VERVE SYMPOSIUM NEWS

7–9 December 2017

in conjunction with LINC Australia

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Welcome to the 2017 VERVE Symposium and LINC Australia

Welcome to the 5th annual VERVE symposium. This year we've taken the meeting to a whole new level. Moving to the state-of-the-art International Convention Centre says a lot about the rate by which we are growing, as interest swells from vascular enthusiasts all over the country. We've expanded our programme, and our live case numbers have also increased to continue to build on the high-level education provided by meetings past. It's extraordinary to consider that in just five years we've moved from a tiny meeting room at Coogee beach to the ICC!

This year's programme has matured into 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 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-one live cases will be transmitted from the University Hospital, ***Leipzig*** 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 expanded our venous programme to include demonstrations of contemporary ablation techniques and include a special focus on deep venous disorders, the interventional treatment of PE and purely venous "disasters". We go further to challenge the peripheral "no-stent-zones", dive deep into thoracic aortic controversies and bring back the great debate.

With the expansion of this year's programme, we feel that we are well on the way to completing our mission to become 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 the Thursday night following the completion of the final session, and for the much-anticipated *Official Symposium Dinner Party* at Dockside on *Darling Harbour*. These are great opportunities to network with colleagues and catch up with friends. I look forward to seeing you at the meeting.

Ramon Varcoe

Course Co-Director, The VERVE Symposium and LINC Australia

Session 1.10: Below-the-knee and retrograde interventions Room 1 **Saturday** 9:00–11:00am

Endovascular-first CLI management – beyond the evidence

Yann Gouëffic (Department of Vascular Surgery, CHU Nantes, France) joins others to discuss below-the-knee and retrograde interventions on Saturday morning, presenting a review of evidence surrounding endovascular-first CLI treatment. There remain distinct controversies in this area which ongoing clinical trials seek to address, yet Professor Gouëffic suggests that there are real-world pressures beyond clinical evidence alone to favour the endovascular-first strategy.

Speaking to *VERVE Symposium News*, Professor Gouëffic described the variation in prevalence of endovascular-first treatment of CLI, noting that it falls to different specialties depending on the country: "In the US, 50% of these procedures are performed by vascular surgeons, and 50% are performed by cardiologists or radiologists. In Germany, it is mostly angiologists, so it is endo-first. In France, it is mostly vascular surgeons, but in France vascular surgeons perform endo as the first line of treatment. So in fact I think there is a trend to have endo as the first line of treatment to treat BTK disease."

To date only one completed randomised controlled trial has directly compared endovascular PTA and open bypass repair – the BASIL (Bypass versus Angioplasty in Severe Ischemia of the Leg) trial, conducted between 1999 and 2004. Therein, intention-to-treat analysis identified no difference at one and two years in amputation-free survival. In addition, for those patients who survived for at least two years after randomisation, bypass was associated with a trend in subsequent amputation free survival.[1]

However, few patients were follow-up after two years, and the benefit in term of amputation-free survival was more related to survival than to amputation. Commenting on the study, Professor Gouëffic said: "BASIL was not powered to assess long-term data. So I don't think we can draw any conclusion from this long-term data."

Professor Gouëffic continued to note some of the main criticisms levelled against BASIL: "Its methodology is not so good, because the type of endo treatment was not so well defined. Also, if you look at the methodology, the primary endpoint was not so well defined."

Two other important findings emerged from BASIL, he added. The first concerns a cost-effectiveness analysis, which showed that open repair was more expensive than endovascular treatment at one year[2]. The second finding, coming from a by-treatment-received analysis, was that patients who underwent bypass following an initial failed angioplasty had poorer outcomes compared to those who underwent bypass as the initial treatment[3]. This latter finding, said Professor Gouëffic, led the authors to suggest an open-first approach in CLI, although the point remains controversial in observational data that has followed, with some arguing that bypass outcomes are not necessarily affected by a prior ipsilateral endovascular procedure.[4,5]

Ongoing randomised clinical trials, including BASIL-2 (Bypass vs. Angioplasty in Severe Ischaemia of the Leg – 2)[6] and BEST-CLI (Best Endovascular Versus Best Surgical Therapy for Patients With Critical Limb Ischaemia)[7], form the next steps in defining the roles of these two strategies in CLI. BASIL-2 compares vein bypass-first and best endovascular treatment-first for severe limb ischaemia only where clinical equipoise is established, and will include around 600 patients. BASIL-2 is UK-based, while BEST-CLI is being carried out in the US and Canada and will include 1,200 patients.[6,7]

These studies are set to give firmer grounding to clinical decision-making in a complex population that is expected to grow in the coming decades. On the topic of clinical evidence, Professor Gouëffic said: "We have a dogma in vascular interventions, which is that in CLI, you have to perform revascularisation as soon as possible. The reason it is a dogma is because we believe it is true without any clinical evidence of it."

> "We have a dogma in vascular interventions, which is that in CLI you have to perform revascularisation as soon as possible."
>
> Yann Gouëffic

Better patient selection will allow only those who are likely to benefit from intervention to undergo it. Currently, noted Professor Gouëffic, those patients who are non-ambulatory, older, diabetic, or those with renal insufficiency, do not benefit from intervention: "At the moment we are revascularising all patients, but I don't think it is always good to do it. We have to improve patient selection.

"But whatever the results of BEST-CLI and BASIL-2, it could not change anything. For example, in my department of vascular surgery, we perform more than 1,000 peripheral endovascular repairs per year. If tomorrow the BEST-CLI and BASIL-2 studies showed a difference between endovascular and open in favour of open, in my department I would not be able to switch to open. I am a surgeon, so performing the intervention is not the problem. But when you perform endo it takes 1-2 hours, with local anaesthesia; bypass is a 4-5-hour intervention, so we would need more surgeons, more operating theatres, more anaesthesiologists. We are not able to make this switch to increasing open repair.

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"I am sure that in most countries in Europe this is also the case. Hospitals have more and more cost pressures. My point is that, okay, we have cost pressures, and perhaps there could be a difference between open and endo, but we should make endo a success because going back to more open surgery is not possible."

On this theme of pragmatism, and asked about the frustrations of seeing such patients at a late stage of disease, Professor Gouëffic noted that the growth of this patient population is precisely why endovascular-first needs to be made a success. Their complexities – a high morbidity rate including factors such as diabetes, age and renal insufficiency – make the CLI population very different to claudicants.

"The part of medical treatment is very, very important," he said. "And when I say medical treatment, I don't refer only to cardiovascular risk factors, but also to, for example, wound care. If you speak about cardiovascular factors to treat diabetes and hypertension, this is also [about] providing information to patients about smoking – because we have to repeat, repeat, repeat, that smoking cessation is very important."

Secondary prevention is an important factor, alongside public education, medical therapy and wound care, that lies apart from surgical or endovascular intervention in improving patient prognoses.[8] "Wound care management is crucial," stressed Professor Gouëffic. "It is pretty complex, because it involves not only an interventionalist, but also a podiatric surgeon, a cardiologist, endocrinologist, infectious physician – not all hospitals have this kind of group. It is very important to emphasise that the management of the CLI patient is very different to a claudicant because of the impact of medical comorbidities. These are very complex patients."

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Session 2.12: Future Technological Development in the Treatment of Vascular Disease Room 2 **Saturday** 2:00–3:30pm

Campaigning to prevent diabetes amputation

A presentation that focusses on the future of amputation prevention in Australia will be delivered on Saturday by Greg Johnson, who has been CEO of Diabetes Australia for five years and leads its national advocacy, policy and health campaign work. Diabetes Australia runs the National Diabetes Services Scheme, a very large government-funded program which has over 1.2 million people with diabetes registered and accessing services. Diabetes Australia also has a significant research programme.

> "The sad truth is also that health outcomes for people with diabetes undergoing major amputations are poor. Many people will die in the first five years after a major amputation."
>
> Greg Johnson

The focus of Professor Johnson's talk will be the diabetes amputation prevention campaign which has been ongoing for the last two years. "The problem is that every year in Australia over 4,400 diabetes-related amputations are performed, and it's estimated that 85% of these are preventable," he explained. "It is a postcode lottery in that the rate of amputations for people with diabetes are much higher in rural and remote areas and disadvantaged communities."

The cost of diabetes-related amputations is significant in Australia. It is estimated that diabetes-related amputations cost the Australian health system around $875 million per year. And this doesn't take into account the huge personal and financial cost to individuals and families, commented Professor Johnson. "The sad truth is also that health outcomes for people with diabetes undergoing major amputations are poor. Many people will die in the first five years after a major amputation," he explained.

He underscored that there are good data on diabetes-related amputations, for example the Australian Council for Safety and Quality in Healthcare, who recently published data on the regional variances in amputation rates across Australia. "Amputations are just part of the hospital burden," he said, adding: "there are around 10,000 hospitalisations every year for diabetes-related foot problems."

What is significant, too, is that Australia has a high rate of diabetes-related amputations compared to many other countries. "In fact, we lag behind many other countries including the UK, Belgium and Germany, where they have successfully reduced the number of major, or above the ankle, amputations, and have made team-based quality foot ulcer care more accessible across their countries," he explained.

Given so much is known about the problem, it seems counterintuitive that a campaign is considered necessary. But as Professor Johnson described, the health system is insufficiently equipped to deal with amputations. "We know a lot about the problem, the real issue is we don't have a strong focus in the health system to prevent diabetes-related amputations," he said.

That's why Diabetes Australia is calling on the Australian government and all the state governments to implement a Diabetes Amputation Prevention Initiative. "We need to re-orient our health system more strongly towards prevention of diabetes-related amputations through a more proactive, systems approach to ensure regular checks and risk assessments, and earlier treatment to keep people with diabetes out of hospital," Professor Johnson explained.

> "We believe that Australia can successfully reduce the number of diabetes-related amputations – as other countries have done."
>
> Greg Johnson

"People should have their feet checked by a health professional twice a year – in line with the annual cycle of care requirements of good diabetes management," he continued, noting that doesn't necessarily mean that people with diabetes receive such services. "Unfortunately, Australia's disjointed and fragmented health system means people are slipping through the cracks. We believe that Australia can successfully reduce the number of diabetes-related amputations – as other countries have done."

According to Professor Johnson, for this to happen, the primary care system should be supported: "We think Primary Health Networks (PHN) should be required to have Diabetes Amputation Prevention Plans in place," he said. "This would ensure diabetes-related amputation prevention is a priority for every PHN in Australia."

That would mean establishing a high-risk multidisciplinary foot care team for each PHN. "Currently there is around one high-risk foot service for every one million Australians living with diabetes. We need to lift that to about one service for every hundred thousand Australians," he explained. The PHNs would also be responsible for monitoring access for people who don't access foot checks, the number of hospitalisations for people with diabetes, and the number of amputations.

"We can end most diabetes-related amputations within a generation – but we need to act urgently," Professor Johnson said in closing.

Session 2.8: Peripheral Intervention Challenging Traditional Surgical Zones Room 2 **Friday** 4:00–6:00pm

Stenting *sans frontières*?

Recent years have seen the gradual encroachment upon so-called no-stent zones such as the popliteal artery around the knee and the common femoral artery (CFA) around the groin. With an eye on the latest developments in technology and data, vascular surgeon and endovascular specialist Frank Criado (MedStar Union Memorial Hospital, Baltimore, MD, USA) will speak of the growing obsolescence of the no-stent zone concept in the age of biomimetics, during a session focussed on peripheral interventions challenging traditional surgical zones.

Dr Criado touched on the developments in our understanding of arterial biomechanics and its application in stent design in an interview with *VERVE Symposium News* ahead of the meeting: "Biomimicry is a fascinating avant-garde approach to innovation that enables conceptualisation and design, emulating nature's (and evolution's) key anatomical and physiologic characteristics."

As a result, he noted, novel stents could be game-changing, overcoming past bugbears such as durability and stent fracture that originally led to the notion of no-stent zones.

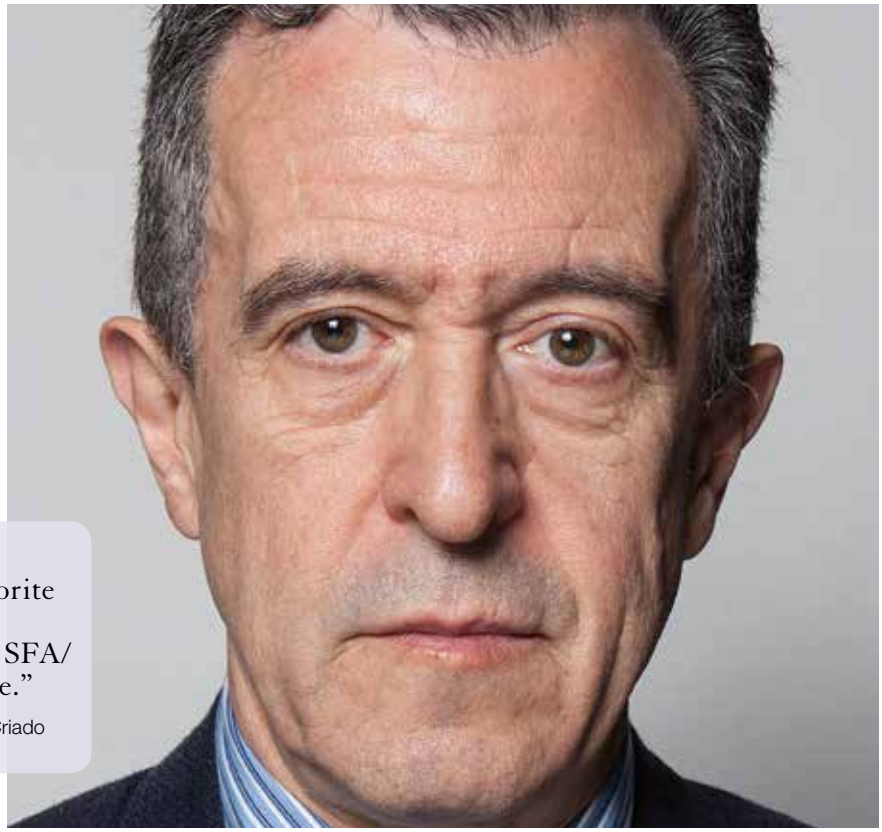
"The prototypical, most palpable outcome of this new approach has materialised in the form of the BioMimics 3D stent [Veryan Medical Ltd., UK]. This device has been designed and constructed in a fundamentally different fashion; it is quite flexible and mimics the natural curvature of the superficial femoral artery (SFA).[1]

"Additionally, and most significantly, it generates normal swirling flow that is known to cause high wall shear stress with its resultant protective effect against both atherogenesis and the development of restenosis."

This concept of protective shear stress was reported by Caro et al, first in 1969[2], opposing at the time prevailing notions that atheromas propagate in vessel regions of high stress. Further work by Caro et al investigated the effect of introducing swirling flow to stent design – via helical centreline geometry – finding this to limit the development of neointimal hyperplasia[3,4].

"Conventional straight stents on the other hand, like all of those (flexible or not) we have used over the last many years, tend to straighten arteries, reduce curvature and impede normal swirling blood flow," said Dr Criado, "Thereby lowering the shear stress down to levels that favor atherogenesis and restenosis.

> "The Supera stent has recently become a favorite in our practice when dealing with complex SFA/popliteal artery disease."
>
> Frank Criado



"The BioMimics 3D stent is perhaps the first of a family of new devices we are sure to see coming down the pike in the years to come, enabling new strategies and greatly enhancing stent performance."

Dr Criado went on to cite the Supera stent (Abbott Vascular, IL, USA) as another example of biomimicry in action: "The three-year results of the SUPERB trial[5], further substantiated by outcomes in the real-world Supera 500 Registry[6] have unequivocally shown this device to perform optimally in some of the worst-case PAD scenarios with extensive SFA/popliteal disease including heavy calcification. And with a near-zero fracture rate!

"It is important to note, however, that optimal deployment technique is crucial for the Supera stent to realise its full potential; optimal results are dependent on stent deployment length as patients in whom the device is deployed to intended length achieve a rather high (80-90%) mid-term patency, while elongation of the stent produces a significant drop in patency and higher TLR rates.

"The Supera stent has recently (two years) become a favorite in our practice when dealing with complex SFA/popliteal artery disease."

> "Biomimicry is a fascinating avant-garde approach to innovation."
>
> Frank Criado

New evidence and better understanding of where and how post-stenting complications occur, explained Dr Criado, have lately overturned traditional concepts in the CFA region too.

"We have long been told that stents in the CFA are unlikely to be successful and likely to fail because of these issues:

1. *The CFA is a high-mobility area subjected to strong dynamic shifts with hip flexion, ambulation and exercise*. Not true: we now know most of the dynamic changes occur in the external iliac artery, not the CFA.
2. *The negative consequences of covering the profunda femoris artery*. Again, not a good argument as CFA stents often spare the profunda, and even when this is not possible, bare-metal coverage is usually inconsequential.
3. *Impediment to subsequent femoral puncture and endovascular access for cardiac or peripheral intervention*. While it is true that the presence of a stent in the CFA might interfere somewhat with such action afterwards, it is entirely possible and totally safe to puncture the femoral artery either above or below the stent (if possible), or right through its matrix. This has been well documented.
4. *Surgical treatment in the CFA (endarterectomy and patch angioplasty) is technically simple, and the operation is minimally invasive and most likely to produce excellent results*. Well…much of this is untrue, especially as it relates to a relatively high rate of wound complications, prolonged and repeated hospitalisations and the like.
5. Lastly, we now have the results of the well-designed French randomised trial that compared endovascular treatment with conventional surgery in the CFA: the TECCO Trial.[7] It showed definitively that, at two years, endovascular treatment is superior to surgery in terms of morbidity and mortality and with equal morphological and hemodynamic outcomes."

Dr Criado concluded with a reminder of the 'leave nothing behind' concept that accompanied the rise of the drug-coated balloon (DCB): "These are perhaps mostly responsible for the profound changes in strategies and approaches to PAD intervention we have experience in the recent past," he noted.

"Like many other practices we now use DCB angioplasty, alone or infrequently combined with stenting, for most cases of non-complex arterial disease above the knee. 'Non-complex' is defined as the absence of extensive calcification and very long lesions, and predominantly stenotic disease (not CTOs)."

There is mounting (but not yet definitive) evidence, he added, that the combination of directional atherectomy and DCB angioplasty works quite well for the majority of instances of in-stent restenosis with an indication for intervention. "We have also embraced this in the recent past.

"The clinical application of DCB technologies has now expanded to include dialysis-access intervention – a most important role indeed. And we all await eagerly clinical trial-derived confirmation that DCB angioplasty can be applied successfully for treatment of arterial disease below the knee. This will almost certainly be the case but it may take another two to three years before it becomes on-label approved therapy in such territory.[8]"

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Session 2.3: What's Wrong with EVAR and How Can it be Improved?
Room 2 **Thursday** 4:00–6:00pm

Explaining the evidence for EVAR

Fabrizio Fanelli, a professor of radiology and Director of the Vascular and Interventional Radiology 'Careggi' University Hospital in Florence, Italy, will focus on the long-term outcomes of EVAR during Thursday's programme. The procedure has emerged as a standard of care for abdominal aortic aneurysm (AAA) repair and a wealth of studies have been published over recent years to compare this technology to open aortic repair (OAR). "The big incentive for EVAR is that it is a less invasive technique, meaning shorter hospital stays," Professor Fanelli told *VERVE Symposium News*.

But while the literature shows that EVAR of AAAs is feasible, efficacious, and has considerable short-term benefits compared with conventional OAR, the long-term verdict is still less certain. That's according to many papers that have come out in recent years, explained Professor Fanelli, but he added that it does make for a particularly interesting discussion during the session. "There will be an overview of some data to understand if EVAR is supported by long-term outcomes," he said.

> "We know that there has been a big change in new technology. The devices now available are safer, especially in terms of long-term durability."
>
> Fabrizio Fanelli

Previously, there was concern over the use of EVAR in the long term, but Professor Fanelli noted that it was the durability of stent grafts, specifically, that many physicians were afraid of.

Things have improved since then, but – as Professor Fanelli outlined – the problem is that there is a significant weakness in much of the literature on long-term benefits of EVAR using today's technology. "The key problem is that the majority of the studies are based on the first or second-generation stent grafts, and the majority of them are also retrospective," he said. "This is something we have to keep in mind when going through the major studies."

The problem with such studies is that they don't necessarily take into account the effects of new, third-generation devices, which came onto the market three or four years ago. "We know that there has been a big change in new technology. The devices now available are safer, especially in terms of long-term durability."

As such, Professor Fanelli relayed that he will also present several examples of other comparative studies between EVAR and OAR. For example, one of the most recent, in Germany, looked at more than 5,000 patients and reported outcomes that were more or less the same in terms of survival rates and mortality if the two techniques were compared.[1]

> "...I'm very confident that in the future data will be better and better for the use of EVAR compared with standard operating techniques."
>
> Fabrizio Fanelli

Another retrospective evaluation, published in April, found that survival rates were similar, and the re-intervention rates for five years were also comparable.[2] "This is another article that can support good option of an EVAR procedure", he added.

Professor Fanelli continued: "Now we have 10 years follow-up data using a mix of first-, second- and maybe third-generation stents, so it's not a clear picture of the situation," he said. "This is the reason why I'm very confident that in the future data will be better and better for the use of EVAR compared with standard operating techniques.

"In the near future we will have new data using new devices, and for sure data will be more in favour of EVAR," he said. "This is very important because now many patients are coming to us asking for an endovascular or minimally invasive treatment. So now we can also offer this as a safe treatment."

> "The big incentive for EVAR is that it is a less invasive technique, meaning shorter hospital stays."
>
> Fabrizio Fanelli

Professor Fanelli looks forward to new studies in the future for other reasons. Today's studies, he said, tend to be based on single centres, and do not encompass large numbers of patients, for example. "There's also another element we need to consider when evaluating these studies. In none of them, or very rarely, was an external Clinical Events Committee needed," he included. "This element – and others – improves the power of the study. It's something that we have to keep in mind."

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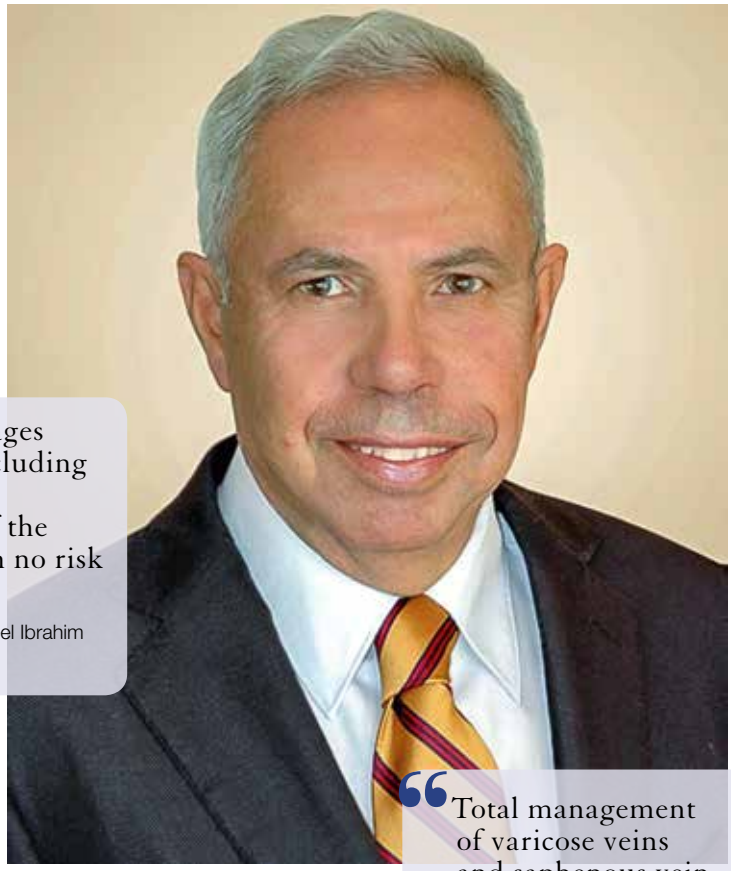
Session 2.4: Challenges in the Treatment of SVD and Truncal Reflux Room 2 **Friday** 8:00–9:30am

SVD and truncal reflux:
Achieving complete care in an ambulatory setting

Tackling the challenges in treatment of superficial venous disease (SVD) and truncal reflux on Friday morning will be Nabeel Ibrahim (Advanced Laser Vein Clinics, Sydney, Australia), who will take a specific look at achieving complete care in an ambulatory setting.

Dr Ibrahim will primarily focus on thermal ablation and cyanoacrylate (CA) – two key treatments that bring with them their own set of pros and cons. *VERVE Symposium News* spoke to Dr Ibrahim to gauge more about these treatments in an ambulatory care environment.

> "…there are clear advantages with [cyanoacrylate], including the ability to apply it to almost the full length of the incompetent trunk, with no risk of nerve damage."
>
> Nabeel Ibrahim



While thermal ablation is safe and effective, does it have drawbacks?

It requires the injection of a modest volume of tumescent anaesthesia which can be both time consuming and uncomfortable, as well as causing post-treatment bruising and pain. In addition, and with all care taken, thermal sensory nerve damage can occur. Finally, safe application can only be delivered to a limited length of the target vein.

CA, on the other hand, has less data, but avoids anaesthesia, compression stockings and nerve damage?

CA has a recent history in the treatment of varicose veins, with limited data in both the short- and long-term, however there are clear advantages with this modality, including the ability to apply it to almost the full length of the incompetent trunk, with no risk of nerve damage. The application itself is nearly painless, and therefore tumescent anaesthesia is not required.

The use of compression stocking may not be required if no other adjunct procedures are carried out. This is a significant advantage… for those patients who are physically unable to apply stockings.

> "Total management of varicose veins and saphenous vein incompetence is safe, effective and accepted by the patients in a well-equipped and adequately staffed ambulatory setting."
>
> Nabeel Ibrahim

Can you walk us through how CA treatment works?

The mechanism of action of CA is a combination of events. Immediately there is adhesive occlusion, followed by an inflammatory reaction to the agent, then granulomatous foreign body reaction, with fibrosis of the vein wall as the end result. The agent itself appears to be less distinguished after two years – as observed on duplex scan.

Are there data directly comparing thermal ablation to CA?

Yes, there is one study from Nick Morrison's group, published in July 2015[1], comparing CA and radiofrequency ablation, which concluded equal efficacy and safety with reduced rate of bruising with CA.

Are there other treatment approaches you will be discussing (e.g. foam sclerotherapy)?

Foam sclerotherapy will only get a mention. I will, however, briefly discuss the application of CA for a pathological perforator, and groin recurrence following stripping.

What are the benefits and challenges in using such treatments in an ambulatory setting?

Our small sample and short-term follow-up is showing both safety and efficacy as well as suitability of all patients with saphenous incompetence. The ambulatory treatment setting can be tailored to include all patients.

What's your take-home message for the VERVE audience?

Total management of varicose veins and saphenous vein incompetence is safe, effective and accepted by patients in a well-equipped and adequately staffed ambulatory setting.

Reference

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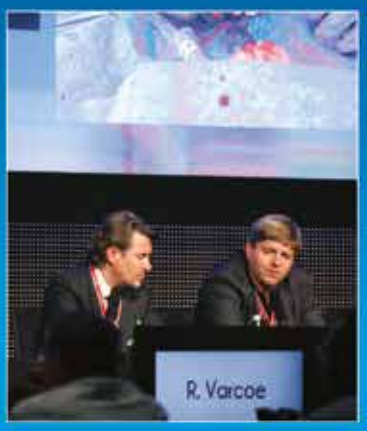

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Session 1.6: Deep Venous Stenting Room 2 **Friday** 11:30–1:00pm

Post-thrombotic iliac and femoral vein obstruction – strategies beyond iliac vein stents

Ahead of Friday's session on deep venous stenting, *VERVE Symposium News* spoke to Ramesh K Tripathi (Vascular and Endovascular Surgery Faculty of Science, Health, Education and Engineering, University of the Sunshine Coast A USC, Maroochydore Queensland, Australia) to gather his perspectives on venous stenting, and other advanced strategies, for post-thrombotic iliac and femoral vein obstruction.

Venous stenting has been playing catch-up on arterial stenting for a long time now. Although some devices are now approved in Europe, what is your overall perspective on the venous stenting field? Does technology fall behind demand?

Although venous stenting evolved as an extension of arterial stent technology, its hardware and technique had to be modified to suit the fundamentally different pathophysiology and indications of venous stenting.

In the beginning, our experience was mainly with Gianturco Z stents and Wallstents, all the way until 2010. Now a wide variety of nitinol stents (Zilver Vena, Sinus XL and Obliqus, Venovo) are available. That we have not yet achieved an "ideal" stent for venous stenting in various pathological situations is clear from the plethora of stents available. Potential issues with venous stents may be in-stent restenosis, stent deformation and compression at cross over points, recurrent DVT from poor common femoral inflow, stent dislocations, contralateral iliac vein partial occlusions, etc.

A dedicated venous stent that overcomes the above issues is clearly desirable. Our understanding of iliac vein obstructive disease is evolving, and although not quite there yet, technology is fast catching up to match its complexities.

> "Our understanding of iliac vein obstructive disease is evolving, and although not quite there yet, technology is fast catching up to match its complexities."
>
> Ramesh K Tripathi

Post-thrombotic iliac and femoral vein obstructions are a major issue, but is it fair to say that in some cases, iliac stenting alone is insufficient to restore proper flow? What are the limitations that hinder results, and are specific considerations important (e.g. stenting that extends into the profunda vein-femoral vein junction).

Yes, in the majority of cases, say around 80%, iliac vein stenting suffices. Debilitating chronic venous insufficiency or recurrent >CEAP C4B disease persists. The main issues are around missed common femoral flows and stenosis/ obstruction at that level, poor profunda/femoral vein out flows or recurrent post-stenting disease/ ISR/ DVT in these areas. These can be tackled with thrombolysis or extension of a stent below the inguinal ligament into the femoral or profunda femoral veins. Stenting issues involve access from jugular or contralateral approaches that allow smaller stents to be placed in larger, previously placed stents, creating shelves and cul-de-sacs – areas prone to DVT.

In addition, the main disadvantage of stent extension below the inguinal ligament is that it only improves outflow of a single stented vein.

Is this where endovenectomy comes in? Perhaps you could introduce the concept and its benefits, particularly for occlusive disease involving the common femoral vein.

Endovenectomy, also called endophlebectomy/ trabeculectomy, is a concept of removal of all obstructive elements (old post-thrombotic collagen, recanalised thrombus and fibroblast tissue) from the common femoral vein into the femoral vein. This clears obstruction to the outflow of not just the common femoral vein, but also the profunda femoral vein at its confluence with the femoral vein and the outflow of many important collateral veins arising in this segment.

Combined with iliac vein stenting, it provides a technically feasible, practical option in patients with extensive occlusive disease involving common femoral veins at the profunda confluence level, especially for recurrent CFV stenosis /occlusion after iliac stent extension below the inguinal ligament or failed endovascular recanalisation in total occlusions. An adequate degree of axial transformation of the profunda vein should be determined before committing to such an invasive procedure.

> "Just because you can stent most things, you cannot afford to drop your scalpel yet. The aim is to restore flow, reduce venous hypertension and correct valvular reflux."
>
> Ramesh K Tripathi

What are the key steps involved (e.g. careful dissection), and what's the growing data surrounding its use?

Key steps involve case selection, review of CT/MR venograms, IVUS, careful dissection of the femoral vein and preservation of all its tributaries, venotomy across profunda confluence, sharp dissection and removal of obstructive elements, placement of sheaths in the iliac vein, stenting down into the cleared area, and meticulous closure of venotomy with or without a patch. Cautious wound closure and vac therapy will help in avoiding sero-lymphatic leaks.

Important details of the procedure can be found elsewhere.[1]

What are the limitations (e.g., an adequate degree of axial transformation of the profunda vein is needed)?

Although patients with occlusion/trabeculation at CFV level with a well-developed, dilated profunda vein are selected for inflow correction via open or endovascular technique, I individualise the choice of treatment between stenting and endovenectomy after discussion with the patient.

I tend to prefer endovenectomy over stenting across the inguinal ligament in more severe occlusions extending across the profunda origin, or those who have failed endovascular attempts.

Those with poorly developed profunda are managed on compression and imaged later on, as with time, axial transformation of the profunda vein could improve.

Are there other strategies beyond iliac vein stents that you will be discussing?

Endovenectomy is again one option. If stents fail, open surgical bypass options (Palma bypass/ Femoro-caval bypass) can be utilised effectively. Valve repairs can be effective as most post thrombotic reflux in the thigh and leg is repairable. Just because you can stent most things, you cannot afford to drop your scalpel yet. The aim is to restore flow, reduce venous hypertension and correct valvular reflux.

Reference

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Session 1.8: Challenges in the Thoracic Aorta Room 1 **Friday** 4:00–6:00pm

Preventing stroke in arch branch grafts

A session dedicated to challenges in the thoracic aorta, held on Friday, sees Brendan Stanley (Mount and Fiona Stanley Hospitals in Perth, Australia) delivering his perspectives on the very latest techniques used to repair aneurysms of the aortic arch using branched grafts. Dr Stanley has spent many years working on the development of fenestrated grafts, and the early technological advances of branched grafts.

The development of this technology has come on leaps and bounds in recent years, according to Dr Stanley, as well as advances in understanding the kinds of patients likely to have the best outcomes. "We are finding out that the patients that really benefit from endoluminal repair of arch aneurysms are obviously those not fit for open surgery," he said.

> "We are finding out that the patients that really benefit from endoluminal repair of arch aneurysms are obviously those not fit for open surgery."
>
> Brendan Stanley

Patients who have undergone surgery in the past, and have developed aneurysms and require repairs are also good candidates for the procedure. "Redo sternotomy or redo surgery in the chest has a high mortality and morbidity associated with it. These patients are better off having an arch branched-device repair," said Dr Stanley.

"The real problem is that, although the mortality and morbidity are less with a branched device, there is still a problem with stroke," he said. "That's where the real advances need to be made."

Thankfully, there are several procedures – before, during and after surgery – that can help lower stroke risk. "There are things we have realised, over a period of time doing these procedures, that can help prevent stroke with this device," he said.

Most important, he says, is selecting the correct patients that are less at risk of having an intraoperative stroke because of an anatomical variance or underlying vascular problems.

"Post-operatively, one of the most important things that usually takes place in the very early stages is the maintenance of high blood pressure to maintain cerebral perfusion," said Dr Stanley. "And we make sure we monitor the bridging stent so that there is decreased risk of acute occlusion. Things like full anti-plasma therapy can prevent any problems with stroke too."

But the intervention that is perhaps at its earliest stage is the use of protection devices to prevent strokes. Originally developed for cerebral protection during TAVI, such devices may be relevant for the branched devices in the aortic arch. "It still too early to say whether they are going to have a major benefit, but they probably do have a place in stroke prevention," said Dr Stanley.

> "...although the mortality and morbidity are less with a branched device, there is still a problem with stroke. That's where the real advances need to be made."
>
> Brendan Stanley

Dr Stanley will speak about three protective devices – Embrella (Edwards Lifesciences, USA), TriGuard (Keystone Heart, USA), and Sentinel (Claret Medical, USA) – and will weigh-up their promise, and limitations, in the arch: "There's no doubt that protective devices are far from perfect. There is still a problem because, unlike in TAVI, we can't maintain continual protection of the vessels whilst we are doing this procedure because we need to come from the carotid arteries to place the bridging stent." Dr Stanley believes there needs to be work on the use of protective devices in these kinds of surgeries.

Similarly, continued Dr Stanley, there must be further advances in methods to operate safely on patients with a so-called 'shaggy' aorta – an aorta that is full of thrombus. "We do know that is one of the biggest problems, and may be one of the major contraindications," he said. "There may be future technologies, such as steerable stents that can maintain centreline navigation and stay away from the aortic wall. That may decrease the risk of getting a shearing of those shaggy aortas, and subsequent emboli up into the brain."

Session 2.6: Current Concepts and Updates for the Future of Carotid Intervention Room 2 **Friday** 11:30–1:00pm

Integrated embolic protection technology: double filtration during carotid artery stenting

The introduction of embolic protection devices (EPDs) almost two decades ago led to a large increase in the number of patients undergoing carotid artery stenting (CAS). Although these devices improved procedural safety, large randomised trials have shown that there remains a higher risk of minor stroke during CAS as compared to carotid endarterectomy (CEA).

This will be the message of Ravish Sachar (North Carolina Heart and Vascular Hospital, UNC-REX Healthcare, University of North Carolina, Raleigh, NC, USA), founder and CEO of Contego Medical, USA, who will introduce the Paladin Carotid Post-Dilation Balloon System with Integrated Embolic Protection, and its associated registry, on Friday.

Speaking to *VERVE Symposium News*, Dr Sachar stressed that there are stroke risks during the entirety of a CAS procedure, but the maximal risk falls in the post-dilation phase, when the stent is pushed into plaque at high pressure, resulting in massive release of embolic particles.

Speaking of the types of EPDs available, Dr Sachar touched upon both distal filter and proximal occlusion devices. "Distal filters allow perfusion throughout the case due to the presence of pores in the filter," he said. "These filters have almost eliminated the risk of large particles reaching the brain, and as a result the risk of major stroke during CAS is equivalent to CEA. However, these distal filters remain in place during the entire procedure, and require a pore size of at least 100 microns to maintain perfusion.

"Consequently, smaller sized

particles can pass right through them. In addition, most of the available filters are of the 'one-size-fits-all' type, which means that it is often not possible to obtain ideal wall apposition needed to create an effective arterial seal. These small particles that reach the brain despite the use of EPDs likely result in the higher risk of minor stroke seen with CAS as compared to CEA."

He continued to note that proximal protection systems, on the other hand, have been developed to overcome these problems, but in general, these devices tend to be larger, result in complete cessation of flow during the procedure, and may require a longer learning curve.

The promise lies in the use of double filtration. Dr Sachar started using double filtration in high-risk cases whereby, after stenting, and before post-dilation, a second EPD was deployed proximal to the first EPD, and distal to the stent. "We quickly realised that there was a significant reduction in the risk of symptoms and events using double filtration," he said. "However, using two separate filters increased the complexity and cost of the procedure. In 36% of patients, there was not enough of a landing zone in the internal carotid artery for a second filter."

To further test the potential of double filtration, Contego embarked on testing the Paladin device – devised as a simple and effective solution to the problem of post-dilation embolic showers via combination of an angioplasty balloon with an integrated distal protection filter on the same device. "Because the filter is only open during the post-dilation phase, we were able to fabricate a filter membrane with 40-micron holes that are optimised to capture small diameter embolic debris. Also, the filter can be custom-sized in-vivo, by the physician, to fit any artery up to 7 mm in diameter, maximizing vessel wall apposition," explained Dr Sachar.

Paladin is the first device where the physician can match the filter to the size and shape of the individual patient's anatomy. Once the stent has been deployed in the vessel, the Paladin System is used to not only post-dilate the stent, but also as a filter to capture embolic debris that is released during post-dilation of the stent.

Initial evaluation of Paladin in its dedicated prospective, multi-centre, non-randomised, single-arm study was conducted with 106 patients in five sites in Germany. All patients were followed through 30 days to determine acute device and clinical performance and 30-day safety. The study showed excellent safety and technical success and confirmed that the system was easy to use, and was able to capture particles less than 100 microns in size.

Use of the Paladin System for post-dilation during CAS was safe and resulted in low (<1%) stroke rates. There were no procedural strokes or TIAs. The only stroke was on day 12, in a patient who was non-compliant with anti-platelet therapy and suffered stent thrombosis. Additionally, a filter particle analysis conducted on a subset of 23 patients demonstrated that not only was embolic debris present in 100% of filters evaluated, but that the majority of particles captured were less than 100 microns. An MRI substudy with 30 patients showed that incidence and volume of new ischaemic foci in the brain was among the lowest ever reported. This underscored that the Paladin System is indeed effective in capturing material that may otherwise flow to the neurovasculature.

During his presentation at VERVE, Dr Sachar will be relaying the latest updates surrounding Paladin, as well as touching upon new directions that the proprietary technology is taking. This includes the Vanguard IEP System with Integrated Embolic Protection – a peripheral angioplasty balloon and distal embolic filter on the same catheter.

> "We quickly realised that there was a significant reduction in the risk of symptoms and events using double filtration."
>
> Ravish Sachar

Vanguard protects the lower limbs during angioplasty without the need for additional devices or exchanges. The device has an over-the-wire design with a sheathless integrated 150-micron pore filter distal to the angioplasty balloon. The System's filter is the first to feature in-vivo adjustability to suit varying vessel sizes and to maximise capture efficiency. Single-step filter deployment and a minimal landing zone (5 mm) offer procedural simplicity and ease of added protection.

> "With the Integrated Embolic Protection technology platform, embolic protection can be used in all cases, without adding extra time or complexity."
>
> Ravish Sachar

Recently, the device has been entered into the dedicated ENTRAP Study, which will evaluate the Vanguard IEP System in patients receiving peripheral angioplasty. Principle investigator of the study is Thomas Zeller, Director of the Department of Angiology at Universitaets-Herzzentrum Freiburg in Bad Krozingen, Germany.

The first cases using Vanguard were performed by Ralf Langhoff at the Sankt Gertrauden Krankenhaus in Berlin, Germany, while the first enrolled patient was treated by Koen Deloose (AZ Sint Blasius, Dendermonde, Belgium). Thirty-five patients have been treated with Vanguard IEP in ENTRAP thus far, but overall enrolment is planned in up to 130 patients.

"The ENTRAP Study represents Contego's latest chapter in our ongoing commitment to provide added protection in endovascular procedures," said Dr Sachar. "Knowing that embolisation occurs with every intervention, we are excited to capture data on the safety impact of the Vanguard IEP System on the large and growing patient population undergoing peripheral angioplasty."

Dr Sachar offered his conclusions on the use of the integrated embolic protection concept of both devices: "We know that embolisation occurs with every interventional vascular procedure. However, in aggregate, embolic protection is fully effective in only about 25% of all cases. Factors such as cost, complexity, and our perception of the clinical consequence of embolisation, all influence our decision to use EPDs. With the Integrated Embolic Protection technology platform, embolic protection can be used in all cases, without adding extra time or complexity. Using this platform, we are developing a portfolio of devices that will enhance the safety of endovascular procedures."

Additional information supplied by Contego Medical.

Session 1.11: The endovascular treatment of ruptured AAA Room 1 **Saturday** 11:30–1:00pm

No room for IMPROVEment:
endo superior to open repair in ruptured AAA

Latest results from the IMPROVE trial have recently emerged, with three-year data on endovascular-first versus open repair in ruptured AAAs falling in favour of the endovascular-first approach in terms of survival[1,2]. Matt Thompson (CMO at Endologix Ltd, USA) presents these data on Saturday at VERVE, during a session dedicated to endovascular treatment of ruptured AAA.

Between 2009 and 2016, IMPROVE randomised 613 patients from 29 UK centres and one Canadian centre with a clinical diagnosis of ruptured aneurysm to either endovascular-first (morphology permitting) or open surgical repair. The principal outcome was mortality, with secondary endpoints of reintervention, hospital discharge, health-related quality of life, financial cost, quality-adjusted life-years, and cost-effectiveness (incremental net benefit).[2]

The investigators have previously reported on 30-day and one-year analyses[3,4]. Early 30-day results indicated no difference in terms of early mortality between open surgery and endovascular repair. "I think this was a surprise to most people," commented Professor Thompson in conversation with *VERVE Symposium News*. He detailed further findings: "There were some clear signals that if you did the procedure under a local anaesthetic in a patient that was not too hypotensive, then the results were good. What the early results did show was that patients with EVAR did tend to get home more quickly and were less likely to be in a residential facility. That was, I think, an early signal of what was to come."

On one-year results, he added: "Again, these did show some signal towards an improved quality of life in patients who had the endovascular technique. Also, there was an analysis of morphology paper that demonstrated that the outcome of surgery was very much dependent on the length of the aortic neck[5]. That was irrespective of whether you had endovascular repair or open surgery."

At the three-year analysis carried out with respect to the period of three months to three years, it was reported that fewer deaths occurred in the endovascular group relative to the open repair group (HR 0.57, 95% CI 0.36-0.90), leading to lower mortality at three years (48% vs 56%). Maximum follow-up was around seven years, at which point mortality within the two groups converged.[2]

Expanding on the implication of the mid-term survival advantage within the endovascular group, Professor Thompson said: "[This] advantage didn't seem to be related to the acute survival; it did seem to be related to the fact that if you had endovascular surgery and you needed any form of reintervention, then that reintervention was much less severe and less life-threatening than you got with the open surgery group and was also possibly related to the need for intensive care during the initial hospital stay and consequent renal dysfunction. It also showed that patients in the endovascular group got home more quickly and that was translated into a big advantage in terms of quality of life and therefore cost-effectiveness.

"Overall, the three-year results ended up showing significant advantages to an endovascular strategy: there was a mid-term survival gain, there were gains in quality of life, there were gains in cost and an endo strategy for ruptured aneurysms was clinically effective, and cost effective, and really now should be provided in all institutions that are offering emergency services for ruptured aneurysms."

> "The implications are significant for how you organise your health service."
>
> Matt Thompson

One interesting characteristic of the data that emerged was evidence that females fared better than males when undergoing endovascular therapy. This finding persisted throughout the study, noted Professor Thompson. When asked whether this phenomenon has an explanation, he responded: "No, but we'd very much like to hear a convincing explanation! There is absolutely no doubt that women get a much better result with an endovascular strategy than they do with an open strategy. It may have something to do with the anatomy that one sees in females, particularly with regard to narrower blood vessels, and in terms of the sorts of significant reinterventions that they often need after open surgery. Actually, we have looked at quite a number of different hypotheses and haven't found a particularly compelling reason why the females do better with endovascular. I'm sure people will continue to look into it, and it is an important finding."

Upon the emergence of 30-day outcome data of the IMPROVE trial, surprise gave way to a reexamination of the data by some, as summarised in a 2015-published written debate[6]. Given the shortcomings that were noted in this debate by co-authors Frank Veith and Caron Rockman – namely, that the high crossover rate from endovascular to open repair invalidated any intention-to-treat analysis – does Professor Thompson now have any reservations about the methodology of IMPROVE? "You have to take the results at face value," he said.

> "People were very quick to jump up and criticise IMPROVE. But actually it has ended up with the result that most people predicted."
>
> Matt Thompson

"One aspect about any randomised trial in any field is that they do tend to get picked over, and they do tend to have their critics. But running randomised trials is hard – and running randomised trials in an emergency, life-threatening medical condition is really hard. People will have a different view on the trial according to their intrinsic bias. I know Frank's opinion, but actually the trial has eventually demonstrated an advantage to an EVAR first strategy. When all is said and done, the randomised controlled trial is the highest level of evidence that we have in medical practice. They are a higher level of evidence than observational cohort studies, which are where most people's ideas of what the idea should be come from."

Summarising his thoughts on the trial, he continued: "The IMPROVE trial, and the other couple of randomised trials that have been done with ruptured aneurysms[7,8], are an example of the evidential culture within vascular surgery.

"And it's an interesting commentary as to how it's ended up. People were very quick to jump up and criticise the IMPROVE methodology and design. But actually it has ended up with the result that most people predicted, although the pathophysiology underlying the findings was unexpected. The mortality benefit doesn't seem to be related to the immediate operation; you tend to see the mortality benefit further down the line, which is probably due to complications that have developed after the initial surgery, and the management of those complications.

"I think it gives us a high quality of evidence, and the implications are significant for how you organise your health service, because there

Continued on page 14

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No room for IMPROVEment

Continued from page 12

is clear Level 1 evidence now that patients do better with an endovascular strategy. Because of that, it is going to mean a lot of services will have to be reorganised to make sure patients have access to EVAR for ruptured AAA."

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Session 1.12: Aorto-Iliac Occlusive Disease Room 1 **Saturday** 2.00–3.30pm

Expanding the use of CERAB

Peter Goverde is a vascular and endovascular surgeon, based at the Vascular Clinic ZNA, part of the Hospital Network of Antwerp in Belgium. He is also a co-director of the ZNA Multi-Disciplinary Diabetic Foot Clinic and of the ZNA Chronic Wound Clinic, with special interests that include vascular access surgery. He is most well-known for developing new technologies and techniques for the treatment of aortoiliac and femoropopliteal occlusive disease, and is extremely interested in the biomechanical and haemodynamical behaviour of the peripheral arterial circulatory system.

> "It has a tremendous impact on the patient in terms of hospital stay, ICU stay and rehabilitation."
>
> Peter Goverde

Dr Goverde will be presenting the latest results on the use of Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) technique. He developed this technique – which combines three covered stents to treat extensive aortoiliac occlusive disease – eight years ago. "It is like every invention, it actually was discovered by coincidence," he said.

The CERAB technique has since been applied around the world, he said, because it has been found to improve upon other procedures that do not use covered stents. "You have bare metal stent constructions that are actually having an influence on the flow," he said. "They have haemodynamic consequences that could trigger early thrombosis and could affect the outcome of the revascularisation in an early stage."

In contrast, CERAB's covered stents are combined in a completely closed entity. "The stents are deployed so there is no bare-metal exposed to the blood or dead space," explained Dr Goverde. "With this technique, the haemodynamics inside the bifurcation are actually preserved and we have a better flow from the distal aorta into both iliacs."

This is one of several sessions Dr Goverde will be presenting at this year's VERVE Symposium, and will be dedicated to a recent study of 130 patients in Belgium and the Netherlands. Results after three years have shown that the CERAB technique can provide significant benefits over traditional methods. "We have three years of data, and when you compare that to the five-year data of classic surgery, it's almost in the same region," he said. "It can be a very good alternative to more aggressive invasive surgery."

One of the benefits of CERAB over classic surgery, said Dr Goverde, is the avoidance of abdominal incision: "[CERAB] requires two punctures in the groin and sometimes a puncture in the arm, in case of occlusion. This is a less invasive technique than the more frequently-used classic surgical opportunity," he said.

"Because it's minimally invasive, we have fewer classic surgical complications like wound infections or risk of hernias and intra-abdominal adhesions."

His group has compared the hospital stay of patients that have undergone CERAB-based procedures with a meta-analysis of earlier research on patients who had undergone classic surgery. "It has a tremendous impact on the patient in terms of hospital stay, ICU stay and rehabilitation," he stressed.

The average hospital stay in the CERAB group was a little over two days, whereas the average in the classic surgery group was around one week. "In terms of rehabilitation, most of the percutaneous-treated patients can walk out of the hospital the next or the second day after the procedure, whereas the classical surgical patients normally stay for one week and then undergo rehabilitation for let's say four to six weeks."

Dr Goverde said that the most recent results are just the latest in a series of papers that have been published on this technique, showing its benefits. "Haemodynamics were actually much better in this CERAB configuration than when you use covered kissing stents," he said. "We carried out in vitro testing and it showed us that CERAB has much better haemodynamic consequences on the bifurcation."

For that reason, Dr Goverde hopes the technique will be used more widely. "It is becoming more and more popular. I estimate that 200-300 each year are done in the Netherlands alone," he said, adding: "Its use is widespread. They do a lot of CERABs in Europe, Brazil, Hong Kong, Singapore, Australia – actually everywhere where the large covered stents are available."

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VERVE 2017 MEDTRONIC LUNCH SYMPOSIUM

The MEDTRONIC **LUNCH SYMPOSIUM** provides an opportunity for participants to hear from local and international faculty on **Vessel Preparation and its Pivotal Role Towards Maintaining Flow.**

GUEST SPEAKERS:

- Assoc. Prof Andrew Holden
  Session Chair
- Prof Fabrizio Fanelli
  "Calcium Effects on Vessel Preparation"
- Dr. Ravish Sachar
  "Vessel Preparation - What, When, & Where is it Needed?"
- Dr. Vikram Puttaswamy
  "Hawk and the Australian Experience"

DATE:
SATURDAY 9 DECEMBER 2017
13:00 - 14:00

VENUE:
VERVE SYMPOSIUM, ROOM 2
PARKSIDE BALLROOM, LEVEL 2, ICC SYDNEY

HOW DO YOU TREAT NO-STENT ZONES? WITH A **GAIN MAINTAIN** APPROACH.

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* DEFINITIVE LE Trial , McKinsey, JACC, 2014

** Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularisation through 12 months. Krishnan, VIVA 2016.

Session 2.1: Current Status and Insights into Contemporary AAA Repair Room 2 **Thursday** 12:00–2:00pm

Fifteen years of EVAR trials: what have we learned?

Contemporary AAA repair is the order of business on Thursday at VERVE, with Jon S Matsumura (University of Wisconsin School of Medicine and Public Health, Madison, WI, USA) stepping up to the podium to offer the lessons learned from more than 15 years of EVAR trials.

Speaking to *VERVE Symposium News*, Dr Matsumura underlined that the faster recovery and lower periprocedural risk of EVAR, as detailed by trial data over recent years, has meant that EVAR has established itself as the preferred strategy in the majority of cases.

However, he added that there are still a minority of experienced surgeons who feel that open repair is the gold standard. "Many surgeons feel that certain groups still are best for open repair – those with poor compliance, small/diseased iliac arteries, horseshoe/pelvic kidneys, severe neck angulations, connective tissue diseases, etc," he said.

During his presentation at VERVE, Dr Matsumura will explore the data and trials that have underpinned the use of EVAR today. "We should be proud of the broad base of evidence that we use to guide care," he said, adding: "EVAR, DREAM, and OVER are early examples of our commitment to clinical science."

Other trials he highlighted include ACE, EVAR 2, the Amsterdam and French rupture trials, PIVOTAL, CAESAR, aardvark, PHAST, CANTOS and beyond. "They all have some pertinent data contributions, in addition to the larger direct comparisons," said Dr Matsumura.

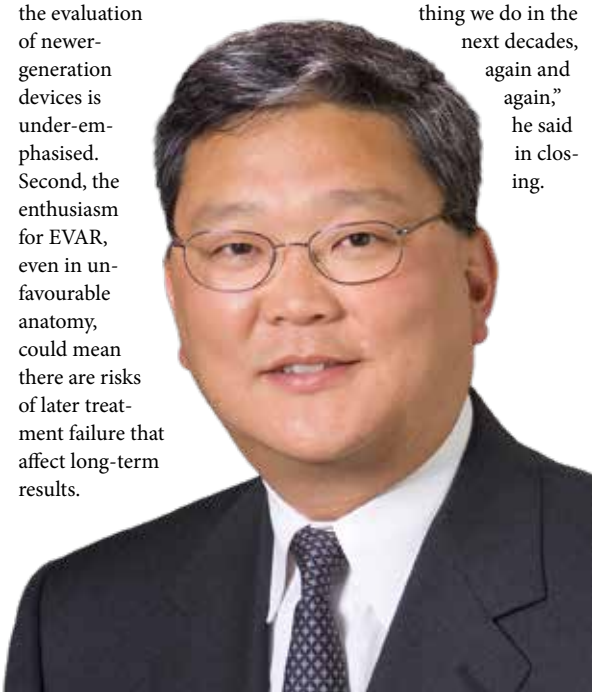
He will also touch upon a few ruptured AAA trials, notably IMPROVE, in another talk held during Saturday's 'The Endovascular Treatment of Ruptured AAA' session. "In general, they offer excellent insight into the complex and challenging care of these desperate patients, clearly establish similarity of the two therapies, and I have a few reflections on where to go next for further improvement," he said.

Looking to the data from large, ongoing EVAR trials, Dr Matsumura spoke of the observation that more secondary interventions were apparent in EVAR, compared to open surgery (e.g. as shown in the EVAR 1 trial). He said it could possibly be down to usage of EVAR in unfavourable anatomy, and closer/stricter follow-up, which may unveil more benign indications for secondary intervention. In addition, patient selection, device sizing and deployment techniques have improved, and studied devices are early-generation, and no longer widely used.

Another minor factor to consider is whether randomised controlled trial data are more intuitively likely to include healthier patients (i.e. those who are eligible to be randomised to either open repair or EVAR). As such, registries and smaller studies might also be important. "They each have their advantages, but randomisation allows balanced allocation of unmeasured factors which makes it critically important for major policy decision making," reasoned Dr Matsumura.

> "New therapies will need to be similarly studied prior to widespread adoption, but likely will change everything we do in the next decades, again and again."
>
> Jon S Matsumura

While the VERVE audience will have to wait until Dr Matsumura's presentation to be privy to his "lessons learned", he did give a glimpse of some of the topics that he will discuss. First, while longer follow-up with older-generation devices helps inform on the strengths and weaknesses of control treatment groups, the evaluation of newer-generation devices is under-emphasised. Second, the enthusiasm for EVAR, even in unfavourable anatomy, could mean there are risks of later treatment failure that affect long-term results.



"We have all made this mistake at least once. Sometimes it is evident in immediate or early follow-up," he said.

Offering his conclusions, Dr Matsumura stressed that we should use look to the commitment to innovation, embrace of change and evidence development that has taken place over the last 15 years as an example of how we need to engage the future. "New therapies will need to be similarly studied prior to widespread adoption, but likely will change everything we do in the next decades, again and again," he said in closing.

Session 2.12: Future Technological Development in the Treatment of Vascular Disease Room 2 **Saturday** 2:00–3:30pm

Bringing endovascular training up to date: the Australian experience

Vascular surgeon Anthony Freeman (University of Sydney, Australia) looks at the current state and future of training in endovascular skills during a Saturday afternoon session dedicated to future technological development at VERVE 2017. Speaking to *VERVE Symposium News* ahead of the meeting, he provided, as he put it, "an interesting juxtaposition to challenge what has been done to date in endovascular training".

> "…the formal components of our assessment are very heavily biased towards open surgery. I think that there, there needs to be a change."
>
> Anthony Freeman

How would you describe the extent and quality of training in endovascular techniques, in your experience?

In Australia we have a very strong vascular surgery training programme. We adopted endovascular intervention very early. We are blessed that there were a number of innovators that were vascular surgeons in Australia and New Zealand that were early adopters of endovascular technology. All vascular and surgical practice in Australia has reflected that.

Similarly, our training programme reflects it. We have a very strong training programme in endovascular surgery. I think our trainees are actually well taught in endovascular skills and are exposed to endovascular skills quite appropriately from a time early on in their experience.

But what I don't think is kept up is in really formalising the requirements around that. While there has been this change from open to endovascular surgery, and the trainees embrace this and get a good endovascular experience, still the formal components of our assessment are very heavily biased towards open surgery. I think that there, there needs to be a change.

Where do the discrepancies lie between assessment and real-world demands of training?

The focus of the requirements of endovascular skills is still reasonably narrow. It hasn't really kept pace with the reality of the experience that the trainees have. In fact, if you have a look at what the requirements are in the curricula, they only necessitate being able to perform straightforward femoropopliteal interventions and infrarenal aortic endografts. But the reality is that if that is all they could do at the end of their training, they would be quite disappointed! The reality also is that the experience that they have is probably much broader.

In fact, if you take a look at the VERVE symposium, it is promoting technical excellence in endovascular intervention. A lot of the trainees aspire to being able to perform a lot of the techniques that are being showcased at the conference. Our curriculum needs to represent that. It needs to include things like complex aortic interventions, endovenous interventions, management of dialysis access – the whole gamut of endovascular procedures that the trainees are performing.

> "A lot of the trainees aspire to being able to perform a lot of the techniques that are being showcased at the conference."
>
> Anthony Freeman

We live in a time of competence-based training. Our trainees do expect to be competent in a much broader range of endovascular interventions than currently they are prescribed to do – particularly because today, vascular conditions are by and large managed endovascularly. That is what the trainees are demanding, and it is also the nature of being an independent practitioner managing people with vascular disease.

What is the role of simulation in training, and its limitations?

My personal feeling is that the best place for the trainees to learn and to be assessed is in the operating theatre. Simulation does have a role early on in training when they are trying to establish fundamental endovascular skills; but, similar to open training, endovascular training – as well as formal assessment – needs to be done in the theatre.

To be an endovascular interventionalist, you need to be able to adapt to what is a dynamic environment, and to adapt to real patients. That is where the assessment needs to be done. Simulation can never take you to high-level cases, where you have to adapt your decision-making. It can't help you with situational awareness around the operating theatre. It can't help you with patient selection.

What do we know to date about the best way to assess training competence? How relevant are factors such as case volume, centre volume, dedicated expert centres, etc., and how do these factors interact?

Historically, this was based on doing a certain number of cases and spending a certain amount of time in a unit. And the reality is that a lot of the tools that are available to us were based upon tools that were used in the open era, and probably aren't as relevant to endovascular practice today. We are going to need to come up with a suite of endovascular-specific tools to assess our trainees' competence.

I don't prescribe to the historical notion that it is all about case volume. What is more important is the quality of teaching during those cases. That is why having specific tools for endovascular training, where we can provide assessments for trainees to guide them where they can direct their efforts, is probably going to have a better yield than simply more cases. In a properly structured training programme, you can have trainees competent in these techniques without necessarily having done hundreds of procedures.

The reality is that a lot of these techniques are specialised, and you might not be exposed to large numbers of them – even in specialist centres. What is important is to take the opportunity to train the trainees and to have a mechanism by which to assess whether they are in a position to do more complex procedures.

There are a lot of centres in Australia and New Zealand that are now doing fenestrated and branched endografting. We need to identify when the trainees are competent in, for example, more simple infrarenal grafting, and then take those opportunities to let them do the more complex procedures. This is about appropriate assessment.

Is there ongoing study dedicated to developing appropriate tools to aid assessment of training competence?

The EVARATE study[1] is a tool that has been developed to assess the ability to perform an aortic endograft. But it is a tool that hasn't yet been validated in the clinical setting.

Reference

1. Strøm M, Lönn L, Bech B et al. Assessment of Competence in EVAR Procedures: A Novel Rating Scale Developed by the Delphi Technique. Eur J Vasc Endovasc Surg. 2017 Jul;54(1):34-41.

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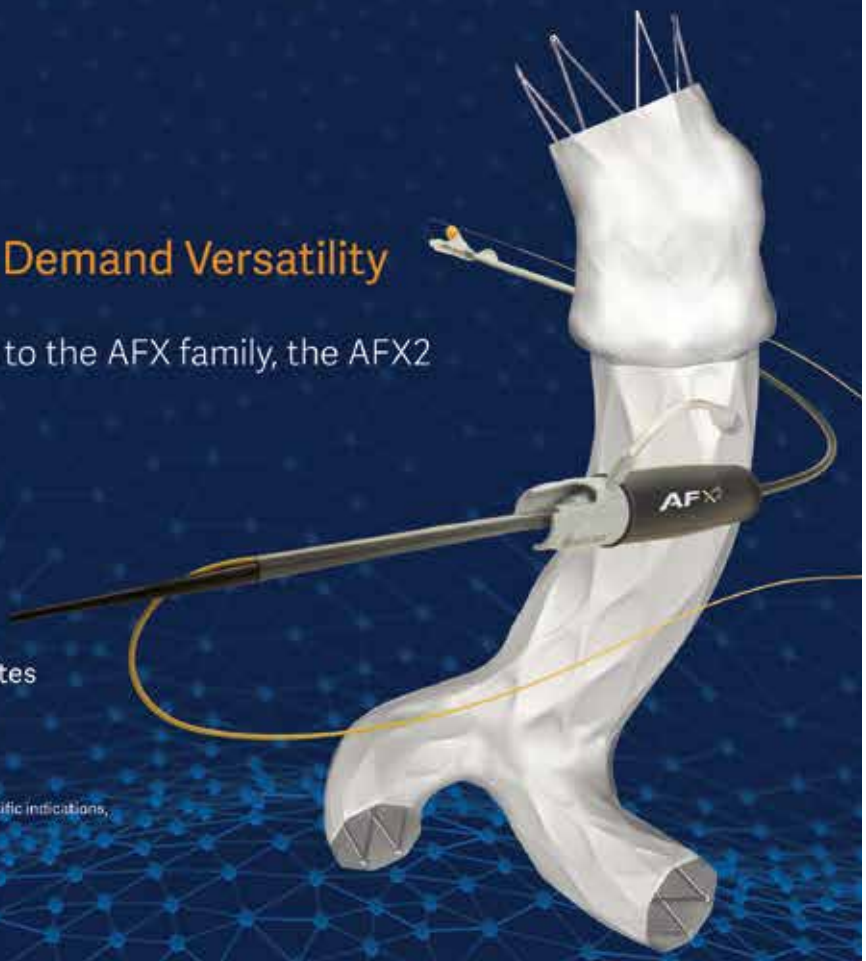

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