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2018 ACP Annual Congress a fresh break from the past

By Vanessa Salvia

This year’s American College of Phlebology Annual Congress, the 32nd, promises to be the most comprehensive yet. Planners have incorporated an important international perspective, refocused established events and added new events to help turn this into one of the most well-attended and important meetings of the year.

More than 1,000 are expected to descend on the Nashville Gaylord Opryland Resort and Hotel Nov. 8 for four days of educational content, exhibit hall demonstrations, events and society gatherings.

All four days are packed with sessions, society events and activities including past favorites like the ACP Foundation Silent Auction and ACPF Annual Fun Run and Walk, as well as new events. “Raise Your Glass,” an ACPF toast, closes out the day’s sessions on Thursday and Friday, and the Venous and Lymphatic Village on Sunday represents a big change to the format of the Congress.

VENOUS, LYMPHATIC VILLAGE

Kathleen Gibson, MD, a vascular surgeon with Lake Washington Vascular in Washington State, organized the village, which she says is like a science fair for grownups.

“We will have distinct areas devoted to different venous and lymphatic conditions, which we’re calling neighborhoods.”

Different tables will cover chronic venous obstruction, compression and wound care, lymphedema, NTNT, pelvic venous reflux, sclerotherapy, superficial vein treatment and thrombosis. At each table, registered vascular technologists and company representatives will be on hand to provide expertise on devices and products – but not for a sales pitch.

“It’s for industry experts to explain how the device was developed, how it works, how it was tested,” Dr. Gibson says. “We want industry to give the backstory about their products and provide an opportunity for hands-on experiences with the products, with no lectures.”

OVERALL IMPROVEMENTS

ACP Congress Program Chair Stephen Daugherty, MD, FACS, FACPh, RVT, RPhS, a vascular surgeon at VeinCare Centers of Tennessee in Clarksville, Tennessee, has served on the ACP Board for the last six years.

Boston Scientific to acquire Veniti

Boston Scientific has signed an agreement to acquire Veniti, a privately-held company in Fremont, California, which developed and commercialized the Vici venous stent system for treating venous obstructive disease. Boston Scientific has been an investor in Veniti since 2016 and owned 25 percent of the company.

The transaction price for the remaining stake consists of $108 million up-front cash, as well as up to $52 million in payments contingent upon U.S. Food and Drug Administration approval of the Vici stent system.

Venous obstructive disease – instances of abnormal, blocked or damaged veins – affects more than 1.1 million people in the United States and Western Europe annually. Vein
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NEWS
1 A Doctor in the House?
Healthcare is going to be either the first agenda item or the second item of the next Congress, depending who’s counting. Twelve of the 14 doctors now in Congress are Republicans. Three are senators. Of the Democratic doctors running for office, all but one are seeking House seats, which could change the complexion of the House.

1 Nashville getting ready for ACP
This year’s American College of Phlebology Annual Congress, the 32nd, promises to be the most comprehensive yet. Planners have incorporated an important international perspective, refocused established events and added new events to help turn this into one of the most well-attended and important meetings of the year. More than 1,000 are expected to descend on Nashville’s Gaylord Opryland Resort and Hotel Nov. 8 for four days of educational content, exhibit hall demonstrations, events and society gatherings.

THE PRACTICE
20 Practicing medicine in Italy
Emma Stout, MD, a phlebologist at American Vein and Vascular Institute in Colorado, grew up in Italy, idolizing her grandfather who was a surgeon. With his influence, she became passionate about the medical field, specifically practicing specialized medicine and providing the best possible care for all patients. Dr. Stout compares practicing specialized medicine in the United States and Italy.

22 Aiding financially strapped patients
James White, MD, of Advanced Surgical Concepts in Chattanooga, Tennessee, offers ideas on how to provide assistance to patients as they navigate the complex maze of insurance coverage and financial constraints.

SECOND LOOK
26 Treating the pregnant patient
Manu Aggarwal, MD, of the Vein Care Center Laser Specialists in Lima, Ohio, says of all venous disease complications, one of her top concerns is the pregnant patient. In the last year, she has seen a handful of pregnant patients with variable superficial venous thrombophlebitis of truncal veins, varicose veins and labial veins. She discusses two cases where early recognition and management was key to the treatments.

30 A safe, less invasive treatment
Kenneth Harper, MD, of Vein Specialists of the South LLC in Macon, Georgia, who pioneered the use of RF Closure in Georgia years ago, is happy to add polidocanol endovenous microfoam (Varithena) to the armamentarium of therapies for varicose veins. He says it is a safe and effective treatment to manage this common problem.
SACRAMENTO AREA VASCULAR/VEIN PRACTICE FOR SALE
Sebastian Conti, MD, FACS, is offering a vascular/vein practice for sale in the Sacramento, California, area near a hospital. Attractive lease, experienced employees, three exam rooms, in office operating room, surgical instruments, VNUS, vascular lab (with tech) EMR >2,000-patient database.
Dr. Conti is a Northern California vein specialist. With more than 30 years of experience, he offers expert diagnosis and treatment of varicose and spider veins, including injection sclerotherapy and office vein surgery. He was the first surgeon in the Sacramento area to use laser and VNUS Closure procedures. Dr. Conti said he has treated thousands of patients, including many prominent Sacramento area physicians and politicians.
For more information, email veinexpert@gmail.com or see advancedveincare.com.

CIGNA’S ACQUISITION OF EXPRESS SCRIPTS SHOULD CLOSE BY DEC. 31
The Department of Justice has given the green light to insurance giant Cigna Corp.’s planned $67 billion acquisition of pharmacy benefit manager Express Scripts. The companies anticipate closing the deal by the end of the year.
The move ends the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, one of the conditions necessary to close the deal, officials said in an announcement. The transaction still remains subject to certain state regulatory approvals and filings, including clearances from certain departments of insurance.
“We are pleased that the Department of Justice has cleared our transaction and that we are another step closer to completing our merger and delivering greater affordability, choice and predictability to our customers and clients as a combined company,” said David Cordani, president and chief executive officer of Cigna, in a statement.
Since then, Cigna and Express Scripts have obtained clearances from departments of insurance in 16 states. The companies are working with regulators in the remaining jurisdictions to obtain clearance for the merger.
The combined entity would retain the name Cigna, and Cigna’s headquarters in Bloomfield, Connecticut will oversee the joint venture. Express Scripts will continue to operate in St. Louis. Cordani will become CEO of the joint venture, and Express Scripts CEO Tim Wentworth will continue as president of the PBM. The deal was approved by the boards of both companies and will include both stock and cash, according to the announcement. Cigna will also assume about $15 million in Express Scripts’ debt.

TAX COURT RULING FAVORING MEDTRONICS ON $1.36B IN BACK TAXES DENIED ON APPEAL
A federal appeals court has thrown out a previous tax court ruling favoring Medtronic on procedural grounds, reigniting a years-long dispute with the IRS over the payment of nearly $1.36 billion in back taxes.
Initially, the IRS took issue with Medtronic’s allocations of incomes between its subsidiaries through royalties and licensing agreements. Using methods such as transfer pricing, the IRS said the medical technology giant shifted too much of its profits to its Puerto Rican subsidiary in an attempt to avoid a higher rate.
Though part of the United States, Puerto Rico is considered international for tax purposes, with the IRS describing the move as a “classic case” of companies trying to move profits offshore. Medtronic has since moved to Ireland, following its $50 billion merger with Covidien.
The agency had first demanded payments of $548 million and $810 million in missed federal taxes for 2005 and 2006, respectively, but a ruling in the IRS’ favor could open the company up to billions more in taxes from the following years – not to mention other transnational companies using similar accounting methods.

HOUSE JOINS TRUMP IN DEMANDING END TO 2.3% MEDICAL DEVICE TAX
The House of Representatives voted overwhelmingly to kill a sales tax on medical devices that the medical-technology industry in Minnesota and around the country have battled for nearly a decade. Republican U.S. Rep. Erik Paulsen of Minnesota’s Third District introduced the standalone repeal legislation. The bill had 277 cosponsors and a seal of approval from the White House going into the vote. It eventually passed 283-132.
The 2.3 percent tax on medical device sales passed in 2010 along with the rest of the Affordable Care Act. Supporters said the tax would be offset by increased device sales prompted by a broad expansion of Americans with health insurance. Critics said collecting the tax on sales rather than profits would hurt small device companies and startups.
The government did not begin collecting the tax until 2013. Congress suspended collection three years later after taking in $5 billion. An initial two-year moratorium in 2016-2017 was extended to 2018-2019 earlier this year.
Meanwhile, getting rid of the tax entirely has been one of the device industry’s top priorities for the past eight years – and one of the most difficult to attain.
But the political landscape has changed significantly since 2015, most notably with the election of Republican President Donald Trump, an avowed foe of the Affordable Care Act. Democratic President Barack Obama once promised to veto any device tax repeal bill that reached his desk because he saw it as a first shot in a Republican-led battle to undercut his signature healthcare reform.
Still, the device industry’s lobbying against the tax has taken a firmer hold in states such as Minnesota that rely on robust medical-technology sectors to sustain their economies.
Industry insiders predicted Senate action to keep device tax repeal legislation from being pushed aside by controversial matters such as the nomination of Brett Kavanaugh to the U.S. Supreme Court.

FUJIFILM, INDIANA MEDICAL SCHOOL TO PARTNER ON DEVELOPING AI FOR IMAGING
Fujifilm Medical Systems USA has signed a research agreement with Indiana University School of Medicine in Indianapolis to jointly develop artificial intelligence algorithms for medical imaging applications.
The collaboration will bring together Fujifilm’s image processing and AI technology with the university’s diagnostic and clinical expertise in hopes of developing medical AI technology and a system optimized to support diagnosis workflow, according to a Fujifilm spokesman. Initially, researchers will focus on using Fujifilm AI technology to segment and quantify sarcopenia on body images, as well as for detecting and quantifying brain lesions on neuroradiology imaging studies.
In addition to working on multiple in-house imaging AI projects, Fujifilm is also currently partnering with AI technology vendors to increase the disease coverage of its systems.

MEDICAL GROUPS APPLAUD CMS EHR APPROACH IN HOSPITAL RULE
Medical groups have applauded steps that the Centers for Medicare & Medicaid Services took to ease administrative burden through a new rule on hospital payments, while still pressing the agency for further changes in its approach to electronic health records.
The CMS on Aug. 2 unveiled the final version of its fiscal 2019 hospital inpatient prospective payment system (IPPS) rule. This sets a 90-day reporting period for certain EHR reporting requirements for 2019 and 2020, a decision welcomed by the American Medical Association (AMA). (Separately, AMA and medical groups, including the Association of American Medical Colleges), are pressing CMS to shorten a reporting period set through the Medicare physician fee schedule to 90 days from a calendar year.)
In a statement to Medscape Medical News, AMA’s chair-elect Jesse M. Ehrenfeld, MD, MPH, said the group supports the “new direction of the promoting interoperability program and the 90-day reporting period” set by CMS in the hospital rule. In the rule, CMS also stripped measures that Ehrenfeld, who called for a shift away from scoring physicians based on how many boxes are checked, described as contributing to administrative burden and taking time away from patients.
“CMS must now remove requirements which solely measure how physicians use electronic health records,” said Ehrenfeld, a Vanderbilt University researcher who has studied how information technology can improve surgical safety and patient outcomes. VTN
INDICATIONS
Varithena® (polidocanol injectable foam) is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena® improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

IMPORTANT SAFETY INFORMATION
The use of Varithena® is contraindicated in patients with known allergy to polidocanol and those with acute thromboembolic disease. Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately. Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease may be at increased risk for tissue ischemia. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately. Varithena® can cause venous thrombosis. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis. The most common adverse events observed were pain/discomfort in extremity, retained coagulum, injection site hematoma or pain, common femoral vein thrombus extension, superficial thrombophlebitis, and deep vein thrombosis. Physicians administering Varithena® must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease and be trained in the administration of Varithena®.

For Full Prescribing Information visit Varithena.com

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Varithena® (polidocanol injectable foam), for intravenous use
Initial U.S. Approval: 2013

Brief Summary of Prescribing Information. For complete Prescribing Information, consult official package insert.

INDICATIONS AND USAGE
Varithena® (polidocanol injectable foam) is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena® improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

DOSE AND ADMINISTRATION
Varithena® is intended for intravenous injection using ultrasound guidance, administered via a single cannula into the lumen of the target incompetent trunk veins or by direct injection into varicosities.

Physicians administering Varithena® must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease, and be trained in the administration of Varithena®.

CONTRAINDICATIONS
The use of Varithena® is contraindicated in patients with:
- known allergy to polidocanol [see Warnings and Precautions]
- acute thromboembolic disease

WARNINGS AND PRECAUTIONS
Anaphylaxis
Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately.

Tissue Ischemia and Necrosis
Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease, such as marked peripheral arteriosclerosis or thromboangiitis obliterans (Buerger’s Disease) may be at increased risk for tissue ischemia. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately.

Venous Thrombosis
Varithena® can cause venous thrombosis [see Adverse Reactions]. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical trials are conducted under controlled but widely varying conditions, adverse reaction rates observed in clinical trials of Varithena® cannot be directly compared to rates in the clinical trials of other drugs or procedures and may not reflect the rates observed in practice.

A total of 1333 patients in 12 clinical trials were evaluated for safety when treated with Varithena® at dose concentrations of 0.125%, 0.5%, 1.0% or 2.0%, including 437 patients treated with Varithena® in placebo-controlled clinical trials.

Adverse reactions occurring in 3% more patients receiving Varithena® 1% than receiving placebo are shown in Table 1.

Table 1: Treatment-emergent adverse reactions (3% more on Varithena® 1% than on placebo) through Week 8 (n=588)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=151)</th>
<th>Varithena® 1.0% (N=149)</th>
<th>Pooled® Varithena® (N=437)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain in extremity</td>
<td>14 (9.3)</td>
<td>23 (15.8)</td>
<td>65 (14.9)</td>
</tr>
<tr>
<td>Infusion site thrombosis</td>
<td>0</td>
<td>24 (15.1)</td>
<td>46 (10.5)</td>
</tr>
<tr>
<td>Contusion/injection site hematoma</td>
<td>9 (6.0)</td>
<td>23 (15.4)</td>
<td>38 (8.7)</td>
</tr>
<tr>
<td>Lumb dissemination</td>
<td>5 (3.3)</td>
<td>18 (12.1)</td>
<td>32 (7.3)</td>
</tr>
<tr>
<td>Thrombosis of injection site pain</td>
<td>5 (3.3)</td>
<td>16 (11.3)</td>
<td>36 (8.0)</td>
</tr>
<tr>
<td>Venous thrombosis limb</td>
<td>0</td>
<td>12 (8.1)</td>
<td>24 (5.5)</td>
</tr>
<tr>
<td>Thrombophlebitis superficial</td>
<td>2 (1.3)</td>
<td>5 (3.5)</td>
<td>10 (2.3)</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>0</td>
<td>7 (4.7)</td>
<td>10 (2.3)</td>
</tr>
</tbody>
</table>

a Includes Varithena® 0.125%, 0.5%, 1.0%, and 2.0% from the placebo-controlled trials.

b Retained coagulum.

c Common femoral vein thrombus extension (non-obstructive thrombi starting in the superficial vein and extending into the common femoral vein).

In Varithena®-treated patients, 80% of pain events in the treated extremity resolved within 1 week.

In the 1333 patients treated with Varithena®, the following venous thrombus adverse events occurred: common femoral vein thrombus extension (2.9%), proximal deep vein thrombosis (DVT) (1.7%), distal DVT (1.1%), isolated gastrocnemius and soleal vein thrombosis (1.4%). Proximal symptomatic venous thrombosis occurred in <1% of patients treated with Varithena®.

Approximately half (49%) of patients with thrombi received treatment with anticoagulants.

Neurologic adverse events (cerebrovascular accident, migraines) have been reported in patients following administration of physician compounded foam sclerosants. None of the 1333 patients in the Varithena® trials experienced clinically important neurological or visual adverse events suggestive of cerebral gas embolism. The incidence of neurologic and visual adverse events within 1 day of treatment in the placebo-controlled studies was 2.7% in the pooled Varithena® group and 4.0% in the placebo groups.

Skin discoloration adverse events were reported in 1.1% of the pooled Varithena® group and 0.7% of the placebo group in the placebo-controlled studies.

DRUG INTERACTIONS
No specific drug interaction studies have been performed. There are no known drug interactions with Varithena®.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category C.

There are no adequate and well-controlled studies of Varithena® in pregnant women. Do not use Varithena® during pregnancy.

Labor and Delivery
The effects of Varithena® on labor and delivery in pregnant women are unknown.

Nursing Mothers
It is not known whether polidocanol, the active pharmaceutical ingredient in Varithena®, is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, avoid administering Varithena® to a nursing woman.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
Of the 1333 subjects in clinical studies treated with Varithena®, 9.1% (n=121) were ≥65 years of age. No clinically important differences in safety or efficacy were observed between older and younger patients in all studies.

OVERDOSAGE
There are no known cases of overdosage with Varithena®. In clinical studies, total volumes of up to 60 mL of Varithena® per treatment session have been administered.

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VIVA THE VEINS!
The VEINS, a 2-day course in VIVA 2018, offers interdisciplinary vascular education

By Larry Storer

For the past 16 years, world-renowned specialists from across the vascular intervention and medicine spectrum have converged in Las Vegas to make VIVA (Vascular Interventional Advances) a growing educational event for the dedicated vascular specialist. This year VIVA 2018 will be Nov. 5-8 at the Wynn Las Vegas.

The VEINS (Venous Endovascular Interventional Strategies) is a two-day interactive course Nov. 5-6, focusing on pulmonary embolism treatment, controversies in VTE management, management of superficial venous disease and late state venous disease. The VEINS will conclude two days before the American College of Phlebology opens its 32nd Annual Congress in Nashville (See related article on page 1).

The VEINS course directors, Raghu Kolluri, MD, and John Kaufman, MD, will head a multidisciplinary faculty of 44 vascular medical specialists as they addressing the challenges of preventing, diagnosing and managing venous disease. The VEINS will explore the complexities of caring for a diverse and growing patient population.

Attending will be Interventional cardiologists, vascular medicine specialists, Interventional radiologists, vascular surgeons, internists, fellows, nurses, nurse practitioners, physician assistants and technologists interested in exploring cutting-edge and future strategies for venous treatment, and those who are interested in a complete understanding of venous disease.

Sessions on Monday, Nov. 5 include two major topics: Pharmacorx and Nurses + Tech. The days moderated sessions include Pharmacotherapy in PAD and New Medical Approaches in PVD; and in Nurses + Techs sessions include Chronic Limb Threatening Ischemia, Carotid Stenosis and Stroke, Venous Disease, New Tools, Tips and Tricks for managing Complex Vascular Issues, and Vascular Pharmacorx – The Road Ahead.

On Tuesday, Nov. 6, moderated sessions on “Critical Limb Ischemia” include: CLI Basics in 2018; The ABCs of CLI Intervention; Controversies in CLI; Overcoming Challenges and Achieving Success; and Case in Point – Expert Management of the Hardest CLI Patients. Sessions under the heading of “Aortic Armageddon” include: Current Challenges and Unmet Needs: Ongoing Dilemmas in Tevar; and Managing Complications. The fellows and residents’ session that will wind up the day is How to Find the Right First Job and Set Yourself Up for Success.

Upon completion of The VEINS, the targeted learners should be able to:

• Understand medical, endovascular and surgical therapies for chronic venous disease.
• Appreciate the role of noninvasive technologies, including physiologic testing, duplex ultrasonography, and CT and MR venography, and invasive diagnostics, such as intravascular ultrasound, in the management of venous disease.
• Appreciate the available therapeutic options and understand contemporary data in the management of superficial and deep vein disease.
• Analyze the guidelines and available data and complications arising from the placement of IVC filters.

Dr. Nick Morrison joins Center for Vein Restoration

Nick Morrison MD, FACS, FACPh, has joined the Center for Vein Restoration (CVR) in Phoenix.

Dr. Morrison is widely known as a researcher, author and physician treating venous disease, and his research and many publications will add to the clinical expertise of the organization.

CVR founder and CEO Sanjiv Lakhanpal, MD, said that as the current president of the International Union of Phlebology and past president of the American College of Phlebology, Dr. Morrison provides an unparalleled perspective on the scope of venous and lymphatic disease and its treatments.

“Dr. Morrison and his decades of being on the forefront of advancing the care of patients with venous disorders will enable CVR to further our mission of improving the human condition by providing state of the art vascular care in a compassionate & cost-effective manner,” Dr. Lakhanpal said.

Dr. Morrison is co-founder of the Morrison Training Institute and Morrison Vein Institute in Tempe, Arizona. He is a member of the American College of Phlebology Foundation Board of Directors, and director of the medical volunteer organization Amigos de Saul.

Dr. Morrison, who has been practicing for 37 years, said he was excited to get started with such a purposeful organization and bring about more positive change to people who are suffering with venous and lymphatic disease and the many complications that result from it.

READ MORE: centerforvein.com or call 800-349-5347.

Metactive touts peripheral artery research results

Kieran Murphy, professor, vice chair and director of research in the department of medical imaging at the University of Toronto, has presented new nonclinical results from Metactive Medical Inc. peripheral vascular research program. Metactive is a Kansas medical device company developing products for the treatment of neurovascular and peripheral vascular diseases.

According to Metactive President and CEO F. Nicholas Franano, MD, the Blockstent Microcatheter is a peripheral vascular embolization device comprising a 3.3 Fr, highly flexible .014” guidewire-compatible microcatheter delivery system and an inflatable, detachable balloon that delivers immediate, complete, and lasting vessel occlusion.

Murphy presented results comparing the use of Metactive’s Blockstent Microcatheter, an over-the-wire embolic device for the occlusion of peripheral arteries and veins, with commercially available vascular plugs and coils to occlude axillary and internal thoracic arteries in a well-accepted model.

Results from the study show that the placement of the Blockstent Microcatheter resulted in immediate and complete occlusion in all eight treatments. At 4-week follow-up, histology showed a mean arterial occlusion of 98 percent. No arteries treated with Amplatzer Vascular Plugs or Nester Coils showed immediate occlusion by angiography.

The average time to achieve complete occlusion was approximately 30 minutes for the Amplatzer Vascular Plugs and approximately 4 minutes for the Nester Coils. At 4-week follow up, arteries treated with the Amplatzer Vascular Plugs showed 57 percent mean occlusion and arteries treated with Nester Coils showed 81 percent mean occlusion, by histology.

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**OPTALYSE PE**

*Published study demonstrates bilateral pulmonary embolism treatment effective, safe*

BTG plc, the global healthcare company, highlighted the publication of OPTALYSE PE trial results in JACC: Cardiovascular Interventions.

The published findings further confirm that bilateral pulmonary embolism treated in as little as two hours with EKOS Acoustic Pulse Thrombolysis therapy shows significant improvement in RV/LV ratio and with a very low one-year mortality rate of 2 percent and an equally low one-year recurrent PE rate of 2 percent. This is with considerably less tissue plasminogen activator (tPA) than used in previous studies, as low as 8mg total.

“The publication of OPTALYSE PE further solidifies these findings as a potential new standard for PE treatment,” said study author Victor Tapson, MD with the Pulmonary and Critical Care Division at Cedars-Sinai Medical Center in Los Angeles. “The body of clinical evidence, including the ULTIMA and SEATTLE II studies, reveals an opportunity to advance PE patient care with more flexible and efficient deployment of intensive care, drug and clinician time, along with enhanced safety and speed.”

OPTALYSE PE included 101 patients with acute proximal PE at 17 centers randomized to one of four cohorts of EKOS therapy.

The first cohort received 4mg per device of a standard clot dissolving medication called tissue plasminogen activator (tPA) over two hours. The second cohort received 4mg tPA per device over four hours. The third cohort received 6mg tPA per device over six hours and the fourth cohort received 12mg tPA per device for six hours.

All four cohorts saw significant reduction in the main indicator of right heart strain from PE, measured as right ventricular to left ventricular diameter ratio (RV/LV), by approximately 23 percent to 26 percent. This is consistent with previous studies where treatment took place from 12 to 24 hours. The OPTALYSE PE results included a very low bleeding rate of 3 percent compared to 10 percent in the SEATTLE II study, in which patients received treatment with 24mg for 12 or 24 hours. One-year data from OPTALYSE PE demonstrates improved quality of life of more than 30 percent.

In addition to Dr. Tapson, the study’s authors include Gregory Piazza, MD, and Samuel Goldhaber, MD, of Brigham and Women’s Hospital in Boston; Keith Sterling of Inova Alexandria Hospital, Alexandria, Virginia, Kenneth Oureil, MD, of Syntacx in New York; and Ping-Yu Liu of the Fred Hutchinson Cancer Center in Seattle.

“The published OPTALYSE PE study shows EKOS therapy achieves similar efficacy as previously successful EKOS trials, as well as better safety, in as little as two hours and with low tPA doses,” said Lynn Allen, vice president of clinical affairs for BTG Vascular.

“The favorable long-term mortality and QOL data and low recurrent PE rate after EKOS therapy are compelling findings when you consider that treating with systemic thrombolysis or angioplasty,2 comparable trials have found a one-year mortality at 8 percent to 10 percent.”

A separate registry study underway, KNOCKOUT PE, is intended to measure how institutions are adopting OPTALYSE PE and this new standard of care. The study is expected to include as many as 100 centers globally and is currently enrolling.

The EKOS system uses ultrasonic waves in combination with clot-dissolving thrombolytic drugs to effectively dissolve clots and restore healthy heart function and blood flow.

In clinical studies, EKOS therapy has been shown to speed time-to-clot dissolution, increase clot removal and enhance clinical improvement compared to either standard catheter-directed drug therapy or thrombectomy. EKOS therapy requires significantly shorter treatment times and less thrombolytic compared to standard catheter-directed drug therapy, lowering the risk of bleeding and other complications.

**THE TRIALS**

Trial summaries include:

- **ULTIMA**, a randomized controlled study comparing EKOS therapy to anticoagulation, looked at 59 patients across eight centers and proved that the EKOS regimen was superior to anticoagulation alone.
- **SEATTLE II**, a prospective single-arm study, looked at 150 patients across 22 centers and demonstrated improvement in RV/LV ratio, pulmonary hypertension and angiographic obstruction with EKOS therapy.
- **OPTALYSE PE** included 101 patients with acute proximal PE at 17 centers randomized to one of four treatment cohorts.

**READ MORE:** btgplc.com

**RESOURCES**


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**RECURRENT PE**

*BTG acquires Novate Medical to add Sentry to EKOS System in PE treatment portfolio*

The global healthcare company BTG plc has acquired Novate Medical Ltd., a medical device company incorporated in the Republic of Ireland that is focused on the prevention of pulmonary embolism in patients at high risk of venous thromboembolic events.

Novate has developed Sentry, the first bioconvertible inferior vena cava filter, which has recently been granted 510(k) regulatory clearance in the United States. Sentry’s 12-month clinical trial data demonstrated no new symptomatic PE and no evidence of device migration, tilt, fracture, perforation or embolization, complications which have been associated with some other IVC filters.

The unique bioconversion feature eliminates the need for an additional interventional procedure to retrieve the device.

Sentry is indicated for the prevention of recurrent pulmonary embolism, or the blockage of a major artery in the lung usually caused by a blood clot that has traveled from elsewhere in the body. The Sentry filter is indicated for patients at high risk of PE for whom anticoagulants have failed or are contraindicated, and in patients requiring emergency treatment for PE.

BTG plans to launch Sentry in the United States in the second half of this fiscal year and will sell the device through its existing vascular sales force, according to Louise Makin, BTG’s CEO.

“This bolt-on acquisition further enhances BTG’s strength in the vascular space,” Makin said. “Novate’s unique IVC filter offers our existing customers a highly complementary product in the management of PE.”

BTG paid $20 million in cash to acquire Novate and may be required to pay additional cash considerations up to $130 million if certain commercial and sales-related milestones are met. The transaction is expected to be accretive to adjusted EPS from the second full year of ownership.

The Sentry device joins a portfolio that includes the Ekos Control Unit 4.0, a BTG system that uses acoustic pulses to dissolve blood clots in patients with PE. BTG acquired that device in its $180 million acquisition of Ekos Corp. in 2013.

BTG has a successful record of growth through acquisition. BTG’s last acquisition was U.S.-based Roxwood Medical, another bolt-on in late 2017 which makes cardiovascular specialty catheters. It paid $65 million up front with an additional $15 for commercial milestones.

In 2016, the company paid $84.5 million up front for a cryoablation company, Galil Medical.

**Research aims to end stents in heart surgery**

A strategy for keeping blood vessels open following angioplasties and bypasses has been developed by researchers from the University of Wisconsin-Madison and Ohio State University. It was recently published in the Biomaterials journal.

When patients have clogged arteries, they usually have to go through a procedure to open the vessel and have a stent placed inside the vessel to keep it open.

Some stents are also designed to release drugs to prevent future clogs. Drug-eluting stents may stop the overgrowth of smooth muscle cells that could cause vessel re-narrowing, but the drugs could also poison the endothelial cells that form the inner wall of the blood vessel. The presence of a stent in the body can also increase the risk of blood clots.

The researchers suggest that they can suppress smooth muscle cell growth while protecting endothelial cells and allow them to regrow after surgery. One of the researchers, Shaoquin Gong, developed drug-loaded nanoclusters coated with a biomembrane that can safely deliver a drug to allow for regrowth.

Doctors can inject the nanoparticle through an IV as the biomembrane coating guides the drug to a targeted location. “You want to deliver your drug more specifically to the injured vasculature,” Gong explained.

Gong and the other researchers received a $2.4 million grant from the National Institutes of Health to create a stent-free approach with nanoparticles for drug delivery.
Center for Vein Restoration

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¹ Gibson K, Adelman M, Elias S, Hager E, Dexter D, Vayuvegula S, Chopra P. A Prospective Safety and Effectiveness Study Using the Endovenous Laser Ablation Technique with the 400 micron Optical Fiber (SeCure Study).

To be presented at the American College of Phlebology Annual Congress, Nashville, TN.
Stradis Healthcare has headquarters in Peachtree Corners, Ga., with a facility in Waukegan, Ill.

ISO 13485:2016

The Stradis Waukegan, Ill., facility specializes in contract medical device development, manufacturing and packaging services. The facility and staff earned ISO 13485 certification from the British Standard Institution (BSI).

The ISO 13485:2016 certification represents the company’s quality management system maintains standards that meet or exceed requirements specific to the medical device industry, including contract services for packaging, manufacturing, fulfillment, design and testing.

The International Organization for Standardization (ISO) is the world’s largest developer and publisher of international standards for the implementation of quality management systems. The ISO quality management standard embodies the requirements for a comprehensive management system for the design and manufacture of medical devices.

“Achieving 13485 certification demonstrates Stradis’ ongoing commitment to raising the bar on an already robust quality system as well as our commitment to patients and customers regarding our quality,” COO Joseph Trznadel said. “Additionally, we felt that receiving certification, coupled with a top down pledge to our employees, reinforced our commitment and expectations around quality.”

Trznadel said these certifications are a testament to the high level of performance and quality control expected at Stradis. “With an expanding portfolio of customers, health indications and reach, this level of attention to detail is important to ensuring that the quality, safety and efficacy meet and exceed requirements.”

WES OWEN

Owen will lead Stradis Healthcare’s Medical Device Packaging Division. CEO Jeff Jacobs said continuous growth and increasing demand from customers has led Stradis to add to its leadership team with a focus on this space.

“Wes brings a wealth of knowledge and experience to Stradis in an aspect of our business that is poised for tremendous growth,” Jacobs said. “He will drive the sales and marketing arm of this division and I am thrilled he is joining our team.”

Before joining Stradis, Owen has held sales and business development positions for MWV Healthcare Packaging (now WestRock) with an emphasis on clinical trials and helping improve patient experience and adherence. In addition to his other sales and management roles in the packaging industry, he spent a portion of his career selling pharmaceuticals for Bristol Myers Squibb.

Owen said he was excited to join Stradis. “Their expertise in healthcare packaging and other manufacturing services will help medical device customers bring their products to market faster and more cost-effectively,” he said.

CHRIS DOBBINS

Dobbins has joined the Stradis financial leadership team as vice president of finance. He has 18 years’ experience in financial management with an emphasis on manufacturing. Before coming to Stradis, Dobbins was director of financial operations for Medline.

Stradis President Adam Sokol said strong financial leadership is a key element to successfully executing strategic growth at Stradis.

“Chris brings a multitude of financial expertise and leadership,” Sokol said. “He has a track record for improving financial efficiencies, including key roles in leading transformational changes.”

“Stradis has enhanced its capabilities by adding a seventh production line in the Chicago location. This will be a key factor towards our strategic growth as we focus on growing the Contract Manufacturing Division.”

Dobbins said it is an exciting time to be joining the team and that he look forward to all the company will accomplish.

“The projects that Stradis is looking to undertake in the next several years are those transformational events that will take the company to the next level,” Dobbins said. “From a financial standpoint, finding new efficiencies will enable us to improve our cost advantage, further solidifying our place in the market.”

WEBSITE OVERHAUL

Stradis also unveiled an overhaul of its website (stradishealthcare.com) this summer. The new site makes ample use of graphics and is easy to navigate with dropdown menus at the top. Stradis urges its employees to give back, and the home page features three organization that Stradis employees work with throughout the year: National Breast Cancer Foundation, Ronald McDonald House Charities, and Bosley’s Place (orphaned neonatal puppies).

READ MORE: stradishealthcare.com

RM details central catheter market

The “Central Venous Catheters Market (By Design; By Product Type; By Property: By Material; By Application; By End User, Hospitals, and Specialty Clinic): Global Industry Analysis, Size, Share, Growth, Trends, and Forecast 2016–2025” report has been added to Research and Markets’ offering.

The central venous catheters are alternatively known as central venous access devices or central lines catheter. It is a thin, long, hollow plastic tube which is inserted through an internal jugular vein, femoral vein, and subclavian vein. With the help of the catheter, nutrients and medications are given and it is also used for collecting the blood samples.

The global central venous catheters market was valued at around $740 million in 2016 and is expected to reach around $1.140 billion by the end of 2025, growing at a CAGR of 4.9 percent between 2017 and 2025.

The increasing number of cancer and cardiovascular patients, aging population, and people suffering from various chronic disorders are the factors that are driving the central venous catheters market.
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Vein911 CEO forms management service for independents

The CEO of Vein911 Vein Treatment Centers, 21-year cancer survivor and healthcare industry veteran Chris Pittman, MD, has launched Health Performance Specialists (HPS), a national Management Services Organization for independent physicians.

HPS helps independent physicians compete, succeed and thrive in today’s medical practice environment. HPS is designed to disrupt current healthcare delivery by uniting top quality independent physicians so they can profit from economies of scale without sacrificing the benefits of being small.

The benefits include group purchasing agreements, sharing operational and information technology solutions, leveraging common back office staff and analyzing healthcare data for better patient outcomes—benefits usually enjoyed by physicians employed by large groups or hospitals.

CEO and Managing Director Pittman said research shows that small, physician-owned practices provide better responsiveness to patient needs, have lower average cost per patient, and fewer hospital admissions than large, independent- and hospital-owned practices. Independent physicians are overburdened by the rising cost of government reporting, information technology and changing reimbursement models.

Many physicians have been forced to sell their practice and become employees of larger physician groups or hospitals.

He said HPS was created to level the playing field across the ever-consolidating medical-industrial complex. The HPS team assists or assumes any or all practice functions so physicians can remain engaged with their patients and provide the best care possible.

“The healthcare environment is changing like a tsunami, volcano or hurricane changes the landscape, making it difficult for doctors to continue operating independently,” Dr. Pittman said.

“Changing regulations, policies and technology are forcing doctors to spend a burdensome amount of time on administrative tasks and not enough on their patients. HPS is designed to help physicians who understand the value of small practices and share our mission of ‘Engaged Physicians. Delighted Patients.’”

Vein911, located throughout the Tampa Bay area and led by board-certified vein care specialist physicians, are providers of both medical and cosmetic vein care, including varicose veins, ankle swelling, restless legs, night cramps, venous leg ulcers, and cosmetically disturbing veins of the hands, face and legs.

Dr. Pittman, who has 25 years in medical practice and practice management, is a nationally recognized expert in healthcare policy, medical economics and health information technology, including EMR, medical informatics, and telemedicine. He said executive team members are recognized experts in digital media, design thinking, operations and financial intelligence. VTN READ MORE: healthperformancespecialists.com/

Venti acquired

continued from page 1

obstructions, often caused by conditions such as deep vein thrombosis, post thrombotic syndrome and May-Thurner syndrome, can prevent proper blood circulation and cause patients to experience pain, swelling, ulcers and a diminished quality of life.

Physicians often choose to open the obstructed vessel with a stent to reinstate proper blood flow to the heart and lungs and reduce a patient’s symptoms.

The self-expanding, nitinol Vici stent system was developed specifically for use in the venous anatomy, which presents different challenges than placing stents in the arterial vascular system. The Vici stent is designed to withstand compression and maintain patency and flexibility over the course of a patient’s life expectancy.

“This stent system was designed with the distinctive demands of the venous system and built to provide physicians with a high-quality lumen across a variety of venous anatomies and disease states,” Jeff Elkins, president and CEO of Veniti, said. “We are excited to see this stent technology become even more accessible to physicians and the patients they treat under the leadership of Boston Scientific.”

The Vici stent system received the CE Mark in 2013 and Veniti submitted a premarket approval (PMA) application to the FDA in June, leveraging results from the recently completed VIRTUS pivotal study. Currently in the United States, there are no stent technologies specifically indicated for use in the peripheral venous system.

Jeff Mirvis, senior vice president and president of peripheral interventions at Boston Scientific, said that with the unique benefits of this differentiated technology and the strong experience of Boston Scientific in the overall venous market, he believes the Vici stent will become an important choice for physicians who choose stents to treat patients suffering from venous disease.

“And with our leading AngioJet thrombectomy platform and venous product pipeline, we look forward to meeting the needs of physicians treating both chronic and acute venous disease,” Mirvis said.

The acquisition of Veniti is expected to be immaterial to Boston Scientific adjusted earnings per share in 2018 and 2019, and accretive thereafter. On a general accepted accounting procedures (GAAP) basis for 2019 and subsequent years, the transaction is expected to be less accretive, or more dilutive as the case may be, due to amortization expense and acquisition-related net charges. For 2018 on a GAAP basis, the transaction is expected to be accretive due to a one-time gain on prior investment. The completion of this transaction is imminent, subject to customary closing conditions.

The Vici Stent System is an investigational device in the United States and is not available for sale. VTN READ MORE: bostonscientific.com

ACP, 170 other med groups oppose provisions of CMS doctor payment rule

The American College of Phlebology joined the American Medical Association and about 170 other medical groups in sending a letter to Seema Verma, administrator of the Centers for Medicare and Medicaid Services, regarding the administration’s proposals included in the 2019 Medicare physician payment rule.

Acknowledging that excessive evaluation and management (E/M) codes do not just take time away from patient care, they also make it more difficult to locate medical information in patients’ records that is necessary to provide high quality care.

The letter proposed changing the required documentation of the patient’s history to focus only on the interval history since the previous visit; eliminating the requirement for physicians to re-document information that has already been documented in the patient’s record by practice staff or by the patient; and removing the need to justify providing a home visit instead of an office visit.

Regarding the proposal to collapse payment rates for eight office visit services for new and established patients down to two each, the letter opposed the implementation of this proposal because it could hurt physicians and other healthcare professionals in specialties that treat the sickest patients, as well as those who provide comprehensive primary care, ultimately jeopardizing patients’ access to care.

The physician organizations also urged that the new multiple service payment reduction policy in the proposed rule not be adopted because the issue of multiple services on the same day of service was factored into prior valuations of the affected codes.

“The proposal also has significant impact on certain services, such as chemotherapy administration, that may be an unintended consequence of altering the current practice expense methodology to accommodate the proposal.”

In addition to the medical groups’ letter, a broad coalition of patient advocates, made up of 126 patient and provider groups, sent their own letter to CMS urging the agency not to move forward with the plan because of negative effect on patient access. VTN

AuntMinnie.com, Voxmedya partner to produce CME courses for imaging

Continuing medical education is an essential part of any field of medicine. Health imaging is no different and with millions of procedures conducted annually, the need for healthcare professionals to be up-to-date on the latest technology and diagnosis remains critical.

AuntMinnie.com, in conjunction with Voxmedya LLC, have teamed together to provide continuing medical education (CME) credit for physicians and other healthcare professionals.

The ability for a radiologist to identify a variety of clinical manifestations of a diagnosis enabling a proper diagnosis is critical to patient care. Voxmedya’s CME Program is intended to enhance physician clinical performance and, ultimately, to positively influence patient outcomes.

The University of Pennsylvania Department of Radiology and the University of Indiana Department of Radiology received corporate grants from AuntMinnie.com for contributing case materials for this educational activity. Scott Williams, MD and a radiologist in Newport Beach, California, prepared the CME course.

The purpose of Voxmedya’s CME Program is to disseminate dynamic, fair-balanced, and independent continuing educational activities to physicians and other health professionals using modalities that suit the demographics of the target audience.

The target audiences for continuing educational activities include primary care and specialty care physicians corresponding to identified gaps in clinical decision-making and/or gaps in clinical practice. VTN READ MORE: cmeplanet.com
Senate plan may protect patients from surprise medical bills

A bipartisan group of senators unveiled a plan Sept. 19 to protect patients from surprise bills and high charges from hospitals or doctors who are not in their insurance networks. The bill is Protecting Patients from Surprise Medical Bills Act.

The draft legislation, which sponsors said is designed to prevent medical bankruptcies, targets three key consumer concerns.

• **Treatment** for an emergency by a doctor who is not part of the patient’s insurance network at a hospital that is also outside that network. The patients would be required to pay out-of-pocket the amount required by their insurance plan. The hospital or doctor could not bill the patient for the remainder of the bill, a practice known as “balance billing.” The hospital and doctor could seek additional payments from the patient’s insurer under state regulations or through a formula established in the legislation.

• **Treatment** by an out-of-network doctor or other provider at a hospital that is in the patient’s insurance network. Patients would pay only what is required by their plans. Again, the doctors could seek more payments from the plans based on formulas set up by state rules or through the federal formula.

• **Mandated** notification to emergency patients, once they are stabilized, that they could run up excess charges if they are in an out-of-network hospital. The patients would be required to sign a statement acknowledging that they had been told their insurance might not cover their expenses, and they could seek treatment elsewhere.

The media has widely covered a $17,850 urine test and a $109,000 bill after a heart attack.

“Our proposal protects patients in those emergency situations where current law does not, so that they don’t receive a surprise bill that is basically uncapped by anything but a sense of shame,” Sen. Bill Cassidy (R-La.) said in his announcement about the legislation.

“Balance billing is ripe for a federal solution,” said Kevin Lucia, a senior research professor at Georgetown University’s Center on Health Insurance Reforms. States regulate only some health plans and that “leaves open a vast number of people that aren’t covered by those laws.” VTN
Intact Vascular summarizes results of iDissection Classification trial

Intact Vascular Inc., a developer of medical devices for minimally invasive peripheral vascular procedures in Wayne, Penn., has released the iDissection Classification trial results.

Post-percutaneous transluminal angioplasty (PTA) dissections are often overlooked, underdiagnosed and left untreated. These dissections can compromise clinical outcomes in both the short and long term. The use of intravascular ultrasound (IVUS) has been found to help visualize the presence and severity of dissections not typically seen on angiography.

In Intact Vascular’s iDissection study, 15 patients with femoropopliteal disease were treated with arterectomy and adjunctive PTA. Angiographic and IVUS images utilizing Philips’s ChromaFlo Imaging were obtained at baseline, post-arterectomy and post-angioplasty and evaluated for the presence and severity of dissections. Dissections seen on angiography were graded per the NHLBI scale, and IVUS images were graded using the iDissection classification. All images were independently adjudicated by multiple core laboratories. While angiography identified eight dissections, IVUS revealed 46 dissections – a ratio of 6:1.

The iDissection study reveals that significant dissections may not be thoroughly observed with angiography yet are substantially more visible when using IVUS, potentially altering the course of patient treatment in real-time.

“Angiography is a suboptimal test to visualize the peripheral arteries,” said Nicolas W. Shammas, MD, founder and research director of the Midwest Cardiovascular Research Foundation in Davenport, Iowa.

“It underestimates vessel size, the presence and extent of calcium, thrombus and stenosis, and does not give a clear picture of optimal stent expansion and apposition. Moreover, the iDissection data confirms that angiography seriously underestimates the presence and severity of dissections following endovascular intervention. “The iDissection study validates the need for more sophisticated imaging, such as IVUS, to evaluate acute procedural results,” Dr. Shammas said.

Bruce Shook, Intact Vascular’s president and CEO, was pleased with the results from the iDissection study and the expanding evidence incorporating IVUS as a useful tool to identify dissections often missed when using conventional angiography. “The Tack Endovascular System is specifically designed to repair dissections while leaving minimal metal in the artery, thereby reducing mechanical stress on the arterial wall and preserving future treatment options.”

Shook said Intact Vascular is sponsoring three clinical trials to evaluate its Tack Endovascular System: TOBA II, TOBA II BTK and TOBA III.

• TOBA II is investigating the combination of the Tack implant with both plain angioplasty balloons and the BARD Lutonix drug-coated balloon (DCB) in the arteries above the knee, and completed enrollment in March 2017.

• TOBA II BTK is investigating the combination of the Tack implant with plain balloon angioplasty in the arteries below the knee and is actively enrolling patients.

• TOBA III has completed enrollment in Europe and is investigating the combination of the Tack implant with the Medtronic IN.PACT Admiral (DCB), inclusive of long lesions.

The Tack Endovascular System, which is CE marked but not available for sale or use in the United States, is designed to improve peripheral balloon angioplasty results in the treatment of peripheral arterial disease. VTN

READ MORE: intactvascular.com

Dr. Lowell Kabnick to give keynote at Australasian APC

The 20th Annual Scientific Meeting of the Australasian College of Phlebology will be May 5-7 at the Pullman International in Cairns, Queensland.

Organizers have issued a call for abstracts for evidence-based research or case presentations before a Jan. 7, 2019, deadline. Notification of acceptances will be announced Jan. 21, 2019. Abstracts must be submitted at acpevents.eventssair.com/PresentationPortal/Account/ Login?ReturnUrl=%2FPresentationPortal%2FFacp2019%2FAbstracts.

Among the keynote lecturers will be Vein Therapy News Editorial Advisory Board member Lowell S. Kabnick, MD and president of the American Venous Forum Foundation and vice president of the International Union of Phlebology. Dr. Kabnick is the former director of the New York University Vein Center.

In addition to keynote lectures at the Annual Scientific Meeting, there will be presentations of original papers, panel discussions and the annual keeapd interactive debates. The Phlebology Refresher Course will be offered before the annual meeting on Saturday, May 4.

Program themes include: Anatomy; basic science research; case presentations; chronic cerebrospinal venous insufficiency; complex disease compression; cosmetic phlebology and cosmetic medicine; deep vein reconstruction; deep venous disease; dermatological; nursing in phlebology; edema; post-thrombotic syndrome; sclerotherapy; ulcers and wound care; ultrasound; vascular anomalies; venous interventions and surgery; venous hemodynamics; and venous thromboembolism.

Early bird registration for the 20th Annual Scientific Meeting opened Aug. 1 and closes Feb. 4, 2019. VTN


AI-powered blood test predicts PAD, revascular need in diabetic patients

An artificial intelligence-powered blood test consisting of one clinical variable and six biomarkers predicted with high accuracy the presence of peripheral artery disease and need for revascularization in patients with and without diabetes, researchers reported at the European Society of Cardiology Congress in Munich.

The HART PAD test (Prevencio) comprises one clinical variable – history of hypertension – plus concentrations of six biomarkers: midkine, kidney injury molecule-1, interleukin-23, follicle-stimulating hormone, angiopoietin-1 and eotaxin-1. The predictors of PAD included in the panel were identified via proteomics and machine learning.

Researchers analyzed the accuracy of the HART PAD test in a prospective cohort of 354 patients in the CASABLANCA study who were referred for diagnostic peripheral angiography and/or coronary angiography. Ninety-four patients had diabetes.

According to the findings, the HART PAD panel showed excellent performance for predicting peripheral stenosis greater than 50 percent in patients with diabetes. The area under the receiver operating characteristic curve was 0.85 for obstructive PAD. The higher the score, the greater the severity of angiographic stenosis.

For detection of PAD in patients with diabetes, the model performed with a sensitivity of 84 percent, specificity of 88 percent, positive predictive value of 76 percent and negative predictive value of 81 percent. Using a 5-point score, a score of 1 had a 100 percent negative predictive value and a score of 5 had a 95 percent positive predictive value, according to a press release.

In other findings, the HART PAD panel was highly accurate in predicting the need for revascularization in patients with PAD. A higher score was associated with shorter time to revascularization during 4.3 years of follow-up, according to the data reported here.

Results were comparable to those in patients without diabetes.

The researchers noted that a limitation of the study is the lack of biomarkers measured at a single point in time; thus, biomarker concentrations may not reflect levels and future time periods.

“Clinically, use of a tool such as this could act as a gatekeeper prior to imaging or invasive testing, thus reducing cost and exposures to intravenous contrast and/or ionizing radiation.

“The score may also be used to evaluate at-risk patients for risk of vascular complications; as such, a role in clinical trials to enrich for PAD-related events or to identify patients at risk for adverse effects of drug therapies is plausible,” McCarthy and colleagues wrote in the posted abstract. VTN

Thread lifts make big comeback for reasonable facelift

Thanks to technological advances, the so-called “thread lift” (using surgical thread to lift sagging skin) has made a comeback in popularity.

According to Plastic Surgery Practice, the new and improved thread lift is FDA-cleared and noninvasive, with little-to-no downtime.

The old threads from the ’90s, which often had negative side effects of scarring, infection and obvious lumps, were made of permanent barbed sutures. “If the knots made to anchor the threads were not performed correctly,” New York City dermatologist Shereene Idriss, MD, said, “it could lead to visible bumps and nodules.”

According to PSP, Dr. Paul Jarrod Frank, New York City dermatologist said the new sutures are composed of polydioxanone (PDO), which has been used safely in cardiovascular surgery for years; doesn't require anchoring; and are fully absorbed by the skin in six months without creating scar tissue. “Sutures, incisions and the risks are dramatically smaller than before.”

Performed under local anesthesia, today’s thread lifts take an hour or two. Sutures embedded with tiny cones are inserted into the skin using a small cannula, similar to those used for injecting fillers. The cones grab skin from underneath and lift it, while
The deal terms will have a Stryker subsidiary make the tender offer for all outstanding Invuity common stock shares at the cash price, subject to the usual terms and closing conditions. After the tender offer is successfully finished, using cash on hand, Stryker will absorb Invuity.

Spencer S. Stiles, Stryker group president for Neurotechnology, Instruments and Spine, said Invuity’s products in the single-use lighted instrumentation and hybrid energy markets offer “best-in-class illumination,” thanks to its patented Intelligent Photonics, making for safer surgery.” PhotonGuide Adapt lets surgeons seamlessly adjust the illumination along the length of the retractor to accommodate the surgical target. The pairing of the flexible illuminator with a range of compatible retractors optimizes visualization deep into the surgical cavity.

The Invuity acquisition comes on the heels of the Aug. 30 definitive merger agreement to acquire all shares of common stock of K2M Group Holdings for $27.50 per share, making the value of K2M about $1.4 billion.

K2M is a key player in the $10 billion spinal market, with yearly sales near $300 million, and brings to Stryker’s spine division a portfolio that will build up its offerings in the core spinal segment, including an attractive, minimally-invasive spine portfolio.

Kevin A. Lobo, Stryker chairman and CEO, said he believes K2M will significantly enhance Stryker’s presence with surgeons, patients and employees in both the spine and related neurotechnology markets.

VEIN THERAPY NEWS  ❯ OCTOBER/NOVEMBER 2018
Phlebologist compares practicing specialized medicine abroad

By Emma Stout, MD

I grew up in Italy, idolizing my grandfather, who was a surgeon. With his influence, I became passionate about the medical field, specifically practicing specialized medicine and providing the best possible care for all patients.

I am a general practitioner licensed to practice medicine in Colorado with a specialty in venous and lymphatic disorders. While I have not practiced medicine in Italy since 2005, my time providing care in both Italy and the United States has given me an exclusive perspective in the differences in healthcare practice between the United States and Italy. The two primary differences include:

• Insurance guidelines and restrictions.
• Patient attitudes and expectations.

INSURANCE GUIDELINES, RESTRICTIONS

In both the United States and Italy, the general mentality is that the United States has the best healthcare options available. Based on my experience and observations from my time practicing in Italy, their preference is to come to America for the best specialized healthcare; however, they sidestep the United States because of the high costs of healthcare here.

Italy practices socialized medicine. As noted in HealthcareManagement.org, “Italy has a national health plan (Servizio Sanitario Nazionale), which provides universal coverage for hospital and medical benefits.” Their taxes are higher but they receive no-cost healthcare. The downside to “free” healthcare is the wait time.

As noted later in this article, patients needing specialized care must wait, sometimes for several months, to see a physician because a gatekeeper (aka primary care) physician is responsible for providing citizens with access to secondary healthcare. Of course, cash is king and those patients with extra cash available to bypass the public healthcare system and visit private practice physicians typically bypass those wait lists.

In the United States where we have many more restrictions and guidelines to practicing medicine, it’s challenging for physicians to practice in the “right direction.” What I mean by that is we want to practice medicine as compassionate human beings and not as people following government guidelines that sometimes seem designed to benefit large drug companies and healthcare organizations rather than patients. We want to do what’s best for the patients versus what’s best for their insurance coverage.

I recall a patient here in the United States that desperately needed a hip replacement. Because she had no insurance, the cost of her hip replacement was going to be $250,000. She ended up temporarily moving back to her home country of Italy and received the hip replacement for free (excluding the health...
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You are encouraged to report any suspected adverse events. To report SUSPECTED ADVERSE REACTIONS, contact your Healthcare Provider, Merz North America at 1-866-862-1211, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please ask your healthcare provider or visit www.asclera.com for Full Prescribing Information.

1. It is estimated that at least 20 to 25 million Americans have varicose veins. *What you need to know about risk factors, symptoms, and treatment* Focus on Varicose Veins. 2012. Vascular Disease Foundation.

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Anaphylaxis: Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are most frequent with use of larger volumes (> 3 mL). The dose of polidocanol should therefore be minimized. Please notify your healthcare provider if you have a known history of severe allergies or allergy to polidocanol.

Venous Thrombosis and Pulmonary Embolism: Asclera can cause venous thrombosis and subsequent pulmonary embolism or other thrombotic events. Your physician should follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization or pregnancy are at increased risk for developing thrombosis.

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Accidental injection into an artery can cause severe necrosis, ischemia or gangrene.

Care should be taken in intravenous needle placement and the smallest effective volume at each injection site should be used. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately.

After the injection session is completed, apply compression with a stocking or bandage, and walk for 15-20 minutes. Your healthcare provider will provide monitoring during this period to treat any possible anaphylactic or allergic reactions.

Maintain compression for 2 to 3 days after treatment of spider veins and for 5 to 7 days for reticular veins, or as directed by your Healthcare Provider. For extensive varicocities, longer compression treatment with compression bandages or a gradient compression stocking of a higher compression class is recommended. Post-treatment compression is necessary to reduce the risk of deep vein thrombosis.

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How many times have these words been uttered by potential patients upon arrival to our vein clinics? Yet, the majority of our patients have no earthly idea what is covered by their individual insurance plan or even what those words “benefits” and “medical necessity” even mean.

We, as providers, are all aware of the criteria for medical necessity regarding insurance coverage for therapeutic options in the treatment of venous reflux. Seems that we, as providers, follow the rules: Use documentation and evidence-based peer-reviewed studies to form our treatment plan decisions.

Despite our best efforts to offer therapeutic options to our patients for venous reflux, several obstacles must be addressed before proceeding with treatment.

But even though the patient meets criteria for medical necessity, multiple financial constraints circumvent “medical necessity.” None of these obstacles have any bearing on medical treatment, just financial constraints. Yet, they have a profound effect on availability of care to our patients.

Some of the obstacles include:

1) Outrageous deductibles.
2) Family out of pocket expenses.
3) Plan limitations.
4) Procedures MUST be completed in a designated time period; if not completed, formal evaluation must start over from day one with a baseline review.
5) Request for independent patient evaluation by a primary care gate keeper prior to predetermination.
6) Great saphenous and small saphenous veins MUST be addressed and treated during a single therapeutic procedure.
7) Policy riders to exclude future treatment options for varicose veins and venous reflux.

The list is ever growing and complex. How can we stop the madness? Unfortunately, at this point, we can’t. But we can offer assistance to our patients to enable them to navigate the complex maze of insurance coverage and financial constraints.

Let’s look at some options and plan strategies:

1) Outrageous deductibles
2) Family out of pocket expenses

Often patients and providers do not fully understand the deductible requirements imposed by specific insurance plans. These requirements are NOT universal. Requirements for coverage are as varied as collateral branches of the great saphenous vein.

With most plans, patients are required to meet deductible and out of pocket expenses for their individual coverage as defined by their individual insurance plan. Then payment for the procedures can be covered. This may be coverage at 100 percent or not, depending on each individual plan.

In a proactive attempt to help each patient, our office staff completes a query to the insurance provider prior to the patient’s baseline office visit. This information is then discussed with the patient from the initial presentation. This has nothing to do with medical care; but is offered as a courtesy to our patients.

By James White, MD

Some plans offer different payment schemes depending on whether the procedures are completed in an office setting or a hospital setting. Some plans have different co-pays based on the provider status, specialists vs. non-specialist. Confusing? You bet it is confusing.

Out of pocket expenses have steadily increased over the last 15 years. In 2005, the average out of pocket expense for patients in our region averaged less than $800 for endovenous ablation of bilateral great and small saphenous veins. Today, our patients routinely expect to have out of pocket expenses in excess of $5,000 per year for similar endovenous ablation procedures.

There are in-house financing options and cash payment options.

Some patients may choose to complete the endovenous ablation procedures on a cash payment basis; as they are aware that their individual deductible is very high and that none of their annual deductible has been accrued. This is easy and basic.

We now have control over the patient-provider relationship and can set the fee for service. However, this places the payment burden on the patient without benefit of payment going toward deductible amounts.

Some of the options for self-pay include: Flex Health Savings Accounts-Flexible spending accounts (FSA) and health savings accounts (HSA).

FSA and HSA are both great healthcare plans that reduce an employee’s income tax liability and allow them to pay for medically-related expenses with pre-tax dollars. Many businesses offer HSA and FSA to their employees as a benefit in lieu of more comprehensive medical insurance plans.

You can also offer healthcare financing credit options such as Care Credit and Prosper Health Care Lending.

Prosper Healthcare Lending provides patients with several different options for financing that best suit their individual needs-different terms, interest rates, and monthly payment amounts. Prosper Healthcare Lending performs a “soft credit” check that will not affect the patient’s credit score. If patients choose Prosper, the funds are sent directly to the patient and the patient then pays the office as a cash payment basis fee for service. The office does not incur any fees for the Prosper Healthcare Lending, but patients must make loans greater than $2,000 to be eligible to use Prosper Healthcare Lending.

Care Credit offers several zero percent interest options to patients for 6- to 12-month time periods. The office is charged a fee for the patient to use Care Credit. Thus, the zero percent credit to the patient is covered by the office-related fees for service. But a word of caution: Counsel your patient in regard to high interest rates that will be imposed if the amount financed exceeds the initial time period for repayment.

Help your patient and family navigate the deductible maze.

If approaching the end of the deductible year, it may be prudent for the patient to wait until the following deductible year in order to reduce out of pocket expenses. In other words, it would not be prudent to have one endovenous ablation procedure completed in December and have the contralateral limb treated in January encompassing two deductible calendar years. It would be better for this patient to wait and have both endovenous ablation procedures completed in the same calendar year.

Varicose veins and venous reflux disease are chronic problems, often times not urgent or emergent. Insurance providers understand this and are not compelled to make it easy for the patient to proceed with endovenous ablation nor do they provide patient advocate assistance. They are more than happy to accept double deductible payment for the endovenous procedures.

3) Plan limitations

Many of our patients work for large corporations that offer benefit insurance coverage to their employees. Insurance coverage plans are bid each year. Often the insurance plan offered goes to the lowest bidder. To be competitive, insurance providers add restrictions and limitations in the fine print.

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Our office provides patient with peer review data regarding the need to treat all sources of venous reflux. Armed with that information, we recommend that the patient contact human resources at their place of employment. We recommend that they, the patient, file a complaint and educate other employees as to the limitations imposed by their current insurance plan.
We encourage the patient to explore options for plan changes in conjunction with human resources and employee management. Often, human resource personnel take into consideration requests from employees regarding future insurance coverage options.

4) Procedures MUST be completed in a designated time; if not completed, formal evaluation must start over from day one with a baseline review.

Educate patients in regard to time limitations imposed by their insurance plans. Place patients on an update list with imposed time limits. This list needs to be reviewed on a regular interval. Dedicate staff to request time extensions to avoid start over from day one with a baseline review.

And the newest ploys:

5) Request for independent patient evaluation by a primary care gatekeeper prior to predetermination

Contact insurance medical director and request name and qualifications of the primary care gatekeeper who is mandated to complete the independent review. Speak with the primary gatekeeper as a peer-to-peer.

6) Great saphenous and small saphenous veins MUST be addressed and treated during a single therapeutic procedure

Be aware that you can request a peer-to-peer review to speak with a physician peer in order to discuss complex patient cases. Your insurance clerk can request a peer review and set a date and time for the phone call.

If all tactics fail, you may contact the insurance medical director to discuss the individual case as a peer-to-peer review. The majority of the time, denials are overturned by the medical director based on pertinent data that was not understood by the initial non peer reviewer.

7) Policy riders to exclude future treatment options for varicose veins and venous reflux

Educate the patient regarding their options to change insurance coverage. Many patients do not realize that they have negotiating power to request plan changes for coverage. Many patients have not even thought of other insurance plan opportunities.

Our office can provide patients with names and numbers of people who specialize as insurance brokers. They are not insurance sales people, but true insurance plan brokers who can analyze and make multiple insurance plans.

We encourage the patient to explore options for plan changes in conjunction with human resources and employee management. Often, human resource personnel take into consideration requests from employees regarding future insurance coverage options.

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INSURANCE continued on page 24
system taxes she paid based on her income). She was willing to endure wait times in lieu of high costs in the United States.

**PATIENT ATTITUDES, EXPECTATIONS**

The United States pays physicians better wages than in Italy. According to Expat Focus, which provides country guides, forums and expat experiences for those considering moving abroad, the annual average salary of a physician in Italy is $84,000 as compared to $230,000 here. Additionally, U.S. patients pay much higher costs for medical care than Italian citizens pay with their health system taxes – as previously noted. And, U.S. patients spend many hours working through various insurance requirements and regulations that must be met before insurance companies reimburse patients for medical care costs.

The costs of their time and money often bring an “I want it now and you better solve all my problems” mentality from U.S. patients. I think the primary difference is that U.S. patients have higher expectations than Italian patients and those expectations translate to additional demands, questions, and sometimes, lawsuits.

In Italy, a patient visits his/her primary care doctor for all issues and then as needed, sits on a waitlist to see a specialist. In the United States, a patient may see a primary care physician first and be referred to a specialist, or, they may go directly to the specialist. Either way, U.S. patients are not waiting for several months to see that specialist and Italian patients often wait that long or longer due to the sheer number of people participating in Italy’s public healthcare system.

By the time Italian patients receive treatment from their specialist physician, they are extremely grateful for the attention from the doctor. They overlook the wait time, the doctor’s personality and the perceived quality of care they receive from the specialist. There are no feelings of entitlement.

The general mentality in the United States, because we rarely have any comparison to healthcare in other countries, is that we’re entitled to prompt, high-quality care from a specialist dedicated to our particular issue. After all, we pay dearly for healthcare in the United States and we have high expectations with that cost.

In summary, it boils down to cost versus wait time, and the level of expectation that comes with it. I believe Italy will trend toward the United States over the next decade, with patients having stricter expectations on wait times, referral process organization and level of care. Only time will tell.

**ABOUT DR. STOUT**

Emma Stout, MD, is a phlebologist who specializes in the treatment of vein disease at American Vein & Vascular Institute. She finished her phlebology fellowship under the direction of Dr. Gordon Gibbs, American Vein & Vascular Institute founder and chief medical executive. Completion of the fellowship ensures that doctors are trained in the American Vein & Vascular Institute treatment philosophy, which focuses on patient-centric, personalized care paired with compassion and expertise.

As a general practitioner licensed to practice medicine in Colorado with a specialty in venous and lymphatic disorders, she has a hospital affiliation with Parkview Medical Center.

Dr. Stout is from Novara, Italy, and graduated from medical school at La Sapienza University of Rome in 2003. The granddaughter of a surgeon, she grew up with a passion for medicine and providing care for those in need. She performed her residency at St. Mary-Corwin Regional Medical Center in Pueblo, Colorado, and has since volunteered in Guatemala as well as in the oncology department at Phoenix Children’s Hospital.

**HHS Secretary Azar dismisses ‘Medicare for all’ as just too good to be true**

Health and Human Services Secretary Alex Azar dismissed “Medicare for all” as a promise that’s too good to be true, according to an article in The Hill.

“When you drill down into the details, it’s clear that Medicare for all is a misnomer,” Azar said during a wide-ranging speech in Nashville in late September. “What’s really being proposed is a single government system for every American that won’t resemble Medicare at all.”

Azar said embracing Medicare for all would mean ignoring the mistakes of ObamaCare, which he called a failure. “The main thrust of Medicare for all is giving you a new government plan and taking away your other choices.”

This was not the first time a top official at the Department of Health and Human Services has tried to discredit the idea of Medicare for all. Centers for Medicare and Medicaid Services Administrator Seema Verma in July called it socialized medicine that would put seniors at risk.

Medicare for all has become increasingly popular among Democrats and is now favored by many of the party’s potential 2020 presidential candidates, as well as physicians running for House seats.

However, many congressional Democrats have yet to completely embrace the idea, and while Sen. Bernie Sanders (I-Vt.) has sponsored a “Medicare for all” bill, there’s no real push for it in Congress.

Republicans have been pointing to Democratic calls for single-payer as a key rebuttal in this year’s midterm campaign, part of an effort to push back against Democratic attacks on GOP bills to repeal ObamaCare.

Aside from attacking Medicare for all, Azar in his speech praised President Trump as a better steward of ObamaCare than former President Obama ever was.

“The president who was supposedly trying to sabotage the Affordable Care Act has proven better at managing it than the president who wrote the law,” Azar said.

He said premiums have been decreasing and there are more plans available for consumers to choose from on state exchanges.
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Superficial Thrombophlebitis in Pregnancy

Practice challenges with no entirely complete guidelines

By Manu Aggarwal

There are a few things that make me take a longer pause in venous medicine. Of all venous disease complications, one of the top concerns is the pregnant patient. In the last year, I have seen a handful of pregnant patients with variable superficial venous thrombophlebitis (SVT) of truncal veins, varicose veins and labial veins. Early recognition and management is key in these patients.

A patient, about two weeks out from a vaginal delivery, presented with terribly tender labia that were very firm to palpation. She had difficulty sitting, sleeping and breastfeeding. Ultrasound of the deep system was normal without evidence of deep venous thrombosis. However, scanning her labia showed multiple non-compressible veins. Her review of systems was negative for chest pain, shortness of breath, abdominal pain or fevers and chills. She was examined by her obstetrician who sent her to our office for evaluation/treatment.

This was the patient’s second pregnancy. She had labial varicose veins with her first pregnancy but did not have any of the concerns she presented to us with after this second pregnancy. We ordered a CT Venogram to rule out any progression of the thrombus. We do not have abdominal venous ultrasound available to give us further information. The CTV report was completed the same day and was negative for any propagation. The SVT was confined to varicose veins on the labia. The patient was instructed to use a heating pad to the area and use a tighter-fitting panties or leggings to provide compression. We discussed that creating compression on the labia will be difficult with the over the counter compressions and she may consider creating a v-shaped strap to provide compression. The patient presented within a few weeks later for follow-up and she was feeling much better. Upon initial presentation, we discussed with her obstetrician whether to anticoagulate this patient for the next six weeks (post-partum time). There were no guidelines that we could find, the SVT was limited to the varicose veins of the labia and the patient was already feeling slightly better between the appointment with her obstetrician and our office – so we opted not to treat the patient with anticoagulation.

Another patient presented to us as a referral from her obstetrician with a several month-long history of venous eczema and firm, tender varicose veins. She was wearing compression stockings occasionally because the itching was so intense. She was using a steroid cream sparingly due to pregnancy per her obstetrician. She had significant great saphenous vein insufficiency that was not addressed prior to her pregnancy – and she had a similar presentation during her last pregnancy.

The patient was scheduled to deliver in the next two weeks after her presentation; thus it was opted to keep the patient on compression stockings and to use an over-the-counter hydrocortisone cream to help with the itching. She was also told to discuss her concerns with her obstetrician to assure that such potency of the hydrocortisone cream would not be a concern during pregnancy because there was a concern by her obstetrician.

The patient presented three months after delivering where an endovenous laser ablation was performed on the great saphenous vein and ambulatory phlebectomy was performed on the varicose veins. At her one-week and at three-month follow-up post procedure, she was much more comfortable and her leg felt less heavy, swollen and had improved skin discoloration. Superficial venous thrombophlebitis affects more than 125,000 people in the United States. The number is likely higher because it is highly unrecognized and undertreated – which can be scary – when we know the likelihood of SVT progressing into at DVT can be 6-40 percent of the time or symptomatic pulmonary emboli in 2-13 percent of patients.

In addition to pregnancy, hypercoagulable states are found in up to 35 percent of patients with SVT. The most commonly inherited forms of coagulopathy are Factor V and Prothrombin gene mutation. The most common acquired form of coagulopathy is antiphospholipid syndrome. Where pregnancy is a coagulopathy – alone or with a coagulopathy on top of it all – the condition predisposes patients to thromboses. Pregnancy itself increases the opportunity for a venous thromboembolism by four-to-five fold. Add a coagulopathy to that and the increase in risk is cringe-worthy.

An interesting fact in my research is that most VTEs occur within the first trimester and early second, with the most likelihood between 11- and 15-week gestation. These findings, however, are not reliably consistent.

The multifactorial nature of VTE doesn’t stop with pregnancy. Obesity, smoking and maternal cardiac disease, personal history of VTE and premature delivery increase the risk of VTE during pregnancy.

At first, I had some difficulty finding any definitive guidelines. The United Kingdom Centre for Maternal and Child Inquiries 8th Report on Confidential Inquiries into Maternal Deaths in the U.K., VTE was the leading cause of direct maternal death in the United Kingdom for all but the final of the two-year eras reported from 1985 to 2008. Maternal death from VTE was more common than death from sepsis, preeclampsia, amniotic fluid embolism or hemorrhage. There was also a significant decrease in maternal death due to VTE in 2006-2008 era after the first publication of the Royal College of Obstetricians and Gynecologist Green Top Guideline “Thromboprophylaxis during Pregnancy, Labour and after Vaginal Delivery” in 2004.

In the United States, ACOG and ACCP have guidelines for the prevention of thromboembolism that can help reduce the rates of VTE-related morbidity and mortality. The following recommendations are based on the “American College of Chest Physicians Evidence-Based Clinical Practice Guidelines” (9th Ed) for venous thromboembolism, thrombophilia, antithrombotic therapy and pregnancy.

Going back to my first patient with the labial SVT, ordering a CTV was to rule out any pelvic VTE. In pregnancy – up to 12-18 percent of DVT are pelvic DVT. Fortunately, her testing was normal. A D-dimer was not ordered because I felt like it would be falsely elevated anyway, and it wouldn’t change my management (ordering a CTV).

If she would have presented with this during pregnancy, based on the guidelines, she could have been managed with conservative treatments (heat, compression) and followed closely. However, if she had a strong family history of VTE or a personal history or confirmed lab coagulopathy, she would have been placed on LMWH or UFH. If she was close to delivery, one may argue to use UFH due to proximity of delivery. Once placed on anticoagulation, it would have to be continued for at least six weeks post-partum time, for a total minimum duration of six months. If she would have had an antithrombin deficiency, she would have required antepartum and post-partum anticoagulation.

Patients with recurrent pregnancy loss (greater or equal to three miscarriages) and women with severe or recurrent preeclampsia, placental abruption or otherwise unexplained intrauterine growth retardation should be screened for thrombophilia and antiphospholipid antibodies.

Women with antiphospholipid antibody syndrome and a history of multiple greater than or equal to two early-pregnancy losses, or greater than or equal to one late pregnancy loss, preeclampsia, intrauterine growth retardation (IUGR), or abortion, require antepartum aspirin plus prophylactic or intermediate-dose UFH or LMWH. Women with APLAs and a history of VTE who are usually receiving long-term oral anticoagulation therapy, should be treated with adjusted-dose LMWH or UFH therapy plus low-dose aspirin and
Given the extent of this patient’s labial SVT and prolonged course of recovery (close to 3 months until resolution of firmness), her second time with labial varicose vein symptoms (with this time being much more symptomatic), her obstetrician and I decided for her to be tested for thrombophilia prior to another pregnancy.

For my patient who presented with significant venous eczema and SVT of the varicose veins, we opted to watch her conservatively because she was within two weeks of delivery. If the great saphenous was involved (greater than 5cm) or within 3-5cm of the SFJ, she would have needed anticoagulation. Perhaps the best would have been UFH due to the shorter half life than LMWH because she was so close to delivery.

VTE in pregnancy is a significant cause of mortality – if not the No.1 cause of maternal mortality based on some statistics. The early recognition and treatment is key in improving patient outcomes. I would encourage all of us to work with your local obstetricians and gynecologists to come up with a standard of care based on the current guidelines that can be agreed upon for community-wide care.

Manu Aggarwal, MHSA, MD, is a board-certified family physician and ABVLM-certified physician at the Vein Care Center Laser Specialists. Since 2007, the VCC has been an IAC-accredited vascular laboratory. In 2015, the VCC was one of the first 50 practices in the country to also be Vein Center accredited. The VCC has been dedicated to venous disease and laser treatments since 2004, and is in Lima, Ohio, with a satellite office in Celina, Ohio. She may be contacted at yourveincarecenter.com.
‘A Wonderful Resource’

By Joseph D. Raffetto, MD

“A Guide to Treating Face Veins” is a wonderful resource and compilation of work by Dr. Ronald Bush and Mrs. Peggy Bush. Facial veins are uncommonly treated in most clinical practices but is a common problem among patients who seek medical advice for unsightly facial veins and would desire treatment. Treating facial veins is not a common practice, and many practitioners who treat patients with lower-extremity varicose veins would be averse to treating veins in the face due to lack of knowledge and experience. However, practitioners treating varicose veins may have referrals from primary care physicians or even patient’s request asking the clinician to help them with their facial veins and improve the patient’s morale, self-esteem and image, and overall happiness.

Although most treatments of facial veins are for cosmetic reasons, the importance is that the patient is self-conscious of this problem, and it is likely affecting their overall well-being and quality of life.

In this comprehensive and one of a kind work I congratulate the authors for their systematic, well-researched, well-written and well-illustrated review in the treatment of facial veins. The authors have done a wonderful job in their illustrations of the anatomy of veins coursing through the face, providing critical details in face vein flow and pathways, and the importance of the connections between visible facial veins and deeper veins within the face.

The review lists the importance of applying specific pressure at critical junctures to control the dispersion of foam during treatment and avoid the foam from entering deeper veins, especially the ophthalmic veins.

The sections are arranged in four anatomic areas of interest in treating the frontal, temporal, suborbital and periorcular veins, and eyelid veins. Each section describes anatomic details, objectives of treatment and clear technical aspects to performing the procedure.

Other interesting sections covered are facial telangiectasia and venous lakes tumors, which are also common disorders seen in older individuals that will likely have the patients ask for treatment options.

The review ends with sections on mixing foam and potential problems and how to avoid and treat if complications do occur. There are important pearls in each of the figures and text, with key points that must be observed while treating veins of the face.

In addition, the authors provide a step-by-step approach to each of the treated veins, with information on cannulation, application of pressure in the veins to keep the foam localized, the dosing of sclerosant foam to use and procedural care following injections as well as expectations.

Discussion on using laser, ohmic thermolysis and radiofrequency energy is also presented in treating telangiectasia and venous lake tumors. The sections are succinct, easy-to-follow instructions and contain essential information for treating different levels of facial veins.

For any clinician considering treating veins of the face, anatomic knowledge and procedural steps are essential, and this illustrated treatise is an excellent resource to the proper treatment of facial veins and to maximize and achieve favorable results. VTN

‘An Excellent Manual’

By Stephen F. Daugherty, MD

“A Guide to Treating Face Veins,” written by Ron and Peggy Bush, is an excellent manual for those who treat or desire to treat cosmetic concerns associated with veins of the face. The normal and abnormal venous anatomy of the face and the important venous drainage to avoid occluding with treatment are reviewed with color photographs and anatomical drawings. The angular vein and other potential pathways for endovenous foam to reach the cavernous sinuses are discussed. The “danger triangle” where the angular, supraorbital, supratrochlear and superior palpebral veins converge is illustrated. Technical maneuvers such as compression points, direction of foam injection, and concentrations and volumes of foam injection are outlined for each of the veins of the face that might be treated with foam.

The importance of occluding the scalp vein inflow to the target veins of the face is discussed as are the techniques for occluding the scalp veins. Methods for treating the frontal veins of the forehead, the temporal veins, suborbital and supraorbital veins, and veins of the eyelids with endovenous foam are described in detail.

The treatment of facial telangiectasia with laser, intense pulsed light or ohmic thermolysis is reviewed. Venous lake tumors present as raised, bluish, smooth masses on the face or lips, which can be treated with laser or ohmic thermolysis with simple techniques described by the authors.

The descriptions of techniques include many suggestions to reduce the risk of complications from treatment of veins of the face. The authors found only one case in the medical literature of blindness after sclerotherapy of a facial vein, though there are more reports of blindness occurring after injections of fillers or adipose tissue, most commonly with injections near the orbit. The authors’ techniques to avoid foam passing into the superior ophthalmic vein and cavernous sinus are described.

Finally, the importance of recognizing blanching of the skin as a sign of potential passage of foam into the arterial system and emergent treatment for such a change are described.

The key concepts for safe treatment of veins of the face with foam are no different from treatment with foam in other venous beds, but the authors provide considerable detail specific to treating veins of the face.

This book will long be a reference source for the neophyte and experienced clinicians who treat veins of the face. VTN


Laser aesthetics market to grow 8% CAGR by 2021

According to the latest market research report released by Technavio, the global laser aesthetics market is expected to accelerate at a compounded average growth rate of close to 8 percent through 2021. The rise in the number of working professionals is one of the key factors triggering the growth of the market.

This research report titled “Global Laser Aesthetics Market 2017-2021” provides an in-depth analysis of the market in terms of revenue and emerging market trends. It also includes an up-to-date analysis and forecasts for various market segments and all geographical regions.

The market research analysis categorizes the global laser aesthetics market into the following products: Body contouring devices and laser resurfacing devices.

In 2016, body contouring devices accounted for more than 41 percent share of the market. This was due to the growing demand from people to enhance their appearance and look healthy.

The growth in medical tourism initiatives is an emerging trend in the laser aesthetics space. Medical tourism initiatives taken by governments have played a major role in the growth of the healthcare industry.

Vital treatment areas of focus for medical tourism include cosmetic surgery, dentistry, cardiovascular, orthopedics, reproductive, cancer and weight loss. These initiatives have allowed people to seek treatment in various countries due to factors such as cost, quality and downtime of the procedure. VTN

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POLIDOCANOL ENDOVENOUS MICROFOAM
A less-invasive modality for treating venous disease

By Kenneth Harper, MD

Chronic venous disease is a highly prevalent condition that frequently goes undiagnosed and untreated. Varicose veins, the most common manifestation of CVD, affect more than 25 million adults in the United States, with some 6 million living with advanced disease.1 Yet clinicians often overlook varicose veins, and even when the condition is diagnosed, some patients refuse treatment. In many cases, patients choose to live with the pain and discomfort of varicose veins because they believe that treatment still requires vein stripping, which was the only option in the past.

Of course, less-invasive modalities for treating venous disease are available today. The most recent addition to the armamentarium of therapies for varicose veins is polidocanol endovenous microfoam (Varithena), which was approved by the U.S. Food and Drug Administration in 2013. I have been using this therapy at my phlebology clinic since it became available. Varicosities represent a chronic disease process that can worsen over time, so having a new, safe and effective treatment has expanded our capacity to manage this common problem.

A SAFER FOAM
Polidocanol endovenous microfoam is a form of sclerotherapy, a treatment for varicosities that works by disrupting the structure of cell membranes in the endothelium, which ablates the vein. Like many clinicians, I formerly used physician-compounded foam (PCF) on occasion to treat varicose veins in select patients. PCF is polidocanol aerosolized by the physician using room air, producing a foam with high nitrogen content that can be unstable, and has in rare instances been associated with safety problems such as neurological sequelae, including strokes.

By contrast, polidocanol endovenous microfoam is produced in a controlled setting, so it contains uniformly small bubbles, resulting in a very stable preparation. Moreover, the foam contains less than 1 percent nitrogen. Not surprisingly, data indicate that polidocanol endovenous microfoam is a safe product. In the pivotal VANISH-2 trial, with 232 patients treated with polidocanol endovenous microfoam, there were no reports of clinically important neurologic or visual adverse events.2 Among all side effects recorded, 95 percent were mild or moderate.

I use polidocanol endovenous microfoam to treat two or three patients per week, and none have experienced serious adverse events. Overall, the therapy is very well tolerated. We advise patients in advance of the possibility that they may experience tenderness in a sclerosed vein following the procedure. When coagulum occurs, we evacuate blood that may have collected in a treated vein, which produces immediate relief. But this is only necessary for a small minority of patients.

PATIENT SELECTION
While safety is critical, patient-reported outcomes in clinical studies indicate that polidocanol endovenous microfoam produces significant improvements in symptoms of varicose veins, including heaviness, aching, swelling, throbbing and itching. Also, patients and independent physician review panels judge appearance of varicose veins to be improved by polidocanol endovenous microfoam compared to placebo. Other modalities produce satisfying resolution of symptoms and improvements in appearance, but polidocanol endovenous microfoam is the only intervention available for certain patients, whose treatment would otherwise be limited to conservative care. In particular, we know from the scientific literature that about one in five patients whose varicose veins were treated with today’s standard therapies — radiofrequency and laser ablation — experience a recurrence of symptoms following ablation of the great saphenous vein (GSV).3 Yet these patients are usually not candidates for a second round of RF or laser therapy. In response to endovenous ablation, the body forms new veins through the phenomenon known as neovascularization. However, these new vessels tend to be not only tortuous, but quite fragile, too. As a result, it’s usually not possible to advance a rigid catheter into such a vein. However, injected foam travels safely around a tortuous vein and gets to where it’s needed with relative ease. Polidocanol endovenous microfoam is also an option for older patients who developed neovascularization after undergoing vein stripping, which was once the standard of care.

PATIENT CASE
A recent case illustrates a typical application of polidocanol endovenous microfoam in our clinic. The patient was a female, age 70, who presented with throbbing pain, fatigue and swelling associated with bulging varicose veins in her left leg, which had progressed gradually over a number of years. Her leg pain and related symptoms were worsened by standing, but improved with leg elevation and the use of compression hose. The patient reported that her leg symptoms limited her daily activities and were having a negative effect on her quality of life. She had been treated previously with endovenous ablation of the GSV and small saphenous vein (SSV) in her left leg at another facility three months prior to being evaluated at our clinic, but her symptoms had not resolved.

Examination of the patient’s leg and duplex ultrasound (US) in supine and standing position produced these clinical findings:
• Ankle edema and flare with spider veins and varicose veins.
• From the knee to the proximal calf there was GSV reflux (3mm diameter with reflux > 0.5 seconds).
• Reflux at the popliteal crease below the saphenopopliteal junction (SPI) feeding into an area of neovascularization from the popliteal crease into the posterior calf varicose veins (5mm VV with reflux of 2.4 seconds).
• Incompetent perforator vein in the medial leg at 34 from the sole of the foot (2.3 mm with reflux > 0.5 seconds).
• Neovascular varicose vein pattern in the post calf below the popliteal crease.
We determined that the patient was an appropriate candidate for treatment with polidocanol endovenous microfoam. Specifically, we elected to administer ultrasound-guided polidocanol endovenous microfoam to the SSV reflux and area of neovascularization in the post calf.

On the day of the procedure, we confirmed the targeted veins with duplex ultrasound and used a marker to draw indicator lines on the patient's skin. After sterile prep and drape of the leg, the patient was placed in the Trendelenburg position and 1 administered 1 cc of tumescent local anesthesia at the needle-access site. The targeted area in the posterior calf that had been previously marked was accessed under ultrasound guidance with a 25-gauge needle, using an attached sterile extension set. Access was confirmed with ultrasound and venous blood return in the extension set.

Next, 5cc of polidocanol endovenous microfoam was pulled from the canister. Within 90 seconds of withdrawal, a total of 4cc of foam was administered under ultrasound guidance, filling the varicose veins (1cc was discarded). After administration of the sclerosant, direct pressure was applied at the superficial/deep vein junction in the popliteal fossa and maintained for 2 minutes. Immediately after the injection, and while holding pressure, the patient was instructed to do calf muscle exercises. Ultrasound visualization was repeated after the compression and prior to applying the post procedure bandage.

The leg was dressed with a single suture strip at the injection site. A multilayer compression dressing was then applied, and later exchanged for a knee-high compression hose following the procedure. Total treatment time was 15 minutes. The patient tolerated the procedure well and no complications were noted. On discharge, we recommended conservative measures, including compression hose, elevation, exercise, and weight management.

We typically see patients for follow-up a week after they receive treatment with polidocanol endovenous microfoam, then again in four to six weeks. At follow-up, this patient reported slight tenderness at the site of the treated varicose veins. Duplex ultrasound indicated that the treated veins were non-compressible, and the patient had no superficial or deep venous symptoms.

Most phlebologists approach the use of polidocanol endovenous microfoam with a plan that they will need to perform two or three treatments, spread out over time, to achieve desired results. But we have been pleasantly surprised to discover that, for many of our patients, one treatment is all that’s necessary. That’s obviously appealing to our patients, who are almost unanimously pleased with the results, and often say they wish they had undergone the treatment sooner. An insurance billing code for the procedure became available this year, eliminating some of the challenges that clinicians had previously experienced in obtaining reimbursement for the procedure. I believe this could open the door to more patients with varicose veins pursuing this therapy.

Kenneth Harper, MD, is the founder of Vein Specialists of the South LLC in Macon, Georgia. Since 1997, Vein Specialists of the South has focused on the diagnosis and minimally invasive treatments for varicose veins, spider veins, venous ulcers and leg swelling. As a leader in comprehensive vein care, Dr. Harper performed the first endovenous radiofrequency closure procedure in Georgia.

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Home-use device, ArtAssist, treats PAD using IPC

By Paul van Bemmelen, MD and Erika Arkans

It has been estimated that more than 20 percent of adults exceeding the age of 70 have developed peripheral arterial disease in lower extremities that cause acute and chronic illnesses negatively impacting quality of life.1

PAD is most commonly caused by atherosclerosis with risk factors including diabetes, cigarette smoking, hypertension, and hyperhomocysteinemia. Not only do PAD patients experience physical impairments (walking and rest muscle pain, decreased mobility, ulcers, decreased tissue viability, etc.), but in effect, their social, mental, and emotional health become compromised correspondingly.2

Some PAD patients suffer from intermittent claudication and in more severe cases, critical limb ischemia, both troubled with problematic treatments. Claudicants experience pain and discomfort in lower limb muscle groups during exercise due to inadequate blood flow, while patients with CLI have rest pain, ischemic ulcers, and/or fortibbling limb amputation.3

Patients who pursue treatment are presented with various options. Those with intermittent claudication face the possible treatments including surgical options (endovascular or bypass surgery), use of drugs (vasodilators, antiplatelet agents and rheologic agents) and exercise.4 These surgical procedures pose possible operative complications with pharmacotherapy being shown to have minimal success with temporary improvements and adverse side effects.5

Exercise has only been shown to be effective to relieve symptoms when supervised, however, this relief tends to be temporary and becomes problematic because of the lack of motivation and attendance to supervised exercise programs. Patients with CLI historically seek treatment involving revascularization with limited long-term success rates that can lead to amputation.5 These types of procedures are risky, costly and are often needed to be redone. Because of these limitations on treatments, there has been a consequence of a substantial financial burden on PAD patients and health care providers.4 An annual economic burden of more than $200 billion has been estimated for PAD patients in women alone, making up half of those affected.6 These troublesome circumstances call for an alternative treatment to provide millions a safer, more effective, and economically efficient way of treating their PAD.

Another form of treatment known to successfully increase lower limb perfusion is by a unique form of intermittent pneumatic compression (IPC).7 Unfortunately, IPC has often been overlooked as a mode of treatment because of inadequate explorations into its successes and usefulness.

A home-use device, known as the ArtAssist device, works by means of IPC and has been shown to effectively increase popliteal arterial blood flow three- to four-fold in diseased limbs.8 This device uses two cuffs, one around the calf and one on the foot and ankle, with a maximum inflation of 120 mmHg and a minimum inflation of 10 mmHg. The cuffs are inflated to a maximum pressure within 0.3 seconds with a one-second inflation delay between the foot and the calf for a three-second inflation time followed by a 17-second deflation time resulting in three compression cycles per minute. There are multiple pulses during the 0.3 second inflation rate which separates this device from all others due to its unique patented Endoshear technology. These parameters have been essentially optimized for PAD. Though the process of this device seems to be fairly simple, its outcomes are extremely advantageous.

There are three major mechanisms of action underlying arterial inflow augmentation with this form of IPC. The ArtAssist device works to increase the arteriovenous pressure gradient by decreasing venous pressure, delays the venoarteriolar response (VAR) by decreasing venous pressure, and produces endothelial vasodilators by means of an increase in shear stress.1

Blood flow through the popliteal artery is increased from the high pressure applied by the foot and calf cuffs, expelling venous blood. The difference in hydrostatic pressure during the compression causes a forward flow from the arterial side after the release, refilling the veins and increasing blood flow. The VAR is a defense mechanism causing vasoconstriction to prevent swelling triggered by postural fluctuations. By decreasing venous pressure, the device transiently eliminates the VAR. This rise in blood flow causes an increase in shear stress across the endothelial cells, stimulating the production of vasodilating factors such as nitric oxide and prostacyclin.9

For claudication patients, the ArtAssist device has been shown to improve initial and absolute claudication distances, reduce rest pain, and increase resting popliteal artery flow within the first three months of treatment through a recently published systematic review and meta-analysis.2 Patients were able to increase their walking distance and felt relief of their symptoms within a few months of using the device, which corresponded to their improvement in quality of life that was assessed across studies. More importantly, these end results have been persistent, lasting up to two years after withdrawing use of the device. It is important to note that this meta-analysis represents the highest form of medical evidence.

The ArtAssist device has additionally presented consistent results in studies to increase ankle-brachial index (ABI) with long-lasting improvements for at least 2 years.10

There has been an implementation of this device on those with CLI with threat of amputation as well. In a study focusing on nonhealing wounds in patients with CLI, all having multi-level occlusive disease, there was an 88 percent limb salvage rate after 18 months.11 Rest pain in all patients was abolished within the first week of treatment and toe pressures significantly increased from 38.2 to 67 mmHg with use of the device.

This intervention also provided an 89 percent ulceration healing rate. Treatment with the device significantly decreased the average length of hospital stay, saving approximately $9,000 per patient in hospital costs. The study further concluded that the device could potentially save $3 to $4 million in patients with limited life expectancy. Without surgical intrusion, this device has provided patients with a pain-free functional limb.

These results show promise to those in high risk of amputation with nonhealing wounds that using an IPC unit, such as the ArtAssist device, can achieve complete wound healing and maintain limb integrity. This poses a convincing indication for intermittent claudicants willing to undergo treatment to strongly consider the ArtAssist device, especially for those where surgery is not indicated and/or are unable or unwilling to partake in supervised exercise programs.

Some studies have focused on resulting collateralization from the use of the ArtAssist device, further supporting the hypothesis of structural remodeling within the network of pre-existing collateral arteries.12,13 Another study displayed ulcer healing of the ankle and Achilles tendon within 6 months, paralleling hemodynamic and angiographic evidence of neovascularization.14

The display of extensive development of collateral arteries holds a primary part in the healing process of patients with PAD, especially those with ulcers by stimulating blood flow to ischemic tissue. Likewise, collateralization has an durable effect over exercise and drug therapy and has proven to be an important mechanism induced by this particular form of IPC.

The results from these studies show an optimal treatment usage of a minimum of three months with three, one-hour sessions each day in order to illustrate benefits and encourage long-term effects of arteriogenesis.

Patients who use the ArtAssist device for their PAD not only demonstrate physical improvements but, in turn, have an increase in their mental and emotional well-being by being able to carry out everyday tasks with less pain and greater physical mobility in addition to limb preservation.8

The benefits of the ArtAssist device using IPC technology are prodigious for the following reasons: this device is a non-invasive, well-tolerated home treatment, cost-effective, requires no physical exertion, has no known adverse reactions, and may be a positive alternative to invasive surgical procedures for those unable to exercise and/or unable to undergo surgical revascularization.15

Paul van Bemmelen, MD, of Temple University is widely known vascular surgeon, writer and speaker, has been an advocate for pneumatic compression treatment in patients with all stages of peripheral artery disease for almost 30 years. His expertise and involvement were vital to the development of the ArtAssist device used in his PAD studies and developed by ACI Medical President and head of product development Ed Arkans, M.Eng.

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32 OCTOBER/NOVEMBER 2018 ❧ VEIN THERAPY NEWS

Study shows HPILC sustains gains with use of home device

Temple University’s systematic review and meta-analysis on eight independent intermittent claudication studies using pneumatic compression pumps has shown significant improvements in walking distances even after treatment was withdrawn.

Paul van Bemmelen, MD, of Temple University conducted the meta-analysis. The objective was to conduct a systematic review and meta-analysis of randomized controlled trials evaluating the efficacy of a unique form of high-pressure intermittent limb compression (HPILC) in improving walking distance in patients with intermittent claudication. The study was published in the Journal of Vascular Surgery, in February 2018.

It is estimated that currently greater than a million adults in the United States have claudication. HPILC significantly increases flow rate in the popliteal artery by decreasing

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He says the ACP Congress is one of the most comprehensive and best attended meetings in the world and the improvements this year just make it better. “This is the largest annual meeting devoted to venous and lymphatic disorders in the world,” he says, “and we’ve continued to make tremendous improvement in the quality and the content of the speakers.”

One important change is an increased international focus. This year, the presentations on superficial venous, deep venous and general sessions will offer simultaneous translation services in Spanish and English.

In year’s past, the Thursday “pre-Congress day” was perceived to be geared toward beginners. In a noteworthy change, the organizers decided to devote the entire meeting from Thursday through its end on Sunday at noon to education appropriate for all levels of physicians and allied health therapists who are involved with the care of venous and lymphatic disorders. “So beginning last year we started covering multiple levels of expertise through the entire meeting and we’ve done that this time as well,” says Dr. Daugherty.

Over a period of a few years, the Congress will thoroughly cover all of the items that are recognized as important in the curriculum that is specified by the American Board of Venous & Lymphatic Medicine. “We are covering a large amount at this meeting and each year for several years we’ll have some overlap but we’re putting in additional efforts to educate on a wide variety of things,” he says.

MORE SCIENCE

Dr. Daugherty says an abstract committee carefully selected from a record number of 96 abstracts submitted for this Congress. “We have beefed up the time that we’re devoting to abstracts for scientific presentations,” he says. “There’s a lot more interest among those who do science who want to present at our meetings.”

The majority of the abstracts are about applications based on and results of studies that have been undertaken in a clinical setting. “The scientific sessions are more robust,” he says.

SPEAKERS

On Thursday, the welcome speaker is Sen. Mark Green, MD, who served as the flight surgeon for the 160th Special Operations Aviation Regiment. After retiring from the military, Sen. Green founded Align MD, a hospital emergency department management staffing company, and Two Rivers Medical Foundation, which operates a free medical clinic in Memphis, Tennessee, and provides healthcare throughout the world via medical mission trips. Sen. Green has served in the Tennessee State Senate since 2012 and is running for U.S. House of Representatives in 2018.

Friday’s keynote address will be given by Juan Schaening, MD and the executive contractor medical director for Medicare Jurisdiction N. “As the medical director for the Florida Medicare Contractor, Dr. Schaening will be sharing some of their perspectives on how they see venous and lymphatic disease being treated and billed.

“We’re working to build relationships with the payers so we want to help them see we’re serious about high quality medical care and we’re also serious about helping them through developing medical policy to identify outliers. We have an opportunity to help the payers with the science and medicine behind medical policy so that they can figure out where there’s misutilization and overutilization so that the funds can be there for people that really need care.”

The Friday session called Improving Wisely will be given by Martin Makary, MD, MPH, who currently serves as the executive director of Improving Wisely, a national project funded by the Robert Wood Johnson Foundation to reduce unnecessary care and lower health care costs. Dr. Makary is a surgical oncologist and chief of the Johns Hopkins Inlet Transplant Center. Improving Wisely launched in 2012 as Choosing Wisely, a program designed to reduce the use of unnecessary tests and treatments in U.S. healthcare. Dr. Makary is the New York Times bestselling author of “Unaccountable,” a book about transparency in healthcare which was turned into the TV series “The Resident.”

Another important Friday presentation on the effect of obesity on vein disease and long-term results will enhance that day’s quality and advocacy theme. “We will be discussing our venous registry and some of the initial results coming out of that,” says Dr. Daugherty, “but we are also very interested in helping to provide the science behind the treatments that we do. We’ll be looking at where the gaps in knowledge exist and assisting the payers in understanding the best available science so that they can make better decisions about the policy. We’ve never had a session like that at the ACP meetings.”

The 32nd Annual ACP Congress would be remiss if it didn’t allow for some time spent on having fun for a good cause. The ACP Silent Auction has been an attendee favorite for the past 11 years. Attending the auction is entertaining, even if you just donate an item or attend only to watch the proceeds. Either way, expect to see bids on medical devices, services and training, vacation getaways, art, jewelry, sports memorabilia, and more. Bidding will likely exceed the 2017 auction, which raised more than $25,000 to support the important mission of the ACP Foundation. Also new for 2018 is a live auction on Saturday night.

On Saturday, the Congress’s closing celebration will have a steeplechase theme including digital horse racing, live entertainment, dancing and a casino area with proceeds supporting the ACP Foundation. On Thursday and Friday, purchase a special ticket to attend the Raise Your Glass Foundation Toast to close out each day with a special cocktail hour. The evening toasts will each feature a special beverage including bourbon and craft beers. All proceeds support the ACP Foundation’s missions.

If education and advocacy is the primary reason you might be thinking of attending the Congress, there’s plenty of that. “We will have a substantial number of the world’s experts on a lot of the topics that are being covered at the Congress and there’s a lot to learn,” says Dr. Daugherty. “I think this meeting is going to be great. There are a lot of things for the very sophisticated physician and there are a lot of things for the person who is new to venous disorders. We are trying to pull together the lymphatic community. The physicians and therapists interested in lymphatic disorders have not had a strong single organization to be their spokesman and around which to rally their effort. We are that organization now.”

MIDTERMS

Republican support but registers low-approval ratings among Americans overall, according to news organization FiveThirtyEight. Democrats also see promise in candidates such as Dr. Davidson, a left-leaning physician who may have a special advantage: firsthand health system experience.

Polls by Quinnipiac University, The Wall Street Journal and the Kaiser Family Foundation suggest healthcare is among voters’ top concerns as midterm elections approach.

Of the Democratic doctors running for office, all but one are seeking House seats. In addition to the nine newcomers, there are two incumbents up for re-election. Each candidate is campaigning hard on the need to reform the healthcare system.

And they present a stark contrast to Congress’ current physician makeup.

Twelve of the 14 doctors now in Congress are Republicans. Three are senators. Half of the 14 practice in high-paying specialties such as orthopedic surgery, urology and anesthesiology.

By contrast, these stumping Democratic physicians hail predominantly from specialties such as emergency medicine, pediatrics and internal medicine, though one is a radiologist. They’re fighting to represent a mix of rural, urban and suburban districts.

Dr. Matthew Goldenberg, MD and a psychiatrist at Yale School of Medicine who has researched political behavior and advocacy among doctors, said electing Democratic doctors would certainly change the face of medicine in Congress, and perhaps lend more credence in that body to more liberal healthcare policies.

Physicians have traditionally trended Republican. The infusion of female and minority doctors, experts said, has changed this.

Now, more than 50 percent of party-affiliated doctors are Democrats, and the medical establishment has — following Republican efforts to undo Obamacare — emerged as a staunch defender of the law.

Indeed, many physician-candidates point to the GOP’s repeal-and-replace efforts as their motivation. Jim Duffett, executive director of the left-leaning Doctors for America which supports universal healthcare, said it is at a boiling point for many of these physicians.

While healthcare consistently emerges as a top issue, Democrats are more likely to rank it No. 1. For independents and Republicans, though, it’s neck and neck with the economy — and some political analysts question how effective it will be in flipping conservative districts.

Jim McLaughlin, a Republican pollster working on several 2018 races who has previously worked with Trump, said Democrat voters blame Republicans for the problems with healthcare right now.

“Republicans blame Democrats. Independents say, ‘A pox on both your houses,’” McLaughlin argued. “They’re making a big mistake thinking they can run on [healthcare].”

That said, doctors can be effective messengers, especially in their communities. Research suggests Americans hold their own physicians in high regard.
“Voters listen carefully to what physicians have to say about health policy,” said Jonathan Oberlander, PhD and a professor of social medicine and health policy at the University of North Carolina. “In a district that’s not so one-sided red or blue, there’s no question that the white coat confers prestige. It’s something physician candidates can speak to with authority.”

Dr. Davidson, for instance, supports a “Medicare-for-all”-style overhaul, an approach that involves expanding the federal insurance program for seniors and disabled people to all Americans. If elected, he said, he intends to join Democrats’ burgeoning support for a single-payer system, in which the government runs the sole health insurance program, guaranteeing universal coverage. He did not have a primary challenge and is running against Congressman Huizenga, the Republican incumbent, in the general election for Michigan’s 2nd Congressional District.

Or there’s Kyle Horton, MD and an internist running in the North Carolina 7th District. She supports expanding Medicare, by lowering the eligibility age from 65 to 50. She also supports a “public option” health insurance plan sold by the government.

Hiral Tipirneni, MD and an emergency physician in Arizona’s 8th Congressional District, asserts all Americans should be able to buy into Medicare. Physicians can have an advantage on other controversial topics by casting them as public health issues, said Howard Rosenthal, a political scientist at New York University.

Dr. Davidson’s campaign, for instance, posts videos on Facebook in which he talks about topics such as healthcare access and gun violence. One – filmed after an overnight ER shift – has gotten 41,000 views so far.

Also spurring physicians: concerns about abortion access.

Cathleen London, MD, is a Maine doctor who launched her campaign against four-term incumbent GOP Sen. Susan Collins for the 2020 election. She said she had been considering a run, but the upcoming vote for a justice to replace Anthony Kennedy on the Supreme Court – which could have sweeping implications for reproductive health law – pushed her to declare.

“Doctors are really frustrated with Washington, frustrated with the lack of listening to us,” Dr. London said.

Many of these Democrats face steep climbs.

Of races featuring newcomer physicians, the Cook Political Report, which analyzes elections, rates only Arizona’s 2nd Congressional District as leaning Democratic, and the doctor in that race is just one of seven candidates in the primary. The outcome for Washington’s 8th District, where Kim

**MIDTERMS**
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20 states ask Texas judge to scrap ACA because Congress removed penalty

Lawyers from 20 mostly conservative states have demanded a Texas federal judge scrap the “hollow shell” of Obamacare. The judge didn’t immediately rule on their request for an injunction, but POLITICO reporter Paul Demko reported that he at times sounded sympathetic to their argument.

The oral arguments opened the latest legal bid to kill the 2010 health care law, which has survived two major Supreme Court rulings and months of repeal efforts in Congress.

While numerous legal experts have deemed the argument outlined in this case a stretch, Attorney General Jeff Sessions has thrown the Trump administration’s weight behind key parts of the legal assault, notably calling on the court to toss out the law’s popular protection for people with pre-existing conditions.

The red states’ lawsuit has already become grist for campaign attacks ahead of the midterm elections, with Democrats pillorying Republicans for putting at risk protections for sick individuals.

More than 7 in 10 Americans — including a majority of Republicans — said maintaining that protection is “very important,” according to the latest survey from the Kaiser Family Foundation.

Two of the attorneys general pressing the lawsuit — Josh Hawley in Missouri and Patrick Morrisey in West Virginia — are running for Senate, challenging incumbent Democrats in states that Trump carried.

POLITICO reported that U.S. District Court Judge Reed O’Connor, a George W. Bush appointee, vigorously questioned attorneys during the three-hour hearing but gave no indication of when he would rule.

“I will think about what you said and try to get something out as quickly as I can,” O’Connor said.

The state attorneys general tried to pick up where the GOP-led Congress left off in its efforts last year to repeal Obamacare. They argued that because Congress gutted the individual mandate — zeroing out the penalty for not having coverage starting next year — the rest of the law must go as well.

“The merits of the ACA are not on trial here, only its constitutionality,” said Darren McCarty, special counsel for the Texas attorney general. “Congress eliminated the only constitutional basis on which the individual mandate was upheld.”

Misha Tseytlin, Wisconsin’s solicitor general, said that it is “nothing but a hollow shell because its core has been invalidated.”

Lawyers for the Trump administration partially agreed with that argument but said that any remedies should not be applied until next year.

“There could be the potential for chaos in the insurance markets,” said Brett Shumate, a deputy assistant attorney general with the Justice Department, noting that open enrollment for 2019 starts in just a few weeks.

No matter how Judge O’Connor rules, the case will almost certainly be appealed.

According to POLITICO, the attorneys representing 16 Democratic-led states who intervened in the case to keep Obamacare intact said it would be extraordinary for the court to overturn the clear will of Congress, which acted to repeal the tax penalty last year while leaving the rest of the law in place.

Neli Palma, deputy attorney general of California, said the plaintiffs aren’t seeking to maintain the status quo, “They’re seeking to blow it up.”

POLITICO’s Demko wrote that Judge O’Connor expressed skepticism that it would be improper to look back to the intent of the lawmakers who enacted Obamacare in ruling on the merits of the lawsuit. He also noted that Supreme Court justices assumed that the individual mandate and the insurance protections of Obamacare were inseparable in twice upholding the constitutionality of the law.

“Every single justice ... concluded this,” he said.

Judge O’Connor also floated the notion that Congress was actually trying to abolish Obamacare when it struck the mandate penalty, because lawmakers knew that the only reason the law was upheld in 2012 was because the mandate was deemed a tax.

“Why isn’t that the proper intent to be drawn from the 2017 enactment?” Judge O’Connor asked.

Associated Press corrects Obama’s midterm rhetoric

Former President Barack Obama’s recent denunciation of President Donald Trump’s treatment of the press overlooks the aggressive steps the justice department took to keep information from the public during his administration, according to the Associated Press.

Obama also made a problematic claim that Republican “sabotage” has cost 3 million people their health insurance. With his return to the political donnybrook on behalf of Democrats in the November elections, Obama has brought a once-familiar style back into the discourse. It’s measured, nuanced and distinct from the torrent of misstatements from Trump. That doesn’t mean Obama always tells the truth, the Associated Press said on Sept. 12. VTN
CMS asks comment on red tape rule

The Centers for Medicare and Medicaid Services have announced a proposed rule to relieve burden on healthcare providers by removing unnecessary, obsolete or excessively burdensome Medicare compliance requirements for healthcare facilities.

Collectively, these updates would save healthcare providers an estimated $1.12 billion annually. Taking into account policies across rules finalized in 2017 and 2018 as well as this and other proposed rules, savings are estimated at $5.2 billion.


President Trump ordered federal agencies to “cut the red tape” and reduce burdensome regulations, and this proposed rule is the response form CMS. In addition, feedback from Requests for Information the agency issued seeking stakeholder input on regulatory burdens helped inform this proposed rule, with particular attention to comments and anecdotal insights from clinicians serving Medicare beneficiaries.

“We are committed to putting patients over paperwork, while at the same time increasing the quality of care and ensuring patient safety and bolstering program integrity,” CMS Administrator Seema Verma said.

“With this proposed rule, CMS takes a major step forward in its efforts to modernize the Medicare program by removing regulations that are outdated and burdensome.

One provision would reduce burden and promote efficiency to support patients who need organ transplants. The rule would eliminate a duplicative requirement on transplant programs to submit data and other information more than once for “re-approval” by Medicare. Re-approval has led to transplant programs avoiding performing transplants for certain patients, causing some organs to go unused. CMS will maintain other requirements in order to continue to monitor outcomes and quality of care in transplant programs after initial Medicare approval.

Verma said the proposed rule is the latest in a series of steps that are reducing unnecessary burden on facilities, generating efficiencies and giving healthcare providers more time to spend with their patients.

Across rules finalized in 2017 and 2018 and current proposed rules to address these topics, CMS projects savings of nearly $5.2 billion and a reduction of 53 million hours through 2021. That results, according to CMS analysts, in saving 6,000 years of burden hours over the next three years. Many of the policies produce ongoing annual savings not reflected in this total.

VENOUS COMPRESSION

HOME DEVICE
continued from page 33

venous pressure, as well as by promoting the release of angiogenic growth factors and nitric oxide, a potent vasodilator. These physiologic effects are postulated to improve symptoms in patients with claudication.

A search through Dec. 31, 2016, was performed to identify all randomized controlled trials evaluating the efficacy of HPILC for the management of intermittent claudication. The primary outcome measured was absolute claudication distance (ACD). Eight studies eligible for inclusion were identified with a combined total of 290 subjects, 172 of whom were randomized to HPILC. An increase in ACD was observed in subjects treated with HPILC in all studies. The overall change in mean ACD ranged from 53m to 275m for subjects receiving compression compared with 5m to 15m for controls.

“HPILC is associated with a significant increase in ACD compared with controls,” Dr. van Bemmelen said. “Limb compression is now seen as an effective, noninvasive treatment option for patients with intermittent claudication.

“Multiple studies have confirmed that pneumatic compression is an effective means of treating intermittent claudication, but there was a need for cohesion. Most of the studies we looked at for this meta-analysis showed vascular improvements lasting months, even years after compression treatment was withdrawn. The reason improvements were sustained can be attributed to collateral arteries that grew as a result of the unique pressure pulses applied by the pneumatic compression device.”

Patients with claudication have leg pain with ambulation that significantly affects their physical and emotional well-being.

President Ed Arkans said the staff of ACI Medical have worked hard to develop the ArtAssist device in step with the latest findings and will continue to do so.

“Meta-analyses are an excellent way to step back and measure our progress, but more importantly, they act as a guide for gaps we can fill to meet the needs of more patients suffering from intermittent claudication,” Arkans said. “We are very pleased to see the results of the meta-analysis demonstrate that ILIC should be considered a valuable treatment modality for lifestyle-limiting claudication.”

The ArtAssist device is a specially designed, patented, non-invasive pneumatic device for the treatment of PAD. Clinical evidence has shown that its use doubles and triples walking distances and has long-term benefits. It is a home-use prescription medical treatment that doubles and triples arterial blood flow without surgery in PAD patients so wounds can heal without amputation. Clinical studies have shown short-term therapeutic benefits, such as reduced pain and improved walking distances, and long-term benefits including collateral vessel formation and improved healing of ulcers. For more information call 760-744-4400 or email at ed@acimedical.com.
HEALING AT THE MID-LEVEL
Two mid-level practitioners discuss challenges, rewards, future of their profession

By Larry Storer

Mid-level practitioners in the medical field include occupations of nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants, to name a few. In this article, I asked two mid-level practitioners from American Vein & Vascular Institute to share their thoughts on the occupation, its challenges, rewards and future.

On behalf of Vein Therapy News (VTN), I want to thank Angela Cole, MS, PA-C, and Janette Trent, APN-BC for taking the time to answer questions and share their perspective.

Angela Cole, MS, PA-C, is a phlebologist at American Vein & Vascular Institute. Cole earned a Bachelor of Science in Cell Biology and Neuroscience from Montana State University and a Master of Science in Physician Assistant Studies from Rosalind Franklin University of Medicine and Science. Before joining American Vein & Vascular Institute, Cole worked in the fields of internal medicine and bariatric surgery. She has been performing ablation procedures for the treatment of chronic venous disease since 2013. Cole is also a member of the Colorado Academy of Physician Assistants.

Janette Trent, APN-BC, is also a phlebologist at American Vein & Vascular Institute. Trent has been a phlebologist since 2001, having worked and trained with many pioneers in the field of phlebology. In her previous roles, Trent was instrumental in establishing and directing a training program that allowed aspiring phlebologists to complete a preceptorship, which prepared them to complete the rigorous requirements for attaining fellowship with the American College of Phlebology (ACP), and assisted them in establishing their own phlebology practices. Trent earned a Bachelor of Science in Nursing from Indiana Wesleyan University and graduated from the Women’s Health Nurse Practitioner program through the Indiana Family Health Council and Indiana University-Purdue University in Indianapolis.

VTN: Here is a “standard” definition for a mid-level practitioner. How accurate is it?

COLE: It’s accurate only from a textbook standpoint. It doesn’t describe the quality and level of patient care we provide, by any means.

TRENT: This is not a reflective definition from a patient’s perspective. It doesn’t describe what we do. For patients, we are practitioners who diagnose, treat and also perform procedures.

VTN: What are the top challenges you face as a mid-level practitioner, and how do you overcome those challenges?

COLE: By far, my top challenge(s) are: Barriers to care due to issues of insurance reimbursement and electronic medical records (EMRs) which are designed to be efficient but are often the exact opposite.

The insurance reimbursement issues are well-known and hard-hitting to patients and their care givers. It is frustrating and oftentimes heartbreaking to find work-arounds to insurance barriers that still provide the level and quality of care needed for positive patient outcomes.

EMRs are created by people who don’t work in the field. These systems are a massive investment by the physician group and basically, once an EMR is chosen and purchased, you’re stuck with it. If you determine it’s not an ideal fit for your practice, it’s too expensive to change and you have to adapt and live with it. The biggest challenge with EMRs is that they require massive amounts of documentation, and that documentation takes time away from the quality of care you provide to patients.

Let me be clear that my employer (American Vein) chose an excellent EMR system, allowing my colleagues and me to maximize the quality of care we provide to patients, while still properly documenting each case. Throughout my career, I’ve worked with numerous EMR systems and I have not always been blessed with good ones. There is simply no incentive for EMR companies to improve their services, so this will remain a challenge.

TRENT: One of my top challenges is the misconception surrounding mid-levels and our qualifications to treat patients.

When I began my career in the mid 90s, there weren’t many mid-level practitioners around and it was a real challenge to be accepted by patients. Today, the mid-level occupation is much more prevalent in the medical field, but I still sometimes encounter patients who are wary of the level of care mid-levels will provide and they are willing to reschedule their appointments to be seen by a physician.

VTN: What do you find most rewarding about your position, and why?

COLE: My phlebology career has afforded me many joyful moments. Phlebology is rewarding because the results of care affect a patient’s life in profound ways. With proper treatment of their condition, patients can regain control in their life. They can resume walking their dog, exercising, sleeping soundly and so much more.

TRENT: Getting to know my new patients and establishing a relationship with them is extremely rewarding. When I first meet these patients, they are in significant amounts of pain and have lifestyle restrictions. I see them often in those first weeks of care and I get to see vast improvements in their quality of life. I meet them at their worst, and one or two months later, they are back to normal activities, nearly pain free.

As an example, Jack (not his real name) is a 48-year-old patient of ours (American Vein) who had leg pain, aching, swelling and fatigue in his legs, particularly at the end of the day after standing all day at work. He works in sales, so he was required to be on his feet for several hours of the day. Because he had no visible varicose veins, it took him about two years after the onset of his symptoms to find his way to us for an evaluation.

In the meantime, his legs were hurting so badly that he had stopped playing golf because he was unable to stand long enough to play without significant leg pain. His initial ultrasound evaluation at American Vein indicated that although he had no visible varicose veins on his legs, he did have considerable venous reflux (faulty blood return out of the legs) in the veins underneath the surface.

We performed three procedures on Jack’s legs to correct this venous reflux, which he tolerated well with no downtime after his procedures. When he returned for his one-month post-treatment evaluation, he was already back to playing golf again without pain and could easily stand for several hours a day at work without pain. He was very happy to have his quality of life back and said that his only regret was that he didn’t know prior to seeing us that venous disease could exist without visible varicose veins.

VTN: How do mid-level practitioners benefit a business/ practice management group?

COLE: Having mid-levels in a practice allows more time for caregivers to spend with patients. A PA is an extension of the supervising physician, a resource that allows the physician to be more productive. The PA can diagnose and treat patients, consulting with the supervising physician as needed. The supervising physician is able to conduct more research on patient conditions and also consult with patients who have more severe care needs. We actually make each other more productive and efficient, thereby providing higher levels of patient care.

TRENT: Mid-levels bring convenience to patients. In my practice at American Vein, mid-levels work in close coordination with physicians. Oftentimes, we are able to see patients the same day they call, whereas, they may need to wait several days to see the physician. Because we work in close conjunction with the physician, we can call on them with any questions or challenges that may arise with the patient’s care.

VTN: What changes do you foresee happening in the mid-level practitioner career field over the next three to five years, and in the next decade?

COLE: I believe the occupation of mid-level provider will continue to grow as patients better understand the concept. Patients will become more comfortable in the care of a mid-level provider and understand the important role we play within a provider organization.

TRENT: The scope of the mid-level practice is expanding and will continue to do so. For example, NPs are now able to perform in-office procedures. As the level of care we are allowed to provide expands, our education requirements will increase, as well. Currently, NPs are required to hold master’s degrees and eventually, I think we will need to have our doctorate degrees. VTN
2018 ACP ANNUAL CONGRESS WILL BE A FRESH BREAK FROM THE PAST

The School of Medicine at Emory University has published a study suggesting that educational videos significantly improve the patient consent process versus traditional face-to-face methods. The physicians who participated in the study also believed that they spent less time during the face-to-face portion of the consent process following video.

Seema Verma, Centers for Medicare & Medicaid Services Administrator, issued a warning to Medicaid plan sponsors on Thursday, warning the agency would begin unscheduled targeted financial audits. The warning came at the 2018 Medicaid Managed Care Summit during a speech Verma delivered in which she vowed to bring more transparency to Medicaid audits.

Medtronic has picked up the rest of Israel-based Mazor Robotics in a $1.6 billion deal that is to close in Medtronic's third quarter ending Jan. 25, 2019. The merger was unveiled at the North American Spine Society 2018 Annual Meeting in Los Angeles Sept. 26. The definitive merger deal

Dr. Ajit K. Naidu, MD, leads the professional medical staff at the Cardiovascular Institute of the Shoals, Al., in providing the best technology, skill and technique for patients in the Shoals and surrounding areas who are suffering from peripheral vascular disease, coronary artery disease and cardiosclerosis. He is committed to keeping up with medical and technological changes to help his patients in the safest and most effective way possible. He is a speaker at vein and heart conferences.

Dr. Naidu treats and manages patients at Eliza Coffee Memorial Hospital in Florence, Ala.; Helen Keller Hospital in Sheffield, Ala.; and Shoals Hospital in Muscle Shoals, Ala. He was the first physician in the Shoals to offer radial artery cardiac catheterizations and coronary interventions, laser varicose vein ablation, and advanced techniques in peripheral vascular intervention.

In addition to being a published author, Dr. Naidu has served as an investigator for multiple national clinical trials. He is also on the faculty of C3, Complex Cardiovascular Catheter Therapeutics, an International Interventional Cardiology Conference.

He is a fellow of American College of Cardiology (FACC),
EchoNous offers AI Station to dock new nursing tools

EchoNous, a Seattle company focused on delivering intelligent medical tools, has released the AI Station, a new docking system especially designed for emerging nursing tools, aimed at raising convenience for nurses and lowering costs for health systems.

With the goal of reinventing what has historically been an afterthought medical device element, EchoNous commissioned an iconic industrial designer, Nike’s former Global Footwear Creative Director and Product Innovation Director Dave Schenone and listened carefully to clinicians and biomedical leaders at one of the nation’s top health systems.

“Everything from colors, to selection of materials, to the most minute of daily functions were reconsidered from a blank sheet of paper and through a fresh set of eyes,” said COO Niko Pagoulatos. “Quite importantly we have integrated a ‘flexible electronic hub’ into the AI Station, aimed at both current and newly emerging AI functionality tasks.”

Pagoulatos said the AI station is a uniquely expandable platform that integrates EchoNous’ current intelligent tools, the recently released EchoNous Vein and Uscan bladder scanner, as well as devices currently in development. “Together, this family of tools will powerfully utilize emerging artificial intelligence methods along with the company’s extremely miniaturized ultrasound platform to conquer everyday problems in healthcare.”

Designed from the ground up, EchoNous reimagined every component of the nursing dock, based on first-hand direct input from nurses and biomedical engineers in the creation of this new AI Station.

Key design elements include a more narrow lateral design for better maneuvering in tight spaces, a lower base height to fit underneath a hospital bed – enabling the entire cart to be closer to the patient, probe cords docked in an “inner channel” to prevent snagging and tripping, and importantly, the use of the best materials available today in consideration of aggressive infection control techniques used in hospitals today.

EchoNous chose AI Station materials with the goal of optimizing durability and cleanability while maintaining a low weight for ease of maneuvering. Featured materials include anodized aluminum, Tritan plastic and stainless steel.

Seeking to bring a sense of art to the otherwise mundane approach to device design, EchoNous commissioned Dave Schenone to apply his “Attract, Engage and Capture” framework of innovating new products. VTN READ MORE: echonous.com

SIA gets FDA OK to market advanced bioabsorbable mesh for cosmetic surgery

Surgical Innovation Associates (SIA), a Chicago start-up medical device company, has received 510(k) clearance from the U.S. Food and Drug Administration for DuraSorb Monofilament Mesh, the first in a line of advanced bioabsorbable technologies for reconstructive and cosmetic surgery.

Each year, more than a million Americans are implanted with surgical mesh to provide the soft tissue support that is necessary in a variety of general and plastic surgical procedures.

Much like an absorbable stitch, DuraSorb Monofilament Mesh is designed to integrate into the patient’s tissue – providing strong support during the critical initial phases of healing – and then slowly dissolve, leaving the patient free from foreign material within one year.

The device brings cutting-edge polymer science and evidence-based engineering to bear on a material that has been safely used in other surgical applications for decades. DuraSorb will be released in select geographies in early 2019.

“The idea of a mesh that is there when you need it and gone when you don’t is appealing, for much the same reason that absorbable sutures have become a key part of a surgeon’s armamentarium – tissue support from a foreign material is crucial during healing, but at some point thereafter may become a liability,” said John Kim, MD and inventor of the device, and Professor of Plastic Surgery at Northwestern University. “This technology was developed in direct response to unmet clinical needs in our field.”

Complications following mesh placements can range from long-term pain to non-healing wounds. Historically there has been a dichotomy between permanent synthetic meshes and biologic meshes. Permanent synthetics provide favorable long-term support in hernia surgery and abdominal wall reconstruction. However, they are known to expose patients to long-term risk of pain, non-healing wounds and complications during later operations.

Biologic meshes – derived from human and animal cadavers – promise long-term biocompatibility once they integrate into the patient’s tissue, but carry excessively high cost, risk of adverse inflammatory reactions and mixed clinical results.

Alexei Mlodinow, CEO of SIA, said that having known people who have gone through the pain of multiple mesh-related operations, she found it gratifying to collaborate closely with opinion-leading surgeons to make DuraSorb a reality.

“Our guidance went into every key decision during product development and will now steer our clinical trial strategy as we replicate our robust preclinical data in a real-world setting.”

Founded in Chicago in 2016 by affiliates of Northwestern University Feinberg School of Medicine and Kellogg School of Management, SIA has taken DuraSorb from the pages of a patent into the operating room, and now has multiple devices in development to improve post-cancer breast reconstruction, minimally-invasive facelift, and other techniques. VTN READ MORE: sia.health

Report details growth of treatment devices for varicose veins; sales to exceed $1.7M

The global varicose veins treatment devices market is expected to reach $1,715,600 by 2025. The growth in investments by the companies in the industry to develop innovative and effective products is likely to increase the market growth over the forecast period.

The 100-page report on the varicose veins treatment device market offered by Research and Markets, “Varicose Veins Treatment Devices Market Size, Share & Trends Analysis Report By Type (Endovenous Ablation, Sclerotherapy, Surgical Ligation & Stripping), By Region, And Segment Forecasts, 2018–2025,” is $5,950 for a single-use electronic PDF with enterprise site licenses are available.

Information highlighted in the May 18 report include:

• In the United States, Medicare provides coverage to the patients undergoing sclerotherapy treatment for varicose veins, which can increase its adoption by the care providers and especially by the patients.

• The endovenous ablation segment is anticipated to witness the fastest growth over the forecast period as it is preferred over the conventional procedures such as surgical stripping and ligation.

• North America dominated the market in terms of revenue share in 2017 because about 30 million Americans suffer from varicose vein each year.

• Asia Pacific is expected to be the fastest-growing market segment in the coming years due to rising awareness about minimally invasive and noninvasive procedures, rising disposable income levels, and large base of geriatric population.

• Key market players include AngioDynamics Inc., Medtronic plc, Syneron Medical Ltd., Biolitec AG, Lumenis Ltd., Energiet Group, Efufoton srl, Quanta Systems S.p.A. and Teleflex Inc.

• Development of innovative products, commercialization, and availability of reimbursements for the product are some of the strategies undertaken by the market players to strengthen their position in the market.

• In addition, market players acquire other vascular businesses to boost their own product portfolio and overall revenue. For instance, Teleflex acquired Vascular Solutions Inc. in 2017.

• Some of the market players play a role of distributors by purchasing products from core manufacturers. For instance, AngioDynamics Inc. purchased Asclera from Merz in March 2016.

READ MORE: researchandmarkets.com/research/mpxvmv/global_varicose?w=5

Report details VTE global epidemiology

The “Global Venous Thromboembolism Epidemiology and Patient Flow Analysis – 2018” report has been added to Research and Market’s offering.

The research provides insights into VTE epidemiology, VTE diagnosed patients and VTE treatment rates for the United States, Japan and European Union countries. The research measures key indicators including prevalence of venous thromboembolism derived from epidemiological analysis, patients diagnosed with VTE, and patients treated with a drug therapy.

The research study helps executives estimate the VTE market potential, assess unmet needs, develop drug forecasting models and build population-based health management frameworks. The information presented in this study is used to evaluate market opportunities, effectively identify target patient population and align marketing decisions.

The research provides estimates and forecasts of VTE prevalence, VTE diagnosis rate, and VTE treatment rate for the period 2017-2026. The information is presented by leading geographies including the United States, Germany, France, Spain, Italy, the United Kingdom and Japan. VTN READ MORE: researchandmarkets.com/research/pdngbr/venous?w=4
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Siemens Healthineers has launched its new ultrasound system, the Acuson Sequoia. The new Acuson Sequoia, a general imaging ultrasound system, was developed in response to one of the most prevalent challenges in ultrasound imaging today: the imaging of different sized patients with consistency and clarity.

With its new Deep Abdominal Transducer (DAX), a powerful architecture and innovative updates to elastography and contrast-enhanced ultrasound, the new Acuson Sequoia produces penetration up to 40cm. With its powerful architecture and innovative features, the new Acuson Sequoia expands precision medicine by enabling high-resolution imaging that adapts to patients’ size and personal characteristics, contributing to more confident diagnosis.

Deep tissue penetration without affecting diagnostic quality has always been the holy grail of ultrasound imaging. DAX from Siemens Healthineers is a patented imaging transducer that allows clinicians to confidently image high BMI patients. With DAX, the new ACUSON Sequoia can deliver images at depths never before seen — up to 40cm — without compromising diagnostic quality.

“Ultrasound imaging has been plagued by variability,” Robert Thompson, head of Ultrasound at Siemens Healthineers, said.

Patients’ varied physical characteristics and user-dependent variabilities can impact a clinician’s ability to deliver an accurate diagnosis. With the new Acuson Sequoia, Siemens Healthineers provides users with a solution that enables real-time imaging for varying patient types, including those with high BMI, without sacrificing image quality and potentially reducing the need for repeat scans and unclear diagnoses.”

Siemens Healthineers built the entirely new Acuson Sequoia system to adapt to the “BioAcoustic Variations” of each patient, characteristics that include tissue density, stiffness, and absorption. The new Acuson Sequoia provides high-resolution InFocus imaging throughout the entire field of view, from the near field to the far field, in real-time.

In addition to increased rates of obesity, prevalence of liver disease is also on the rise. Clinicians utilize ultrasound elastography to determine shear wave speed, a parameter correlated with tissue stiffness in the liver which can correlate to chronic disease progression. Imaging in these patients can be challenging, particularly in larger patients where the signals are attenuated. The innovative power architecture of the new Acuson Sequoia provides six times the energy capacity available for shear wave elastography, enabling imaging at greater depths and a reduction in image variability.

As the most widely used medical imaging modality, ultrasound scanning preferences vary from user to user, making it a highly-personal experience. In a collective effort to eliminate variability and long-term ergonomic injuries, Siemens Healthineers hosted 170 workshops with 365 worldwide ultrasound users to create a platform designed by the user, for the user. The new Acuson Sequoia improves workflow by introducing user-friendly features, such as gesture detecting transducers — activated by touch, automated protocols, and streamlined registration which adapts to user preferences over time. A new ergonomically designed InTune transducer family reduces operator stress while increasing comfort.

A new capability among diagnostic ultrasound systems, “UltraArt” provides several image choices which are automatically generated with a user’s preferred image parameter settings, right on the touch screen. The user can select the image that best matches the patient’s BioAcoustic characteristics, avoiding manual adjustment of multiple individual image parameters.

The new Acuson Sequoia offers innovative technologies, unique transducers, and user-defined features to enhance workflow and personalize medicine.

Penumbra releases advanced catheters to remove thrombus

Penumbra has released what a spokesman says is its “most advanced technology,” the Penumbra JET 7 and Penumbra JET D reperfusion catheters. The devices work with the company’s Penumbra ENGINE system, which provides the vacuum aspiration that’s necessary to pull a thrombus from inside a vessel in the brain.

The JET 7 is designed for larger vessels that are closer and easier to access, while the JET D is for distal clots that require a narrower, more compliant catheter. The JET 7 has a .072” lumen, which is quite large, and the construction of the catheter includes 20 different sections that help achieve easier access and navigation through the vasculature, including so-called “Quad-Wire” technology closer to the handle that makes pushing the catheter a more confident and consistent process.

“The JET 7 Reperfusion Catheter with its advanced tracking technology and large 0.072” aspiration lumen is the most advanced device for stroke,” Alejandro M. Spiotta, MD, Medical University of South Carolina, said.

“In my clinical experience, I was able to easily and quickly navigate the JET 7 through tortuous anatomy to the face of the clot and achieve full revascularization after a single pass.”

“We know from our own published experience that increases in aspiration lumen size have led to faster recanalization times and higher likelihood of success at first pass without compromising safety. I eagerly await collecting and publishing our clinical experience with JET 7.”

Fujifilm Sonosite offers two new transducers for SonoSiteiViz unit

Fujifilm Sonosite Inc., a Bothell, Washington-based developer of point-of-care ultrasound solutions, announced the launch of two new transducers for the company’s SonoSiteiViz point-of-care ultrasound, adding to the two transducers already available with the handheld diagnostic tool.

With the addition of the L25v and C60v transducers to its portfolio, the miniaturized iViz ultrasound system gives clinicians the ability to view superficial applications, such as venous, arterial, ophthalmic, lung and nerve, as well as deeper applications, including abdominal and obstetrics, company officials say.

According to Diku Mandavia, MD, FACEP, chief medical officer and senior vice president, Fujifilm Sonosite designs, manufactures and tests transducers in-house with real-world customer needs in mind.

“Our transducers exceed stringent military specifications for drop-testing so you can use them with confidence in the most demanding of environments,” Dr. Mandavia said.

The iViz combines a seven-inch, high-resolution display and proprietary imaging technology to provide superior image quality for quick interpretations and diagnoses by physicians.

Dr. Mandavia said the iViz is manufactured using aircraft aluminum with beveled edges to protect the display and device from fluid ingress. Additionally, the transducers are drop-tested up to three feet and are IPX-7 rated, making them fully submersible in water and approved disinfectants.

READ MORE: sonosite.com

Cearna Aesthetics patents OcuMend hydrogel to speed cosmetic procedure healing

Cearna Aesthetics, an aesthetics company developing plastic surgery and dermatology products, has announced that the U.S. Patent and Trademark Office granted a patent protecting its OcuMend hydrogel technology. Cearna Aesthetics’ technology reduces bruising, pain, swelling and inflammation. OcuMend deploys arnica in a topical gel pad with 50 times the potency of other arnica gels. U.S. Patent No. 10,022,335 protects Cearna Aesthetics’ innovative manufacturing procedure for its high-potency arnica topical gel pad delivery system.

“I congratulate Cearna Aesthetics on receiving this important patent,” Tina Alster, MD, said. “OcuMend is unparalleled in its ability to reduce bruising and swelling after a wide variety of aesthetic procedures. As such, it has quickly become an indispensable addition to the post-treatment regimen that is prescribed to my patients.”

OcuMend is designed for cosmetic injectable procedures such as Juvéderm, Restylane and Botox and cosmetic surgery procedures such as rhinoplasty and blepharoplasty. According to the International Society of Aesthetic Plastic Surgery, 23 million aesthetic procedures were performed worldwide in 2016. On average, 66 percent of dermal filler patients bruise, based on 2,967 patients and 28 studies reported in Juvéderm and Restylane package inserts. According to the American Society for Aesthetic Plastic Surgery, average surgical recovery time is one to two weeks.

Josephine Polich, MD, inventor of OcuMend and founder and CEO of Cearna Aesthetics, said too many patients are afraid that bruising and swelling from dermal fillers will embarrass them when their husband, family or friends see it.

READ MORE: cearna.com
SAVE THE DATE!!
Spring and Fall Residents & Fellows Courses

2018 Spring Residents and Fellows Course
May 18-20, 2018
Englewood Hospital and Medical Center
350 Engle St, Englewood, NJ 07631

2018 Fall Residents and Fellows Course
December 7-9, 2018
University of Texas San Antonio
San Antonio, TX

OVERVIEW
The Residents and Fellows Course in Venous Disease is presented for the benefit of Fellows and Residents within the specialty of vascular surgery, interventional radiology, cardiology, vascular medicine and associated programs.
The goal of the course is to educate and update the Fellows and Residents regarding the latest theories and developments in the clinical practice of vein disease management. Residents and Fellows will gain an overall understanding of vein disease to allow them to successfully incorporate venous knowledge, skills and techniques into their overall practice as they make the transition from training to the clinical practice.

FEES
Residents and Fellows in an accredited training program, do not pay registration fees to attend. In addition, the AVF provides a travel stipend, hotel accommodations, and meals while at the Course. "Attendees must provide a credit card to hold their hotel reservation. If registration is not cancelled three weeks prior to the event, the credit card will be charged for one-night hotel"

ADDITIONAL BENEFITS OF ATTENDING
By attending the 2018 Courses you will receive complimentary registration to AVF's 2019 31st Annual Conference scheduled to take place at the Westin Mission Hills Golf Resort and Spa in Rancho Mirage, CA from February 19-22, 2019. You will also receive a one-year complimentary Resident/Fellow membership to the American Venous Forum, and all of the membership benefits associated with an AVF membership. (Please note that the complimentary conference registration and membership are nontransferable or redeemable for cash).

MEETING ATTIRE
Dress is casual including dinners.

FELLOWS GRANT - TRAVEL REIMBURSEMENT
The courses are funded through a Grant Program that covers registration and travel expenses. To be eligible for the grant, all participants are required to attend the entire course. Each will receive two nights of lodging at the designated hotel, transportation to and from the airport, and food and beverage supplied during the course. AVF will reimburse travel expenses up to a total of $550. This includes travel to and from the course (i.e., coach airfare, gas mileage, train ticket, etc.), parking and nominal food and beverage purchases on days of travel. Please note that our policy is that all travel reimbursements must be submitted within 30 days of the completion of the course.

NOTE: Alcoholic beverages will not be reimbursed. A travel reimbursement form will be provided. Each Resident and Fellow must complete their own reimbursement form and forward it to the AVF office along with itemized receipts to receive reimbursement. Failure to provide completed form will delay reimbursement.

NOTE: Failure to attend the entire course will result in forfeiture of any travel reimbursement.

For more information regarding the Spring and Fall Residents and Fellows Courses or anything AVF related please contact the AVF office at (727) 350-1580 or email us at info@veinforum.com, or www.veinforum.com, or check us out on social media.
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