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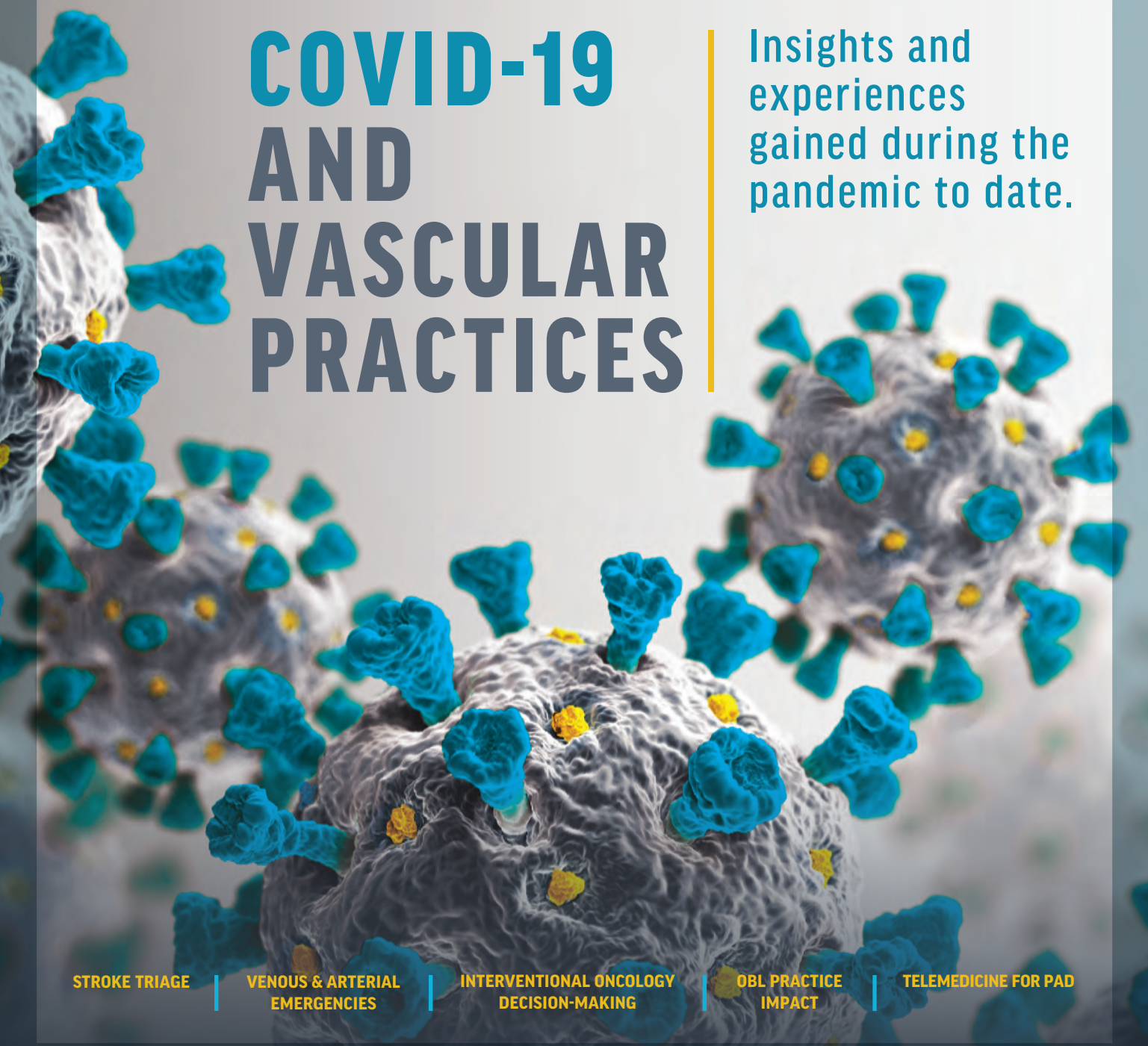
Endovascular TODAY

August 2020 • Volume 19, No. 8



COVID-19 AND VASCULAR PRACTICES

Insights and experiences gained during the pandemic to date.

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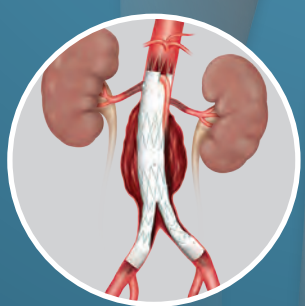

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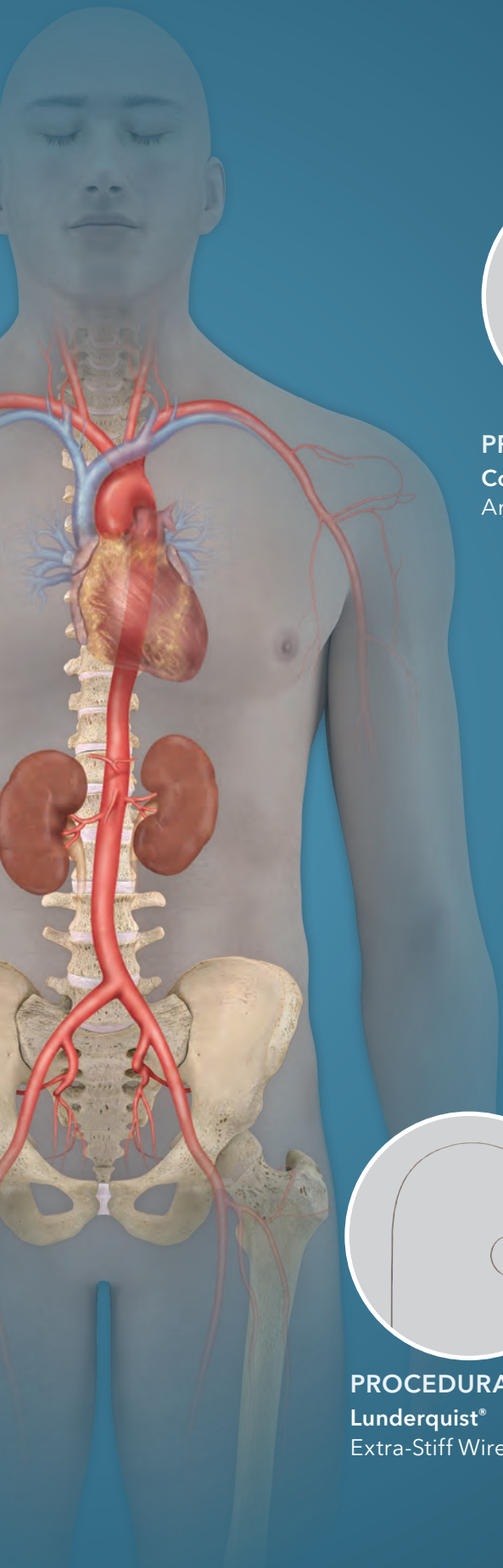

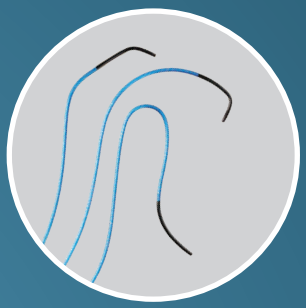

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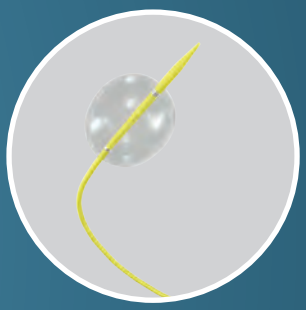

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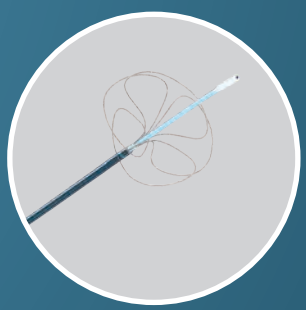

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COVID-19 AND VASCULAR PRACTICES

Think back to what you were doing on New Year's Eve, December 31, 2019. Maybe at a big party celebrating with friends and family, a small gathering of family, or (like some of us) providing patient care. Few, if any, of us understood how the report that day of the outbreak of a novel coronavirus (COVID-19) in Wuhan, China, would directly and deeply impact personal and professional lives across the globe. Nearly everything we do has changed due to COVID-19, and everyone is affected. In rare instances, we have seen favorable developments, such as those who are fortunate enough to still be working quickly learning how much they can do remotely, an arrangement that is likely to persist after the pandemic. But of course, many if not most other aspects of life are more challenging. In patient care, especially procedural-based fields, direct human-to-human interaction is often a necessity.

In every area of endovascular care, COVID-19 has presented new clinical challenges in addition to logistical hurdles. The purpose of this issue is to highlight how our colleagues have managed to continue providing care while keeping patients, coworkers, and themselves safe.

First, Akhilesh Sista, MD, explains what has been learned so far about venous emergencies during the COVID-19 era for practice, safety protocols, and decision-making. Two additional articles highlight how stroke care has changed in a pandemic environment. Kurt A. Yaeger, MD; Johanna T. Fifi, MD; and J Mocco, MD, provide insights on how the Mount Sinai Health System in New York City responded and continues to manage stroke care. Then, Ameer E. Hassan, DO; Thabele (Bay) Leslie-Mazwi, MD; Ashkan Mowla, MD; William J. Mack, MD; and Stavropoula Tjoumakaris, MD, each offer one practice adaptation that has made a difference in managing stroke at their institution.

We then look at how treatment is changing for another emergent procedure. Niten Singh, MD, and Benjamin Starnes, MD, share their experience at the University of Washington School of Medicine in Seattle and how they adapted to maintain patient and physician safety during emergency arterial repairs.

Then, Divya Sridhar, MD, elucidates on the considerations for interventional oncology, including risk mitigation strategies and treatment decision-making for COVID-19–positive cancer patients.

Outside the hospital setting, office-based labs have also seen significant shifts in process. We gathered a panel that includes Bryan Fisher, MD; Mark J. Garcia, MD; Yazan Khatib, MD; and Sonya Noor, MD, to discuss the impact this novel coronavirus has had on procedural volume shifts, hospital referrals, follow-up scheduling, and more.

Finally, we look at how to ensure quality when using telemedicine for treating peripheral artery disease (PAD). Tony Das, MD, and Nicholas Macpherson, MD, describe the unique opportunities telemedicine offers for PAD and dispel perceived barriers to adoption.

Each of these authors has given generously of their limited time and considerable expertise—thanks to all of you. The readership of *Endovascular Today* is greatly in your debt. I would also like to thank the nimble editorial staff of *Endovascular Today* for their flexibility, adaptability—and unflappability. The topics for these issues are chosen well in advance, but this topic chose itself and *Endovascular Today* executed a perfect pivot.

In closing, it is important to acknowledge that the COVID-19 pandemic has also been a backdrop for seismic shifts in awareness of the historic and ongoing problems of inequality and racial injustice. COVID-19 has emphasized issues in the differential impact among economically disadvantaged communities and communities of color. However, this pandemic is also a stage on which we can collectively work to address these problems. We will get through this and be stronger, smarter, and more equal for it. ■

John A. Kaufman, MD
Guest Chief Medical Editor

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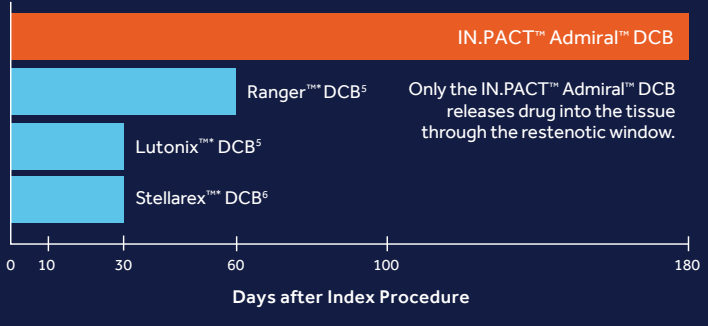
DURATION OF PACLITAXEL IN TISSUE



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† Primary patency not assessed after 3 years.
** Data and additional comparative data on file with Medtronic.
†† The potential for fewer visits to a healthcare provider may reduce exposure to COVID-19-related risks.

Medtronic
Further, Together

1. IN.PACT Admiral 5Y data: Laird J, et al. *Circ Cardiovasc Interv.* 2019;12:e007702.
2. Virmani, R. Charing Cross, 2016: Arterial wall response to drug coated balloon, Data on File.
3. Schneider PA, Laird J, Tepe G, et al. Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries: Long-Term Results of the IN.PACT SFA Randomized Trial. *Circ Cardiovasc Interv.* January 2018;11(1):e005891.
4. Based on the mortality data from the LEVANT 2 IDE in the Lutonix™* DCB IFU (BAW1387400r6) and the IN.PACT SFA Trial in the IN.PACT™ Admiral™ DCB IFU (M052624T001).
5. Gongora C, et al. Impact of Paclitaxel Dose on Tissue Pharmacokinetics and Vascular Healing: A Comparative Drug Coated Balloon Study in the Familial Hypercholesterolemic Swine Model of Superficial Femoral In-Stent Restenosis. *JACC Cardiovasc Interv.* 2015 Jul;8(8):1115-23. Ranger™* DCB is not approved for commercial use in the US.
6. Spectranetics Stellarex 035 DCB Advisory Panel Briefing Package. June 2019.

INDICATIONS FOR USE
The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

CONTRAINDICATIONS
The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

WARNINGS
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years posttreatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

PRECAUTIONS
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

POTENTIAL ADVERSE EFFECTS
The potential adverse effects (e.g., complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.

Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.

Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.

Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manualsmedtronic.com.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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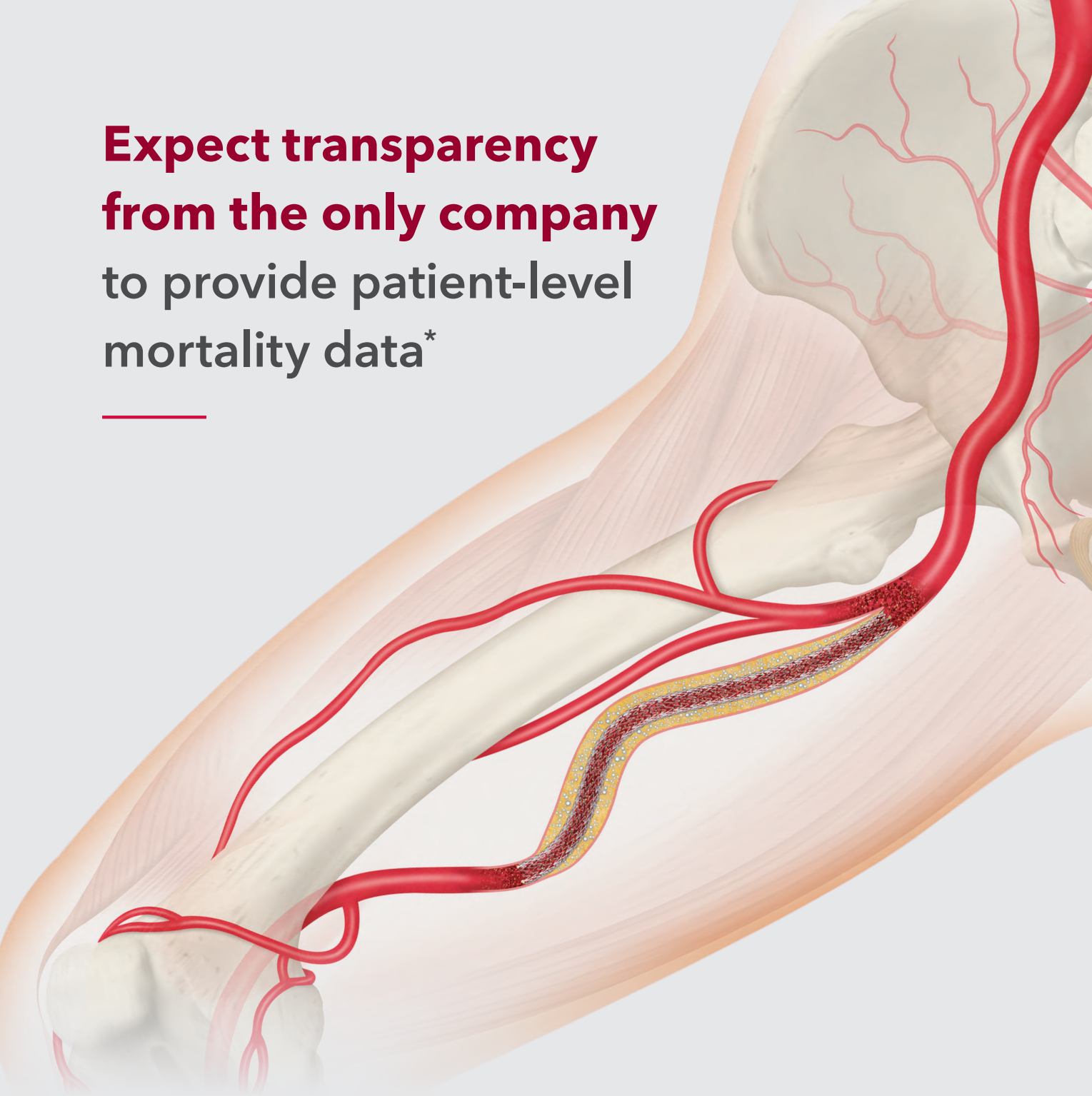

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cookmedical.com/peripheral-intervention/paclitaxel/

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*All data have been de-identified to protect patient privacy.

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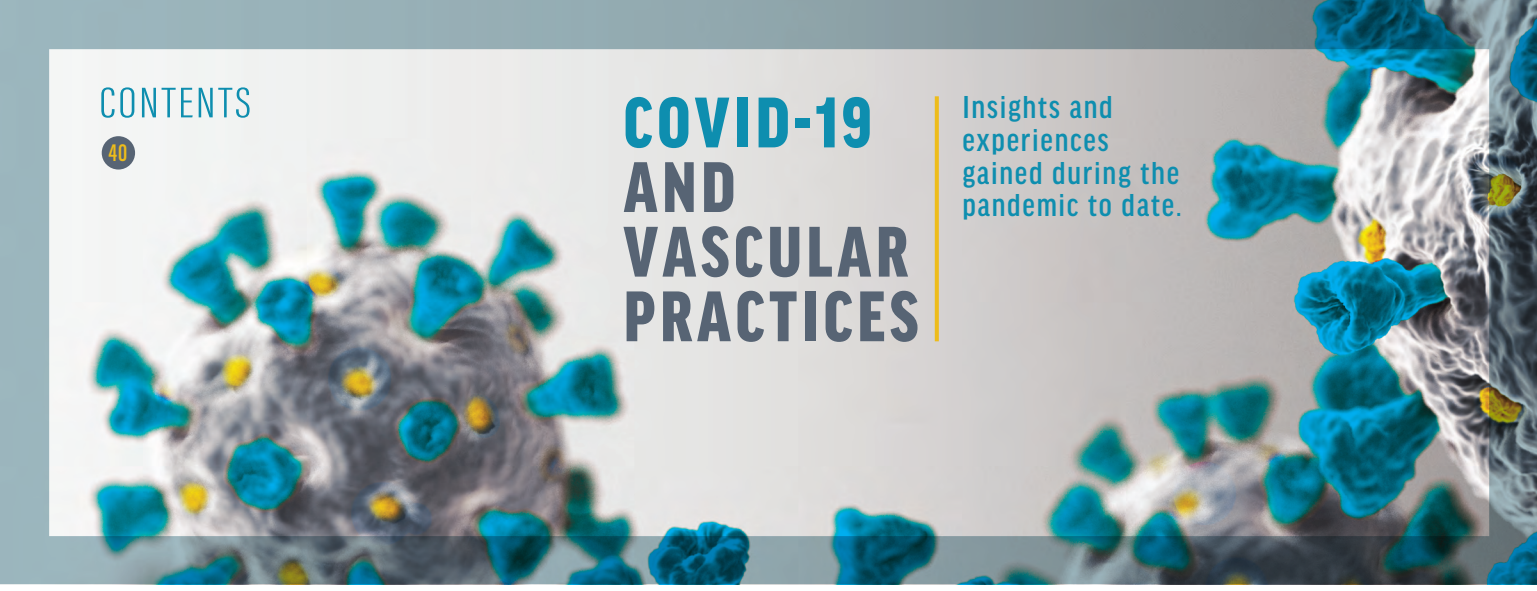
COVID-19 AND VASCULAR PRACTICES

Insights and experiences gained during the pandemic to date.



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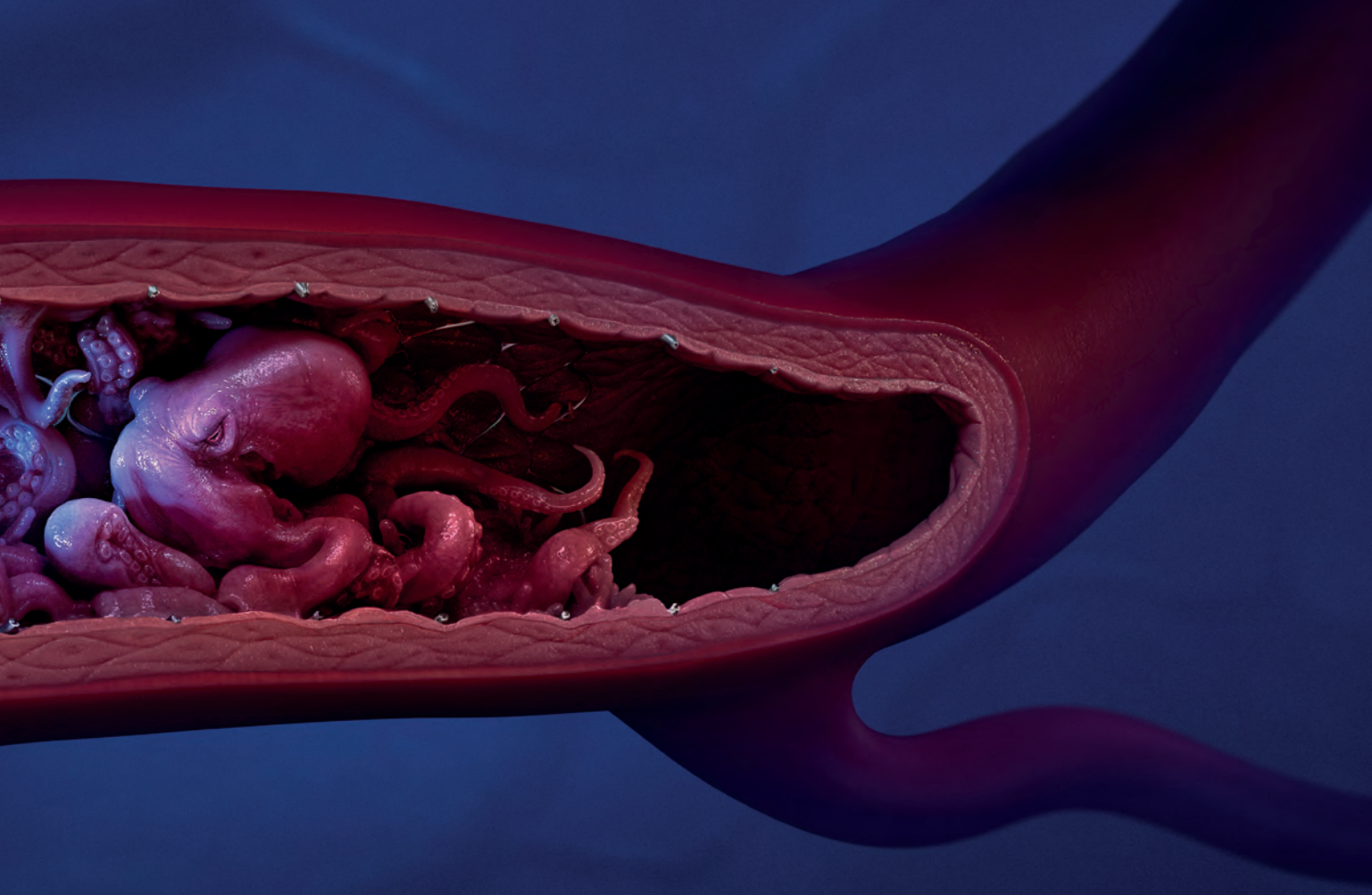
References: 1. Rundback J, Chandra P, Brodmann M, et al. Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser™ IDE study. *Catheter Cardiovasc Interv.* 2019;94(7):1010-1017. **2.** Shammas NW, Chandra P, Brodmann M, et al. Acute and 30-day safety and effectiveness evaluation of Eximo Medical's B-Laser™, a novel atherectomy device, in subjects affected with infrainguinal peripheral arterial disease: results of the EX-PAD-03 trial. *Cardiovas Revasc Med.* 2020;21(1):86-92. **3.** Auryon. Instructions for use. AngioDynamics; 2019.



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INDICATIONS FOR USE

The AURYON™ Atherectomy System is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions, including in-stent restenosis (ISR).

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Caution: Federal (USA) law restricts the use of the system by or on the order of a physician.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

angiodynamics

Endovascular NEWS
VOLUME 19, No. 8 | August 2020

COVID-19 COVERAGE

National Blood Clot Alliance Receives CDC Grant to Support COVID-19 Research and Public Awareness Campaign

July 28, 2020—The National Blood Clot Alliance (NBCA), in partnership with the University of Oklahoma, has received an award through an Association of University Centers on Disabilities—Centers for Disease Control cooperative agreement to facilitate and advance research into blood clots as a complication of COVID-19. The award will also fund researchers' efforts to raise awareness among certain high-risk populations, including how blood clot complications related to COVID-19 affect Black and pediatric patients.

NBCA is a patient advocacy organization focused on life-threatening blood clots. More information is available at stoptheclot.org.

As noted in the NBCA announcement, blood clots have been commonly observed in patients hospitalized with COVID-19 since the outset of the pandemic. The condition is often characterized by elevations in fibrinogen and D-dimer levels, as well as by clinical events including deep venous thrombosis, pulmonary embolism, and arterial events including stroke.

Medical experts in the field are concerned about data suggesting that approximately one in three patients who are critically ill with COVID-19 will develop a potentially life-threatening blood clot. Additionally, patients with milder illness or those who are asymptomatic or unaware that they are infected with the coronavirus are developing dangerous blood clots. However, little is known about the incidence, prevalence, and outcomes of COVID-related blood clots in adult and pediatric patients.

NBCA's Medical & Scientific Advisory Board hopes to fill the gap in knowledge by coalescing data that are being collected across the United States into a central repository for information about COVID-related blood clots so that experts can develop the most effective treatment regimens and best practices.

NBCA outlined the following key objectives of this work:

- Developing a COVID-19 blood clot data repository that will gather and analyze information regarding the prevalence of venous and arterial thromboembolic events in adult and pediatric hospitalized, intensive care unit, and postdischarge settings.
- Examining Black and pediatric populations at high risk by collecting and disseminating information regarding rates of thromboembolic events among these less-studied populations.
- Establishing best treatment practices by planning and hosting a survey of best practices regarding blood clot treatments for hospitalized patients with COVID-19, intensive care unit patients with COVID-19, and adult and pediatric patients discharged after hospitalization for COVID-19.
- Educating clinicians and health care professionals regarding COVID-19–related blood clot prevalence, incidence, and anticoagulant best practices by developing a narrative and/or systematic review that analyzes and interprets data from the above surveys as well as input from patients and patient advocates.

Another critical component of the grant program is the development of a public awareness campaign to provide new knowledge and information about the association between COVID-19 and the development of blood clots to higher-risk populations, the general public, and health care professionals through educational materials made readily available online.

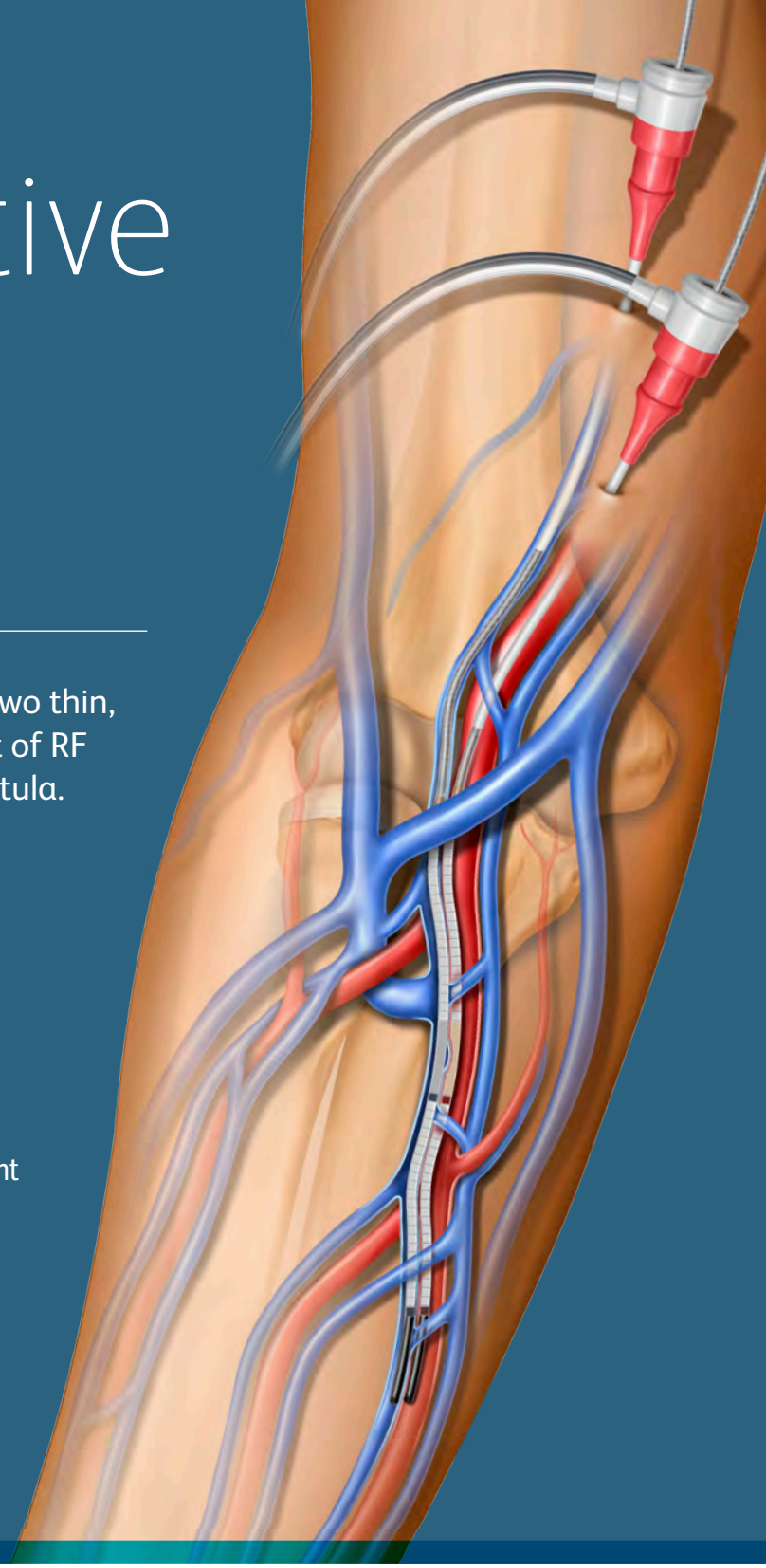
INDUSTRY NEWS

Sirtex Medical Launches the Siros System for Delivery of SIR-Spheres in Liver Cancer Treatment

August 3, 2020—Sirtex Medical US Holdings, Inc. announced the launch of the Siros system for the delivery of the company's SIR-Spheres yttrium-90 resin microspheres in the targeted treatment of liver cancer.

According to Sirtex, the Siros system's visually controlled administration allows physicians to determine

An Attractive AV Fistula Option



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[1] Compared to surgical AVF creation
[2] Yang S, Arnold R, Lok C, Rajan D, Glickman M. J Vasc Access 2017; 18(Suppl. 2): 8-14. As demonstrated with the WavelinQ™ 6F EndoAVF System compared to a propensity-score matched surgical AVF cohort, comprised of a 5% CMS sample of claims data . N=60 for each. Total Intervention Rate of 3.4 versus 0.6, respectively.

The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. The WavelinQ™ System is contraindicated in target vessels <2mm in diameter. The WavelinQ™ System should not be used in patients who have (i) known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation, (ii) a known allergy or reaction to any drugs/fluids used in this procedure, or (iii) known adverse reactions to moderate sedation and/or anesthesia.

The known potential risks related to the WavelinQ™ System and procedure, a standard AVF, and endovascular procedures may include but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; sepsis; steal or ischemia; swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

Please consult product labels and instructions for use for all indications, contraindications, hazards, warnings and precautions.

BD

and adjust the precise quantity and speed of SIR-Spheres microspheres delivery. Additionally, the system is designed to be simple and versatile to allow expanded options for patient-tailored delivery. Siros features a peel-and-place tubing set; the company's needleless D-Vial that suspends SIR-Spheres into a vortex that may allow for a more even distribution; and a locking cover that safely secures the microspheres during delivery.

Stryker's Neuroform Atlas Stent Approved to Treat Aneurysms of the Posterior Circulation of the Neurovasculature

August 3, 2020—Stryker announced that it has received FDA approval for an expanded indication of its Neuroform Atlas stent system as an adjunctive stent for use in the posterior circulation of the neurovasculature. In May 2019, the device was approved for use in the anterior circulation.

According to the company, the approval makes the long-term treatment of aneurysms in the posterior circulation more feasible; these aneurysms rupture more frequently and are generally more difficult to treat.

The Neuroform Atlas is a self-expanding nitinol stent indicated for use with neurovascular embolization coils in the anterior and posterior circulation of the neurovasculature for the endovascular treatment of patients aged ≥ 18 years with saccular wide-necked (neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2 and ≤ 4.5 mm. The stent is positioned across the aneurysm neck to hold metal coils in place and occlude the aneurysm.

The premarket approval application for the expanded indication was granted based on clinical trial evidence proving the safety and efficacy of the device. The trial's anterior and posterior cohorts were composed of a total of 298 patients.

Siemens Healthineers Plans to Acquire Varian for $16.4 Billion

August 2, 2020—Siemens Healthineers AG and Varian Medical Systems, Inc. announced an agreement for Siemens Healthineers to acquire all shares of Varian for $177.50 per share in cash, corresponding to a purchase price of approximately $16.4 billion. Varian, headquartered in Palo Alto, California, focuses on cancer care, especially radiation oncology and related software. Siemens Healthineers, based in Erlangen, Germany, plans to finance the acquisition of Varian with a mix of debt and equity.

The agreement was unanimously approved by Varian's Board of Directors, which recommended that Varian shareholders approve it. The acquisition of Varian is expected to close in the first half of the calendar year 2021, subject to approval by Varian shareholders, receipt of regulatory approvals, and satisfaction of other customary closing conditions.

According to the announcement, Varian is increasingly leveraging technologies such as artificial intelligence, machine learning, and data analysis to improve cancer treatment and expand access to care. In the 2019 fiscal year, the company generated revenues of $3.2 billion with an adjusted operating margin of approximately 17%.

Since 2012, Siemens Healthineers and Varian have been collaborating in the strategic "EnVision" partnership, combining Varian's therapeutic systems and Siemens Healthineers imaging technology. This transaction builds on this partnership to develop improved cancer therapy solutions, including imaging for treatment planning to focused radiation therapy, for efficient workflow, and effective, personalized treatment, stated the companies.

Bentley's BeYond Venous Stent Approved in Europe

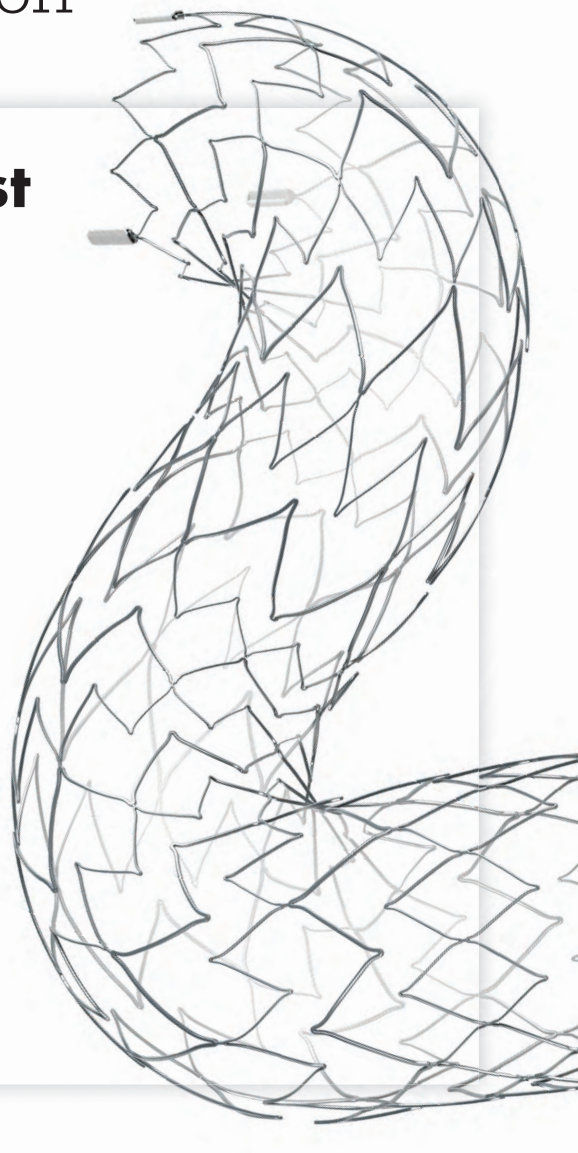
July 31, 2020—Bentley announced CE Mark approval for the BeYond venous self-expanding stent system. The initial commercial launch of the device in Europe will be limited to a circle of leading venous experts. Full availability is expected at the beginning of 2021.

The first-in-human procedure using the BeYond system was performed by Professor Houman Jalaie, MD, et al at the European Venous Center

stryker

Neuroform Atlas® Stent System

The only PMA approved stent indicated for the **posterior** circulation



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Retreatment rate

Results of ATLAS posterior PMA cohort at 1 year.

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Neuroform Atlas Stent System

RX ONLY

See package insert for complete indications, contraindications, warnings and instructions for use.

Indications for use

The Neuroform Atlas Stent System is indicated for use with neurovascular embolization coils in the anterior and posterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked (neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm.

Contraindications

- Patients in whom the parent vessel size does not fall within the indicated range.
- Patients in whom antiplatelet and/or anticoagulation therapy (e.g., aspirin and clopidogrel) is contraindicated.
- Patients who have not received anti-platelet agents prior to stent implantation.
- Patients with an active bacterial infection.
- Patients in whom angiography demonstrates the anatomy is not appropriate for endovascular treatment due to conditions such as:
  - Severe intracranial vessel tortuosity or stenosis;
  - Intracranial vasospasm not responsive to medical therapy.
- Patients in whom a pre-existing stent is in place in the parent artery at the target intracranial aneurysm location.

Potential adverse events

The potential adverse events listed below, as well as others, may be associated with the use of the Neuroform Atlas Stent System or with the procedure:

- Aphasia
- Allergic reaction to Nitinol metal and medications
- Aneurysm perforation/rupture, leak or contrast extravasation
- Blindness
- Cardiac arrhythmia
- Coil herniation through stent into parent vessel
- Cranial neuropathy
- Death
- Embolus
- Headache
- Hemiplegia
- Hemorrhage (i.e., intracerebral, subarachnoid, retroperitoneal, or in other locations)
- Hydrocephalus
- In-stent stenosis
- Infection
- Ischemia
- Mass effect
- Myocardial infarction
- Neurological deficit/intracranial sequelae
- Pseudoaneurysm
- Reaction to radiation exposure (i.e., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, or delayed neoplasia)
- Reactions to anti-platelet/anti-coagulant agents
- Renal failure
- Seizure
- Stent fracture, migration/embolization, or misplacement
- Stent thrombosis
- Stroke
- Transient ischemic attack
- Vasospasm
- Vessel occlusion or closure including parent vessel or non-target side-branches
- Vessel perforation/rupture, dissection, trauma or damage
- Vessel thrombosis
- Visual impairment
- Other procedural complications including but not limited to anesthetic and contrast media risks, hypotension, hypertension, access site complications (including pain, hematoma, local bleeding, local infection, and injury to the artery (i.e. dissection), vein, or adjacent nerves)
- Unplanned intervention

Warnings

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

- This device should only be used by physicians who have received appropriate training in interventional neuroradiology or interventional radiology and preclinical training on the use of this device as established by Stryker Neurovascular.
- Persons allergic to nickel titanium (Nitinol) may suffer an allergic response to this stent implant.
- Higher adverse event rates may be experienced for distal aneurysms located in the anterior and middle cerebral arteries.
- The safety and effectiveness of the device has not been established in the treatment of ruptured intracranial aneurysms.

Cautions / precautions

- Take all necessary precautions to limit X-ray radiation doses to clinical operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.
- The Neuroform Atlas stent may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm occlusion.
- Safety and effectiveness of the Neuroform Atlas Stent System in patients below the age of 18 has not been established.
- The benefits may not outweigh the risks of device use in patients with small and medium asymptomatic extradural intracranial aneurysms, including those located in the cavernous internal carotid artery.
- Carefully weigh the benefits vs. risks of device treatment for each individual patient based on their medical health status and risk factors for intracranial aneurysm rupture during their expected life time such as age, comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefits may not outweigh the risks associated with device use in certain patients; therefore, judicious patient selection is recommended based on clinical practice guidelines or tools to assess the life time risk of intracranial aneurysm rupture.

Safety Information Magnetic Resonance Conditional

Non-clinical testing and analysis have demonstrated that the Neuroform Atlas Stent is MR Conditional alone, or when overlapped with a second stent, and adjacent to a Stryker Neurovascular coil mass. A patient with the Neuroform Atlas Stent can be safely scanned immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla
- Maximum spatial gradient field up to 2500 Gauss/cm (25 Tesla/m)
- Maximum MR system reported whole body averaged specific absorption rate of 2 W/kg (Normal Operating Mode) and head averaged specific absorption rate of 3.2 W/kg.

Under the scan conditions defined above, the Neuroform Atlas Stent is expected to produce a maximum temperature rise of 4 °C after 15 minutes of continuous scanning. The Neuroform Atlas Stent should not migrate in this MRI environment.

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the Neuroform Atlas Stent when imaged with a spin echo pulse sequence and 3 Tesla MRI System. The artifact may obscure the device lumen. It may be necessary to optimize MR imaging parameters for the presence of this implant. See additional precaution related to the image artifact from the implant in the "Precautions" section of this labeling.

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

strykerneurovascular.com

Date of Release: JUL/2020

EX_EN_US

Aachen-Maastricht, in Aachen, Germany.

According to the company, the Beyond venous self-expanding stent system is an open-cell nitinol stent, indicated for acute and chronic symptomatic obstructions of the femoral or iliac vein. It is available in a range of diameters from 10 to 18 mm and lengths up to 150 mm.

Endologix Launches the Alto Abdominal Stent Graft System in the United States

July 30, 2020—Endologix Inc. announced the United States commercial release and the first commercial implantation of its Alto abdominal stent graft system for the treatment of abdominal aortic aneurysms. Endologix announced FDA approval of the Alto endograft in March 2020.

According to the company, the Alto is a workhorse endograft with broad indications to treat the widest range of patients. The device features an anatomically adaptive sealing technology and 7-mm neck indication to provide a precise seal near the renal arteries.

In addition, Alto's low profile (15-F outer diameter) enables the treatment of patients with small vessels and challenging access. An integrated balloon helps optimize the seal during the procedure.

Endologix noted that its core anatomically adaptive sealing technology has been studied in the ELEVATE investigational device exemption trial and the ENCORE database. ENCORE demonstrated favorable midterm durability evidenced by successful aneurysm exclusion and 5-year freedom from aneurysm-related mortality.

Artio Medical Acquires Flow Forward Medical

July 23, 2020—Artio Medical, Inc. announced it has acquired Flow Forward Medical, Inc., a medical device company developing methods for establishing and maintaining high-quality vascular access sites to improve outcomes for hemodialysis patients.

Flow Forward's Arteriovenous Fistula Eligibility system stimulates flow-mediated vein dilation to expand the initial vein diameter prior to the creation of an arteriovenous fistula (AVF). This aims to increase the number of hemodialysis patients eligible for AVF and to enhance the usability and lifespan of newly created AVFs.

The stock-for-stock merger transaction in which Flow Forward merged with and into Artio was approved by the Board of Directors and stockholders of both companies. The transaction closed on June 8, 2020.

First Patient Enrolled in Japanese Study of MedAlliance Selution SLR Sirolimus-Eluting Balloon for PAD

July 22, 2020—MedAlliance announced that its partner in Japan, MDK Medical, has enrolled the first patient in a clinical study of MedAlliance's Selution SLR sirolimus-eluting balloon for the treatment of peripheral artery disease (PAD). Earlier this month, a clinical trial notification was approved by Japan's Pharmaceutical and Medical Device Agency.

According to the company, the study will enroll up to 132 patients across multiple centers in Japan with the objective of assessing the safety and efficacy of Selution SLR for the treatment of superficial femoral and/or popliteal artery lesions.

The study is a prospective, controlled, multicenter, open, single-arm clinical investigation. The primary endpoint is the primary patency rate at 12 months. Secondary endpoints include major adverse events/target lesion revascularization; primary patency; and the change in Rutherford classification, ankle-brachial index, and Walking Impairment Questionnaire.

In February 2020, MedAlliance announced European CE Mark approval for the Selution SLR sirolimus-eluting balloon for the treatment of PAD.

Xact's Ace Robotic System Cleared by FDA for Image-Guided Percutaneous Procedures

July 15, 2020—Xact Robotics Ltd. announced that its Xact Ace robotic system was cleared to market in the United States for CT-guided percutaneous procedures. The Ace system is the second-generation robotic system from Xact Robotics, which is based in Massachusetts and Israel.

The company has begun a controlled market release with select radiology centers of excellence partners and is planning for a broader commercial launch of the Ace system later this year.

According to the company, the Ace system is a hands-free robotic solution combining image-based planning and navigation with insertion and steering of various instruments to the desired target with accuracy, consistency, and efficiency. The Ace robotic system was designed to treat a wide range of clinical applications and indications and to be compatible with multiple imaging modalities. In addition, the system's remote procedure capabilities will allow users to operate the system from outside the radiology procedure room to minimize staff and patient exposure and enhance safety measures, stated the company.

Terumo Acquires Quirem Medical

July 15, 2020—Terumo Corporation announced it has completed the acquisition of Quirem Medical BV, a Netherlands-based health care startup specializing in next-generation microspheres for selective internal radiation therapy (SIRT) based on the radioactive isotope Holmium-166 to treat liver tumors. Quirem Medical is now a wholly-owned subsidiary of Terumo.

Under the terms of the agreement, Terumo acquired 80.1% of the shares of Quirem Medical. Terumo will make a one-time, up-front payment of $20 million with up to $25 million additional payments based on the achievement of future milestones by 2030. Terumo invested in Quirem Medical in 2015 and became the exclusive global distributor of the company's technology. Previously, Terumo held 19.9% of the company's shares.

According to Terumo, Quirem Medical's full Holmium SIRT platform includes QuiremSpheres, QuiremScout, and Q-Suite.

- QuiremSpheres are commercially available microspheres containing Holmium-166. Recent trials have shown the safety and efficacy of Holmium microspheres for the treatment of unresectable liver cancer. QuiremSpheres can be visualized and quantified in low concentrations by means of single-photon emission CT (SPECT) and MRI to improve patient selection, therapy planning, and treatment verification.
- QuiremScout is a low-dose Holmium microsphere that helps evaluate the biodistribution of microspheres before therapy.
- Q-Suite is a dosimetry software package used to plan QuiremSpheres treatments based on QuiremScout dose imaging. Q-Suite is also able to determine SIRT success immediately after the procedure by converting SPECT imaging and MRI into absorbed dose distributions.

The three products have received CE Mark approval and are available in Europe, the Middle East, and Africa. In the coming years, Terumo intends to launch the Holmium platform globally as part of the ongoing expansion of its interventional oncology portfolio.

Avicenna.AI Cina Head Neurovascular Imaging Tool Cleared by FDA

July 14, 2020—Avicenna.AI, a France-based company focused on medical imaging artificial intelligence (AI), announced it has received FDA 510(k) clearance for its Cina Head triage AI solution for neurovascular emergencies.

The FDA clearance covers Cina's automatic detection capabilities for both intracranial hemorrhage (ICH) and large vessel occlusion (LVO) from CT imaging.

According to the company, Cina Head uses a combination of deep learning and machine learning technologies to automatically detect and prioritize acute ICH and LVO cases within 20 seconds, to alert radiologists within their existing systems and workflow. Cina's ICH detection capability was validated using data from 814 cases conducted at > 250 imaging centers across the United States demonstrating 96% accuracy, 91.4% sensitivity, and 97.5% specificity. The product's LVO detection capability was validated based on 476 cases with 97.7% accuracy, 97.9% sensitivity, and 97.6% specificity.

Cina Head is Avicenna.AI's first product for emergency radiology. Subsequent products in the trauma and vascular fields are expected to be unveiled in the next 12 months, advised the company.

Penumbra Launches Indigo System Lightning 12 and Appoints Medical and Scientific Leadership

July 14, 2020—Penumbra, Inc. announced the United States commercial availability of the Indigo System Lightning 12, which is the company's next-generation aspiration system for peripheral thrombectomy. Penumbra also announced appointments for two newly created positions: Corey L. Teigen, MD, as Chief Scientific Officer and James F. Benenati, MD, as Chief Medical Officer.

According to Penumbra, Lightning 12 combines the company's new Indigo System Cat 12 aspi-

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Reflux Control Microcatheter

Reduce microspheres reflux[1].
Go with the flow.

Flow dynamics based technology. Contrast media fluid barrier.

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1. Vessel Flow Dynamic Indication (Beads Reflux) Bench Test report TR-002.

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ration catheter with its Lightning Intelligent Aspiration to enable physicians to focus on optimizing thrombus removal using the system's clot detection mechanism. Cat 12 is a large-lumen aspiration catheter that incorporates laser-cut hypotube-based catheter to provide deliverability and torqueability within the body.

Regarding the Chief Scientific and Medical Officer appointments, the company advised that Dr. Teigen joins Penumbra immediately and will contribute his extensive scientific and clinical expertise to ongoing and future research and development efforts. Dr. Benenati will join Penumbra on September 1, 2020, and will contribute to clinical and medical affairs strategies and advise upon global commercialization and market development activities.

Biotronik's Dynetic-35 Iliac Stent Launched in Europe

July 14, 2020—Biotronik announced the availability of Dynetic-35, the company's next-generation balloon-expandable cobalt-chromium iliac stent system. Dynetic-35 is indicated for the treatment of de novo or restenotic atherosclerotic lesions in the iliac arteries and is approved for use in Europe and other markets that recognize CE Mark certification.

According to the company, the entire Dynetic-35 stent size matrix is 6-F compatible, including stent diameters of 5 to 10 mm and lengths of 18 to 78 mm. The device comes in working lengths of 90, 130, and 170 cm. The thin-strut stent combined with the low crossing profile of the balloon catheter delivery system is designed to enhance deliverability. The company noted that with the 170-cm catheter length option, the Dynetic-35 system also enables a radial access approach.

Michael Lichtenberg, MD, commented in Biotronik's announcement, "The flexibility, lower profile, and improved deliverability allow direct stenting even in more challenging lesions. In my clinical experience with the new stent system, I have been impressed by the smooth placement and deployment for a direct stenting approach, as well as the radial strength of the stent." Dr. Lichtenberg is Chief of Angiology at Arnsberg Vascular Center in Arnsberg, Germany.

Medtronic Begins Global DISSECT-N Postmarket Study of the Valiant Navion System for Thoracic Aortic Dissections

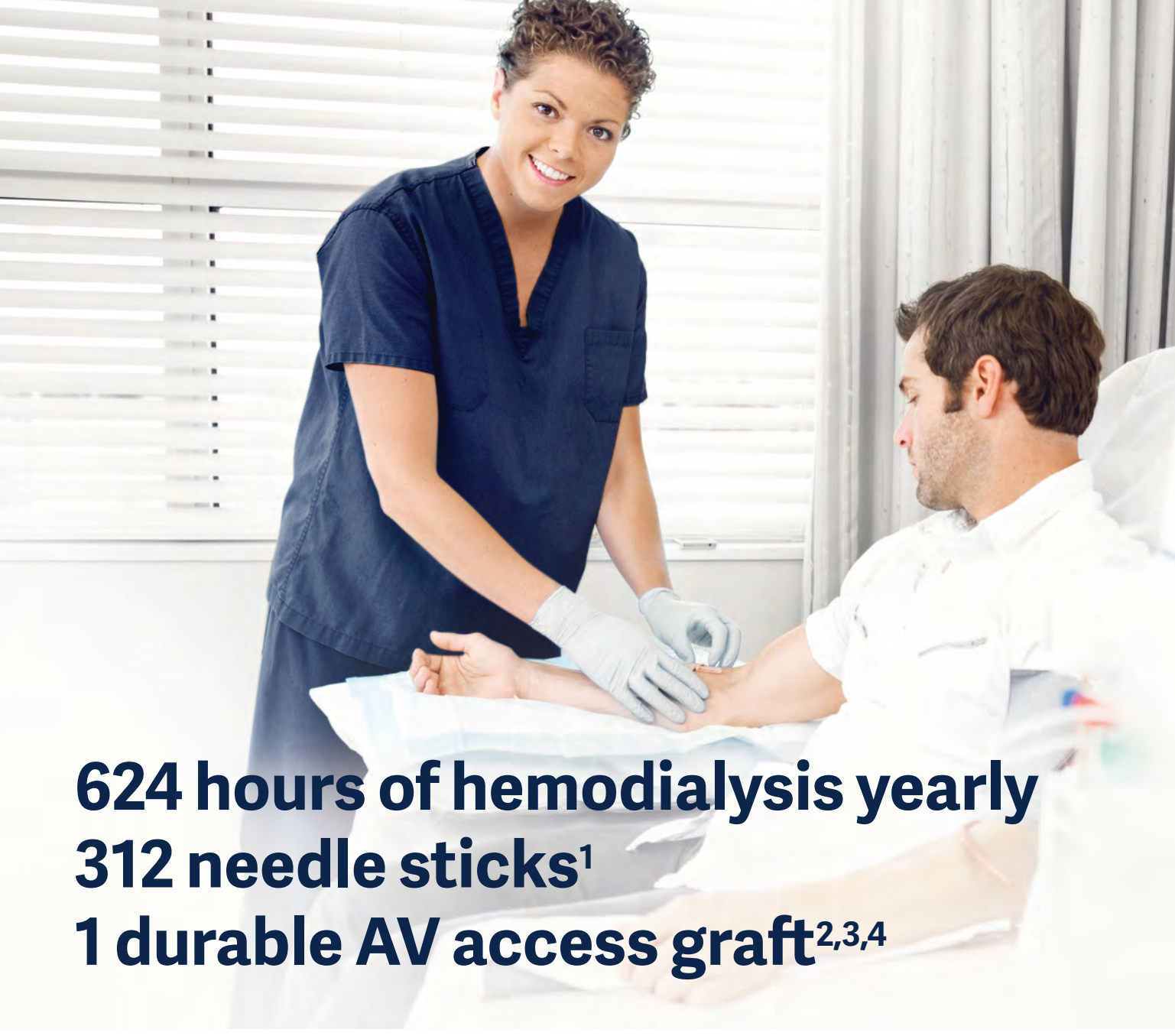
July 6, 2020—Medtronic announced the start of DISSECT-N, a prospective, observational, global, multicenter, real-world, postmarket study to evaluate the safety and effectiveness of the company's Valiant Navion thoracic stent graft system in the treatment of thoracic aortic dissection. The first patient procedure in the study was performed by Derek Brinster, MD, Director of Aortic Surgery at Northwell Health in New York, New York.

According to Medtronic, the DISSECT-N study will enroll at least 200 patients with an acute or chronic thoracic aortic dissection across approximately 45 sites in North America, Europe, and the Asia Pacific. The primary endpoint is composite safety and effectiveness, including technical procedure success and freedom from major adverse events, reported up to 1 month following the index procedure. Patients will be followed for 3 years.

The DISSECT-N study's primary investigators are Ross Milner, MD, in the United States, and Robin Heijmen, MD, in Europe.

Dr. Heijmen commented in the company's announcement, "Thoracic aortic dissection is dangerous, with some cases leading to severe internal bleeding or irreversible organ damage; with the Valiant Navion system, more patients with aortic dissection are eligible for thoracic endovascular aneurysm repair." Dr. Heijmen is a cardiothoracic surgeon at St. Antonius Hospital in Utrecht, the Netherlands.

In October 2018, Medtronic announced FDA approval for the low-profile Valiant Navion system. European CE Mark approval was announced in November 2018. The company announced approval in Japan in September 2019.



624 hours of hemodialysis yearly
312 needle sticks[1]
1 durable AV access graft[2,3,4]

Flixene AV access graft:
Premium performance for dialysis access

Flixene's unique 3-layer ePTFE construction is specifically designed to handle the rigors of multiple needle cannulations related to dialysis care. It has been demonstrated in multiple independent, peer-reviewed journals to be a safe and effective option for early cannulation within 24 to 72 hours.[5, 6, 7]

1. National Kidney Foundation, *How long will each hemodialysis treatment last?* Retrieved 5/2019 kidney.org/atoz/content/hemodialysis **2.** Chiang N, Hulme KR, Haggart PC, et al *J Vasc Access*. 2014 Mar-Apr;15(2):116-22. **3.** Lioupis C, Mistry H, Rix T, et al. *J Vasc Access*. 2011 Jan-Mar;12(1):36-44. **4.** Berard X, Ottaviani N, Brizzi V, et al. *J Vasc Surg*. 2015 Jul;62(1):128-34 **5.** Data on file. **6.** Schild AF, Schuman ES, Noicely K, et al. *J Vasc Access*. 2011 Jul-Sep;12(3):248-52. **7.** Schild AF, Baltodano NM, Alfieri K, et al. *J Vasc Access*. 2004 Jan-Mar;5(1):19-24.

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CONFERENCE COVERAGE

Results Presented From REACH PVI Study of CSI's Transradial Orbital Atherectomy Systems in Lower Extremities

July 27, 2020—Cardiovascular Systems, Inc. announced that procedural data from its REACH PVI study were presented at NCVH 2020: New Cardiovascular Horizons 21st annual conference, held as part of the NCVH digital education series.

REACH PVI is a prospective, observational, single-arm, multicenter postmarket study that enrolled 50 patients at six sites across the United States. The study prospectively evaluated acute clinical outcomes of orbital atherectomy via transradial access for the treatment of peripheral artery disease in lower extremity lesions using CSI's 5-F extended length Diamondback 360 and Stealth 360 peripheral orbital atherectomy systems.

According to the company, the results of the REACH PVI study demonstrated a high rate of procedural and treatment success and effectiveness in reducing residual stenosis across all lesions. In the study, 98% of patients achieved both procedural and treatment success, with no reports of serious transradial access-related events. One dissection (type D-F) was reported. The average time to ambulation reported was 2.7 ± 1.3 hours and lengths of stay averaging 7.2 ± 5.2 hours. Although 68% of lesions were in the superficial femoral artery, other lesion locations included the common femoral artery, popliteal artery, and below the knee.

Data Presented From Global and European Analyses of Daiichi Sankyo's ETNA-VTE Study of Edoxaban

July 15, 2020—Daiichi Sankyo Europe GmbH announced results from five analyses of 12-month data from ETNA-VTE, a noninterventional safety study evaluating edoxaban (Lixiana, Daiichi Sankyo) treatment in routine clinical practice in patients with venous thromboembolism (VTE). Edoxaban is a non–vitamin K antagonist oral anticoagulant. The findings were presented during the International Society on Thrombosis and Haemostasis (ISTH) 2020 Virtual Congress, held online July 12-14.

The primary objective of ETNA-VTE is overall symptomatic VTE recurrence rate during an overall observational period of 18 months in unselected patients with acute VTE. The coprimary objective is to collect rates of real-world safety data on bleeding events, drug-related adverse events, and mortality in VTE patients treated with edoxaban.

According to Daiichi Sankyo, the study showed low rates of bleeding and VTE recurrence in a range of VTE subpopulations in routine clinical practice in 4,595 patients (mean age, 64 years) with VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE), who were enrolled at sites in Europe, Japan, East Asia, and Southeast Asia.

The company summarized the findings as follows.

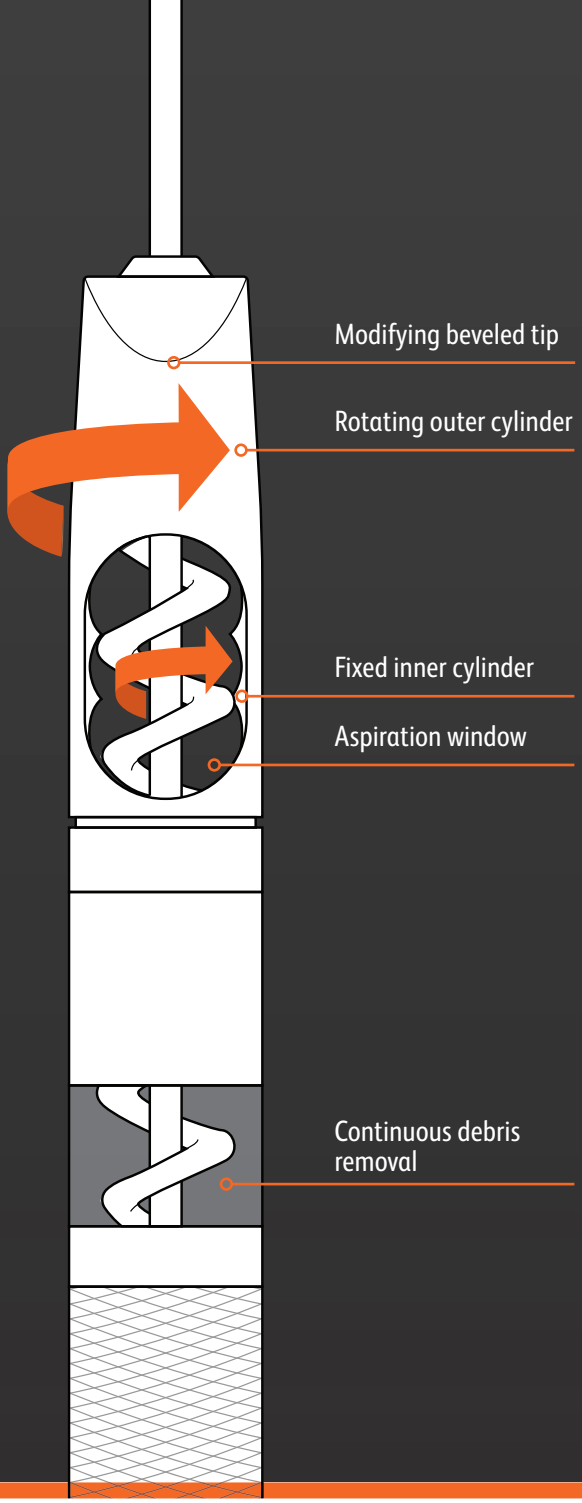
The Global ETNA-VTE subanalysis showed that at 12 months, rates of major bleeding were low across all age groups, recurrent VTE decreased with increasing age, and all-cause mortality increased with age as would be expected. However, most of the mortalities were not cardiovascular (CV)-related.

Per year, globally:

- VTE recurrence occurred in 3.65% of patients aged < 65 years; 2.83% of those aged ≥ 65 to 75 years; 2.3% of those aged ≥ 75 to 85 years; and 3.07% of those aged ≥ 85 years.
- ISTH-defined major bleeding occurred in 1.34% of patients aged < 65 years; 3.16% of patients aged ≥ 65 to 75 years; 2.97% of patients aged ≥ 75 to 85 years; and 5.72% of patients aged ≥ 85 years.
- CV-related mortality occurred in 0.35% of patients aged < 65 years; 1.08% of patients aged ≥ 65 to < 75 years; 1.96% of patients aged ≥ 75 to < 85 years; and 3.04% of patients aged ≥ 85 years.

The first of two ETNA-VTE Europe subanalyses showed low rates of major bleeding and VTE recurrence in patients with PE (with or without DVT) and patients with DVT alone. Patients with PE, with or without DVT, had a tendency toward a higher risk of mortality and bleeding events than those with DVT alone, but they also had higher-risk baseline characteristics.

Per year, in the European index VTE event group:



Refining Atherectomy & Aspiration Together

After years of refinement in Europe, BD's Rotarex™ Rotational Excisional Atherectomy System is finally available in the United States. Swiss-made precision synchronizes three distinct mechanisms of action to negotiate even complex lesions with an atraumatic design and active aspiration, all in a small equipment package that sets up in minutes.

Intelligently Designed

- Excisional atherectomy without exposed blades
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Dual Indicated

- Indicated for peripheral arterial atherectomy & thrombectomy

Simple to Setup & Use

- No warm-up, infusion, or repeated catheter clean-out required
- All required material is included in a single, sterile set

Rotarex™

Rotational Excisional Atherectomy System

Rotarex™ Rotational Excisional Atherectomy System

Safety and Risk Information: The Straub Endovascular System is herein referred to as the BD Rotarex™ Rotational Excisional Atherectomy System

Indication For Use: When operated with a Rotarex™ single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

Contraindications: Use of the Rotarex™ family of catheters is contraindicated in the following situations and locations: · In the cardiopulmonary, coronary, cerebral, iliac and renal vasculature · In the venous vasculature · In instances of persistent vasospasm · In patients not suitable for atherectomy/ thrombectomy · In patients with known or suspected allergies to any component of the Straub Endovascular System · In patients with hemodynamic instability, shock or severe coagulatory disorders · In patients where it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition · In areas of known or suspected infection, especially at the puncture site or target vessel segment · In vessels which are oversized or undersized for the particular Rotarex™ catheter used · In stents, stent grafts or bypass grafts · Without the use of a Straub provided guidewire · When the Straub provided guidewire cannot completely cross the target lesion · Where the Straub provided guidewire is in a subintimal position of any length · Where the Straub provided guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Where the target lesion is located in a region of marked vessel tortuosity (has a radius of curvature ≤2 cm) or is heavily calcified · Where pre-existing damage is present in the vessel wall at or near the target lesion from prior surgery, aneurysms or other disease · During MRI procedures or where electrical current may be passed to an undesired location via the catheter, e.g., during electrocautery, electrosurgery or defibrillation. The Rotarex™ catheter and guidewire must be entirely removed before these therapies are administered, even in an emergency situation · Where the recommended separation distances from Radio Frequency and Electro-Magnetic Interference (EMI) sources cannot be maintained (Reference the manual for the Drive System) · Where any component of the Straub Rotarex™ Endovascular System has sustained damage, including any breech of the sterile barrier

Please consult package insert for more detailed safety information and instructions for use.

- Major bleeding occurred in 2.39% of patients with PE (with or without DVT) and 1.57% of patients with DVT alone.
- VTE recurrence of any kind occurred in 2.89% of patients with PE (with or without DVT) and 2.78% of those with DVT alone.

The second European subanalysis, which stratified patients by body mass index (BMI; 18.5 to < 25 kg/m^2 [normal weight]; 25-30 kg/m^2 [overweight]; ≥ 30 kg/m^2 [obese]), showed that obesity did not substantially affect the risks of recurrent VTE and other bleeding complications.

Per year, in the European BMI group:

- VTE recurrence occurred in 2.67% of patients overall (2.44%, 2.83%, and 2.71%, respectively).
- Major bleeding occurred in 1.69% of patients overall (1.75%, 2%, and 1.11%, respectively).
- All-cause mortality occurred in 2.16% of patients overall (2.97%, 1.77%, and 2.39%, respectively).

An additional Global ETNA-VTE presentation and another ETNA-VTE Europe presentation showed that high versus low bleeding risk (as identified by the VTE-BLEED score) was associated with similar VTE recurrence risk but higher all-cause and cardiovascular mortality and incidences of any bleeding type or category. They also showed that edoxaban is largely used adequately in real-world practice in Europe, respecting the recommendations for treatment initiation, dosing, and dose adjustments in special patient populations, reported Daiichi Sankyo.

Study Evaluates Rivaroxaban Versus Warfarin in Obese Patients With Acute VTE

July 13, 2020—An analysis of electronic health record (EHR) data was conducted to evaluate the effectiveness and safety of rivaroxaban (Xarelto; Bayer AG and its partner Janssen Research & Development, LLC) versus warfarin for treatment and prevention of recurrent venous thromboembolism (VTE) in obese patients.

The findings were presented at the International Society on Thrombosis and Haemostasis 2020 Virtual Congress, held online July 12-14, and published online on June 25 by Olivia S. Costa, PharmD, et al online in *Journal of Thrombosis and Thrombolysis*. The study is funded by Janssen.

According to the abstract of the presentation, the background of the study is that rivaroxaban has demonstrated consistent drug levels and anticoagulation activity in obese patients compared with those of normal weight. However, there are limited data on the effectiveness and safety of rivaroxaban compared with warfarin in obese patients with VTE.

The investigators performed a cohort analysis using Optum deidentified EHR data from November 1, 2012, to September 30, 2018.

The study included patients with a body mass index (BMI) ≥ 30 kg/m^2 who were admitted to the hospital, emergency department, or observation unit for VTE; received rivaroxaban or warfarin as their first oral anticoagulant (OAC) within 7 days after; and had ≥ 12 months of EHR activity before the acute event. Patients with evidence of OAC use at baseline were excluded.

Patients receiving rivaroxaban were 1:1 propensity score-matched to patients receiving warfarin (standard differences < 0.1 achieved for all covariates). Outcomes included recurrent VTE and major bleeding at 3, 6, and 12 months using an intent-to-treat approach. Subanalyses stratified by BMI (30-34.9, 35-39.9, and ≥ 40 kg/m^2) were performed. Risk was compared using Cox regression.

The investigators identified 6,755 rivaroxaban users and 6,755 warfarin users with a BMI ≥ 30 kg/m^2 who were experiencing an incident VTE.

The investigators found that rivaroxaban was associated with a reduced risk of recurrent VTE compared with warfarin at 3, 6, and 12 months. No difference was observed in major bleeding between rivaroxaban and warfarin at 3, 6, or 12 months. Additionally, subanalyses did not show a statistically significant interaction across BMI categories for either the recurrent VTE (P for interaction ≥ .43) or major bleeding (P for interaction ≥ .58) outcomes at any time point.

Among obese patients experiencing an acute VTE, rivaroxaban was associated with a significantly reduced risk of recurrent VTE versus warfarin at 3, 6, and 12 months, without impacting major bleeding, concluded the investigators in the ISTH presentation. Investigators also noted that these findings remained consistent across evaluated BMI classes. ■

Advancing the Science of Laser Atherectomy for Peripheral Artery Disease

A review of clinical data on the Auryon laser atherectomy system and the laser parameters that contribute to optimal outcomes.

BY NICOLAS W. SHAMMAS, MD, MS; HILARY F. ARMSTRONG, PHD; YOSSI MUNCHER, PHD; AND VENKAT SHANKARRAMAN, PHD

Atherectomy procedures use catheters to remove the buildup of plaque in arteries that have become narrowed or occluded. There are three types of atherectomy devices on the market that are designed to cut, shave, or vaporize atherosclerotic or calcified plaques: directional, rotational, and laser. Directional atherectomy includes the HawkOne (Medtronic) and the optical coherence tomography–guided Pantheris device (Avinger, Inc.). Rotational atherectomy includes the peripheral Rotablator rotational atherectomy system (Boston Scientific Corporation), Diamondback 360 (Cardiovascular Systems, Inc.), Jetstream atherectomy system (Boston Scientific Corporation), Rotarex S (BD Interventional), and Phoenix atherectomy system (Philips). Laser atherectomy includes the CVX-300 Excimer laser system (Philips) and the Auryon system (AngioDynamics, Inc.). Each device has its own strengths and weaknesses derived from the product's attributes. However, the lack of data and complete understanding of the science behind these devices has prevented the technologies from being used as the default therapy. For these technologies to be adopted as a frontline therapy, it is extremely critical to understand the physics behind its operation. This article focuses on the Auryon laser atherectomy system, which showed significant promise in the recently concluded EX-PAD-03 trial, and the laser parameters that play a vital role in providing optimal patient and procedural outcomes.[1,2]

AURYON LASER ATHERECTOMY SYSTEM

The CVX-300 Excimer laser system uses a mixture of a rare gas and halogen, xenon monochloride (XeCl), that emits radiation at a wavelength of 308 nm, fluence output between 30 and 80 mJ/mm^2, repetition rate between 25 and 80 Hz, and pulse width of 125 to 200 ns. It weighs 650 lb and occupies 8 sq ft. In contrast, the Auryon laser system shown in Figure 1 weighs 187 lb and occupies slightly more than 2.5 sq ft. It is a solid-state, third-harmonic Nd:YAG laser with a wavelength of 355 nm, fluence between 50 and 60 mJ/mm^2, repetition rate of 40 Hz, and pulse width of 10 to 25 ns. As discussed by Herzog et al, 355-nm laser sources possess short pulse durations, making them superior candidates for opening arterial occlusions (particularly calcified lesions).[3] Thus, laser parameters are very critical in determining overall performance, especially during atherectomy procedures. The following section discusses the major parameters that determine the safety and efficacy of the laser system in the treatment of peripheral artery disease (PAD).

Figure 1. The Auryon laser system.

Laser Parameters

Wavelength determines absorbed/scattered energy and penetration depth, and longer wavelengths generally have weaker absorption.[4] Absorption depth is a critical component of atherectomy because

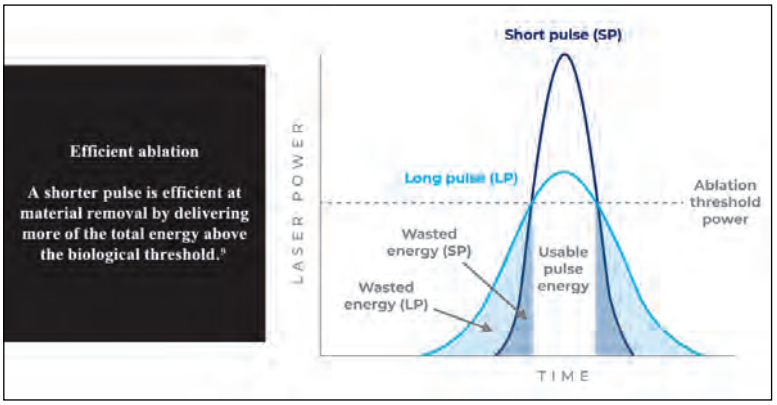


Figure 2. Relationship between pulse width and usable energy. A shorter pulse delivers more of its total energy above the ablation threshold (minimum peak intensity required to ablate material). In contrast, much of the energy of a longer pulse goes into heating the target tissue.[9] Adapted from Haupt O, Müller D, Gäbler F. Shorter pulse widths improve micromachining. EuroPhotonics. 2013;18:28-30.

the interaction between tissue type and wavelength varies and the potential for perforation or dissection exists. The Philips Excimer laser has been associated with a 13.1% dissection rate, likely attributed to high peak pressures in contrast media and blood.[5,6] This is due in part to the high optical absorption of the 308-nm wavelength. In the presence of iodine-based contrast media, pressures are two times higher than in blood, making a saline flush (flush and bath) necessary to remove any contrast in the vessel before use.[7,8] This process is challenging, especially in cases of chronic total occlusions (CTOs). Also, the photon energy of the 308-nm Excimer laser is 4 eV and can dissociate common organic bonds found in vessel walls, such as carbon-carbon (3.6 eV) and carbon-oxygen (3.6 eV), which explains why the laser can be used to ablate lesions but also cause perforations. In contrast, the Auryon system has a longer wavelength, weaker photon energy absorption, and minimal interaction with contrast media. The result is targeted biological interactions without a contrast flush requirement.[7]

The 355-nm wavelength and photon energy of 3.5 eV of the Auryon system yields a threefold higher affinity for lesion tissue than for vessel endothelium. This means that the laser can cause photomechanical ablation in lesions while practically avoiding photochemical dissociation of bonds in the vessel endothelium, thereby resulting in zero flow-limiting dissections and perforations, as seen in the EX-PAD-03 investigational device exemption (IDE) trial.[1-3]

Other parameters that play an essential role are pulse width and amplitude. Pulse width (pulse duration) is the length of time each pulse is delivered (Figure 2).[9] In short pulses, modest amounts of energy may be condensed into high peak power, as expressed by the following equation: pulsed energy = (peak power) × (pulse duration). The Auryon system uses shorter pulses to create acoustic waves (cavitation bubbles in liquid). These photomechanical interactions (force per unit area) create pressure transients that evaporate target tissue.[10] Adjusting the size and shape of these pressure waves allows for localization and optimization of the ablation while minimizing collateral damage.[11]

A laser's amplitude determines the fluence, defined as the delivered energy divided by the area of the projected beam.[12] The fluence and intensity required for ablation varies based on numerous characteristics of the specified lesion. These characteristics include the degree of calcification, fibrosis, and morphologic arrangements of layers. The Philips Excimer laser pulse width is often restricted due to concerns of fiber-optic damage and kept in a range of 125 to 200 ns. For lesions that may be highly calcified, the power produced from this range may not be enough for complete

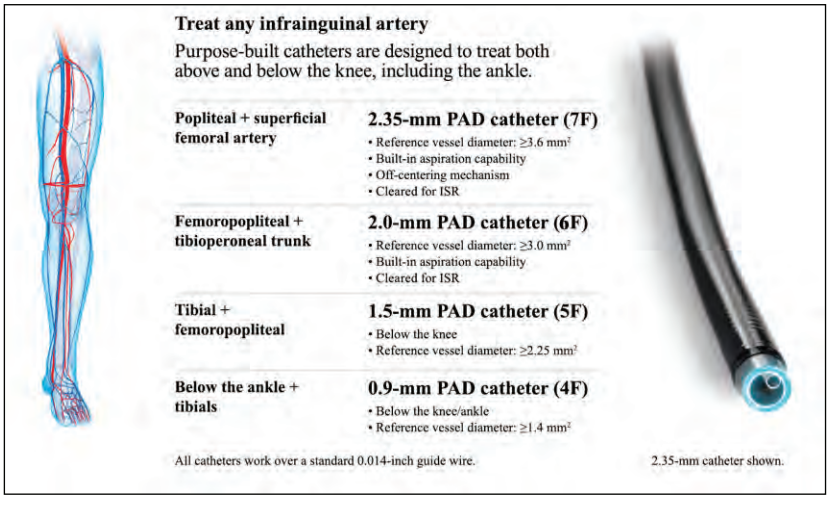


Figure 3. Infrainguinal arteries and Auryon system catheter sizing guide.

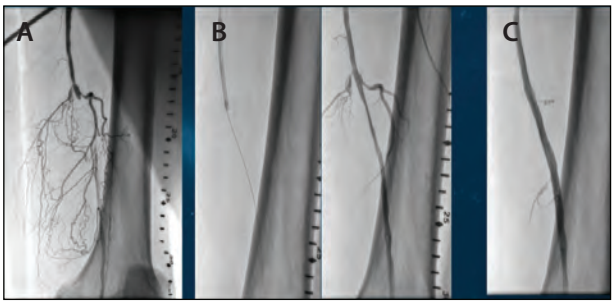
ablation. However, the Auryon system has been shown to be highly effective in severe calcifications, achieving delivery of approximately 10 times shorter pulse widths and resulting in 10 times the laser power and intensity, while maintaining the same fluence and energy.[1,2]

Clinical Evidence

The Auryon system consists of single-use catheters (Figure 3) that come in four sizes ranging from 0.9 to 2.35 mm (4-7 F). The catheters can be used above and below the knee, including below the ankle. All catheter sizes work with a standard 0.014-inch guidewire. Built-in aspiration capability is available in the 2- and 2.35-mm catheter sizes, which allows for removal of debris and addresses the risk of distal embolization. Additionally, the 2.35-mm catheter has an off-centering mechanism for large lumen creation and eccentric lesions. This mechanism lets the user keep the catheter tip in the direction of the artery trajectory to avoid deflection off the vessel wall, while allowing for more debulking.

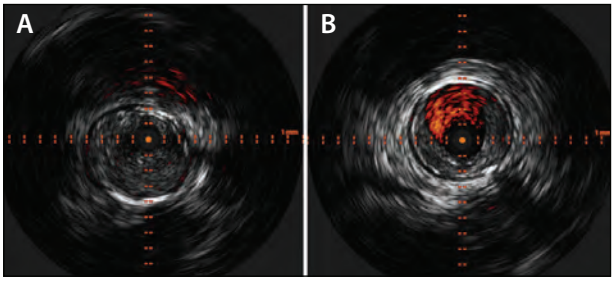
The EX-PAD-03 study (NCT03157531) validated the use of the Auryon system in ablating infrainguinal lesions safely and effectively.[1] The prospective, single-arm, international, multicenter, open-label, pivotal IDE study was conducted at eight sites in the United States and three sites in Europe. A total of 97 patients (107 lesions) with symptomatic PAD (Rutherford class 2-4) were enrolled and treated (51 males; mean age, 70.5 years). Of the 107 lesions treated, calcification was observed in 83 (77.6%) lesions, with 28 (26.2%) lesions having severe calcification. There were 23 (21.5%) lesions that were CTOs and 22 (20.6%) lesions that were restenotic, including 17 (15.9%) lesions that were in-stent restenosis (ISR). The average lesion length was 5.4 cm (range, 1-24 cm) and located in the femoropopliteal (88 lesions, 82.2%) or tibial (19 lesions, 17.8%) regions.[1,2]

Results showed that the average reduction in residual stenosis after atherectomy alone, prior to any adjunctive therapy, was 33.6% and was not affected by degree of calcification, lesion type, or length. The average final stenosis after adjunctive therapy was 17.7% and was similar between the subgroups of lesion types and the type of adjunctive therapy administered. Clinically driven target lesion revascularization occurred in 3% of lesions, with none in the ISR group. The average improvement in Rutherford class was two points, and 93% of patients showed improvement. There was one major adverse event (non–device-related death), no periprocedural device-related complications requiring intervention, and no dissections greater than grade C after balloon angioplasty. Additionally, there were no periprocedural distal embolizations, and only two filters were used. Bailout stenting was reported in one patient but was determined to be unrelated to the atherectomy.[1] This can be compared to the CELLO Excimer trial, which saw a 23% stent use rate.[13]



Courtesy of Dr. Nicolas Shammas.

Figure 4. Baseline (A). Post Auryon laser (B). Post adjunctive angioplasty (C).



Courtesy of Dr. Nicolas Shammas.

Figure 5. Intravascular ultrasound of the superficial femoral artery before (A) and after (B) treatment with the Auryon system and adjunctive therapy.

Figure 4 shows the treatment of an occluded superficial femoral artery in an elderly patient with severe claudication of the left lower leg. The procedure (with percutaneous transluminal angioplasty and drug-coated balloon) resulted in no distal embolization or arterial dissection, as seen in the intravascular ultrasound images (Figure 5).

CONCLUSION

Multiple devices and therapies are required during a PAD procedure due to the diverse nature of the lesions (types, lengths, locations). With a 355-nm wavelength and short pulse width of 10 to 25 ns, the Auryon system appears to allow for successful luminal gain regardless of lesion morphology, including moderate and severe calcific plaque.[1,2] The 355-nm, wavelength-based solution has an affinity that is three times higher for lesion tissue than for vessel endothelium, providing interventionalists the ability to ablate the lesion while preserving vessel endothelium and addressing the risk of clinically significant dissections and perforations. Additionally, it is nonreactive to contrast media, which allows for debulking of lesions while simultaneously

monitoring fluoroscopy images. The 10- to 25-ns, 40-Hz high-intensity pulses result in vaporization of tissue without thermal ablation.

The Auryon system is also three times smaller and lighter than current laser atherectomy devices, with a solid-state medium that allows for short warm-up time (approximately 15 seconds) and no need for catheter calibration. Clinically, studies have shown lower perforation and flow-limiting dissection risk, thereby making the Auryon system a valuable addition to the atherectomy market. Specifically, this laser system treats all levels of calcification (also indicated for ISR) above and below the knee, is nonreactive to contrast media, addresses the risk of perforations, has built-in capabilities for eccentric lesions in the largest catheter and aspiration in the two largest catheters with excellent safety profile, and is designed to be portable and quiet. ■

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VASCULAR LITERATURE HIGHLIGHTS

Meta-Analysis Evaluates Dual-Layered Stents for CAS

July 27, 2020—One-year results from a patient-based meta-analysis of the safety and efficacy of dual-layered stent (DLS) systems for carotid artery stenting (CAS) were published by Eugenio Stabile, MD, et al in *Journal of American College of Cardiology (JACC): Cardiovascular Interventions* (2020;13:1709-1715).

The investigators concluded that the findings suggest that DLS use for CAS is associated with a low 1-year death and stroke rate, and the specific DLS stent used could affect the restenosis rate.

For this study, the investigators performed an individual patient-level meta-analysis including studies enrolling > 100 patients treated by CAS with a DLS (either Roadsaver [RS, Terumo Europe] or CGuard [CG, InspireMD]. Patients were divided into two groups according to DLS (RS, n = 250; CG, n = 306).

The primary endpoint was the death and stroke rate; secondary endpoints were restenosis and in-stent thrombosis rates at 1 year.

The 1-year findings were summarized in *JACC: Cardiovascular Interventions* as follows:

- 11 (1.97%) patients died at 1 year, with seven (2.8%) patients in the RS group and four (1.31%) patients in the CG group
- 10 strokes occurred at 1 year, four (1.6%) in the RS group and six (1.96%) in the CG group
- The overall death and stroke rate was 3.77% (n = 21), with 11 (4.4%) events in the RS group and 10 (3.27%) events in the CG group
- Symptomatic status was the only predictor of death and or stroke
- Restenosis occurred in 12 (2.1%) patients with 10 (4%) in the RS group and two (0.65%) in the CG group (P = .007)
- In-stent thrombosis occurred in one (0.18%) patient in the CG group (0.32%)
- RS use was the only independent predictor of restenosis

Differences Between ESVS 2019 and NICE 2020 AAA Guidelines Analyzed

July 21, 2020—An analysis of the differences between the European Society for Vascular Surgery (ESVS) 2019 guidelines for abdominal aortic aneurysm (AAA) and the United Kingdom (UK) National Institute for Health and Care Excellence 2020 AAA guidelines was published by Janet T. Powell, MD, and Anders Wanhainen, MD, in the *European Journal of Vascular and Endovascular Surgery* (*EJVES*; 2020;60:7-15).

Drs. Powell and Wanhainen reviewed the approach, methodology, and evidence used by the two committees to understand why the sets of guidelines for the diagnosis and management of patients with AAA have discordant recommendations in several important areas. Dr. Powell is with the Vascular Surgery Research Group at Imperial College London in London, UK. Dr. Wanhainen is Professor of Vascular Surgery, Department of Surgical Sciences, at Uppsala University in Uppsala, Sweden.

The investigators reported the following in the *EJVES* abstract:

- NICE guidelines used a multidisciplinary committee to address a limited number of prospectively identified questions.
- NICE guidelines used rigorous methods heavily reliant on evidence from randomized controlled trials (RCTs) supported by in-house economic modeling, with the purpose of providing the best cost-effective health care in the UK in 46 main recommendations.
- ESVS guidelines used an expert committee to encourage clinical effectiveness across a range of European health economies.
- ESVS guideline topics, but not questions, were prospectively identified, assessment of evidence was less rigorous, and 125 recommendations were made.

Regarding specific recommendations, Drs. Powell and Wanhainen found:

- The ESVS committee's more up-to-date evidence searches partially underscored the differences in recommendations for screening women.
- The NICE committee did not consider sex-specific analysis or evidence for thresholds for

intervention but relied on sex-specific modeling to support the advice to use endovascular aneurysm repair (EVAR) for ruptured AAA in women.
- NICE guidelines' recommendation to use open repair for ruptured AAAs in men aged < 71 years was based on in-house economic modeling.
- NICE guidelines' recommendation to use an open-first strategy for nonruptured AAA is mainly based on earlier RCTs and UK-specific economic modeling.
- ESVS guidelines' recommendation for an EVAR-first strategy is based on modern, but lower-quality evidence from observational studies.
- Similar reasons explain differences in the recommended treatments of juxtarenal aneurysms.

The analysis concluded that differences between the NICE and ESVS guidelines can be explained, at least in part, by their differing perspectives, methodologies, and quality assurance. Future ESVS guidelines may benefit from more multidisciplinary input and prospectively identified questions, advised Drs. Powell and Wanhainen in *EJVES*.

In the March 2020 issue of *Endovascular Today*, Dr. Wanhainen published "Highlights and Key Updates to the ESVS AAA Guidelines," which reviewed important revisions to the guidelines and their impact on practice (2020;19:60-66).

Also in the March issue of *Endovascular Today*, "NICE AAA Guidance: Where We Are Now and How We Got Here" by Michael Jenkins, BSc, MBBS, provided an overview of the criticism, support, and validity of the draft NICE guidelines for managing AAA, plus a first look at the finalized guidance.

Avenu Medical's Ellipsys Vascular Access System Evaluated for Percutaneous AVF Creation

July 21, 2020—Avenu Medical, Inc. announced that findings from a study of the company's Ellipsys vascular access system were published by Alexandros Mallios, MD, et al online in *Journal of Vascular Surgery*.

According to the company, the study demonstrated the benefits of the Ellipsys system to easily and safely create durable vascular access for patients with end-stage renal disease who require hemodialysis.

The investigators also offered a standardized process for using the minimally invasive technology that other physicians can follow to reproduce the results. According to Dr. Mallios, the process allows more practitioners to adopt this approach.

In contrast to open surgical procedures, the Ellipsys system uses a small needle puncture and catheter to create a percutaneous arteriovenous fistula (pAVF) without an implant or suture, leaving the vessels and tissue around the AVF undisturbed. Ellipsys was cleared by the FDA in 2018 for patients with end-stage renal disease. In 2016, Avenu Medical received European CE Mark approval of the Ellipsys vascular access system for hemodialysis.

The study by Mallios et al included 232 patients who had an Ellipsys pAVF created between May 2017 and July 2019. There were no adverse events. At 1 year, 96% had fully functioning fistulas with strong blood flow, whereas published rates for surgically created fistulas average around 60% after 1 year, the company noted.

In addition, the study reported that the pAVF could be used for dialysis an average of 4 weeks after creation, with 6% of fistulas becoming functional in as little as 2 weeks. The company noted that this rapid maturation can have a significant impact on patient safety because it avoids the use of a central venous catheter if a patient needs to begin dialysis quickly.

An important aspects of the study is that it offers a protocol for fistula creation, maturation, and maintenance, which should make it easier for other physicians to adopt the relatively new procedure. For example, the study shows the benefit of adding a new step to the procedure: performing balloon angioplasty immediately after a fistula is created. This step improves blood flow, speeds maturation, and could improve patency rates without increasing the need for additional maintenance procedures.

Avenu Medical noted that Dr. Mallios et al published a case report of Ellipsys in *Journal of Vascular Surgery* (2020;71;1395). Dr. Mallios also coauthored two recent papers published online in *The Journal of Vascular Access* discussing patient eligibility and the similarities between an Ellipsys pAVF and a surgical AVF.

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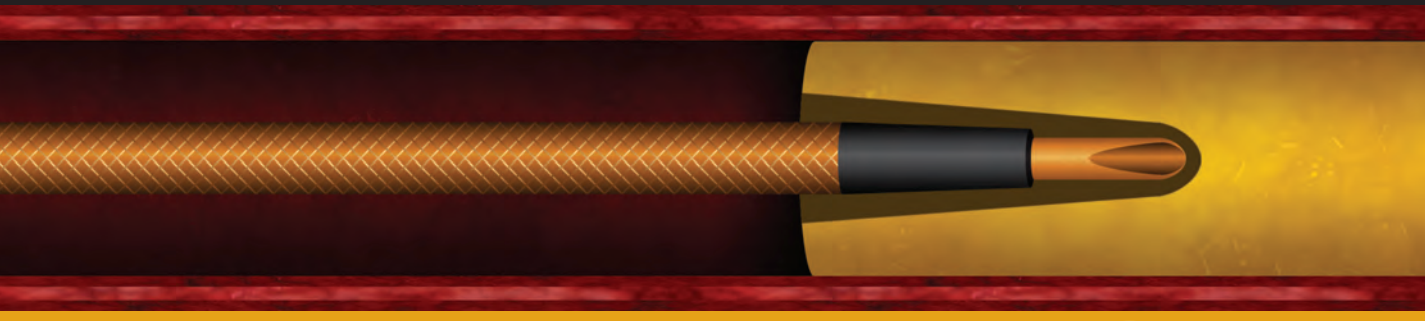

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Results From SAVE-US IDE Study of Bluegrass Vascular Surfacer

July 16, 2020—Bluegrass Vascular Technologies announced that the results of its prospective, multicenter SAVE-US study were published online by Principal Investigator Mahmood Razavi, MD, et al in *The Journal of Vascular Access*. According to the company, SAVE-US is an FDA-approved investigational device exemption study designed to evaluate the performance and safety of the company's Surfacer Inside-Out access catheter system when used to facilitate central venous access in patients with thoracic central venous obstructions.

"The SAVE-US study met both its primary safety and effectiveness endpoints while demonstrating the ability to use the Surfacer system to gain central venous access in patients with upper body venous obstructions," commented Dr. Razavi in the company's press release.

The FDA granted de novo classification of the Surfacer system based on the results of the SAVE-US study, which the company announced in February 2020. Launch of the Surfacer system in the United States is in progress, and the first commercial cases were successfully performed in May 2020. The device, which also has CE Mark approval, is currently distributed in North America and Europe by Merit Medical.

Study Shows Improved 5-Year Survival of Ruptured AAA Treated With EVAR

July 1, 2020—Investigators from the Society for Vascular Surgery's Vascular Quality Initiative registry reported findings on 5-year survival after endovascular aneurysm repair (EVAR) of ruptured abdominal aortic aneurysms (AAA) over the past 14 years compared with open repair. The study was published by Rens R.B. Varkevisser, BS, et al in *Journal of Vascular Surgery* (*JVS*; 2020;72:105-113).

The investigators concluded in *JVS*, "The 5-year survival after EVAR for ruptured AAA has improved over time, whereas survival after open repair remained constant. Consequently, the relative survival benefit of EVAR over open repair has increased over time, which should encourage further adoption of EVAR for ruptured AAA."

In the study, the investigators identified repairs for ruptured infrarenal AAA within the Vascular Quality Initiative registry between 2004 and 2018. They compared the 5-year survival of EVAR and open repair between the early (2004-2012) and late (2013-2018) cohorts. In addition, EVAR was compared with open repair in the early and late cohorts. The investigators used propensity score modeling to create matching cohorts for each analysis. Kaplan-Meier analysis was used to estimate survival proportions and univariate Cox proportional hazards analysis was used to compare differences in hazard of mortality in the matched cohorts.

As summarized in *JVS*, of the 4,638 ruptured AAA repairs identified, there were 409 EVARs in the early cohort and 2,250 EVARs in the late cohort. There were 558 open repairs in the early cohort and 1,421 in the late cohort.

Propensity matching resulted in 366 matched pairs of late versus early EVAR and 391 matched pairs of late versus early open repair. When comparing EVAR with open repair, propensity matching resulted in 277 matched pairs of early EVAR versus open and 1,177 matched pairs of late EVAR versus open.

The investigators found that in matched EVAR patients, 5-year survival was higher in the late cohort (63% vs 49%; hazard ratio [HR], 0.77; 95% CI, 0.61-0.97; $P = .027$), whereas there was no difference between matched late versus early for open repair patients (52% vs 59%; HR, 1.04; 95% CI, 0.85-1.28; $P = .69$).

In the early cohort, there was no survival difference between EVAR and open repair (51% vs 46%; HR, 0.88; 95% CI, 0.69-1.11; $P = .28$). However, in the late cohort, EVAR was associated with higher survival compared with open repair (63% vs 54%; HR, 0.69; 95% CI, 0.6-0.79; $P < .001$), reported the investigators in *JVS*. ■

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Navigating the Ins and Outs of CLI Care During the COVID-19 Pandemic

By Gregory A. Stanley, MD, FACS

The current COVID-19 pandemic has caused unprecedented disruption and strain on the health care system worldwide. Much of the focus and many of the health care resources have been diverted to pandemic management. Challenges arising from this health emergency such as reduced access to care, personnel safety concerns, disruption of the supply chain, and job loss (including loss of health care coverage and financial stress) have led to delays in diagnosis and treatment of many health conditions. Cardiovascular diseases including peripheral artery disease (PAD) require continuous care and, in some cases, rapid intervention to prevent debilitating consequences such as limb loss. The impact of the pandemic is exacerbated in the sicker and vulnerable patient population, including those with critical limb ischemia (CLI).

As the most advanced form of PAD, CLI is defined by ischemic foot pain at rest, nonhealing wounds or ulcers, and/or gangrene in one or both extremities as a result of severe arterial insufficiency. CLI is estimated to be prevalent in approximately 2 million people in the United States,[1] and it is likely to increase in the aftermath of the pandemic as patients defer medical care. Patients with CLI tend to present with multilevel occlusive disease and multiple cardiovascular comorbidities, leading to an increased risk of cardiac events and mortality.[2] The major amputation rates in patients with CLI are as high as 40% within 6 months of presentation.[3] These poor baseline outcomes have only been compounded further by the COVID-19 pandemic. An observational study in Italy reported an almost 50% increase in the rate of amputations during the pandemic compared with the previous year.[4]

CLI is a complex disease that requires a multidisciplinary team approach with the goal of limb salvage and improving quality of life. At our institution, this approach includes aggressive medical management, revascularization, wound care, podiatric and orthotic care, nutritional assessment and supplementation, management of risk factors (eg, smoking cessation), and optimization of home care and other resources. We have streamlined the outpatient care process with urgent preprocedure appointments with all necessary subspecialists to minimize hospitalization and maintain continuity of care. Fortunately, endovascular therapy often offers a suitable revascularization option because of its wide applicability, shorter postoperative recovery time, and reduced infection risk.

To achieve our outpatient goals, we attempt to leverage the most effective endovascular technologies available that provide high patency rates, decreased reinterventions, and significant wound healing potential. Lesion debulking with directional atherectomy is a reliable and effective endovascular strategy that allows the operator to reach their desired level of debulking; in my experience, it has been enhanced further when followed by drug-coated balloon (DCB) angioplasty. The DEFINITIVE LE study, a core-lab adjudicated, multicenter, prospective study, demonstrated the safety and effectiveness of directional atherectomy in 799 patients with PAD (1,022 target lesions).[5] The study included patients with CLI, infrapopliteal lesions, and subcohorts of sicker patients. The 12-month primary patency rate across all anatomic vascular beds was 78% in claudicants, 71% in patients with CLI, and 77% in the diabetic group. There was a 95% rate of freedom from major amputation in patients presenting with CLI, including those with a Rutherford classification of 5 or 6 and tissue loss. With the addition of paclitaxel-based endovascular therapies for superficial femoral artery (SFA)/popliteal lesions based on data reported from the IN.PACT SFA trial,[6] we expect similarly high primary patency rates and single-digit target lesion revascularization rates at 1 year. An examination of this treatment strategy was performed in the DEFINITIVE AR study.[7] Although the study was not powered to provide a statistically significant

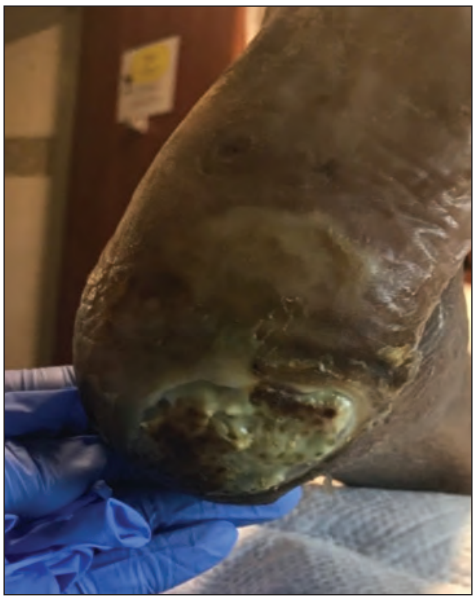

Figure 1. A 3-month-old left heel wound in a patient with CLI.

	Discipline	Strategy
Initial Examination	Imaging	• Left foot MRI shows osteomyelitis of calcaneus
	Ambulatory Status	• Stands to transfer
Risk Factor Management	Smoking Cessation	• Nonsmoker
	Endocrine	• Hgb A1C: 8.1 • Strict blood glucose monitoring, daily goal <200
	Renal	• Cr 1.46
	Nutrition	• Albumin: 2.6 g/dL • CRP: 4.4 mg/dL (elevated) • Initiate Juven and Glucerna supplements
Medications	Infectious Disease	• Intravenous broad-spectrum antibiotics pending bone biopsy for speciation/sensitivity
	Antiplatelet/ Anticoagulation	• Continue warfarin • Initiate clopidogrel daily post-procedure
	Lipids	• Continue high-dose statins
Limb Treatment & Care	Vascular	• Rutherford 6 • Planned revascularization (angiogram with intervention)
	Wound Care	• Debridement with negative pressure dressing placement
	Podiatry	• No urgent needs
	Offloading	• Orthotics consult for heel offloading shoe
	Follow up	• Wound check within 1 week of discharge • Medical specialty follow-up

Figure 2. The limb salvage plan for the patient with CLI in case 1. Cr, creatinine; CRP, C-reactive protein; Hgb, hemoglobin.

conclusion, the combination of directional atherectomy and DCB angioplasty was found to be effective and safe. We await more definitive results of this combination treatment from the REALITY trial, which is currently collecting and analyzing adequate follow-up data.

The following cases demonstrate some of the challenges to CLI care during the COVID-19 pandemic. The standardized and aggressive institutional protocols for CLI patients have been adapted and optimized through positive and negative lessons learned as we continue to cope with the unprecedented obstacles of care amidst the global pandemic.

CASE 1

A woman in her early 70s was admitted with congestive heart failure exacerbation (ejection fraction, 20%) and was found to have a 3-month-old left heel wound (Figure 1).

The patient was a nonsmoker with stage 3 chronic kidney disease, diabetes mellitus, coronary artery disease, and previous stroke with right lower extremity paralysis. She was using her left leg to transfer and therefore remained surprisingly mobile. A left lower extremity arterial duplex ultrasound demonstrated occlusion of the SFA, with reconstitution of the popliteal artery, severe stenosis in the P1 segment, and monophasic tibial waveforms. MRI demonstrated osteomyelitis of the left calcaneus. The decision was made to proceed with limb salvage attempts to maintain her mobility, which would be nonexistent after left leg amputation.

Given her inpatient status and CLI (Rutherford classification 6), she was deemed an essential surgical candidate per our institution's COVID-19 operative case classification. Therefore, she was medically optimized with the initiation of a limb salvage plan (Figure 2) and started on intravenous antibiotics.

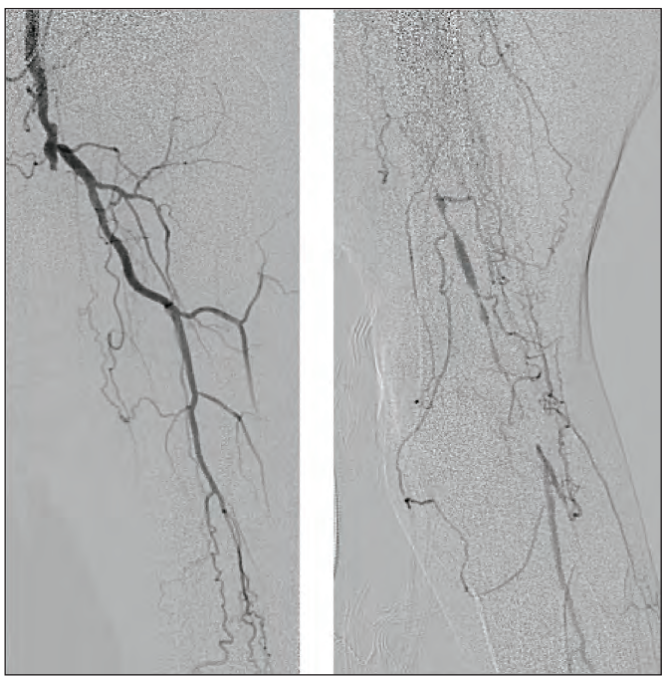

Figure 3. Initial angiograms demonstrating sequential SFA and popliteal artery chronic total occlusions.

The patient underwent heel debridement with bone biopsy and negative pressure wound dressing. The day after debridement, she underwent left lower extremity angiography via right femoral access, which demonstrated severe stenosis of the external iliac artery and SFA/popliteal chronic total occlusions (Figure 3).

Successful recanalization was performed with directional atherectomy of the SFA and popliteal artery using the

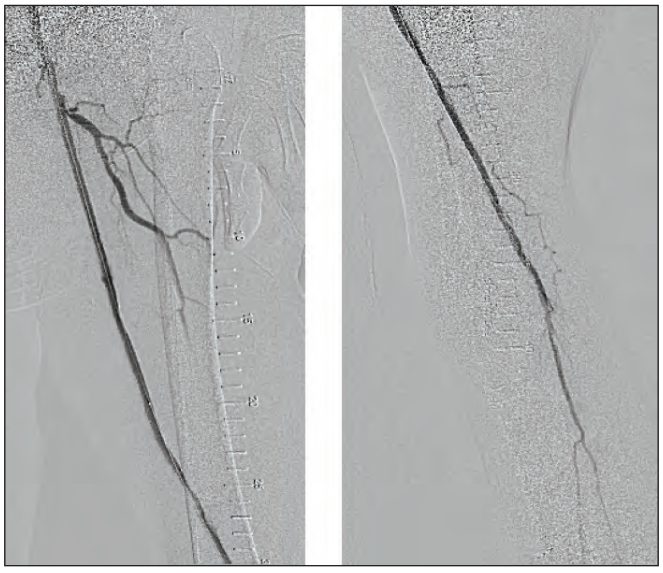

Figure 4. Completion angiograms of the SFA and popliteal artery after directional atherectomy with the HawkOne LX catheter over a 7-mm SpiderFX embolic protection device filter wire, followed by 5- X 250-mm and 5- X 200-mm IN.PACT Admiral DCBs.

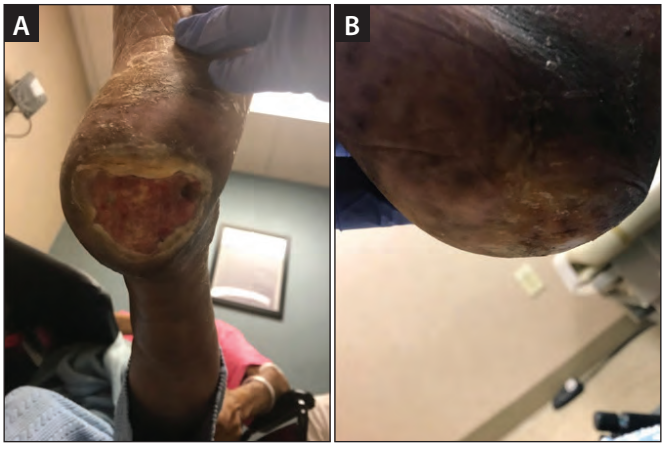

Figure 5. The first follow-up visit after the index procedure within 7 days of discharge showing the heel wound granulating well (A). The healed heel wound at the 2.5-month follow-up visit (B).

HawkOne™ LX directional atherectomy system catheter (Medtronic) over a 7-mm SpiderFX™ embolic protection device filter wire (Medtronic), followed by 5- X 250-mm and 5- X 200-mm IN.PACT™ Admiral™ drug-coated balloons (Medtronic). Completion angiograms are shown in Figure 4. The external iliac artery stenosis was treated with angioplasty and a bare-metal stent.

With a palpable posterior tibial artery pulse after the intervention, the patient had a final inpatient heel debridement 4 days later. She was medically stable, with all limb salvage treatment goals optimized, continued outpatient management was coordinated including intravenous antibiotics, and the patient was then discharged home. Her first follow-up visit was in person and completed within 7 days of discharge, and her heel wound was granulating well (Figure 5A). Our CLI nurse navigator confirmed all outpatient care was continuing as planned. Throughout the COVID-19 pandemic, weekly or biweekly virtual visits were performed using real-time video documentation of the heel wound with assistance from the patient's family members. The patient continued to attend weekly wound care clinic visits with appropriate personal protective equipment. The patient took Juven™* nutritional supplements (Abbott) until wound healing was confirmed. The coordination of virtual visits with medical specialty clinics successfully maintained comorbidity equipoise, and all challenges to care were addressed by our nurse navigator. Over the course of 2.5 months, the patient's left heel wound healed and continues to do well (Figure 5B).

CASE 2

A man in his early 60s with hypertension, poorly controlled diabetes, and severe PAD after a right below-knee amputation 3 years ago presented for evaluation after the development of gangrene on multiple toes of the left foot. He underwent left second toe amputation at an outside hospital 3 weeks before presentation and had breakdown of the incision with several new areas of ulceration. The ankle-brachial index was falsely elevated (0.96), and the toe pressure was 0. A left lower extremity arterial duplex ultrasound showed a patent femoropopliteal segment, with monophasic flow through the anterior tibial and occluded posterior tibial/peroneal arteries. Osteomyelitis of the fifth metatarsal head was confirmed by an MRI.

The patient remained ambulatory with a right lower extremity prosthesis and was motivated to save his left leg to maintain employment. Therefore, we elected to proceed with limb salvage attempts and again applied our systematic approach for limb salvage treatment (Figure 6).

Because the patient presented to the ambulatory clinic early in the COVID-19 outbreak, we elected to treat him via our standard outpatient pathway to preserve inpatient beds for an expected surge of COVID-19–positive patients. The patient was taken to the hybrid operating room and underwent left lower extremity angiography via antegrade left femoral access, which demonstrated severe infrapopliteal occlusive disease (Figure 7) with a dominant anterior tibial artery that occluded distally and reconstitution of the dorsalis pedis artery.

Intervention and recanalization of the anterior tibial artery were performed with directional atherectomy using a HawkOne S catheter (Medtronic) over a 3-mm SpiderFX protection device embolic filter wire (Medtronic) (Figure 8A). Postdilatation was performed with a 2.5-mm angioplasty balloon. Completion angiography is shown in Figure 8B. Mild vasospasm visualized in this angiogram resolved with intra-arterial nitroglycerin administration. The

	Discipline	Strategy
Initial Examination	Imaging	• Left foot MRI shows osteomyelitis of 5th metatarsal head
	Ambulatory Status	• Ambulatory with RLE prosthesis
Risk Factor Management	Smoking Cessation	• Former smoker • Quit in June 2019
	Endocrine	• Hgb A1C: 8.1 • On metformin
	Renal	• Cr 0.78
	Nutrition	• Juven samples provided
Medications	Antiplatelet/ Anticoagulation	• Aspirin + Atorvastatin + Xarelto
Limb Treatment & Care	Vascular	• Rutherford 5-6 • s/p right below knee amputation • Left lower extremity arterial duplex shows patent femoropopliteal segment with monophasic flow through anterior tibial and occluded posterior tibial/peroneal artery • Plan for left lower extremity revascularization (angiogram with intervention)
	Wound Care	• Multiple toe wounds • Local wound care with Aquacel Ag dressings and santyl to amputation sites • Betadine to necrotic areas • Weekly visits at the nearby wound care center
	Podiatry	• Evaluated pre-COVID-19 at the Local Foot & Ankle Clinic
	Offloading	• Referral to orthotics for front offloading shoe
	Follow up	• Plan for video virtual visit within 1 week of discharge • Medical specialty follow-up

Figure 6. The limb salvage plan for the patient with CLI in case 2. RLE, right lower extremity; s/p, status post.

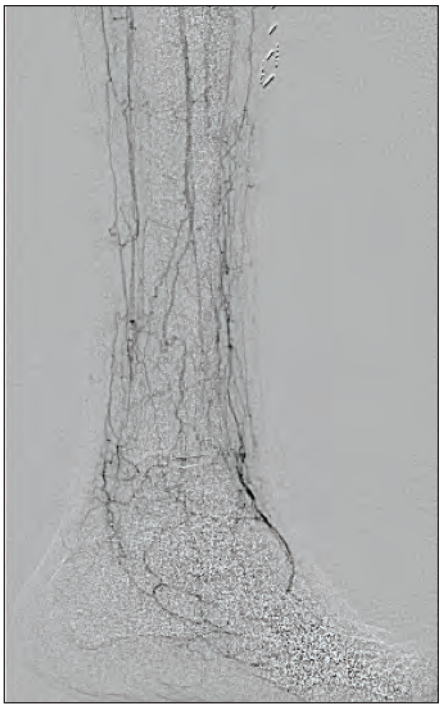

Figure 7. The initial angiogram of the left anterior tibial artery showing distal occlusion with reconstitution of the dorsalis pedis artery.

patient had a palpable dorsalis pedis pulse. He underwent ray amputation of the third, fourth, and fifth toes, as well as debridement of the nonhealing second toe amputation site. The patient was discharged home the same day.

The first planned virtual follow-up visit was within 7 days of discharge, and it was converted from a video visit to a phone visit because the patient was unable to connect adequately. His own assessment of the incision was satisfactory, but he did not have an adequate understanding of how to take or deliver pictures of his incision to our team. We initiated home health wound care and received a poor-quality phone picture demonstrating wound breakdown several days later (Figure 9). The patient was unable to attend requested in-person visits with our clinic or the wound care clinic because of transportation issues during the shelter-in-place order. The patient was also unable to obtain a front offloading shoe due to store closure and transportation issues. Despite good compliance with medications, he did not notify the team that his nutrition supplementation supply was extinguished, and he did not obtain refills.

Ultimately, the patient presented for an in-person visit 4 weeks postprocedure. His dorsalis pedis pulse was palpable and the great toe pressure measured 86 mm Hg. Unfortunately, by that time, the wound breakdown and lack of appropriate wound care left the foot beyond salvage. The patient underwent below-knee amputation shortly thereafter.

> "At the crux of each case is not only a fundamental assessment of the patient's health condition but also an honest judgment of the patient's functional care network and their capacity to operate within that network."

DISCUSSION

Patients with CLI remain a complicated and challenging population to treat, necessitating a successful revascularization procedure followed by strict coordination and oversight of multiple competing treatment plans. An incomplete execution of any one plan addressing the required healing components may be sufficient to derail the entire project and thus result in limb loss. This task is formidable in our standard operating environment and has only been exacerbated by the COVID-19 pandemic.

As the previous cases illustrate, acceptable and successful treatment of CLI patients and limb salvage remains possible amid a crippled health care system during a pandemic. However, we must recognize that the magnitude of obstacles we face to achieve adequate CLI care has mul-

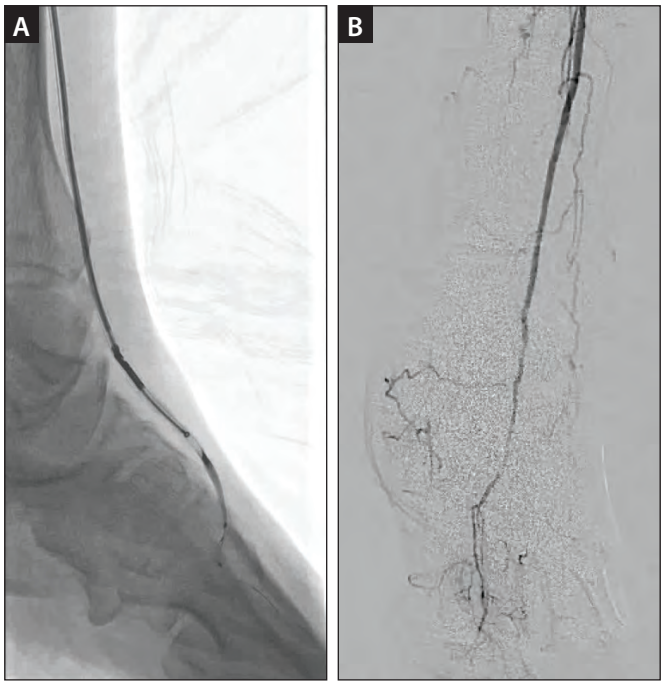

Figure 8. Revascularization of the anterior tibial artery with directional atherectomy using a HawkOne S catheter over a 3-mm SpiderFX embolic filter wire (A). A completion angiogram of the anterior tibial artery (B).

tiplied significantly. At the crux of each case is not only a fundamental assessment of the patient's health condition but also an honest judgment of the patient's functional care network and their capacity to operate within that network. In pre–COVID-19 times, a formal medical assessment (wound status, type of revascularization) would be the driving consideration for inpatient versus outpatient care because, in most instances, we have established and optimized the outpatient care network and treatment plan for CLI patients. However, during the pandemic, the status of the outpatient care network has become the primary driver of inpatient admission. Without a functioning outpatient network and a reliable patient, the likelihood of limb salvage decreases dramatically. Limited in-person clinic visits and closed specialty offices because of social distancing specifications/requirements may lead to suboptimal medication adjustments, improper or nonexistent wound debridement and/or dressing changes, and the inability to obtain prosthetic equipment, among other impediments. Furthermore, elderly patients who do not own smartphones or understand how to adequately use the camera are ill-equipped to provide adequate updates on their progress, whether for virtual visits or wound healing progress. A strong family unit may be able to overcome some of these issues provided they do not become ill themselves, but for solitary patients, any one of these obstacles (including transportation) can be a hindrance to a standard treatment strategy. Ultimately, the expected and required level of care for limb salvage in the outpatient setting may no longer be available.

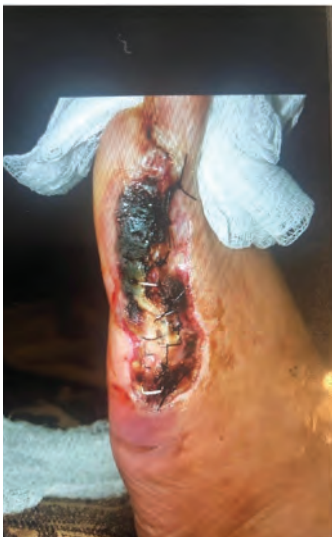

Figure 9. A phone picture taken by the patient showing wound breakdown after initiating home health wound care 7 days post–index procedure.

Understanding that it is impractical and frankly unnecessary to place every CLI patient into inpatient status, it is entirely appropriate to consider a number of these patients as "urgent" cases that justify operative/procedural and inpatient resources. The focus is placed on early medical specialty consultation, expedient revascularization, and wound debridement/care. Active engagement with the functioning outpatient care providers prior to discharge and having contingency plans in place can avoid early missteps and treatment plan failures. Further, an outpatient CLI nurse coordinator may help the patient navigate and troubleshoot obstacles out of the hospital as they arise, which will help keep the treatment plan on track. It is with early and aggressive health care intervention followed by strict and persistent coordination of care that we can provide CLI patients with the best possible opportunity for limb salvage.

CONCLUSION

Patients presenting with CLI require an intense, focused treatment plan to optimize limb salvage. Many of the components in the treatment strategy may be disrupted or nonexistent during the COVID-19 pandemic because of the severe strain placed on the health care system. The reliability of both outpatient care providers and patients has proven to be a significant limiting factor for adequate treatment. As such, the delicate balance of inpatient versus outpatient care of CLI patients may require a paradigm shift during the pandemic to optimize outcomes. ■

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Indications for Use:
The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications
- The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the *Instructions for Use* (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

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

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HawkOne™ directional atherectomy system Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The HawkOne directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

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SpiderFX™ embolic protection device Brief Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
- **Lower Extremity (LE) Interventions**
  The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.
- **Carotid Interventions**
  The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.
- **Saphenous Vein Graft (SVG) Interventions**
  The SpiderFX embolic protection device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

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Venous Emergencies During COVID-19: What We've Learned

A conversation with Dr. Akhilesh Sista about the impact that COVID-19 has had on practice, safety protocols, decision-making for venous emergencies, and postprocedure medical therapy and follow-up.

First, how would you briefly summarize the impact on venous services at your hospital during COVID-19?

In all procedural areas, there was a shift to medical management to the extent possible for acute pulmonary embolism (PE) and deep vein thrombosis (DVT). We really had to have a good reason to move a patient around the hospital on the inpatient side and definitely on the outpatient side. Before COVID-19, there had been a trend toward more outpatient-based acute DVT procedures, but most of these procedures and those for chronic venous disease and superficial ablations were put on hold. With time, we started to add procedures for urgent cases, such as for patients who were in pain or who had severe postthrombotic syndrome.

Have you seen more, fewer, or roughly the same amount of venous emergencies during this time?

The number of PE response team (PERT) calls at our institution actually decreased a little during the COVID-19 outbreak, and it's hard to tease out why. I'm not sure how the other New York City hospitals fared in their PERTs, but we noticed a drop-off, perhaps because the physicians taking care of these patients were overwhelmed. There was an influx of physicians caring for COVID-19 patients who were not used to managing intensive care unit (ICU)–level patients because we were drawing from other specialty pools. Thus, some physicians who were volunteering in the ICU or moved to the ICU to help out were not accustomed to the usual processes for PE management. When a COVID-19 patient in the ICU developed clinically significant PE, they were often diagnosed by bedside ultrasound with an echocardiogram showing right heart strain or clot in transit, with the presumption that there was pulmonary artery thrombus because you do not really want to move these patients from the ICU, even to the CT scanner. If patients were doing badly enough, they received systemic thrombolytics, and this is a pretty difficult line to straddle because COVID-19 patients also tended to bleed. So, with the combination of COVID-19 and PE, we were sometimes in a difficult situation.

Have you observed any differences in the clinical presentations or demographics of COVID-19–positive patients presenting with DVT versus those without the virus?

Only anecdotally. It appeared there were more massive DVTs than before and that they would more often propagate despite the patient being on therapeutic anticoagulation, which I have rarely seen. Again, this is only my personal observation. To manage these patients, we had to consider things that we wouldn't have ever considered before. For example, there was a patient with bleeding from COVID-19–related organ damage who then developed a calf DVT, and we had to consider placement of an inferior vena cava (IVC) filter because that patient couldn't be anticoagulated, and there was concern that COVID-19 patients are more likely to have DVT propagation. At the time, there were no data to guide decision-making. You cannot necessarily universally apply traditional venous thromboembolism (VTE) guidelines to all COVID-19 patients because we don't yet understand how COVID-19 modifies VTE.

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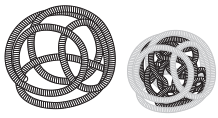

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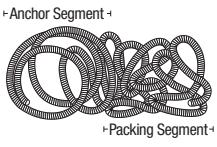

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a. Data on file at Penumbra, Inc.
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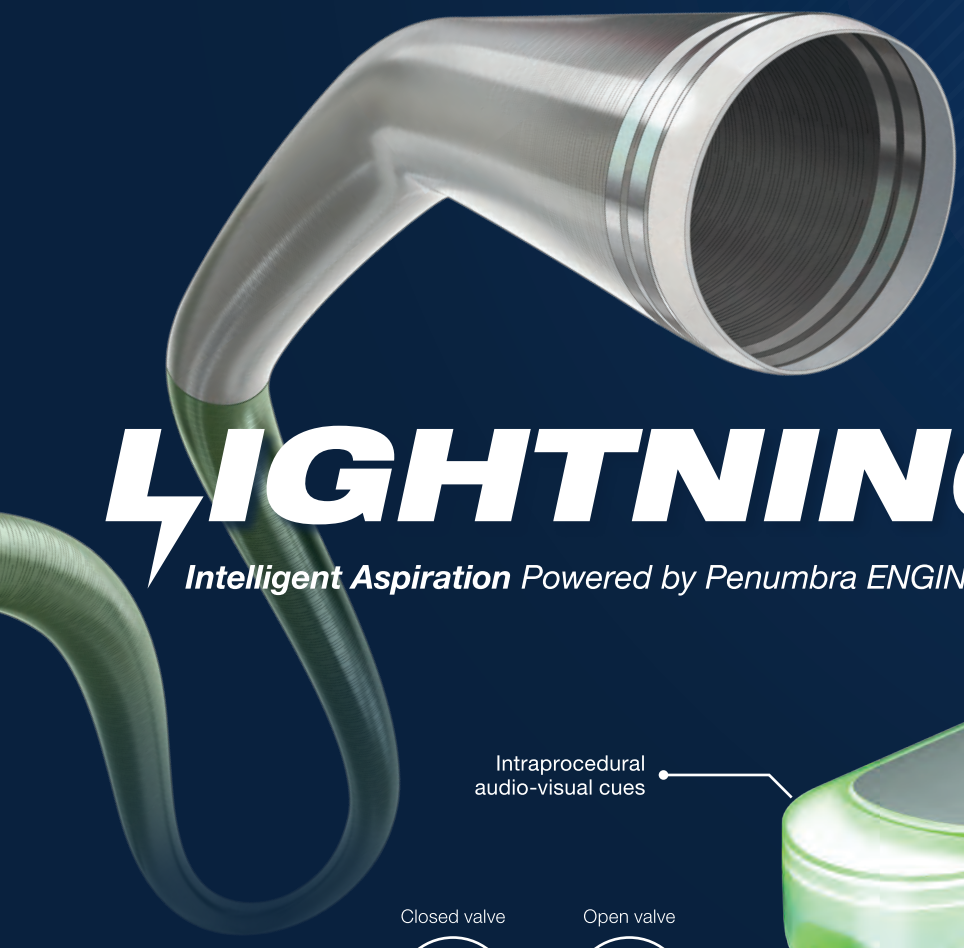

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Would you say that IVC filter use increased in general during that time?

We'd have to look at our numbers; I don't think there was a significant increase. We had attending-to-attending discussions regarding the decision to place an IVC filter. If we decided to place an IVC filter, it had to be pretty compelling, because it meant bringing down a COVID-19–positive patient to the interventional radiology (IR) suite, which we all took very seriously.

What are your team's safety protocols when encountering VTE in a COVID-19–positive patient?

Before we could work clinically, we were all tested for COVID-19. We have a daily symptom check to ensure we have no fever or chills, body ache, loss of taste, or loss of smell. Then, we have appropriate personal protective equipment in the form of an N95 respirator or equivalent, a face shield, and double-gloving gowning to ensure droplets won't touch any part of the skin. After the procedure, we perform a very thorough handwashing.

For the suite itself, we use the hybrid operating room because it has negative pressure. But, if that suite is in use for another case, we put a HEPA (high-efficiency particulate air) filter in another suite and close down the room for an hour after the procedure. The CT scanner is not in a negative pressure room either, so for a CT-guided procedure, we then put the HEPA filter in the room and leave it on for an hour after the procedure ends.

If you could design the perfect facility to handle this situation, what would it look like? Would you have negative pressure capability in every room as a starting point?

This is where COVID-19 is interesting because it has forced us to think about efficiencies in patient transport in ways that we didn't have to think about before. Even before COVID-19, bringing an ICU patient down to the IR suite was a production. You have to gather 15 drips and make sure that somebody is manually ventilating the patient during transport. It usually takes a team of five people to transport that patient down to the IR suite and make sure that the patient is not coding on the way down. It's a big deal, and that's not just for procedures, it's also for CT scans and other nonportable imaging.

Overall, I think this is an issue with the ICU, and I'm sure every ICU physician would say the same. The question is whether there are enough cases in an ICU setting to call for making it easier to move the patient into

a CT scanner on the same floor or into an interventional suite on the same floor. Perhaps there is a role for placing lines under fluoroscopy. Right now, ultrasound is used, but wires are not placed under fluoroscopy. It's an additional safety measure for the patients who can least afford a complication.

Has communication between physicians and teams been affected as a result of the need for safety precautions?

No, I don't think communication has been affected. It is very important for any consulting service to have an individual who is assessing the patient independently and knows what is entailed by having a particular patient undergo a procedure. If you already have the proper communication channels in place, it doesn't necessarily change because the patient has COVID-19. On our side, it was very clear what precautions we had to take. The pandemic has reinforced our process because we are often communicating and interacting with physicians who we would not typically interact with.

How has a COVID-19–positive status affected therapeutic decision-making in VTE cases?

I think everybody became more conservative about VTE procedures. I treated a COVID-19–positive patient who underwent a kidney biopsy and subsequently bled. I went into the renal artery and was attempting to embolize a segmental branch, and I was astounded at how much the patient was clotting intra-arterially on the table. With any sort of catheter manipulation, coils—it was a highly thrombogenic environment. That experience made me really think twice about being aggressive about VTE work. If it were a COVID-19–positive patient with a stable submassive PE, I would have 100% recommended anticoagulation with the understanding that we could consider something else if things worsened, but we really don't know how thrombolytics and aspiration catheters interface with the pulmonary artery in a COVID-19–positive patient.

How has your follow-up care scheduling been modified, and what are your current protocols? How are you typically doing telehealth visits?

NYU really embraced telehealth and so did our division. We mostly converted our visits to telehealth, and frankly, my patients with chronic venous disease were appreciative of telehealth. I don't think we lost a lot from not physically seeing patients. There's a lot of bureaucracy associated with an in-person clinic visit, and is it always necessary? I think that's a question that COVID-19 made very plainly clear, not just in terms of outpatient clinical visits but even inpatient operations.

We do telehealth visits through our electronic medical record, which has the capability to interface with patients. The patient opens an app on their smartphone, and we are notified that a video visit has commenced. We either use our phone or an iPad to connect with that patient, and the visit goes from there.

Has your postprocedural medical therapy regimen changed during the pandemic? If so, why and how?

My hope is that as papers come out on VTE and COVID-19, we're going to get a better sense of what exactly is happening so we can properly make therapeutic decisions. Higher D-dimer levels portend worse outcomes, but it is unclear if those higher levels reflect more thrombus formation and the thrombus itself then causes mortality or if higher D-dimer levels are just a marker for more severe disease. The big debate is whether the inflammation in the pulmonary circulation is causing in situ thrombosis or if thromboembolism actually originates in the pelvic veins or the deep veins of the leg. There is a lack of clarity about the role that thrombosis plays in the morbidity of these patients. I think many of us believe that thrombosis is happening more commonly in COVID-19 patients, although that hasn't uniformly been found in the studies. Some of the European meta-analyses might argue against that, but one Dutch study and a French study demonstrated pretty high rates of VTE in ICU patients. There are a lot of unanswered questions.

What advice do you have for venous practices that may be seeing increased COVID-19 cases in their regions?

My main advice would be to spend time with physicians who will be initially seeing COVID-19 patients. Understand what they are going to be asking of you and develop protocols. Come together about which patients you would consider intervening on and how you're going to handle those patients in terms of keeping yourself and staff safe, keeping the room clean, and what you're going to do after the patient leaves the room. Have escalation policies. Revisit any algorithms and see if they need to be modified for COVID-19–positive patients. ■

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Maintaining a Robust Acute Stroke Care Network During the COVID-19 Pandemic

A perspective on how a busy health care system in New York City adapted to ensure appropriate stroke care during pandemic conditions.

BY KURT A. YAEGER, MD; JOHANNA T. FIFI, MD; AND J MOCCO, MD, MS

During April 2020, the peak of the coronavirus (COVID-19) pandemic in New York City, there were 6,000 daily new infections with the SARS-CoV-2 virus, with > 500 deaths reported each day.[1] To accommodate the physical strain on the health care system, officials from the city hospital administration tripled the bed capacity throughout the boroughs, adding nearly 800 intensive care unit beds to treat critically ill patients.[2] Although most admissions were due to the respiratory and infectious sequelae of COVID-19, we observed a concurrently increased incidence of emergent large vessel occlusion (ELVO) acute ischemic stroke presenting to our health system hospitals during this time, possibly related to a hypercoagulable state induced in these patients.[3] In this article, we share our perspective on maintaining a robust acute stroke care network during pandemic conditions.

STROKE CARE NETWORK MODEL

The Mount Sinai Health System includes eight hospitals, seven of which are spread around New York City, accounting for nearly 8,000 hospital beds. For the neurosciences specifically, we have two dedicated neurointensive care units staffed by neurocritical care faculty. Our stroke care network consists of one centralized comprehensive care center, surrounded by three thrombectomy-capable stroke centers and a network of referring primary stroke centers, both within and external to our health system. As we have previously reported,[4] our model for acute stroke treatment is one of "trip-and-treat," defined by mobilizing the neurointerventional team to a satellite thrombectomy center for rapid endovascular treatment, as opposed to always transferring a patient into a centralized stroke hospital for thrombectomy. For patients with ELVO presenting to a nonthrombectomy-capable center, the patient and neurointerventional team are simultaneously transferred to whichever thrombectomy center is geographically closest for endovascular treatment. We have found this strategy to facilitate fast overall stroke recanalization times.

HOW THE NETWORK ADAPTED TO COVID-19

Department Structure

The first major change to normal operations during the early COVID-19 pandemic was reorganization of our departmental structure. Given the expected need for critical care services, our neurointensive care unit was converted into a high-volume COVID-19 unit, with two beds and ventilators per room, staffed by our neurocritical care intensivists and providers. Reallocation of personnel left a gap in routine neurointensive care for non-COVID-19 patients with ischemic or hemorrhagic stroke, neurotrauma, and other neuroemergencies, which was filled by neuroendovascular faculty and neurosurgery residents. To relieve additional burden on the health system's peripheral hospital intensive care units, the overwhelming majority of neurocritical care was centralized to the comprehensive stroke center in Manhattan.

As cases of COVID-19 grew, we also noted an increase in ELVO incidence across our acute stroke network.[5]

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As we recently reported, during the 3-week period of peak COVID-19 incidence (March 21-April 12, 2020), 45 patients with ELVO were evaluated, 53% of whom were confirmed positive for COVID-19 infection. Ultimately, 20 (44%) patients were treated with endovascular thrombectomy. During this time, we noted an influx of younger patients with fewer comorbidities presenting with concurrent COVID-19 and ELVO, a concerning finding reported by Oxley et al.[6] This finding has been corroborated in a larger series comparing patients with ELVO presenting before or during the COVID-19 pandemic, with the COVID-19–era cohort being significantly younger age and having better functional baseline (modified Rankin Scale) compared to the pre-COVID-19 cohort.[5] A retrospective case-control study at our institution compared neuroimaging of patients with acute ischemic stroke and observed that infection with COVID-19 was an independent risk factor for positive acute stroke imaging.[7]

Postoperative Transfer

During the COVID-19 pandemic, our acute stroke workflow was similar to prepandemic times. We continued to adhere to the "trip-and-treat" model for the mobile neurointerventional team, treating patients at satellite thrombectomy centers. However, one difference was the postoperative transfer of patients to the centralized neurocritical care unit to relieve the burden on the satellite intensive care units, which at the time were inundated with critically ill COVID-19 patients. During the peak pandemic, we performed significantly more endovascular thrombectomies in the boroughs of Brooklyn and Queens, the areas with the highest incidence of COVID-19 (unpublished data).

Infection Prevention Strategy

Prior to performing a thrombectomy procedure, we followed a strict infection prevention strategy to ensure the safety of the neurointerventional team, technologists, nurses, and anesthesia team. This included maintaining a dedicated COVID-19–only interventional suite for all patients under investigation. All nonessential devices for the single procedure were removed from the room. In addition, full airborne personal protective equipment was required for all providers involved in the thrombectomy. Most importantly, once we recognized the high rate of COVID-19 positivity among stroke patients, all stroke patients were designated as patients under investigation until proven otherwise by a nasopharyngeal swab.

As published in our early case series of the first ten thrombectomies during the COVID-19 pandemic,[8] good radiographic and clinical outcomes were observed after endovascular reperfusion for ELVO. Furthermore, by following our strict guidelines, to our knowledge, only one team member had confirmed COVID-19 infection during this time, which appeared to be from community spread, although this cannot be confirmed. In our larger case series (manuscript in preparation), there were no differences in the rates of successful reperfusion (thrombolysis in cerebral infarction ≥ 2B) or short-term neurologic recovery (National Institutes of Health Stroke Scale score from admission to discharge) between pre-COVID-19 and COVID-19 cohorts. Taken together, these results suggest that endovascular thrombectomy should be offered to patients with COVID-19.

SUMMARY

It is our hope that sharing this experience will aid other communities experiencing the devastation of COVID-19. Given the very persistent need for thrombectomy care during COVID-19, we encourage other systems and communities to take special efforts to ensure continued care for this vulnerable population. ■

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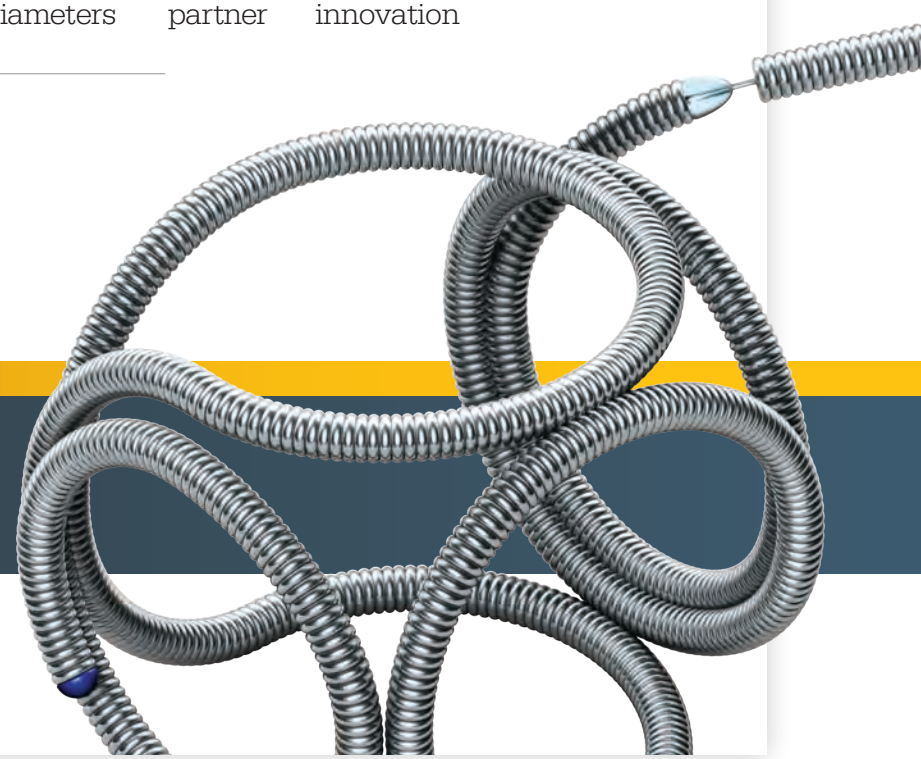

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In south Texas, COVID-19 did not have a significant effect on our practice early on in the pandemic, but it became a totally different world after Memorial Day when the state started easing restrictions and reopening. Today, our area has approximately 3.5% of the population of Texas but has approximately 15% of all COVID-19–positive hospitalizations in Texas. Thankfully, we have had more than 2 months of preparation, and the one practice adaptation that has made the biggest difference is the use of telemedicine (virtual visits). In late March, we started making changes to the inpatient and outpatient services in order to safely evaluate and treat patients on the stroke service, whether or not they were COVID-19–positive. With the implementation of telemedicine and the use of Viz LVO and Viz CTP (Viz.ai), we can communicate with the emergency department (ED) staff to appropriately triage acute strokes very quickly and have not seen a significant change in the door-to-device time for patients receiving mechanical thrombectomy. The inpatient stroke service has been able to see patients in the ED and initiate power plans, and the workup is typically started before the patient receives a bed in the stroke unit or neurology intensive care unit (ICU). With virtual visits, rounding throughout the hospital (ED, COVID-19 unit, stroke unit, step-down unit) has been very efficient. For example, we can see a dozen stroke patients waiting in the ED every day by 8 AM, so there is no delay in their stroke workup or recommendations. At the peak of the Texas COVID-19 census (when the hospital was at 110% capacity), some patients actually had the complete stroke workup and were discharged after spending 2 days in the ED, without ever going up to the stroke unit. The other major benefit of the virtual visits is that we can save precious personal protective equipment (PPE), which is crucial to the ED and ICU staff due to the nationwide shortage.

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We were hit hard in the Northeast and in Boston in particular. Early on in the course of the COVID-19 outbreak as we watched the challenges in Italy, we convened a group called the Northeast Comprehensive Stroke Center (CSC) Collaborative. This group, composed of stroke leadership from the region's CSCs, met virtually every week to share experiences and best practices across seven states. This proved invaluable in two ways: First, we were all undertaking various changes to our processes, and the forum allowed us to share these local approaches and advise each other on refinements. Second, we were able to coordinate a regional triage process through the collaborative in the event that any single CSC was overwhelmed with COVID-19 admissions and could not accept acute stroke patients. This triage was required for three of our centers during March and April 2020, the peak of the pandemic here. Referring hospitals used their usual referral process, but triage of the patient to a thrombectomy-enabled environment occurred at the level of the CSC, based on a shared centralized process. In this way, we rapidly were able to construct a resilient system to maintain access to advanced stroke therapeutics in the face of the immense strain applied to the system by COVID-19 admissions. It provided a strong sense of shared determination and community in addition to the manifold therapeutic advantages. This group currently is exploring options for research in the COVID-19 aftermath here and preparing for a possible second wave in the fall or winter. I would recommend regions being affected now to consider similar approaches if they haven't already. Collaboration and flexibility are the keys to success.

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At the USC hospitals, our goal is to ensure safe and timely endovascular treatment for acute stroke patients while minimizing the risk of infectious exposure for both health care workers and patients. We have adapted our practices in the setting of the COVID-19 pandemic. In the case of emergent endovascular procedures such as mechanical thrombectomy for acute stroke, because there is a lack of appropriate COVID-19 testing, we consider all patients to be "COVID-19 positive" or "COVID-19 rule out." We obtain a COVID-19 test at the earliest possible time after arrival to our hospitals to enable postprocedure disposition. The patient is transported to the radiology department for acute stroke imaging. We do not have a dedicated CT scanner for patients with suspected or confirmed COVID-19; however, our radiology departments have protocols and procedures in place for expedited decontamination based on Centers for Disease Control and Prevention (CDC) guidelines.

As soon as the need for an emergent endovascular procedure is confirmed, we electively intubate the patient in the ED or ICU negative airflow room before arrival to the neuroangiography suite. We transport the patients to the neuroangiography suite using transport ventilators with exhaust port viral/bacterial filters and keep the transport ventilator for the duration of the procedure to avoid breaking the ventilator circuit while outside of a negative pressure room. Physical barriers/dividers are placed in the operating rooms, and all equipment is isolated for COVID-19–positive/rule out procedures. After completion of the procedure

and once admitted to the ICU, attempts are made to extubate the patient as soon as deemed safe. Of note, we do not have a dedicated neuroangiography suite for COVID-19 patients or suspected cases; however, after each procedure, our suite undergoes a terminal clean of all exposed material from ceiling to floor, including lighting. Endovascular surgeons and neuroangiography suite personnel caring for patients assume all of the emergent cases are COVID-19–positive and are provided with N95 masks or equivalent respirators for each procedure. Furthermore, we use CDC-recommended PPE for COVID-19, which consists of handwashing, surgical mask, hair covering, eye protection, nonsterile contact gown, and gloves during the procedure.

These adaptations have made a difference. To date, we have been fortunate and have not had any COVID-19 transmission to or among health care workers or patients. We have streamlined the process so that it adds little extra time to the procedure. It is worth mentioning that at the beginning of the pandemic, our neuroendovascular team had a training session with the infection control department of our health system for proper PPE utilization and to familiarize the team with the COVID-19–related workflow changes, such as donning and doffing of PPE, thereby minimizing treatment delays.

For urgent endovascular procedure such as ruptured aneurysm embolizations, nasopharyngeal swab polymerase chain reaction (PCR) testing is obtained on all patients prior to the procedure, regardless of whether they have any COVID-19–related symptoms. We proceed with the procedure as soon as testing results are obtained. If the result of testing is positive, we proceed according to the same protocols noted previously. If the result is negative, our team members wear masks (N95 or surgical), eye protection, gloves, and a gown.

In our institution, all patients coming in for an elective endovascular procedure will also undergo nasopharyngeal swab PCR testing prior to the procedure. If the result is positive, the procedure is postponed until the patient is no longer infectious and has shown recovery from COVID-19 with negative results from two PCR tests ≥ 24 hours apart.

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Over the past several months, endovascular cerebral surgery has adapted to the restrictions imposed by the COVID-19 pandemic on a global scale. Endovascular care of emergent stroke patients has improved as hospitals become better equipped with PPE and physicians have gained expertise in the management of these patients. Our initial experience regarding stroke patients with COVID-19 at Thomas Jefferson University Hospital suggested a correlation of stroke incidence with younger patients without significant comorbidities. In addition, we observed that these patients tended to have an increased thrombus burden, such as tandem extracranial and intracranial occlusions. The protocol for both endovascular and medical management of these patients was adapted to provide best practice outcomes. All stroke patients were examined emergently through our established telehealth network during both admission and postoperative outpatient follow-up. Robotic video rounds were also used in the neurologic intensive care and stroke units. This minimized potential viral exposure for the patient and associated medical staff.

In the emergent endovascular management of these patients, the endovascular team was prepared for complex thrombectomy procedures, at times incorporating stenting of an occluded proximal cervical internal carotid artery and distal intracranial thrombectomy. The utilization of intraoperative anticoagulation and antiplatelet therapy was more frequent. Based on the potential for particle aerosolization during surgery with coughing and secretions, the neuroanesthesia threshold to intubate was lowered, especially in patients with aphasia or a posterior circulation stroke. In the postoperative medical management of these patients, collaboration of our institution's stroke neurology and the vascular medicine antithrombotic service allowed for the implementation of protocols, which included indications for early systemic anticoagulation in some high-risk patients.

Overall, the management of cerebral aneurysms in COVID-19 positive patients was not significantly altered. However, patients with systemic COVID-19 were more likely to be treated via a minimally invasive endovascular route to decrease operative time and potential pulmonary complications from prolonged intubation procedures.

All elective endovascular and cerebrovascular patients are required to be tested via a nasopharyngeal PCR swab within 72 hours from the procedure. Positive tests require a 14-day retesting and procedure rescheduling, to the surgeon's discretion.

In sum, the endovascular community continues to provide excellence in health care delivery of cerebrovascular patients during the COVID-19 pandemic. Until an effective vaccine becomes available, heightened clinical acumen and hypervigilance remain stalwart principles. ■

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AXS Infinity LS Plus Long Sheath: The AXS Infinity LS Plus Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. AXS Vecta Intermediate Catheter: (1) The AXS Vecta Aspiration Catheter, as part of the AXS Vecta Aspiration System is indicated in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment. (2) The AXS Vecta Intermediate Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices. Trevo NXT ProVue Retriever: (1) The Trevo Retriever is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should start within 6 hours of symptom onset. (2) The Trevo Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. (3) The Trevo Retriever is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (0-50cc for age < 80 years, 0-20cc for age ≥ 80 years). Endovascular therapy with the device should start within 6-24 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Warnings

Contents supplied sterile using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. AXS Infinity LS Plus Long Sheath: When the long sheath is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the long sheath if resistance is met during manipulation; determine the cause of the resistance before proceeding. AXS Vecta Intermediate Catheter: Torqueing or moving the device against resistance may result in damage to the vessel or device. This product is intended for single use only, do not re-sterilize or reuse. Re-sterilization and/or reuse may result in cross contamination and/or reduced performance. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter if resistance is met during manipulation; determine the cause of the resistance before proceeding. If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device. This device is coated with a hydrophilic coating at the distal end of the device for a length of 25 cm. Please refer to the Device Preparation Section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events. Limit the usage of the AXS Vecta Intermediate Catheter to arteries greater than the catheter's outer diameter. The AXS Vecta Aspiration Catheter has not been evaluated for more than one (1) clot retrieval attempt. The AXS Vecta Aspiration Catheter was evaluated for an average duration of direct aspiration of 4 minutes. This product is intended for single use only, do not re-sterilize or reuse. Operators should take all necessary precautions to limit X-Radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-Ray technical factors where possible. Trevo NXT ProVue Retriever: The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established in patients with large core infarcts (i.e. ASPECTS ≤ 7). There may be increased risks, such as intracerebral hemorrhage, in these patients. The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established or evaluated in patients with occlusions in the posterior circulation (e.g., basilar or vertebral arteries) or for more distal occlusions in the anterior circulation. To reduce risk of vessel damage, take care to appropriately size Retriever to vessel diameter at intended site of deployment. The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established in patients with large core infarcts (i.e., ASPECTS ≤ 7). There may be increased risks, such as intracerebral hemorrhage, in these patients. The safety and effectiveness of the Trevo Retrievers in reducing disability has not been established or evaluated in patients with occlusions in the posterior circulation (e.g., basilar or vertebral arteries) or for more distal occlusions in the anterior circulation. Users should validate their imaging software analysis techniques to ensure robust and consistent results for assessing core infarct size. Administration of IV t-PA should be within the FDA-approved window (within 3 hours of stroke symptom onset). To reduce risk of vessel damage, adhere to the following recommendations: do not perform more than six (6) retrieval attempts in same vessel using Retriever devices, maintain Retriever position in vessel when removing or exchanging Microcatheter. To reduce risk of kinking/fracture, adhere to the following recommendations: immediately after unsheathing Retriever, position Microcatheter tip marker just proximal to shaped section; maintain Microcatheter tip marker just proximal to shaped section of Retriever during manipulation and withdrawal; do not rotate or torque Retriever; use caution when passing Retriever through stented arteries. The Retriever is a delicate instrument and should be handled carefully. Before use and when possible during procedure, inspect device carefully for damage. Do not use a device that shows signs of damage. Damage may prevent device from functioning and may cause complications. Do not advance or withdraw Retriever against resistance or significant vasospasm. Moving or torqueing device against resistance or significant vasospasm may result in damage to vessel or device. Assess cause of resistance using fluoroscopy and if needed resheath the device to withdraw. If Retriever is difficult to withdraw from the vessel, do not torque Retriever. Advance Microcatheter distally, gently pull Retriever back into Microcatheter, and remove Retriever and Microcatheter as a unit. If undue resistance is met when withdrawing the Retriever into the Microcatheter, consider extending the Retriever using the Abbott Vascular DOC guidewire extension (REF 22260) so that the Microcatheter can be exchanged for a larger diameter catheter such as a DAC Catheter. Gently withdraw the Retriever into the larger diameter catheter. Administer anti-coagulation and anti-platelet medications per standard institutional guidelines. Users should take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

Precautions

Do not use kinked, damaged, or opened devices. Use the device prior to the "Use By" date specified on the package. Maintain a constant infusion of appropriate flush solution. Examine the device to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used. The device should be used only by physicians trained in percutaneous procedures and/or interventional techniques. Store in a cool, dry, dark place. Do not use open or damaged packages. Use by "Use By" date. Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave. Upon removal from package, inspect device to ensure it is not damaged. Do not expose device to solvents. Use device in conjunction with fluoroscopic visualization and proper anti-coagulation agents. AXS Vecta Intermediate Catheter: The Scout Introducer should be used with a guidewire and Microcatheter inserted when in vasculature. Medical management and acute post stroke care should follow the ASA guidelines. There is an inherent risk with the use of angiography and fluoroscopy. Operators should take all the necessary precautions to limit X-Radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-Ray technical factors where possible. Ensure the RHV is fully open before inserting the AXS Vecta Intermediate Catheter. Avoid over- or under-tightening the RHV. Do not insert or advance the AXS Vecta Intermediate Catheter if resistance is encountered without careful assessment of the cause.

Adverse Events

Access site complications; acute vessel occlusion; air embolism; allergic reaction and anaphylaxis from contrast media; anesthetic risks; aneurysm perforation/rupture; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at the puncture site; hemodynamic compromise; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficit including stroke; pseudoaneurysm; risks associated with angiographic and fluoroscopic radiation including but not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia; sterile inflammation or granulomas at the access site; stroke; tissue necrosis; transient ischemic attack; vessel spasm, thrombosis, trauma, dissection, occlusion or perforation.

Trevo Trak 21 Microcatheter

RX ONLY

See package insert for complete indications, contraindications, warnings and instructions for use.

Intended use/indications for use

The Microcatheter is indicated for use in the selective placement of devices and/or fluids, such as contrast media, into the peripheral, coronary, and neuro vasculature during diagnostic and/or therapeutic procedures.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Possible complications include, but are not limited to the following: death, emboli, hematoma at the puncture site, hemorrhage, ischemia, neurological deficits including stroke, vasospasm, vessel perforation.

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia.

Compatibility

Refer to product label for device dimensions. Refer to labeling provided with other medical technologies to determine compatibility.

- Minimum recommended guide catheter inner diameter: 0.058in (1.47mm)
- Maximum recommended guide wire outer diameter: 0.018in (0.46mm)

Warnings

- Contents supplied STERILE using an ethylene oxide (EO) process. Nonpyrogenic.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Do not exceed maximum recommended infusion pressure. Excess pressure may result in catheter rupture or tip severance.

Catheter	Maximum Infusion Pressure
Trevo Trak 21 MC	1034 kPa (150 psi)

- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter.

Precautions

- Prescription only – device restricted to use by or on order of a physician.
- Store in cool, dry, dark place.
- Do not use open or damaged packages.
- Use by "Use By" date.
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Upon removal from package, inspect device to ensure it is not damaged.
- Do not expose device to organic solvents.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate microcatheter with saline for 2 minutes minimum before use. Once hydrated, do not allow it to dry.
- To maintain hydrophilic coating lubricity, provide continuous flow of appropriate solution between microcatheter and guide catheter.
- Hemostatic side-arm adapters may be used to provide seal around guidewire and microcatheter.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.
- Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

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Arterial Emergencies During COVID-19: Ensuring Safety in Emergent Repair

Lessons learned from one Seattle center's experience.

BY NITEN SINGH, MD, FACS, AND BENJAMIN STARNES, MD, FACS

As the novel coronavirus, SARS-CoV-2, spread around the globe causing an infection known as COVID-19, hospital policies and procedures needed to be implemented quickly and on the fly to preserve supplies and protect hospital staff. This article provides lessons learned from a busy academic practice in Seattle, Washington—the heart of the United States ground zero for the COVID-19 pandemic.

BACKGROUND

The United States patient zero arrived on January 19, 2020, in Seattle after returning from a trip to Wuhan, China. The Centers for Disease Control and Prevention confirmed the patient's sputum sample was positive with COVID-19 on January 20. A month later, Dr. Helen Chu of the University of Washington ran COVID-19 tests, against a cease-and-desist order by the federal government, on 2,500 sputum samples used in another study of the flu virus. This action resulted in identifying the first community-acquired case in a 17-year-old boy who was asymptomatic and on the verge of returning to high school in Renton, Washington.

By early March, Seattle reported > 170 confirmed cases, including 22 deaths related to an outbreak at a skilled nursing facility. As a result of the increasing severity of the pandemic, leadership at the University of Washington Medicine canceled all work-related travel and halted all elective surgeries. As cases continued to climb in our region, our hospital began to conserve masks and other personal protective equipment (PPE).

Within the Division of Vascular Surgery, we decided to continue to offer surgery for patients with abdominal aortic aneurysms (AAAs) > 5.5 cm, dialysis access, and surgery for those with chronic limb-threatening ischemia (CLTI) with a potential for limb loss. However, by March 15, these decisions swiftly changed as a result of conversations with our colleagues Pierantonio Rimoldi and Germano Melissano in Milan, Italy. Their description of a health care system overrun by severe COVID-19 cases forced us to reevaluate the steps needed to manage our patients' needs.

Now, 5 months later, it is astonishing how our daily lives have changed. Our intent with this article is to provide lessons learned from our experience with this crisis. If we can offer even one small piece of information that might make a big difference in a different health care system, we will take that as a success.

VASCULAR TRAUMA

Upon shutting down all elective cases and being available only for true emergencies, we noticed an increase in the number of arterial emergencies. Penetrating vascular trauma initially spiked with gunshot wounds, both intentional and self-inflicted, in the city of Seattle. Our health system established a set of rules for dealing with these emergent cases.

The operating rooms were initially divided into COVID-19–positive and non–COVID-19 rooms, separated by a physical distance (we refer to them as East and West, respectively). The difference between these physical locations was that the operating rooms on the East side of the hospital could easily be converted to negative pressure ventilation rooms, which are preferable for the management of airborne infectious diseases. These operating rooms were therefore identified for COVID-19–positive patients.

The West-side operating rooms are all positive pressure ventilation rooms with the ability to perform 15 air exchanges per hour. Because of this, in the setting of an emergent case with unknown COVID-19 status, only those providers considered essential for the induction of the patient were present in the room during intubation. These few providers would don maximum PPE during this potentially highly contaminated portion of the surgical procedure. Liberal use of tourniquets for extremity vascular injuries allowed a pause of at least 30 minutes at the beginning of the case to allow all the air in the room to completely recycle with 99.9% efficiency.

Our essential faculty and providers were all fit tested for N95 respirator masks. If any provider failed a fit test, they were required to wear a PAPR (powered air-purifying respirator) hood, which decreased the ability to communicate dramatically for both speaking and hearing. We decided to make one of our hybrid operating theaters on the West side a COVID-19–positive room because we did not want to exclude high-quality imaging technology from being used for our urgent and emergent patients, especially given the high volume of ruptured AAAs that we historically see. This required that we cleverly protected all of our providers' lead with clear plastic bags, made special garbage containers in the room, created a "minimal cart" for the anesthesia providers, covered all cabinets that could not be closed or removed them from the room, and used a back room as a pass-through room to allow scrub nurses to bring supplies into that room so they could be collected by the nurse in the room separately (Figure 1).

Figure 1. Extra precautions for converting a hybrid operating room to a COVID-19–positive room. Outside the room: contact precautions cart with taped-off doffing zone and a yellow bin for dirty PAPR hoods (A); a donning cart and precautions signage (B); donning procedure signage, an N95/PAPR hood cart, red PPE disposal bin, and doffing procedure signage (C); all cabinets closed or placed outside of the operating room with alcohol-based hand disinfectant on an intravenous pole (D). Inside the room: additional PPE and disinfectant wipes (E); a pass-through area with closed cabinets (F).

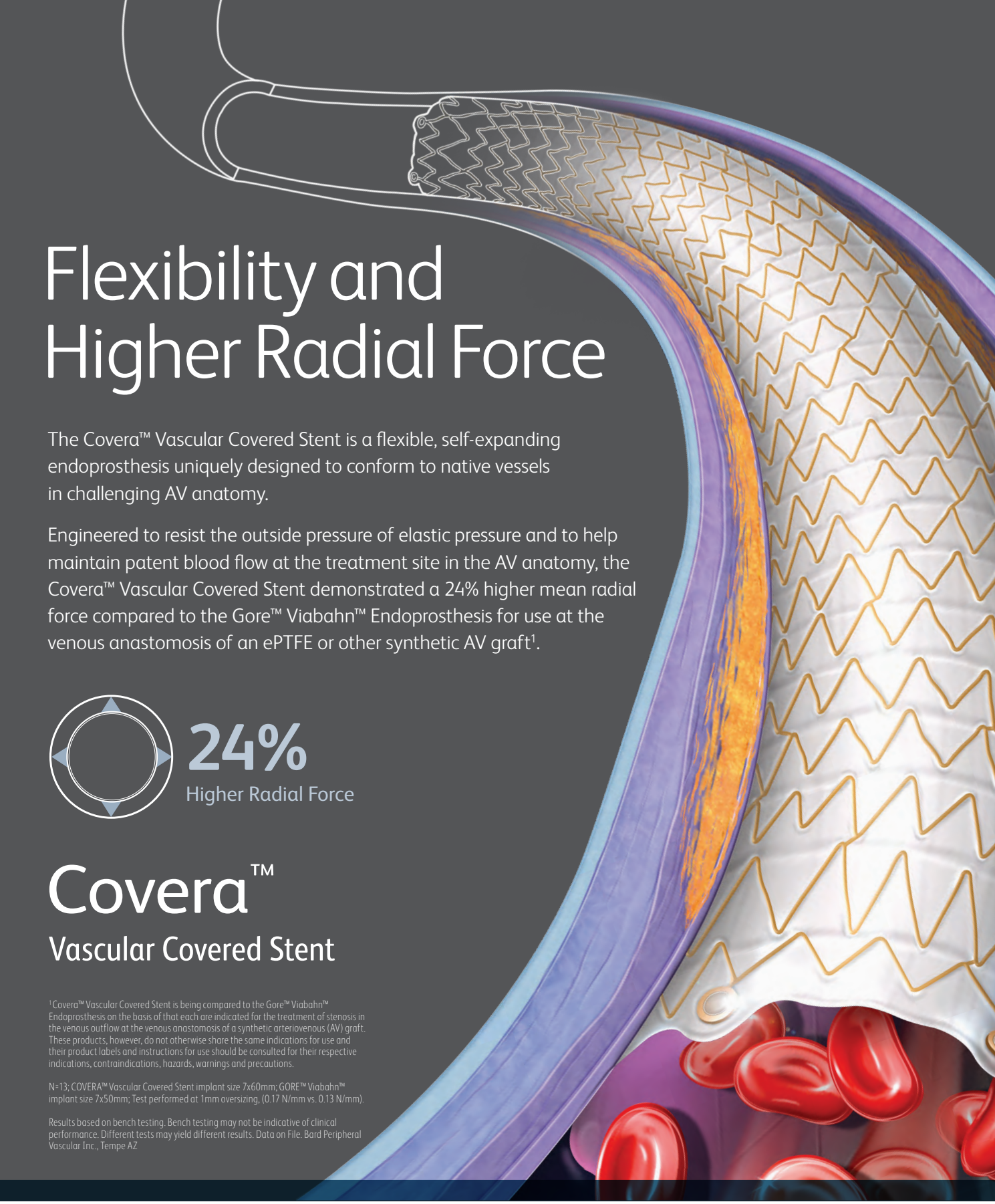
The reality of the situation is that not many COVID-19–positive patients need surgery other than central line placement or extracorporeal membrane oxygenation cannulation. The ultimate goal in managing emergent vascular trauma is to safely perform a standard bypass or repair with the focus being to "protect the fighting strength" of the providers.

TEAM DIVISIONS

The consideration for surgeons and interventional specialists is determining our role in a pandemic and how we can continue to care for our patients without being a burden on the system. Resource use during a pandemic can be daunting, and the disposable PPE we use for procedures are a valuable commodity. We initially approached the pandemic with the idea that we needed to define what procedures were essential for vascular surgeons and which patients were truly elective versus emergent. We decided if a patient was seen in the clinic and scheduled for a procedure, then the patient was elective. This classification included AAAs > 5.5 cm as well as patients with CLTI or in need of dialysis access. Patients who were classified as emergent needed immediate care, such as a ruptured AAA and acute limb ischemia. Although we initially had some reservations about this classification, we felt that most elective patients do not undergo immediate intervention upon being seen, and many of these patients were hesitant to come to the hospital due to fear of contracting the virus.

The other aspect was how we, in a large academic system, ensure that we are available to take care of vascular emergencies. We quickly devised a rotation with one attending surgeon covering for a week and a second as backup. In addition, we divided our resident team to mirror the attending surgeons and used virtual platforms for education and team reports on our inpatients. By avoiding placing our entire team in the same room daily and the potential exposure that could wipe out a service at a hospital, we were able to effectively treat the emergent vascular patients.

At the University of Washington, we created a deployment pool for the faculty and residents. Our system encompasses four hospitals; therefore, it was imperative to have a system in place that could handle a large volume of ill patients. A graduate medical education–based surge management tool was created to allow trainees and faculty to rotate at sites that were needed to man the COVID-19 units. In particular, 90% of deployments were required to fill intensive care unit needs with 5-day rotations created with enough time off between these deployments to ensure rest as well as testing for potential exposure before the resumption of normal duties. Numerous trainees volunteered for these duties, and it was impressive to see their spirit in wanting to do something to help. These shifts were grueling for those residents and faculty who participated, being in full PPE and caring for sick patients on ventilators. Many of



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N=13; COVERA™ Vascular Covered Stent implant size 7x60mm; GORE™ Viabahn™ implant size 7x50mm; Test performed at 1mm oversizing, (0.17 N/mm vs. 0.13 N/mm).

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the procedurally oriented trainees were involved in these rotations and were coveted for their skill in placing invasive lines and their comfort level with treating very sick patients.

Capacity in the hospital was created because elective procedures were halted, and as the number of COVID-19 patients increased, we were able to absorb this volume. Interestingly, when the Washington governor's mandate on elective procedures was lifted, we did not note any ruptured AAAs from those that were postponed electively. In addition, the number of acute aortic dissections did not increase, and none of the patients with CLTI who were postponed for 3 weeks underwent major amputation. We have noted recently several patients who presented with very advanced tissue loss and required an amputation who were afraid to come to the hospital earlier for intervention.

CONCLUSION

We have resumed our normal pace of procedures and incorporated COVID-19 testing within 72 hours of any elective procedure. For patients who require emergent treatment, we perform these procedures using full PPE with N95 masks or PAPR hoods as indicated until their test is performed and is negative. We have not encountered a positive COVID-19 test in our emergent vascular patients thus far, but these precautions will continue for the foreseeable future.

Our service has been very busy of late, and we have successfully been able to navigate elective and emergent cases at our institution. As the financial and educational implications of the pandemic are realized, we must remain nimble in our pursuit of safely caring for patients as well as providers and continuously evolve our capabilities. This situation will not change until we have an effective vaccine, but the lessons we have learned from the first wave of this pandemic should serve us well, as it is likely we will encounter another surge of patients in the near future. ■

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Interventional Oncology: Maintaining Essential Practice During the COVID-19 Pandemic

Considerations and risk mitigation strategies for interventional oncology practice in the COVID-19 era.

BY DIVYA SRIDHAR, MD

The global challenge of clinical decision-making during the COVID-19 pandemic centers around the staggering limitations of our knowledge about this novel disease. COVID-19, or SARS-CoV-2, was first identified slightly more than 6 months ago. The data that have been gathered, analyzed, described, and published in that very short time can provide some insights to guide practice, but they are understandably limited in quantity as well as context. At best, most guidelines offered in this desert of data will constitute educated guesses crafted from a combination of best available evidence, common sense, personal observation, and anecdotal lore.

Amid this global pandemic, patients continue to need care for non–COVID-19 illnesses. Patients with cancer are among the most vulnerable to the impacts of delays in care and also have an increased susceptibility to infection. Devising a plan to safely provide care to oncology patients is a critical aspect of pandemic response. Our interventional radiology department in a busy public hospital in New York City, one of the first epicenters of the pandemic in the United States, continued to provide essential interventional oncology (IO) procedures through the city's outbreak peak and into our postpeak plateau phase, while continually developing and adapting strategies based on emerging evidence and accumulated experience.

RISK ASSESSMENT: CANCER VERSUS COVID-19

Risk-benefit assessment is crucial to determine the timing of oncology procedures during the COVID-19 pandemic. Although bringing a patient to a hospital, outpatient center, or other procedural setting may increase their risk of exposure to COVID-19, this potential risk must be weighed against the known risk of delaying diagnosis or treatment of cancer. For this reason, IO procedures, including image-guided biopsy, port placement, chemoembolization, yttrium-90 (Y-90) radioembolization, and ablation, are time-sensitive and have been continued at most institutions nationwide even when elective procedures have been suspended.

Consideration may be given to deferring less time-sensitive procedures during a period of very high regional or institutional COVID-19 rates to decrease patient risk and conserve resources, including personal protective equipment and staff time. During the peak of the spring 2020 outbreak in New York City, our department elected to defer oncology procedures for which the risk of delayed care was deemed to be less than the risk of exposure to COVID-19, such as thyroid nodule biopsy, embolization for indolent neuroendocrine tumor metastases, and ablation of slow-growing renal masses. These procedures were rescheduled promptly after COVID-19 rates decreased a few weeks later. Institutions may also elect to continue these types of procedures because the duration of any local outbreak is uncertain.

Assessment of risk must be extended to include the psychoemotional impact of changes to care. Clear and frequent communication with patients is imperative in this uncertain period. For today's oncology patients, fears related to the COVID-19 pandemic can compound the anxiety and dread of a cancer diagnosis. Speaking directly with patients allows physicians to not only convey a procedure plan but also express empathy, address concerns, and assure them that the principal focus is always their health and safety. The impact of despair should not be underestimated in patients who know or fear they may have cancer. During the spring 2020 peak in COVID-19 infections in New York City, many patients whose oncology care was delayed due to the pandemic expressed a sense of abandonment and despondency, which in extreme cases even culminated in attempted suicide.[1] A personal discussion with the treating interventional oncologist can help reassure understandably concerned patients that careful consideration is guiding their care, whether the decision has been made to delay a procedure or proceed as scheduled.

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PERIPROCEDURAL RISK MANAGEMENT

At this time, all patients presenting for outpatient procedures in our hospital system are required to undergo COVID-19 polymerase chain reaction (PCR) testing via nasopharyngeal swab before the procedure. The test should be performed as close to the procedure date as possible, taking into account the pragmatics of test turnaround time; currently, the recommendation is to test within 5 days of the procedure. Patients are instructed to strictly socially distance between the time of the test and the procedure to minimize the likelihood of new infection after the test. A nurse calls each patient 24 to 48 hours before the procedure to ask whether new symptoms have developed as well as to confirm preprocedural instructions.

The periprocedural areas, including registration, preparation, and recovery rooms, are therefore considered to be COVID-19–free zones, and visitors are not permitted in these areas. Patients and staff are required to wear masks at all times. Minimizing the risk of exposure to COVID-19 in perioperative areas is important for all patients and critical for oncology patients, who may have compromised immune function. Procedures are scheduled to minimize the number of patients in the waiting area, and seats are clearly marked to indicate where patients may sit to ensure adequate distancing. Patients are brought out of the periprocedural area to meet the person who will escort them home after their procedure.

If resources permit, designating a fluoroscopy suite and CT scanner for COVID-19–positive patients or patients under investigation and separating outpatient from inpatient procedure areas are potential strategies for risk mitigation. When resources do not permit dedicated areas, infection control should be consulted to develop a sanitization process for each room used for infected patients/those under investigation, which may include use of a HEPA filter in addition to cleaning of all surfaces.

Most of our clinic visits, including initial consultations and follow-up appointments, have been transitioned to video visits or televisits to minimize potential patient exposure to infection, unless there is a specific indication for physical examination.

MANAGING COVID-19–POSITIVE PATIENTS

A patient with a positive preoperative COVID-19 PCR test can present a particular challenge. If the patient has symptoms of viral illness, whether the classic respiratory and constitutional presentation or other symptoms (eg, gastrointestinal), most IO procedures should be deferred for the safety of the patient. Our hospital system's guidelines recommend waiting until at least 72 hours after resolution of symptoms and 14 days after initial symptoms or 14 days after a positive test if the patient has no symptoms.

Rare cases of highly time-sensitive procedures may arise that warrant exceptions to these guidelines, such as biopsy or treatment of rapidly growing tumors. In these cases, precautions should be taken as if the patient has active and transmissible COVID-19 infection regardless of symptomatology.

It remains controversial whether patients who tested positive for COVID-19 should be retested prior to a procedure. PCR positivity may continue for weeks to months after initial infection, although most experts agree that it is highly unlikely that the patient continues to be infectious throughout this period. Waiting until the PCR test is negative could result in a prolonged delay in care. In one small study, no live virus could be isolated from patients after day 8 of infection, and antibodies were developed in all patients by day 14.[2] These findings support time-based criteria in deciding when to proceed with a procedure, given concerns over accuracy of antibody testing; however, protocols should be adjusted as additional evidence emerges.

Regardless of the criteria used to determine eligibility for procedures, patients who have had recent COVID-19 infection should be managed very carefully. Many infected patients may not return to their usual state of health for at least a few weeks after initial illness, according to a Centers for Disease Control and Prevention survey,[3] possibly longer based on extensive anecdotal reports. Patients who have had severe illness requiring hospitalization may additionally have prolonged renal and hepatic dysfunction, which should be taken into account in planning procedures. Specific areas of concern in outpatients undergoing IO procedures after COVID-19 infection include cardiopulmonary changes, generalized fatigue, and hypercoagulability.

Cardiac and pulmonary sequela of COVID-19 infection have been demonstrated clinically and on follow-up imaging and may affect patients' response to moderate sedation medications. Extreme caution should be used in administering procedural sedation to patients after infection. In our department, we have chosen a conservative approach. Anesthesiology provides sedation for patients with recent infection to ensure patient safety because we have observed that some of these patients demonstrate more lability in vital signs and may be at higher risk for sedation-related respiratory failure. It is unknown whether patients who have had asymptomatic infection are also at increased risk.

Many patients also report prolonged malaise and fatigue after COVID-19 infection. Performance status should be reassessed prior to treatment, as it may impact the patient's ability to tolerate postprocedural effects such as postembolization syndrome after bland embolization or chemoembolization or fatigue after Y-90 radioembolization.

Marked hypercoagulability has been widely described in patients with COVID-19 infection. Anticoagulation has been incorporated into the treatment regimen for patients hospitalized with COVID-19 at many institutions. Extreme elevation of D-dimer levels has been reported as a poor prognostic indicator in hospitalized patients[4] but can also occur in patients who are not severely ill. Both arterial and venous thrombotic events have been seen as an initial presenting symptom in otherwise asymptomatic patients. COVID-19–related hypercoagulability could increase the rate of postprocedural thrombotic complications, particularly if superimposed on an underlying paraneoplastic hypercoagulability, and should be taken into consideration prior to performing IO procedures such as therapeutic embolization and thermal ablation. It is unclear whether routinely including a D-dimer level in laboratory tests sent prior to these procedures is warranted in patients with a recent positive COVID-19 test based on the limited data available.

CONCLUSION

IO practitioners have had to adapt to meet the challenges of the COVID-19 pandemic, and risk mitigation strategies will continue to evolve as new data emerge. By implementing focused policies, including rigorous testing, protected periprocedural areas, and special considerations for patients after COVID-19 infection, interventional radiologists can continue to provide safe and expeditious cancer care through this unprecedented time. ■

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ROUNDTABLE DISCUSSION

Office-Based Vascular Practices During the COVID-19 Pandemic

A discussion about how COVID-19 has affected the office-based practice, including procedure volume shifts, protocol changes and safety procedures, hospital referrals, and follow-up scheduling.

WITH BRYAN FISHER, MD; MARK J. GARCIA, MD, MS, FSIR, FACR; YAZAN KHATIB, MD, FACC, FSCAI, FABVM, FSVM; AND SONYA NOOR, MD, FACS

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Overall, how has the pandemic impacted your office-based practice?

Dr. Fisher: Certainly, I think the impact for the office-based lab (OBL) has been smaller than at the hospital because the OBL is an environment that you can control a lot easier. We can screen patients better and set up our own stringent protocols, whereas in the hospital environment, you are really at the mercy of the hospital and the hospital system to keep patients safe.

Dr. Garcia: The pandemic has definitely had an impact on the practice. Initially, because we rescheduled nonurgent, nonemergent cases, we saw a dip not only in the number of cases we performed in the OBL but also in the number of patients seen during normal office hours. For the months of April and May, we were down 60%. The big issue now is having the lack of resources to handle the combination of normally scheduled patients, those that need to be rescheduled, and the urgent/emergent cases

on top of the normal elective procedures. June was the busiest month since starting the new practice in 2017.

Dr. Khatib: Like all businesses, we have seen a decline in cases partly due to executive orders early on and then patient fear later. Yet, the pandemic has further distinguished our hospital independence, a trait that is favored more by patients now.

Dr. Noor: The pandemic affected us starting the week of March 9 when New York State went on pause. The OBL saw an initial increase in cases as we tried to get urgent cases done as quickly as possible not knowing if we would shut down, and our patients were extremely anxious to go to the hospital in the midst of a pandemic. Any cases that could safely be done in the OBL continued to be done during the pandemic, but these were only emergent or urgent cases that could not be postponed for 6 to 12 weeks.

We quickly adopted all Department of Health and Centers for Disease Control and Prevention (CDC) guidelines at the OBL to ensure the health of our doctors, employees, and our patients who came to the OBL. The patients felt safe to have procedures done in the last few months. In fact, they prefer the OBL to the hospital even now. We also pivoted quickly and partnered with multiple urgent care and immediate care facilities, offering them Doppler studies and telemedicine visits, and new urgent and emergent procedures came from these new relationships as well.

We sent out weekly communications to all the referring doctors that we were open, the OBL was functioning, and we were compliant with all CDC and Department of Health guidelines and safety practices. With elective cases placed on hold, volume initially dropped to < 50% of regular cases, then with an increase of new relationship urgent cases and dialysis cases, our volume increased to between 60% and 70% in the next 2 months. The total number of dialysis graft interventions and catheter placement increased overall in the last 3 months because we were one of the few outpatient facilities open. In July, we were at 90% of our previous volume since the pandemic started in March.

Of the procedures you perform in your OBL, which volumes were most significantly affected and why?

Dr. Khatib: In the beginning, elective procedures for claudication, heart catheterizations, and loop implants were significantly affected, but all other procedures were not affected. We have seen resurgence in new referral patterns after the peak because patients are favoring outpatient settings. I also believe the lower-cost setting will be more favored as the economic stress continues.

Dr. Fisher: I do not perform a lot of elective procedures, so most of my procedures were not affected. I perform procedures more in the range of urgent to semi-urgent. So, iliofemoral deep vein thrombosis (DVT), chronic DVT with alteration, patients with rest pain and ulceration from arterial disease—these shouldn't wait. I've picked up some patients from hospital-based physicians who were unable to perform procedures.

Dr. Noor: All elective procedures were placed on hold, such as any procedures for claudicants, diagnostic angiograms, and elective venograms for symptomatic iliac vein compression. This accounts for 70% of our usual volume.

Dr. Garcia: Elective procedures, whether arterial or venous in nature, were the most affected. We adhered to state and national recommendations, performing only those procedures that were deemed urgent/emergent. All elective procedures as well as normal office visits were rescheduled. As previously mentioned, this led to a 60% drop in volume for the practice.

What changes have there been in interactions with local hospital referrals? Has your OBL had to take on more or fewer cases referred out by hospitals?

Dr. Noor: The hospital had completely stopped urgent and elective cases, so those patients were brought to the OBL to have procedures done if they were appropriate cases. We increased staffing and hours to accommodate additional procedures that needed to be done. These procedures were mostly critical limb ischemia, DVT, hemodialysis graft interventions, and some catheter placements.

Dr. Garcia: The major change in hospital referrals was due to a decrease in admissions and therefore subsequent referrals for April and May. Both the hospital and OBL postponed nonurgent, elective cases. There were a few instances where urgent cases were performed in the OBL due to patient requests to avoid the hospital. For example, patients with chronic DVT were postponed given their chronic, nonemergent status. Like many institutions, we had COVID-19–positive patients who experienced thrombotic events and needed urgent attention. With the reopening of many businesses in the state, both the hospital and OBL practice are essentially back to running at full capacity with both referrals and scheduled cases.

Dr. Khatib: We have seen more referrals, but they are more so from patients seeking an office-based setting than from hospitals. We have also seen a definite drop in hospital procedure and census volumes that continues to date. I believe there is a real window of opportunity for better cooperation with the hospital systems for the common good.

Dr. Fisher: Local hospital referrals have not necessarily been affected. The biggest issue has just been beds and our capacity to get work done. Right now, it's not necessarily a bed crunch but more of a personnel crunch. Nurses are testing positive for COVID-19 in blocks and they also work very close together, so the risk of spread is high there. So, it's just our ability to accommodate patients and have the personnel there to take care of them that's been a challenge.

How have you modified processes/patient flow in the OBL to ensure patient and health care worker safety? How have you managed testing/screening of patients for COVID-19?

Dr. Khatib: We have followed the ever-evolving CDC guidelines. We originally had a team A and team B approach, which became harder to follow later on with vacation time planned. We have tried to procure on-site testing for our staff and patients to reduce the wait and inconvenience of testing elsewhere as well as the time lag for results; however, we have only been successful in procuring antibody testing, which is less helpful unless IgG is positive, and even then accuracy might be questionable.

Dr. Garcia: We have followed state, CDC, and societal guidelines for handling patient flow as well as screening patients for COVID-19. All hospital patients, whether admitted or undergoing a procedure, get tested for COVID-19 by the hospital within 48 hours of the scheduled case. All patients are tested upon being admitted. Concerning the OBL and clinic patients, they are all questioned via phone the day prior to arrival, their temperature is taken on arrival to the clinic or OBL, and they fill out and sign the standard COVID-19 questionnaire. All patients are required to wear a face mask. There is a limited number of patients in the waiting room at one time, with social distancing in place. Additionally, family members wait in their car while procedures are being performed.

Dr. Fisher: We have a very rigorous screening program where a couple of days before the procedure, the patient is forwarded an assessment and provided information about the procedure. Two days before the procedure, we call and ask about the basic things and remind them about handwashing and wearing a mask out in public. The day of the procedure, the patient has their temperature taken upon entering the door and they are again screened to understand if they've had any sick contact or have symptoms of COVID-19. If there are no flags during the screening process, we proceed. If there's an issue or if we have any questions, we have a very low threshold for canceling or rescheduling the case.

We follow screening protocols based on the CDC recommendations. We basically use that as a blueprint as far as screening is concerned. Testing has been fairly limited outside of the hospital setting, although we do have community-wide testing. To be able to coordinate testing patients for COVID-19 and then decide how long to quarantine patients has been a challenge.

Dr. Noor: We adopted CDC guidelines, and all employees and patients entering the facility have their temperature checked before entering the facility with a mask. A mask is provided if they do not have one. All patients are called the day before to confirm their appointment and answer a set of COVID-19 questions related to recent travel, exposure to a family member exhibiting COVID-19 symptoms, or if they themselves were sick. If there is an affirmative answer to these questions, the appointment is rescheduled.

Starting in July, any patient who requires a procedure has to have a COVID-19 nasal swab test 3 to 5 days prior to the procedure, in addition to not being sick or having been around someone who has a positive COVID-19 test, not having traveled to any of the blacklisted states, and being completely afebrile and asymptomatic on the day of the procedure. No family members are allowed in the facility, and they must pick up the patient after the procedure from the back door only. No families are allowed in the waiting room, and only one or two clinic patients are allowed to enter the facility at a time, while others wait in their cars.

Any employee who is concerned they have COVID-19 is asked to stay at home and undergo a COVID-19 swab test. The OBL allows 5 days paid leave while they await the results. If the result of testing is negative, they return to work. If the employee tests positive for COVID-19, they quarantine until symptoms resolve and they are afebrile for 72 hours, and they must wear a mask for 2 weeks upon return to work. They must also provide a doctor's note to return to work.

How has COVID-19 impacted your sedation/anesthesia protocols?

Dr. Noor: Patients are screened for COVID-19 symptoms such as fever, cough and shortness of breath, and

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if they have any of the symptoms, the procedure is rescheduled. We have not treated any COVID-19–positive patients and have not changed our sedation protocol.

Dr. Garcia: In the hospital, I have utilized the anesthesia team more readily than the pre-COVID-19 scenario. In the OBL, I have been more cautious in the initial moderate sedation dosage.

Dr. Khatib: Our sedation protocol has not changed much. We only perform conscious sedation so that was not an issue. Of course, hospital procedures requiring intubation or general anesthesia have been impacted.

How has your follow-up care scheduling been modified, and are you incorporating telehealth? What are your current protocols?

Dr. Khatib: We have become more liberal in using remote patient monitoring for chronic conditions. We are quick to offer telehealth visits but have also come to learn that the value is limited in patients who are really sick. We have increased same-day appointment availability to reduce patient need to go to the emergency department.

Dr. Noor: Before patients leave the OBL, they are scheduled for a postprocedure follow-up appointment to take place 4 to 6 weeks later. Appointments are confirmed via phone the day before the follow-up appointment, where we usually perform a Doppler study. We adopted telemedicine on our electronic medical record platform in March, so patients are given the option to discuss the Doppler findings with either the doctor in person at the time of the Doppler study or with a telemedicine or a telephone visit later in the week as a remote follow up.

Dr. Garcia: We haven't significantly changed our protocols regarding follow-up scheduling except that the time to follow-up has been prolonged due to the overwhelming volume of patients as well as using social distancing and minimizing interaction in the office. Currently, postprocedure follow-up visits are now extended 3 to 4 months rather than the normal time of 4 to 6 weeks.

Dr. Fisher: Because our volumes weren't significantly affected, we have slowed scheduling to be able to spread appointments out more. We have quite a bit of patient referrals from out of state, so we had already incorporated telehealth into our patient care, but it's now become a larger part to accommodate our out-of-state patients.

If you were to begin planning an OBL practice to open in 2021, how would it differ from when you first opened your current office?

Dr. Fisher: I think I would look for advice from an expert who already had a site open to work out some of the kinks regarding OBL setup to find what's optimal.

Dr. Garcia: Personally, because I took on all financial/business and clinical aspects of opening my current practice, I would probably delegate much more of the day-to-day business issues to the office manager and focus more of my time on the clinical care. I would also look for additional physician and nurse practitioner help sooner. One thing that has been very beneficial that I would not change has been the relationship with the hospital and having the OBL in the medical office building attached to the hospital. This has made life much easier, handling the OBL practice as well as hospital referrals and emergencies, as it is only a flight of stairs from the outpatient center to the hospital interventional radiology lab and inpatient vascular unit.

Dr. Noor: The design of the OBL may need to be larger to allow employees and patients more space for social isolation, in the waiting room, recovery room, and in employee workspaces. Employees would be educated and trained on safe practices for social isolation and wearing masks so they can answer patient questions before a procedure. Because patients and families have anxiety about having a procedure during a pandemic, explaining to them that the OBL follows all policies and is a safe place to have the procedure with low risk of COVID-19 is extremely important. Developing policies for employees regarding COVID-19 or such illnesses and for patients who may be exposed or may be sick the day of the procedure is essential. Additionally, although staff are aware that only one family member can accompany a patient to a procedure, this seems to be a sticking point for a lot of patients and family members, so upfront communication makes for a better experience for everyone. ■

Ensuring Quality in Telemedicine for PAD

How telemedicine is uniquely suited for peripheral artery disease and dispelling the perceived barriers to adoption.

BY TONY DAS, MD, FACC, AND NICHOLAS MACPHERSON, MD

Peripheral artery disease (PAD) ranges from asymptomatic to critical limb ischemia (CLI) and has long been underestimated as an urgent condition. However, when left untreated, CLI leads to severely negative outcomes, including limb loss, which is especially prevalent in vulnerable patients. The COVID-19 pandemic has required that clinicians more critically define urgent versus elective procedures to reduce the potential surge of ill patients requiring hospitalization and preserve precious personal protective equipment.

When urgent and nonelective procedures are defined as those that would lead to loss of life or limb if delayed, it was accepted that CLI fits into the nonelective category. Telemedicine for this patient population was not systematically adopted or reviewed until recently, but the need for telemedicine technology to assist in evaluating and managing wound care and PAD from a remote location has become paramount, especially during shelter-in-place orders.

BACKGROUND

Telemedicine services have become a necessity during COVID-19 to help limit exposure of staff to infected people, either knowingly or unknowingly. Additionally, the ability to triage patients by adopting telemedicine avoids unnecessary use of hospital facilities. Telemedicine is a subset of the broader term of telehealth, which employs digital technology in both real-time and "store-and-forward"/asynchronous methods. It allows for patient care without direct patient contact. Telemedicine growth was beginning to rise before the pandemic, but it has exponentially grown for better patient access with the reduction of barriers, including waivers to allow swift transformation from in-office and in-person visits to telemedicine visits. Certain chronic and acute cardiac conditions such as blood pressure (BP) control, congestive heart failure management, and arrhythmias have lent themselves to an easier transition to telemedicine than peripheral vascular disease until the last 5 years.

UNIQUE FEATURES OF TELEMEDICINE FOR PAD

How applicable is PAD to telemedicine? One of the greatest limitations of telemedicine is the inability to adequately examine patients or perform testing outside of the clinic setting. Quality wound care clinics see their complex PAD wound patients as frequently as every week for wound measurement, assessment, Doppler analysis, and treatment to increase the chances of healing. Without these intense evaluations, amputation rates could increase in this vulnerable population. This at-risk population often has the greatest challenges dealing with the social determinants of health, including access to transportation and Wi-Fi or a reliable internet connection. However, in a recent Harris Poll, 60% of patients with chronic conditions reported they would be open to adopting telemedicine as an alternative to an in-person visit with a health care provider.[1] We should expect consumer interest in telehealth-enabled chronic care to rise steeply as more health systems make it a part of their treatment model. The good news is that many of them are already incorporating telehealth into specialty care, chronic care, and follow-up care programs. Chronic disease care management accounts for approximately 75% of health care spending,[2] and reductions in hospitalizations, readmissions, lengths of stay, and cost have been realized with home monitoring and more frequent patient check-ins. Technologies to assess wounds from afar and remotely measure patients to prevent amputation are also being developed and implemented at rapid speed in the United States and throughout the world to serve the PAD population.

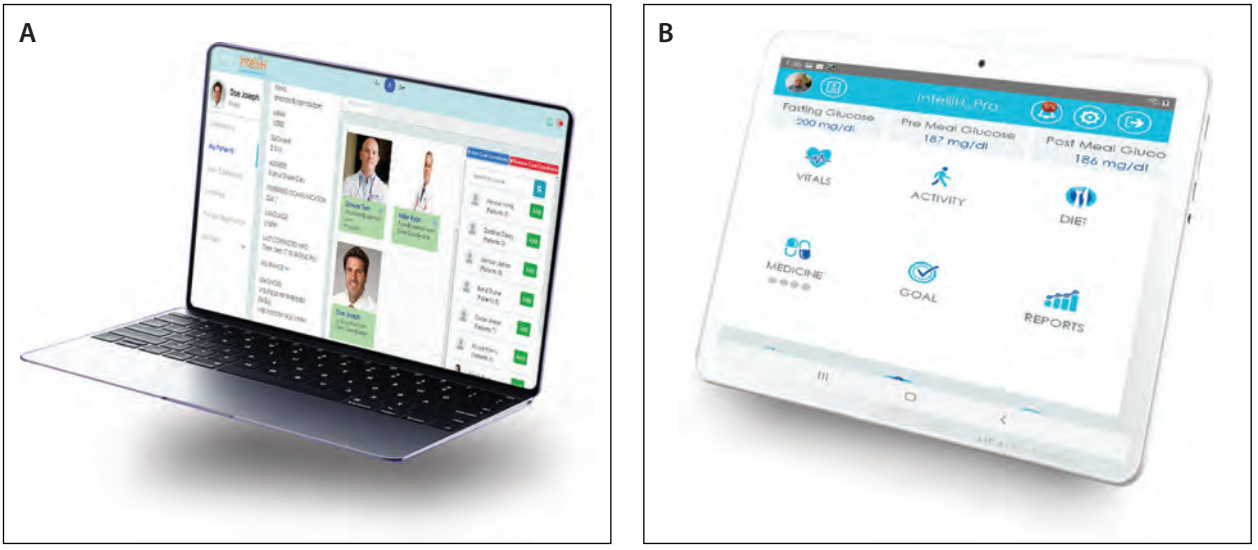

Figure 1. The IntelliH portal system.

BENEFITS AND NEW SOLUTIONS FOR REMOTE PAD MONITORING

Unlike for PAD, remote monitoring solutions for cardiovascular chronic conditions have exploded, including emerging companies such as Orma Health (www.ormahealth.com), which uses cellular-enabled BP cuffs and weight scales; JedMed (www.jedmed.com) and Eko (www.ekohealth.com), which use digital stethoscopes; LIVMOR (www.livmor.com), which uses a continuous atrial fibrillation detection wearable; and IntelliH (Figure 1; www.intellihinc.com), which has a sophisticated platform connected to multiple devices. These companies have created technologies that greatly complement video telehealth by enabling the patient to conduct more thorough at-home examinations and have that information directly synced with their video telehealth solution. In the PAD space, telemedicine and activity tracking have had mixed results in previous studies. Lifestyle coaching, wound monitoring, and activity tracker technologies have been tested in small series and are felt to be valuable in the daily management of PAD patients.[3] In the randomized clinical HONOR trial, wearable technology and coaching did not show an improvement of exercise performance at 9 months without periodic on-site visits.[4] Prior to this trial, Stanford University launched a PAD study using Apple's HealthKit technology and the VascTrac app on patient's iPhones.[5] In the study, 114 patients with PAD performed a supervised 6-minute walk test (6MWT) using the VascTrac app while simultaneously wearing an ActiGraph GT9X activity monitor (ActiGraph). Steps and distance walked during the 6MWT were manually measured and used to assess the bias in the iPhone CMPedometer algorithms. It was found that the iPhone CMPedometer step algorithm underestimated steps with a bias of -7.2% ± 13.8% (mean ± SD) and had a mean percent difference of 5.7% ± 20.5% with the Actigraph (Actigraph-iPhone). The iPhone CMPedometer distance algorithm overestimated distance with a bias of 43% ± 42% because of overestimated stride length. The correction factor improved distance estimation to 8% ± 32%. The ankle-brachial index correlated poorly with steps (R = 0.365) and distance (R = 0.413). Therefore, the study investigators concluded that in PAD patients, the iPhone's built-in distance algorithm did not accurately measure distance, suggesting that custom algorithms are necessary when using iPhones as a platform for monitoring distance walked. Although the iPhone measured steps accurately, more research is necessary to establish step counting as a clinically meaningful metric for PAD.

More recently, emerging technology gathers physiologic and wound data remotely to improve the utility of telemedicine monitoring for established or at-risk patients with PAD. Promising companies such as Siren (Figure 2; www.siren.care), which has developed a washable neuroyarn sock with built-in sensors to detect slight temperature changes and predict neurotropic ulcers, and platforms for wound assessment such as CarePICS (www.carepics.com) that allow clinicians to receive photos from wound care patients, track healing and invite collaboration with care teams.

MYTHS ABOUT ADOPTING TELEMEDICINE

Myth 1: The Technology Is Too Challenging

A common excuse for the slow adoption of telemedicine by physicians includes the comment, "My patients can't figure out telemedicine." This comment couldn't be further from the truth. American Well, a national telehealth leader, announced the findings of its 2019 telehealth consumer survey, which revealed that 66% of Americans surveyed are willing to use telehealth, and 8%

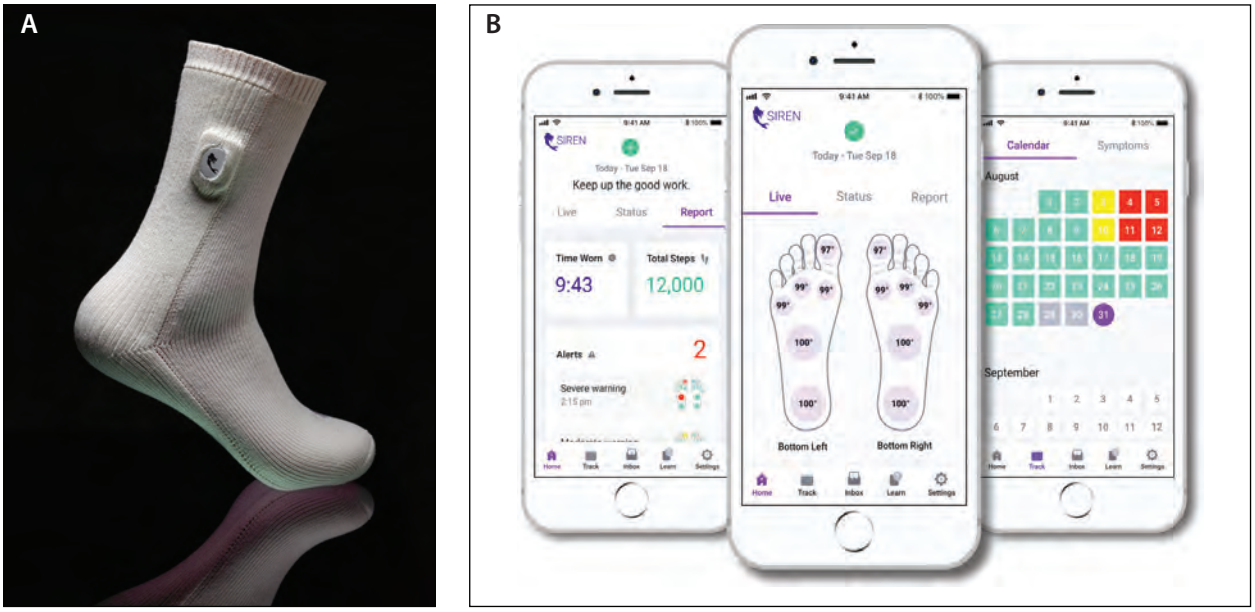

Figure 2. Siren socks (A) and foot monitoring system app (B).

have had a telehealth visit with a doctor.[6] According to a 2015 survey by Software Advice, only 16% of patients said they would prefer to seek care in an emergency room if they also had the option of telemedicine.[7] Maybe that's because 97% of patients are frustrated by doctor's office wait times,[8] but maybe they prefer the convenience of being treated with no commute or inconvenience. In our practice, we have noticed that the success of figuring out the technology of televisits is not well correlated by age. In a survey of 100 patients at my center (Connected Cardiovascular Care Associates) using telemedicine from March to April 2020, age was not directly correlated with the success of the televisit connection with the providers. In fact, we have had patients in their late 80s easily log on, while patients in their mid-50s were unable to connect. In 2019, the Pew Research Center found that 90% of Americans use the internet and 81% of Americans own a smartphone.[9,10] The technology needed to practice telehealth has become widely accessible and more widely adopted.

Myth 2: Telemedicine Lessens the Doctor/Patient Relationship

This may be the least true statement. Because virtual visits are more convenient for patients, fewer patients get lost to follow-up. In my experience, patients appreciate the personal feeling of a televisit and consider it personal communication with their doctor, perhaps because they are in their home environment. Our patients have felt more connected and cared for with televisits, especially during the unsettled time of the COVID-19 pandemic. Many important medical issues such as uncontrolled BP, chest pains, and vascular wounds have been uncovered with routine check-ins by telemedicine. These same issues would have led to critical emergency room visits or costly urgent care evaluations.

Myth 3: Telemedicine Costs Too Much and Doesn't Pay

A cost analysis of televisits in 2014 found the average cost of a televisit to be almost 50% less than traditional visits.[11] In our electronic health record system, eClinicalWorks, the cost to physician practices for televisits is a minimal cost per visit, with a monthly cap for each provider. Reimbursement for televisits is the same as the evaluation and management codes, with modifiers for televisits. Commercial insurances require that modifier 95 is used for synchronous, live, interactive, real-time audio and video (patient portal), and the GT modifier is used for interactive audio and video telecommunication systems (eg, Skype, Doxy.me). Medicare does not require modifiers but designates that Place of Service (POS) 2 is used to describe telehealth/virtual visits (see Sidebar). Additionally, e-visits can be billed under codes 99421, 99422, and 99423 for a physician phone call with durations of 5 to 10 minutes, 11 to 20 minutes, and > 20 minutes, respectively. The codes for the same times for a physician extender are 98966, 98967, and 98968. Due to the rapid evolution of telehealth and the various policy changes, there is diversity in how claims are being paid and processed for telehealth services. Providers cannot submit a regular claim and expect to be reimbursed accordingly.

MEDICARE CODES FOR E-VISITS

Medicare designates that POS 2 is used to describe telehealth/virtual visits. E-visits can be billed under codes for a physician phone call based on duration:

- 99421: 5 to 10 minutes
- 99422: 11 to 20 minutes
- 99423: > 20 minutes

Codes for the same times for a physician extender are 98966, 98967, and 98968, respectively.

Sometimes telehealth has an out-of-pocket contribution that differs from a regular office visit or the claim may need to be submitted with modifiers. To ensure maximum reimbursement and lessen the risk of claim denials, a telehealth program must have the flexibility to handle every transaction and claim process. However, telemedicine is associated with a low cost to implement and a high yield on payment overall.

Myth 4: Telemedicine Increases Malpractice Risk

Telemedicine may decrease your risk of malpractice by adding another chance for treatment documentation. It also facilitates follow-ups and allows you to check in more frequently to ensure patients are staying on track and adhering to treatment. Whether you're a cardiologist checking on a patient's BP or a podiatrist checking on a wound using telemedicine technology like CarePICS, telemedicine gives you more points of contact.

Myth 5: Telemedicine Is Not HIPAA Compliant

Unlike Skype and other video chat technologies, many telemedicine platforms are compliant with the Health Insurance Portability and Accountability Act (HIPAA) and are often engineered with military-grade security. If you are concerned about a security risk, ask the telemedicine provider how they've built their platform to ensure 100% security and compliance with HIPAA. For example, Samsung Galaxy smartphones and tablets come with Samsung Knox security, which has been certified by HIPAA.

BEST PRACTICES FOR PAD ASSESSMENT WITH TELEMEDICINE

Telemedicine has been rapidly adopted during COVID-19 for acute and chronic conditions. During the "new normal," clinicians will need to transform to a virtual care practice for vulnerable wound care patients, with strategies to maintain the patient/doctor interaction while maintaining reasonable thresholds for escalation to in-person visits when needed, including interventional procedures. Best practices include methods that increase the accuracy and quality of physiologic parameters of wound care and CLI.

CONCLUSION

Telemedicine is here to stay. Remote monitoring of patients will continue to grow as the population ages and chronic conditions (including PAD) continue to increase. Regardless of the adoption before the COVID-19 era, regulators, payors, patients, and providers have all now realized the significant advantage of remote evaluation of patients between traditional visits. This field will keep evolving as companies continue to develop technologies for more accurate physiologic assessment of patients from nontraditional sites of service, like their homes. ■

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Easing the Burden of VTE Treatment

How single-session mechanical thrombectomy avoids thrombolytics, reduces ICU stays, and gets patients home sooner.

WITH JONATHAN LINDQUIST, MD; ETHAN MUNZINGER, MD; AND PAUL J. GAGNE, MD, FACS, RVT

No patient, physician, or hospital system wants an extended hospital stay. Aside from the obvious benefits of being sent home sooner, patients with shorter hospital stays experience lower rates of hospital-acquired infection, are less cost-intensive, and develop fewer venous thromboembolism (VTE) events.[1,2] In addition, approximately 18% of patients with VTE are readmitted to the hospital within 30 days, and 10% to 30% have recurrent VTE within 5 years. When including long-term VTE-related morbidities such as postthrombotic syndrome and chronic thromboembolic pulmonary hypertension, the projected annual cost of hospital-acquired VTE is $7 to $10 billion per year.[3]

In this new era of medicine after the COVID-19 outbreak, shortening hospital stays and freeing up intensive care unit (ICU) beds has become increasingly vital. ICU beds are the most resource-intensive beds in hospitals, costing approximately $4,300 per day and bringing in less revenue for the hospital than floor beds, which generates an estimated $5.8 billion loss for hospitals.[4-6] These beds should remain available for the patients who need them most, as well as to allow hospitals to avoid unnecessary ICU use, which is economically unviable.

What can be done to minimize VTE-related ICU stays and expedite hospital discharge? Inari Medical has developed the FlowTriever and ClotTriever Systems as single-session therapies for VTE that avoid the need for thrombolytics. The presentation of VTE often does not inherently necessitate an ICU stay; instead, it is the use of thrombolytics that requires the patient to be monitored in the ICU. Because of the associated bleeding risks, patients must spend upward of 1 to 2 days in the ICU when undergoing thrombolytic therapy.[7] Although the placement and removal of a thrombolytic catheter may be faster for an interventionalist than a typical mechanical thrombectomy procedure, the time and resources spent on caring for the patient can be tremendous. Furthermore, thrombolytic therapy enacts a physical and emotional toll on patients, who must endure 1 to 2 days of discomfort, lying flat in bed while connected to monitors and intravenous lines.

"The presentation of VTE often does not inherently necessitate an ICU stay; instead, it is the use of thrombolytics that requires the patient to be monitored in the ICU."

The FlowTriever System is the first mechanical thrombectomy device to be FDA-cleared for the treatment of pulmonary embolism (PE). It takes advantage of its large-bore design and controlled aspiration to effectively extract large volumes of thrombus in a single session, without the need for thrombolytics. Patients experience immediate on-table improvements in hemodynamics and vital signs. In the FLARE trial using the first-generation system, all patients with PE were treated in one session, only 1.9% received adjunctive thrombolytics, and > 40% of patients did not require any time in the ICU.[8] Preliminary data from the ongoing FLASH registry using the current third-generation system show that nearly two-thirds of patients avoid the ICU after treatment.[9] Also, a recent single-center analysis demonstrated a significant decrease in ICU time for patients treated with FlowTriever as compared with conservative treatment with anticoagulation alone.[10]

The ClotTriever System, FDA-cleared for treatment of the peripheral vasculature and most often used for lower extremity deep vein thrombosis (DVT), consists of a nitinol coring element and integrated collection bag for effective thrombus removal. Data from the first 105 patients with DVT enrolled in the CLOUT registry show that 99% of patients were treated in a single session, none required thrombolytic drugs, only 4% were sent

TABLE 1. UTILITY MEASURES IN PATIENTS TREATED WITH FLOWTRIEVER AND CLOTTRIEVER

	PE Patients Treated With FlowTriever	DVT Patients Treated With ClotTriever
Single session	100%[8]	99%[11]
Patients receiving thrombolytics	1.9%[8]	0%[11]
ICU after treatment	36.4%[9]	4%[11]
Hospital LOS	4.1 days[8]	2 days[11]

Abbreviations: DVT, deep vein thrombosis; ICU, intensive care unit; LOS, length of stay; PE, pulmonary embolism.

to the ICU, and the median hospital stay was 2 days.[11] Furthermore, a multicenter study of 12 patients with DVT showed that all patients avoided the ICU and had an average hospital stay of 2 days.[12] Table 1 summarizes utility measures in patients treated with FlowTriever and ClotTriever.[8,9,11]

In this article, we present three cases demonstrating how a mechanical-based approach using the FlowTriever and ClotTriever Systems allows patients to avoid ICU stays and be quickly discharged home. We describe a recent lung transplant patient treated for an acute PE who did not require an ICU stay, a phlegmatic DVT patient who experienced immediate symptom improvement and was discharged less than 12 hours later, and a lower extremity DVT patient treated in an office-based laboratory (OBL) and discharged the same day.

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Successful FlowTriever Pulmonary Embolectomy in the Setting of a Recent Single Lung Transplant

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A 69-year-old man with interstitial lung disease presented to the hospital for his regularly scheduled pulmonary rehabilitation after a single lung transplant 10 weeks before. He reported not feeling well earlier that day when working on his car, followed by acute exertional dyspnea and difficulty walking into the hospital. His oxygen saturation was in the 80% range, and CTA revealed a large thrombus burden in the transplanted left pulmonary arteries (PAs; Figure 1). Consolidation in the lower lobe of the transplanted left lung was present, which is suspicious for early or impending pulmonary infarct. There was no sign of right heart strain. The patient was initiated on therapeutic enoxaparin, and due to concerns with the transplanted lung and a lack of pulmonary reserve, our interventional radiology group was consulted for consideration of catheter-directed therapy for the PE.

PROCEDURAL OVERVIEW

Right common femoral vein (CFV) access was achieved via ultrasound-guided micropuncture. A pigtail catheter was used to traverse the right heart and gain access to the main PA. Pulmonary angiography confirmed a large embolus in the main left PA, extending into the lower lobe (Figure 2A). PA pressures (PAPs)

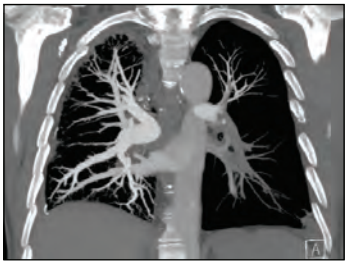

Figure 1. CTA showing extensive thrombus throughout the PAs of the recently transplanted left lung.

were relatively normal, with a mean PAP of 25 mm Hg, and there was no involvement of the native right lung. Due to the extensive thrombus burden, the decision was made to pursue large-bore mechanical thrombectomy via the FlowTriever System. A 24-F DrySeal sheath (Gore & Associates) was placed, and the 24-F Triever24 (T24) aspiration catheter (Inari Medical) was tracked over an Amplatz Super Stiff guidewire (Boston Scientific Corporation) into the main left PA (Figure 3). Initial aspirations yielded small fragments of organized thrombus. The T24 was then repositioned into the left lower lobe, and an additional aspiration yielded the remainder of the embolus in one large, highly organized, fibrous piece (Figure 2C). Immediate improvements in heart rate (from 73 to 64 bpm) and blood pressure (from 100/56 to 115/61 mm Hg) were noted. Postprocedure angiography revealed restored perfusion to the entire left lung (Figure 2B). An inferior vena cava (IVC) filter was placed due to a small amount of thrombus on lower extremity Doppler ultrasound, and hemostasis was achieved via manual compression. The procedure took 69 minutes in total. The patient was sent to a step-down unit for observation and was prepared to be discharged the next day, but a complication unrelated to the PE led to an extension of his hospital stay. A follow-up ventilation/perfusion (V/Q) scan 3 weeks later revealed normal perfusion of the treated left lung (Figure 4).

DISCUSSION

Lung transplant recipients are at particularly high risk for PE, with one autopsy study showing a 27% PE rate after transplant.[1] PE in lung transplant recipients is associated with increased risk of pulmonary infarction, occurring in 37.5% of patients,[1] as well as potential graft complications including bronchial stenosis and restrictive chronic lung allograft dysfunction, which has a median survival of < 1 year from time of diagnosis.[2] Therefore, even though this patient presented without signs of right heart strain and had normal PAPs, the extent of thrombus burden and the lack of pulmonary reserve led us to aggressively treat the PE. The patient avoided the high likelihood of an impending pulmonary infarct, and the transplant graft was preserved.

Importantly, treating this patient with the FlowTriever System enabled us to forego the use of thrombolytics. The option to quickly extract large amounts of thrombus with the T24 catheter allowed the patient to avoid an ICU stay and instead recover in a step-down bed. Thrombolytics not only carry a risk of major bleeding,[3,4] but their use also likely would not have been successful in treating this thrombus, which was organized and fibrous despite the patient's acute symptoms. It is probable that this thrombus was

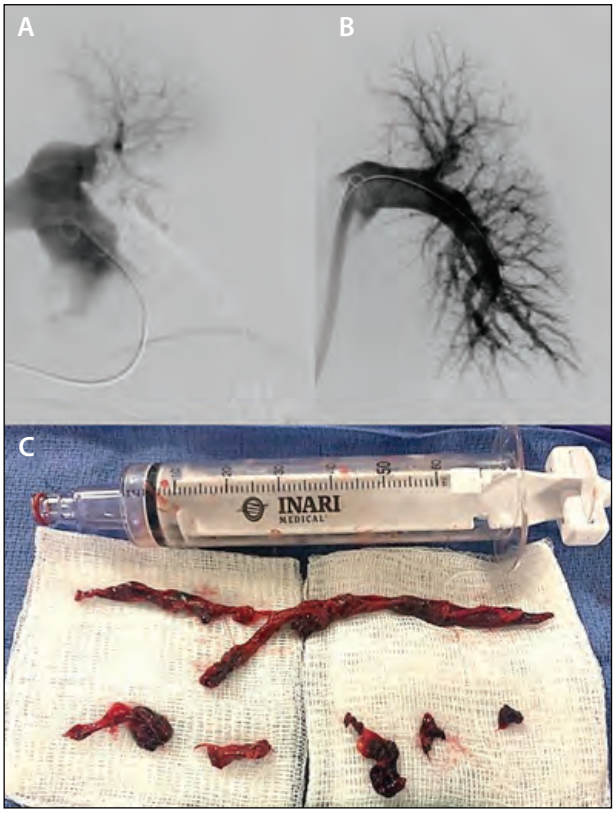

Figure 2. Preprocedure pulmonary angiogram demonstrating large filling defect in the left main PA (A) and postprocedure angiogram (B) showing restored perfusion of the recently transplanted left lung after extraction of extensive and highly organized thrombus (C).

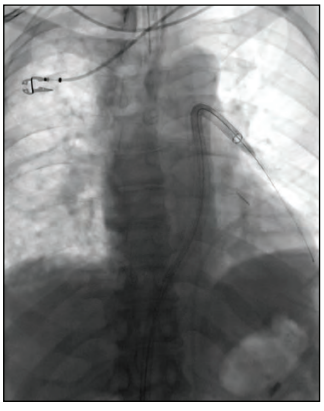

Figure 3. The T24 catheter traversed through the right heart and positioned in the left main PA for aspiration.

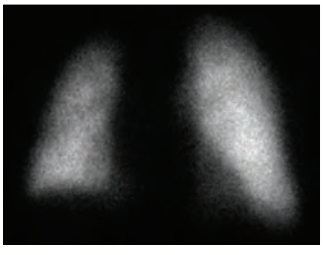

Figure 4. V/Q scan taken at 3-week follow-up showing normal perfusion of the transplanted left lung, while the untreated right lung remains diseased.

present for an extended period of time before the acute event exacerbated the patient's symptomology.

We were prepared to discharge the patient from the hospital 1 day after the procedure. However, the patient developed upper extremity compartment syndrome related to bleeding from an arterial line, which unfortunately required additional time in the hospital. After his eventual discharge, a follow-up V/Q scan at 3 weeks revealed continued restoration of pulmonary perfusion to the transplanted left lung.

In conclusion, percutaneous pulmonary thrombectomy via the FlowTriever System allowed us to quickly and efficiently extract a fibrinous embolus, restore lung perfusion, normalize the patient's hemodynamics, and avoid thrombolytics in a recent lung transplant patient.

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Rapid Extraction With ClotTriever of DVT Causing Phlegmasia Cerulea Dolens

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Disclosures: None.

A 21-year-old woman reported to the emergency department (ED) complaining of severe pain and swelling of her left lower extremity. Her symptoms began 3 days prior, originating with back pain that had progressed to her left hip. She visited a chiropractor earlier in the week with no resolution of symptoms. The day of presentation, she developed severe pain and swelling, as well as a bluish discoloration in her leg. She reported no recent long-haul travel and no family history of VTE, but she did take oral contraceptive pills. On examination, the patient's left lower extremity showed cyanotic changes at the toes and was tender to the touch (Figure 1). Bedside ultrasound revealed extensive thrombosis of the left leg, and she was diagnosed with acute DVT causing phlegmasia cerulea dolens, a limb-threatening condition without rapid treatment. Due to her severe symptoms and after we discussed different therapeutic options with the patient, we decided to pursue mechanical thrombectomy with the ClotTriever System.

PROCEDURAL OVERVIEW

Left popliteal vein access was achieved via ultrasound-guided micropuncture. Prethrombectomy venography revealed extensive thrombus extending from the popliteal vein to the common iliac vein (CIV; Figure 2). The access sheath was exchanged for the specialty 13-F ClotTriever sheath. The ClotTriever

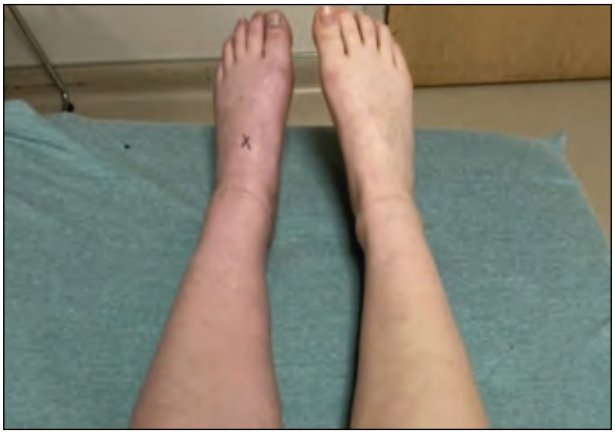

Figure 1. The left lower extremity diagnosed with phlegmasia cerulea dolens prior to mechanical thrombectomy with the ClotTriever System.

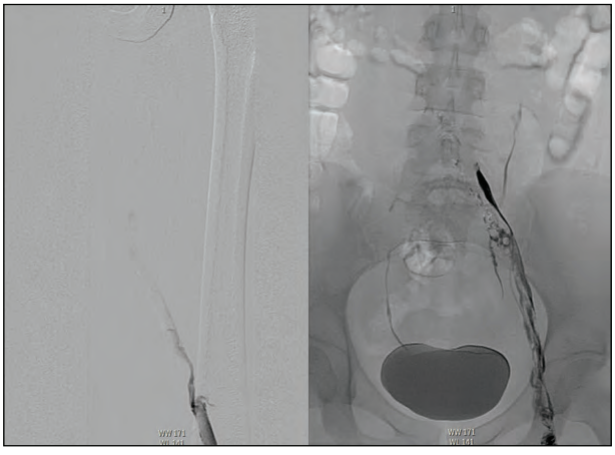

Figure 2. Prethrombectomy venograms showing occlusive DVT.

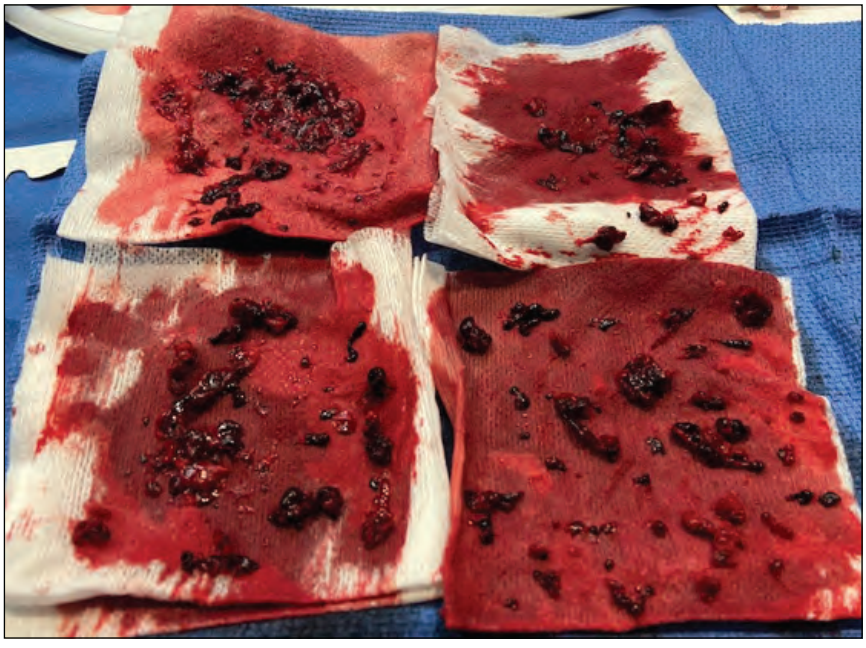

Figure 3. Extensive thrombus extracted from the left lower extremity in four passes.

catheter, consisting of a laser-cut coring element and integrated woven nitinol collection bag, was introduced over a 0.035-inch guidewire, advanced beyond the thrombus burden, and unsheathed to deploy the coring element. Four passes of the ClotTriever catheter were made toward the sheath, extracting a large volume of acute, subacute, and chronic thrombus with each pass (Figure 3). Postthrombectomy venography showed restored blood flow and no residual thrombus (Figure 4). No thrombolytics were required, and the total procedure time was approximately 80 minutes. There were no procedural complications, and the patient was sent to the medical floor for monitoring.

The next morning, the patient's leg was warm with normal color. Her pain and edema had improved, and she did not require narcotic pain medication. She was discharged from the hospital < 12 hours after the procedure and resumed normal activities and exercise later that week. At 1- and 3-month follow-up, she remained symptom-free and had no evidence of post-thrombotic syndrome.

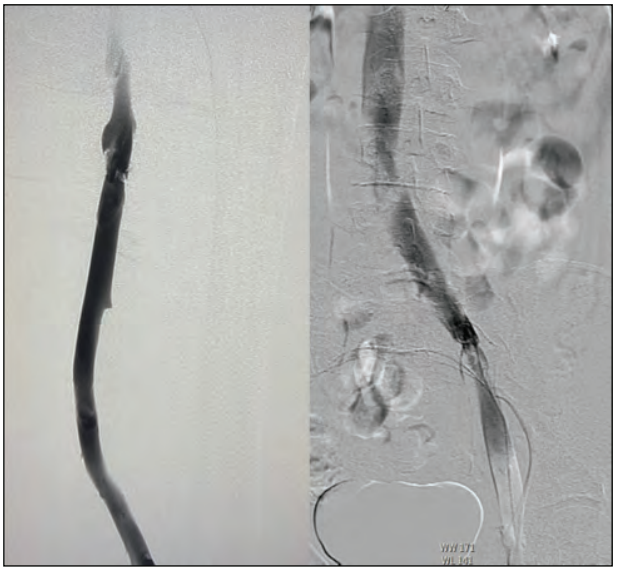

Figure 4. Postthrombectomy venograms showing restored blood flow, lack of residual thrombus, and underlying compression that was not stented due to the patient's young age.

DISCUSSION

Phlegmasia cerulea dolens is a potentially limb-threatening complication of severe DVT. If left untreated, it carries a 25% to 40% mortality rate and an amputation rate of 20% to 50%.[1,2] Due to the severity of this young patient's symptoms, we sought to rapidly extract the DVT via mechanical thrombectomy with the ClotTriever System, restoring blood flow and potentially saving her left lower limb.

Because the patient did not require thrombolytics, ICU admission was avoided, and she was admitted directly to the medical floor to recover. This approach offered multiple advantages, including avoiding the risk of bleeding from thrombolytic therapy, saving the hospital money and resources related to an ICU admission, and making an ICU bed available for another patient, which was particularly important because this patient presented during the initial COVID-19 outbreak.

In conclusion, single-session mechanical thrombectomy via the ClotTriever System allowed us to rapidly extract the limb-threatening DVT, avoid thrombolytic drugs and the subsequent need for ICU monitoring, and discharge the patient shortly after the procedure.

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Treating Acute DVT in an OBL in the COVID-19 Era

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Disclosures: Consultant to Philips and BD/Bard.

A 30-year-old woman presented to the ED complaining of progressive swelling and worsening stiffness in her left leg, which had started 4 days prior. She had deferred going to the ED to avoid exposure to COVID-19 in the midst of surging hospitalizations in the region.

The patient had no history of shortness of breath or chest pain. She was on birth control pills, and her mother had a history of DVT. She had no recent surgery, trauma, or travel. The patient denied any history of leg swelling, leg heaviness, varicose veins, or varicose vein therapy. She had no history of superficial thrombophlebitis or DVT, and there was no other significant medical history or signs and symptoms of COVID-19, pneumonia, or flu. Her physical exam revealed notable swelling of the left leg from the foot to the upper thigh, and the leg was mildly cyanotic in the calf. The skin was distended but not threatened.

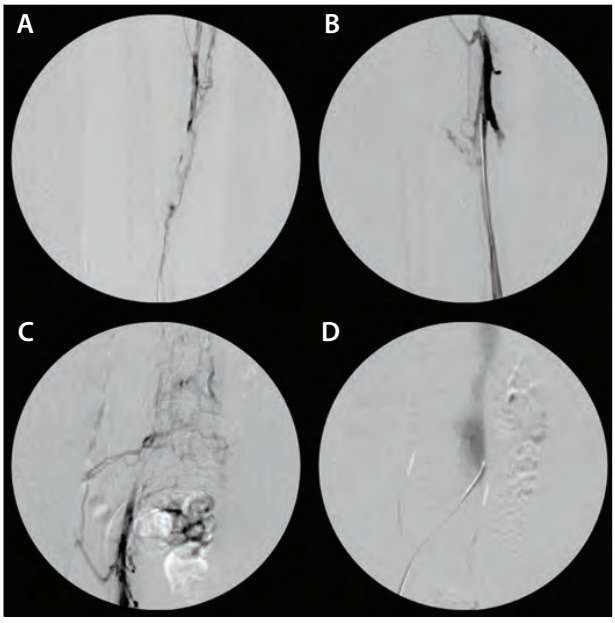

Figure 1. Prethrombectomy venography showing acute DVT of the left FV, CFV, EIV, and CIV (A-C). Collateral flow to the IVC was present via paravertebral collaterals. The IVC was free of thrombus (D).

A left leg venous duplex ultrasound revealed partial thrombosis of the posterior tibial, peroneal, gastrocnemius, and soleus veins. The popliteal vein, femoral vein (FV), and caudal CFVs were fully thrombosed. The cranial CFV, external iliac vein (EIV), and CIV were also partially thrombosed. The deep femoral vein (DFV) was patent. The CFV waveform was monophasic. DVT or occlusive disease were not present in the deep veins of the right leg from the calf to the iliac veins.

The patient was started on 10 mg of apixaban every 12 hours and compression therapy. She was discharged and scheduled for outpatient follow-up. On reexamination 3 days later, the patient noted decreased swelling, but on physical examination, the left leg was twice the size of the right to the level of the upper thigh. The cyanosis had resolved.

Our concern was that this young, otherwise healthy woman would be at significant risk of long-term post-thrombotic syndrome without prompt removal of the acute thrombus from her left leg. Due to her concern about potential COVID-19 exposure and the hospital's COVID-19 guidelines limiting interventional procedures to patients with life- or limb-threatening conditions, we sought a therapeutic option that could be accomplished in the OBL. Having experience with the ClotTriever System, I scheduled a percutaneous thrombectomy procedure to treat this acute occlusive DVT in a single session in our OBL.

PROCEDURAL OVERVIEW

The patient was positioned prone and administered conscious sedation with fentanyl and midazolam. The caudal segment of the left popliteal vein was accessed under ultrasound guidance. An ascending left leg venogram confirmed the acute occlusive DVT findings that were predicted by duplex imaging (Figure 1). A catheter placed at the CFV confirmed the duplex ultrasound findings of CIV and EIV occlusion. The IVC was free of thrombus. A 260-cm Rosen guidewire was introduced and advanced into the right internal jugular vein. The access site was then upsized to the 13-F ClotTriever sheath, the ClotTriever catheter was introduced over the guidewire, and the coring element was deployed above the left CIV thrombus. The ClotTriever catheter was brought back to the access site, extracting mostly red and some salmon-colored thrombus from the left CIV, EIV, CFV, and FV (Figure 2). Two passes in total were made with the device. Some resistance was noted at the cranial portion of the left CIV, suggesting a May-Thurner compression lesion.

Figure 2. Thrombus extracted from the left CIV, EIV, CFV, and FV.

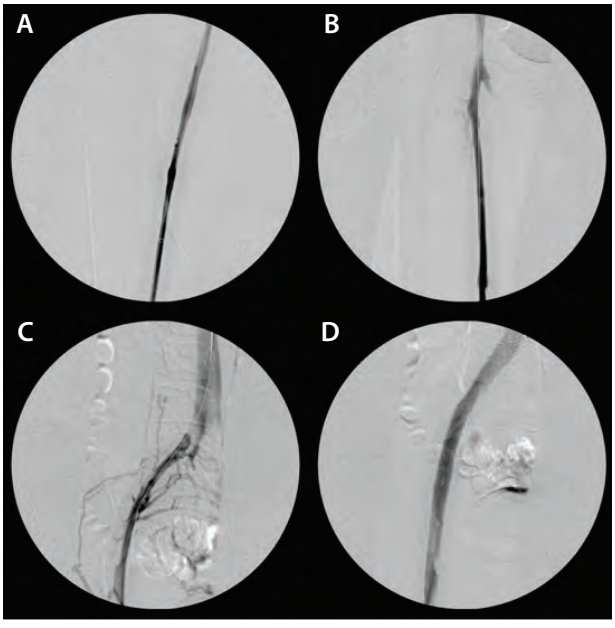

Figure 3. Postthrombectomy venography showing the FV and CFV free of thrombus and the EIV and CIV with minimal residual thrombus (A-C). Collateral transpelvic and paravertebral flow remained due to May-Thurner compression of the CIV. After iliac stenting, there was no collateral flow and the lumen was widely patent, with rapid and spontaneous contrast evacuation (D).

Completion venography and intravascular ultrasound (IVUS) imaging revealed a patent FV, stagnant flow with significant CIV and EIV stenosis, and a small amount of residual acute clot in the EIV (Figure 3). Cross-pelvic collaterals were prominent, suggesting long-standing chronic outflow stenosis of the left CIV. IVUS further revealed that the CIV and EIV had diffuse intramural wall thickening and sclerotic contraction. The CFV was free of scar, and the confluence of the DFV and FV was widely patent. The FV was free of thrombus, with no evidence of wall thickening or postthrombotic intramural or intraluminal scar.

To treat the underlying stenosis, the CIV and EIV were dilated with a balloon to 14 mm and the CFV was dilated to 12 mm. A 14- X 140-mm Venovo venous stent (BD Interventional) was placed at the confluence of the IVC and left CIV (avoiding jailing of the right CIV) and extended to the EIV. This was postdilated with a 14-mm balloon. The caudal CFV was then stented, preserving inflow from the FV and DFV, with a 14- X 90-mm Wallstent (Boston Scientific Corporation), which overlapped by 2 to 3 cm into the Venovo stent. The Wallstent was then postdilated to 12 mm in the CFV and 14 mm in the EIV. On completion, the iliofemoral vein outflow tract was widely patent with brisk and spontaneous drainage of contrast on venography (Figure 3D). The FV was also patent and free of thrombus, although contrast drainage was slow.

The patient was anticoagulated with therapeutic unfractionated heparin during the procedure. She was given a 1-mg/kg subcutaneous dose of enoxaparin before leaving the interventional suite, which was continued for 4 weeks. Oral anticoagulation with apixaban was planned for continued anticoagulation thereafter. She was also given 81 mg of aspirin in the recovery room to be continued for 3 months.

One month after the procedure, the patient has no leg swelling, cyanosis, erythema, or stiffness. She has no pain or problems walking and has resumed jogging. Her FV has rethrombosed, likely due to inadequate inflow, but her DFV and stents are widely patent, and she is clinically asymptomatic.

DISCUSSION

We treated a young female patient with extensive lower extremity DVT in an OBL in the midst of the COVID-19 outbreak, allowing her to avoid the risk of infection at the hospital and freeing up scarce hospital resources. Two passes with the ClotTriever catheter extracted a majority of the thrombus, followed by balloon angioplasty and stenting to treat the underlying chronic stenosis in the CIV and EIV. The patient was pleased with her improvement, especially given the circumstances of an extensive and major leg DVT occurring in the middle of a frightening and surging pandemic characterized by capacity overload of our local hospitals. ■

(Continued from page 82)
They also represent many different subspecialties within cardiology, as well as a variety of practice settings.

What is the background of House Resolution 643, which is focused on improvements in women's cardiovascular health care? Why do you support this legislation, and what can others do to help support this initiative and others like it?

House Resolution 643 was introduced in October 2019 to recognize that women's cardiovascular health is a critical health care priority, emphasizing certain facts including that heart disease is the number one killer of women in the United States and accounts for 400,000 deaths each year. The resolution also highlights that the symptoms of heart disease and heart attack among men and women are different, and it also brings into account the fact that maternal mortality is much higher in the United States compared to other developed countries. More than 700 women die from pregnancy-related conditions every year, and cardiac disease and stroke are the leading causes of pregnancy-related deaths. Symptoms of heart disease are inadequately recognized and not treated appropriately, leading to significant cost in terms of morbidity, mortality, and financial burden. The House wants to create awareness and support for the promotion of gender-specific cardiovascular research and the development of economic impact data.

I think all of these points are extremely critical. Women constitute 50% of the population, and we would be remiss not to address such an important issue affecting half the population. Education of patients and physicians is extremely important but so is providing the resources to perform robust research to find optimal solutions.

Earlier this year, I was part of a group of physicians that went to Capitol Hill to lobby our elected representatives to help pass this law. I cannot understate how essential it is to reach out to our local and state representatives to ask for their support; passage of the law will provide adequate financial backing and legislation to allow for research on this very important topic. Several health care organizations, including the ACC, have materials available that you can use to reach out to your local representatives.

In your opinion, what is the greatest need to address in cardiac care for women?

Similar to the previous question, we know that cardiac disease is the number one killer of women. We have also learned that heart disease can manifest differently in women than in men. Not only is patient education essential but also physician education on the various presentations of heart disease in women. We need to initiate research and increase the number of women in research studies to find the best medications and other treatment options for women with heart disease.

What is your personal strategy for preventing physician burnout, and what advice would you give to those coming into the field? How can societies/physician groups help?

My personal strategy involves spending time with my family. I have a wonderful husband who is a Jeopardy fan and an avid sports fan, so I keep up with trivia and some sports. We love to travel with our children to new destinations as a family, taking in the local culture and cuisine. I love to read and have been part of a book club for more than 13 years with a group of amazing women. I have read many books that I would never have picked up on my own. Locally, I am part of an all-female investor group where I meet entrepreneurs and learn about fields outside of medicine. Having a variety of interests keeps things interesting.

I have a very strict rule that I do not bring work home unless it's absolutely unavoidable. I do not sign onto my electronic medical record from home unless I am on call and need to look up information. Several societies provide tools to help recognize and provide solutions for burnout, and the ACC also has several robust resources.

If you had to choose, what would you say has been your most memorable volunteer experience?

One of my most rewarding experiences was starting the Midwest WIC conference in 2017, which was the first regional meeting we've ever had for WIC. Working on finding the support and getting it off the ground was truly satisfying. This meeting has now served as a model for several regional conferences throughout the country, which has increased participation at the local and national level and allowed us to reach out to medical students and residents interested in cardiology. ■

Editor's Note: Portions of this interview were previously published in the January/February 2020 issue of Cardiac Interventions Today.

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Disclosures: None.

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AN INTERVIEW WITH...

Toniya Singh, MBBS, FACC

Dr. Singh discusses her role as Chair of the National Women in Cardiology section of the American College of Cardiology and her goals to increase female presence in cardiology and leadership roles, her role models, why she supports House Resolution 643 to improve women's cardiovascular health care, and more.

As the current Chair of the National Women in Cardiology (WIC) section of the American College of Cardiology (ACC), what are your personal goals in taking on this role, and what advice do you have for those seeking similar positions of leadership? How can male physicians participate in furthering these goals to improve the society and field overall?

My personal goal has been to smooth the path of any women physicians who choose to pursue cardiology and provide them with tools and introduce them to role models to show them that cardiology is an excellent profession for both men and women.

My advice for women seeking positions in leadership is to start at the local level. We all have good ideas and the key is to raise your hand and get involved. I strongly encourage physicians to be part of organizations that support physicians. As you work on various projects in those organizations, you can make your way up to a leadership role. I would also recommend reaching out to these organizations to get involved instead of waiting to be asked.

Because cardiology is a male-dominated profession, many men in higher-ranking positions can help sponsor and mentor women who are interested in pursuing a career in cardiology.

As a managing partner at St. Louis Heart and Vascular, what can employers, institutions, and practices do to promote inclusivity and improve the lives of all physicians in their health system?

I am fortunate to be able to work in a private practice setting where I have a lot of control over my work environment. I work with 13 other physicians, and we are able to figure out what works best for all of us so that we can be the most efficient without having to work through a large bureaucratic hierarchy. We are a very diverse group with physicians from all over the world, which brings a diversity of opinion and thought to our work. Owning our practice gives us the opportunity to remain flexible and physician friendly.

What clinical research projects are you currently involved in?

Our practice is actively involved in several clinical research trials. We were one of the biggest recruiters for the COMPASS trial, which has changed how we treat coronary artery disease and peripheral vascular disease. We are also involved in trials looking at SGLT2 inhibitors for congestive heart failure and novel treatment strategies for congestive heart failure, including some new devices.

In your 2017 TEDx talk, you discussed how the power of seeing others like yourself represented in higher positions can provide encouragement that success is attainable. Who in your life encouraged your path, and who were/are your role models?

My alma matter Lady Hardinge Medical College is a historical institution that is more than 100 years old and is the only all-female medical college in India. I was surrounded by successful women physicians at all levels of the college. As medical students surrounded by amazing classmates, we all believed we could achieve anything we set our minds to. While I was there, I met Dr. S. I. Padmavati, who was an alumna of my college and was the cardiologist to the President of India. Having met her, I felt that being a cardiologist was something that I could aspire to. I look up to the many women leaders in cardiology as role models, including but not limited to Drs. Sandra Lewis, Roxanna Mehran, Pamela Douglas, Minnow Walsh, Claire Duvernoy, Nanette Wenger, Annabelle Volgman, Dipti Itchhaporia, Athena Poppas, Gina Lundberg, Laxmi Mehta, Martha Gulati, and Malissa Wood, to name a few. They are all doing fantastic and important work and provide mentorship and sponsorship to the women in cardiology.

(Continued on page 80)

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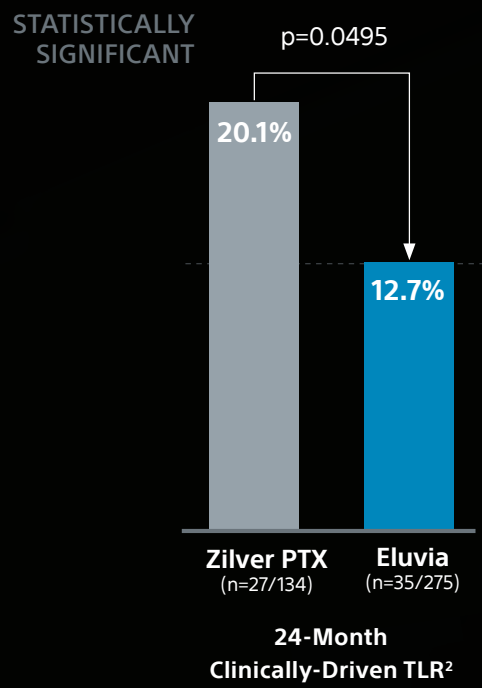
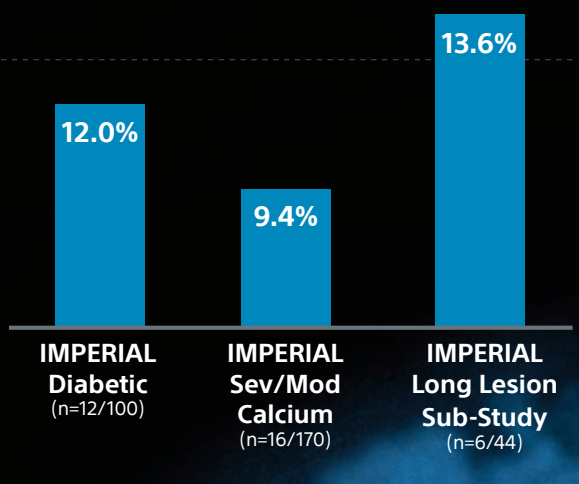


24-Month Clinically-Driven TLR[2]

CONSISTENTLY LOW 2-YEAR CD-TLR IN CHALLENGING SFA DISEASE WITH ELUVIA



1. RCT, As-Treated Clinically-Driven TLR at 2-years: 20.1% for Zilver PTX vs. 12.7% for Eluvia (p=0.0495). 2. Intention to treat. A target lesion revascularization will be considered clinically-driven if it occurs within 5 mm proximal or distal to the original treatment segment with diameter stenosis ≥50% by quantitative angiography (QA) and the subject has recurrent symptoms (≥ 1 change in Rutherford Classification or associated with decreased ABI/TBI of ≥20% or ≥0.15 in the treated segment. TBI allowed in cases of incompressible vessels. Please see page 81 for Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.