



## A Year in Review: The Current State of Clinical Interventional Oncology

Targeted therapies and precision medicine offer potential for enhanced treatments.

By Brenda Silva

As the 9th Annual Symposium on Clinical Interventional Oncology gets underway, important sessions look at CIO and its approach to cancer management. Course Director Dr. Shaun Samuels, M.D. began the first session by welcoming attendees, and offered a look at what's new in the industry such as precision medicine, and practice building in interventional radiology (IR).

The first speaker, Dr. Daniel Brown, M.D., provided an overview of metastatic liver cancer. He referenced the SIRFLOX study with its intent of progression-free survival, noting the next step involves additional data and FIREFOX results estimated for next year.

Taking the podium next was Dr. Robert Lewandowski, M.D., who discussed key hepatocellular carcinoma (HCC) data. He pointed out the MELD upgrade, as well as industry excitement for immune checkpoint inhibitors.

Addressing renal cell carcinoma (RCC) was Dr. Deb Gervais, M.D., who focused on emerging trends such as microwave ablation, attitudes toward "salvage surgery," and niche utilization in younger patients.

"Looking to recent data, there's a growing trend towards ablative therapy. In addition, conversations are also changing when it comes to salvage surgery."

Rounding out the first session, Dr. William Alago, Jr., M.D., reported on lung cancer treatments and therapies. He reviewed data supporting radiofrequency ablation (RFA) in non-small cell lung cancer. He also noted updates on microwave ablation for patient survival, as well as cryoablation.

"We're seeing microwave ablation and cryoablation emerge as ways of treating lung tumors. When it comes to treatments, size matters with RFA best for smaller lesions, microwave for larger ones. But, in my opinion, more data is need for cryo right now."

Beginning a new session, Dr. Ziv Haskal, M.D. focused on the benefits of drug-eluting and conventional transarterial chemoembolization (TACE).

He reviewed studies on drug-eluting embolics, considerations of size in single arm studies, ethiodized oils, and the uptake correlation with necrosis.

The next speaker was Dr. Karen Brown, M.D., who addressed the current role of bland embolization. She said, "When patients presented with liver cancer in the past, they were usually at much later stages than patients who present today."

She added, "When considering treatment options; however, there's no evidence that chemoembolization is either safer or more effective than bland embolization."

Following a short break, the session continued with Dr. Daniel Brown, M.D., who offered information on how particle size can affect the treatment of liver tumors.

"Of three key randomized trials, none has shown a superiority of one size over another with patient outcomes. Ultimately, we need more data sets, then we can revisit the findings and go forward."

The next speaker was Dr. Bradford Wood, M.D., who asserted bead technology can further optimize drug delivery in liver-directed therapy, and explored available data as references.

Also addressing optimization, Dr. Nadine Abi-Jaoudeh, M.D. spoke to the benefits of optimizing cone beam computed tomography (CBCT) in practice.

"The value of CBCT can be seen with improved lesion detection, feeder detection, and assessment of lesion coverage and area treated. Even though there's a learning curve with CBCT, it's definitely worth it."

The next speaker, Dr. Ricardo Lencioni, M.D., offered data on using ablation with embolization. He summarized, "The combination therapy is becoming more popular, and is superior to either therapy alone for local control and overall survival."

Dr. Riad Salem, M.D. finished the liver-directed therapy topic with tips for understanding the role of portal vein embolization. He suggested complete elimination of PV thrombus is not necessary at the time of TIPS placement, and said PVR TIPS should



The 9th Annual Symposium on Clinical Interventional Oncology began with sessions on the current state of CIO, as well year-in-review reports from distinguished panel members.

be considered in patients eligible for transplants with chronic PVT.

Speaking next, Dr. Marcelo Guimaraes, M.D., presented data on radial access for liver-directed therapy. He summarized patients prefer radial access to femoral access 4:1, and that it's a simple and safe technique that may help with procedure cost reduction.

Beginning the last morning session, Dr. Alda Tam, M.D., focused on understanding the role of tissue biopsy in 2017.

She asserted, "Histology is no longer sufficient, tissue biopsy combined with genomic testing offers an option based on its predictive value. It helps us create treatments that consider genetic susceptibilities to specific cancers."

Following next was Dr. Daniel Sze, M.D., who explored the potential role in IR for immunotherapy. He said, "We need to identify unmet needs within IR, and devise solutions for IR. Immunotherapy is not a threat to IO, it's a huge opportunity for IR/IO."

Wrapping up the morning was Dr. Jian Zhang, M.D., who presented the CIO's best abstract, entitled, "Transradial Versus Transfemoral Access in Radioembolization for Hepatocellular Carcinoma with Y-90 Microspheres," which echoed earlier data from speakers that detailed the benefits and preferences of radial access over transfemoral access in HCC.



## Interventional Oncology Looks to Enhance Outcomes with Focused Treatments Disease management and palliative care offer potential for increased positive outcomes.

By Brenda Silva

As the CIO sessions continue, physicians gathered for further discussions on topics and treatments in interventional oncology (IO) technology. Among the topics were treatments and ablation in lung cancer, therapies for pancreatic carcinoma and thyroid, as well as MSK palliation and interventions.

The first session focused on lung cancer as Dr. Kamran Ahrar, M.D., presented information on how to navigate treatments. He said surgery remains the gold standard for NSCLC, and additional data suggests stereotactic ablative therapy may be better than lobectomy in some cases.

Dr. Alda Tam, M.D., offered tips and tricks for lung biopsies such as “go co-axial,” which allows for multiple samples with one pleural puncture; using prone positioning to avoid pneumothorax; and using ultrasound for real-time biopsy needle imaging.

Speaking on lung ablative therapy, Dr. William Alago, Jr., M.D., pointed out radiofrequency ablation (REA) has a large following and cryoablation is becoming a preferred modality, but irreversible electroporation (IRE) is not ready for use outside of clinical trials.

Dr. Kamran Ahrar, M.D., returned with advice on how to prepare for complications that occur. “The simplest complication we can manage is pneumothorax, with other complications requiring more time and attention.”

Dr. William Alago, Jr., M.D. discussed ablation in metastatic disease, and offered tips for lung ablation. He asserted that for lung metastases, ablation appears to be safer. Among his tips for lung ablation were importance of location; increasing tidal volume to expand the lung, and the benefits of anesthesia techniques.

Finishing the session, Dr. Marcelo Guimaraes, M.D., presented data on reconstructing the central vein in patients with malignancy. “The strategies for treating central vein occlusion (CVO) in malignancy include primary stenting, lytic therapy, and mechanical thrombectomy, with stenting offering the quickest improvement of symptoms.”

Starting a new session, Dr. Govindarajan Narayanan, M.D., explored therapies for pancreatic carcinomas. “Only 10-20% of patients qualify for surgery, so we’re performing more percutaneous IRE of the pancreas, which is minimally invasive, allows for precision placement, and has less morbidity.”

Following next, Dr. Heung Kyu Ko, M.D. addressed IO therapies for the thyroid, noting the moving tip technique of REA with real-time ultrasound guidance can be a good alternative for benign tumors of the thyroid.

Dr. Peter Littrup, M.D. continued with focal breast therapies. He said, “The best options visually are MR-guided laser and HIFU, and options with the broadest compatibility and cost-efficacy are cryo, laser, and MR-HIFU. In the future, I think we’ll see more ultrasound tomography, which will keep the cost down and is compatible with surgical options.

Following next, Dr. Jinoo Kim, M.D. spoke about lymphatic duct intervention, and managing chylous effusions. He reported, “We used to do pedal lymphangiography and now we do intracanal lymphangiography, which helps speed up procedures, and may have a therapeutic effect.”

Dr. Peter Littrup, M.D. returned to address ablation of lymphadenopathy, and presented studies that showed tumors, their specific challenges, and treatments that were most effective in each case.

Finishing the session, Dr. John Sangjoon Park, M.D. addressed expanding the limits of endovascular therapy. “Palliative treatment is to improve quality of life, not to cure. In endovascular therapy, we have to find the best treatment for disease, and for the patient’s quality of life.”

After a short break, Dr. Sean Tutton, M.D. began the final session of the morning, which focused on MSK issues in interventional oncology. He summarized patient selection and planning imaging, patient positioning and equipment preparation, protection measures, and perioperative pain must all be considered.



The CIO Symposium continued Sunday with further discussions on interventional oncology treatments for lung cancer, exotics and occasionals, and MSK.

Continuing, Dr. Matthew Callstrom, M.D., presented information on cementoplasty in MSK palliation. He asserted, “Pain palliation can be achieved with cementoplasty, it’s an effective treatment for metastatic spine disease.”

Presenting data on arterial embolization in bone and soft tissue lesions, Dr. Alda Tam, M.D., listed important roles for arterial embolization, including pain palliation, local disease control as an adjunct to ablation, and pre-operative embolization for prevention of intraoperative blood loss.

Next, Dr. Matthew Callstrom, M.D. addressed technical considerations in nerve monitoring during MSK interventions, pointing out common areas that should have nerve monitoring: the sciatic nerve, lumbar plexus, S1 motor nerve, femoral nerve, brachial plexus, and spinal cord.

The final speaker was Dr. Afshin Gangi, M.D., who spoke about management of long bone lesions. “The first thing to consider is the Mirel score, because a score higher than eight means there’s risk of fracture. While cementoplasty may be good for pain reduction, it also presents the risk of fracture; it’s not an option for tumors.”

When he finished, Dr. Gangi remained at the podium and was joined by Dr. Sean Tutton, M.D. The two physicians then presented dueling cases as the final session of the morning ended.

# New Research on Critical Limb Ischemia Shows Improved Results

The latest studies make progress in life expectancy and quality-of-life issues for CLI patients.

By Brenda Silva

**R**ecent clinical studies and trial data analyses show a continued focus on finding safe and effective treatment options for critical limb ischemia (CLI), with ongoing efforts to diagnose the disease in its early stages and slow its advance in later ones.

In addition, new research also evidences increased attention to better classification and treatment of infrapopliteal lesions, utilizing data from follow-up studies, and improving life expectancy and quality-of-life issues for patients with critical limb ischemia, a disease that often has a noticeable impact on both a patient's outlook and their outward appearance.

## INFRAPOPLITEAL LESIONS: EXPANDED CLASSIFICATION AND EFFECTIVE TREATMENTS

In 2015, the TASC Steering Committee introduced an important supplement to the 2007 TASC II guidelines. It provides "an updated literature review of endovascular techniques and practice patterns, as well as a complete lower limb TASC lesion classification, which includes the infrapopliteal segment." By offering complete lesion classification, the supplement enhances diagnostic accuracy for patients with CLI.<sup>1</sup>

However, while the new TASC supplement did not include any "formal treatment recommendations," another 2015 study of infrapopliteal treatment options did offer its performance results, which focused on the use of drug-eluting balloons vs plain balloon angioplasty for CLI patients. Zeller et al compared the safety and efficacy of a "novel paclitaxel-coated, drug-eluting balloon (DEB) versus an uncoated percutaneous transluminal angioplasty (PTA) balloon catheter for the treatment of stenotic, restenotic or occluded infrapopliteal arteries in patients experiencing claudication or CLI," with results from its 72 patients showing the DEB option was safe and effective, with outcomes comparable to existing PTA treatments.<sup>2</sup>

## PATIENT STUDIES: TRIALS, TESTING, RISKS, AND RESULTS

As any physician knows, the key to advancing treatment of a disease or condition is patient trials, with long-term trials providing the best data for patient prognosis. A recent 2015 study by Iida et al focused on OLIVE registry patients who received infrainguinal endovascular therapy (EVT) for CLI, and their results after 3 years. The percentage of these patients who completed the 3 years was 95%, with 55.2% being amputation free, 84% free from major adverse limb events (MALE), and 49.6% wound free after 3 years. The study concluded the results were "reasonable, despite the high reintervention and moderate ulcer recurrence rate."<sup>3</sup>

Another 2015 study, by Bunte et al, focused on the accuracy of ankle-brachial index (ABI) and toe-brachial index (TBI) in evaluating CLI. In a study lasting almost 2 years, 89 patients underwent non-invasive testing for "indications of rest pain, as well as minor and major ischemic tissue loss." Results showed that nearly "one-third of patients with ischemic tissue loss had a normal or mildly reduced ABI." The researchers also concluded that clinical severity assessment and the use of TBI "are likely to enhance the diagnostic evaluation of CLI over ABI alone, especially among individuals with tissue loss."<sup>4</sup>

In a study published in 2014, results reported were from the IDEAS trial that compared paclitaxel-coated balloons (PCB) with drug-eluting stents (DES) in long infrapopliteal lesions for the treatment of CLI. This trial, by Siablis et al, lasted just over a year and included 50 patients who underwent PCB angioplasty or primary DES placement. The authors concluded that, "compared with PCB, DES are associated with significantly better immediate residual post-procedure stenosis, and reduced vessel restenosis at six months." However, they also asserted that larger trials are needed to verify these results even further.<sup>5</sup>

Also focusing on DES therapy, a significant metaanalysis by Fusaro et al evaluated 611 patients from 5 trials. The patients — diagnosed with atherosclerotic disease of infrapopliteal arteries — were randomly assigned to DES vs a control of plain balloon angioplasty/bare-metal stent (BMS) implantation. At a follow-up of 1 year, results showed the "DES therapy demonstrated reduced restenosis and greater clinical efficacy compared with plain balloon angioplasty or BMS therapy, and reduced the risk of reintervention and amputation without any impact on mortality and Rutherford class."<sup>6</sup>

## LIFE EXPECTANCY: FINDINGS AND FACTORS AFFECTING PATIENT OUTCOMES

When faced with a disease as serious as CLI, physicians are forced to consider all the factors that can potentially have an impact on a patient's medical prognosis and mortality. A recent study by Soga et al that focused on life expectancy in CLI patients included 995 patients who underwent endovascular therapy. The study authors used a "risk score based on predictors of all-cause mortality within 2 years."<sup>7</sup>

The results of the study included patient data from a follow-up period of less than 730 days, and concluded that 7 independent prognostic factors were responsible for the 2-year life expectancy (2YLE) of CLI patients. According to the authors, the factors included "age, body mass index, nonambulatory status, hemodialysis, cerebrovascular disease, left ventricular ejection factor, and tissue loss." The study reported that a "2YLE score of less than or equal to 8 points indicated a greater than 50% probability of 2-year survival, and seemed to be helpful in identifying CLI with a poor prognosis."

In a commentary to this study, Beckman et al agree the study's findings have "helped improve the process of patient selection for revascularization." The same authors suggest that additional factors should be included

in the patient's prognostic assessment, such as "the impact of the procedure on sustained functional recovery, independence, and quality of life."<sup>8</sup>

## QUALITY OF LIFE: IMPROVING OUTCOMES AND OUTLOOKS

When looking to heal a patient, physicians and surgeons also must consider how each treatment option and surgical procedure will affect the patient's quality of life. A 2016 study by Katsanos et al focused on results from the ACHILLES trial, which compared a sirolimus-eluting stent (SES) with PTA for the treatment of infrapopliteal arterial occlusive lesions. The study included 200 patients, and results showed that complete wound closure was higher in the DES group — 72.9% vs 55.6% with PTA. In addition, the DES was also the winner in health-related, quality-of-life scores, as well as with a trend of more quality-adjusted life years up to 1 year after randomization. Katsanos et al ultimately concluded that "infrapopliteal SES accelerates wound healing, and may improve quality of life compared to PTA."<sup>9</sup>

However, a 2016 editorial comment by Hawkins on the study of the ACHILLES trial took issue with the findings of the trial analysis and report. The main point of the follow-up comment asserted that, "although ACHILLES demonstrated benefits in restenosis and patency with SES in infrapopliteal arteries, it remains unclear whether those results translate into meaningful clinical benefits for the patients." As such, the comment suggests further research is necessary to ensure CLI patients receive a treatment that best contributes to their quality of life.<sup>10</sup>

Among physicians and surgeons who treat CLI patients, clinical trials continue to be key for researchers, with many closely guarding their optimism for a better tomorrow because of an inadequate today. These same authors and medical professionals

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look forward to new and emerging treatment options that address the causes of disease better than current standards of care, which can only serve to benefit both patients and physicians alike.

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## ISET 2017: Critical Limb Ischemia – An Epidemic Challenge

Interventionalists explore treatments and technologies to enhance current therapies.

By Brenda Silva

As ISET 2017 began, Dr. Barry Katzen, M.D. reported the status of critical limb ischemia (CLI), a condition that continues to challenge interventionalists and healthcare professionals alike. He referenced topics for discussion including biodegradability and drug elution, and CLI topics such as raising awareness, treatment options, improving quality, and reducing amputation rates.

The Town Hall discussion started with Dr. Michael Jaff, D.O., who focused on understanding the CLI epidemic and its implications. He pointed out the prognosis for CLI patients: one year after diagnosis, 25% had died and 30% were alive, but had a major amputation.

"CLI patients have a high risk of limb loss and morbidity/mortality, and there needs to be an urgent sense of revascularization."

Dr. Barry Katzen, M.D. then explained CLI programs, and focused on their measures of success or benefit. "Building a CLI program means data that validates its need. Currently, we need a definition of CLI we can use that works for everyone in the healthcare system."

Following next was Dr. Alik Farber, M.D., who also addressed challenges in CLI diagnosis and treatment. He agreed diagnosis of CLI remains a challenge due to a difference in nomenclature and definitions, and suggested "WIFI" (wound, ischemia, foot infection) from the Society of Vascular Surgery could help that challenge.

Dr. Sean Lyden, M.D. offered data on understanding CLI costs from a Cleveland Clinic experience. They

included costs to hospitals and reimbursements, as well as cost differences between inpatient and outpatient procedures. He suggested physicians work with supply chains, and be flexible about switching or reducing supplies when data supports it.

Looking at limb salvage, Dr. Thomas Zeller, M.D. interpreted CLI data, and highlighted the importance of patency in limb salvage. "Patency is very important to limb preservation, and we need more devices that provide efficient limb preservation."

Up next, Dr. Richard Neville, M.D. gave a definition of a multi-disciplinary limb salvage program. He reported there are 350 million diabetic patients worldwide, and asserted a multi-disciplinary program would increase awareness and success of limb preservation, streamline care, and offer a forum for CLI education.

Following him, Dr. Jihad Mustapha, M.D. discussed the relationship between amputation and mortality, explaining their association.

"Amputation is associated with an increased mortality risk, which increases more when patients have co-morbidities, and they should be treated aggressively with therapy."

Looking at available technologies for CLI, Dr. William Gray, M.D. addressed the benefits and advantages for certain patients. "It's unknown whether long-term patency is needed for ulcer healing. In CLI patients and clinical outcomes, they have not been tightly linked, and there remains a paucity of randomized, multi-center data available."



ISET 2017 began with a Town Hall discussion of important topics in IR, and included live cases from the Miami Cardiac and Vascular Institute (MCVI).

After a short break, live cases were presented with the panel accepting questions as the cases were presented.

The second session focused on bioabsorbable devices, and what benefits they can offer for the future of interventions.

Dr. Juan Granada, M.D., discussed choosing drugs and delivery method based on available data, noting, "Sustainability over time is very important in drug delivery methods, and as the industry continues to evolve, further investigations are needed and will be invaluable."

Addressing bioabsorbable scaffolds for peripheral applications, Dr. Michael Daka, M.D. reported encouraging data from the ESPRIT-I trial including three-year results that demonstrated its safety and feasibility.

Wrapping up the session, Dr. Juan Granada, M.D., focused on bioabsorbable devices for coronary interventions. He asserted, "With bioresorbable scaffolds (BRS), even though it feels like a stent, it also has to be as safe as a traditional stent."

# Latest Research Looks to Enhance Treatment Options for CLI Patients

## Recent Technology and New Products Offer Potential for Improved Prognoses

By Brenda Silva

Among the latest data and developments for treating critical limb ischemia (CLI) are options with clinical results worthy of consideration as potential therapies for advanced peripheral arterial disease (PAD) patients. Recent data analyses from studies and clinical trials, as well as new stent procedures and products, evidenced results that suggest more optimistic patient outcomes.

### RECOMMENDATIONS AND RESEARCH HIGHLIGHT BENEFITS FOR PATIENTS

The latest guidelines for treating PAD include recommendations on the use of antiplatelet therapy to reduce the risk of blood clots as well as the use of statin drugs to lower cholesterol. The recommendations also include advising patients to participate in an exercise program as part of their medical therapy. These new guidelines, published in *Circulation* and in *the Journal of the American College of Cardiology*, are intended to replace guidelines last updated in 2011.

In addition, the new guidelines offered recommendations for when vascular procedures such as angioplasty and stent placement should be considered for patients who have less severe PAD, but who continue to have limitations in walking despite treatment with medication and exercise. However, in a separate study, researchers found that restoration of leg blood flow is better than exercise for PAD patients, and may stop the progression of scarring in their leg muscles. For the study, researchers looked at the levels of transforming growth factor-beta and the amount of collagen in calf muscle biopsies from patients with PAD severe enough to be considered for surgery.

After 6 months, researchers compared changes in biopsy results, which showed that scarring factors increased in the exercise and control groups, but not in the patients who underwent revascularization. Additional findings

showed that while patients in both the revascularization and exercise groups increased their walking on a treadmill, only the revascularization group improved the distance they could walk for a set period of time.

Also focused on blood flow restoration, the Akesys PRAVA scaffold system from Akesys Medical is designed for the treatment of blockage in the superficial femoral artery (SFA). The product, which recently had its first clinical trial and successful implant, restores blood flow to the leg and then is resorbed into the body, leaving no permanent implant behind.

Along with monitoring the blood flow and exercise regimen of PAD patients, one company is advancing treatment of PAD by way of measuring oxygen. Profusa has received a \$1.75 million grant from the National Institutes of Health (NIH), which will allow for the support of fast-tracked phase I and II studies of the company's Lumee tissue-integrated biosensors for continuous oxygen monitoring. The results of the studies are intended to improve the clinical outcomes of patients suffering with PAD.

### PROCEDURE SAFETY AND EFFICACY DETAILED IN CLINICAL TRIAL DATA

In an attempt to reduce the risk of stroke, a new surveillance project will evaluate the safety and efficacy of transcarotid artery revascularization (TCAR) in a comparison with carotid endarterectomy (CEA). Launched by the Society for Vascular Surgery Patient Safety Organization (SVS-PSO), the project is designed to obtain additional data about real-world outcomes of TCAR vs CEA, as performed by centers participating in the Vascular Quality Initiative (VQI).

Another study recently introduced was the ECLIPSE clinical trial, which will compare the Diamondback 360 Coronary Orbital Atherectomy System (Cardiovascular Systems, Inc [CSI]) against conventional angioplasty – including specialty balloons, for

vessel preparation prior to drug-eluting stent (DES) implantation. The randomized trial will include up to 2000 subjects in up to 60 sites in the United States. The trial is expected to begin recruiting in the spring of 2017.

One study that has already completed its enrollment is the LIBERTY 360°, which will evaluate acute and long-term clinical and economic outcomes of endovascular device interventions, including CSI's orbital atherectomy system, in treating PAD. The study enrolled over 1200 patients at 53 sites across the United States, with patients followed for 5 years and a risk score developed as a clinical predictor of outcomes to provide guidance for interventions.

Shockwave Medical announced positive clinical results from the DISRUPT PAD study, a multicenter study that evaluated the safety and performance of lithoplasty to treat PAD. Results from 95 patients with calcified vascular stenosis of the superficial femoral and popliteal arteries enrolled at 8 sites demonstrated that lithoplasty technology provides a safe and successful treatment option.

Also announcing positive results of its Tack Optimized Balloon Angioplasty – Below-the-Knee 12-month clinical study was Intact Vascular. The study indicated that of 35 subjects enrolled at 6 sites in Europe and New Zealand, 87.1% had freedom from major amputation. All the subjects suffered from CLI in one or both legs, and 32 patients were treated with the 4 Fr Tack Endovascular System following standard balloon angioplasty in the tibial and peroneal arteries. Patients in the study demonstrated an improvement after the procedure, and results suggest an increasing number of patients continue to improve as more time passes.

### PRODUCT-SPECIFIC CLINICAL STUDIES OFFER GLOBAL IMPORTANCE

Along with clinical studies that seek to validate the safety and efficacy of an emerging vascular procedure based on patient outcomes, the same

is often true with new products introduced to the medical industry that are also seeking to validate their usage in patients with PAD and CLI. One such product is the Stellarex drug-coated balloon (DCB), an angioplasty balloon that was the subject of the ILLUMINATE multicenter, single-arm study designed to assess its clinical performance in the superficial femoral and popliteal arteries. Twelve-month interim data showed that the first 153 of 371 patients enrolled demonstrated a primary patency rate of 84.7% at 12 months.

In the HEROES-DCB clinical trial, the Lutonix (Bard Peripheral Vascular) and IN.PACT (Medtronic) DCB technologies will be evaluated for their efficacy with respect to patient outcomes. The multicenter, randomized trial will enroll 275 patients, and is intended to determine if there is any difference in patient outcomes between the two similar Food and Drug Administration (FDA)-approved DCBs to treat PAD.

Also from Medtronic, new data from two studies involving the company's IN.PACT Admiral DCB found that it maintains durable, consistent, and safe outcomes in trials involving chronic total occlusion when studying gender and diabetes subgroups. Data included 1-year results from the chronic total occlusion imaging cohort from the IN.PACT Global Study, and the 2-year gender and diabetic subgroup analyses from the IN.PACT SFA trial.

On a larger scale, enrollment has been completed on the BIOFLOW-V clinical trial, with 1334 patients enrolled at 91 sites in the United States, Canada, Europe, Israel, and the Asia-Pacific region in less than 1 year. The study is designed to determine the safety and efficacy of BIOTRONIK'S Orsiro hybrid DES system. Patients with coronary artery disease were assigned to receive either the Orsiro or another currently available DES, with the primary goal as target-lesion failure at 12 months post index procedure.

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## PRODUCT LAUNCHES LOOK TO ADVANCE CLI TREATMENT

New product introductions are often viewed as either an immediate asset for the medical industry, or as an immediate liability until it's proven indispensable by the industry. One company looking to prove the import of its products is Asahi Intecc, whose new

peripheral guidewires feature diameters of 0.014" and 0.018", along with precision braiding ACT ONE dual-coil technology, which improves torque transmission and durability. The wires also offer tapered micro-tips to better cross complex lesions, and hydrophilic coating in the spring coil with uncoated distal tips for better tactile feedback.

Looking to expand treatment options for patients with end-stage CLI,

LimFlow has received the CE mark for its LimFlow System, designed for venous arterialization of the lower limbs in end-stage patients at risk of limb amputation for CLI. The system is for patients who have exhausted all current revascularization options, and it is intended to bypass diseased arteries and divert blood flow into the tibial vein to successfully vascularize the ischemic foot,

thus promoting chronic wound healing and avoid major amputation.

For as much research that is completed in a lab, and as many new products that are born of necessity, there will never be a substitute for clinical trials with real patients to evidence the results. It's this method that allows physicians and surgeons to see firsthand the kind of treatment that can become a life and limb saver for patients with CLI.



## Endograft Treatments: Current Therapies and Future Improvements

Patient and device selection remain key issues for enhanced patient outcomes.

By Brenda Silva



ISET 2017 continued on Tuesday with a panel discussion on patient selection and endograft options.

Opening the session on endograft therapy, Dr. Frank Arko, M.D. began with the current state-of-the-art in fenestrated endografts, and where it's headed. "When considering endograft therapy, chimneys are more relevant for urgent cases, and feVAR is better for elective procedures, but results are good for both."

Speaking on patient and device selection with snorkels was Dr. John Angle, M.D. He referenced the PROTGORAS Registry, and said choice of BES versus SES remains the operator's decision.

Next, Dr. Robert Bersin, M.D. addressed options for venting and snorkeling. "Venting visceral vessels can be performed in short necks reliably with the Ovation endograft."

Dr. Jason Lee, M.D., referenced the PERICLES registry, and detailed initial

data on patients, along with follow-up data, which showed excellent results when compared to the use of fenestrated endografts.

Next, Dr. Michel Makaroun, M.D. spoke about managing complex AAA (type 3 or 4), and noted, "Treatment choice depends on physiologic risk and life expectancy, but fenestrated and chimneys offer some advantages."

Ending the session, Dr. Frank Criado, M.D., asserted no repair and open surgical repair should be considered in complex AAA anatomies. "Patient evaluation is no longer about age, it's all about anatomy."

Following Dr. Criado, the Charles J. Tegtmeier, M.D. Annual Lecture was presented by Dr. Gary Ansel, M.D., with live cases presented after from the Miami Cardiac and Vascular Institute (MCVI).

The second session focused on dissection management. Dr. Michael Dake, M.D. offered data on indications for endovascular therapy in type B dissections, and said, "Increasingly, data is focusing on physiological features, which allow for better treatments and outcomes."

Dr. John Angle, M.D. detailed techniques of endovascular therapy with chronic type B dissections. The data

showed considerations for using TEVAR, and suggested an octopus approach may be seen in the future.

Next, Dr. Goetz Richter, M.D. reported on secondary interventions following endografts for dissection. "Challenges exist, and discussions with patients are essential about why we need to use complex procedures."

Dr. Dake returned to address technology for dissection treatment, with an emphasis on branched endografts. "We're poised to enter the next frontier with purpose-filled endograft solutions."

Addressing management of the false lumen in chronic dissection, Dr. Fabrizio

Fanelli, M.D. pointed out TEVAR has been increasingly used in chronic type B dissection despite controversial results that have been reported.

Exploring spinal drainage and revascularization in preventing complications was Dr. Jon Matsumura, M.D., who said, "We've been able to reduce complications and paraplegia, but we need more RCT and risk prevention."

Finishing the session, Dr. Thomas Forbes, M.D. spoke about iatrogenic type A dissections with thoracic endovascular repair. He reported 1-3% of TEVARs are responsible RTADs, and remain an important complication of TEVAR.

### The Charles J. Tegtmeier, M.D. Annual Lecture

Lecture questions the role of physicians and the future of healthcare in the U.S.

By Brenda Silva



The Charles J. Tegtmeier, M.D. Annual Lecture was presented by Dr. Gary Ansel, M.D., who explored the topic "System Health Care Management: Is the Sun Rising or Setting on Healthcare Delivery in the United States?"

Dr. Ansel began by asserting that there is a change occurring from independent hospitals to systemic healthcare, and reported the current cost of medical expenses in U.S. is 20% over the GDP, accounting for the biggest outlay in the federal budget. "Healthcare in the U.S. is undergoing an unprecedented change, as hospitals are consolidating to combat growing strategic and economic factors."

He continued, "There's also a trend for physicians to be employed, and increasingly, physicians are playing a role as a medical assistant. Some things we fundamentally need to address include duplication of services, and we need to move toward outcome reinforcement."

Ending the lecture, Dr. Ansel said, "No one can afford the current system, and we have to lead the effort ethically so it stays focused. This crisis may push us to optimal affordable care."