

LINC TODAY 2023

LEIPZIG INTERVENTIONAL COURSE

The official newspaper of LINC

Issue 1 Tuesday

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LINC 2023 opens its doors



Welcome to Leipzig for the 2023 edition of the Leipzig Interventional Course (LINC). It's our great pleasure to see you all come together for a four-day programme committed to advancing the scientific and clinical evaluation and treatment of patients with complex vascular disease through an interdisciplinary discussion of novel endovascular techniques.

All in attendance can expect explorations of cutting-edge interventional practice, formed over a multidisciplinary programme

of lectures, debates, trial updates, device innovations and expert-driven narrative. Also look out for the dedicated 'First-time data release' sessions, running throughout the programme, which offer the first glimpses of data from the latest important studies and technologies.

Of course, as always we are looking forward to our live transmissions from national and international centres, all offering surgical spotlights on the latest-and-greatest techniques, devices, tips and tricks, as well as demonstrations of how to tackle challenging

situations head on.

We also thank our collaborators and dedicated '@LINC' session participants for their time and expertise in creating a programme of talks that capture unique perspectives and regional challenges from leading meetings around the globe.

On behalf of the LINC faculty, organisers and sponsors, we express our sincere thanks to all of this year's delegates and industry partners for their continued support. Wishing you a great LINC 2023, and an enjoyable stay here in Leipzig.

Latest long-term safety and efficacy outcomes at LINC 2023

- **Luminor DCB + iVolution pro self-expanding stent in complex and long femoropopliteal lesions**
TINTIN trial 4 years by Dr. Koen Deloose
- **Luminor DCB in BTK arteries**
MERLION trial 2 years by Dr. Tjun Täng

luminor
Paclitaxel eluting PTA balloon dilatation catheter

iVolution pro
Peripheral self-expanding stent system

iVascular
therapies for living

CONNECT THE WORLD SESSION: JAPAN – in collaboration with JET: Innovations and latest data in femoropopliteal interventions.
Main Arena 1 Tuesday 09:15

A little ELEGANCE in the study of under-represented patients

First-time data from an important study of the real-world treatment of lesions in the peripheral vasculature will be previewed this afternoon by Marianne Brodmann, Head of the Division of Angiology at the Medical University of Graz, Austria. As part of the international steering committee for the ELEGANCE registry, Professor Brodmann been asked to share some of the exciting results from an interim analysis of their registry data.

ELEGANCE (Drug-Eluting Registry: Real-World Treatment of Lesions in the Peripheral Vasculature) aims to collect real-world data on peripheral artery disease (PAD) patients treated with drug-eluting devices. It is an international, non-randomised, prospective, open-label, multi-centre post-market registry evaluating the Ranger paclitaxel-coated percutaneous transluminal angioplasty balloon catheter, and ELUVIA drug-eluting vascular stent system (Boston Scientific, USA). Ultimately, the researchers hope to enrol 5,000 cases.¹

Importantly, Professor Brodmann's group is specifically focusing on enrolling patients from groups typically underrepresented in PAD research. "Our goal is to enrol at least 40% women and 40% underrepresented minority patients," she told *LINC Today*. "We took a very careful approach in designing the ELEGANCE registry to ensure that patients who are typically underrepresented in PAD research were well represented."

Professor Brodmann will be sharing initial results in under-represented groups treated with the Ranger drug-coated balloon (DCB). So far, enrolment has been educational. "We are thrilled to report that our enrolment targets for underrepresented populations are exceeding our goals," she said, reporting that amongst the 566 patients enrolled thus far who were treated with the Ranger DCB, 45.3% are women and 44.7% are under-represented minority patients, i.e. those identifying as other than non-Hispanic white. "We are seeing significant differences in baseline medical, disease, and lesion characteristics between these groups," she added.

The group is currently collecting post-treatment outcome data on these patients, so it's unclear how patient outcomes differ amongst those treated with the Ranger DCB. "That said, we can say that there

are significant differences in clinical presentation of women and minority patients," she said. "These groups are presenting to us with a higher burden of atherosclerotic risk factors like smoking history, diabetes, and hyperlipidaemia."

The researchers are also seeing differences in lesion presentation itself. For example, black patients have a longer mean lesion length at the time of treatment than their non-Hispanic white counterparts. Conversely, Asian patients are presenting with significantly shorter mean lesion length, but with a higher prevalence of moderate and severe calcification.

Crucially, Professor Brodmann said conducting a study able to uncover such important disparities could only be done intentionally. It was a conscious choice to select sites in diverse communities, to invite the participation of women and minority investigators, and to employ diversity training for study staff. Additionally, despite specifically selecting sites and physicians in areas known for higher rates of underrepresented populations, Professor Brodmann said establishing just who was seen was important too. "It was critical for us to work with the institutions to determine if they actually saw these underrepresented patients in their practice," she said.

"If they did not, we attempted to help establish referral pathways to help bring in those patients (such as providing site materials, referral letters and other methods). These challenges were discovered and addressed through individual discussions with sites to review their diversity and inclusion metrics."

Professor Brodmann stressed that the approaches her group has used – to ensure that they intentionally choose diverse communities – could be replicated. "We would love to see some of these approaches employed in the design and development of future randomised controlled trials," she said.

Women and minority patients are chronically underrepresented in clinical research across myriad disease states, she said. "The issue of representation in clinical research at all levels – from investigators and study staff, to communities and patients – is a pressing one," she said. "It is our sincere hope that ELEGANCE helps to provide answers to help close the gap in PAD disparities, and that it serves as an example for addressing health disparities for other conditions."



"We would love to see some of these approaches employed in the design and development of future randomised controlled trials."

Marianne Brodmann

Interim data from the ELEGANCE registry showing that differences in baseline clinical presentation could be observed between sex and racial/ethnic groups builds on previous research. "These results validate previous smaller studies which indicated that women and minority patients are disproportionately affected by PAD – not just in prevalence, but also in severity of disease," she said. "We hypothesize that these differences suggest variability in time to diagnosis, treatment planning, and access to care."

She concluded: "We are excited that the one-year outcomes data are coming in from patients enrolled at the registry's launch last year, and look forward to sharing interim analyses from those patients within the next year."

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CONNECT THE WORLD SESSION: JAPAN – in collaboration with JET: Innovations and latest data in femoropopliteal interventions. Main Arena 1 Tuesday 09:15

Sirolimus offers an attractive SELUTION in latest Japan data

The first results from the MDK-1901 trial in Japan will be announced today by Osamu Iida, an interventional cardiologist at Osaka Police Hospital, Japan, and principal investigator for the trial. Dr Iida, who will also be previewing data from other interesting trials at LINC, including: the ConteMporary

strategy For aORToiliac intervention (COMFORT) registry; Wound-directed Angiosome Revascularization approach to patients with critical limb ischemia (WARRIORS) study; and the Comparison of contemporary outcomes following drug-Coated balloon [DCB] versus drug-eluting stent in femoropopliteal artery disease

(CAPRICORN) study, will report on 12-month safety and efficacy outcomes of a novel sirolimus-eluting balloon for the treatment of femoropopliteal lesions in Japanese patients.¹

In his presentation – which takes place during a special Connect the World Session with the Japanese

Continued on page 4

Welcome to LINC 2023! Join our first-to-podium presentation:

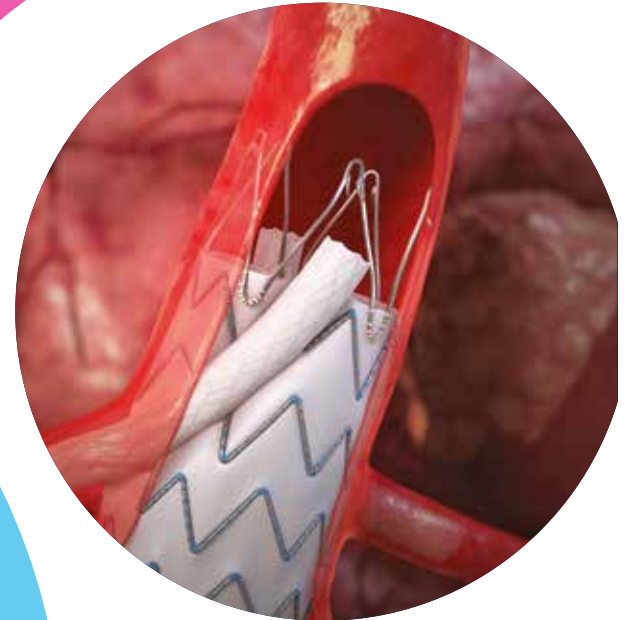
ENCHANT Trial Interim Analysis: Endurant ChEVAR Technique for the Treatment of Juxtarenal Aortic Aneurysms with a Short Infrarenal Neck

Thursday, June 8
11:15 - 11:20 CEST (GMT+2)
Room 2, MA2

Prof. Giovanni Torsello
University of Münster
Münster, Germany

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Continued from page 2

Endovascular Treatment Conference – Dr Iida will focus on a prospective, randomised controlled trial evaluating the SELUTION SLR (MedAlliance, Switzerland) for the treatment of superficial femoral and popliteal artery lesions in Japanese peripheral artery disease patients. “As well as being the first report of a sirolimus DCB clinical trial in Japan, this is also the first clinical trial report sponsored by a corporation since the first-in-human trial of the SELUTION SLR DCB published by Professor Thomas Zeller et al.²” he told *LINC Today*. “Therefore, I believe that this report has significant clinical implications.”

In 2018, the meta-analysis by Katsanos et al.³ suggested an increased mortality in patients with femoropopliteal disease following treatment with paclitaxel devices in the medium term. Even despite the paclitaxel controversy, the clinical efficacy of a sirolimus DCB in Japanese patients is of great interest, noted Dr Iida. “This study successfully demonstrated favourable treatment outcomes using a sirolimus DCB in Japanese patients, which is a significant clinical achievement,” he said.

Dr Iida commented on the “extremely exciting” results “exceeding expectations” he’ll be discussing today, highlighting that despite having the most severe lesion backgrounds in DCB clinical trials in Japan (with an average lesion length of 127 mm, 48% popliteal artery involvement, and 43.9% PACSS 3/4), the primary patency rate was 87.9% and there was no perioperative death, major amputation, nor surgical reintervention. Given these results, sirolimus technology has been proven to be effective and safe for Japanese femoropopliteal lesions, similar to paclitaxel, noted Dr Iida.

“If evidence for sirolimus grows in the treatment of severe phenotypes... it will likely replace paclitaxel-based devices because the paclitaxel controversy is not completely eliminated.”

Osamu Iida

“Moving forward, however, whether the SELUTION SLR DCB will replace paclitaxel is a major clinical question,” he added.

Dr Iida also referred to the first-in-human SELUTION SLR trial, a multicentre, prospective study enrolling 50 patients with femoropopliteal lesions (lesion length, 64.3 ± 42.8 mm; calcification, 88%).⁴ The primary endpoint was 6-month late lumen loss assessed

by angiography. This study showed that median angiographic late lumen loss was 0.19 mm (range –1.16 to 3.07), while mean angiographic late lumen loss was 0.29 ± 0.84 mm (95% CI: –0.01 to 0.58). “This demonstrated that through six months, the SELUTION SLR DCB appears to inhibit restenosis effectively and safely, improving outcomes in subjects with symptomatic femoropopliteal disease,” he said.

As Dr Iida pointed out, the latest guidelines recommend the application of paclitaxel-based devices for the treatment of complex femoropopliteal lesions because they have the capability of reducing restenosis. “But sirolimus-coated balloons would be an attractive alternative to paclitaxel-coated balloons,” he said.

To that end, Dr Iida reasoned that randomised controlled trials comparing the SELUTION SLR with a paclitaxel DCB are necessary. “If evidence for sirolimus grows in the treatment of severe phenotypes, such as in-stent restenosis, chronic total occlusions,

“This study successfully demonstrated favourable treatment outcomes using a sirolimus DCB in Japanese patients, which is a significant clinical achievement.”

Osamu Iida

calcification and long lesions, and with acceptable safety, it will likely replace paclitaxel-based devices because the paclitaxel controversy is not completely eliminated,” he said in closing.

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Live case transmissions @ LINC 2023

Don't miss this year's programme of live cases, performed from national and international centres!

Case centres:

- Universitätsklinikum Leipzig, Abt. Angiologie, Leipzig, Germany
- Policlinico Abano Terme, Abano Terme, Italy
- Osaka Police Hospital, Osaka, Japan
- Klinikum Hochsauerland Arnsberg, Arnsberg, Germany
- Beijing Anzhen Hospital, Beijing, China
- Adventist Heart & Vascular Institute, Colorado, United States
- University Hospital Galway, Galway, Ireland
- Universitäres Herz- und Gefäßzentrum UKE Hamburg, Hamburg, Germany
- Universitätsklinikum Jena, Jena, Germany
- St. Franziskus Hospital Münster, Munster, Germany
- Mount Sinai Hospital New York, New York, United States
- Hôpital Marie Lannelongue Paris, Paris, France
- Urayasu Ichikawa, Tokyo Bay Medical Center, Urayasu, Japan

Scan this QR code to find the details of the planned live cases.



LINC

SNAPSHOTS
@ LINC 2023

Take a glimpse of upcoming lectures –
and get a flavour of what you may have
missed – with SNAPSHOTS @ LINC 2023.

Scrub in with the expert: Innovative solutions for complex CTO's Technical Forum Tuesday 16:45

A unique intraluminal crossing and subintimal reentry catheter for use in treating complex disease throughout the vascular system

SNAPSHOTS
@ LINC 2023

Robert E Beasley, MD, FSIR, FSCAI
Palm Vascular Centers, Coral Gables,
FL, USA

It is estimated that peripheral arterial disease (PAD) affects more than 200 million people worldwide.¹ An extreme form of PAD known as critical limb-threatening ischemia is when a partial or complete blockage occurs and impedes the flow of blood to the lower extremities of the body. Being able to cross these blockages from an endovascular standpoint is generally the first line in preventing worsening symptoms, amputations, and bypass surgeries.

There are a multitude of devices that assist in crossing these difficult blockages as well as a variety of techniques (antegrade, retrograde,

“The success of the BeBack catheter is in its ability to provide shorter procedure times, less contrast use, and reduction in radiation.”

Robert E Beasley

CART, etc.) that can be utilized to assist in revascularisation. A newer device on the market is the BeBack catheter (Bentley InnoMed, Germany), a low-profile catheter that comes in 2.9 Fr (.014" guidewire compatible) and 4 Fr (.018" guidewire compatible) outer diameters. The unique aspect of the BeBack catheter is that it is indicated for both crossing and re-entry by exhibiting a curved nitinol needle that extends from the tip of the catheter. This low-profile design allows for easy access from antegrade, retrograde, or up-and-over procedures.

My experience with the BeBack catheter

My algorithm starts with utilizing a guidewire and micro catheter to access and cross any chronic total occlusion. If this attempt initially fails, I then escalate to using specialty catheters like the BeBack catheter to save time, contrast use, and radiation. The 4 Fr BeBack catheter has been a staple in crossing in-stent reocclusions of the superficial femoral and iliac arteries, and also re-entry when my guidewire goes subintimal. The 2.9 Fr BeBack catheter has helped in revascularizing tibial disease, as well as using for crossing and re-entry from a retrograde access, even in the same patient.

The addition of the BeBack catheter in my lab has not only expedited procedure time, but has allowed me to cross some of the most difficult blockages that may have ended up going for surgery otherwise.

Conclusion

Endovascular treatment of complex total occlusions in the peripheral extremities is one of the most difficult procedures interventionalists perform. With new tools that can provide directionality in a low-profile design, we can revascularize these patients and prevent unnecessary amputations. The success of the



4 Fr BeBack re-entry in the superficial femoral artery

BeBack catheter is in its ability to provide shorter procedure times, less contrast use, and reduction in radiation.

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Radiation: how low can you go?

Achieving the optimum ultra-low dose radiation in endovascular cases will be discussed on Wednesday afternoon by Maani Hakimi, a vascular surgeon specialised in aortic surgeries. Professor Hakimi has established ultra-low dose procedures for standard infrarenal endovascular aneurysm repair (EVAR) at his clinic in Luzerner Kantonsspital (Lucerne, Switzerland), where he is head of the Vascular Center, and co-chief of the Department of Vascular Surgery. "Due to the frequent work on complex endovascular cases in the hybrid operating room, dealing with radiation dose is becoming increasingly important," Professor Hakimi said in conversation with *LINC Today*. "I have been involved in benchmarking and radiation reduction since 2011."

Professor Hakimi will be talking specifically about the application of ultra-low dose protocols in fenestrated aortic arch reconstruction. "The establishment

"The establishment of ultra-low dose procedures should start in a standardised environment."

Maani Hakimi

of ultra-low dose procedures should start in a standardised environment, for example standard infrarenal EVAR," he said. "I will discuss how to set up this environment, as well as how this working method can later be transferred to complex procedures, such as the aortic arch and abdominal cases, to reduce dose levels significantly." Professor Hakimi will then present his own results from ultra-low dose procedures for standard and complex procedures, as well as discuss the so-called dose corridor.

Professor Hakimi pointed to the REVAR¹ observational study, which evaluated radiation exposure in standard EVAR using intra-operative

guidance with pre-operative computed tomographic angiography (CTA) fusion imaging and strict As Low As Reasonably Achievable (ALARA) guidelines in a modern hybrid room. With adherence to the ALARA principle, when compared to published literature, the researchers found that lower radiation exposure can be achieved in a real-world setting. "All of us who work with radioactive beams in the operating room or cath lab should be aware of the importance of radiation exposure for ourselves, our teams and our patients," he said. "The topic is becoming more important with the increasing number of endovascular cases, and complexity of interventions."

Professor Hakimi intends to demonstrate the magnitude of radiation exposure and the extent to which both technology and people play an important role in reducing it, as there are several discrepancies and gaps in knowledge on this topic, he commented. For example, there are significant differences in so-called diagnostic reference levels (DRLs). "These DRLs are very imprecise, vary regionally or nationally, and also differ significantly from the results that we achieved in our study. To give just one example, in the USA the reported dose is often the skin dose, and in Europe it is the dose area product, which is a significant difference."

As another example, one national survey involving hospitals representing 77% of the Spanish population (46.7 million inhabitants) assessed patient dose values from mobile X-ray systems from nine hospitals (sample of 165 EVAR procedures), and data from hybrid rooms in seven hospitals, with dosimetric data from 123 procedures in order

to establish DRLs.² In this context, it is fundamental to discuss what a so-called ultra-low dose procedure looks like, said Professor Hakimi. "From which dose values can one speak of ultra-low dose?" he said. "It is also not at all clear whether partly incongruent guidelines or specifications are even known, or are taken into account in everyday clinical practice."

Furthermore, the question of radiation avoidance and radiation reduction is controversial too. There are approaches to avoiding radiation in the first place, for example, using fibre-optic instruments. "It is very exciting to discuss whether radiation can be completely dispensed with in the foreseeable future," he added. "One can hear such voices at conferences as to whether this is realistic. It's certainly debatable."

Professor Hakimi will discuss preparatory work for ultra-low dose cases, as well as lessons learned and experience gathered in setting up his own hospital's hybrid operating room, which was created by Siemens Healthineers

"It is very exciting to discuss whether radiation can be completely dispensed with in the foreseeable future."

Maani Hakimi

(Germany). "Above all, we were amazed at how big the savings in rays can be and which factors – not least manual habits – can all be positively influenced," he said.

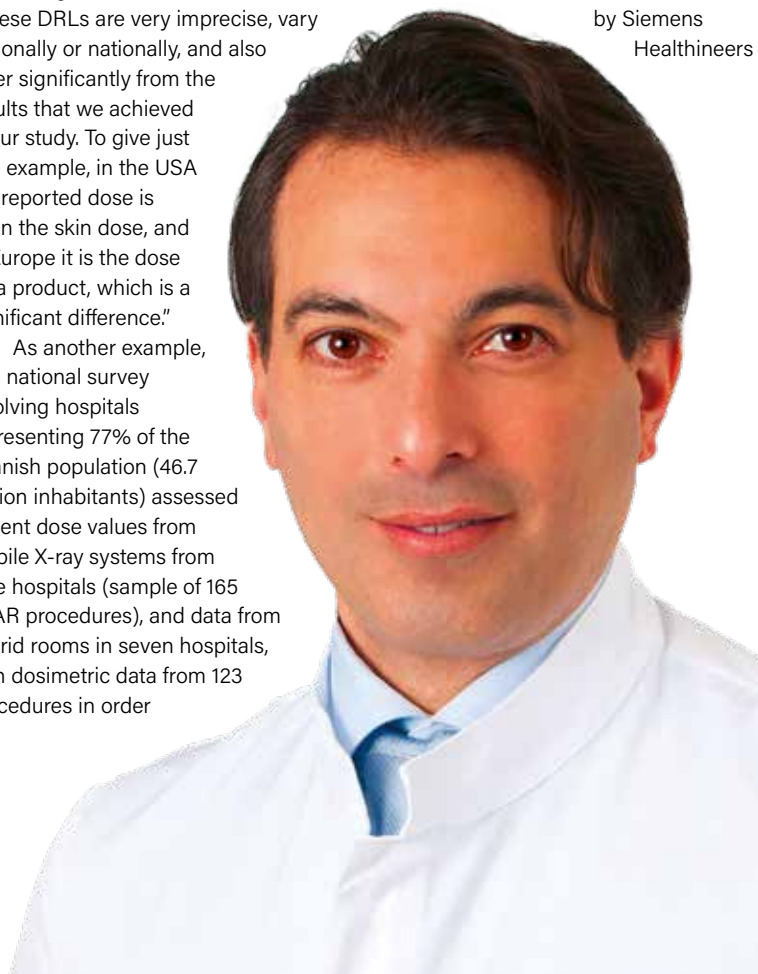
According to Professor Hakimi, the implementation of standardized interventions is much less complicated if physicians have developed a technical understanding of the imaging system in their own operating room, and their own behaviour. "The transfer to complex cases is quite possible," he said. "But in order to implement all necessary measures and rules regularly, and to achieve ultra-low dose procedures as standard, a lot of experience and detailed work is still required."

In the future, Professor Hakimi would like to understand to what extent other vascular specialists deal with radiation dose benchmarks. "Do you know what dose you are using?" he questioned. "What dose do colleagues in the same hospital need for the same procedure? Are you comparing?"

Ultimately, such knowledge should become a curricular component of specialist training, said Professor Hakimi, closing by underlining that previously official specified reference levels cannot be used. "They do not correspond to technical reality. That's why we should deepen our knowledge in this area. It should be known what is technically possible, and how to achieve it"

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LINC Today Issue 2
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Advanta V12
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Right from the start Still going strong

Advanta V12 is a balloon expandable, fully encapsulated PTFE stent with first to market covered balloon expandable stent technology that has served more than 700,000 patients. Known for its precision and predictability – the versatile Advanta V12 has been meeting the needs of surgeons and patients for 20 years and is the only durable solution backed up by decades of real-world evidence and more than 550 publications.

FlowTrierer embolectomy for acute pulmonary embolism

During today's session dedicated to acute venous thromboembolism, panellist and speaker Gary Ansel (Columbus, United States) will discuss the FlowTrierer System (Inari Medical) – the first mechanical thrombectomy device indicated for the treatment of pulmonary embolism (PE).

Speaking to *LINC Today*, Dr Ansel introduced the device, its benefits, and gave a glimpse of some of the key considerations he will be sharing with the LINC audience.

Am I right in saying the FlowTrierer system is the first mechanical thrombectomy system for PE? What are some of the unique characteristics important to highlight?

The FlowTrierer system is certainly the first system that went beyond the application of thrombolysis, or pure aspiration, for the treatment of PE. Full-dose thrombolysis and even limited-dose thrombolysis via catheter were associated with a risk of bleeding, and I feel that this led to guidelines limiting aggressiveness in the treatment of PE.

Rheolytic thrombectomy was one of the first aspiration-based procedures but it was associated with arrhythmia and significant haemolysis. The risks seemed to outweigh the benefits and its use received a Food and Drug Administration black-box warning in the US. What's more, smaller-French aspiration devices were not very efficient, and had significant blood loss.

There's always a fine line to navigate between enough clot removal and blood loss. The Angiovac from Vortex was the first large-lumen aspiration catheter, but it was not able to be manipulated beyond the main pulmonary artery. It did auto-transfuse the patient, which allowed for minimum blood loss, but required a centrifugal pump system.

The FlowTrierer system from Inari was a big technological step forward, offering improved flexibility, and allowing for the advancement of the large-bore main system. Furthermore, it incorporated collapsible baskets to facilitate the removal of the pulmonary emboli with a more organised thrombus, and allowed for the operator to create improved aspiration due to a unique larger-bore syringe and attachment.

Large blood loss with the FlowTrierer system was an initial shortcoming, but that has now been addressed with the addition of the FlowSaver component. The initial Inari system allowed for the swift, effective treatment of large pulmonary emboli and typically, an 'on-table' result that could be utilised by a broader base of practitioners. It changed our institutions' approach to the treatment of PE from a lytic-based to a mechanical-removal-based approach.

Can you briefly run through the specifics of the clot-removal process?

Using a brief description: venous access is obtained, typically with ultrasound guidance, either at the common femoral or jugular venous site. Most commonly, a balloon-tipped catheter is used to keep the initial wire out of the tricuspid valve chordae, although .035 wire placement into the pulmonary vasculature may be accomplished with various catheters.

A large-bore sheath is then positioned. The main FlowTrierer aspiration catheter is placed over the wire and then the FlowTrierer main device (of which there are multiple generations) is chosen and advanced to the main pulmonary artery. Optimal placement for the large-bore catheter is just proximal to the beginning of the clot. Aspiration is then started with the large-bore



"In my opinion, the Inari FlowTrierer system has helped usher in a new paradigm of effective treatment for clinically significant PE."

Gary Ansel

syringe. The blood and clot combination is aspirated and then filtered to allow for the replacement of the removed blood component.

On occasion, the clot will occlude the catheter, and flow ceases. If this occurs, the catheter is slowly withdrawn (while leaving the wire in place) and externalised. This is often quite successful in removing a very large clot. Pulmonary angiography is easily completed with dilute contrast to assess the result, and the procedure is then repeated in the same fashion in other areas if needed. Finally, the access site may be addressed with a figure-of-eight soft-tissue suture technique.

Then, if the clot persists, do you use the FlowTrierer catheter mesh discs (of various sizes) to engage the clot and pull it back through? Tell us more about this technology.

If after several attempts at aspiration there is a stubborn area of PE, then the mesh discs are used to attempt the removal of the wall-adherent clot. These cases are typically a mixture of acute on chronic PE, and the chronic component may be associated with wall adherence.

The basket technology can be of some assistance, especially in the left lower lobe where the angle can be suboptimal for the large-bore catheter to pass over the clot, and the baskets can often assist in moving the embolus to a more favourable position. However, it's surprising how often the mesh discs are not needed for a successful procedure, especially when using larger French devices.

What are some of the core benefits associated with this system?

In my opinion, the Inari FlowTrierer system has helped usher in a new paradigm of effective treatment for clinically significant PE. In my previous institutions' experience, the device is typically a single-session treatment, and this has now been born out in trials.

Very often, sick patients would become haemodynamically, clinically, and symptomatically stable, before one's very eyes. This was the finding in the recently presented FLAME trial, where patients with high-risk, massive PE were treated with FlowTrierer and had remarkably low mortality. To have a patient express their gratitude during the actual procedure and say that they can breathe normally again is wonderful.

The lack of apparent need for thrombolytic therapy in the majority of these patients is a huge step forward for several reasons. The traditional use of thrombolytics via catheter-directed thrombolysis for this process was difficult for the patient, as they often had to lay flat in an ICU bed with persistent symptoms. It's also tough for the allied health team in the ICU, and the physician. Both groups disliked the traditional treatments due to the delay in improvement and bleeding risks.

Many patients with PE who have contraindications to thrombolysis, such as recent surgery or an underlying cancer diagnosis could not even be offered thrombolysis due to bleeding risk. And in the US, there's a significant legal risk with thrombolysis use as well.

The other potential core benefit of effective mechanical thrombectomy appears to be cost. Though the treatment is expensive, it typically does not require an ICU bed and often reduces the number of in-patient hospital days, so can be more cost-effective than thrombolysis.

Will you be talking about the FlowSaver component as well, i.e., blood loss?

Yes, the FlowSaver component is an important advancement in the treatment of PE with FlowTrierer, as it allows for the replacement of the removed blood and a low rate of haemolysis. Replacement of the blood loss now allows physicians to define the end of the procedure more clearly, based on clot removal, instead of trying to balance clot removal and blood loss.

Any challenges, limitations, or device iterations that you will be focussing on?

My experience managing various specialities and levels of hospitals in the Ohio Health System has given me a unique perspective on the challenges of large-bore catheter use for PE treatment.

I'd like to point out that Inari has quickly improved many of the early limitations of the FlowTrierer device. It has also added to the literature on the treatment of PE and funded clinical trials. Randomised trials with the FlowTrierer device are important to help us compare it to the currently enrolling HI-PEITHO Trial. As complications associated with PE treatment are hopefully lowered, we may see a broadening of indications for treatment beyond the simple mortality statistics that the traditional guidelines focus on.

One of the ongoing limitations of the FlowTrierer procedure, or any device treatment, is being able to safely navigate through the right heart. Though cardiologists frequently navigate the pulmonary vasculature and are comfortable with arrhythmia treatment (due to this experience, clinically significant

arrhythmia is seen infrequently), this has to be more formally addressed because of the other specialties now performing PE treatment.

There is also a skill set for safe wire placement into the distal pulmonary vasculature. A perforation here can be devastating, especially if perforation treatment is not in the skill set of the institution.

I do think there is a difference in using advanced devices in community hospitals versus tertiary care hospitals. As for acute myocardial infarction (STEMI), even though PE is frequently diagnosed in community hospitals, we need to demonstrate that the low risk evident in trials can be transferred to use in community hospitals – especially since many of these procedures are completed with a company representative resource present. Most advanced interventional treatment success is often facilitated by an expert hospital support staff.

Let's look at the device's development. The first generation of FlowTrievers was somewhat stiff and could be difficult to place, especially in the left lower lobe vasculature and in patients with significant right-heart dilation. Inari addressed these issues with a span of 16-, 20- and 24 French systems, as well as improvements in flexibility and shaped catheter designs. Again, with increasing French-device size there was a transition to more aspiration and less disc retrieval. The early blood loss before FlowSaver was a real problem, and has

“The Inari FlowTrievers system is the first truly mechanical thrombectomy system to offer reliable on-table PE clot removal.”

Gary Ansel

been addressed as well.

One of the other limitations is trying to balance the desire to do other interventional procedures with the expertise required for treating the broader disease process. There are increasing physician shortages in many specialties around the world. Providing the level of expertise needed for the advanced treatment of PE has to be balanced with the desire of various physicians to add another treatment to their skill set.

In our system, there were and are interventional cardiologists who wanted to start performing the

FlowTrievers procedure that do not routinely treat the various levels of PE associated with deep vein thrombosis and clotting disorders. Yes, they may be able to do a FlowTrievers procedure, but is this optimal for that patient?

We also had vascular surgeons and radiologists at some of the smaller institutions that were not comfortable with manipulating large-bore catheters through the right heart. So, while the FlowTrievers system is a big step forward in the treatment of PE, there are many environments where smaller diameter aspiration or thrombolytic devices may be more suitable.

For the LINC audience, what's your take-home message on FlowTrievers and the arena of embolectomy for acute PE?

The Inari FlowTrievers system is the first truly mechanical thrombectomy system to offer reliable on-table PE clot removal. The system continues to be improved, both in terms of useability and clinical efficacy, and should be considered by all healthcare systems offering advanced PE treatments regularly. Institutional experience, support systems, and outcomes will be important in evaluating whether the FlowTrievers system is optimal for their environment. Ongoing research, especially randomised trials, will be important, as more devices become available to successfully treat PE.

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Intravascular lithotripsy lives up to its promise

Since intravascular lithotripsy (IVL) was first described in peripheral arterial disease, a growing evidence-base has underlined its efficacy and safety as a vessel preparation technique. The data will be reviewed tomorrow morning by Erwin Blessing, Clinic Director at the University Heart and Vascular Center of the University Hospital in Hamburg-Eppendorf, Germany. Professor Blessing spoke to *LINC Today* to discuss the relevant research and give his take on how IVL fits into the toolbox for vessel preparation.

Professor Blessing began by highlighting the importance of vessel preparation in general, especially regarding long-term patency in challenging lesions. "Preparation itself has gained tremendous recognition over the last few years, as we had an unmet need with the high bailout stent rate in challenging lesions," he said. "We now know that in such lesions we have to invest a little more into the initial index procedure to provide sustained long-term patency, and that's where preparation is key."

Considering when to choose IVL as a preparation strategy – as opposed to other options such as standard balloon angioplasty with prolonged inflation, specialty balloons, or atherectomy – Professor Blessing drew attention to the mode of action of lithotripsy. Since the technology utilises acoustic pressure energy to make microfissures in intimal and medial calcium, IVL is naturally only appropriate for calcified lesions.

"Obviously non-calcified lesions are not going to respond to that technology, so patient selection is very important – there's no role for IVL in fibrotic, soft or thrombotic lesions," he stated.

In calcified lesions where IVL is appropriate, Professor Blessing believes that this technology has certain advantages over atherectomy. "Atherectomy devices have quite a learning curve, somewhat of a complication rate, and they add complexity and cost to the procedure," he commented. "That's where IVL really comes in handy. IVL is a very easy to use, safe and effective way to prepare calcified lesions throughout different territories."

The challenges of vascular calcification are well-recognised: calcium deposition in the intima and media can interfere with drug delivery, as well as limiting compliance, raising the risk of flow-limiting dissections and perforation. This results in a greater need for stenting, but to compound this picture, calcification is also a risk factor for in-stent restenosis. IVL emerged as a novel technology to help address these issues, and Professor Blessing noted that early hopes have not been disappointed.

"In the field of peripheral arterial disease there are so many new kids on the block; we've seen many technologies come and then go within a couple of years because they didn't live up to expectations," he observed. "The jury was out with IVL to begin with – we needed solid clinical data to show it lived up to our expectations. We've now seen that with two very important studies."

These two studies were the DISRUPT PAD III randomised controlled trial (RCT) and the DISRUPT PAD III observational study. Professor Blessing drew attention to the former first, emphasising the value of RCT evidence.

The DISRUPT PAD III RCT enrolled 306 participants with moderate or severe femoropopliteal artery calcification; patients were randomised 1:1 to receive vessel preparation with either IVL (Shockwave Medical Peripheral Lithoplasty System) or percutaneous transluminal angioplasty (PTA) prior to drug-coated balloon treatment or stenting. The primary endpoint

was core lab-adjudicated procedural success, defined as residual stenosis of $\leq 30\%$ without flow-limiting dissection.

Initial analysis of acute outcomes revealed significantly higher procedural success in the IVL group (65.8% IVL vs. 50.4% PTA; $p=0.01$). Looking into this in more detail, the occurrence of flow-limiting dissections was higher in the PTA group (1.4% IVL vs. 6.8% PTA; $p=0.03$), while the percentage of lesions with residual stenosis $\leq 30\%$ was higher in the IVL group (66.4% IVL vs. 51.9% PTA; $p=0.02$). The frequency of stent placement was also notably lower in the IVL group (4.6% IVL vs. 18.3% PTA; $p<0.001$).¹ Follow-up analysis revealed a sustained benefit of IVL: primary patency in the IVL group was higher at one year (80.5% IVL

"Intravascular lithotripsy is a very easy to use, safe and effective way to prepare calcified lesions throughout different territories."

Erwin Blessing

vs. 68.0% PTA; $p=0.017$) and two years (70.3% IVL vs. 51.3% PTA; $p=0.003$).²

"This superior performance at one and two years was primarily due to the lower need for bailout stenting, which was included within the primary patency endpoint," commented Professor Blessing. "To sum up, there was a clear technical benefit provided by IVL – we saw superior results with fewer stents implanted."

This RCT data is very valuable, as it demonstrates the benefit of IVL compared to standard PTA treatment. However, Professor Blessing noted that the subpopulation included in the trial will not reflect the full picture seen in the clinic. "As important as RCTs are, there's an element of cherry-picking," he acknowledged. "There are so many exclusion criteria that the results will not fully represent the real-world scenario where we see long lesions and we treat critical limb ischaemia (CLI) patients and dialysis patients. Also, what works well in the femoropopliteal area doesn't necessarily work so well in the iliacs or below the knee. So, we needed more real-world data to answer these questions."

Real-world evidence was provided by the DISRUPT PAD III observational study, a prospective, multicentre, single-arm study assessing the acute safety and efficacy of the Shockwave Medical Peripheral IVL System for vessel preparation in

calcified, stenotic lower limb arteries. Analysis of data from a total of 1,367 patients revealed very similar outcomes to those observed in the DISRUPT PAD III RCT. Specifically, in terms of diameter stenosis, the observational study found a decrease from 81% pre-procedure to 33% post-IVL and 24% after final treatment. In the RCT, these values were 85%, 27% and 22%, respectively.^{3,4}

"Overall, the observational study findings were very comparable to the RCT results," summarised Professor Blessing. "Note that the comparison is limited to acute technical success, as we don't have follow-up data to one or two years for the observational study. But the acute technical success is very comparable."

It is encouraging also that this picture was maintained in subgroup analysis, Professor Blessing remarked. "Looking at the data, we still see very comparable results across different territories – the iliacs, common femoral artery, superficial femoral artery, the popliteal and below the knee. And the same is true across different types of challenging lesions: whether they're long, eccentric, occlusive or severely calcified. And across different groups of patients, including CLI patients, dialysis patients and renal patients. Altogether there's very solid data that we can relate to the real-world situation."

Professor Blessing next moved on to consider ongoing research that will shed more light on the safety and efficacy of IVL. He drew attention to the DISRUPT PAD BTK II study, a prospective, multicentre, single-arm study of the Shockwave Medical Peripheral IVL System for the treatment of calcified, stenotic lesions below the knee.⁵ This study will provide more real-world evidence on a difficult-to-treat patient population, which will be valuable as research on treating these patients is currently very limited.

"It's positive that this study aims to include at least 80% of patients with CLTI," Professor Blessing said. "It's important to look at the CLTI cohort because there's so much more unmet need – we're talking about limb salvage in these patients. The study will also include

patients on dialysis, who have been excluded from almost every single trial on endovascular treatment.

We have very little

"There was a clear technical benefit provided by intravascular lithotripsy – we saw superior results with fewer stents implanted."

Erwin Blessing



“Altogether there’s very solid data that we can also relate to the real-world situation.”

Erwin Blessing

data on these patients and the amputation rate in this population is tremendously high.”

Overall, Professor Blessing is optimistic about the future of research on IVL. “I would expect that the wealth of data is going to increase and the technology is going to improve,” he predicted. “I would expect a confirmation of the already rather convincing picture we have, with more data on specific subsets of patients who are difficult to treat and have historically been excluded from trials.”

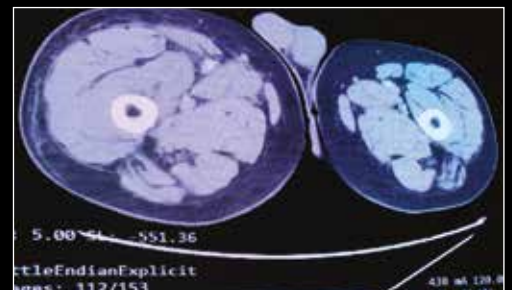
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PAIRS@LINC: Challenging venous interventions Speakers' Corner Tuesday 12:30

Varicose veins: updates in thermal and non-thermal ablation

SNAPSHOTS
@ LINC 2023

Mohammed Almoaiqel, MD, FRCPC, FPAIRS King Abdulaziz Medical City & King Abdullah Specialised Children's Hospital, Riyadh, Saudi Arabia

Background

Chronic venous disease is common – it can affect up to 25% of women and 15% of men. Symptoms are variable, but it can be worsened, including the presence of ulcers, for those ignoring and delaying treatment.

Nowadays there is always debate and controversy among phlebologists and endovascular specialists as to which is the treatment of choice. What is superior, more effective and more convenient for patients? Is it thermal ablation treatment (endovenous laser, radiofrequency, steam or even microwave), or is it non-thermal ablation (glue, mechanochemical, or the old choice: ultrasoundguided foam sclerotherapy)?

“Nowadays there is always debate and controversy among phlebologists and endovascular specialists as to which is the treatment of choice.”

Mohammed Almoaiqel

Insights

Endovenous ablation therapy continues to evolve, especially with 'mega' great saphenous veins, with an occlusion rate in up to 96% of cases during early follow-up. Using high-power laser therapy with a wavelength of 1940 nm, and the concept of flush endovenous ablation closure with no residual blind spot (as opposed to the classical ablation 2 cm from the saphenofemoral junction and saphenopopliteal junction) should be not touched.

Ablation under ultrasound guidance

is important, but nevertheless in selected cases – especially severely tortuous great saphenous veins, or even in morbid patients – utilising fluoroscopy will be an additional tool to successfully complete and shorten the procedure time.

Take-home message

Mastering all techniques is highly recommended in this era, based on different levels of evidence. Thermal ablation is recommended in cases of intrafascial, straight, non-tortuous great



saphenous vein and small saphenous veins with diameters larger than 10 mm. On the other hand, if great/small saphenous veins are extrafascial, superficial, tortuous, have presence of axial reflux, or if the patient is obese or very anxious, non-thermal ablation will be an excellent choice.

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SNAPSHOTS
@ LINC 2023

Prospective, multicentre registry of drug-coated balloon treatment for peripheral artery disease: Results from the Japan POPCORN registry



Yoshimitsu Soga

Kokura Memorial Hospital, Japan

Aim

To evaluate two-year freedom from restenosis after a drug-coated balloon (DCB) for femoropopliteal (FP) lesions in clinical settings.

Methods and results

This multicentre, prospective cohort registered 3,091 de novo or restenotic FP lesions (mean lesion length 13.5 ± 9.3 cm; chronic total occlusions, 25.9%; severe calcification, 14.6%) that underwent successful DCB (Lutonix

“Two-year clinical outcomes after DCB use for femoropopliteal lesions in real-world practice were favourable. The additive risk factors were associated with a lower rate of freedom from restenosis.”

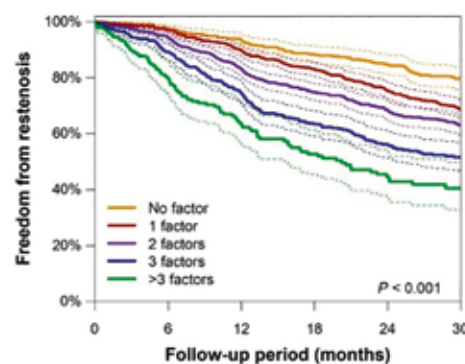
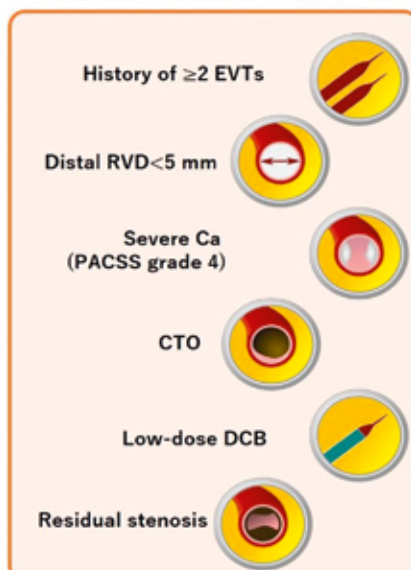
Yoshimitsu Soga

[24.2%] and IN.PACT Admiral [75.8%]) were two-year freedom from restenosis and freedom from target lesion revascularization (TLR). Bailout stenting

was performed in 3.5% of cases. No atherectomy device was used.

The post-procedural slow-flow phenomenon was observed in 3.9% of patients. The Kaplan-Meier estimate of freedom from restenosis was 84.3% and 70.0% at 12 and 24 months, respectively. Freedom from TLR was 91.3% and 81.8% at 12 and 24 months, respectively. One-year restenosis risk factors (a history of revascularisation, smaller distal reference vessel diameter, severe calcification, chronic total occlusion, low-dose DCB, and residual stenosis) were maintained up to two-year primary patency.

Accumulation of primary restenosis risk factors



Follow-up period	0	6	12	18	24	26
Number at risk	462	447	399	340	298	268
No factor	1004	904	764	640	509	439
1 factor	929	794	626	497	386	338
2 factors	520	419	322	238	175	150
3 factors	190	133	94	69	53	42
>3 factors						
Estimate ± SE						
No factor	100.0±0.0%	97.4±0.7%	93.4±1.2%	88.5±1.5%	84.6±1.8%	82.2±1.9%
1 factor	100.0±0.0%	97.0±0.6%	89.8±1.0%	83.1±1.3%	75.4±1.5%	72.7±1.6%
2 factors	100.0±0.0%	94.4±0.8%	83.1±1.3%	75.0±1.6%	68.4±1.7%	65.8±1.8%
3 factors	100.0±0.0%	89.3±1.4%	74.4±2.0%	63.3±2.3%	55.9±2.5%	53.8±2.5%
>3 factors	100.0±0.0%	80.0±3.0%	63.7±3.7%	52.8±4.0%	44.6±4.2%	42.9±4.2%

Conclusions

Two-year clinical outcomes after DCB use for FP lesions in real-world practice were favourable. The additive risk factors were associated with a lower rate of freedom from restenosis.

Take-home messages

One-year risk factors for restenosis were a history of revascularisation, smaller distal reference vessel diameter, severe calcification, chronic total occlusion, low-dose DCB, and residual stenosis/ restenosis. These six risks have been maintained for up to two years in terms of primary patency and TLR.

From the largest Japanese DCB registry, two-year primary patency and freedom from TLR were feasible, despite lower bailout stenting, and no atherectomy device.

An update on trials for DCBs below-the-knee

Trials focused on the use of drug-coated balloons (DCBs) in below-the-knee (BTK) disease will be discussed on Thursday morning by Francesco Liistro, an interventional cardiologist and Chief of Cardiovascular Intervention at the San Donato Hospital in Tuscany, Italy. Specifically, Dr Liistro will discuss the five-year results of the randomised controlled single-centre ACOART-BTK (Evaluation of the Use of ACOTEC Drug-Eluting Balloon Litos in Below-the-Knee [BTK] Arteries to Treat Critical Limb Ischemia) study. Also under the spotlight will be the DEBATE-BTK DUELL study, including its design, details of the population enrolled and some clinical cases.

The ACOART-BTK trial compares the Litos paclitaxel-eluting balloon (Acotec Scientific, China) versus conventional plain balloons in the treatment of BTK vessels in diabetic patients with critical limb

“The ACOART-BTK trial demonstrated a significant advantage of this DCB in reducing late lumen loss and the need for target lesion revascularisation.”

Francesco Liistro

ischaemia. “The trial demonstrated a significant advantage of this DCB in reducing late lumen loss and the need for target lesion revascularisation,” Dr Liistro told *LINC Today*.

The DEBATE BTK DUELL trial was designed in response to the advent of sirolimus-eluting balloons after the paclitaxel controversy a few years ago. The trial was necessary to explore a head-to-head comparison of paclitaxel versus sirolimus, explained Dr Liistro, who noted that another trial, SELUTION4BTK with a different sirolimus-eluting balloon, SELUTION SLR (MedAlliance, Switzerland) is still ongoing.

To date there are three recent studies, ACOART-BTK¹, ACOART II² and IN.PACT BTK³ which have all showed the efficacy of DCBs for BTK vessels, particularly in reducing longitudinal late lumen loss and vessel re-occlusion, said Dr Liistro. “All these three trials faced real-world BTK disease, with high rates (80–100%) of chronic total occlusions (CTOs), and a mean



lesion length of 180–200 mm,” he commented. In these settings, lesion preparation is important, as is evaluation with angiography and Duplex ultrasound before enrolment, reducing the risk of mechanical failure. “Reducing vessel re-occlusion is a major endpoint because it reduces target lesion revascularisation, which is of key clinical impact in these patients,” he said. Importantly all three studies showed no major limb amputation.

What is also clear, continued Dr Liistro, is that the use of DCBs in BTK revascularization has shown contradictory results, including the IN.PACT DEEP,⁴ SINGA-PACLI⁵ and BIOLUX P-II⁶ randomised trials. On Thursday he will outline some of the key considerations and outcomes from these trials important to consider.

BTK disease is a real challenge for interventionalists, continued Dr Liistro, with interventional procedures being complex, and requiring dedicated skills for CTO

“In the next five years we will probably be able to increase the patency after revascularisation of BTK vessels.”

Francesco Liistro

crossing, predilatation and evaluation. “Patients should be scheduled for close follow-up, where flow team and toe team work together,” he said. That’s why he recommends a team composed of interventionalists, diabetic foot specialists, nephrologists and infectivologists. “The clinical and interventional activities must be in continuous contact, and react immediately as needed,” he explained.

In the future, Dr Liistro said the release of an antiproliferative drug is the last step towards effective BTK interventions. “We are testing several devices to prepare the lesion, which is the most important part of revascularisation,” he said. “We are testing lithotripsy before DCB in the DEBATE BTK SHOCK trial to see if breaking the calcium barrier may increase the effect of drugs.” The availability of atherectomy devices, particularly orbital atherectomy, may also offer better plaque debulking and increase the effect of DCBs as suggested by a recent pilot study.⁷ Resorbable stents are also tested for the BTK space, but the usual length of the lesion may be a major limitation for this strategy, he said.

In conclusion, Dr Liistro stressed that DCBs could be *the* tool for BTK intervention: “Their efficacy could be increased by new systems for lesion preparation. In the next five years we will probably be able to increase the patency after revascularization of BTK vessels.”

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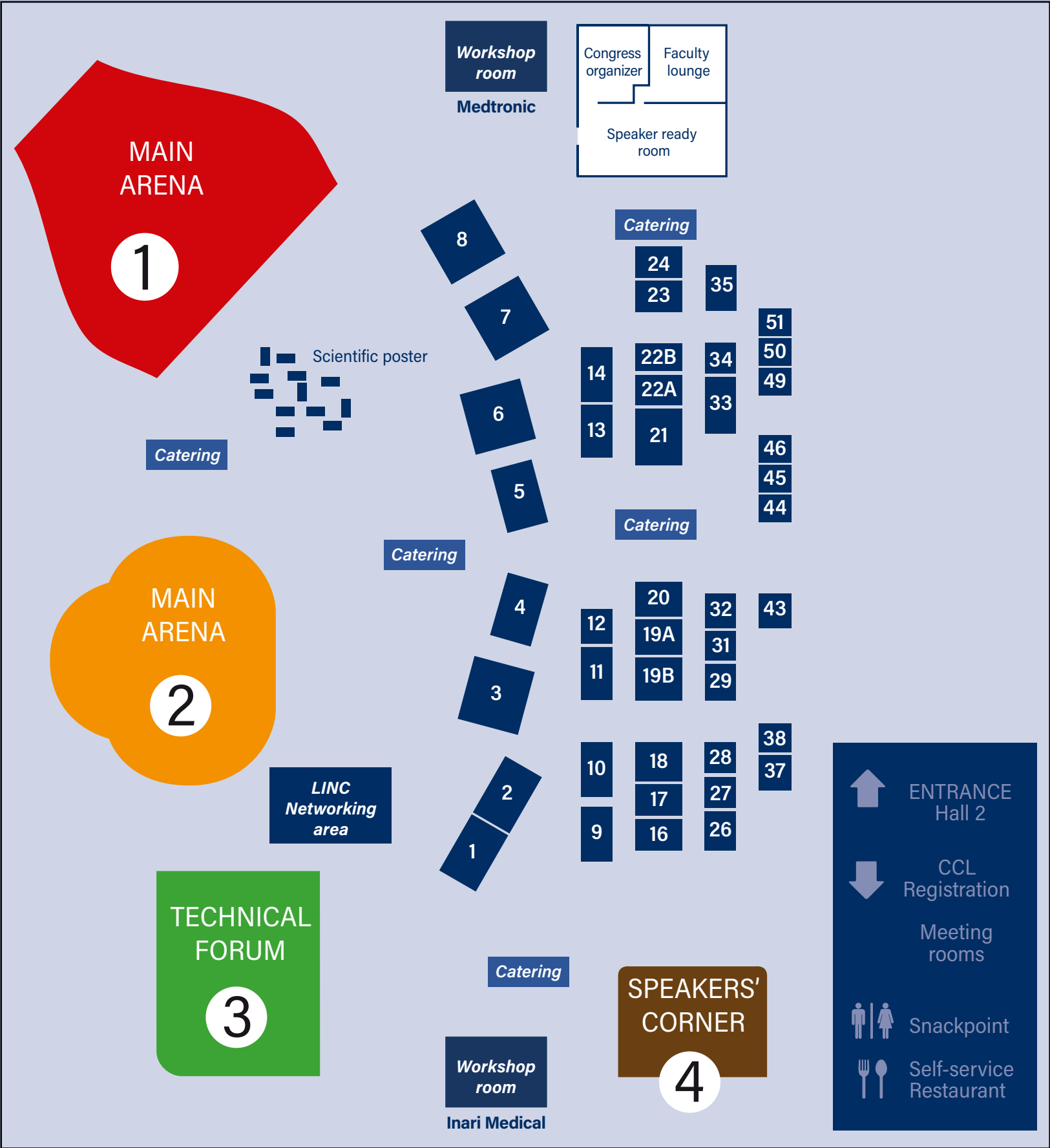


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LINC Floor plan Hall 2 6-9 June 2023



Exhibitors:

1	Philips
2	Abbott Vascular
3	BD
4	Cordis
5	Boston Scientific
6	W. L. Gore & Associates
7	Concept Medical
8	Medtronic
9	BIOTRONIK
10	Siemens Healthineers

11	Inari Medical
12	Getinge
13	Acotec Scientific
14	B. Braun Melsungen
16	Abbott Vascular
17	Asahi Intecc
18	Alvimedica/CID S.P.A.
19A	Ziehm Imaging
19B	Cardionovum
20	Angiodroid
21	iVascular
22A	Shockwave Medical

22B	Veryan Medical
23	Zylox Tonbridge
24	Axio Biosolutions
26	Artivion
27	Argon Medical Devices
28	Bentley
29	Penumbra
31	LifeTech Scientific
32	InspireMD
33	Optimed
34	Meril
35	CSI

37	BrosMed Medical
38	Shape Memory
43	SCITECH Medical
44	Avinger
45	PrediSurge
46	Vascular News and CX Symposium
49	Future meeting table
50	Lombard
51	Control Medical Technology/Control Transit GPX

Table top exhibitors:

(located in the transition from CCL to Hall 2)	
TT1	EVDT
TT2	Minerva Medica
TT3	SITE
TT5	Wisepress
TT6	Future meeting table
TT7	HMP Global

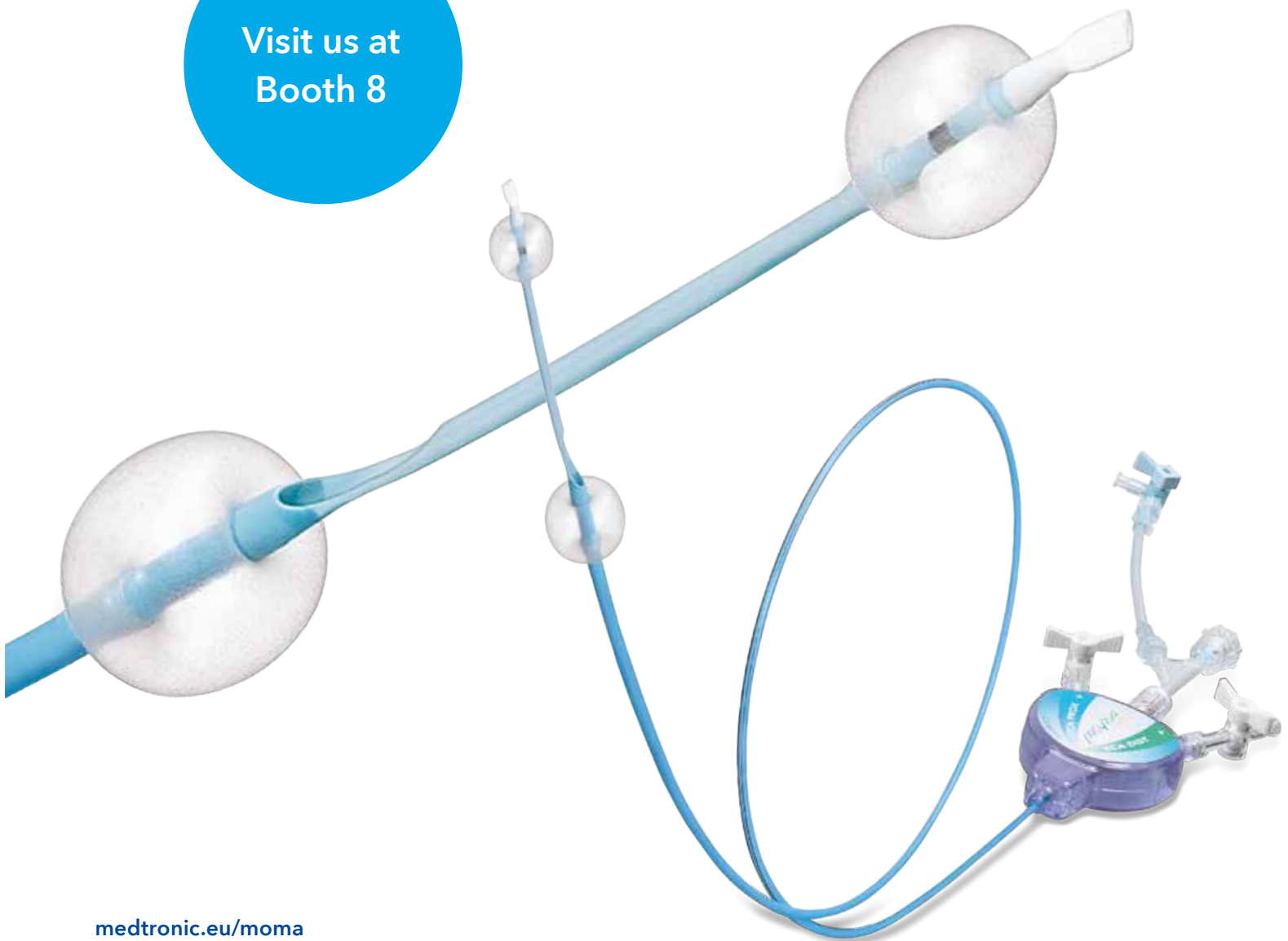
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† The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis indication includes de novo or restenotic lesions in iliac arteries, including those at the aortic bifurcation. The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface indication includes lesions in the iliac arteries only.

1. Piazza M, Squizzato F, Dall'Antonia A, et al. Outcomes of self expanding PTFE covered stent versus bare metal stent for chronic iliac artery occlusion in matched cohorts using propensity score modelling. *European Journal of Vascular & Endovascular Surgery*. 2017;54(2):177-185.

2. Panneton JM, Bismuth J, Gray BH, Holden A. Three-year follow-up of patients with iliac occlusive disease treated with the Viabahn Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy*. 2020;27(5):1.



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