Welcome to NCVH!

“Putting this all together is the single greatest achievement of the meeting,” said Dr. Walker. NCVH was the first conference to dedicate a full day to CLI, and will continue to do so with tomorrow’s CLI Summit.

“CLI is the most dangerous, and most expensive, form of PAD,” said Dr. Walker. “It leads to amputation and is associated with very high mortality rates and historically has been treated very poorly. And it’s increasing because the population is aging and there is a higher prevalence of diabetes.”

One message that will be heard over the next three days is that amputations can occur for patients with PAD. The conference will focus on strategies to prevent amputations, including the use of new therapies and techniques to improve patient outcomes.

Continued on page 6

Today’s Action Labs Schedule

Dr. Craig Walker, NCVH Chairman, welcomes attendees to the NCVH Fellows Course.

What’s on the Horizon?

Wednesday, May 29

NCVH’s Fellows Course kicked off a week of education focused on the prevalence of peripheral artery disease (PAD), critical limb ischemia (CLI) and venous disease. Presenters not only spoke about diagnosis and treatment approaches, but also the financial impact of these deadly diseases.

Tuesday’s agenda provided a comprehensive overview, covering everything from diagnosis and screening methods to the latest technological advances. The lectures were reinforced with hands-on training opportunities at 10 stations during yesterday’s program, and additional hands-on training today at LSU’s Russell C. Klein, MD, Center for Advanced Practice.

NCVH Chairman Craig Walker, M.D., opened the Fellows course with a look at progress being made to increase awareness about PAD, CLI, venous disease and lymphatic disorders.

“We’ve come a long way since we first started,” said Dr. Walker. “NCVH has played a major role, knocking down many walls that were stopping progress.”

Dr. Walker discussed the current epidemic, with reports stating the number of Americans with PVD exceeding 20 million. By 2020, it’s estimated that 2.8 million Americans will have CLI.

“Putting this all together is the single greatest achievement of the meeting,” said Dr. Walker. NCVH was the first conference to dedicate a full day to CLI, and will continue to do so with tomorrow’s CLI Summit.

“What has made NCVH succeed is that we had an idea and we had course participants and presenters who bought in and became evangelists to treat PVD. They share the same enthusiasm for patients who have had poor outcomes in the past.”

Continued on page 7
THINK LONG.

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3 out of 4 patients treated with IN.PACT™ Admiral™ DCB remain reintervention-free through 5 years.\(^1\)

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\(^1\) Laird JR. IN.PACT SFA 5-year Results. Presented at VIVA 2018; Las Vegas, NV.
OBLs Offer Possibilities While Reducing Costs

In a busy cardiovascular practice, office-based labs (OBLs) can improve caseload congestion and reduce treatment cost while increasing access for patients outside of the traditional hospital setting. During Tuesday’s Business of Peripheral Interventions course, OBLs were newly included as a topic of focus given the exciting possibilities they bring. John Blebea, M.D., explained, “Peripheral artery disease (PAD) affects more than 8.5 million patients in the United States, which has resulted in a shift from inpatient to outpatient procedures. Use of OBLs have also resulted in cost reduction between 60-75%.”

Setting up an OBL can be a daunting task. A majority of the session was focused on outlining these challenges and providing guidance on how to navigate them. Mike Ferguson, Philips, detailed the high initial overhead costs, compounded by ever-changing reimbursement and regulatory guidelines. Having appropriate staff with experience in billing, proper referral channels and a good location are all key business considerations in setting up OBLs, and he emphasized, “If there is one thing to take away from this talk, make sure that you have staff experienced in billing and coding.”

While OBLs have been in community practice for more than 10 years, Dr. Gomes, National Interventional Radiology Partners (NIRP), stated “the idea of chain OBLs really took off in 2015.” In line with the course’s focus on the business of OBLs, Dr. Gomes presented NIRP’s standardized step-by-step method in setting up an OBL. “NIRP depends on systems, rather than really smart people, because there are a limited number of geniuses in the world,” said Dr. Gomes. This simple principle breaks down all the complicated aspects of setting up an OBL into accessible bodies of knowledge, which Dr. Gomes would continually refer to as being “all binarized, there is no guesswork.”

Key components of the presentation by Dr. Gomes included hiring an initial staff of at least 2 MBA/MHA degrees while having an intrinsic level of business acumen as the CEO.

“You don’t want to become a person-dependent system,” Dr. Gomes explained. He estimated a total cost of $450,000 with $50,000 upfront, while stating that this system would produce financial returns in the course of one year, assuming 20 cases per week. Another significant obstacle of setting up OBLs is garnering enough referrals for revenue, which Dr. Gomes stated could be bypassed by setting up a JV ownership model. This is comprised of 40% syndicated investors, like primary care physicians and podiatrists, that would then internally refer to the OBL. He emphasized that this system can also be compliant with anti-kickback policies.

Today’s Live Case Schedule

8:40 – 9:00 a.m.  
Thomas Zeller, M.D.  
University Heart Center Freiburg- Bad Krozingen  
Bad Krozingen, Germany

1:50 – 2:10 p.m. 
Yazan Khatib, M.D.  
First Coast Cardiovascular Jacksonville, Fl.

1:20 – 2:30 p.m.  
Thomas Shimshak, M.D.  
Florida Hospital Heartland Medical Center  
Sebring, Fl.

4:30 – 5:40 p.m.  
Yazan Khatib, M.D.  
First Coast Cardiovascular Jacksonville, Fl.

4:50 – 5:10 p.m.  
Thomas Shimshak, M.D.  
Florida Hospital Heartland Medical Center  
Sebring, Fl.

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POTENTIAL ADVERSE EFFECTS

The potential adverse effects (e.g., complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation (loss of limb); erythema; arterial aneurysm; arterial thrombosis; arteriosclerotic (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypertension; hyperkalemia; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the distal artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasm or recoil; vessel trauma which requires surgical repair. Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion. Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; toxicologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthritis; myositis/myositis; peripheral neuropathy. Refer to the Physicians’ Data Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time. Please refer to the appropriate product Instructions for Use for a detailed list of indications, warnings, precautions, and potential adverse effects. This content is available electronically at manuals.medtronic.com.

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INDICATIONS FOR USE

The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 550 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

CONTRAINDICATIONS

This IN.PACT Admiral DCB is contraindicated for use in:

- Coronary arteries, renal arteries, and supra-atrial/cerebrovascular arteries
- Patients who cannot receive recommended antiplated and/or anticoagulant therapy
- Patients who have had a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the device
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

WARNINGS

- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBB is 14 atm (141.5 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBB is 11 atm (111.5 kPa). The RBB is based on the results of vitro testing. Use only pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 14.5 mg of paclitaxel in a patient has not been clinically evaluated.

PRECAUTIONS

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Asses risks and benefits before treating patients with a history of severe reaction to contrast agents.
Regenerative Medicine, APWCA Partnership Highlight Podiatry and Wound Care Track

N

CVH’s mission to be a multi-
disciplinary and inclusive
conference is demonstrated by
the conference’s Podiatry and
Wound Care track, which con-
tinues to grow in size and scope.
Each year, Conference Co-chairman
Frank Tursi, DPM, seeks to develop a pro-
tagonistic programming include new topics, a partnership with the
American Professional Wound Care
Association and a schedule change to
courage live case viewing.

“With podiatric and wound care principles are constantly evolving,
your goal each year is to capture the
newest techniques in real time,” said
Dr. Tursi. “Introducing the most in-
novative and advanced wound care
treatment paradigms through talks
delivered by our national leaders in
wound care has been my goal and I
believe that we will certainly accom-
plish this at NCVH 2019.”

The track’s first session will focus
on regenerative medicine, which Dr.
Tursi described as a topic that’s near
and dear to him and his practice.

“In the private sector, we offer re-
generative options of treatment for
advanced wound healing as well as for
the treatment of foot and ankle mala-
dies such as sports injuries, overuse
syndrome and to optimize surgical re-
sults,” he said. “Our regenerative med-
icine session will kick off Wednesday
morning and I am extremely pleased
with our lineup of speakers.”

Learning opportunities, however,
are not limited to a focus on podiatry
and wound care. On Thursday, rather
than holding sessions that would com-
pete with the CLI Summit, the podiatry
and wound care track takes the day off
– a decision that was made to encour-
age viewing of live cases, a hallmark of
NCVH’s educational offerings.

“Dr. [Craig] Walker and I have al-
ways promoted the collaborative care
network and recognize the immense
value of educating the vascular spe-
cialist about advanced wound healing
techniques as well as the signiﬁcance
of educating podiatrists and wound
care specialists about vascular treat-
ment options,” said Dr. Tursi. “We felt
that by integrating the podiatric and
wound care attendees into the main
conference we would afford them a
live look at complex vascular cases and
the techniques performed to help
them not only save the limbs of their
patients, but the lives as well.”

When the track resumes on Friday,
sessions will be presented in partner-
ship with the American Professional
Wound Care Association (APWCA).

“This elite consortium of many of
the most respected wound care profes-
sionals in the nation will deliver
Friday’s advanced wound care track,” said Dr. Tursi. “The latest and
greatest peer reviewed data, tech-
niques and protocols of healing the
complex wound will be discussed in
this session.”

And stay tuned for more informa-
tion about future collaborative events
planned more collaboration with the
NCVH Philadelphia regional confer-
ence on November 2.

“I am excited to be the first to an-
nounce that APWCA plans to in-
tegrate their Board review course,
certification examination and offer
their regional APWCA conference at
NCVH Philadelphia,” he said. “An-
other epic event!”

NCVH Adds Radiation Protection to Agenda

R

adiation safety... is it top-
off? If not, it should be.
Today’s Radiation
Protection session, 3:30–5 pm,
will discuss the dangers of radia-
tion exposure and which preven-
tive measures healthcare profes-
sionals can take.

“It’s a real credit to NCVH
that this topic is being highlight-
ed,” said Robert Wilson, M.D.
“Radiation is a bit like the ‘asbestos’
of medicine. You can’t see it.
The effects are devastating but delayed by decades. Only now
are we coming to terms with the risk.
NCVH is on the forefront of this important problem for
healthcare workers.”

Scatter radiation is a type of secondary radiation that occurs when the useful beam intercepts any object.

“Exposure to scatter radiation can be quite significant over time and it has been linked to cancer, cataracts, vascular disease and genetic changes,” said Dr. Wil-
son. “Interventional physicians receive the highest dose of radia-
tion of any profession and they have a correspondingly high occu-

cupational health risk, including one of the highest occupational
mortalities for high volume op-
erators. With proper equipment
and shielding, the risk can now be minimized. The challenge
now is to modernize the cath lab
safety environment.”

Ways to reduce scatter ra-
diation include the use of lower
dose x-ray units and good x-ray

technique. Obese patients and
angled views will increase scatter
radiation.

Another contributing factor is the longer, more complex cases
that increase exposure times.

“Unlike patients who receive a
dose of ionizing radiation during their procedure, interventional cardiologists and endovascular operators in addition to the labo-
ratory staff are repeatedly ex-
posed to radiation during their
 duties over a lifetime of their career,” said Dr. George. “This
issue has been further magni-

fied by increased exposure in the
longer duration of complex coro-
nary chronic total occlusions and
complex peripheral revascular-
ization procedures.”

Dr. Wilson hopes today’s ses-

sion raises awareness about this
topic amongst attendees.

“It’s easy to forget about ra-
diation protection and good an-

dagnostic techniques because
you can’t see the x-rays and
the health effects are delayed,” he
said. “This is an area where we
need to take care of ourselves
and the team.”

Robotics

Dr. George will be speak-

ing about recent developments
made regarding robotics in re-
gards to radiation safety.

“Robotics have paved a new
era in coronary and endovas-
cular revascularization using
advances in technology and re-
moving the operator from direct
radiation exposure,” he said. “By
optimizing the technology, the
reality of performing complex
procedures while minimizing
the radiation exposure is closer
than ever. ALARA (As Low As
Reasonably Achievable) is the
goal in radiation exposure and
in the current era, robotics might
hold that key.”

OBLs

Continued from page 3

cies, and referred to the website for
further information.

There are also mixed business
models for outpatient clinics that are
 not completely free-standing. David
Konur, CEO, Cardiovascular Insti-
tute of the South (CIS), stated that
their business model involved work-
ing in conjunction with 14 partner
hospitals using a co-managed model.
He made the case for partnering with
larger health systems as a way to nav-
igate the ever-changing landscape of
healthcare in order to make proce-
dures more accessible under patients’
health insurance. “The Silver plan on
the Healthcare Exchange now has a
$6,500 deductible,” he said, which
then corresponds to patients being
much more active consumers of their
healthcare given that they pay for
that much out of pocket.

Access to an OBL also impacts recr-
uiting. “We lost 3 really good can-
didates to competitors who had OBL
access in the same town,” said Konur.
Additionally, he said there was a con-
cern that having OBLs would can-
nibalize the volume of hospital pro-
cedures. However, Konur explained
that this is unfounded, as CIS data
from the past 10 years actually show
that OBLs have increased hospital
procedures. “Not every case should
be done in an OBL, some of these
need to be done in the hospital,” he
said, which then results in increased
revenue for the partnering hospital.

Mary Yost, left, discusses the economic impact of PAD and venous disease as Dr. Osama Ibrahim looks on during the Business of Peripheral Interventions Stakeholders Forum on Tuesday.
From the leaders in radial access…discover what’s next in peripheral intervention.

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be prevented. “Limb salvage is less expensive and is associated with lower death rates than amputation,” said Dr. Walker.

Recent published data has shown that amputation rates are declining, even though there’s a higher incidence of CLI.

“Healthcare practitioners are seeing that there are other options,” said Dr. Walker, who pointed to the story of Claude Minor, M.D., who has attributed NCVH to changing the way he treated PVD patients. “Dr. Minor said he came to NCVH performing amputations and left performing limb salvage. Many others have echoed his sentiments.”

Dr. Walker also pointed to a “fraternity of friends” who connected through NCVH and now regularly discuss cases and provide support to each other. “Physicians encounter tough cases, and they can call someone to discuss challenges they are facing.”

Multidisciplinary Approach

Dr. Walker has often said that “people look at PAD as a sick leg. We want them to see a sick patient.” And it takes a team to provide these sick patients with the care they need to save limbs and lives.

“All disciplines are required to achieve ideal outcomes in patients with PVD,” said Dr. Walker. “Different specialties working together will result in better patient outcomes.”

First the diagnosis has to be made, which often starts with the primary care provider (PCP) or podiatrist. Then neurosensory testing is needed, which will involve the PCP, podiatrist or a neurologist. There may also be a need for a wound care specialist or endocrinologist, as well as classic surgical and interventional techniques.

“What has made NCVH succeed is that we had an idea and we had course participants and presenters who bought in and became evangelists to treat PVD,” said Dr. Walker. “They share the same enthusiasm for patients who have had poor outcomes in the past.”

Conference Highlights

An integral part of the NCVH experience since day one, live cases provide unique learning opportunities for attendees.

“We again have live cases coming in from around the world with the world’s greatest operators,” said Dr. Walker. “Live cases teach something not taught by a taped case. Nothing can replace a live case in terms of instructional efforts.”

Attendees will see, in real-time, the challenges that an operator may face. “You may not be able to cross a lesion,” said Dr. Walker. “It forces people to see what is option number one, then option number two, in order to solve a problem.”

Ankur Lodha, M.D., will perform a live case on Thursday that will demonstrate the radioartery approach, which Dr. Walker described as one of the “new waves.”

Attendees will also have the opportunity to visit Action Stations, where they can get hands-on experience using wires and deploying stents.

Yesterday NCVH kicked off with the ninth annual NCVH Fellows Course, which continues to grow each year, and the Business of Peripheral Interventions course, which added a focus on office-based labs to the program.

Returning to the agenda this year is Friday’s “Gender and Racial Disparities in Peripheral Interventions” session. Speakers will build on some of the topics introduced last year, with a greater focus on treating women with cardiovascular disease.

And don’t forget fun – join us for tonight’s Anniversary Celebration or tomorrow night’s Exhibitor Reception.
Fellows
Continued from page 1

“I’m here to tell you that this is the greatest time ever for treating patients,” he said, pointing to the challenges he faced as a cardiologist. “We weren’t supposed to be in the peripheral space. And we didn’t have the devices that we have today. It’s almost never that we find a patient we can’t help with interventional procedures if we do it properly.”

He spoke about what the PARTNERS Trial showed us, and how important it is to check the ABI. “Sick legs are never attached to healthy people,” he said. “As ABI falls, so does survival rates. If the foot pulse is not there, you’ve identified a problem. If you want to improve health in your community, check foot pulses.”

Amputation is not the answer, something that will be heard often during the next three days. Dr. Walker stated that approximately one-third of patients undergoing an amputation are discharged to a nursing home, and 40 percent are dead in two years.

He then presented a case study, showing images of a foot with black toes and open wounds. The patient told Dr. Walker that if he couldn’t help him, he was prepared to commit suicide. With multiple interventions, Dr. Walker was able to save his leg, and the man went on to live for 13 years.

“There are a lot of people getting amputated that may not need it,” he said. “Amputation is not quick and simple for the patient. Amputation should always be the last resort.”

Why are You Attending the NCVH 2019 Fellows Course?

“It’s a great opportunity for me as a cardiovascular fellow to learn more about peripheral vascular disease, which is under-recognized and under-treated.”

Mustafa Elheshmaty, M.D.
Maimonides Medical Center, Brooklyn, N.Y.

“I wanted to update myself, listen to the latest advances in vascular surgery, share experiences with fellows from other places and receive training at different workshops.”

William Daza, M.D.
Universidad Del Rosario, Bogota, Colombia

“It is a great opportunity for any vascular surgery, cardiologist or interventional radiology fellow to update his knowledge in the evolving field of PAD. This Fellows Course is outstanding and very dynamic. It gives us a huge chance to get familiar with different devices, new technology and game-changing innovations.”

Nader Hamada, M.D.
Ain Shams University, Cairo, Egypt

“I decided to attend after I had heard Dr. Walker give a talk at a prior conference. His ability to deliver such high yield and pertinent points about peripheral angiography was inspiring. And when I found out that NCVH existed, I knew I had to come and learn more.”

Chakavath Obangoue, M.D., MPH
Maimonides Medical Center, Brooklyn, NY

“I want to know about the different techniques that are available at this time about endovascular management.”

Sandra Milena Rojas Molina, M.D.
Universidad Surcolombiana, Neiva, Huila, Colombia.

“To save some legs and eat some gumbo.”

Alexander Postalian, M.D.
Texas Heart Institute/Baylor College of Medicine, Houston, TX

“The future of medicine depends on new physicians working with experienced physicians and industry to achieve the best possible patient outcomes. The NCVH Fellows Course provides the perfect opportunity for that kind collaboration.”

Micah Jones, D.O.
Franciscan St. James Health, Olympia Fields, IL

“Amputation is not the answer, something that will be heard often during the next three days. Dr. Walker stated that approximately one-third of patients undergoing an amputation are discharged to a nursing home, and 40 percent are dead in two years.”

Dr. Mathews also reviewed the variance of PAD and CLI, angiographies and pedal loop recanalization.

Richard Kovach, M.D., opened the session by outlining the roles of different imaging modalities in diagnosis and treatment of PAD. He emphasized the need to look for PAD, given that 70% of patients with coronary artery disease (CAD) will have PAD, and vice versa. “If you don’t look for PAD, you won’t find it,” he said, adding, “So many of your colleagues have to be reminded to take off the patient’s socks.”

He stressed the importance of monitoring the ankle brachial index (ABI). “If the patient has symptoms of PAD, with normal ABI, do not stop there,” he said, explaining that patients with diabetes can have normal ABIs, as do those with calcified vessels.

While ultrasound is used primarily in diagnostica, CTA and MRA are the next steps with regards to procedural planning. “If intervention is highly likely, use angiography in conjunction with the planned intervention to reduce radiation,” clarified Dr. Kovach. Disadvantages of CTA include imaging being obscured by calcium, while MRA can be inconsistent because it is highly technique-dependent.

“Angiographies are based off the principle that if you revascularize the artery to the wound, you will do better than without,” said John Rundback, M.D., during in his presentation on angiographies. The idea is to angiographically determine flow and perfusion to ischemic tissue, understanding that wounds occur from watershed areas.

Angiographically determining blood supply to a wound is superior to using traditional understanding of angiosomes primarily because angiosomes do not reliably apply in CLI and because anatomic variations are common. It is critical to look in multiple planes,” he said. He also emphasized the importance of identifying wound blush prior to the procedure because it might be inadvertently worsened.

Pedal loop recanalization techniques were presented by Jos van den Berg, M.D. There were two common techniques for pedal-plantar loop recanalization, which includes an antegrade technique as well as an antegrade-retrograde technique. Dr. van den Berg also recommended considering the use of collateral vessels when planning an approach. Techniques can involve using both a wire and balloon, but are also conducive to wire-only approaches. He also encouraged attendees to perform distal, selective angiography as well as consider anatomical variants of vessels.

S. Jay Mathews, M.D., provided a summary on diagnosis and endovascular treatment of CLI. “Early detection is critical given the high rates of mortality, especially with co-morbid diseases like diabetes,” he emphasized. When stratifying the severity of CLI, “a toe brachial index (TBI) of less than 55 is consistent with ischemic ulceration,” he said.

Initial treatment is usually conservative, and may include smoking cessation, hypertension and hyperlipidemia control and aerobic exercise. “Oftentimes patients with CLI can’t exercise though, so this is a catch-22,” he acknowledged. When comparing endovascular versus surgical outcomes, he did note that drug-eluting stents have improved endovascular outcomes significantly. As a rule, he said, “indirect revascularization is nice, but direct revascularization is always better.”

Dr. Mathews also reviewed the various devices in an interventionalist’s toolbox, including support catheters, wires, ultrasound, scaffolds, drug-coated balloons, drug-eluting stents, focal force balloons, and finally, the arterIALIZATION of veins.
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1. **19.8 Million People in the U.S. Suffer from PAD with An Annual Incidence of 300,000-400,000 Cases**

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- For use in the coronary or neurovasculature.

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