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# Welcome to the 2018 VERVE Symposium and LINC Australia



It is hard to believe that this is the 6th annual VERVE Symposium! Every year the meeting grows, and this year is no different. We are back at the International

Convention Centre and we've expanded our programme throughout two rooms over three full days to continue to build on the high-level education provided by meetings past.

The programme itself has continued to mature and now maintains a place as one of the best examples of a comprehensive, multidisciplinary, vascular discussion forum found in this part of the world. We have gathered together more than 100

faculty from all over the globe to provide world-class education on the latest topics, techniques and scientific data.

More than 200, quick-fire presentations will be given on topics which cover the breadth of vascular disease, diagnosis, interventional and open-surgical procedures. There will be more discussion forums and dedicated panel interactions than ever before. Twenty live cases will be transmitted from the University Hospital, Leipzig, Germany and Sydney's Prince of Wales Private and Mater Hospitals, to showcase cutting-edge interventional practice and technique. Our intention is to intersperse these demonstrations with

the latest evidence and expert opinion to underscore what you are seeing live.

This year we have enhanced our venous program to include a special focus on deep venous disorders, the interventional treatment of DVT/PE, challenging cases and worst-ever "disasters". We go further to challenge the peripheral "no-stent-zones", explore new technologies and methods of vessel preparation for the treatment of PAD and continue the great debate.

At VERVE we continually strive to complete our mission of becoming a premier educator in the field of vascular medicine and intervention by maintaining scientific integrity, promoting research and advancing the vascular field with a spirit of collegiality and inclusion.

Once again, this year we will collect all oral presentations and live case recordings to include in our online library. This complementary offering will be accessible to all registered delegates a month after the symposium, so that you can review lectures attended or catch up on those that you missed.

VERVE isn't just about the education but the social opportunities as well, and we believe that these should be included as part of your registration. Join us for a glass of Champagne on Thursday night following the completion of the final session, and for the much-lauded Symposium Dinner Party at the Sergeants Mess on Sydney Harbour. These are great opportunities to network with colleagues and catch up with friends. I look forward to seeing you during the meeting.

**Ramon Varcoe**

*Course Co-Director; The VERVE Symposium and LINC Australia*

## What is Proven, Reliable and Trusted?

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GETINGE 

# Thinking outside the box: Pushing EVAR beyond IFU

Use of endovascular aneurysm repair (EVAR) devices outside of their instructions for use (IFU) can offer truly potential benefits, and experienced practitioners should not be scared to venture into uncharted territory. So will be the message of Glen Benveniste, a vascular surgeon from Adelaide, Australia, who takes to the podium on Thursday afternoon.

“If I see an aneurysm, it should be approached endoluminally first, and open only if it is absolutely not possible,” he told *VERVE Symposium News*, beginning to frame his argument that EVAR should be placed front-and-centre of aneurysm treatment, whether within the IFU or not.

IFUs, continued Dr Benveniste, are very generalised, specifying

little more than optimal aneurysm diameters or angulations, while other crucial considerations such as degree of thrombus or calcium are hard to quantify. It would also appear, he added, that manufacturers have not (significantly) updated their IFUs as technology has evolved.

Speaking more historically, he relayed his experience with colleague Michael Lawrence-Brown, a pioneer in the emerging field of EVAR in the early 1990s, whose work at the Royal Perth Hospital contributed to the development of early graft technologies. “Michael is a very honest and straightforward surgeon. He basically said that this technique, EVAR, is now around, and yes it may all fall to bits and we’ll have egg on our faces in years to come, but what we should do is [approach] every aneurysm we can with a stent, and then document everything and see what happens,” said Dr Benveniste.

This documentation led to a comprehensive review which offered an element of guidance in EVAR decision-making, i.e. if the aneurysm neck is less than “X mm”, or the angle is more than “Y degrees” then there is likely to be complication “Z” in the future.

Dr Benveniste went on to reason that the debate for and against IFU restraints is multifactorial. He responded first to the argument that using grafts for more challenging cases means, naturally, likely higher mortality than in less complex patients. This,

in turn, has been theorised to mean relatively poorer outcomes feed back into the data for each graft, and muddy the water of their success overall. Not so, he said, according to the data.

Indeed, Dr Benveniste underlined that key publications looking at complication rates outside of IFU, for example the work of Oliveira-Pinto et al.<sup>1</sup>, have shown that results inside or

outside IFUs are largely comparable.

But that’s not to say that he began using grafts outside of their IFU without trepidation. “I was cautious to begin with ... I was sceptical, but the thing that convinced me was listening to Professor Lawrence-Brown,” he said. Delving deeper, in the early usage of EVAR grafts in the 1990s, he continued, reintervention rates were around 30%, but Professor Lawrence-Brown was an outspoken voice reasoning that reinterventions were relatively minor, and thus should not hinder progress. This went a long way to add an air of confidence to the endovascular approach, said Dr Benveniste.

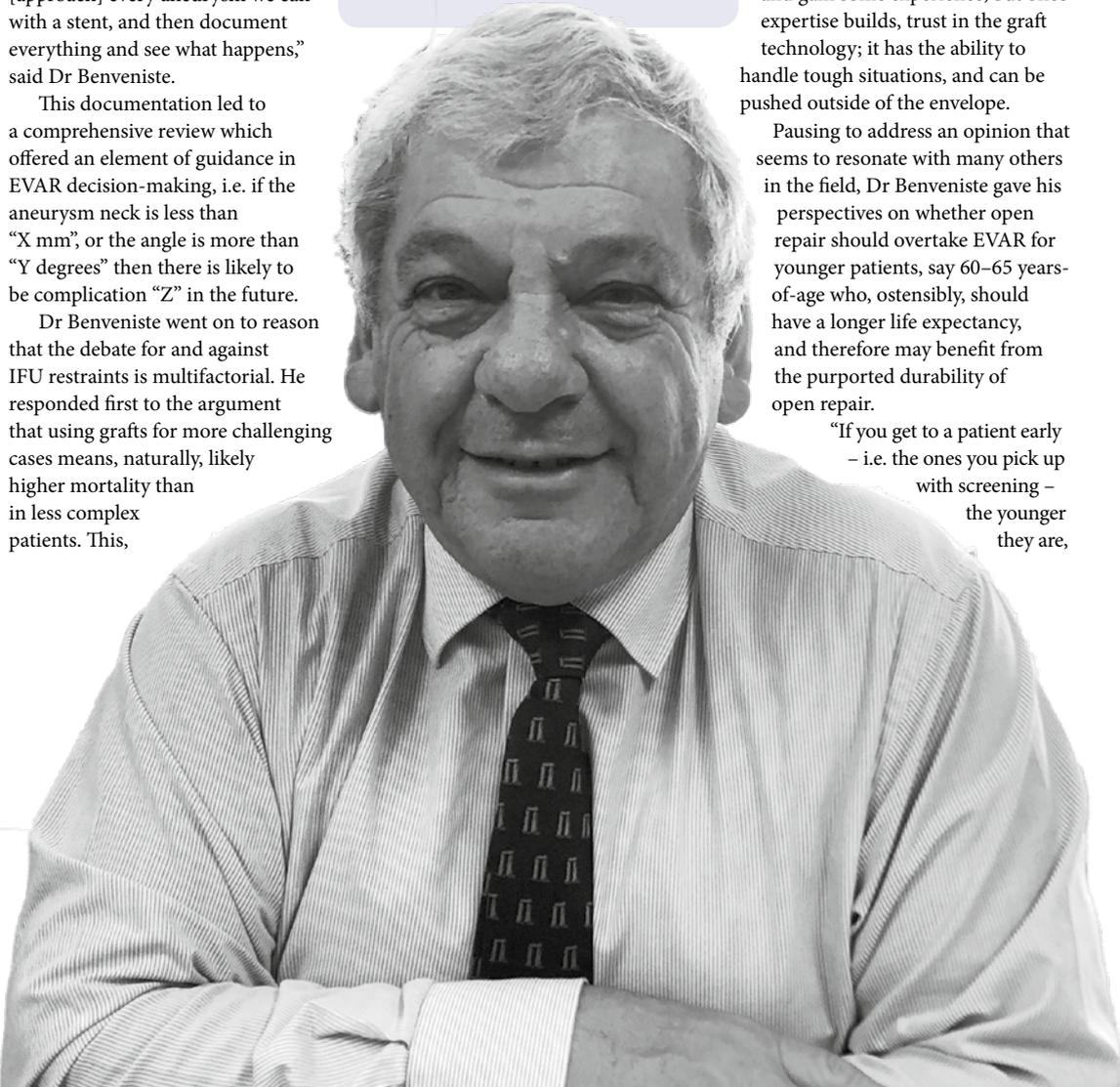
Another point of consideration is operator experience, and Dr Benveniste will argue that if you are new to EVAR, stick to the IFUs and gain some experience, but once expertise builds, trust in the graft technology; it has the ability to handle tough situations, and can be pushed outside of the envelope.

Pausing to address an opinion that seems to resonate with many others in the field, Dr Benveniste gave his perspectives on whether open repair should overtake EVAR for younger patients, say 60–65 years-of-age who, ostensibly, should have a longer life expectancy, and therefore may benefit from the purported durability of open repair.

“If you get to a patient early – i.e. the ones you pick up with screening – the younger they are,

“As a practical surgeon, once you have done one, two, three cases, if something doesn’t seem to work, that’s the end of it. You are not going to do a randomised controlled trial.”

Glen Benveniste



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the less likely an aneurysm is going to be close to the renals,” he said. “One of the ongoing arguments is when do you fix these aneurysms? I grew up in the open era, where if you drew a graph of risk of rupture versus size of aneurysm, at approximately 5 cm, the estimated risk of rupture was at least 5–10% ... which was [also] the mortality of open surgery. So until it got to 5 cm you’d say the risk of rupture is less than the risk of surgery, therefore we won’t do it.

“What is being debated now is, if we can put a stent graft in with a mortality of 1%, shouldn’t we be doing that at smaller aneurysm diameters, where are more likely to be able to stent it? The bigger the aneurysm gets in diameter, the longer it becomes. If I see a 60-year-old with a 5 cm aneurysm, I will stent them because in another five years it might be only 5.5 cm, but it will be closer to the renals and therefore it will make the stenting more difficult”

But again this opinion is not shared by all, conceded Dr Benveniste. “We had a trainee workshop a year or so

ago, and I said, ‘I am in my mid-60s, and I am healthy and don’t have an aneurysm, but if I did have one would you recommend open surgery or a stent graft?’, and a lot of them – who come from conservative units – said I should have an open operation because I am young.”

He added: “I said, if I had an aneurysm I would get a stent on Friday, go home on Sunday and go back to work on Monday, and I’d then [happily] turn up every six months for an ultrasound.”

Of course, the argument becomes ever more EVAR-centric with older, more frail patients: “If you have an 85-year-old man with a degree of renal failure, some angina – to do an open operation you’ve got a 10% chance of killing him, and probably 15–20% chance of putting him in a nursing home,” said Dr Benveniste.

In such situations, he added, stepping outside of the IFU to apply EVAR for these complex cases would again be warranted. Yes, there is a

higher chance that there may be problems in the future, “but that is better than sending a guy to the morgue, or doing nothing at all,” he said.

But what of the hard evidence for EVAR usage outside of IFU? “As a practical surgeon, once you have done one, two, three cases, if something doesn’t seem to work, that’s the end of it. You are not going to do a randomised controlled trial,” he said. “30% of cases in the US are outside of the IFU,” he added, underlining that real-world practice clearly mandates the push to use these graft technologies outside of their ‘comfort zones’ – albeit with expert opinion driving that decision.

In his presentation at the VERVE Symposium, Dr Benveniste will be offering case reports and analogous

examples of why we shouldn’t be afraid to step outside IFU (stay tuned for a clip featuring Madonna being driven through busy city streets at high speed). Going forward, he is formally compiling some of his case data to publish perspectives on graft technologies, and underpin his argument that their use should be at least considered for all aneurysm cases, whether in or out of the IFU.

“If I had an aneurysm I would get a stent on Friday, go home on Sunday and go back to work on Monday, and I’d then [happily] turn up every six months for an ultrasound.”

Glen Benveniste

**References**

1. Oliveira-Pinto J, Oliveira N, Bastos-Goncalves F, et al. Long-term results of outside “instructions for use” EVAR. *J Cardiovasc Surg.* 2017;58(2):252-260.

**Session 2.10: New Technology with the Potential to Improve Outcomes in PAD Treatment** Room 2 **Friday** 4:00–6:00 pm

# Making waves: intravascular lithotripsy improves vessel compliance and mobility in latest trial

The 12-month results of DISRUPT PAD II<sup>1,2</sup>, evaluating the safety and effectiveness of localised intravascular lithotripsy (IVL) of calcified obstructive femoropopliteal lesions using the Shockwave Medical Lithoplasty System (Shockwave Medical, USA), will be presented on Friday afternoon by Andrew Holden (Auckland City Hospital, New Zealand).

IVL technology was adopted in peripheral artery disease for the modification of calcified plaque. In summary, electrohydraulic-generated sonic pressure waves interact with high-density calcium while soft tissue remains unaffected. Pressure waves produce shear stresses that create microfractures in both intimal and medial calcium. In this way, vessel compliance and vessel mobility are improved. IVL emitters are situated on an angioplasty balloon, which is inflated to low pressure so as to achieve calcium apposition. A detailed description of IVL mechanisms of action in calcified lesions was recently described using optical coherence tomography by Ali et al<sup>3</sup>.

Dr Holden headed the New Zealand site during the non-randomised multicentre DISRUPT PAD I study, which included a total of 60 patients with complex calcified peripheral arterial lesions enrolled between June and December of 2015. The primary safety endpoint was major adverse events (MAE) through 30 days. The primary effectiveness endpoint was patency as adjudicated by duplex ultrasonography (DUS). Key secondary endpoints



“There were some hopes that IVL would be a standalone treatment, but clearly it is not. It’s more of a vessel preparation therapy.”

Andrew Holden

included acute procedure success, freedom from re-intervention, and functional outcomes.<sup>2</sup>

In this cohort, the post-procedural residual stenosis was found to be 24.2%, with an average acute gain of 3.0 mm. The 30-day MAE rate was 1.7%, which comprised one grade-D dissection that resolved following stent placement. Primary patency at 12 months was 54.5%, and clinically driven target lesion revascularisation (TLR) at 12 months was 20.7%. Furthermore, it was found that optimal IVL technique, defined by correct balloon sizing and avoiding therapeutic miss, improved 12-month primary patency and TLR outcomes to 62.9% and 8.6%, respectively.<sup>2</sup>

Summarising the lessons learned during this study, Dr Holden told *VERVE Symposium News*: “With the combined experience of DISRUPT I and II – a series of 95 patients – we saw (not surprisingly) a significant incidence of restenosis given the complexity of the lesions. But we also found that, rather than going back to square one when you retreat these patients, they were actually very simple to treat with a drug-coated balloon (DCB). We appeared to get a durable result. It was those findings that really stimulated the design of DISRUPT III.

“There were some hopes that IVL would be a standalone treatment, but clearly it is not. It’s more of a vessel preparation therapy – and that is what DISRUPT III is trying to assess.”

DISRUPT PAD III is the prospective, multicentre, single blind, randomised (1:1) study of Lithoplasty treatment used in combination with DCB versus

# Making waves: intravascular lithotripsy improves vessel compliance and mobility in latest trial

Continued from page 3

standard balloon angioplasty, to treat moderate and severely calcified femoropopliteal arteries. Up to 400 subjects of Rutherford class 2-4 will be recruited at 60 sites in Europe, the United States and New Zealand. Subjects will be followed through discharge, 30 days, and 6, 12 and 24 months. DUS assessments will be completed at 12 and 24 months.<sup>4</sup>

Dr Holden described some of the technical lessons of DISRUPT II. “One of our questions was, can you primarily deliver this low-profile balloon (over an 0.014” guidewire) through very calcified arterial lesions, and then deploy it without problems and with a reasonable acute result? Actually, we didn’t need to predilate the lesions very often at all. The need for predilatation was in the single figures. And, despite being quite hostile lesions, you could pass a guidewire and dilate with IVL successfully.”

Dose delivery was also found to be dependent on calcium characteristics, he continued: “We are delivering a dose of energy to the vessel wall so that we can microfragment the calcium and change the compliance of the vessel. In areas that are refractory and heavily calcified, you often need to treat several times to try to really change the compliance and open the vessel up.”

“This changes the concept of a balloon as just dilating a lesion. Here, you are delivering a dose of energy to the vessel wall and trying to change the compliance.”

Dr Holden added that, early on in the adoption of IVL technology, it was suspected that microfragmentation of calcium would mean increased embolic risk. Indeed, embolic protection

was routinely used in DISRUPT I. However, no significant debris was collected in this study, and as such IVL has since been used without embolic protection.

IVL is now being adopted into clinical use around the world, too. “The IVL device has been released in Europe, and there is clinical access in the US as well.

“There probably was some initial scepticism that a simple over-the-wire balloon-based therapy could be as effective as other much more invasive treatments.”

Andrew Holden

“There probably was some initial scepticism that a simple over-the-wire balloon-based therapy could be as effective as other much more invasive treatments (e.g. directional atherectomy). But there have been multiple key opinion leaders around the world that have been very strong advocates for the technology. It is certainly growing in its uptake. And we are learning more and more.”

Addressing what is known so far about the ideal lesion types suited to IVL treatment, Dr Holden said: “If we think about types of calcium and lesions, we tend to see, as well as there being medial and intimal calcification, that there may be more diffuse calcification on all sides of the arterial wall, versus

calcification that is more polypoid. You would think that IVL is great for concentric calcium because it is microfragmenting the whole wall, but that maybe it wouldn’t work so well for eccentric lesions. The DISRUPT series tried to characterise the calcium as concentric or polypoid, and they couldn’t actually show a difference between the two types of calcium.

“Having said that, my own impression is that it works best in the patients that have concentric calcium. If you have a focal polyp of calcium producing a narrowing, I suspect that IVL may not be the way to go, that it may be better to do directional atherectomy. But we haven’t actually clearly proven that at this stage.”

Concluding with his expectations of DISRUPT III, he added: “This trial will be important. This is a really exciting technology, and there is still much to learn. With the device now out in clinical practice, there will be some important learning coming from that as well.”

## References

1. Shockwave Lithoplasty DISRUPT Trial for PAD (DISRUPT PAD). ClinicalTrials.gov <https://clinicaltrials.gov/ct2/show/NCT02369848> (accessed Dec 2018).
2. Brodmann M, Werner M, Holden A, Tepe G, Scheinert D, Schwandt A et al. Primary outcomes and mechanism of action of intravascular lithotripsy in calcified, femoropopliteal lesions: Results of Disrupt PAD II. *Catheter Cardiovasc Interv*. 2018.
3. Ali Z, Brinton T, Hill J, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions: First description. *J Am Coll Cardiol Img*. 2017;10(B):897-906.
4. Shockwave Medical Peripheral Lithoplasty System Study for PAD (Disrupt PAD III). ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT02923193> (accessed Dec 2018).



# Clinical needs and value-based healthcare in peripheral vascular interventions

**T**he tension between clinical needs and costs will be the focus of a presentation by George Adams, an interventional cardiologist at UNC REX Hospital in Raleigh, NC, USA, and associate professor of medicine at the University of North Carolina at Chapel Hill.

Dr Adams is involved in around 100 clinical and translational research studies and 20 medical advisory boards for industry. In addition, he works with the United States Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid services (CMS) bodies tasked with regulatory approval and reimbursement of new devices and biologics. That, he said, has given him direct experience of the rise of value-based healthcare within the US. “Healthcare is evolving, with an emphasis placed on fiscal responsibility and cost effectiveness,” he told *VERVE Symposium News*, adding that contemporary practice demands the cost of new technology be weighed against the clinical outcome for the patient.

“The proposition of this ‘cost effectiveness’ model is that technologies with clinically proven benefits will be adequately reimbursed.”

Despite the emphasis on cost effectiveness, there are several examples where the benefit of a technology – based on sound clinical research – has not been adequately backed up by reimbursement, said Dr Adams: “This has resulted in the underutilisation of several products.”

The opposite is also true, he added. “There have been medical devices which have had a paucity

of clinical evidence and received a high reimbursement resulting in overutilisation of the product. I propose that ‘cost effectiveness’ has turned into a state of ‘reimbursement effectiveness’ which may not be in the best interest of the US healthcare system.”

Luckily, there are some proposals to ensure reimbursement and cost effectiveness become more aligned in future. For example, if reimbursement for atherectomy is to continue, Dr Adams reasons that the FDA and CMS should encourage future randomised controlled trials comparing device to device. “This will help in personalising care, and identify which atherectomy devices are best used in different patient populations,” he said.

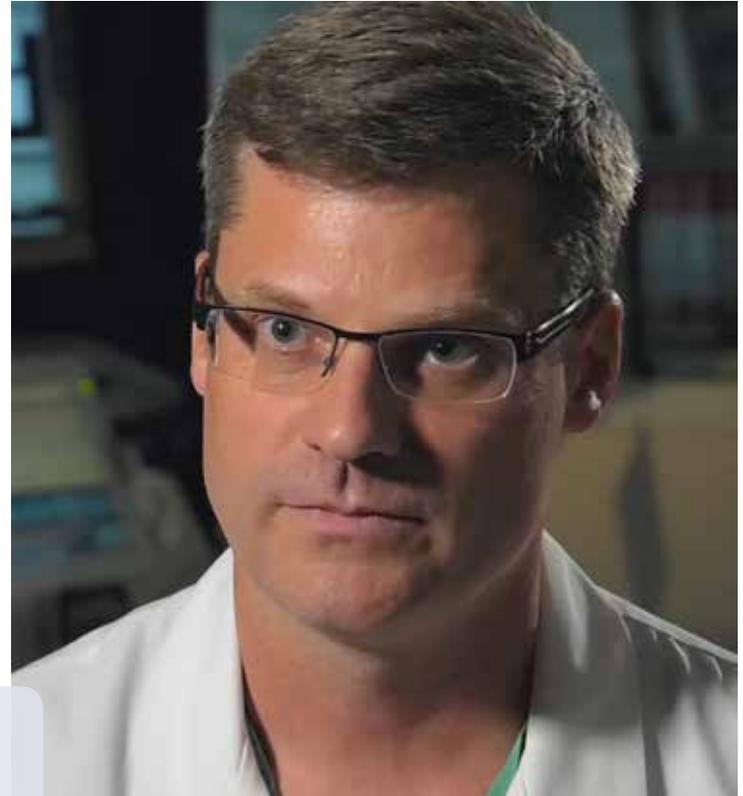
Importantly, Dr Adams will talk about some important work that has been started to address these kinds of healthcare challenges in the United States. He has recently been appointed

“I propose that ‘cost effectiveness’ has turned into a state of ‘reimbursement effectiveness’ which may not be in [our] best interest.”

George Adams

as chair of the Cardiovascular Round Table, which has brought together healthcare providers, administrators and industry for the last three years. The group is conducting studies on just this issue. “Together we have identified this so-called cost effectiveness conundrum as a point of interest and are investigating it further to formulate solutions,” he said.

That has involved looking at the



use of specific devices. “We’ve seen the recent loss of the pass-through code for drug-coated balloons (DCB), a technology with abundant positive outcome data,” he explained. “We have been looking at how that factor has affected the use of DCBs, and thus far it looks as if there is at least a 15% reduction in usage at some sites six months following this reimbursement change.”

“It looks as if reimbursement can change behaviour even when evidence shows the benefit of a technology.”

The next stage of this project will look at how clinical outcomes

are affected by this reduction in use. “If DCB use has declined, what are operators doing instead? Additionally, how has this changed outcomes, specifically patency and target vessel revascularisation?” said Dr Adams.

In parallel, the group will be appraising policymakers of their findings and offering solutions as a collaborative. The hope is that this will effect change. “We welcome colleagues nationally and internationally to join our collaborative; understanding this issue not only affects the United States but many other countries,” he concluded.

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# Tackling popliteal artery athero-occlusive disease

## What is the way forward?

Exploring endovascular treatment options for the popliteal artery, with particular emphasis on how new technologies really perform will be Victor Charles Bourke, a consultant vascular and endovascular surgeon at Prince of Wales Public and Private, and Gosford Public and Private Hospitals, NSW, Australia. With a wide set of interests, Dr Bourke has been a regular live-case demonstrator at the VERVE Symposium since its inception.

VERVE Symposium News caught up with Dr Bourke ahead of his presentation to catch a glimpse of his main messages.

**You will be speaking about endovascular treatment options for the popliteal artery. What particular challenges of this artery have guided approaches to treating athero-occlusive disease?**

The popliteal artery is unique. Unlike the superficial femoral artery (SFA), it is not contained within a muscular sheath, and as it crosses the knee joint it is subjected to significant forces of flexion, elongation, shortening, and torsion. For this reason, surgeons have traditionally opted for surgical bypass to treat disease in this vessel.

**What effect has stenting had?**

Early nitinol stents did not perform well due to high rates of stent fracture, in-stent restenosis and reduced primary patency, and fared worse compared with stent outcomes for the SFA.

Failures of the early generations of stents prompted a closer examination of the particular forces and characteristics of the popliteal artery. Understanding this has led to targeted improvements in stent technology, as well as investigation of the role of other treatments such as drug coated balloons and atherectomy.

**What evidence is there for endovascular treatment of a diseased popliteal segment?**

Research studies have traditionally combined the SFA and popliteal artery, and often only include data for the P1 segment, meaning that valuable data for endovascular treatment of isolated popliteal artery disease (P1–P3 segments) is lacking. This is partially due to strict enrolment criteria in RCTs, and partly due to the relative rarity of popliteal artery disease. Much of our current understanding comes from real-world registry data, or post-hoc subgroup analysis of RCTs examining the SFA and P1 segment of the popliteal.

The advent of next generation nitinol stents with characteristics specifically designed for the popliteal artery opens up possibilities for improved stenting outcomes in this region. Stents placed in the popliteal artery need to be flexible and compliant, demonstrate high radial compression resistance and be fracture-proof. Stents which handle severe calcification are a bonus. The improvements in stent technology now



“The optimal endovascular treatment algorithm for the diseased popliteal artery remains unknown.”

Victor Charles Bourke

challenge the traditional mantra that the popliteal is a “no stent zone”.

**What evidence is there for other technologies?**

Drug-coated balloon technology offers the opportunity to take stents out of the equation. Again, data for isolated disease of the popliteal artery is scant and limited to the P1 segment. Post-hoc subgroup analysis of some studies has demonstrated clinically significant improvements in more complex lesions involving the P2 and P3 segment. However, the rates of clinically driven target lesion revascularisation appear to be higher when the P2 and P3 segment are involved.

Atherectomy in the popliteal artery has very limited data, however it does open up the possibility of de-bulking atheromatous plaque and reducing stent requirement.

**Tell us more about your experience with endovascular treatment of disease in the popliteal artery.**

In my experience, complete occlusive disease of the entire popliteal artery is rare. I often find there are synchronous occlusive lesions at the adductor magnus and tibioperoneal trunk, meaning that there is a “hibernating” segment of popliteal artery. Targeted treatment of the index lesions, and efforts to maintain an intraluminal recanalisation, can often lead to surprisingly good results. With this in mind the endovascular surgeon can be more confident in approaching a “total occlusion” of the popliteal artery (P1–P3). There is invariably significant tibial outflow vessel disease present, and it is important to establish brisk outflow to the foot to maintain patency of the popliteal segment.

Because there is an inherently higher risk of restenosis and loss of primary patency, a careful follow-up protocol with clinical assessment and duplex ultrasound is essential. Dual anti-platelet therapy is also important.

**What is your take-home message for the VERVE Symposium audience?**

The optimal endovascular treatment algorithm for the diseased popliteal artery remains unknown. However, improvements in balloon, stent and atherectomy technology, and the understanding of the dynamic characteristics of the popliteal artery, means that clinically meaningful improvements can be achieved in patients with complex disease of this artery.

Session 2.15: Challenging Case Presentations: Aortic and Beyond Room 2 Saturday 4:00–5:45 pm

## A complex patient and an inventive endovascular solution

In the final hours of the VERVE Symposium, Shannon Thomas presents a novel endovascular approach in a highly unusual case of complex endoleak repair in an enlarging aneurysm in a patient with an autotransplanted kidney. Dr Thomas is a vascular and endovascular surgeon at the Prince of Wales Hospitals, NSW, Australia.

The patient had originally undergone abdominal aortic aneurysm repair approximately 20 years ago, with accompanying autotransplantation of the left kidney into the pelvis. Over the course of subsequent years, the patient developed an endoleak.

“His presentation was very unusual,” commented Dr Thomas, in conversation with *VERVE Symposium News*. “It looked as though, over time, the neck of the aneurysm had expanded. That was why the graft was no longer apposed to the wall.

“An attempt was made to repair the leak last year, by a different surgeon at another hospital. During this repair, they ruptured the artery just beyond the transplanted kidney (the external iliac). They also had a graft limb from

that left side dislodge and end up in the neck of the aneurysm.”

As such, blood flowing into the left kidney was doing so through the dislodged graft limb located across the aortic neck and common iliac. The ruptured artery was tied off and surgically repaired, explained Dr Thomas. In addition, a femoral-femoral crossover was performed in order to supply the left leg from the right groin.

Describing the patient in more detail, he continued: “This was a very high-risk patient. He had ischaemic heart disease, congestive cardiac failure, and COPD as well. Open surgery was not possible, he was deemed too high risk.”

Commenting more generally on the evolution of EVAR techniques as well as those

developed to minimise the occurrence of complications such as stent dislodgement and migration, he said: “The original aneurysm repair was performed in the 1990s. It has kept him alive for almost 20 years. The earlier devices are not as durable as the latest devices. I think that is why he developed problems, ultimately. I think the current generation of grafts and techniques really improve durability. This patient was

just very unusual in his presentation – an exception rather than the rule.

Dr Thomas and colleagues performed endovascular revascularisation of the left kidney from the left groin. In order to do this, they ‘rebuilt’ the conduit of the left external iliac

“ [The patient’s] presentation was very unusual, but also the way we repaired it was highly unusual.”

Shannon Thomas

artery that had previously been surgically removed due to rupture. “We managed to get a wire across the free tissue in the abdomen, and then we managed to place some stents there. That way, the fem-fem crossover graft was not only feeding the left leg, but also the left kidney now. We put a large plug into that aberrant limb that was floating in the neck. Then we performed a two-vessel chimney EVAR on the neck.

“His presentation was very unusual, but also the way we repaired it was highly unusual,” he added. “I don’t think anyone would figure out how to fix it endovascularly. This was all elective and planned. It is a very novel technique in aneurysm grafting.”

Dr Thomas describes a full account of the case during his presentation in Session 2.15: Challenging Case Presentations: Aortic and Beyond, in Room 2 from 4:00 to 5:45 pm on Saturday.

“ It is a very novel technique in aneurysm grafting.”

Shannon Thomas



Session 2.13: The Current Landscape in Carotid Revascularisation Room 2 Saturday 11:30 am–1:00 pm

## Making the case for individualised approaches to carotid disease

Differing perspectives on the treatment of asymptomatic carotid disease will be discussed by Mehdi H. Shishehbor, an interventional cardiologist and professor of medicine at Case Western Reserve University School of Medicine, Cleveland, OH, USA. “There is a lot of controversy around this condition and what to do,” he told *VERVE Symposium News*.

Professor Shishehbor has a special interest in the management of severe carotid disease. During the presentation, he will compare and contrast currently available data on medical, surgical and endovascular therapy. Importantly, he will also be discussing the Carotid Revascularization Endarterectomy

Versus Stenting Trial (CREST)<sup>1</sup>, one of the largest randomised prospective studies to date to compare carotid artery stenting and carotid endarterectomy.

“... there are groups of physicians and advocates out there supporting the idea that we treat patients with asymptomatic carotid disease only with medical therapy.”

Mehdi H. Shishehbor

“I’ll also look at some of the recent observational data looking at operator experience and outcomes – a few of the meta-analyses that look at medical therapy for carotid disease,” he explained, adding that comparison of the pros and cons of each approach, and analysis of their validity will hopefully translate to being able to synthesise all data and come up with some recommendations as to which approach works for which patients.

Thirty years ago, patients for the most part were treated medically, noted Professor Shishehbor, with surgical carotid interventions and endovascular therapy gained momentum in the

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# Making the case for individualised approaches to carotid disease

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last 15 years. “However, for the most part, because of reimbursement in the United States especially, endovascular therapy never really took off fully,” he said. “Now, the field of carotid disease is coming full-circle, with a preference for treating medically.”

Today, newer endovascular approaches to treat carotid disease are promising, continued Professor Shishehbor. One is Transcarotid Artery Revascularization (TCAR), a new hybrid approach, which is part surgical and part endovascular. “This has raised some interest amongst the various people that treat this condition,” he explained.

Other things have changed, too. “I think we are technically much more advanced, and we understand better that operator experience is extremely important when it comes to carotid interventions, especially endovascular therapy,” he said. “We also understand patient selection is much more critical.”

Given these advances, Professor Shishehbor said there is not – and should not – be a one-fits-all approach for all asymptomatic patients. “However, there are groups of physicians and advocates out there supporting the idea that we treat patients with asymptomatic carotid disease only with medical therapy,” he said. “It’s ridiculous. So that’s the challenge.

“When patients have asymptomatic carotid disease, it’s very difficult to explain to them that we’re not going to do anything and that we should wait until they are symptomatic, which is a stroke, before we do something.

Conceptually this is very difficult to explain to patients.”

Lack of agreement on approaches stems from a lack of definitive data, said Professor Shishehbor, adding that indeed there is no head-to-head randomised trial comparing medical therapy, surgical therapy and endovascular therapy for carotid disease.

“The data are 30 years old, at a time when we did not have interventions like ACE inhibitors, we didn’t take smoking so seriously, and we didn’t control people’s blood pressure effectively,” he said.

This lack of data may contribute to why some medical professionals are veering towards medical therapy, said Professor Shishehbor. “While medical therapy has advanced significantly, we don’t have any level I data showing patients with severe symptomatic carotid disease should not be treated. That data is missing, so to say that all patients with asymptomatic carotid disease should be treated medically is not based on data at all.”

The lack of definitive data is the driver behind Professor Shishehbor’s work on a major NIH-funded large-scale follow-up to the CREST trial, CREST-2, which actually comprises two independent

multicentre, randomised controlled trials to compare medical, surgical and endovascular treatment of asymptomatic carotid disease. One trial will compare endarterectomy versus no endarterectomy (or medical management) and another will compare carotid stenting with embolic protection versus no stenting. “They are extremely important,” continued Professor Shishehbor. “I think they will at least show us if it’s beneficial to do some form of revascularisation, whether it’s open or stent, and whether that is superior to medical therapy alone.”

Whether the trial will answer the question of superiority between endovascular stenting and surgery is unclear however. “That is questionable because it may not be powered to show us that. We may never get the answers to that,” said Professor Shishehbor.

He will also cover how recommendations should differ, based on the current literature, as to the management of carotid disease for different kinds of asymptomatic patients. “Recommendations should be different for females versus males, and

also age is a very significant contributor, mainly in terms of life expectancy,” he said. “We will come up with an algorithm as to who we think should get interventions and who should be treated medically, based on the available data.”

For example, with carotid surgery or stenting there is an upfront risk of a stroke from the procedure, yet a patient who survives is likely to benefit for between 5–10 years. “So, if the patient’s life expectancy is two years, we should do only medical therapies,” he reasoned.

In other words, nuanced approaches should be employed when managing severe carotid disease, Professor Shishehbor said in closing: “There are people who say they only do medical therapy, people who will only do surgical therapy, or some who only do endovascular. The truth is, in my opinion, we need to tailor it to the patient.”

## References

1. Brott TG, Hobson RW, Howard G et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med.* 2010;363(1):11-23.

“When patients have asymptomatic carotid disease, it’s very difficult to explain to them that we’re not going to do anything and that we should wait until they are symptomatic, which is a stroke, before we do something.”

Mehdi H. Shishehbor



Shishehbor Mehdi

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# Finding the value in IVUS

**L**aura Villalba is an associate professor and head of the vascular department at Wollongong Hospital, NSW, Australia, where she also founded its Vascular Care Centre. Wollongong's only female vascular surgeon, she also heads up the Illawarra Shoalhaven Health District in New South Wales, with a keen interest in deep venous pathology. At the VERVE Symposium, she will be speaking on the issue of cost-effectiveness of intravascular ultrasound for deep vein reconstruction.

Her interest in cost-effectiveness grew out of necessity when hospital administrators started to question her requests to access new devices, Dr Villalba told *VERVE Symposium News*. She recalled that this first began when she started to perform endovascular thrombectomies. "I had to do a business case and prove its cost-effectiveness. Since then, I have made it a priority to routinely assess any new technology into the unit, not only from a clinical outcomes point of view, but in terms of cost-effectiveness," she explained.

Dr Villalba will outline results from her study on IVUS – a technology that is largely restricted by its cost,

she said: "The medical community has been claiming its superiority over angiography for many years, however no studies on cost-effectiveness have been done. In Australia, and in other parts of the world except the USA, IVUS has no Medicare rebate for its use in the periphery and this has been a tremendous obstacle for us."

Dr Villalba's clinician-initiated trial investigated the introduction of IVUS in a deep-venous practice. "Firstly, my intention was to compare my findings with the findings of others before me, in particular I compared my results with the results of the VIDIO (Venogram vs IVUS for Diagnosing Iliac vein Obstruction) trial<sup>1</sup> to see whether IVUS would have a significant impact on my decision making or not," she explained.

The VIDIO trial found that IVUS is more sensitive for assessing treatable iliofemoral vein stenosis compared with multiplanar venography.

For example, venography identified stenotic lesions in 51 out of 100 subjects, whereas IVUS identified lesions in 81 out of 100 subjects. Investigators revised the treatment plan in 57 out of 100 cases after IVUS, most often because

of the failure of venography to detect a significant lesion.

"The VIDIO trial confirmed in a solid scientific way what many have been saying for years: that venography is inadequate to assess and treat venous obstruction, however there is no data to analyse what that means," added Dr Villalba.

**“The medical community has been claiming [IVUS]’ superiority over angiography for many years, however no studies on cost-effectiveness have been done.”**

Laurencia Villalba

There are significant concerns as to the continued use of venography as the gold standard, given the evidence that it either underestimates or overestimates pathology when compared to IVUS she said. Importantly, the knock-on effects of not using IVUS-guided procedures could mean significant harm and additional costs. "What happens if we don't use IVUS and we leave significant lesions behind? What happens if we deploy a stent too low because it is impossible to visualise the artery crossing on venography? What happens if we don't assess stent expansion or stent apposition or inflow vessels properly?," What happens if we stent

lesions that are primarily dynamic in nature? she said. "Nobody has assessed the implications of the lack of routine IVUS use versus its cost."

All-told, Dr Villalba's study concluded that IVUS is essential. "My findings support the fact that IVUS is an indispensable tool for anyone planning to perform deep venous reconstructions," she explained. "Despite its cost it proves cost-effective in the end."

Though her findings are very compelling, Dr Villalba said the biggest challenge will be to change practices within the health care system. Administrators within the health system require robust data to prove the tool improves patient safety and patient outcomes and by doing so, it's cost-effectiveness. "Ideally a bigger multicentre international study should be undertaken to confirm my findings and I am in the process of organising that," she said.

"IVUS is undeniably a necessary tool in deep venous reconstructions and its current cost and lack of reimbursement should not be an obstacle for its use," concluded Dr Villalba.

## References

1. Gagne PJ, Tahara RW, Fastabend CP et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction J Vasc Surg Venous Lymphat Disord. 2017;5(5):678-687.

## Further reading

**Dr Villalba: Clinical studies suggest that IVUS has a diagnostic sensitivity of >90%, and is now considered the gold standard for deep venous interventions.**

- Bækgaard N, Just S, Foegh P. Which criteria demand additive stenting during catheter-directed thrombolysis? *Phlebology*. 2014 May 19;29(1 suppl):112-118.
- Virchow R. Über die Erweiterung kleinerer Gefässe. *Arch Path Anat* 1851;3:4279.
- McMurrich JP. The occurrence of congenital adhesions in the common iliac veins and their relation to thrombosis of the femoral and iliac veins. *Am JMSc* 1908;135:342-6.
- Raju S, Neglen P. High prevalence of non-thrombotic iliac vein lesions in chronic venous disease: a permissive role in pathogenicity. *J Vasc Surg*. 2006;44(1):136-43;discussion 144.
- Mussa FF, Peden EK, Zhou W, Lin PH, Lumsden AB, Bush RL. Iliac Vein Stenting for Chronic Venous Insufficiency. *Tex Heart Inst J*. 2007; 34(1):60-66.
- Meissner MH, Eklof B, Smith PC, Dalsing

- MC, DePalma RG, Gloviczki P, Moneta G, Neglen P, O'Donnell T, Pertsch H, Raju S. Secondary chronic venous disorders. *J Vasc Surg*. 2007;46 Suppl 3:S68S-83S.
- Murphy EH, Broker HS, Johnson EJ, Modrall JG, Valentine RJ, Arko FR 3rd. Device and imaging-specific volumetric analysis of clot lysis after percutaneous mechanical thrombectomy for iliofemoral DVT. *J Endovasc Ther*. 2010;17(3):423-33.
- Kibbe MR, Ujik M, Goodwin AL, Eskandari M, Yao J, Matsumura J. Iliac vein compression in an asymptomatic patient population. *J Vasc Surg* 2004;39:937-43.
- Neglen P and Raju S. Intravascular ultrasound scan evaluation of the obstructed vein. *J Vasc Surg* 2002;35:694-700.
- Canales JF, Krajcer Z. Intravascular ultrasound guidance in treating May-Thurner syndrome. *Tex Heart Inst J*. 2010;37(4):496-7.
- Vaidya OU, Buersmeyer T, Rojas R, Dolmatch B. Successful Salvage of a Renal Allograft after Acute Renal Vein

- Thrombosis due to May-Thurner Syndrome. *Case Rep Transplant*. 2012;2012:390980.
- Forauer AR, Gemmete JJ, Dasika NL, Cho KJ, Williams DM. Intravascular ultrasound in the diagnosis and treatment of iliac vein compression (May-Thurner) syndrome. *J Vasc Interv Radiol* 2002;13(5):523-7.
- Hurst DR, Forauer AR, Bloom JR, Greenfield LJ, Wakefield TW, Williams DM. Diagnosis and endovascular treatment of ilioacaval compression syndrome. *J Vasc Surg* 2001;34:106-13.
- Alhalbouni S, Hingorani A, Shiferson A, Gopal K, Jung D, Novak D, Marks N, Ascher E. Iliac-femoral venous stenting for lower extremity venous stasis symptoms. *Ann Vasc Surg*. 2012;26(2):185-9.
- Meissner MH, Gloviczki P, Comerota AJ, et al. Early thrombus removal strategies for acute deep venous thrombosis: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg* 2012;65: 1449-1462.
- McLafferty RB. The Role of Intravascular Ultrasound in Venous Thromboembolism. *Semin Intervent Radiol*. Mar 2012; 29(1): 10-15.



Laurencia Villalba



**VERVE SYMPOSIUM NEWS**  
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in conjunction with LINC Australia

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**Welcome to the 2018 VERVE Symposium and LINC Australia**

It is hard to believe that this is the 6th annual VERVE Symposium! Every year the meeting grows, and this year is no different. We are back at the International Convention Centre and we've expanded our programme throughout two rooms over three full days to continue to build on the high-level education provided by meetings past.

The programme itself has continued to mature and now maintains a place as one of the best examples of a comprehensive, multidisciplinary, vascular discussion forum found in this part of the world. We have gathered together more than 100 faculty from all over the globe to provide world-class education on the latest topics, techniques and scientific data.

More than 200, quick-fire presentations will be given on topics which cover the breadth of vascular disease, diagnosis, interventional and open-surgical procedures. There will be more discussions than ever before. Twenty live cases will be transmitted from the University Hospital, Leipzig, Germany and Sydney's Prince of Wales Private and Mater Hospitals, to showcase cutting-edge interventional practice and technique. Our intention is to intersperse these demonstrations with the latest evidence and expert opinion to underscore what you are seeing live.

This year we have enhanced our venous program to include a special focus on deep venous disorders, the interventional treatment of DVT/PE, challenging cases and worst-ever "disasters". We go further to challenge the peripheral "no-stent-zones", explore new technologies and methods of vessel preparation for the treatment of PAD and continue the great debate.

At VERVE we continually strive to complete our mission of becoming a premier educator in the field of vascular medicine and intervention by maintaining scientific integrity, promoting research and advancing the vascular field with a spirit of collegiality and inclusion.

Once again, this year we will collect all oral presentations and live case recordings to include in our online library. This complementary offering will be accessible to all registered delegates a month after the symposium, so that you can review lectures attended or catch up on those that you missed.

VERVE isn't just about the education but the social opportunities as well, and we believe that these should be included as part of your registration. Join us for a glass of Champagne on Thursday night following the completion of the final session, and for the much-lauded Symposium Dinner Party at the Sergeants Mess on Sydney Harbour. These are great opportunities to network with colleagues and catch up with friends. Look forward to seeing you during the meeting.

**Ramon Varcoe**  
Course Co-Director: The VERVE Symposium and LINC Australia

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# Saccular aneurysms: treat them early

**D**uring Friday afternoon's session on complex issues in EVAR, Jacques Busquet (Clinique Chirurgicale Val D'or, Paris, France) discusses the anatomy and endovascular therapy strategy of sacciform aortic aneurysms.

Dr Busquet is a vascular and endovascular surgeon with training in cardiovascular surgery from Bordeaux (France) and London's Brompton Hospital (UK). He specialised in endovascular techniques during their nascence alongside other pioneers in the early 1990s, and is co-founder of the International Society of Endovascular Specialists (ISES).

The uniqueness of the saccular aneurysm, he told *VERVE Symposium News*, boils down to its morphology. Its consequence is that such aneurysms must be recognised as more prone to rupture relative to fusiform morphologies – and treated as such.

"There is definitely something about the pressure inside the sac which makes this morphology more dangerous," began Dr Busquet. He referred to recently published work by Natsume et al. (2016) that provides such evidence. Here, the authors characterised the geometry-flow dynamics in saccular aortic arch aneurysms, building upon previous work associating low wall shear stress with accelerated atherosclerosis, aneurysm growth or rupture.<sup>1</sup>

Natsume et al. carried out multiplanar CT aneurysm reconstruction and 4D-Flow MRI wall shear stress and vortex flow, finding that the saccular aneurysm diameter-to-aneurysm length and sac depth-to-neck width ratios were higher and more variable than corresponding ratios in fusiform aneurysms. As such, fusiform and saccular aneurysms behave differently as they grow: the fusiform type elongates with dilation, with wall shear stress inversely proportional to diameter; on the other hand, saccular aneurysm dilation is not proportional to elongation, with higher and variable sac depth-to-neck width ratio, especially in those aneurysms occupying the inner arterial curve.<sup>1</sup>

"These [methods] gave us some very nice images," commented Dr Busquet. "Since we are dealing with the aorta and an endovascular technique, this reconstructed MRI with the pressure indicated has given a real vision of what is happening in the aorta in terms of

blood pressure and blood perfusion."

He continued, noting that it has also been a goal of his research to understand what happens with these kinds of aneurysms. "And speaking with my colleagues, especially the more experienced ones, they say it is more dangerous. But it was proven by this biomechanical wall stress study."

**“We, the endovascular surgeons of the new era, have been influenced by the closure techniques used for cerebral aneurysms.”**

Jacques Busquet

Speaking of additional methods useful in the elucidation of aneurysmal characteristics, he went on: "First, there is the CT scan, which is always informative, especially regarding the wall itself. Traditional MRI shows the lumen only. The CT scan shows, with injection, the lumen and the wall. That is very useful for the surgeon, to see the quality of the wall: the thickness, sometimes the fineness and the status of the calcification, and sometimes the presence of thrombus.

"Angiography, performed in the operating room before any decision is made, can also be a good adjunct to diagnosis and to the analysis of the morphology of such sacciform aneurysms. You see the exact location of the mouth of the aneurysm, the lateralisation, and also the perfusion inside the sac (is it turbulent, or is it just a little 'fillet'? Is it very pressurised?). This can be very helpful. It is also helpful in the detection of any other aneurysms in the arterial system."

Dr Busquet will also explore the anatomical similarities between aortic and intracranial saccular aneurysms during his talk. While their disease processes – and fates – are clearly distinct, this biomechanical and histopathological overlap has previously been investigated<sup>2,3</sup>. Dr Busquet added: "We, the endovascular surgeons of the new era, have been influenced by the closure techniques used for cerebral aneurysms."

In a 2013 editorial, Frank Criado described the potential consequences of lumping together fusiform aneurysms with their generally rarer counterparts, saccular aneurysms and penetrating ulcers, in the clinical study of stent graft aneurysm treatment. He writes: "Saccular aneurysms are rarely

encountered in the abdominal aorta, but this is not so in the thoracic aorta... The saccular-type aneurysm may be inherently more dangerous because of the increased propensity for rupture at diameters well below the threshold used to recommend elective repair for fusiform lesions." He further notes that, due to its morphology, it is reasonable to conclude that the landing zone required by the sacciform aneurysm is much shorter than that of its fusiform counterpart.<sup>4</sup>

Commenting on these propositions, Dr Busquet said: "Frank Criado – a very good friend, and one of the pioneers – wrote this paper on fusiform versus sacciform aneurysms at the same time that I decided to go into this subject. So we were on the same panels together and spoke together, published together. This

is the real and only paper which is concordant with my talk."

Comparing and contrasting fusiform and saccular morphologies, he went on: "First, this is the same pathology. It is an aneurysmal process of the aorta. A very old surgeon, very well-known in France in the 1920s, Henri Mondor, wrote that every aneurysm must be operated upon. It is the same pathology and it has to be investigated in the same manner.

"Second, there is a difference in morphology, and there is a difference between these two entities in evolution. The characterisation of this kind of aneurysm has to be done clinically with X-ray, MRI, and with angiography.

"Third, you have to treat fusiforms, which have their own evolution, with the rule of Laplace – the bigger the diameter, the bigger the forces on the wall, and by definition the bigger



Jacques Busquet

the risk. Regarding sacciforms, this is something different, because it is a pouch or appendage. Everybody understands that this is at higher risk of rupture.

“Regarding their treatment, in France we have some recommendations regarding the management of aneurysms by endovascular techniques. An aneurysm should be at least 5 or 5.5 cm in diameter to be treated, or a progression of 1 cm in diameter within six months. The third indication is abdominal pain, whatever the diameter. The fourth is sacciform aneurysm, whatever the diameter.”

As such, he concluded, saccular

“This is a topic that should be addressed for the youngest generation of surgeons: don’t wait for 5.5 cm diameter to treat your [saccular] aneurysm.”

Jacques Busquet

aneurysms should be treated as soon as they are diagnosed, and by the use of stent graft or multilayered stent, which may provide additional benefits,

namely reducing vortex velocity and wall shear stress.

“All the most experienced surgeons I have talked with agree to treat early,” said Dr Busquet. “This is a topic that should be addressed for the youngest generation of surgeons: don’t wait for 5.5 cm diameter to treat your aneurysm. If you see a saccular aneurysm, treat it early.

“There are very few articles in the literature speaking of real-world [experience]. This is why we try to demonstrate by experience, by evidence, and by the examination that we have to do before operating, that this type is dangerous. But it is commonly accepted.”

Dr Busquet speaks during Session 2.5: Complex Issues in EVAR: Gender, Difficult Access and Infection, which takes place in Room 2 between 4:00 and 5:30 pm on Friday.

References

1. Natsume K, Shiiya N, Takehara Y, Sugiyama M, Satoh H, Yamashita K et al. Characterizing saccular aortic arch aneurysms from the geometry-flow dynamics relationship. *The Journal of Thoracic and Cardiovascular Surgery*, 2107;153(6):1413–1420.e1.
2. Humphrey JD, Taylor CA. Intracranial and abdominal aortic aneurysms: similarities, differences, and need for a new class of computational models. *Annu Rev Biomed Eng*. 2008;10:221–46.
3. Rouchaud A, Brandt MD, Rydberg AM, Kadivvel R, Flemming K, Kallmes DF et al. Prevalence of Intracranial Aneurysms in Patients with Aortic Aneurysms. *AJNR Am J Neuroradiol*. 2016;37(9):1664–8.
4. Criado FJ. Aneurysm morphology matters: fusiform vs. saccular. *J Endovasc Ther*. 2013;20(2):207–9.

Session 1.14: Challenges in the Treatment of Thoracic Aortic Dissection Room 1 Saturday 2:00–3:30 pm

# Alternative access options for complex EVAR

**K**orana Musicki (Royal Melbourne Hospital, Parkville; Alfred Hospital, Prahran; Epworth Hospital, Richmond; Victoria, Australia) discusses alternative access options for complex endovascular aortic aneurysm repair (EVAR), during Saturday’s session on challenges in the treatment of thoracic aortic dissection.

Dr Musicki will evidence the safety and efficacy of axillary artery access with data pertaining to a series of 38 patients treated at the Royal Melbourne hospital – purportedly the largest patient series to date.

While a great deal more literature exists on upper extremity artery cutdown in EVAR, experience with percutaneous access has recently been reported. From the San Raffaele Hospital (Milan, Italy), Bertoglio et al. (2018) published a patient series with upper extremity access in fenestrated and branched EVAR, with 14 patients undergoing axillary artery access with off-label use of the Perclose ProGlide (Abbott Vascular, USA) device. The investigators noted the adequacy of axillary access in

terms of both vessel calibre and lack of calcifications, as well as proximity to visceral target vessels. They also found the Perclose ProGlide device to be clinically safe and technically feasible with high rates of success.<sup>1</sup>

Harris et al. (2018) also published data pertaining to a series of patients treated at the Albany Medical Center Hospital (NY, USA) who underwent axillary access for endovascular intervention, including 13 patients undergoing complex EVAR. Closure was carried out using both the Perclose and Angio-Seal (Terumo, Japan) devices. This technique was deemed to be a relatively safe and practical alternative to approaches involving exclusively femoral and brachial access.<sup>2</sup>

Alternative access, Dr Musicki suggested to *VERVE Symposium News*, is increasingly relevant during an era of the EVAR population’s expansion, and in particular the increasing adoption of fenestrated and branched techniques, meaning that femoral access may not always be sufficiently accommodating.

“We moved into EVAR in the 1990s,” she said. “Access was still achieved through

a cutdown of the femoral arteries, but these were much smaller than in laparotomy or thoracotomy. Then in the 2000s we got the ProGlide device, which revolutionised what we could do percutaneously. Up until that point, percutaneously we could only manage much smaller sheaths.

“Nowadays we are comfortable with complex EVAR. But we know that femoral access is not enough sometimes and we have to

remain apprehensive about percutaneous upper limb access, falling onto cutdown as a preferred method. Transposing of the femoral skill set, she added, includes bail-out skills: “Much the same as in the femorals, you have the option of cutting down to fix up whatever mess you have made, which happens in < 10% of situations. Our own hospital’s case series shows that, in the hands of those that routinely do percutaneous femoral access

under ultrasound guidance, using your wires with image intensifier guidance, safely deploying your ProGlide – then the chance of ending up with ischaemia in our cases series was 1/38, or about 2%.”

Ischaemic risk due to vessel occlusion during upper and lower limb access is of course ameliorated by use of heparin, explained Dr Musicki. And while the axillary artery accommodates a maximum of a 12 Fr sheath, the upper limbs have the possible advantage of a more generous collateral circulation. Ischaemia, therefore, is not as profound here. Dr Musicki added: “Upper limb access is usually for a shorter period of time than in lower limb access, generally speaking, so maybe if sheaths were in there longer we would see something different.

“However, if there is any ischaemia because of issues with the closure device (e.g. dissection or stenosis), the arms tend to be more tolerant. There was an instance where we had a dissection, but it wasn’t flow-limiting and the upper limb perfusion was preserved. It seemed to right itself. In another case there

“Now that we have got the skill set for percutaneous access and closure, why can’t we transpose that to axillary access?”

Korana Musicki

go for upper limb access. Up until now, we haven’t done upper limb access because we have been a bit precious about cut-downs here. We still do it, much like we still do cut-downs in the femorals. But, now that we have got the skill set for percutaneous access and closure, why can’t we transpose that to axillary access?”

Dr Musicki went on to observe that many

for large-sheath devices, they can successfully use those skills in upper limb access and have very safe outcomes.”

There are particularities of axillary access that must be kept in mind, however. Ischaemic complications can develop, for example, via needle introduction, wiring, or sheath or closure device. “If you do everything in the safest way possible – puncturing

# Alternative access options for complex EVAR

Continued from page 13

was a stenosis and the upper limb was mildly ischaemic, which responded very nicely to angioplasty and the pulses were restored.”

Conversely, haemorrhage is also a risk, and can be caused by inadequate closure: “You are in a deeper area,” commented Dr Musicki. If you are not confident and the closure device has not grabbed enough tissue, then you can get a haemorrhage. That happened in one instance in our series, and the resolution was a

cutdown. Where we advocate to puncture gives us enough room to cut down adequately onto the axillary artery, clamp it and repair it.

“The thing that makes my colleagues nervous about that, as opposed to the femoral artery, is the brachial plexus that is close to the axillary artery. That does encourage a risk in an emergency situation. But, again,

“If you do everything in the safest way possible ... then the chance of ending up with ischaemia in our cases series was 1/38, or about 2%.”

Korana Musicki

it depends on what skill set you are comfortable with. And we have demonstrated that this can be done safely.”

The Royal Melbourne patient series is as yet unpublished. Percutaneous

axillary access has been carried out there since 2012, with Dr Musicki joining the unit in 2016. “I just assumed it was something that everybody is now doing. But when I did a literature review there were only two publications that I could find. Actually, we have the largest case series. We haven’t published, but it is on the agenda.”

Session 1.14: Challenges in the Treatment of Thoracic Aortic Dissection, takes place on Saturday in Room 1 from 2:00 to 3:30 pm.

## References

1. Bertoglio L, Mascia D, Cambiaghi T, Kahlberg A, Melissano G, Chiesa R. Percutaneous axillary artery access for fenestrated and branched thoracoabdominal endovascular repair. *J Vasc Surg.* 2018;68(1):12-23.
2. Harris E, Warner CJ, Hnath JC, Sternbach Y, Darling RC 3rd. Percutaneous axillary artery access for endovascular interventions. *J Vasc Surg.* 2018;68(2):555-559.



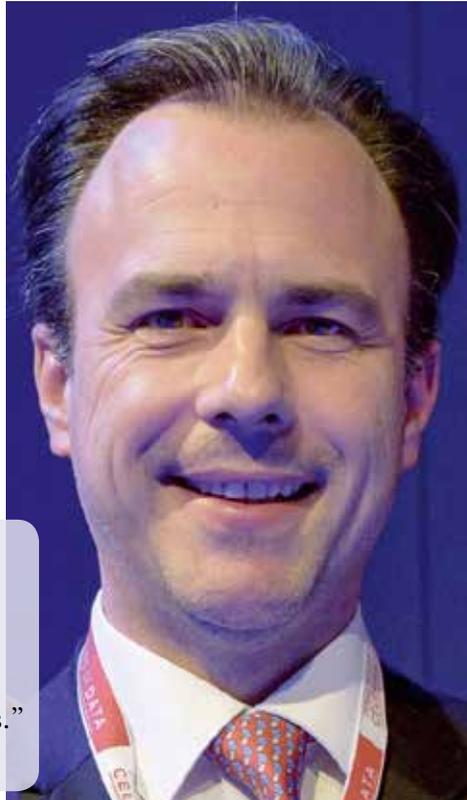
# Putting TASC C and D iliac stenting to the test

**T**he Belgian Trial Investigating the LifeStream Stent in Complex TASC C and D Iliac Lesions (BELSTREAM), will be laid bare by Koen Deloose, head of the vascular surgery department at AZ Sint Blasius Dendermonde, Belgium, who will relay the drivers behind the genesis of the trial, its endpoints, and present some of the first cases enrolled. In an interview with *VERVE Symposium News*, Dr Deloose underlined that his department has always been oriented heavily towards endovascular procedures, and clinical trials too. “I have tried to continue this philosophy and nowadays we are treating more than 90% of our patients in an endovascular way.”

Essentially, the idea for a trial was prompted by a now famous meta-analysis<sup>1</sup> which established – for the first time – that stenting is the most successful procedure in the iliac space. “Other people were

“In the more complex TASC C and D iliac lesions, COBEST showed there was a clear advantage in terms of freedom from re-stenosis for the covered stents over the bare-metal stents.”

Koen Deloose



still in doubt and tried to say that angioplasty alone was sufficient,” said Dr Deloose. “This meta-analysis clearly showed that stenting was the way to go.”

Of course, stenting also has its disadvantages including a risk of distal embolisation and perforation, noted Dr Deloose. In addition, there are problems associated with kissing stents. “From the moment the aortic bifurcation is involved, the kissing configuration is also a consideration, as it can show more stenosis than normally accepted,” he explained. “And so, based on this, there were some initial studies with covered stents to see the result in the kissing configuration as well as to avoid the aforementioned potential complications of distal embolisation and perforation. In other words, to see if these covered stents are doing a better job.”

There are existing observational studies on covered stents, but possibly the most rigorous, today, is the Covered Versus Balloon Expandable Stent Trial (COBEST),<sup>2</sup> a prospective, multicentre, randomised controlled trial of 168 iliac arteries in 125 patients with severe aortoiliac occlusive disease who were randomly assigned to receive a covered balloon-expandable stent or bare-metal stent. “Professor B. Patrice Mwapatayi showed very clearly that in the treatment of simple TASC A and B iliac lesions, there is no difference between regular bare-metal stents and covered stents,” said Dr Deloose. “In the

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# Putting TASC C and D iliac stenting to the test



“Some of the companies with covered stents really need to have the courage to do randomised controlled trials to see, finally, which is the best device to treat these complex TASC C and D lesions.”

Koen Deloose

eminently successful: “The delegates will see at the end a perfect realigned artery on both signs without any complications, or distal embolisation,” continued Dr Deloose.

In the future, Dr Deloose said he'd like to see more in the way of randomised controlled studies focussing on other devices. “The weak point about this trial that

it is a single arm study,” he said. “Of course, it would be better to have a randomised study, like COBEST, except with the other covered stents that are available right now. But with randomised trials then you need a bigger budget and sample size.”

Such trials must be the future, said Dr Deloose.

“Some of the companies with covered stents really need to have the courage to do randomised controlled trials to see, finally, which is the best device to treat these complex TASC C and D lesions,” he stressed.

Until that happens, said Dr Deloose, a good compromise is to emphasise the advantages of covered stents compared to bare-metal stents. “I want to show, with this trial, that other devices can reach similar results in the complex TASC C and D lesions,” he said. “But ultimately we need to wait until next year when I can present hopefully the six and 12 month-results to see if this device is really doing a great job.”

## References

1. Ye W Liu CW, Ricco JB, et al. Early and late outcomes of percutaneous treatment of Transatlantic Inter-Society Consensus class C and D aorto-iliac lesions. *J Vasc Surg.* 2011;53(6):1728–1737.
2. Mwiripatayi BP, Thomas S, Wong J et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease. *J Vasc Surg.* 2011;54(6):1561–1570.

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more complex TASC C and D iliac lesions, COBEST showed there was a clear advantage in terms of freedom from re-stenosis for the covered stents over the bare-metal stents.”

Based on this information, Dr Deloose pursued similar analysis of another covered stent in the marketplace, the LifeStream Peripheral Stent Graft System (BD / CR Bard, USA), focussing in the treatment of iliac stenotic or occlusive lesions. It's a physician-initiated prospective single-arm multicentre trial investigating the graft specifically for complex TASC C and D iliac lesions. Initiated in November 2017, the trial plans to enrol 70 patients with a primary endpoint of primary patency at one year, as determined by duplex ultrasound. The primary safety endpoint is freedom from empirical serious adverse events.

Secondary endpoints include technical success

rates, primary patency at one and six months, occlusion of the graft at one, six and 12 months, amputation rate and clinical success rate.

The biggest challenge has been enrolment, noted Dr Deloose. A little over a year in to the trial, there have only been 37 enrolled cases. “That's because TASC C and D lesions are not that easy to find, and in a number of hospitals all over the world these patients are treated in an open surgical way,” explained Dr Deloose.

Turning back to his presentation, Dr Deloose noted that he will include a few cases with immediate procedural success rates. “One patient, at the start, had quite disastrous full occlusion of the iliac on one side with a high-grade stenosis on the other side. According to TASC recommendation guidelines this should be operated on in a classical way – in an open way,” he said.

However, an endovascular approach was



# ‘Use dedicated venous stents!’

An expert opinion on deep venous stenting, including patient selection, techniques and clinical outcomes will be showcased on Friday afternoon. Speaking to *VERVE Symposium News*, Michael Lichtenberg (Karolinen Hospital, Arnsberg, Germany) outlined some of the key aspects that he is eager present for the audience, particularly an emphasis on the use of dedicated venous stents.

## How important are dedicated venous stents? Are radial force and flexibility particularly crucial characteristics?

PTA stenting of a post-thrombotic vein with intraluminal scarring, and frequently also with external compression, is not similar to arterial PTA stenting in the presence of arteriosclerosis. Stents for venous recanalisation are required to fulfil their own standards. Therefore, special stents have been developed for interventions in the iliac veins. The diameter of veins is larger than the diameter of the corresponding arteries, for instance stents with a diameter of 14–18 mm are used for iliac vein recanalisation.

Other key points include:

1. Longer stents are needed because the post-thrombotic lesion is usually elongated. The use of several overlapping stents does not resolve this problem adequately because it reduces flexibility.
2. Post-thrombotic veins are often scarred over a longer area. Furthermore, an additional external compression may be present, such as May-Thurner syndrome, therefore, we need stents with high radial force.
3. Venous recanalisation requires very flexible stents which can be aligned to the anatomical course of the veins even during movement –not vice versa. Especially in the iliac confluence, at the junction between the external iliac vein and the common iliac vein, angulation is at its highest (ranging up to 90°) in the sitting position.

## What aspects of patient selection are important to consider?

Firstly, don't treat the lesion, treat the patient! Secondly, ascertain whether the lesion can be stented to a high patency rate. Patients with clinical symptoms in accordance with the CEAP (clinical, etiologic, anatomic and pathophysiologic) classification



“Patient selection is the most crucial aspect for venous outflow obstruction treatment. Patients are usually young and need to live with the endovascular outcome for their whole life.”

Michael Lichtenberg

3–6 should be scheduled for revascularisation therapy when the clinician finds evidence of an iliac vein obstruction affecting the patient's haemodynamic condition.

In addition to the CEAP classification, currently the VCSS score, the CIVIQ-20 score, the VEINES-QoL score and the Villalta score permit a much better classification of objective and subjective venous symptoms in the presence of chronic venous disease. These validated and established scores should be used as standard procedures when following patients after surgery in order to assess their clinical progress.

One limitation of the scores is that they do not register whether a patient has a venous claudication. The latter has a major impact on physical capacity, especially in young patients. In terms of clinical appearance, venous claudication does not differ from

pain due to arterial causes, but the duration of pain is usually longer after a stress phase, and is an expression of high venous pressure in the lower leg under stress. Phlebodynamometry is performed to obtain objective evidence of elevated venous pressure. Finally, venous claudication is an indication for pelvic vein recanalisation.

**How important is it to strive for a perfect circular stent after placement, in terms of improving flow? I believe you have looked into stent compression and its correlation with patency?**

Stents implanted in the iliofemoral veins are subjected to both external compressions at “anatomical choke points” and/or recurrent postthrombotic stenosis. Increases in area should correlate with greater flow volume and reduced peripheral venous pressure. The ability to predict patient outcomes through assessment of stenosis using different imaging modalities has also been recently published. Gagne, et al.<sup>1</sup> found that a threshold stenosis of 54% was optimal to indicate stenting in venous outflow obstruction, correlative with future clinical improvement. The threshold was higher, 61%, in the subset of non-thrombotic patients.

If we examine the theoretical science of fluid dynamics on flow rate, volume, and pressure, can we apply this to stenting of venous outflow obstruction in the treatment of venous disease? It follows, that there may be other technical performance characteristics of venous stents that bear investigation, as we seek to better understand the relationship between stent performance and patient outcomes.

Lumen shape is defined by aspect ratio, expressed as a ratio of maximum diameter to minimum diameter. A perfect circle has an aspect ratio of 1. As the ovality of the vein increases, so does the aspect ratio. When a perimeter is held constant, the area is dramatically different for various shapes, from a perfect circle to that which is dramatically oval, and flow volume is dramatically reduced with an increase in ovality. The science also demonstrates that, in order to maintain the same flow rate, measured as L/min, an increase in pressure would be required to overcome the resistance in flow due to the flatter shape.

**You will be sharing your experience with the Venovo and Veniti Vici Venous stents (BD/CR Bard, USA). Can you give us a glimpse of what you will be presenting?**

We sought to determine the patency and clinical symptom relief of the Venovo venous stent in the endovascular treatment of non-thrombotic (NIVL) or post-thrombotic venous obstruction (PTO) of the iliofemoral track over a period of six months. A total of 80 patients (45 female, mean age 57 years) treated in

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# ‘Use dedicated venous stents!’

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2016 and 2017 were included in the Arnsberg venous registry. Clinical improvement was determined by the revised venous clinical severity score (rVCSS) as well as the CEAP score. Primary and secondary stent patency was evaluated using Duplex ultrasound.

Overall six-month patency rates were 98% (primary) and 100% (secondary). For NIVL, primary patency was 97%, whereas for PTO primary patency was 96%. Early stent re-occlusion occurred in three patients within 34, 59 and 156 days after intervention. Two of these patients were successfully treated by endovascular mechanical thrombectomy and stent-in-stent implantation. Clinical improvement with a gain of  $\geq 2$  rVCSS

levels was observed in 51%. CEAP scores decreased from 4.3 to 2.7.

In this first-time report, the novel Venovo venous stent showed adequate patency rates associated with reasonable clinical improvement and low device-related complications throughout a six-month follow-up in both NIVL and PTO. 12-month follow-up data will be presented at the VERVE Symposium.

Finally, I will also present first prospective registry data for the Veniti stent from the Arnsberg registry

**What’s your final words on the importance of patient selection, technique and clinical outcomes**

“Venous recanalisation requires very flexible stents which can be aligned to the anatomical course of the veins even during movement – not vice versa.”

Michael Lichtenberg

successfully recanalised with good inflow and outflow. For the procedure itself, you always need to be prepared for bail-out techniques (hybrid operation, endophlebctomy, AV-fistula, etc.) to establish inflow. It is obsolete [thinking] today not to use dedicated venous stents for venous outflow obstruction treatment.

## in deep venous stenting?

Patient selection is the most crucial aspect for venous outflow obstruction treatment. Patients are usually young and need to live with the endovascular outcome for their whole life. It is therefore the task of the individual endovascular specialist to answer the question if a patient can be

## References

1. Gagne PJ, Gasparis A, Black S, et al. Analysis of threshold stenosis by multiplanar venogram and intravascular ultrasound examination for predicting clinical improvement after iliofemoral vein stenting in the VIDIO trial. *J Vasc Surg: Venous and Lym Dis.* 2018;6:48-56.



# LUCY registry finds gender equipoise at one year post-EVAR

**T**he TriVascular Evaluation of Females Who Are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair (LUCY) released its one-year final results earlier this year. Presenting its principle findings on Friday morning is Jennifer Ash (Christie Clinic Vein & Vascular Center, Peoria, IL, USA).

LUCY is the prospective, consecutively enrolling, non-randomised, multicentre post-market registry evaluating the Ovation Abdominal Stent Graft System (Endologix, USA) for the endovascular treatment of abdominal aortic aneurysms (AAA) in women. The study enrolled a total of 225 patients, including 76 females and 149 male controls, at 39 US sites. The primary endpoint of the study was 30-day major adverse event rate, with secondary endpoints including serious and non-serious adverse events through one year.<sup>1</sup>

Speaking to *VERVE Symposium News*, Dr Ash described why women tend to be underrepresented in EVAR trials, and how their more complex aortic anatomy tends to give rise to inequalities in reported outcomes of EVAR. “Historically, women have been underrepresented because they just don’t, generally speaking, meet the inclusion criteria,” she said. “That seems to be primarily due to either small access or more complicated proximal and distal anatomy in terms of angulation, calcification and those sorts of things. Generally speaking, because of that, women just haven’t had the opportunity to participate in most of the aneurysm trials to date.”

Calls have been made for the improved management of women in AAA<sup>2</sup>, due to their poorer prognosis evidenced in retrospective study. While there is a higher rate of undiagnosed cardiovascular disease in women, AAA

repair is also often delayed in women and applied at older age<sup>3</sup>. In a recent systematic review, Stoberock et al. evaluated gender differences in AAA treatment carried out between 1999 and 2018, finding that women have a higher rate of complications and longer hospitalisations compared to men, and that they seem to have a higher risk of rupture, a lower survival rate in AAA, and a higher rate of complications, regardless of endovascular or open treatment.<sup>4</sup> Nevertheless, in

“Because we generally assume that women are more high risk and more prone to perioperative complications, women are often turned away from treatment.”

Jennifer Ash

addition to more dedicated study of women, advancements in endograft devices have been proposed as a solution to anatomy-dependent and hence sex-dependent adverse outcomes in EVAR<sup>5</sup>.

“Historically, if you look at outcomes in terms of women and aneurysmal disease regardless of the treatment – be it open or endovascular – generally speaking women fare worse than their male counterparts,” confirmed Dr Ash. “That has been shown time and time again. There are a few more contemporary trials that perhaps have argued that that is not always the case. But as a general rule women fare worse.”

“What makes this very interesting and unique is that it provides an opportunity for people to look at when and how they treat women with aneurysmal disease. Because we have a lot of data to steer us away from treating women with aneurysmal disease, we find that women are achieving treatment far less than their

male counterparts. Because we generally assume that women are more high risk and more prone to perioperative complications, women are often turned away from treatment. So that is also part of the reason why we see higher rupture rates than the men and higher death rates when they are diagnosed with aneurysmal disease.”

Dr Ash explained that the Ovation system (and potentially others that come to market) addresses anatomic issues with a small delivery size (14 Fr), flexibility and hydrophilic coating. “These all lend themselves to providing a platform upon which you can build a treatment option for women with aneurysms.

“What is important about this particular trial, and probably some of the data that this trial has now stimulated, is that there are ways in which we can safely and effectively treat women with aneurysmal disease.”

The results of LUCY demonstrated that at least 28% more women are eligible for EVAR when using the Ovation

system. And, despite having more complex anatomy than men, women experienced

“There are ways in which we can safely and effectively treat women with aneurysmal disease.”

Jennifer Ash

similar outcomes to men at one year, including freedom from AAA-related mortality (100% in women vs 98.6% in men), freedom from reintervention for type 1A endoleak (98.6% in women vs 97.9% in men), freedom from rupture (100% in both groups), freedom from conversion (100% in both groups), and freedom from all device-related reintervention (97.2% in both groups).

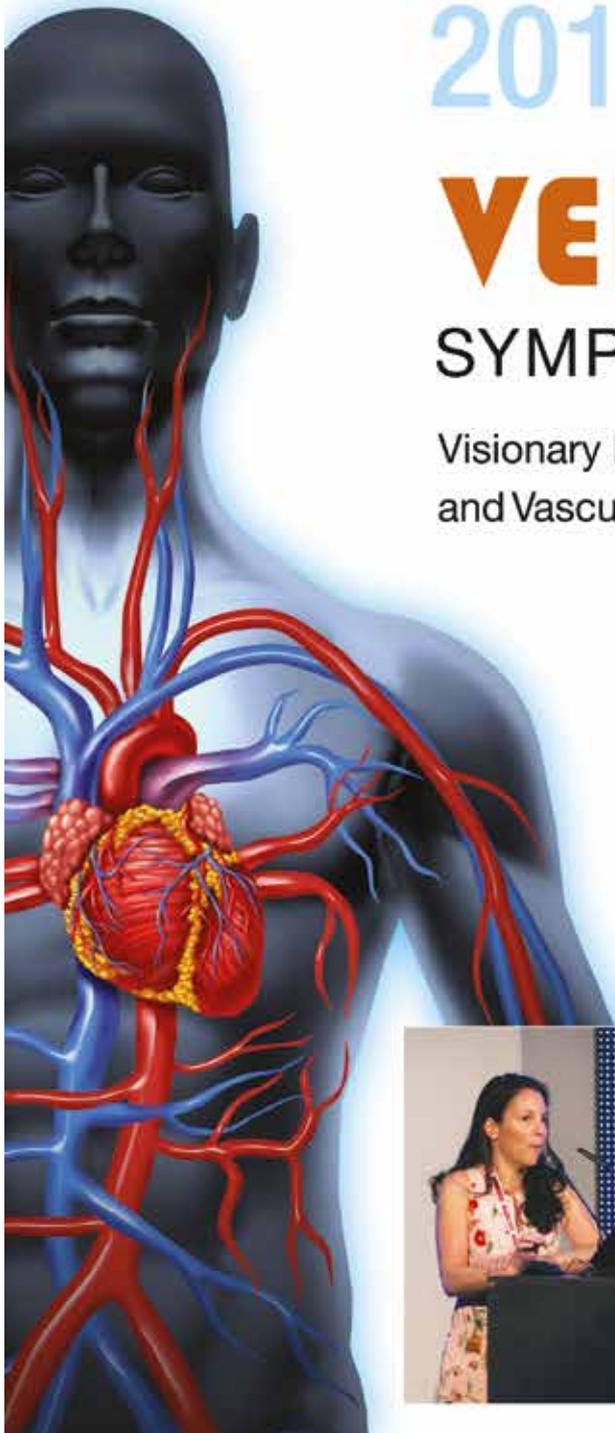
“What is significant about this trial is that it is non-significant,” confirmed Dr Ash. “When you look at trials – or at least results that are reported comparing women to men – there are always significant differences between their outcomes. At least in this population with this stent graft, women can be treated as safely and as effectively as men.”

In her concluding remarks, Dr Ash addressed why there were no plans to extend follow-up of patients enrolled to LUCY: “Generally, when we look at some of the data previously reported, we see those poor outcomes in women typically within the first 30 days and sometimes within the first year. The aim of this study was to demonstrate that we can overcome those odds. The study has done that successfully.”

## References

1. LUCY Study: TriVascular Evaluation of Females Who Are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair (LUCY). *ClinicalTrials.gov* <https://clinicaltrials.gov/ct2/show/NCT02479191> (accessed Dec 2018).
2. Ulug P, Sweeting MJ, von Allmen RS, Thompson SG, Powell JT; SWAN collaborators. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis. *Lancet*. 2017;389(10088):2482-2491.
3. De Rango P, Simone G, Manzone A, Farchioni L, Cieri E, Verzini F et al. Mortality Risk for Ruptured Abdominal Aortic Aneurysm in Women. *Ann Vasc Surg*. 2017;39:143-151.
4. Stoberock K, Köbel T, Atlihan G, Debus ES, Tsilimparis N, Larena-Avellaneda A et al. Gender differences in abdominal aortic aneurysm therapy - a systematic review. *Vasa*. 2018;47(4):267-271.
5. Chung C, Tadros R, Torres M, Malik R, Elozy S, Faries P et al. Evolution of gender-related differences in outcomes from two decades of endovascular aneurysm repair. *J Vasc Surg*. 2015;61(4):843-52.



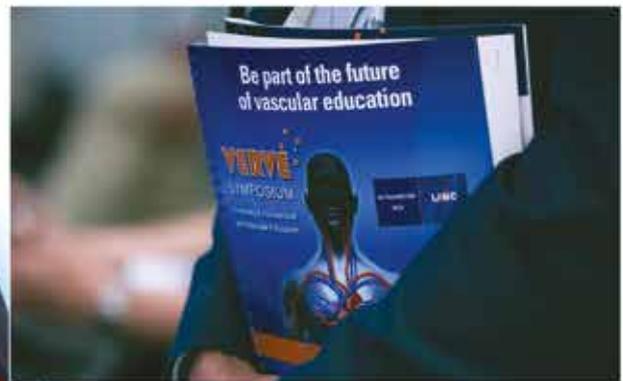


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