Critical limb ischemia (CLI) took center-stage yesterday during the 12th CLI Summit. Now a staple on the conference program, NCVH has carved out its position as a leader in CLI education.

“The CLI Summit has been the backbone of NCVH for so many years,” said NCVH Chairman Craig Walker, M.D. “Twelve years ago, having a summit focused on CLI was not done anywhere else. We’ve kept the focus on CLI but felt the conference should include PAD from head to toe.”

Speakers looked at the scope of the disease and necessary screening methods, all while stressing a key message of NCVH – amputation can be avoided. The impact of diabetes was also covered by multiple speakers. “CLI is most commonly a multi-level disease,” said Dr. Walker. “It’s about how a patient does long-term. If you’ve taken a person from multi-level to single-level disease, we have achieved a lot.”

Treating CLI starts with understanding its prevalence. But Mary Yost, The Sage Group, reported that there aren’t any published worldwide CLI estimates. “We can estimate CLI from PAD numbers,” she said, adding that 202 million people had PAD in 2010 worldwide, a 24 percent increase over the prior decade. From this data, it is estimated there are 11 million CLI cases worldwide. “Seventy percent of CLI cases are found in low and middle income countries.”

Vein Forum, CO₂ Angiography Society Conference Tomorrow

NCVH’s educational offerings continue tomorrow with:
- NCVH CO₂ Angiography Society Annual Conference, 8:00 a.m. – 12 p.m., Chamber I and III
- NCVH Vein Forum, 8:30 a.m. – 4:30 p.m., Orpheum Ballroom

For more information, visit the NCVH registration desk.

Today’s Live Case Schedule

8:40 – 9:00 a.m.
Christopher Metzger, MD
Wellmont CVA Heart Institute
Kingsport, TN

9:00 – 9:20 a.m.
Carlos Mesa, MD
Yale-New Haven Hospital
New Haven, CT

11:02 – 11:22 a.m.
Thomas Zeller, MD
Universitäts-Herzzentrum Freiburg - Bad Krozingen
Bad Krozingen, Germany

11:22 – 11:42 a.m.
Robert Beasley, MD
Mount Sinai Medical Center
Miami, FL

1:50 – 2:20 p.m.
Christopher Metzger, MD
Wellmont CVA Heart Institute
Kingsport, TN

4:50 – 5:10 p.m.
Robert Beasley, MD
Mount Sinai Medical Center
Miami, FL

Continued on page 9
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NCVH Expands Focus on Aortic Therapies, Targets Interventional Cardiologists

NCVH’s mission as a multi-disciplinary meeting is no longer limited to peripheral interventions. Today’s agenda includes an afternoon session covering the full aortic perspective, including both thoracic aortic repair and abdominal aortic repair. In partnership with the International Society for Endovascular Specialists (ISVES), “Emerging and Evolving Techniques for Endovascular Aortic Repair” will begin at 1 p.m. in the Crescent City Ballroom.

“We have been holding an aortic component at NCVH for the past four years,” said Grayson Wheatley, III, M.D. “It’s expanded each year in both content and faculty.”

Dr. Wheatley said the sessions have seen steady growth in attendance and support, which he attributes to increased interest from interventional cardiologists and innovations from medical device companies.

“It is very clear that endovascular aortic therapies are not the preeminent domain of vascular surgeons anymore,” said Dr. Wheatley. “For interventional cardiologists, the first step is to educate themselves about therapies and treatments. We feel NCVH can be a bridge to interested specialists who want to learn more about aortic therapies.”

Delivery sheath size had been one barrier for interventional cardiologists, Dr. Wheatley said, because of the requirement for a cutdown.

“But now closure devices have improved and delivery sheaths have reduced in size,” he said.

The conference’s collaborative environment positions it to become a leader in aortic therapies beyond the vascular realm.

“No meeting has really bridged this gap,” he said. “We feel we have an opportunity to do so because of the interventional cardiologists in attendance. NCVH can be the preeminent educational meeting to bridge the gap between interventional cardiology and aortic therapies.”

Today’s agenda will include lectures on a realm of topics, ranging from introductory to complex, including fenestrated aortic stent graft repair and ascending aortic repair, and two live case presentations.

New NCVH and WebCME Online Course Expands CLI CME Opportunities

Healthcare practitioners seeking to expand their knowledge of critical limb ischemia (CLI) and wound care can now do so without leaving home with the new NCVH/WebCME Critical Limb Ischemia & Vascular Introductory Course. Online courses can be taken at home, at your own pace, and at the conclusion of the training, you will receive 7.5 CME/CEUs.

The Critical Limb Ischemia & Vascular Introductory Course provides a comprehensive overview to the evaluation and management of patients presenting with critical limb ischemia.

For more information, visit www.webcme.net or call (414) 269-5337.
Thursday afternoon’s sessions of the CLI Summit continued the focus on this deadly, multi-layered disease. Speakers looked at developments in imaging and medical devices.

“We need to use our imagination to overcome obstacles that CLI brings to patients and physicians every day,” said Larry Diaz-Sandoval, M.D., a comment that stands in line with NCVH’s education initiatives.

Dr. Diaz-Sandoval introduced the audience to the concept of 2D perfusion, a new functional perfusion technology for CLI patients. He reviewed the technique, which requires automated power injection.

“It is important to remember that the catheter tip needs to be at same point for pre- and post-procedure images,” he said. “Another important part is immobilizing the foot, as well as using the same angiographic projection to compare pre- and post-procedure images.”

Reviewing papers recently published on 2D perfusion, he pointed to one common observation – foot movement is an important technical limitation. “2D perfusion is a useful technique to quantify foot perfusion before and after a procedure,” he said. “We need to standardize the protocol of image acquisitions and interpretation to compare pre- and post-PVI images.”

Mehdi Shishehbor, DO, PhD, spoke about angiogenesis and why it’s important in the field of CLI. Angiogenesis is a local tissue response to chronic ischemia, he explained, while vasculogenesis is a response from the bone marrow.

SDF-1 is a signaling compound that promotes new blood vessel growth that is sustained for two months following treatment. “It's been shown in animal models that SDF-1 promotes angiogenesis in CLI,” he said.

Dr. Shishehbor introduced the STOP-PAD Trial, a randomized, double-blinded study enrolling 120 patients. To enroll, patients must have had successful revascularization to the foot. “This is a unique trial because it focuses on patients that have already been revascularized,” he said. “We wanted to see if there’s a therapy that could be adjunctive to what we do.”

Turning the focus to devices, Jason Yoho, M.D., reviewed specialty balloons and what they offer for treating CLI.

“A lot of the mechanical interventions are largely ineffective for restenosis,” he said, before looking at the problems with POBA, which included torsional stress and radial stress. “The problem is when you use a regular balloon, the force isn’t going to where we want it,” he said. “We're getting less force on the more calcified areas, which leads to problems and complications.”

He reviewed a number of products, including Flextome, VascuTrak, AngioSculpt, Chocolate PTA and the Bullfrog Micro-Infusion Device. Building on yesterday’s discussion about IN.PACT DEEP, Jon George, M.D., focused on use of DCB for below-the-knee (BTK) revascularization and its challenges. These include long lesions, calcified lesions and high restenosis rates.

“The characteristics of lesions are very different above and below the knee,” Dr. George said. “We know that BTK knee lesions will have more calcified composition.”

He also discussed the importance of patency – “limb salvage is more correlated with secondary patency rather than primary patency,” he said.

Before looking at IN.PACT DEEP, he reviewed data available prior to that trial. “Clearly there was a need for a bigger trial that provided level 1 evidence if drug-coated balloons (DCBs) were beneficial in CLI BTK,” he said. “But it failed to meet primary efficacy endpoints.”

Reviewing the meta-analysis, he said there are more studies currently being conducted that will provide more data. “Because calcium is a significant component of these BTK lesions, maybe calcium needs to be addressed,” said Dr. George.
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Nurses Play Key Role in Treatment of CLI and Chance of Limb Salvage, Say Panelists

NCVH’s focus on critical limb ischemia (CLI) carried over into Thursday’s nursing session, which looked at the role nurses have in the treatment of the disease. Ricardo Rao, M.D., kicked off the session by declaring that he was “honored” to speak to the nurses and gave an overview of CLI, calling it the end-stage of PAD as well as a “marker for other cardiovascular morbidity.”

It’s a condition that he said requires aggressive intervention, both medically and surgically, to prevent limb loss. And nurses are a key element in the treatment of CLI, especially in the diagnostic stage.

“The patient’s history and a physical exam is really all you need to diagnose PAD and CLI,” Dr. Rao said. He stressed the importance of physical contact with the patients, which can help health care professionals determine factors such as heart rate and if a patient has cold limbs. “In the age of computers, we’ve lost the art of actually putting our hands on patients.”

Comparing data on CLI compiled during several different trials, Peter Soukas, M.D., expressed his dismay at the high number of amputations performed on patients with CLI. More than 150 thousand lower extremity amputations due to CLI are performed each year, he reported.

The biggest problem with that number, according to Dr. Soukas, is that the majority, 70 percent, of those amputees did not have an angiogram or revascularization prior to amputation.

“We should be ashamed of that fact,” he said. “This is a national disgrace.”

While Dr. Soukas believes that the use of drug coating balloons have revolutionized the treatment of CLI, he acknowledges that there’s still more to learn. Ongoing trials, such as BEST-CLI and BASIL-2, will ultimately help determine the best treatment options for CLI patients.

For now, he said, all disciplines should work together to increase limb salvage rates. “CLI treatment absolutely requires a team approach with timely intervention and dedicated wound care,” said Dr. Soukas.

Jacob Townsend, M.D., also touched on new technology during his presentation – drug-eluting stents. Determining whether this type of stent is the current standard of care is a complicated question, according to Dr. Townsend.

“Yes, maybe and no are all the right answer,” he said. “There are few things in peripheral intervention that should be considered ‘standard.’ This implies that others are substandard.”

The biggest reason that the term “standard of care” is problematic, said Dr. Townsend, is that no two peripheral diseases are the same. “To lump all peripheral diseases together is like comparing apples, oranges and grapes.”

Ultimately, he believes that drug-eluting stents (DES) are an ideal choice with short lesions behind the knee, but not in the iliacs. Depending on the patient, a DES might be the best choice in the superficial femoral artery, Dr. Townsend said.

During his presentation, John Lantis, M.D., discussed nursing care techniques in patients with acute arterial ischemic disorders.

Nurses are often the first stop on the path of CLI diagnosis, and as such, observation and open communication with patients is imperative. According to Dr. Lantis, pain is a common complaint among patients with arterial ulcers. Nurses should ask patients about foot and leg pain and whether pain is exacerbated when the limb is elevated, a major indication of an arterial ulcer.

Post-op care is also crucial, and the first visit after procedure is a prime opportunity to educate patients, he said. Nurses should encourage patients to:

• Take baths regularly
• Pat the skin dry rather than rub
• Have podiatrists or other professional cut nails and trim callouses
• Make sure their shoes fit properly

Moderator Valerie Harris, R.N., also touched on pre- and post-op care. Quality care should always be a high priority, she said, because the quality of life for those living with CLI is poor, as are the disease’s psychological effects.

Harris also discussed the link between renal insufficiency and CLI. Among CLI patients, 25 – 29 percent have some type of renal failure or insufficiency. Revascularization may help reduce those numbers, said Harris, as it helps to establish optimal blood flow and typically reduces procedure time.

In addition, an atherectomy plus the use of a drug-coated balloon has shown to provide long-term patency in CLI patients, she said. Finishing up her presentation, Harris implored practitioners to be aware that “there is no effective drug for renal protection.”

Monitoring blood work and testing kidneys between procedures are effective patient management tools.

“As practitioners, we will be challenged by this disease process,” she cautioned. But ensuring that patients have as much information as possible before, during and after their procedure and sticking to a multi-disciplinary approach when treating CLI patients can yield positive results, Harris said.
**Minneapolis Joins NCVH Regional Conference Portfolio**

NCVH is growing in leaps and bounds – and expanding its reach into the upper Midwest with NCVH Minneapolis: Clinical Updates and Advances in Vascular Medicine, set for October 8 at the Hyatt Regency Minneapolis.

Chairman Osama A. Ibrahim, M.D., is looking forward to bringing a little bit of the NCVH feel to Minneapolis, while also closing the gap on peripheral artery disease (PAD) education.

“I think it’s a very exciting time for PAD,” he said. “It’s one of the biggest challenges we are facing in cardiovascular medicine. Bringing the different specialties to the table will be very helpful.”

Dr. Ibrahim said improving care for PAD patients needs to start with the healthcare professionals that first see these patients – primary care providers, emergency rooms and urgent care centers. Increasing awareness about symptoms of PAD, and what tests to order, is a necessary first step in the fight against this disease.

“It’s a matter of creating champions from the audience,” said Dr. Ibrahim. PAD is a very challenging disease, as Dr. Ibrahim pointed out that 50-60 percent of patients are asymptomatic.

“Primary care providers need to be educated about this disease, otherwise it’s underdiagnosed or misdiagnosed,” he said.

Agenda topics will include screening procedures, diagnostic testing and symptoms, as well as what the next step will be in terms of where to refer a patient for follow-up.

“There is a big discrepancy in vascular medicine,” said Dr. Ibrahim. “We are going to need to align the multidisciplinary approach. NCVH is in a prime position – you don’t see the multidisciplinary approach anywhere else.”

**CLI Continued from page 1**

Looking at the global prevalence of diabetes in 2013, Yost reported that diabetic patients are at a 6-7 times greater risk for CLI.

In addition to the lack of data, another pitfall is suboptimal medical management of CLI, including lack of proper risk stratification of PAD patients, often leading to amputations, sometimes without any screening or revascularization.

Yost reported that a recent study showed that 37 percent of patients in Germany did not have an angiogram before amputation, which she said some experts said was due to the lack of multidisciplinary team approach to such patients.

Another challenge related to CLI treatment is the disease’s definition.

“We should recognize that limb ischemia is a spectrum,” said Joseph Mills, M.D. “We need to focus on the limb – we need to think about the limb differently.”

He also looked at the diabetic population in relation to CLI. When CLI was defined in 1982, Dr. Mills said a majority of the patients at that time were smokers, not diabetic.

“Diabetes has changed the landscape of this condition,” he said, adding that someone is diagnosed with diabetes every 17 seconds. And it’s estimated that 70 percent of non-traumatic amputations are performed on diabetic patients.

“Our patients have changed but our classification system has not,” said Dr. Mills.

He introduced the WIfI (wound, ischemia, foot) index, explaining that three spheres influence outcome: limb status, patient status and anatomy. Each factor is graded on a severity scale from 0 to 3 (severe).

**NCVH Welcomes Six Physicians from China**

Six young physicians from China wrapped up their month-long training program by attending the NCVH annual conference, a fitting conclusion to their mentorship program.

Now in its third year, this program is a collaborative effort between Horizons International Peripheral Group (HIPG) and Boston Scientific. The mission of this partnership is to introduce these physicians to new and innovative endovascular techniques which they will be able to share with their Chinese colleagues when they return home.

Learning environments included hands-on simulation labs and cath lab observation sessions.

“This is an outstanding opportunity to truly make a difference in global education and raise the bar in worldwide peripheral procedures,” said NCVH Chairman Craig Walker, M.D.

Medical training sites included the Louisiana State University Health Sciences Center in Shreveport, Cardiovascular Institute of the South in Houma and Lafayette, the Deborah Heart and Lung Center in Browns Mills, New Jersey and the Louisiana State University School of Medicine in New Orleans.
Speakers Discuss Benefits of Exercise, Lipid Management for CAD Patients

Thursday’s Family Practice session drew attendees from a number of disciplines, from podiatry to primary care. Panelists compared therapy types and treatment options for the management of coronary artery disease (CAD). The disease is the leading cause of death for both men and women in the U.S.

“Looking at the agenda, this seems to be quite a varied and exciting program,” announced Barry Bertolet, M.D., who moderated the session.

S. Jay Mathews, M.D., opened the session with a look at the use of Cardiopulmonary Exercise Testing (CPET) in female patients.

Also referred to as Exercise Treadmill Testing (ETT), CPET is an initial tool for the evaluation of CAD but can also yield positive results when used in tandem with therapy. According to Dr. Mathews, studies show that patients who are able to exercise more typically live longer. Conversely, lower exercise capacity is associated with mortality. Dr. Mathews concluded that, in a low-risk population, ETT is a more cost-effective option than perfusion imaging.

Darrell Solet, M.D., also emphasized the importance of exercise in treating CAD.

Lipid management, such as physical activity, may go a long way in improving CAD, he said. This includes making a diet plan that is low in saturated fat, trans fat and cholesterol as well as high in fiber. The use of statins has also proven to be effective, he said, but many patients are reluctant to take statin medications because of bad press the treatment has seen.

Mid-session, the topic shifted to atrial fibrillation (AF) treatments. AF affects more than 2.3 million people in the U.S. and is projected to increase at least twofold by 2050. Marc Saad, M.D., discussed atrial fibrillation ablation therapy (AFAT), which he called “an improving technology that’s advancing quickly.”

Health care professionals now understand that the development of AF requires a “trigger” and a susceptible substrate. Thus, successful ablation procedures are ones that either eliminate the trigger and/or alter the arrhythmogenic substrate, according to Dr. Saad.

Treatment options for AF include cardioversion, anti-arrhythmic drugs and surgery. While they technically qualify as treatment, he said, these makers are not curative. After citing several studies, Dr. Saad stated that catheter ablation is potentially curative, with success rates of around 60-80 percent, with a less than 5 percent risk of major complications.

Medication has traditionally been the go-to for AF treatment, but one of the most common should be discarded as a viable option, said Dr. Bertolet during his presentation on anticoagulants.

“Finally, there is a replacement for Warfarin,” he declared. The medication was introduced as a rat poison in 1948 and was used in medicine for human use in 1954, but Warfarin has not been used on rats since 1975.

“In my opinion, it’s time to stop using Warfarin on humans as well,” said Bertolet. “We need to jump on the bandwagon.”

Direct thrombin and Factor Xa inhibitors show promise and should be considered as a viable replacement, he said. Cost comparisons show these agents to be more cost-effective than Warfarin, according to Dr. Bertolet. Their use also leads to less bleeding, less events and shorter lengths of hospital stay.

Interventional procedures were covered by Peter Fail, M.D. This type of therapy is used in patients who demonstrate a bleeding risk or high risk of stroke, and the best choice is not quite clear, said Dr. Fail, as more research and trials are needed.

“Currently, no FDA-approved interventional procedures exist for an left atrial appendage (LLA) exclusion that is not an anticoagulant,” he said. The only LLA exclusion solution is a surgical one, he said. The AtriClip is a device that compresses tissue but does not pierce or puncture the tissue.

“There is no recommendation from the FDA for patients that cannot take an anticoagulant other than ‘wait for trials,’” Dr. Fail concluded.

Vinod Nair, M.D., presented on a subject that’s an “exciting area for cardiologists,” according to Dr. Bertolet.

“Just do transradial,” Dr. Nair said. The procedure reduces the risk of bleeding and the subsequent need for a transfusion, and is more cost-effective. Its estimated savings to the healthcare system is $1.8 billion annually, he said, and patients experience a better quality of life from the first day. However, drawbacks to the transradial approach include the learning curve and possibility of technical difficulties.

Following Dr. Nair’s presentation, Dr. Bertolet weighed in on his feelings about transradial. “The technique is quite rewarding for obese patients,” he said.

Satish Gadi, M.D., also favors a transradial approach, as demonstrated from his presentation comparing Bivalirudin and Heparin. The short answer is that the best procedure is patient-specific.

“If everyone did radial interventions, we probably wouldn’t have seen the rise of Bivalirudin,” he said.
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