast majority of ulcers are venous in origin rather than arterial, he said.

Osama Ibrahim, MD, said calcification is one of the biggest issues in PAD, and CTO is common in patients with CLI. Balloon therapy is problematic because it can’t get past the calcium deposits, he said. Atherectomy can debulk the calcium, he said, but it carries some risks.

“We have a lot of toys [to address PAD], but every toy has a limitation,” Dr. Ibrahim said. The key is to mix and match the various devices to achieve the desirable outcome.

Revamped NCVH Healthcare Professionals Forum Introduced

The NCVH agenda has frequently included programming geared towards allied health professionals treating PAD and CLI patients. Some courses have been focused on nursing, while others targeted technologists.

As planning began for the NCVH 2018 Annual Conference, the program committee identified a need for one unified course that would provide a comprehensive look at developments in the diagnosis and treatment of cardiovascular disease.

“Just like the frequent changes and advances in medicine, this program needs to stay current and remain open-minded to change,” said Valerie Harris, RN, a member of the course’s program committee. “We felt that there is always room to grow and improve. The hope is that we have created a program that invites new audience members and provides well-balanced topics.”

The revamping also involved taking the focus beyond CLI and limb salvage to include all aspects of cardiovascular disease, said David Slovut, MD, who has served as program chairman since 2012.

Harris explained that the program committee wanted to create coursework that complemented the NCVH general session.

The session was renamed to include all allied health professionals and recognize the critical role they play in patient care.

“We wanted to create a unified message to the participants, so everyone leaves with the same educational foundation,” said program committee member Ryan Hebert, RT(R). “Attendees will be able to take a role in further developing their programs by having unified key takeaways.”

Topics covered during the course included latest advances in PAD, venous care and pharmacology over the past year, risk management, cath lab advanced, and special topics such as advanced heart failure.

“Time and attention is often spent on making sure that the topics are applicable to the day-to-day responsibilities of our audience members,” said Harris. “We strive to bring in what is current and what affects daily practices.”

Hebert said the cath lab component, which used to be a stand-alone program, was designed to focus on both patient care and the business of that care.

“We wanted to create a more robust format that will provide a guide for facing today’s challenges in patient care,” he said.

“We looked at finding a balance for improved patient outcomes while also having a positive financial impact on the hospital.”

A popular component of previous NCVH nursing courses—live case viewing streamed in from the general session—remained on this year’s agenda. These discussions, Dr. Slovut said, are less focused on the technical aspects of the procedures and more on the nuances related to caring for patients before and after a procedure.

The live cases provide real scenarios about how to apply the scientific quality into real-world practice,” said program committee member Denise Broussard, RN. “The audience is more focused on the aspects that related to the nursing and cath lab challenges of the procedures. It’s a great learning opportunity.”

Meet the Titans

Returning for its second year, the “Meet the Titans of Peripheral Interventions” networking reception on Tuesday, May 29, connected Fellows and conference attendees with leaders in healthcare innovation.
Disparities

Continued from page 1

in women. Should we use the same aortic measurement for an aneurysm in men and women?”

Twenty-one percent of women present with AAA rupture compared to 16 percent of men, and women are three times more likely to have higher acute rupture.

Overall, vessel size matters, Dr. Walker said. Women have smaller peripheral arteries in general. That makes access more difficult, particularly brachial access. Sheaths are more apt to be occlusive, and vascular rupture is more common with dilation of the aorta and external iliac.

Women also have different CAD symptoms, and are often attributed to other causes like fibromyalgia, “nerves,” osteoporosis or arthritis.

“Diagnostic tests may have decreased sensitivity and specificity for women,” he said, noting that it’s best to use cardiopulmonary exercise tests or nuclear tests rather than treadmill tests for females.

Dr. Walker said men are 20 times more likely to have popliteal artery aneurysms than women, but women are twice as likely to have gut ischemia. Fibromuscular dysplasia and venous varicosities are also far more common in women.

PAD is Ignored in Women

When it comes to PAD, Dr. Walker said men and women have similar levels of occurrence, but women typically present much later in life, with advanced disease—mainly because the disease is often ignored by patients and practitioners.

Women account for 18 percent of PAD admissions versus 27 percent of men, Dr. Walker said, and have 33 to 49 percent fewer vascular procedural hospitalizations than men. Women are persistently more likely than men to be admitted emergently (57 percent versus 53 percent in 2007) and discharged to a nursing home. Procedural mortality is 4.95 percent in women versus 4.37 percent for men, and female mortality rates are persistently higher after amputations (9.9 percent versus 8.9 percent in men).

On the other hand, women’s prognosis with medical therapy is better, probably because “we know women are far more likely to take their medications than men,” Dr. Walker said.

In terms of leg ischemic symptoms, women are less likely to experience claudication, he said. Consequently, they are much more likely to be treated via a CLI presentation rather than a claudication presentation.

“Women are the people that make and enforce the decisions about their family’s healthcare. Until we make them aware that this is a problem for themselves and their families, we are never going to solve the problem of access of care,” he concluded.

Mary Yost, MBA, cited statistics showing that three times more women have PAD than breast cancer. Overall, in 2015, 10.8 million U.S. women were diagnosed with PAD compared to 9.0 million men. For CLI, diagnoses were equal: 1.7 million men and 1.7 million women.

Yost said PAD is also a disease of disadvantaged women. The women most frequently diagnosed tend to be non-Caucasian, unmarried and unemployed, she said.

Women Are Not 70 kg Men

Maureen Kohi, MD, said, “If I leave you with a message today, this is it: Women are not 70 kg men.”

There’s clearly an underlying biological condition that accounts for gender differences in PAD presentation, and it’s not just because of hormones, Dr. Kohi said. But it’s difficult to discover what those factors are because women are so underrepresented in PAD clinical trials.

There is some evidence, however. Dr. Kohi said one study showed women had a 12-month reintervention rate compared to men. Another study showed that the clinically driven TLR rate is twice as high in men than women. Yet other trials demonstrate no differences, Dr. Kohi said, so maybe there were platform differences.

Robert Beasley, MD, discussed the LUCY study, which was the first prospective trial designed to specifically evaluate EVAR in women.

LUCY showed women traditionally have limited eligibility for and worse outcomes after EVAR. However, EVAR in women showed low 30-day MACE and endoleak rates. And the European Post Market Registry demonstrated that women and men derive similar benefits from Ovation EVAR through three years.

Steve Henao, MD, said women with CLI are more likely to undergo endovascular procedures rather than open procedures.

Dr. Henao cited studies showing that procedure and surgery outcomes are similar for men and women, but diagnosis outcomes are worse for women. Primary patency and limb salvage rates were not statistically different; however, female sex was associated with poorer secondary patency. Juan Pastor-Cervantes, MD, said data from the 2005 Healthy From the Heart campaign, which included 1,979 women ages 35 and older, with an oversampling of African-American and Hispanic women, found that only 21 percent of participants were concerned about heart disease, and most didn’t know about treatment options.

Women are roughly 10 years older than men when they present with MI, and have more comorbidities—although they frequently present without chest pain. Women who smoke have a sixfold risk of MI compared to threefold in male smokers, Dr. Pastor-Cervantes noted.

In the setting of STEMI, Dr. Pastor-Cervantes said it’s estimated that for every 1,000 patients treated with PCI compared to thrombolysis, 82 deaths will be prevented for women compared to 61 deaths prevented for men.

Why are you at NCVH?

“As an interventional cardiologist and vascular specialist, this is my passion. I have a lot of patients that suffer from PAD. Learning new treatments and learning new device technology is the way I impact my patients and the way I impact the medical community I am a part of.”

– Charisse Ward, MD
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