VERVE DAILY NEWS

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CONTENTS

Coming to you live from Sydney...

Shannon Thomas and his Prince of Wales team present the first live case of VERVE 2015

The first session at VERVE 2015 commenced with a live case from Sydney's Prince of Wales Hospital, where operator Shannon Thomas was joined by Andrew Lennox and Victor Bourke to undertake a challenging case of bilateral ischaemia of the legs with extensive vessel occlusion.

The patient, a 57 year-old male and smoker of 20 pack-years, was experiencing bilateral ischemic rest pain with recurrent ulceration. He was largely invalid due to the severity of rest pain. He did not have any known ischemic heart disease, COPD or renal impairment.

"He tells me that he saw another surgeon in a rural area who actually recommended bilateral amputations," explained Dr Thomas. "That is why the plastic surgeons had sought us for a second opinion."

CT angiogram indicated a largely patent aorta, relatively spared of disease as far as the inferior mesenteric artery (IMA). Three cenimetres of occlusion followed down to the common iliac arteries, which were circumferentially calcified. These occlusions extended as far as the distal external iliac vessels, although circumflex vessels were supplying the common femoral arteries. On the left-hand side, the superficial femoral artery was also occluded from the ostium. On the right-hand side, the mid-superficial femoral artery was occluded.

> "This is a case that only became possible in a reliable way due to the availability of covered stents."
>
> Dierk Scheinert

The aorto-iliac bifurcation was heavily diseased, noted Dr Thomas, with occlusion of the origin of the internal iliac arteries present. As such, the IMA and lumbar arteries, feeding the lower legs, were large and prominent, indicating the long-standing nature of the presently evident occlusions.

Opting for endovascular reconstruction by stenting of the segment of the aorto-iliac bifurcation to the common femoral arteries, Dr Thomas explained some of the factors that played into the team's pre-operative decision-making: "Because of his young age, we wish to preserve the future bypass option, should that need arise in the next 10 or so years.

"The plan is to do reconstruction using Viabahn covered stents (Gore Medical, USA) in a double-barrelled fashion, bringing wires up from both groins through the chronic total occlusion, aiming to re-enter exactly where the IMA is coming off. We also do not want to cover those circumflex collaterals with these covered stents, which seem to be an important collateral supply to the legs. So we will use bare stents at that point; you can see that those vessels are still quite diseased where those re-enter. Then we will post-dilate the whole system."

With a view to the possibility of open surgery, he highlighted the preservation of

Continued on page 2

Session I: Challenges and Unmet Needs in Peripheral Intervention Thursday **1:00–2:30pm**

Coming to you live from Sydney...

Continued from page 1

a significant proportion of the infra-renal aorta for possible proximal anastomosis, as well as the preserved groin should a demand for distal anastomosis makes itself known with time.

The team combined brachial and groin access, puncturing the arm with a 6 French sheath, placing a 0.014" protection wire into the IMA to allow for bail-out stenting should the IMA become occluded in the process of stenting the aortal segment. Groin access was achieved using two 5 French sheaths. The patient was administered high-dose heparin and lesion crossing was carried out with a Glidewire (Terumo, Japan).

Commenting on the case planning, panel member Andrew Holden said: "One of the things I look at in these cases is the quality of the common femoral artery and the run-off…I think that is something I want to be careful of. And obviously if you can preserve those inferior epigastric arteries, I think that is important. Using covered stents there is important. That is one technical issue.

"In terms of how you reconstruct the aortic bifurcation, obviously you can use a CERAB [covered endovascular reconstruction of aortic bifurcation], a single big stent and then stents within it, or you can use single tubes or a double-barrelled approach. I don't think that, with a short aortic occlusion like this, this is very important.

"I am a little concerned, given the degree of calcification, as to how well the Viabahn stents on their own will maintain the lumen. I would be cautious about not relining those with balloon-expandable stents as well; we have a lot more experience with balloon-expandable stents in terms of durability. I like the idea of the safety wire in the IMA, because it is obviously a big collateral."

Noting that calcification is a major procedural barrier in a case like this, Ramon Varcoe asked fellow session chair Dierk Scheinert what his approach would be with respect to the use of balloon-expandable stents to shore up already-deployed covered stents. "To have a good understanding of the degree of calcification is important," responded Professor Scheinert. "That is why a CT is really essential to get a good impression. Maybe a balloon-expandable stent, particularly in these highly calcified areas, would be appropriate. However, the length of those devices is a limitation so you would need to overlap several. Placing a Viabahn and potentially augmenting certain areas with a balloon-expandable stent may also potentially be a good solution."

With respect to choice of access, he continued: "We would probably traditionally cross the lesion first with a brachial approach from above, just to have a good alignment in the aortic segment. [Dr Thomas] is struggling a little bit here to get a good re-entry; sometimes you dissect here into the aortic wall. However, preserving the circumflex is also important so probably a bilateral approach – primarily crossing from above and then using a second sheath wire from below, maybe even with a double balloon technique – is probably the way we would approach that."

These comments were well met by Dr Thomas, who confirmed that they would indeed reinforce the covered stents should they not provide sufficient radial pressure on their own.

"From an interventional standpoint, not being a surgeon," continued Professor Scheinert, "I would say that this case is stretching the limits of endovascular surgery a bit. I think it is doable, and I think this case illustrates that. This is a case that only became possible in a reliable way due to the availability of covered stents. Of course ten years ago we also did cases like this with non-covered stents, but I truly believe that we are getting better reconstruction with covered stents."

Contributing thoughts on his approach to procedural planning, Koen Deloose highlighted the importance of evaluating outflow, to ensure that it will be sufficiently expanded as a result of the chosen intervention: "It has been proven quite clearly in a lot of studies that outflow is really determining the final result of your endo procedure (also of your open procedure)," he said.

> "In cases like this one the radial force of the device is more important than whether it is covered, non-covered, or whatever."
>
> Koen Deloose

"But I also want to stress the inflow. If the aortic occlusion is running up through the renal arteries, this is for us also a clear indication for open surgery; we try to avoid embolisation in the renal arteries."

With a word on the changing landscape of endovascular interventions, Michael Jaff questioned how well-trained vascular surgeons will be in the future in open aortic surgery.

"That is a point that we struggle with in this form of occlusive disease, as well as aortic disease particularly," responded Dr Varcoe. "What we seem to be seeing in [Australia] is not so much endovascular centres of excellence (because the majority of centres are performing endo to some extent), but more traditional open centres where trainees are seeking them out to gather those open skills that are a lot harder to come by sometimes."

Generally, the panel agreed that approaching from above offered advantages, giving assurances in terms of solving problems associated with re-entry into the aorta, an allowing safe predilatation from above.

Highlighting the importance of considering the possibility of restenosis, Professor Scheinert explained that the covered stent ought to fare better than bare metal at limiting intimal hyperplasia. This physical barrier provided by the Viabahn covered stent was discussed by Dr Deloose, who noted that the RELINE trial, although a study of in-stent restenosis, demonstrated its value. "Of course, right now we are discussing native pathology," he asserted. "The RELINE results of the Viabahn in in-stent restenosis are tremendously good to avoid more intimal hyperplasia and to take the stimulus for in-stent restenosis away from the equation. But of course, in cases like this one

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the radial force of the device is more important than whether it is covered, non-covered or whatever.

"In cases like this with aortic bifurcation reconstruction, there are cases of radial mismatch. It is clearly proven in some in-vitro models that if you put two self-expandable stents or stent grafts next to each other at the bifurcation, you create a lot of dead space – dead space where you have afterwards some mesenchymal tissue growth. Finally, this is a stimulus for restenosis. So this is, for me, an argument for the double-barrelled technique or a CERAB technique where balloon-expandable stents are fitted to each other to reconstruct the bifurcation."

The operating team crossed the occluded vessel segment from both sides. Subsequent angiography confirmed re-entry and IMA preservation, and some return of flow to the common iliac arteries was observed. Two Supra Core wires (Abbott Vascular, USA) were inserted via each arm, and a pigtail catheter was used to measure the exact length of the stenting segment, which was found to be approximately 20cm. Bringing up an 8 French sheath through which to deploy the Viabahn covered stent, the team encountered mild resistance in the common iliac, which they remedied using an expanded balloon.

"We are using the balloon as a trocar here," said Dr Thomas, explaining that they had also predilated the aorta. "It is quite tight. We are then going to bring the 8 French sheath up from one and then the other side, probably using the balloon as a trocar. Once we have our two 8 French sheaths in from the bottom, we will then deploy our first set of Viabahns, and then the second set. So it will be 8mm at the top and 7mm, and then bare stents at the bottom. I presume that there will then be a lot of post-dilatation that we need to do. At that point we will put a balloon at the ostium of the IMA."

Asked whether he would always protect the IMA in complex cases such as these, Dr Thomas responded: "If I was doing this case not as a live case, I wouldn't be protecting the IMA! The celiac artery is patent; the SMA is patent. There is a nice collateralisation between all three of these vessels. The IMA is, I believe, patent and quite big, because it is feeding the feet. Because it is an important collateral supply to the feet, it is not really my belief that, if we did take out the IMA, we would get an ischaemic gut. However, in the interest of being diligent, we will demonstrate that we are protecting it. The plan is that, when the stents go in, if we do have some problems with the IMA we have our pre-emptive wire access and we can do whatever we need to."

In response to this, Dr Holden noted that protecting the IMA with a temporary balloon or filter could not be justified in terms of embolic risk. With a wire in place, he reasoned, a parallel stent could be placed in order to restore patency if the IMA was lost in the process of stent reconstruction.

"It is very important that you assess the superior mesenteric artery (SMA) thoroughly at the point of doing the procedure," he added. "Because this will influence your decision-making. If you have SMA circulation in collateral pathways that are intact, it is not a bowel issue; it is really to maintain the potential collateral pathway should one of your reconstructions go down in the future. In practise, it is something that is nice to do as long as it doesn't add a lot of complexity and risk to the procedure. I don't think it does, because of your access with a .014" wire. It's pretty low profile."

Sagittal CT imaging demonstrated the extent of disease in the aorta above the IMA, encroaching on the renals. Asked how far he intended to carry the main iliac stenting, Dr Thomas responded: "When we have looked at the CT scan, there is a little bit of thrombus and disease lining the infrarenal aorta. But there is a nice 'sweet spot' about 1 to 2cm above the IMA take-off. We will be able to see where that is, and then we can just land above it. When we deploy our stents we are going to have a balloon in that IMA origin; that way, it will be protected when the stents go in from the bottom end."

Comparing the double-barrelled technique with the CERAB technique, he went on to say that, while the latter is very well described and efficacious, the distal segment is left with bare stents, despite the aortic bifurcation being reconstructed. "What we want to try to do here is move the bifurcation proximally, and do it in such a way that preserves future bypass options," he stressed. "I don't want to have an unnecessary amount of stents sitting close to the renal arteries, which might happen depending on how we would configure this CERAB technique. Those where some of the things that I thought about in deciding which way to go with this patient – mainly anatomical factors.

"We have a couple of patients that had this CERAB technique for whom we had to do open surgery afterwards," responded Dr Deloose. "I can say to you that if you are really doing the CERAB in the correct way, and not too close to the renal arteries, there is no contraindication to doing open surgery. I did not encounter one technical complication because of a previously-done CERAB. So this is not really an issue. But if it is too close to the renals then I fully agree with you; if it is too close to the renals this is for us one of the last indications – besides endovascular failures – for open surgery."

Commenting on the general mood of the audience, Michael Dake said: "We have to beware the courage of the non-combatant here! There are many, many ways you can do this; there is clearly no wrong or right way. We have no relative outcomes analysis to direct us. What can be said about being right under the renals, is that this is the type of case that you need to be very wary with."

The two Viabahn stents were placed successfully, preserving the IMA. The entire system was post-dilatated, using 0.6 x 10cm Fox balloons (Abbott Vascular). While mild residual stenosis was evident in the Viabahn stents, the IMA demonstrated good flow. This proximal section was then ballooned to 7mm in order to relieve some of the residual compression. A XIENCE Prime (4 x 38mm; Abbott Vascular) was deployed into the IMA segment as a protective measure during the more aggressive angioplasty.

Post-intervention angiography demonstrated patency of the IMA, as well as some of the lumbar collaterals. As a result of revascularisation, the circumflex iliac vessels was now filling in the correct direction. The patient demonstrated good groin pulse and iliac pressure. Dr Shannon noted that the patient would be placed on dual antiplatelet therapy for at least six months.

> "We have to beware the courage of the non-combatant here! There are many, many ways you can do this… We have no relative outcomes analysis to direct us."
>
> Michael Dake

One of the key issues of the procedure related to the expansion of the two Viabahn stents at the bifurcation, which were residually compressed, with a slight indentation remaining visible on the left side despite good flow.

"To me, this looks like a very good result," commented Professor Scheinert. "If you don't go for the CERAB technique, you probably cannot expect to get an absolutely perfect alignment of these iliac stents into the aortic segment. So I think this step has to be accepted. Functionally, this is a very good result."

Session XI: Latest Techniques and Technologies for the Treatment of Lower Limb Ischaemia Saturday **9:30–10:45am**

Image fusion in peripheral procedures

> "It is much easier and safer when you do all of this pre-operative work, and fuse it during the procedure with your live image."
>
> Koen Deloose

This morning's session dedicated to the latest techniques and technologies in lower limb ischemia management explores the cutting-edge devices, monitoring and therapeutic options aiming to increase the scope of success in this challenging arena.

Advanced imaging strategies have the capacity to improve anatomical understanding in procedural planning, as well as guiding the procedure itself. Koen Deloose (AZ Sint Blasius Hospital, Dendermonde, Belgium), who opens the session with a discussion of GE Healthcare's Discovery 740, a mobile angiography system designed for hybrid operating rooms, spoke to *VERVE Daily News* about the advantages that such technologies can bring – not only in improving procedural efficiency, but crucially in reducing radiation exposure for both operators and patients.

"You see everywhere the use of fusion and 3D reconstruction and other things," said Dr Deloose. "Because I am mainly interested in peripheral work, my question was, can we transfer the enthusiasm in imaging that is in the fields of EVAR, TEVAR and TAVI nowadays to the peripheral area? I discussed this with the engineers and people at GE and yes, definitely we can. This is brand new technology, and it is the first time we are using it."

During his talk, Dr Deloose will share some examples of how his team have used the system since its purchase a year ago. He explained how, by performing pre-operative MR or CT imaging, image processing can be carried out quickly and semi-automatically using a pipeline whose steps include bone removal, vessel segmentation, and lumen tracking for demarcating the vessel occlusion.

"The software is very intuitive in doing this," commented Dr Deloose. "For me, it is important that it does not involve extreme IT hocus pocus. There is a line drawn onto the occlusion, which I can adjust manually if it is not correct, based on calcifications and other things. Then when I have done this work, which takes just a couple of minutes, I can save it and keep it until I am doing the procedure."

During the procedure itself, the pre-operative image can be fused with live intra-operative imaging in order to improve visual guidance: "I can perfectly see where I need to start to recanalise. I can follow the line perfectly with my wire, so that I am not entering collaterals or other things. I can perfectly see where the re-entry zone is without adding more contrast – all of this is just based on this fused line.

> "If I see what (for example) the Belgian government is investing in safety and radiation protection and so on, I think it is very worthwhile to invest money in this."
>
> Koen Deloose

"It is much easier and safer when you do all of this pre-operative work, and fuse it during the procedure with your live image. You can easily monitor and follow all of the steps…It is safer for the patient and for the staff."

Dr Deloose stressed that this safety was both in terms of radiation exposure and presumable procedural success, adding that with the gains in technical understanding over the past decades that have made way for the treatment of increasingly complex cases, we have witnessed the vast expansion of the role of the endovascular team whose parallel increased exposure to radiation cannot be overlooked.

"We are performing procedures from Monday morning up to Friday night," he continued. "All of our staff are irradiated all of the time with very high doses of radiation. We try to limit exposure as much as possible and take all of the precautions to avoid all of the very bad, unhealthy consequences of radiation exposure."

Although the ALARA principle (As Low As Reasonably Achievable) has been adopted in order to minimise radiation exposure in such settings, additional safety demands entailed by higher workloads may be met in many ways by the capabilities of newer imaging systems: "There are two goals that I want to realise with this machine and with these techniques: the goal is of course to make it easier for me, but the most important thing is to restrict radiation and the contrast media."

Significant reductions in radiation exposure may be achieved with hybrid systems such as these; but muddled into the ethical decision to safeguard staff and patients is the financial burden that they bring – a burden that not all healthcare systems can shoulder. "This is the big problem," conceded Dr Deloose. "The hybrid room costs almost 2 million dollars. But on the other hand, if I see what (for example) the Belgian government is investing in safety and radiation protection and so on, I think it is very worthwhile to invest money in this.

"It is especially important in endovascular services for people like me. But yes, it is about investment, cost-effectiveness and cost-safety. This is a difficult question relevant to all healthcare organisations all over the world."

Dr Deloose will go into further detail on this topic during his talk, 'When Advanced Imaging Enters the Field of Complex Lower Limb Disease Management,' taking place during Session XI: 'Latest Techniques and Technologies for the Treatment of Lower Limb Ischaemia,' between 9:30 and 10:45 this morning. He co-chairs the session with Giancarlo Biamino.

Session XI: Latest Techniques and Technologies for the Treatment of Lower Limb Ischaemia Saturday **09.30–10.45am**

Can we improve outcomes with 2D perfusion angiography?

The development of novel imaging techniques in critical limb ischemia could help to illuminate the state of a patient's limb before an intervention, as well as serving as a prognostic tool. With that in mind, the use of adjunctive 2D perfusion angiography in CLI will be discussed this morning by Jos van den Berg, who spoke to *VERVE Daily News* about his recent work in this field.

With extensive involvement in the research and application of 3D rotational angiography in peripheral interventions, Dr van den Berg has more recently co-authored an article with Marco Manzi outlining the importance 2D perfusion angiography as a tool to enable greater understanding of the level of perfusion to the foot that sufficiently facilitates wound healing.[1]

One of the major problems that 2D perfusion angiography seeks to address, explained Dr van den Berg, is the uncertainty that operators face when undertaking complex revascularisations of the lower leg and foot. Current tools, he noted, lack robustness: "A lot of people use the angiosome concept, but there are a lot of controversies about it. There are the 'true believers', and there are some that are more sceptical. When you look at the literature you can find arguments for both, which really indicates that nobody knows."

While wound blush has also been adopted as a surrogate marker of skin perfusion pressure – and associated positively with limb salvage[2] – wound blush has its limitations as a qualitative measure.

Technologies to measure perfusion do exist, including laser Doppler perfusion, CT and MR imaging – but the fact that none of these can be used in the angio suite is an issue, commented Dr van den Berg: "It can get very cumbersome, because you need to remove all of the sterile drapes to get the patient out of the angio suite. So it is not really a practical method. We don't have any tools that we can use in the angio suite to measure perfusion."

Previous studies have demonstrated the feasibility of perfusion in many regions of the body, including the peripheral vessels. More recently, 2D perfusion angiography was tested in 18 CLI patients as part of a feasibility study published by Jens et al.[3]

The technique itself involves the processing of a rapid sequence of angiographic images, using the rate of change of pixel saturation as an estimate of contrast density. Hence, a perfusion map can be created, colour-coded according to a particular parameter, such as the time taken for contrast to arrive at a given pixel. Dr van den Berg said: "2D perfusion angiography is actually just a software addition to the angiography that we already make. It does not cost any additional contrast. You don't need specific equipment, except for the additional software, which you need to buy.

Jos van den Berg moderates Friday's opening session

> "2D perfusion angiography is actually just a software addition to the angiography that we already make. It does not cost any additional contrast."
>
> Jos van den Berg

"The principle of 2D perfusion angiography is based on three frames-per second-angiography. In the system that I work with from Philips Medical Systems, the images are sent to a workstation (the same workstation we use for 3D rotation angiography), which is able to measure flow from the appearance of pixels that turn a darker colour in the images."

The rate of change of contrast density within the pixels of a specified region of interest (the region around a wound on the heel of the foot, for example) allows the calculation of estimated time-density curves, arrival time, and time to peak density. "You can see a dynamic change with the contrast arriving," said Dr van den Berg. "You can actually measure the volume flow in the whole foot. That means you see the large vessels – the macrocirculation – but also the capillary circulation – the microcirculation. The microcirculation is the most important for patients with CLI because that is where the wound healing needs to come from."

Insufficient reintroduction of a patient's microcirculation could spell the loss of a limb that may in many cases be preventable. As such, 2D perfusion angiography could be an economical option in terms of maximising interventional outcomes and reducing long-term costs by ensuring that revascularisations carried out are both necessary and sufficient to promote wound healing.

Another advantage of 2D perfusion angiography is that it essentially uses a post-processing algorithm, one that does not require any additional radiation exposure to be carried out – something that is pertinent to many patients and operators alike.

Dr van den Berg is part of a group that is currently working on the evaluation and validation of 2D perfusion angiography software. Currently, it allows for the visualisation of differences in pre- and post-angioplasty angiography, and hence the relative increase in perfusion in individual patients.

Continued on page 6

Session XI: Latest Techniques and Technologies for the Treatment of Lower Limb Ischaemia Saturday **09.30–10.45am**

Can we improve outcomes with 2D perfusion angiography?

Continued from page 5

By developing a method to measure flow in millilitres per second, the investigators hope to be able to make comparisons between patients, with the possibility to understand whether there is a minimum threshold that must be reached in order for proper wound healing to occur.

"Right now we don't know really how much flow we need to get wound healing, so that is under a lot of investigation," he commented. "There certainly will be a lot of variation between patients, and that is why we need to get more into the basics of this technology. The idea is that this system can be a new endpoint for the intervention.

Citing the investigations of Jim Reekers and colleagues at Amsterdam's Academic Medical Centre into this technology, Dr van den Berg explained: "They are also looking at whether this is a technique that can be used to predict outcome, and whether a patient will benefit from a revascularisation procedure. They did a preliminary study, performing perfusion angiography pre- and post-dilatation. With that technique you can see whether the microcirculation is still reacting, and thus get an indication of whether the patient will benefit from a procedure or not."

> "Right now we don't know really how much flow we need to get wound healing, so that is under a lot of investigation."
>
> Jos van den Berg

Macrocirculation alone is not sufficient for wound healing, with microcirculation making up 90% of the circulation of the foot.[4] "If you just get the macrocirculation open again, the blood will not be able to transmit all the oxygen the tissues need because of the disrupted microcirculation," said Dr van den Berg. "So that is probably one way to look at this technique in the future and the potential of it: for functionality, and to predict the positive outcome of your intervention."

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*Prof. B. Patrice Mwipatayi, FCS (SA), MMed, FRACS Department of Vascular Surgery, RPH School of Surgery, University of Western Australia, Perth, LINC Leipzig presentation, 2015

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Session III: Current Strategies … Treatment of Calf Artery Disease & CLI Thursday **4:00–6:00pm**

Here today, gone tomorrow
Bioresorbable scaffold results laid bare

VERVE Co-Director Ramon Varcoe (Prince of Wales Hospital, Sydney) stepped up to the podium on Thursday afternoon to share his experience in using bioresorbable scaffolds below-the-knee (BTK).

Bioresorbable scaffolds offer a revascularisation solution that promotes vessel scaffolding and anti-proliferative drug release, as well as being specifically designed to be gradually absorbed over time, allowing restoration of a vessel's contractile function, and avoidance of prolonged metallic elements in the vessel.

During his presentation, Dr Varcoe shared 12-month clinical and imaging data from the first in-man study examining the use of the Absorb Bioresorbable Vascular Scaffold (BVS) System (Abbott Vascular, USA), taking the time first to set up the impetus for such a study. "For almost 10 years now we have been using drug-eluting stents, and the reason we do this is because it works," he began. "We have three randomised controlled trials which tell us, quite categorically, that drug-eluting stents are more effective in terms of maintaining patency, when compared to either bare metal stenting or PTA.

"A little while back we started to think why we use these devices, and I think most people in the room will be aware of their use in terms of elastic recoil and treating flow-limiting dissection. But probably less thought of would be to deliver a drug to the area of vascular injury, directly to the site of where the intima is damaged, to prevent restenosis and thus prevent late lumen loss and patency failure.

"But once that elution of drug has taken place, we are left with a permanent metallic implant that serves no further purpose. In fact it acts as a chronic irritant, and it can itself insight further neointimal hyperplasia, as well as act as an artefact with cross-sectional imaging, and an impairment to further intervention or even vascular surgery."

The Absorb BVS features a poly (L-lactide) scaffold, with a bioresorbable poly (D,L-lactide) coating, alongside an everolimus drug delivery system (similar dose density and release to Abbott's XIENCE V platform).[1] "It reduces neointimal hyperplasia, and then as soon as it hits the aqueous environment of the human circulatory system, the ester bonds between these polymer molecules begin to breakdown," continued Dr Varcoe.

"The polymer gets broken down into smaller parcels, and ultimately they can be engulfed by macrophages, and processed through the Krebs cycle – in what's quite an inert process… This is very gentle on the vessel wall."

> "This bioresorbable vascular scaffold can be implanted safely within the tibial vasculature."
>
> Ramon Varcoe

Showing photomicrographs comparing the Absorb BVS versus the XIENCE V at 1 – 42 months, he stressed the differences: "You see that between 12 and 18 months, the polymer structure is almost completely removed and replaced by extracellular matrix. And over time that matrix is also replaced by vascular smooth muscle cells, so that the structure itself completely disappears in around three to four years.

"What is perhaps more interesting about the device is the type of neointima that forms over its surface. When you put a permanent metallic stent in, you get a really haphazard laying down of vascular smooth muscle cells, which have no further function: they are basically just scar tissue. But with this bioresorbable structure, you get a very well-aligned laying-down of vascular smooth muscle cells, which appears very much like media.

"These vascular smooth muscle cells have a contractile phenotype which means that they can contract over time. And we've seen this in the Cohort B study – which was a coronary study, and also in a porcine model – that over time as the structure is lost, the vascular function is seen to return as you give it an acetylcholine challenge. So this is a new paradigm in stenting, one in which you see vascular repair: rather than a rigid tube, we see return of a healthy blood vessel."

Dr Varcoe went on to describe the details of his Absorb BVS study, which was set up almost three years ago, featuring a single centre design, with three implanters, and a patient cohort suffering from CLI

Continued on page 10

Andrej Schmidt beams in live from Leipzig to present a live case on Thursday afternoon

Here today, gone tomorrow
Bioresorbable scaffold results laid bare

Continued from page 8

(the majority) or claudication.

"We used [Absorb] as a direct replacement for drug-eluting stents in our practice, which meant de novo lesions of short lengths (less than 4cm), and diameter ranges that suited the coronary size matrix of this particular device [2.5 – 4.0mm]," he said. "We were mainly targeting proximal tibial arteries, but we did include distal popliteals in the study, if that was continuous with the tibial disease.

"In the outset, from the pilot stage, we were most interested in safety and feasibility endpoints, so we focussed very much on adverse limb events in the first 30 days, and the technical success of delivering and deploying this device in the peripheral vasculature – which it was not designed for."

As Dr Varcoe described, it became apparent quite quickly that the Absorb BVS was a safe device that could be used in the peripheral vasculature, thus he and his fellow investigators focussed their attention on clinical improvement and duplex ultrasound follow-up. "We saw these patients at predetermined time points of one, three, six and 12 months," he said. "We assessed them clinically through Rutherford-Becker class, and then we used a peak systolic velocity ratio, which is very sensitive, of 2.0, to determine patency or lack thereof. And through that we were able to define primary, assisted primary and secondary patencies, as well as target vessel and target lesion revascularisation [TVR / TLR]."

Results were collected from 37 limbs (32 patients), 73% of which had CLI – the age range being between 65-97 years old, and with a male to female ratio of 51/49%. The mean length of lesions were short at 18.7mm. Thus far, 48 scaffolds have been implanted, throughout the tibial vasculature, but with a particular predilection for the tibial-peroneal trunk (19 out of 48 scaffolds) because, given its size and diameter, the Absorb BVS really suits the vessel.

"So far we have had 100% procedural success," commented Dr Varcoe, adding: "We have a pretty astonishing 12-month primary patency rate of 95.5%."

> "So far we have seen excellent immediate angiographic results, and extremely promising 12-month primary patency results."
>
> Ramon Varcoe

Commenting on one patient's outcome, he continued: "There was one acute occlusion which was unfortunately an oversight on our part. That patient was on warfarin prior to their treatment, but they had their treatment taken away, and no antiplatelet therapy was started, so the implantation went on without any protection whatsoever, and they occluded the first post-operative day.

As such Dr Varcoe noted that he would recommend dual antiplatelet agents in all of these patients to avoid thrombosis of the scaffolds, continuing six months as mandatory.

Harking back to the patient that occluded in the study, he added: "But because we were able to salvage that one acute occlusion through endovascular means, overall we achieved an assisted primary and secondary patency of 100%, limb salvage of 100%, and then there was one TLR and TVR."

Dr Varcoe also noted that there were three deaths – all of which were outside of the 30-day window, and all of which were unrelated to the device. Furthermore, one patient was lost to follow-up after a diagnosis of pancreatic cancer. Overall, sustained clinical improvement was 73%.

Demonstrating the sorts of results that could be achieved using the Absorb BVS system, Dr Varcoe showed angiographic images of diffuse disease (tibial peroneal trunk into peroneal) which was treated using two Absorb scaffolds. When the patient came back for at 14 months for a nintervention in the same leg at a distal site, and with the opportunity to interrogate the region, he relayed how it still looked 'pristine', with smooth remodelling on the surface, and even a hint of positive remodelling in the proximal segment, with no evidence of significant restenosis.

"In conclusion, this bioresorbable vascular scaffold can be implanted safely within the tibial vasculature, and so far we have seen excellent immediate angiographic results, and extremely promising 12-month primary patency results."

Reference

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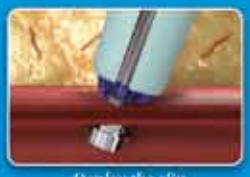

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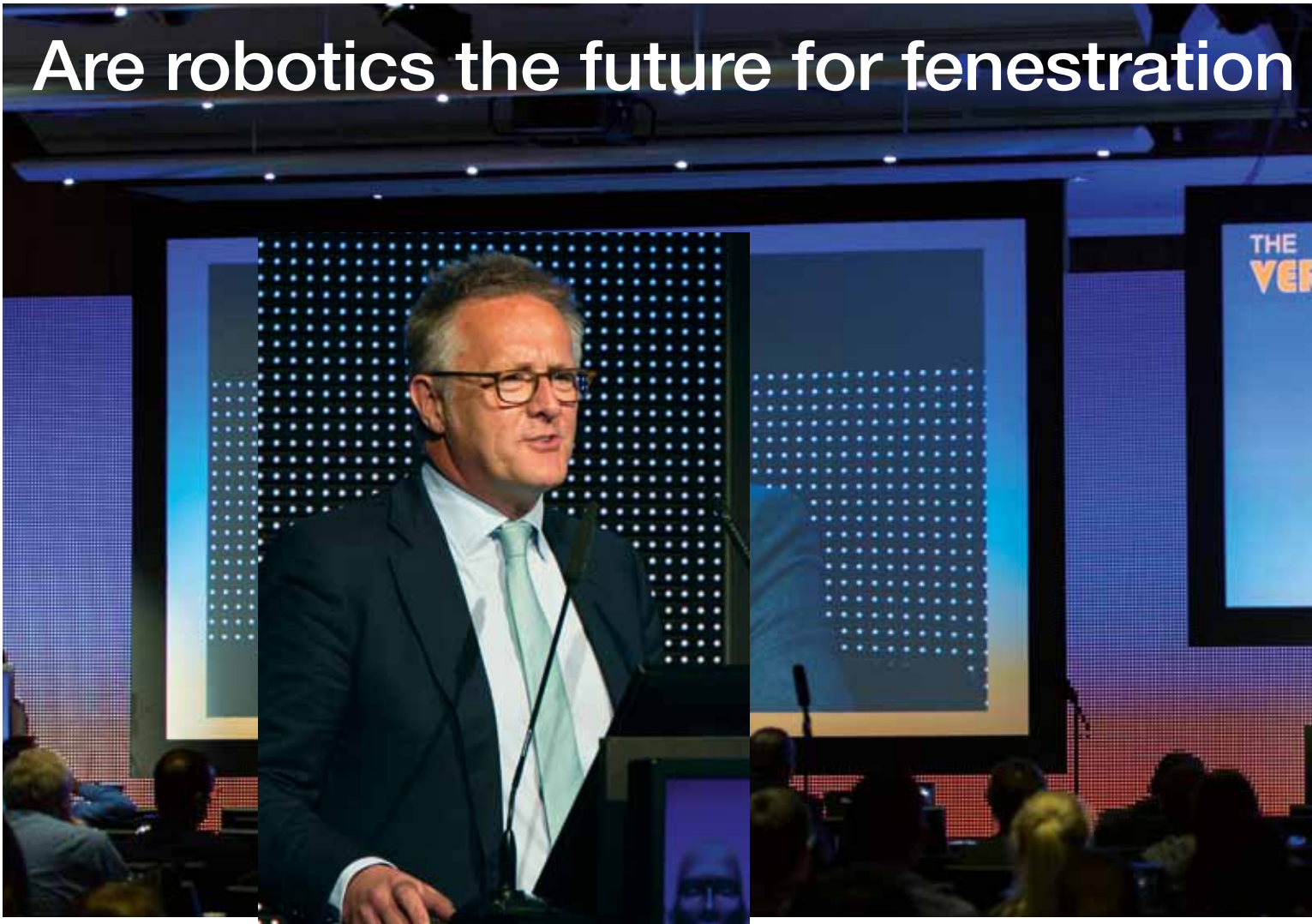
Suture brings the tissues together to promote primary healing

Session II: Unmet Clinical Needs in the Treatment of Abdominal Aortic Aneurysms Thursday **2:30–3:45pm**

Are robotics the future for fenestration



Complex thoracoabdominal aneurysm disease is associated with high morbidity, and patients are often unsuitable for traditional surgery. Instead, a completely endovascular approach can be used – with encouraging results. Also encouraging are novel technologies, such as remotely-steerable robotic endovascular catheter devices, which may be useful for cannulating vessels in such complex anatomy. With that in mind, Thursday's session on the unmet needs in AAA treatment played host to Nick Cheshire (Imperial College, London, UK) who described the advantages of robotic navigation systems, focusing on fenestration and branch cannulation in particular.

"It is interesting because, for patients and the general public, robots in healthcare are still seen as something that's very much cutting edge," he began. "It's something to do with the autonomous and almost humanoid nature of robots; and also something to do with overcoming human error and being able to perform tasks repetitively and efficiently."

> "The greatest advantage [of robotics] seems to be for those who are least experienced."
>
> Nick Cheshire

Philosophically he questioned the future and efficiency of this slave system and advantages it may offer in endovascular care, "Like most slaves, its benefit lies with its ability to perform tasks that a 'human master' cannot do, or does not want to do because it is too dangerous."

Professor Cheshire then described various different systems, firstly the Hansen Medical (USA) steerable catheter system: "Far from being humanoid or autonomous – this catheter is steered using a combination of finger switches, foot pedals and a steering wheel."

He continued: "The steering catheter does not have to be robotic, nor does it have to be as expensive as the Hansen system; there are single wire systems, and also MR-deflectable systems, which allow you to enter in three dimensions."

Professor Cheshire framed the question of whether such a steerable system can cannulate through the fenestration and into the branched vessel more easily than using standard-shaped catheters. Describing some preclinical studies using desktop simulations and animal models, firstly investigating the left renal artery, he said: "If we take a simple measure like, 'how long does it take?', the answer seems to be yes, it is quicker. We took a range of people in our department, surgeons and radiologists and found that, the greatest advantage seemed to be for those who are least experienced[1]. Despite considerable variation time taken in complex lesions for conventional technique, the robot seems to overcome most of those things."

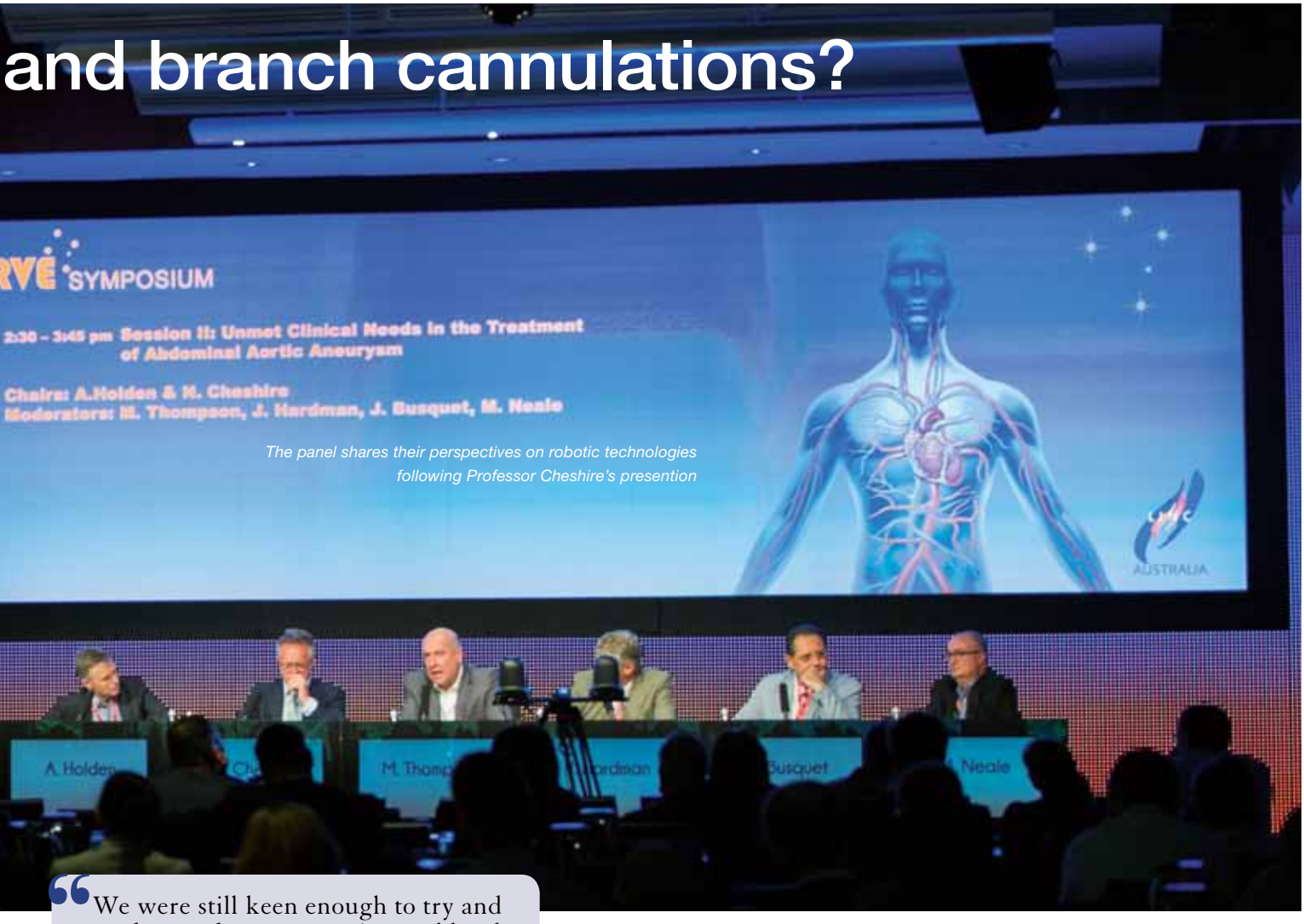
Expanding on this with a desktop model, Professor Cheshire showed how the robot was less likely to dislodge a catheter when passing a stiff wire through, and importantly, how the catheter remains fixed in that position when the operator stops steering[2].

These model data were sufficient to persuade Professor Cheshire and his group to attempt a real-life renal cannulation through a fenestration system. "We were keen to try to understand something a little more sophisticated than just shorter times, and smaller amounts of radiation exposure. So we set up automated tracking[3] and measured path length and studied the first 10 fenestrated endovascular surgeries in real patients. We showed that with the robot, there was a significantly shorter path length."

He added: "This is perhaps not so important when you're driving within the fabric of a stent graft, but is potentially more important in the arch when the risk is the wall content and embolisation. So it perhaps makes it easier to do complex manoeuvres."

As well as improving established techniques, Professor Cheshire is keen to highlight near-impossible real-life procedures that robots could perform, for example, looking at a number to ways to

and branch cannulations?



The panel shares their perspectives on robotic technologies following Professor Cheshire's presention

> "We were still keen enough to try and understand on an experimental level something a little more sophisticated than just shorter times and smaller amounts of radiation exposure."
>
> Nick Cheshire

puncture Dacron to access a side-branch. "Here is another area where a robot might have some advantage over standard human work, particularly with the combination of coordinating the robot with more sophisticated ways of imaging."

A key feature of remotely-operated robots is the protection from radiation, Professor Cheshire explained: "We performed observations looking at an alive system with a neck-mounted dosimeter in some of these procedures, and we discovered a single cannulation may be offering as much as 1% of annual exposure [20 mSv/yr]. If you're outside the room steering the cannula, potentially that's a very important advantage to this system[4]."

Summing up, he said: "So in our early preclinical and clinical experience, this robotic slave system seems to have some advantage for speed and ease of complex procedures. There are some possible technical combinations – new procedures – for example in-situ fenestrations … that are difficult to perform using standard techniques. This has the potential to be very important for the future of this technology."

The preceding questions brought up some important issues, such as costs and expertise. Professor Cheshire agreed that justification of the inherent large capital cost would be difficult to swallow for some healthcare providers, commenting, "In the UK, in order to promote robot use (which the government sees as a way of reducing in-hospital stays) you can have additional reimbursement for recurring costs, making it viable. But if you don't have that and you are on a fixed tariff for a procedure it would incredibly difficult to justify it."

He concluded by touching upon how quickly surgeons assimilated technical expertise for controlling the robot: "What we found was surgeons took to it very naturally: people were trained with a series of 10 practice runs."

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Session XV: Technological Developments to Improve Success and Durability Saturday **4:15–6:00pm**

Getting to grips with calcium below the knee

Technological developments to improve the success and durability of endovascular interventions will be discussed this afternoon, with Giancarlo Biamino presenting the issues surrounding below-the-knee (BTK) calcium deposition, and the current best options in techniques to recanalise vessels, promote wound healing and prevent restenosis and reocclusion.

BTK calcification is exacerbated in clinical conditions such diabetes and renal dysfunction, with more than 70% of CLI patients having these conditions. Current understanding of the process of calcification, and the factors impinging upon it, is incomplete.

"Angiographically, it is practically not possible to determine if the calcification is on the wall of the vessel or inside the vessel," said Professor Biamino, during an interview with *VERVE Daily News*. "You can only feel how hard the calcification is in trying to pass the guidewire through the occlusion. This is not a problem for stenosis, where you can pass a guidewire and you can dilate.

"We do have the possibility, with very complex non-invasive technologies such as MRI and CT, to analyse not only the longitudinal but also the square diameter of the vessel below the knee. However, this is a very costly procedure, and nobody knows if it is worthwhile to do that."

> "Angiographically, it is practically not possible to determine if the calcification is on the wall of the vessel or inside the vessel."
>
> Giancarlo Biamino

Calcium deposition, suggested Professor Biamino, is probably connected to metabolic factors as well as to the process of atherosclerosis itself. Its mechanisms are heterogeneous, affecting vessel compliance and elasticity, and it occurs non-uniformly. "You have some segments of the tibial vessels without any calcium," noted Professor Biamino. "And then you may have rocks that you cannot pass without any type of guidewire.

"What is very surprising for us in our daily practise is the fact that, in many cases, you cannot pass a calcified lesion in an antegrade way, but you can pass in a retrograde way from the distal tibial arteries. Then it is possible to pass with a double-wire technique to reopen the vessel. This is a new technological development, which is shifting the success rate of recanalisation from 50 – 60% to now more than 92 – 95%."

Being often diabetic, CLI patients' lesions tend to reach lengths of 15cm or greater, and more than 80% of cases involve two or three BTK vessels. In such cases, should attempts be made to reopen all of these vessels? "The opinion of the leaders on this field is that you should try to recanalise as much as possible," said Professor Biamino. "It depends on the quality of the intervention – some don't have limits, and they can recanalise nearly every type of vessels."

Maintaining vessel patency following intervention is critical to wound healing, which cannot occur without sufficient microcirculation. Patient management must therefore be strict, explained Professor Biamino, involving many care parties.

> "In many cases, you cannot pass a calcified lesion in an antegrade way, but you can pass in a retrograde way from the distal tibial artery."
>
> Giancarlo Biamino

Recanalisation itself entails a number of options, which Professor Biamino discussed in relation to the difficulties presented by often long and highly stenosed or occluded vessels. Speaking of angioplasty, he said: "It is very important to stress that with very long balloons with a low profile, results are significantly improving in the long term. You have to have this system, and of course you have to use in many cases a .014" guidewire, and not a .018" or .035" guidewire."

With relation to drug-eluting stents (DES), he noted that significantly better results have been obtained in relation to bare metal stents, yet – importantly – DES are suitable only for short lesions of around 4 – 4.5cm, and only in the proximal BTK segment. On top of this, their being balloon-expandable carries a greater risk of stent fractures and compression. "I know that some companies are working on this," he said. "But at the moment we don't have any real solution or a solution in the near future.

"The industry is trying to develop new stents for the distal vessels, but the big problem will be in relation to the length of the lesion. The second problem is that the more distal vessels have a lumen diameter of 2 to 2.5mm, so in the range of coronary vessels."

Calcium excision, he said, is poorly evidenced, and not widely used: "Some interventionists have the impression that an excision in calcium below the knee before the balloon dilatation may improve results. But this is again very questionable, and in the majority of cases, we do not perform any type of desobliteration before balloon dilatation."

The best achievable results, explained Professor Biamino, should come with drug-eluting balloons (DEB), given their excellent track record in the SFA and popliteal artery. "DEB are approved for these areas," he said. "We have good indications that the DEB are also working below the knee.

"However, in this context we do not have any data with regard to the problem of calcification. We expect of course that heavy calcification may be a barrier against the diffusion of the drug into the vessel wall, reducing the possibility of restenosis. But at the moment we do not have any clear indication. In this context, it could be of interest in the future to use a debulking technology before applying a DEB below the knee."

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Session XII: Advanced Techniques in the Treatment of Venous Disease Saturday **11:00–12:30**

New interventional treatment options for massive PE

Massive pulmonary embolisms (PE), characterised by haemodynamic compromises such as arterial hypotension and cardiogenic shock,[1] remain a major healthcare problem resulting in early mortality in a high number of patients[2]. In order to reduce this burden, research into the various therapeutic options for massive PE treatment options is critical. With that in mind, *VERVE Daily News* reached out to vascular medicine expert Abdullah Omari (St. Vincent's Hospital, Sydney, Australia), who will be exploring new treatment options for massive PE during his talk this morning.

Professor Omari broadly described several treatment options for massive PE, including systemic thrombolysis, catheter-driven interventions and surgical embolectomy. He began: "For massive PE in haemodynamically compromised patients, without contraindications to thrombolytic therapy, a 'standard dose' systemic thrombolytic therapy may be utilised; in patients with submassive PE, favourable outcomes may be obtained with 'half-dose' systemic thrombolysis regimens while minimising the adverse bleeding risks.

"Catheter-directed interventions can be used in a variety of ways to treat massive PE – as mechanical fragmentation devices – such as suction catheter devices, manual aspiration measures, and clot maceration interventions, for example. Catheter-directed interventions have been used as stand-alone techniques or in combination with other endovascular interventions such as the infusion of thrombolytic agents that act locally at the site of the embolus within the pulmonary arterial tree, thereby minimising any systemic adverse effects. Combined interventions may also involve pharmaco-ultrasonic techniques using catheter-based technology to deliver local infusions of thrombolytic drugs at the site of the clot as well as ultrasonic energy to facilitate its delivery into the thrombus.

"Finally, Surgical embolectomy: this is usually considered in haemodynamically-compromised patients with a centrally-located massive PE, and when thrombolytic measures have failed or are contraindicated."

All of these techniques can be efficacious in treating massive PE in certain circumstances, so it is important to quickly and accurately determine which technique is most suitable, Professor Omari explained: "Patient stratification should be based on parameters that identify those with higher early mortality risk. Algorithms that incorporate measures to assess the degree of haemodynamic instability (clinical cues such as hypotension; cardiovascular biomarkers; and imaging assessments of right ventricular dysfunction and strain) are useful in identifying those patients at higher risk of early adverse outcomes who may benefit from such advanced therapeutic interventions."

> "Intraosseous access was used as the patient was quite unstable and routine methods for venous access were unable to be achieved in a timely manner."
>
> Abdullah Omari

It is widely agreed that a prudent multidisciplinary approach should be adopted to manage haemodynamically unstable patients with PE. This overarching expert approach from diverse medical speciality groups serves to improve the quality of care and optimise patient outcomes in complex situations. Professor Omari pointed out the importance of early diagnosis and treatment, "This may influence patient mortality, and accordingly, it is vital that multidisciplinary teams have a clear strategy for patient care and that team members have clearly defined roles. This multidisciplinary care must enhance patient outcomes rather than lead to delays in treatment.

"Regarding smaller centres with fewer resources or limited expertise, multidisciplinary approaches may be more difficult to implement, so referral to larger centres may assist in supporting smaller centres in their surrounding region."

Talking about his recent publication on intraosseous thrombolysis with extracorporeal membrane oxygenation (ECMO) as a rescue therapy[3], Professor Omari described that in this particular case, "Intraosseous access was used as the patient was quite unstable and routine methods for venous access were unable to be achieved in a timely manner; and this was amplified due to the rapid deterioration in the patient's condition.

"ECMO has the potential to be used as a bridge during the period of significant haemodynamic compromise among patients who are unresponsive to conventional therapeutic techniques or until other therapeutic interventions may be utilised, and therefore among patients with massive PE, may be lifesaving."

> "Patient stratification should be based on parameters that identify those with higher early mortality risk."
>
> Abdullah Omari

Considering the feasibility of these procedures in the routine management of massive PE, he added, "such advanced rescue therapy does require appropriate expertise and resources to be available and, therefore, its use may be limited to larger centres with specialised services."

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Session XIV: Cutting-Edge Endovascular Techniques … Aortic, Iliac & Branch Arteries Saturday **2:30–4:00pm**

Endovascular techniques take the crown in subclavian and innominate arteries

The reign of endovascular therapy for subclavian and innominate artery (SCA / IA) interventions will be dissected this afternoon, within a session that frames an overarching discussion of cutting-edge endovascular techniques for the aortic, iliac and branch arteries.

In his presentation, Jacques Busquet (Clinique Chirurgicale Val d'Or – Saint Cloud, Paris, France) will introduce the particular challenges of endovascular intervention in both the SCA and IA. As he told *VERVE Daily News*, the incidence of SCA stenosis in the general population ranges from 3–4%, but can be as high as 11–18% in patients with peripheral artery disease. What's more, of those patients affected by SCA stenosis, 50% have concomitant coronary artery disease, 27% have peripheral artery disease, and 24% carotid obstructive disease.

"Symptoms are based upon consequences of ischaemia and vertebrobasilar hypoperfusion caused by steal syndrome," added Dr Busquet, before listing the following key symptoms of note: arm claudication; rest pain; finger necrosis from embolic debris; visual disturbance; syncope; ataxia; and coronary ischemia.

There are other endovascular challenges as well, including IA trunk obstruction, which brings similar problems, but is associated with potential right-carotid events if there is migration of plaque debris. Crucially, Dr Busquet underlined that subclavian-coronary steal syndrome is a severe circumstance to be treated rapidly.

Looking to present-day opinions in the field, Dr Busquet commented on whether bypass or endovascular approaches in the IA or SCA are now taking the lead. "An endovascular approach is definitely the first-line technique – an opinion shared by the majority of international endovascular specialists worldwide."

> "An endovascular approach is definitely the first-line technique – an opinion shared by the majority of international endovascular specialists worldwide."
>
> Jacques Busquet

He added: "The procedure is safe, fast and immediately efficient. Surgery is now reserved for failure of endovascular techniques, perhaps when there is an inability to cross an old calcified thrombosis, for instance."

Commenting on patency rates, he added that post-stenting follow-up shows a 4–25% restenosis rate at three years, and while bypasses tend to have good long-term patency (>70% at five years), there is a higher overall mortality rate of around 2.5 %, as well as higher complication rates.

In his final remarks, Dr Busquet briefly touched on what other key talking points he will be concentrating on during his presentation: "I will also focus on the brachial approach – i.e. a more direct approach using shorter guides and catheters. Post-procedural surveillance of these post-endovascular patients is mandatory at one week, one month, three months and six months by duplex scan."

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