venousnews

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Published ATTRACT data call into question validity of the Villalta scale

Following the publication of the ATTRACT trial in the *New England Journal of Medicine* (*NEJM*) in December 2017, *Venous News* spoke to experts in the field to analyse the data and formulate future research questions. One of the interesting points raised was whether the Villalta scale is an altogether valid measure of post-thrombotic syndrome, even though its use is recommended by international guidelines. The Villalta scale is considered the gold standard for the diagnosis and classification of post-thrombotic syndrome, when combined with a venous disease-specific quality-of-life questionnaire.

The ATTRACT (Acute venous thrombosis: Thrombus removal with adjunctive catheter-directed thrombolysis) triallists set out to assess the treatment effect obtained by adding pharmacomechanical thrombolysis and ancillary measures including thrombus aspiration/maceration, with or without balloon angioplasty/stenting vs. anticoagulation alone on the incidence of post-thrombotic syndrome.

Stephen Black

Lowell S Kabnick

As reported in *NEJM*, Suresh Vedantham (Professor of Radiology and Surgery, Mallinckrodt Institute of Radiology, Washington University in St Louis, USA) and colleagues randomly assigned 692 patients with acute proximal deep-vein thrombosis to receive either anticoagulation alone or anticoagulation plus pharmacomechanical thrombolysis. The primary outcome of the study was defined as the cumulative incidence of post-thrombotic syndrome, as diagnosed and measured by the Villalta scale, between six and 24 months of follow-up.

Secondary outcome measures included the severity of post-thrombotic syndrome; resolution of presenting deep venous thrombosis symptoms; the prevalence of valvular reflux and residual thrombus, the degree of clot lysis; and cost-effectiveness within 24 months of randomisation. Further, major bleeding, symptomatic pulmonary embolism, recurrent venous thromboembolism, and death within 10 days and 24 months after randomisation formed part of the secondary outcome.

According to the data published in the *NEJM*, the ATTRACT trial data did not show a significant between-group difference in the percentage of patients with the post-thrombotic syndrome (47% in the pharmacomechanical thrombolysis group and 48% in the control group; p=0.56) between six and 24 months. Pharmacomechanical thrombolysis led to more major bleeding events within 10 days (1.7% vs. 0.3% of patients; p=0.049). However, no significant difference in recurrent venous thromboembolism was seen over the 24-month follow-up period (12% in the pharmacomechanical thrombolysis group and 8% in the control group, p=0.09). "Moderate-to-severe post-thrombotic syndrome occurred in 18% of patients in the pharmacomechanical-thrombolysis group vs. 24% of those in the control group (p=0.04). Severity scores for the post-thrombotic syndrome were lower in the pharmacomechanical thrombolysis group than in the control group at six, 12, 18 and 24 months of follow-up (p<0.01 for the comparison of the Villalta scores at each time point), but the improvement in quality of life from baseline to 24 months did not differ significantly between the treatment groups," the authors report.

Based on the data obtained from the study, the triallists concluded that "among patients with acute proximal deep vein thrombosis, the addition of pharmacomechanical catheter-directed thrombolysis to anticoagulation did not result in a lower risk of the post-thrombotic syndrome but did result in a higher risk of major bleeding."

Stephen Black, consultant vascular surgeon at Guy's and St Thomas' Hospital, London, UK, and one of the editors-in-chief of *Venous News*, says: "The triallists have done an immense job in completing this study to gather these data. While it is easy to be an armchair critic, perhaps the biggest change I would have made is to not have a binary outcome measure of post-thrombotic syndrome. The most interesting ATTRACT trial data were the two tables: one showing binary data (ie., yes or no to the incidence of post-thrombotic syndrome) and the other showing continuous outcome data. What is striking is that the binary data (which was used as the primary outcome measure) shows no difference; however, the continuous data shows that patients who had the more aggressive inter-

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Brave Dreams trial finds venoplasty "safe, but largely ineffective" for MS patients

Paolo Zamboni, Ferrara, Italy, the proponent of the chronic cerebrospinal venous insufficiency (CCSVI) theory, and his colleagues have reported that the randomised, double-blinded, sham controlled Brave Dreams trial has not demonstrated a benefit for venous angioplasty in the treatment of patients with multiple sclerosis (MS).

Zamboni, presented the results of the Brave Dreams trial at VEITHSymposium (14–18 November, New York, USA). The results were also simultaneously published online ahead of print in *JAMA Neurology* on 18 November.

Chronic cerebrospinal venous insufficiency (CCSVI) is a term that describes compromised flow of blood in the veins draining the central nervous system. According to Zamboni, it is characterised by restricted venous outflow from the brain and spinal cord. "Whether this condition is associated with MS and whether venous percutaneous transluminal angioplasty is beneficial in persons with MS and CCSVI is controversial," the authors write in *JAMA Neurology*.

Many MS patients and advocacy groups are disillusioned by the influence of drug companies in their medical treatment regimens and have become passionate torchbearers of CCSVI and venous angioplasty after it was first proposed in 2009. The rapid spread of information regarding the scientifically unproven condition, CCSVI, and also angioplasty as a proposed treatment option via the internet resulted in patients travelling afar to receive this treatment, much before it was rigorously tested. Recent well-designed randomised controlled trials

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Brave Dreams trial finds venoplasty "safe, but largely ineffective" for MS patients

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Paolo Zamboni

have not shown a benefit for venous angioplasty for MS patients.

As reported in *JAMA Neurology*, Zamboni and colleagues noted that in the Brave Dreams trial, which included 115 patients with relapsing-remitting multiple sclerosis, venous angioplasty did not increase the proportion of patients who improved functionally nor did it reduce the mean number of new combined brain lesions on magnetic resonance imaging at 12 months. The team further reported that there was a tendency for more patients to become free of new lesions after venous angioplasty, mainly because of a reduction in new lesions appearing six to 12 months after randomisation. These findings led them to conclude that venous angioplasty cannot be recommended for patients with relapsing-remitting multiple sclerosis.

The trial was carried out in six MS centres in Italy from 2012 to 2016. Patients were randomly allocated (2:1) to either venous angioplasty or catheter venography without venous angioplasty, which was the sham arm and the findings analysed on an intention-to-treat basis.

The two primary endpoints assessed at 12 months were: a composite functional measure (ie, walking control, balance, manual dexterity, postvoid residual urine volume, and visual acuity) and a measure of new combined brain lesions on magnetic resonance imaging, including the proportion of lesion-free patients. Combined lesions included T1 gadolinium-enhancing lesions plus new or enlarged T2 lesions.

The authors concluded: "Venous angioplasty has proven to be a safe but largely ineffective technique; the treatment cannot be recommended in patients with MS."

Early results of iliocaval reconstruction with stents for venous outflow obstruction patients are encouraging

James Budge

"Endovascular reconstruction of the chronically obstructed iliocaval venous tract with stents is technically feasible, minimally invasive and has an acceptable safety rate, said James Budge, Department of Vascular Surgery, Guy's and St Thomas', London, UK.

"Patients who underwent this procedure reported overall significant early improvement in the severity of post-thrombotic syndrome. Still, longer-term data and larger studies are needed to evaluate procedural durability, clinical efficacy and cost-effectiveness," he said.

Budge was speaking at The Vascular Societies' annual scientific meeting (22–24 November, Manchester, UK) and reported the results from a study that aimed to investigate the early outcomes of endovascular iliocaval reconstructions with stents in a single centre.

Chronic iliocaval obstruction, particularly secondary to deep venous thrombosis, may result in disabling chronic venous insufficiency or post-thrombotic syndrome of the lower limbs. "Recent advances in venous stent technology have enabled such pathologies to be treated with minimally invasive endovascular iliocaval reconstruction, whilst it was previously amenable to unsatisfactory conservative therapy, or invasive open surgical reconstruction," Budge explained.

Investigators obtained data from consecutive patients who underwent endovascular iliocaval reconstructions with stents for chronic iliocaval obstruction between 1 February 2013 and 1 August 2017. The data were retrospectively identified from a prospectively collected patient database.

"Outcome measures and data collected included patient demography; patency (primary, primary-assisted and secondary, or blockage). We also collected perioperative details, including technical details and complications in the period. Pre- and post-operative Villalta scores were collected and analysed," he reported.

All patients were managed by a multidisciplinary team that included haematologists, interventional radiologists, vascular surgeons and clinical nurse specialists.

"The most common stent configuration used in this study was a double-barrelled venous-specific nitinol stent, which, where necessary, entered into a single lumen stent cranially," Budge reported.

Researchers included data from 36 patients (23 male; with a median age of 34 [19–73]). There were 32 patients with a previous deep venous thrombosis; three with previous pulmonary embolism; 13 with recognised thrombophilia and two who had undergone previous deep venous intervention. The median follow-up was 15 months.

"With regard to the distribution of the disease, there were 30 patients with infrarenal disease that may or may not have involved the iliacs. There other six patients had supra and infrarenal disease, with or without iliac involvement," Budge said.

"There was no post-interventional statistically significant deterioration of renal function measured as serum creatinine and estimated glomerular filtration rate. In this study, we saw no symptomatic major haemorrhage, although three patients required a single unit of red blood cell transfusion; and there were no other immediate or major complications," Budge noted.

"The results at one year showed a 47% primary patency rate; 67% primary-assisted patency and 80% secondary patency rate. We feel that our primary patency rate is comparable to other groups in the published literature, although the follow-up period is much shorter. The median Villalta score pre-intervention was 18, which corresponds to severe post-thrombotic syndrome. Post-intervention, this dropped to a median of 9.5, which corresponds to mild post-thrombotic syndrome, and this is a statistically significant improvement," Budge concluded.

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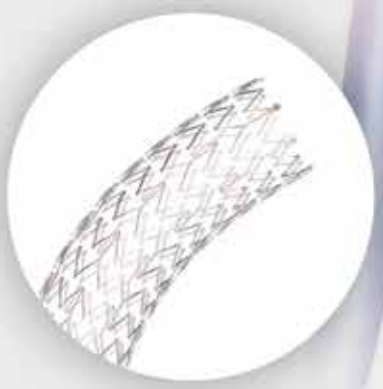

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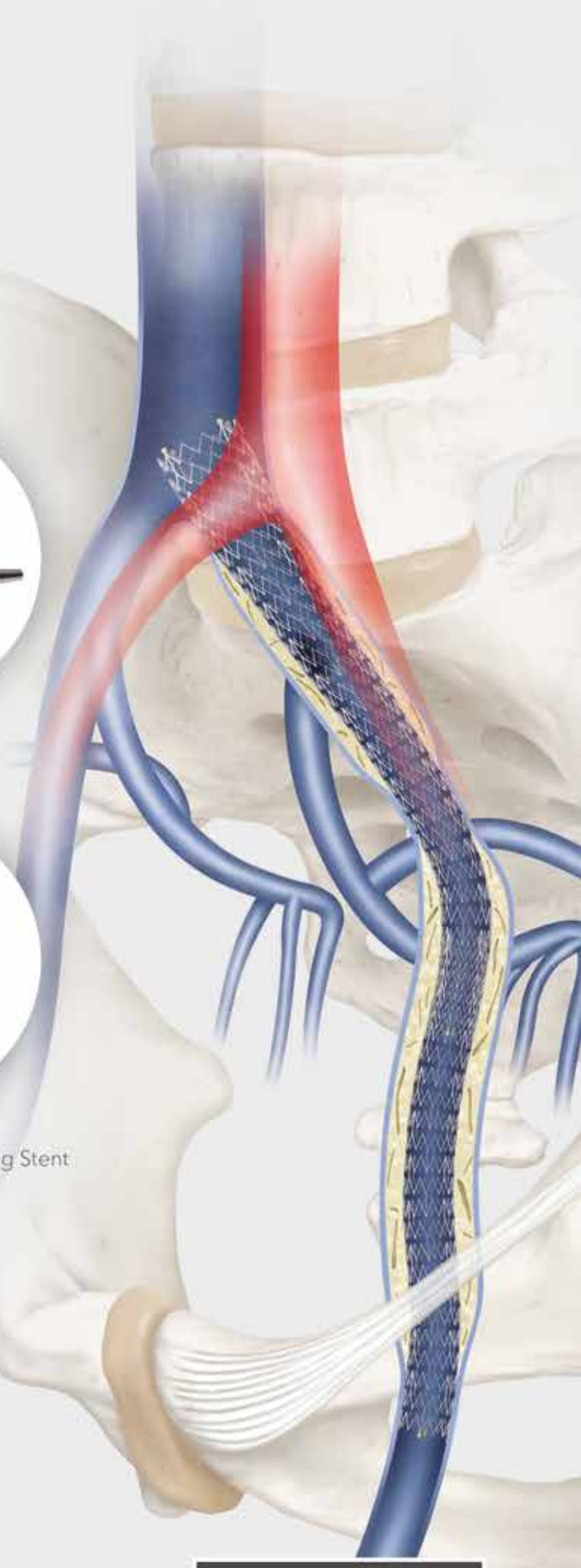

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vention were significantly better, based on symptoms at every time point. This suggests that while lysis did not prevent the onset of post-thrombotic syndrome, those patients who had pharmacomechanical catheter-directed thrombolysis were significantly better, based on symptom improvement. In other words, had the endpoint been focused on symptom improvement, this would have been a study that favoured intervention. This appears to have been largely overlooked in the presentation of the trial data."

Lowell S Kabnick, director, NYU Vein Center, Division of Vascular Surgery, NYU Langone Medical Center, New York, USA, and the immediate past president of the American Venous Forum, notes: "The lack of clinical significance for the primary endpoint between groups was disappointing; however, the decrease in severity of post-thrombotic syndrome with pharmacomechanical catheter-directed thrombolysis is important."

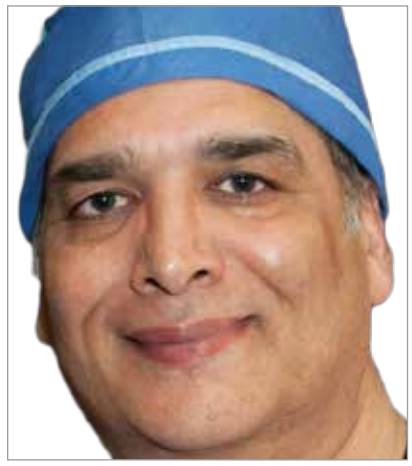
For Gerry O'Sullivan, vascular and interventional radiologist, University Hospital Galway, Galway, Ireland, the single biggest take-home from the trials was that "regardless of whether you are an interventionalist or an internal medicine specialist, the rate of post-thrombotic syndrome was incredibly high—nearly 50%—in both groups at two years. So whether we use anticoagulation or catheter-directed thrombolysis (or any of the other techniques), at the moment we are not doing these patients any favours as these treatment outcomes are unacceptable."

Ramesh K Tripathi, adjunct professor, Faculty of Science, Health, Education and Engineering, University of the Sunshine Coast, Australia, states: "ATTRACT showed encouraging trends between the two studied subgroups analysed. Unfortunately, when evaluated separately, they were not sufficiently powered to show statistically significant differences. That may be one of the reasons why this study does not change my current practice protocols. It struck me that only one out of every 52 patients that met the inclusion criteria was recruited into this study. At a sample size of 692 recruited patients, it is assumed that 30% of patients will develop post-thrombotic syndrome during 24 months with a 33% risk reduction in the pharmacomechanical thrombolysis group. In reality, the outcomes at 24 months show a 48.2% post-thrombotic syndrome with anticoagulation compared with 46.7% in the catheter-directed lysis group."

Is the Villalta scale fit for purpose?

The Villalta scale has widely been used as a scoring system to diagnose and classify post-thrombotic syndrome. International guidelines recommend that post-thrombotic syndrome is assessed using the Villalta scale, a clinical measure that incorporates venous symptoms and signs in the leg ipsilateral to a deep venous thrombosis. In the main, criticism of the Villalta score in the literature appears to be based on its reliance on subjective measures. Arany Soosianathan and colleagues proposed in the *Journal of Vascular Surgery* (2013) that "the Villalta score, combined with a venous disease-specific quality-of-life questionnaire, should be considered the 'gold standard' for the diagnosis and classification of post-thrombotic syndrome."

Gerry O'Sullivan



Ramesh K Tripathi

Importantly, the post-thrombotic syndrome is a hard entity to precisely define—a "very difficult diagnosis to pin down, particularly in the less severe cases", according to O'Sullivan. The ATTRACT trial investigators also alluded to this in the publication. "Because the post-thrombotic syndrome varies in its clinical manifestations, we evaluated its presence and severity in complementary ways. Assessments made with the use of the Villalta scale and the Venous Clinical Severity Score were consistent in suggesting that pharmacomechanical thrombolysis reduced the severity of the post-thrombotic syndrome, which raises the possibility that the aetiologic factors that predispose patients to the development of the post-thrombotic syndrome may differ at least partly from those that determine progression to advanced post-thrombotic syndrome," the ATTRACT authors write.

O'Sullivan says: "The issue with post-thrombotic syndrome is that there is no method to identify it and measure it, and really the Villalta scale is a rather imperfect method. Indeed, it has never been formally published and therefore, never been subjected to the standard scrutiny that publication brings. Again, this is not in any way to criticise the triallists for employing this; because it is generally accepted as the best measure that we currently have; it is just that it is less than ideal and this is not only problematic for the results of this trial, but also for any studies in the field of deep venous thrombosis research.

"At two years following a deep venous thrombosis, my patients usually do not have ulcers, or skin changes; they might have a degree of oedema, but the most common symptoms are venous claudication and weight gain. There is currently no accepted measure for venous claudication, which is incredible. In the arteries we have the ankle brachial pressure index (ABPI; a method for quantifying the severity of arterial occlusion in the leg), yet there is no such comparable measure in veins and this is a huge problem.

"The bigger issue with the Villalta scale is that it has been shown fairly conclusively (by Fedor Lurie *et al*, for instance) that even *without* a history of deep vein thrombosis, a patient can achieve a score of five on the scale and by the definition employed in ATTRACT be labelled as having post-thrombotic syndrome. So it is questionable to me at least what the nearly 50% rate really means."

Black echoes these doubts about the Villalta scale as a reliable measure of post-thrombotic syndrome. "One key question for me remains the outcome measure we choose to assess these patients. Villalta is undoubtedly inadequate and until we find a more robust measure to assess these patients, we will continue to find it difficult to accurately answer questions about post-thrombotic syndrome," he notes.

> ***"The issue with post-thrombotic syndrome is that there is no method to identify it and measure it, and the Villalta scale is a rather imperfect method. It has never been formally published and therefore, never been subjected to the standard scrutiny that publication brings."***

Inclusion of femoropopliteal patients

Many experts also believe that the inclusion of femoropopliteal patients into the trial might have confounded its results. Since recruitment into the trial was slow, the investigators pursued a strategy of including patients with femoropopliteal disease as well as iliofemoral disease (56% of the cohort).

Kabnick commented that with designing a trial such as ATTRACT "there are always trade-offs". "The cohort of patients with acute femoral-popliteal deep venous thrombosis could have confounded the results of the trial. Thus, the primary outcome measure may have been attainable by decreasing the magnitude of post-thrombotic syndrome through pharmacomechanical catheter-directed thrombolysis in iliofemoral deep venous thrombosis. However, without the addition of the femoropopliteal segment, completion of the decade-long study would have been longer and other study obligations would have surfaced. Regardless of these results, or lack of results, I believe that clinicians will strongly consider procedural intervention in the patients with acute iliofemoral deep venous thrombosis. Of course, further investigation is necessary to determine treatment as well as eligible candidates."

Tripathi states: "The sample pool was contaminated by the inclusion of more distal deep venous thrombosis cases (43% overall) in order to ensure adequate enrolment."

Black agrees: "Clearly the slow rate of enrolment hindered the study and led to the inclusion of femoral deep venous thrombosis patients which has hampered the analysis."

Venous stenting following thrombus removal

Tripathi also commented on the low stenting rate in the trial. "Although 62% patients underwent iliac venoplasty, only 28% underwent iliac vein stenting. Given the high rate of recoil of lesions that underwent venoplasty, this may be of critical importance as in real life practice most of these patients would undergo stenting," he said.

O'Sullivan talks about the low stenting rate in the trial by referring to current European thinking that 80–90% of iliofemoral deep venous thrombosis patients, following removal of thrombus

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Continued percutaneous valvuloplasty development “is promising”

Continuing work to develop an improved percutaneous valvuloplasty procedure “is promising”, said Johann Chris Ragg (Angioclinic Vein Centers, Berlin, Munich, Germany, and Zurich, Switzerland), as he updated delegates on the technique at the annual American College of Phlebology meeting (ACP; 2–5 November, Austin, USA). He also argued that now is the time to “prepare the stage” for this treatment, primarily by recognising early phase reflux as its own specific disease.

Valve zone dilation is one of the three ways by which primary venous insufficiency can develop (alongside congenital valve defects and valve degeneration). This leads to consecutive local overload and progression of venous incompetence. “If dilation is the problem, compression could be the solution,” Ragg told ACP delegates, by treating the temporary reflux that marks the beginning of the disease process. In the case of percutaneous valvuloplasty, this can be achieved using perivenous hyaluronan gel to shape the vein and restore flow.

A “good” percutaneous valvuloplasty procedure requires the selection of patients with failing, but still intact and mobile, cusps, Ragg explained. The hyaluronan gel must have an appropriate balance of injectability (which improves as viscosity is reduced) and durability (which improves as viscosity increases). Finally, the injection technique should place minimal amounts of gel as close as possible to the vein wall, in order to make the procedure more affordable.

The first two trials of percutaneous valvuloplasty conducted were very similar in design, but used two different gels. The first study took place in 2013 and used Macrolane (VRF 30), which is a low-cost, large-particle (>1mm) gel previously approved for breast enhancement procedures. The second trial ran from 2014 to 2015 and used Princess (Croma/Austria), which is a smooth, small-particle (<0.2mm) gel approved for aesthetic use.

The first study included 23 patients (15 female and eight males aged 38–67 years). The second study enrolled 18 patients (12 females and six males aged 34–69 years). Both trials were for proximal valve incompetence of the greater saphenous vein. The patient cohort for the first trial had vein diameters of 7–11.5mm with a mean diameter of 8.6mm. The cohort for the second trial had vein diameters of 7–11.8mm with a mean diameter of 8.9mm. Follow-up for both trials went out to 52 weeks and used ultrasound 3D scans.

Initial haemodynamic success was achieved in 92.6% (n=22) of Macrolane patients and 100% (n=18) Princess patients. A second session was required for 31.8% (n=7) of Macrolane patients and 27.8% (n=5) of Princess patients. Supplementary injections at one year were given to 31.8% (n=7) of Macrolane patients and 22.2% (n=4) of Princess patients. At one year follow-up, 100% of both groups had orthograde flow. The volume of gel used was higher in the Macrolane group (12–35ml, mean 19.4ml) than in the Princess group (4–9ml, mean 6.9ml). As for cost, Macrolane was much cheaper (US$18/ml) than Princess (US$120/ml), with a mean procedure cost of US$350 versus US$830.

Johann Chris Ragg

A third study, conducted in 2017, evaluated hyaluronan gel, which Ragg described as the next step in the “evolution of injectable gels”. The average human has approximately 15g of hyaluronan in their body, one third of which is degraded and synthesised every day. Linkage of monophasic hyaluronan molecules with sorbitol is one way in which the viscosity, stability and persistence of injectable products can be modified.

Ragg explained that the 2017 trial used this approach to inject hyaluronan gel with local anaesthesia and ultrasound monitoring, with no bandages or compression stockings used afterwards. Twelve patients (six female and six male aged 32–54 years) with proximal valve incompetence of the greater saphenous vein were treated. Vein diameters ranged from 7–12mm with a mean of 8.3mm. Orthograde flow was established in 100% (n=12) of cases, with no migration observed at six months. The gel volume used was 3–6.2ml with a mean of 4.7ml, and the potential mean cost was US$260—less gel and lower costs than in both the Macrolane and Princess trials.

“If you can modify a vein’s diameter by using a natural substance with a simple small-needle injection, big question marks arise concerning many kinds of vein surgeries,” Ragg suggested. “For example, thermal occlusion, sclerotherapy and gluing are all just killing veins with varying levels of risk.”

“Percutaneous valvuloplasty is a simple procedure for anyone who is used to ultrasound-guided punctures,” Ragg continued. “It is minimally invasive, easily adjustable and rechargeable, and is suitable for the early stages of vein valve insufficiency. Work to simplify injections and use smaller volumes is promising, and we now need to prepare the stage by recognising early phase reflux as a specific disease.”

Published ATTRACT data call into question validity of the Villalta scale

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“would typically need a stent.” He also commented that future research would need to mandate intravascular ultrasound (IVUS) and multiplanar venography so that the procedural imaging protocols reflect current practice.

Tripathi concurs: “In this study, IVUS was not used to assess luminal diameters or adequacy of deep venous thrombosis clearance and subsequent endovascular treatments towards achieving the concept of “open vein hypothesis”. Instead modified Marder Scores were used, that are arbitrary, based on subjective observations of clot volume and therefore open to inaccuracies of interpretation. It is also limited by its failure to separate the relative contributions of thrombus within the iliac veins, and the contributions of the profunda femoral vein and the inferior vena cava. I would like intravascular ultrasound to be part of any future study to objectively assess post–thrombolysis/post-venoplasty evaluation of residual stenosis,” he says.

So which patients are suitable for pharmacomechanical lysis?

Experts opine that the ATTRACT trial is a really important addition to the literature as it showed “encouraging trends” in the subgroups analyses.

ATTRACT data from subgroups and secondary analyses suggest that catheter-directed thrombolysis may have a benefit in patients who have acute iliofemoral deep vein thrombosis. The data also showed a trend towards greater treatment effect for catheter-based interventions with patients who present with more severe symptoms. However, triallists emphasise that ATTRACT was not statistically powered to draw definitive conclusions from these secondary analyses and outcomes and that the treatment effect seen in these should be seen as trends only.

Commenting on the patients for whom pharmacomechanical thrombolysis would be a suitable treatment option in light of the trial data, Black notes: “ATTRACT suggests we should not be offering lysis except for severe patients, so it is difficult to answer this based on the presented data. My view is that we will continue to offer lysis to patients with iliofemoral deep venous thrombosis, particularly to those who have significant symptoms (pain and swelling plus venous claudication) on presentation.”

O’Sullivan suggests: “The ATTRACT trial showed us who *not* to treat, and therefore also who we should potentially concentrate on, namely, iliofemoral patients under the age of 70, who are very symptomatic. This is what we are effectively doing now and have done so for some time. I cannot recall the last time I treated a patient with purely femoropopliteal disease.”

Tripathi agrees: “A young patient (age <65years) who has iliofemoral deep venous thrombosis with severe symptoms and a low risk of bleeding will most likely benefit in terms of reduction of acute deep venous thrombosis symptoms and post-thrombotic syndrome severity.”

Kabnick believes: “Catheter-based procedures will be offered to the appropriate patient; however, this should not be based on age! For those patients who are not candidates for procedural intervention, the ATTRACT trial in of itself has justified anticoagulation.”

Future research

The experts agree that future research needs to focus on iliofemoral disease as the treatment group most likely to benefit from catheter-based therapies, so as to usher in a more targeted approach to therapy. It will hopefully also redirect efforts to better mechanisms of clot removal and care of the residual vein. They say imaging follow-up should involve the use of colour Doppler ultrasound (used in about 200 of the nearly 700 patients in the ATTRACT trial, which meant that in a large proportion of patients, it was unknown whether veins were open or blocked).

There should also be improvement in patient selection; better definition of the extent of disease and an improved measure of outcomes, they add.

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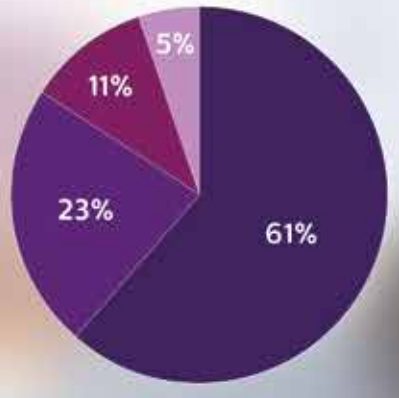

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Gagne PG, Tahara RW, Fastabend CP, et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. J Vasc Surg: Venous and Lym Dis. 2017;5:678-87.

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Phlebology world heads Down Under for UIP

Venous specialists from around the globe will meet in Melbourne for the much anticipated 2018 World Congress of Phlebology (UIP; 4–8 February, Melbourne, Australia) hosted by the Australasian College of Phlebology.

The president of UIP (International Union of Phlebology), Nick Morrison (Scottsdale, USA) said that there has been an exciting build up to UIP 2018 since the last gathering held in 2013 in Boston, USA, then hosted by the American College of Phlebology.

"This World Congress meeting in Melbourne has been anxiously awaited to provide a global update of the diagnostic and therapeutic changes in venous and lymphatic disorders. The 65 international member societies will be well-represented, and it is anticipated that the meeting will be of very high scientific quality. And, of course, colleagues from around the world will enjoy reconnecting with each other after so long an interim period. I personally look forward to greeting old friends and making new acquaintances," Morrison commented to *Venous News*.

Kurosh Parsi (Sydney, Australia), who, as president of the Australasian College of Phlebology, is host of the 2018 meeting, previously told *Venous News* that in Melbourne, "the scientific content of this meeting will be interactive. Each day will host a 'café session' followed by a debate. We believe phlebology encompasses a wide scope of practice usually not reflected in most venous meetings. Other than important superficial and deep venous topics, you can expect sessions and themes dedicated to dermatology in phlebology, vascular anomalies, antiphospholipid syndrome, ovarian veins, lymphatic disease, the latest interventional techniques, post-thrombotic syndrome, paediatric phlebology, duplex ultrasound themes, and many more."

In anticipation of the upcoming meeting, *Venous News* caught up with Alun Davies and Ian Franklin (both London, UK) who are part of the committee hoping for the chance to host the 2021 UIP meeting in their home city of London, UK.

Why is the UIP meeting such an important one on the venous calendar?

The UIP meeting occurs only every four years, and is a unique chance to meet the global experts of the venous world and to engage with industry on an international basis.

What are you most looking forward to at the UIP meeting in Melbourne?

We are most looking forward to meeting with a diverse group of phlebologists, to learn about different management pathways for patients and to hear the latest theories and practical procedures in the venous arena.

The Royal Society of Medicine – Venous Forum is bidding to host the 2021 UIP meeting in London. What do you believe the Society will bring to the UIP meeting?

The Royal Society of Medicine – Venous Forum is one of the oldest venous societies in the world, it has a long track record in academic endeavour, hosting many successful meetings often with other organisations.

In terms of the UIP meeting in 2021, the Royal Society of Medicine – Venous Forum would host in conjunction with the Charing Cross Symposium. Through this collaboration, the UIP would have the chance to have a very successful meeting building on the strengths of the Royal Society of Medicine – Venous Forum and the Charing Cross Symposium, supported by the European Venous Forum (EVF), the Vascular Society (VS), the British Association of Sclerotherapists (BAS), and the European College of Phlebology (ECP). We have also already received positive feedback from many members of the industry, who would also support

Direct oral anticoagulant-associated bleeding and available methods for reversal

TIMOTHY K LIEM

COMMENT & ANALYSIS

In the past decade, warfarin was the medication most commonly associated with hospitalisation for adverse drug events in older Americans.[1] Presumably, the majority of these were for some form of bleeding complication. Fortunately, the direct oral anticoagulants (DOACs) such as dabigatran, rivaroxaban, and apixaban are associated with a reduced risk of major bleeding when compared with warfarin, writes Timothy K Liem, Portland, USA.

This improved safety profile, in combination with a significantly decreased number of drug and food interactions, and the ability to avoid ongoing monitoring, have resulted in a steady rise in the number of prescriptions written for DOACs, particularly rivaroxaban and apixaban.

Nonetheless, DOAC–associated bleeding still occurs, and recent data suggest that the bleeding characteristics may differ from those of the vitamin-K antagonists. In a recent review of oral anticoagulant–associated bleeding complications at five tertiary care hospitals in Canada, Xu *et al* demonstrated that warfarin tends to cause more intracranial haemorrhage, haematomas, and haematuria. Whereas, DOACs tend to cause more gastrointestinal bleeding.[2] Regardless of the anatomic site of major bleeding, urgent reversal of the DOAC may be required. The general guidelines for DOAC reversal for active bleeding first recommend to stratify patients into those with mild, moderate or severe bleeding. Patients with mild bleeding may be managed with local measures, and possibly, temporary discontinuation of the DOAC. Physicians should be aware, however, that the half-lives of these medications may vary considerably, depending on the particular DOAC (five to nine hours for rivaroxaban, eight to 15 hours for apixaban, 12–14 hours for dabigatran) and the presence of co-morbidities such as chronic kidney disease.

Patients with moderate to severe bleeding should receive treatment for symptomatic hypotension, typically with large bore IV access, fluid resuscitation, and blood product transfusions with red blood cells, plasma, and platelets as needed. These transfusions should be administered with the goal of correcting dilutional coagulopathy, and not for the intent of reversing DOAC-mediated thrombin or factor Xa inhibition. In patients with an identifiable site for ongoing major bleeding, surgical, interventional radiologic, or endoscopic repair should be expeditiously pursued. In addition, other adjunctive treatments commonly have been employed in the absence of a direct reversal agent. Haemodialysis is one option for removing dabigatran, but drug levels may rebound after dialysis is discontinued. Dialysis is likely ineffective in patients receiving direct factor Xa inhibitors. Other adjunctive treatments include prothrombin complex concentrates (PCC), activated PCCs, tranexamic acid, desmopressin, and recombinant factor VIIa. However, the evidence for the efficacy and safety of these agents for this specific indication is extremely limited, and they should be administered only for severe or life-threatening bleeding, in consultation with a haematologist.[3]

Targeted reversal agents have been developed for direct thrombin inhibitors, as well as for factor Xa inhibitors, but their use should be reserved for patients with severe or life–threatening haemorrhage. Currently, the only FDA–approved agent is idarucizumab (approved October 2015), a monoclonal Fab fragment that specifically binds to free– and thrombin–bound dabigatran. When indicated, idarucizumab 5g administered intravenously provides near complete reversal of dabigatran, based on correction of dilute thrombin time or ecarin clotting time. In clinical trials, this translates to effective control of bleeding within three hours.

Andexan*et al*fa is a modified factor Xa molecule that acts as a decoy target for oral factor Xa inhibitors (rivaroxaban, apixaban, edoxaban), with potential efficacy against indirect factor Xa inhibitors as well (enoxaparin and other low-molecular-weight heparins). Initial clinical trials have evaluated andexan*et al*fa in patients with factor Xa inhibitor-associated acute major bleeding.[4] Dosing protocols were somewhat more complex. All patients received an initial andexanet bolus (400–800mg IV), followed by a two-hour infusion (480–960mg IV), depending on the type of anticoagulant requiring reversal, and the timing since the last administered dose. The majority of patients exhibited a marked reduction in anti-factor Xa activity, ranging from 89% to 93%, with most of the reversal effect occurring during the bolus or infusion. Despite a slight return in anticoagulant activity at the infusion's end, this did not seem to translate into additional late bleeding events. The majority of patients (79%) were able to achieve good to excellent haemostasis when evaluated 12 hours after infusion.

Currently, andexan*et al*fa is under review by the FDA. An initial action date of 3 February, 2018 was pushed back to 4 May, 2018, likely to allow a more thorough review of the application and decisions on dosing, labelling, and post-approval surveillance. Once available, andexan*et al*fa will be a significant additional tool, which will help physicians ameliorate a hopefully rare complication of DOAC-associated bleeding.

Timothy K Liem is professor of Surgery at Knight Cardiovascular Institute, Oregon Health & Science University, Portland, USA

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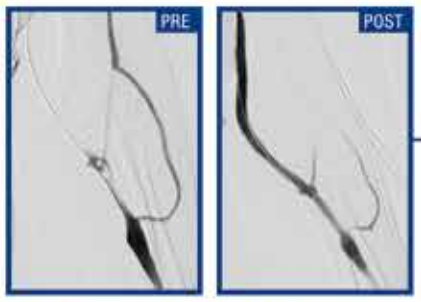
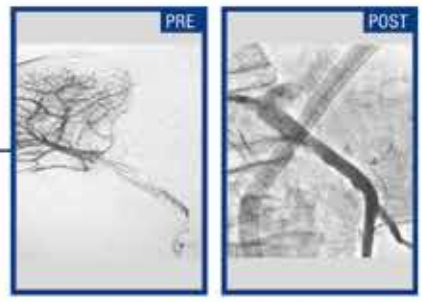
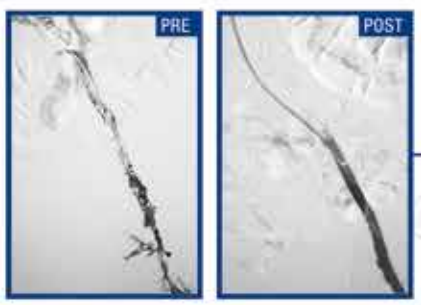


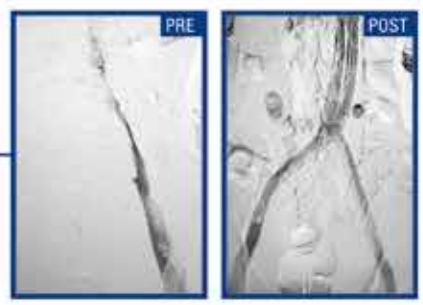
Aspiration of Thrombus from Radiocephalic Fistula
Dr. Bella Huasen, Royal Preston Hospital, United Kingdom



Aspiration of Thrombus from Portal Vein
Dr. Rafik Lababidi, Largo Medical Center, FL, USA

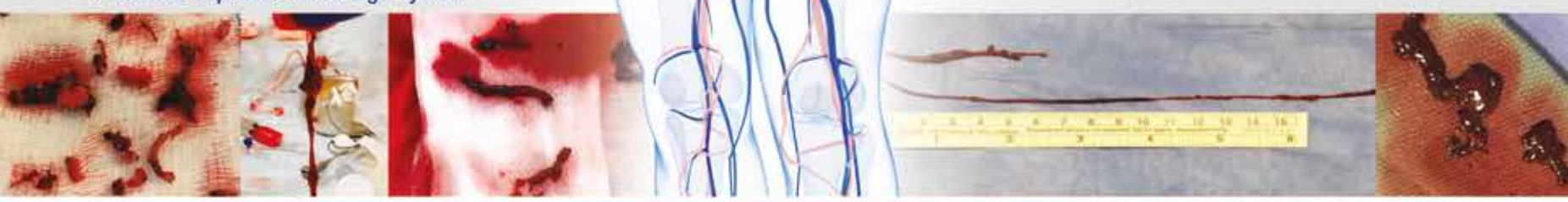


Aspiration of Thrombus from Iliofemoral Vein
Dr. Corey Teigen, Sanford Health, ND, USA



Aspiration of Thrombus from IVC & Iliac Vein
Drs. Patrick Muck & Matthew Recht, Good Samaritan Hospital, OH, USA

Thrombus Aspirated with Indigo System



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Profile

Armando Mansilha

Armando Mansilha is professor of Angiology and Vascular Surgery, Faculty of Medicine at the University of Porto, Porto, Portugal. In this interview with *Venous News*, he speaks about his early work and mentors, the biggest developments in venous medicine over the course of his career, and what he sees as the main challenges in the management of venous thromboembolic disease.

Why did you decide you wanted a career in medicine, and why in particular did you choose to enter the vascular and venous fields?

I am not sure when my interest in medicine was born but in my early teenage years this attraction for a medical career, and specifically for surgery, was already very clear to me. And this happened even though I come from a non-medical family—my father being a lawyer and my mother a French teacher. My interest in vascular surgery came at the end of university and during the period as a general training practitioner. The main reason for my choice was, at that time, the opportunity to deal with arterial, venous and lymphatic disorders, both medically and surgically, electively and in an emergency setting. Also dealing with invasive and non-invasive imaging, with technics, a large field for research, and the possibility to teach at university were key points in this early interest.

Who have been your most important career mentors and what wisdom did they impart?

I had the privilege to be in contact with many distinguished physicians, researchers and professors in my career, which makes it difficult and even unfair to list only a few. I started to learn the principles of research and monitoring of anatomy classes during the fifth year of university with the future patroness of my graduation year, who currently is the director of the Faculty of Medicine of Porto: Maria Amélia Ferreira. My strongest influence during my training period and even afterwards, as consultant of angiology and vascular surgery, was my PhD mentor, António Braga, who taught me the most important attributes of a surgeon, including clinical judgement, technical skills and ethical principles. I was fortunate to meet and spend time with Joaquim Barbosa, the first secretary general of the Portuguese Society of Angiology and Vascular Surgery (SPACV) and later president, with me as secretary general, which was a tremendous motivator in all my national and international career, and the great driver of many of my involvements and commitments with the SPACV, the European Union of Medical Specialists (UEMS), the International Union of Phlebology (UIP) and the European Society for Vascular Sugery (ESVS).

In the venous world, my references were, and still are, Andrew Nicolaides and Michel Perrin for their scientific rigor and at the same time the "outside of the box" thinking, which resulted in original research projects and publications that generated guidelines and recommendations for best practice. In Portugal, my reference was Paulo Correia, with whom I learned the most important principles of phlebology by working alongside him every week for more than 10 years.

What have been the biggest developments in venous medicine during the course of your career?

The biggest developments have been the endovascular revolution with the introduction of venous stents and the catheter-based interventional techniques. Furthermore, the advancement of imaging methods, namely duplex ultrasound for clinical investigation, surgical mapping and endovenous treatments. Recently the introduction of the new oral anticoagulants (DOACs/NOACs) completely changed the paradigm of medical treatment of venous thromboembolic disease.

What is the most interesting paper or presentation that you have seen recently?

Because of my international positions I travel extensively to vascular meetings so it is difficult to identify only one paper or presentation amongst so many outstanding contributions. Recently, and specifically related with venous disease management, I would highlight the importance of the consensus decision pathway on management of bleeding in patients on oral anticoagulants. Next year, the update of the European Venous Forum (EVF) guidelines on chronic venous disease will be published. It is important to applaud recent contributions from different areas in the world, with publications in languages other than English that, for this reason, go largely unnoticed by the journals with the highest impact factors.

What are your current research interests?

I am the national coordinator of three international research projects: RE-COVERY, WHITE and VOYAGER PAD. At a national level, I am the coordinator of the REVEAL-CEAP, the largest epidemiological study on chronic venous disease, using the CEAP classification, performed at primary healthcare. Moreover, I am tutoring PhD students in the field of abdominal aortic aneurysm, carotid pathology, varicose veins and diabetic foot. I am also truly engaged with the project ESVS CAMES Needs Assessment in the field of medical education and simulation.

How have new technology and thinking evolved our approach to venous thromboembolic disease? What challenges still remain in this area?

I would classify the recent advances in our knowledge and approach to venous thromboembolic disease as a revolution! It includes the introduction of venous stents, the pharmacomechanical devices and medical treatment with the new oral anticoagulants. But there is still a long way to go in the endovenous treatment of distal femoral lesions, the use of DOACs in oncology as well as during pregnancy or for patients with SAF, aggressive prophylaxis in patients with known risk factors for venous thromboembolism (VTE), and the duration of anticoagulation for the majority of patients considering this is a chronic disease.

You are currently the Secretary General of the UEMS Section and Board of Vascular Surgery—how does the Society approach training and certification?

The UEMS was created in 1958, and since the foundation the main objectives are to promote the highest level of patient care in the European Union (EU), to promote the harmonisation of high-quality training programmes within the various specialities throughout the EU and to facilitate the free exchange of training and work of trainees and medical specialists between the various member countries.

Since 2004, the Section of Vascular Surgery is independent and separate, and according to the statutes of the UEMS Section and Board of Vascular Surgery: "The main objective is to guarantee the highest standards of care in the field of the vascular surgery in the countries of the EU, by ensuring that the training of the specialist doctor is raised to the highest possible level".

Currently the European specialist qualification in any speciality, including vascular surgery, does not replace the accreditation by the national authorities, which is the primary specialist accreditation recognised by law by all member countries. Thus, the European qualification, entitling those who pass the examination as Fellow of the European Board of Vascular Surgery (FEBVS), must be seen as a respected qualification and a European quality mark.

How has the training curriculum changed to cover the modern endovascular technology being introduced?

There are still large differences in requirements and length of training in vascular surgery within the EU concerning the minimum training required which ranges from five to nine years. Other types of differences remain in the programme accreditation, trainee certification—including national association, speciality society, government, university, speciality board, general medical council—and the national exit examinations required.

Therefore, this stresses the importance of harmonisation in training and certification in vascular surgery within the EU. This is even more important for endovascular technology as in some countries the vascular trainees face several difficulties to learn and train the endovascular skills in an independent way. For this reason, it is important to have training requirements approved by the council and accepted by the national authorities.

What achievements are you proud of during your time as President of the EVF?

At the European Venous Forum Annual Meeting (29 June–1 July 2017, Porto, Portugal), the centerpiece of our daily sessions were the peer-reviewed presentations (34 oral and 52 electronic) selected from the best of the submitted abstracts from 32 countries. The number of registrations and participants—more than 850—was the highest in the history of the Society. I would like to highlight the didactic sessions on different topics and the quality of the panel of expert international speakers. A great achievement that I am very proud of was to have the presence of the most representative delegates from different international societies (AVF, ACP, JSP, ESVS, UIP, LAVF, SPACV) and their participation at the scientific programme. Last but not least, the Glossary for Phlebology was approved in Porto and the printed document will be distributed in 2018.

You are also the chairman of the Porto Vascular Conference. What will the highlights for 2018 be?

For this two-day conference (18–19 May) we expect more than 700 participants. The scientific programme includes specific sessions for vascular specialists and trainees as well as for vascular nurses, technicians and GPs. At the same time, two workshops per period will be devoted to different techniques, endovascular and open, but also to venoactive drugs, DOACs, elastic stockings and sclerotherapy. Two specific sessions will be dedicated specifically to anticoagulation in different pathologies with a multidisciplinary approach. A great moment of the conference is always the awards ceremony for the best e-posters of last year's University of Porto medical students. This year we will also give prizes to the best GP clinical cases in the vascular field and the best European Vascular Surgeons in Training (EVST) clinical cases. A book of articles related to the presentations will be published and distributed to the participants.

What are some of the proudest moments in your career?

In my clinical and academic career I had several moments of great significance that would certainly include successfully entering the Faculty of Medicine at the University of Porto in 1986, the year with the lowest ever number of students, only 40 in my Medical School; when I chose, in 1994, the speciality of angiology and vascular surgery, after a national examination which gave me the opportunity to be resident in the Hospital S João; in 2000, when I won my first international research grant, awarded by the International Society for CardioVascular Surgery, due to my work on genetic polymorphisms and deep venous thrombosis in younger patients; when I obtained the title of FEBVS in 2002, during the ESVS annual meeting in Istanbul; when I made my PhD in Angiology and Vascular Surgery and obtained the title of Professor in my university, in 2005, on the same day as my son's fifth birthday.

Other proud moments in my career, in a different perspective, were when I was elected Secretary General of the Portuguese Society of Angiology and Vascular Surgery in 2008, Secretary General of the UEMS Section and Board of Vascular Surgery in 2009 and President of the European Venous Forum in 2016.

What three questions in venous medicine still need to be answered?

1. Understanding in detail the cellular mechanisms and biomechanical forces related with the chronic venous disease and how to make recommendations for primary prevention;
2. Endoapproach to recanalise the popliteal and femoral segments, without reflux, to ameliorate symptoms after an episode of deep venous thrombosis and prevent a late post-thrombotic syndrome;
3. Classification of detailed anatomical patterns of varicose veins to establish the best strategy and interventional technique.

What advice would you give to young surgeons starting out in their careers?

They must be prepared to be exposed to different approaches to treat vascular patients. In fact, fellowships in different departments and with different targets are of great importance. Training has to include open and endovascular techniques. Sharing ideas and working with colleagues is beneficial for trainees and specially to patients. Young surgeons should continue to expect and embrace continuous changes, promote research even thinking in an original manner. Nothing will be easy to achieve and they will have to work hard.

What are your interests outside of medicine?

First of all, I like to spend time with my family. Travelling around the world, exploring wonderful places, meeting different cultures and local people are passions of mine. I have one list with a lot of possible destinations to visit and discover and this grows every year. Sport, and particularly outdoor activities including tennis, sailing and skiing, play an important role in relaxing during holidays. Usually, I try to attend the football matches of my favourite team, FC Porto, namely at the "mythical" dragon stadium! In addition to all these hobbies and interests I have to include cinema, fashion, arts and museums and especially music. Jazz and classic are the most often heard styles in my daily playlist.

Fact File

Education (selected)

1986	Medical Student, Faculty of Medicine of University of Porto, Portugal
1995	Resident, Department of Angiology and Vascular Surgery, Hospital S João, Porto

Certification

2001	Specialist in Angiology and Vascular Surgery, Portuguese Medical Association
2002	Fellow of the European Board of Vascular Surgery, UEMS
2005	PhD in Angiology and Vascular Surgery, Faculty of Medicine of University of Porto

Appointments (selected)

2001	Consultant, Department of Angiology and Vascular Surgery, Hospital S João Porto
2005	Professor of Angiology and Vascular Surgery, Faculty of Medicine of University of Porto
2010	Director, Department of Angiology and Vascular Surgery, Hospital CUF Porto
2016	Associate Professor of Angiology and Vascular Surgery, Faculty of Medicine of University of Porto

Positions (selected)

2005	Council Member, Union International de Phlébologie
2006	Executive Committee, College of Angiology and Vascular Surgery, Portuguese Medical Association
2008	Secretary General, Portuguese Society of Angiology and Vascular Surgery
2009	Secretary General, UEMS Section and Board of Vascular Surgery
2009	Council Member, European Society for Vascular Surgery
2013	Council Member, Mediterranean League of Angiology and Vascular Surgery
2013	Honorary Member, The Vascular Society for Great Britain and Ireland
2014	Council Member, International Union of Angiology
2015	President of the LOC Annual Meeting, European Society for Vascular Surgery
2016	President, European Venous Forum
2016	Vice President, Portuguese Society of Angiology and Vascular Surgery
2017	Moynihan Club Member
2017	Honorary Member, Societat Catalana d'Angiologia, Cirurgia Vascular I Endovascular

New research indicates that stenting below the inguinal ligament does not result in inferior outcomes

Endovenous treatment of iliocaval and infrainguinal post-thrombotic venous obstruction results do not appear to be adversely affected by extension of the iliac vein stents into the femoral venous system, according to a US report in the *Journal of Vascular Surgery: Venous and Lymphatic Diseases*.

Deep venous thrombosis remains a significant problem with well over 500,000 people affected in the USA alone, the report states. Over a quarter of these patients will experience post-thrombotic syndrome (PTS), despite appropriate anti-coagulation. Patients with iliocaval thrombosis face a three-fold risk of PTS. Treatment of the complications of PTS, including leg swelling, venous claudication, skin changes and ulceration, results in US healthcare costs estimated at US$7–10 billion per year.

Popularised by Seshadri Raju and Peter Neglen, venous stenting for symptomatic patients has increased significantly in this setting. Several large series since then have demonstrated safety, efficacy and good durability of this technique in iliocaval obstruction. Questions, however, remain as to the outcomes with regards to aetiology (ie. thrombotic versus non-thrombotic occlusion) and extent of stenting (ie. extension below the inguinal ligament). Concern for the latter is raised as the mobility of the common femoral vein may result in stent fracture and thrombosis.

Researchers from UCLA, led by vascular surgeon Brian DeRubertis, retrospectively evaluated their single-centre experience with percutaneous treatment of post-thrombotic iliocaval obstruction. In this series, 31 patients (42 limbs) presented with pain/swelling (100%) including venous claudication (81%) and active ulceration (10%). Percutaneous interventions, including iliocaval angioplasty/stent in 81% with extension into the femoral system (38%), resulted in 100% technical success. Of those with inferior vena cava (IVC) filters, 46% were able to be removed.

At an average of 15 months of follow-up (range 2–49 months), the following results were achieved:

- Improvement in pain/swelling in 84% of patients
- Resolved pain/swelling in 42% of patients
- Decreased CEAP classification in 65% of patients
- One-year primary stent patency in 66% of patients
- One-year secondary stent patency in 75% of patients.

Those patients requiring infrainguinal extension of the

Brian DeRubertis

stent saw no significant difference in primary stent patency at one year compared to those who did not (68% vs. 65%). However, in those whose IVC filter could not be removed, resolution of symptoms was achieved in only 17% of cases.

"Our aim was to better understand risk factors for poor clinical outcomes in patients undergoing percutaneous intervention for symptomatic chronic venous obstruction secondary to post-thrombotic lesions," comments first author Johnathon Rollo. "Our results suggest that stenting below the inguinal ligament does not result in inferior outcomes, at least in the short-term, and may be necessary in a higher percentage of patients than previously reported. Additionally, the failure to remove an IVC filter in this setting appears to result in inferior outcome and an attempt to safely remove the filter should be made in this high-risk population."

This data suggests a role for early filter removal after, or not even placing them at all, during iliocaval lytic therapy.

The authors emphasise stenting from normal vein above to normal vein below the occlusive disease, if technically possible. Based on these results, going below the inguinal ligament to achieve adequate inflow "makes sense", they say.

Identifying standard practices of antithrombotic therapy post-venous stenting

Venous stenting has evolved over the last 15 years, quickly becoming an established procedure, with Class II recommendations from the American Heart Association and American College of Phlebology. Speaking at the Vascular Society of Great Britain and Ireland's Annual Scientific Meeting (VSGBI; 22–24 November 2017, Manchester, UK), Ankur Thapar presented results from the Venous Research Unit at Imperial College (London, UK) reviewing an expert consensus on antithrombotic therapy following venous stenting.

Following the Class II recommendations, Thapar said the practice of venous stenting has rapidly increased. However, though recommendations for patient selection exist, there is a lack of guidance available regarding antithrombotic therapy following venous stenting.

Describing in-stent thrombosis as the "Achilles Heel" of stenting, Thapar pointed to the importance of optimising antithrombotic care, which currently tends to be extrapolated from deep vein thrombosis (DVT) or arterial stenting strategies.

Thapar and colleagues addressed this knowledge gap by aiming to characterise global practice and identify areas of consensus to inform centres in the process of setting up venous stenting services, as well as to identify research priorities for the community. To examine the trends and practices of venous stenting procedures, the study investigators created a survey for doctors who refer, treat and follow up patients in venous stenting centres.

Collaborating with venous experts, three scenarios of patients with iliac vein stenosis were devised: a case of acute iliofemoral DVT undergoing thrombolysis; post-thrombotic syndrome with ulceration and multiple DVTs and a final scenario of a non-thrombotic lesion with swelling and varices. The three hypothetical cases were sent to a range of international organisations for vascular surgery, haematology and radiology in order to ascertain local practices. In an interim analysis, the 106 survey responses were analysed to create consensus statements, which were then sent back for review and voting. Responses were received from 78 centres in 28 countries, with a majority of respondents being radiologists based within Europe.

Presenting the results, Thapar highlighted the diversity of approaches to venous stenting, commenting, "The community is doing pretty much anything they want at the moment." However, three strong consensus statements could be made. Firstly, analysis of responses revealed 72% of respondents' preference

Ankur Thapar

for anticoagulation, rather than antiplatelet agents, for the first six to 12 months after stenting a non-thrombotic iliac vein lesion. Secondly, following thrombolysis, 87% of respondents agreed it was acceptable to discontinue anticoagulation after six to 12 months for cases with negative thrombophilia screens and no prior DVTs, providing the stent appearance was satisfactory. Finally, for patients with multiple DVTs, it was agreed by 85% of respondents that anticoagulation should be continued indefinitely.

"Two areas which did not quite hit consensus but are useful because they may inform your practice if you are starting service", Thapar said, are low molecular weight heparin and thrombophilia screening. The study revealed that 67% of respondents opt for a low molecular weight heparin anticoagulant during the first two to six weeks, "in case they needed to re-intervene during the first admission." The same percentage of respondents also considered thrombophilia screening to be an essential requirement before discontinuing anticoagulation following DVT thrombolysis—an opinion which radiologists were more likely to hold than haematologists.

However, "no consensus whatsoever" was found on the use of antiplatelet therapy either after stopping anticoagulation. Respondents were also highly divided on whether adding an antiplatelet agent to anticoagulation in a patient with multiple DVTs has "any important clinical benefit".

The study pointed to a need for UK-based centres to capture data in the National Vascular Registry and initially recommended the use of registry data to assess the primary patency of direct oral anticoagulants vs. vitamin K antagonists following venous thrombolysis and stenting. Further work includes examining the duration of anticoagulation following venous thrombolysis and stenting. The article will shortly be in press in the *European Journal of Vascular and Endovascular Surgery*.

AESTHETIC PHLEBOLOGY

By Kasuo Miyake and Lonnie Whiddon

CLaCS technique superior to sclerotherapy or laser for telangiectasias of the legs

Sclerotherapy of telangiectasia of the leg is generally accepted as the best treatment for this aesthetic problem. Failure to achieve removal of most telangiectasia of the legs is a common problem, and stubborn clusters that defy all attempts using different sclerosants are frequently encountered. This has led to treating underlying reticular veins, the so-called "feeder veins", that are thought to cause the regional increase in venous pressure, which prevents the telangiectasia from responding to treatment. These feeder veins are thought to be the cause of the recurrence of telangiectasia clusters that initially disappear after treatment only to recur after short intervals. The difficulty is in demonstrating the existence and visualisation of the underlying feeder veins so that they can be treated.

> The CLaCS (Cryo-Laser and Cryo-Sclerotherapy) technique employs the following features: (1) augmented reality (AR) viewing of the feeder veins; (2) application of transdermal laser energy to the feeder veins and overlying telangiectasias; (3) injection of the feeder vein and surface telangiectasias with a sclerosant; (4) skin temperature protection and numbing of the skin with application of a flow of cold air throughout the procedure.

The CLaCS session begins with AR viewing of the telangiectasia treatment areas. The 1064nm (YAG) transdermal laser is set to 6mm spot size, 70j/cm^2 fluence, and 15msec pulse width. The skin cooling device (SCD) is used throughout the laser and sclerotherapy treatment. The cold air directed onto the skin diminishes the discomfort of the laser and the needle punctures. With AR guidance, the transdermal laser shots are directed to the feeder veins causing endothelial thermal injury and swelling of the tunica media. At times, partial or total contraction of the veins is seen immediately after the laser shots. More commonly, alteration of the AR image of the veins occurs after a short interval, which may extend up to 10 minutes. Then, using AR to determine the best sites for injection, sclerotherapy of the feeder veins is performed.

The overlying and nearby telangiectasias are then treated with the trandermal laser using the same laser settings. Lastly the telangiectasias are injected with a sclerosant. The authors have used 75% Dextrose as their sclerosing agent of choice for both the feeder veins and the telangiectasias.

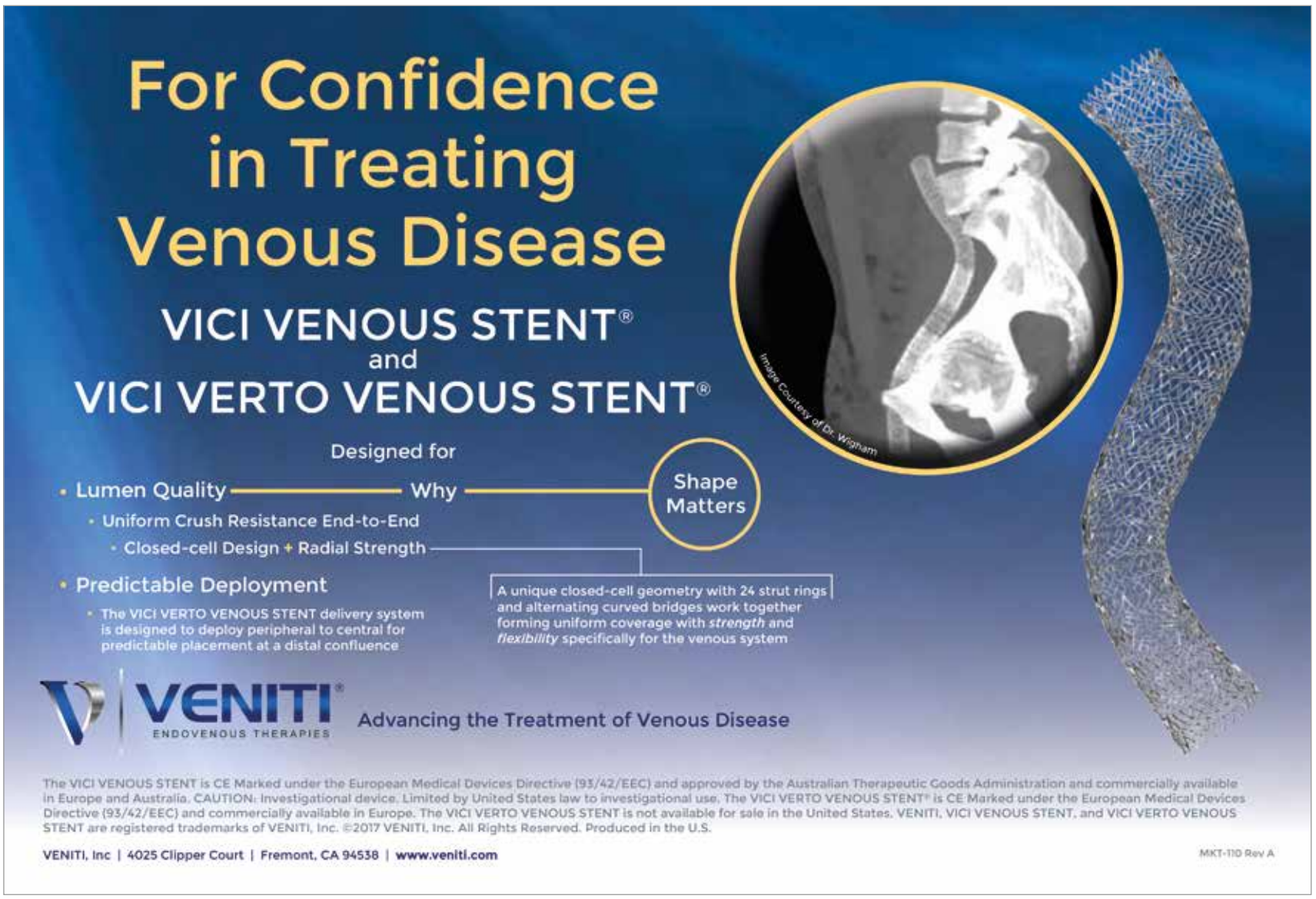
Cotton pledgets secured with tape are applied to the sites of injections. The patient is told that these dressings may be removed after two hours.

No compression is applied to the legs, and there are no restrictions of sun exposure or exercise. The interval between treatment sessions is approximately 30 days.

Refluxing saphenous vein trunks and perforator veins directly connected to feeder veins are excluded from the CLaCS treatment.

We are convinced that the CLaCS technique guided by AR to treat telangiectasias of the legs is superior to either sclerotherapy or laser. Visualisation and treatment of feeder reticular veins when present in addition to the treatment of telangiectasia is key to produce optimal resolution and to prevent recurrences. The sequence of laser first followed immediately by sclerotherapy serves to potentiate both treatment modalities.

Kasuo Miyake is at Clinica Miyake, São Paulo, Brazil, and Lonnie Whiddon is at Dallas Vein Specialists, Dallas, USA



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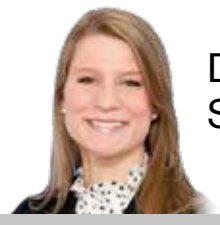
VQI Varicose Vein Registry: A tool to help guide decision-making at the patient and policy level

NICHOLAS OSBORNE



DANIELLE SUTZKO

ANDREA OBI

THOMAS WAKEFIELD

COMMENT & ANALYSIS

Members of the venous community have had a longstanding commitment to collecting and analysing the outcomes of venous procedures. The Vascular Quality Initiative (VQI) Varicose Vein Registry (VVR) grew out of a previous registry established by the American Venous forum, and is a joint initiative of the American Venous Forum and the Society for Vascular Surgery, write Nicholas Osborne, Danielle Sutzko, Andrea Obi, and Thomas Wakefield, Ann Arbor, USA.

The purpose of the VVR is to analyse procedural and follow-up data, benchmark outcomes regionally and nationally for continuous improvement, develop best practices, and help meet Intersocietal Accreditation Commission (IAC) certification requirements for vein centres. Inclusion criteria include percutaneous (closed) and/or cutdown (open) procedures to ablate or remove superficial truncal veins, perforating veins or varicose vein clusters in the lower extremity (C2 or greater venous disease by the clinical CEAP classification). Exclusion criteria include any treatment of deep veins of the lower extremity, any intervention done for trauma, and treatment of C0 or C1 disease. The VVR is one of the 13 modules of the VQI. There are currently 444 centres in the VQI, in 46 US states and in Canada, with 18 regional quality groups. There are over 420,000 entries in all the registries combined (as of 01/11/2017) and over 16,000 in the VVR, ranking it seventh of all the registries as far as the number of procedures entered. The benefit of the VVR lies not only in its utility for quality initiatives, but as a tool to establish the effectiveness of various treatments.

The VVR offers rich clinical data that can be used to answer relevant research questions. We have now published three studies within the VVR. The first analysis examined the initial 10 months of the registry and established the utility of the registry to demonstrate patient improvement following treatment. There was a total of 1,406 patients, mean age 55 years, 72% female, with a mean BMI of 29. Caucasians made up 78% of the group, while African Americans made up 7%. Approximately one-third of the patients had previous varicose vein treatment, 7% had a history of deep vein thrombosis (DVT), and 8% were on anticoagulation; 2,661 veins were treated on 1,803 limbs with 1,751 procedures (either in office or operating room). Laterality was equally distributed between the right (48%) and left (49%), with a small number undergoing bilateral procedures (3%). Endovenous treatment of axial reflux was the preferred treatment in 89%, divided largely between radiofrequency ablation (55%) and endovenous laser ablation (34%). Clusters were often treated concomitantly with truncal reflux (76%). In this study, there was significant improvement in C class, venous clinical severity score (VCSS) of -4.68±3.35 and seven different components of the patient-reported outcome score including leg heaviness, achiness, swelling, throbbing, itching, appearance and work impact between pre-procedure and post-procedure, total score -10.8±6.9.[1]

In the second study, we used the robust data from the VVR to answer a clinically relevant question—do patients 65 years of age and older (who are Medicare-eligible) benefit from venous procedures? We identified 2,691 patients less than 65 years of age with 3,631 limbs undergoing 3,441 procedures, and 1,068 over 65 years of age with 1,467 limbs undergoing 1,400 procedures. There were statistically less Caucasians in the younger group and a greater number of females. The younger group had a statistically significant higher BMI, a smaller number of patients with a history of bilateral varicose vein treatments, and a smaller number of younger patients who were on chronic anticoagulation (5%) compared to older patients (16%). Both groups demonstrated a statistically significant improvement in VCSS and patient-reported outcomes, with equivalent improvements in VCSS scores pre to post-procedure. Younger patients showed more improvement in patient-reported outcomes but were also more likely to undergo combined procedures, as compared to the older group. Complication rates were equivalent between the groups with the exception of a higher wound infection rate in the older group, although the overall infection rate was low in both groups.[2]

Finally, in our most recent analysis, we examined the outcomes of geriatric patients (age greater than 80 years). For this analysis, we looked at the patients less than 65 years of age, those 65 to 79 years of age, and then the group ≥80 years old. In total 4,043 patients <65 years of age underwent 8,608 procedures; 1,334 patients between 65 and 79 years of age underwent 3,226 procedures; and 161 patients ≥80 years of age underwent 428 procedures. Patients in the ≥80 group had an overall lower average BMI, were more likely to be on anticoagulation and undergo truncal procedures alone compared to the other groups. The oldest group had more procedures performed for patients with C6 (active venous ulceration) compared to the younger age groups. Over 64% underwent a truncal procedure only in the group ≥80 years of age, while in the younger patients, the proportion undergoing truncal and truncal plus cluster procedures was fairly equal. In all groups, VCSS improved equivalently, while the youngest group had the most improvement in patient-reported outcome at 10.6, the middle group improvement of 9.6, and the oldest group improvement of 8.8. With regards to octogenarians with active ulceration or C6 disease, 55% of procedures (n=29) with post procedure follow-up resulted in a healed ulcer. Complication rates were low amongst all age groups.[3]

These three studies underscore the utility of the VVR not only as a research tool, but as a tool to help guide decision-making at the patient and policy level. For instance, these data clearly show the benefit of operative treatment of superficial venous disease in the elderly based on objective, provider generated criteria and patient-reported outcomes. Such information support coverage decisions for Medicare-eligible patients. The VQI VVR has combined a vast number of procedures performed by various providers across regions and serves as an enriched data source for many potential research questions that cannot be answered at a single institution. We urge all centres performing varicose vein procedures to join the registry, to track and compare their results to other centres in their region and in the country, and utilise the database to ensure quality improvement.

> *The VQI VVR has combined a vast number of procedures performed by various providers across regions and serves as an enriched data source for many potential research questions that cannot be answered at a single institution.*

Nicholas Osborne, Danielle Sutzko, Andrea Obi, and Thomas Wakefield are with University of Michigan, Ann Arbor, USA

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Pressure monitoring may be required to ensure consistent compression during venous ulcer treatment

Compression therapy for venous ulcers requires accurate monitoring to ensure successful delivery and the desired compression dose. However, according to a study presented at the American College of Phlebology annual meeting (ACP; 2–5 November, Austin, USA), the level of pressure actually delivered is "highly variable" even after a training and feedback period, which suggests that pressure monitoring devices may be required.

Felix Trinh (Jobst Vascular Institute, Toledo, USA) explained that the use of compression therapy for venous ulcers has grade 1, level A evidence, as documented by Society for Vascular Surgery and American Venous Forum guidelines. However, there remains no recommendation for the ideal amount of compression to be used. Existing evidence is limited, and current practice commonly uses 30–40mmHg of compression for patients without significant arterial disease.

Trinh told delegates that pressure-measuring devices are not routinely used at the skin-bandage interface to ensure that adequate pressure is being achieved, meaning that users cannot be sure of variations in pressure delivery. Trinh and colleagues thus designed a study to investigate whether wound clinic staff could be trained to consistently deliver the desired amount of pressure.

The study was carried out at a community-based wound clinic. Pressure was measured during compression bandage application using a PicoPress device (MediGroup), with measurement taken at position B1.

The trial ran for 12 months. In the first three months, nurses were blinded to the 163 pressure measurements taken. After this, nurses applied bandages and were unblinded to pressure measurements for six months, which formed the training period. For the final three months of the study, nurses were again blinded to 38 pressure measurements during bandage applications.

During the first three months, "there was quite a bit of variability" in pressure levels achieved by the nurses, Trinh said. In the final three months of the study, variability was slightly reduced and application was "a little better," but variability remained relatively high. Trinh said that there was no difference in the mean pressure ratings in the two periods.

"Delivered pressure was highly variable both before and after the training and feedback periods," Trinh said. "We conclude that to really know what kind of pressure we are delivering, we have to use measurement devices. Training seems like it can improve variability, but maybe not to the level that we need to ensure proper treatment."

"Further studies are now needed to increase the number of measurements to provide more statistical power, using multiple points of compression to measure levels of graduated compression", he added.

Research team finds notable decrease in IVC filter usage after FDA advisory

A research team led by Riyaz Bashir, professor of Medicine and director of Vascular and Endovascular Medicine at Temple University Hospital, Phildelphia, USA, examined nationwide utilisation rates of inferior vena cava (IVC) filter placement in the USA and assessed what impact the 2010 FDA advisory had on these rates. The team's findings were published in the 10 July issue of *JAMA Internal Medicine*.

Among the team's findings:

- An estimated 1,131,274 patients underwent IVC filter placement over the 10-year study period
- There was a 22.2% increase in the rate of IVC filter placement from 45.2/100,000 in 2005 to 55.1/100,000 in 2010.
- Following the FDA safety communication, there was a 29% decrease in the rate of IVC filter placement from 55.1/100,000 in 2010 to 39.1/100,000 in 2014.
- The rate of venous thromboembolism-related hospitalisations remained steady between 2010 and 2014.

Despite the significant reduction in IVC filter use following the FDA advisory, implantation rates across the USA remain high compared to the IVC filter implantation rate in five large European countries each of which was less than 3/100,000 population.

"In the USA, the IVC filter implantation rates are 25 fold higher than in Europe. The hospitals across this country collectively are spending close to a billion dollars on these devices every year without a known significant benefit. With current level of evidence we believe that the appropriate implantation rate in the USA should be similar to, or lower than, the rate observed in Europe," says Bashir.

Product News

Medtronic receives favourable CMS ruling on VenaSeal

The US Centers for Medicare and Medicaid Services (CMS) has posted the 2018 Medicare Physician Fee Schedule (CMS-1678-F) and Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1678-FC). As part of the final rulings, healthcare providers will now be able to bill for VenaSeal utilising the new CPT codes 36482 and 36483. These new codes took effect on 1 January, 2018.

Medtronic launched VenaSeal in the USA in 2015 following US Food and Drug Administration approval. Since then, VenaSeal has utilised a self-pay model, by which patients paid for the procedure out of pocket as reimbursement was limited. Together with clinicians, Medtronic has been working to demonstrate the clinical and economic benefits of the procedure and pursue payer coverage with major payers in the USA.

While there are other treatments on the market including radiofrequency and laser ablation, Medtronic states that the VenaSeal closure system is the only non-tumescent, non-thermal, non-sclerosant procedure that uses a proprietary medical adhesive to close superficial veins of the lower extremities in patients with symptomatic venous reflux.

The VenaSeal closure system is supported by three-year data from the VeClose US pivotal clinical trial, which demonstrate long-term clinical and quality of life benefits. Furthermore, the VenaSeal closure system is designed to allow rapid recovery with minimal downtime and patients may not need to use compression stockings.

The "unique approach" of VenaSeal eliminates the risk of nerve injury that is sometimes associated with certain thermal-based procedures, according to a company press release. The procedure is administered without the use of tumescent anaesthesia, minimising the need for multiple needle sticks. Patients also report minimal-to-no bruising post procedure.

BTG receives finalised category I CPT codes for Varithena

BTG has announced its finalised category I CPT codes, received from the US Centers for Medicare and Medicaid Services. The codes became effective from 1 January, 2018.

The fee schedule details payments for conducting Varithena treatments in the physician office setting of US$1,624.30 for a single vein and US$1,697.02 for multiple veins. The new CPT codes define Medicare payment rates and enable automatic and electronic processing of claims, "providing physicians in the USA with further predictability of payment and streamlining the reimbursement process," a company press release says.

"We believe the new CPT codes are appropriate and have the potential to underpin our current expectations for the product," commented Louise Makin, BTG's CEO. "However, we must wait and see how they impact physician adoption and insurer practices, and we should have a better understanding of that by the end of 2018."

Inari Medical announces completion of enrolment in the FLARE study for the treatment of pulmonary embolism

Inari Medical has announced that it has completed enrolment of its investigational device exemption (IDE) study. The FlowTriever Pulmonary Embolectomy Clinical Study (FLARE) study is designed to evaluate the safety and effectiveness of the FlowTriever Retrieval/Aspiration System for the treatment of pulmonary embolism.

"The completion of the FLARE study marks an exciting advancement in the treatment of acute pulmonary embolism patients," stated Ken Rosenfield, section head for Vascular Medicine and Intervention, Massachusetts General Hospital, Boston, USA, and co-principal investigator of the study. "Until now, there has not been a percutaneous approach to rapidly restore flow to reverse right heart strain without the use of thrombolytic drugs and the associated risk of bleeding complications."

"Completion of enrolment is the result of strong collaboration between a talented group of physician investigators," added Victor Tapson, associate director, Pulmonary and Critical Care Division, Cedars-Sinai Medical Center, Los Angeles, USA and co-principal investigator of the study. "We appreciate their dedication and expertise in evaluating the first thrombectomy device designed specifically to treat pulmonary embolism".

"Finishing enrolment of FLARE represents another major milestone for Inari," said CEO Bill Hoffman. "We are encouraged by our investigators' enthusiasm for the FlowTriever System and commitment to enrolling the study so efficiently. The FLARE study reflects Inari's focus on transforming the treatment of venous thromboembolism by developing solutions for removing large clot volume from big vessels without the use of thrombolytic drugs".

The FlowTriever Retrieval/Aspiration System is a catheter-based mechanical thrombectomy device for percutaneous endovascular retrieval and disruption of emboli from the peripheral vasculature without the need for thrombolytics.

The FLARE study is a prospective, multicentre, single-arm study evaluating the FlowTriever in 106 patients with acute pulmonary embolism at 18 sites in the USA. More information on the FLARE study can be found at www.clinicaltrials.gov under NCT#02692586.

FDA approves new 10mg dosing for rivaroxaban to reduce continued risk of VTE

Janssen Pharmaceuticals has announced that the FDA has approved the 10mg once-daily dose of rivaroxaban (Xarelto) for reducing the continued risk for recurrent venous thromboembolism (VTE) after completing at least six months of initial anticoagulation therapy.

The approval follows a FDA Priority Review and is based on data from EINSTEIN CHOICE, which found that a factor Xa inhibitor, specifically rivaroxaban, demonstrates superior efficacy in reducing the continued risk of recurrent VTE and with major bleeding rates similar to aspirin.

"We believe the availability of the 10mg Xarelto dose will change clinical practice and the management of VTE recurrence," said Paul Burton, vice president, Medical Affairs, Janssen. "The landmark EINSTEIN programme results yet again demonstrate Xarelto is a safe and highly effective option, not only for the initial treatment of a VTE, but also for the continued prevention of a recurrent event."

With this approval, the rivaroxaban prescribing information provides instructions for physicians to begin treatment with rivaroxaban 15mg, dosed twice daily, for the first 21 days after a VTE occurrence. On day 22 through at least day 180, the daily dose decreases to rivaroxaban 20mg once daily. After at least 180 days, physicians can prescribe rivaroxaban 10mg once daily in patients at continued risk for DVT and/or PE.

"If anticoagulation therapy is stopped, up to 20% of patients will have a recurrent VTE within three years. To prevent this, physicians have long debated how best to extend anticoagulant use beyond the initial treatment window," said Jeffrey Weitz, professor, Departments of Medicine and Biochemistry and Biomedical Sciences, McMaster University, Hamilton, Canada and Executive Director, Thrombosis & Atherosclerosis Research Institute. "The FDA's approval of the 10mg dose of Xarelto for preventing recurrent VTE, along with clinical evidence confirming the superiority of Xarelto over aspirin for extended VTE prevention, means we can finally put this debate to rest."

The EINSTEIN CHOICE study evaluated patients with VTE who were already treated with six to 12 months of initial anticoagulation therapy and then received rivaroxaban 10mg once daily, rivaroxaban 20mg once daily or aspirin 100mg once daily for up to an additional 12 months of treatment. Patients taking either rivaroxaban dose had significantly fewer recurrent VTE compared to those taking aspirin. Specifically, rivaroxaban 10mg reduced the risk of recurrent VTE by 74% and rivaroxaban 20mg by 66%. All three treatment groups had low rates of major bleeding (0.4% with rivaroxaban 10mg, 0.5% with rivaroxaban 20mg, 0.3% with aspirin).

In September 2017, Janssen's development partner Bayer announced the Committee for Medicinal Products for Human Use of the European Medicines Agency granted a positive opinion to update the Xarelto label to include the 10mg once-daily dose in the European Union; the European Commission granted approval on 19 October 2017.

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UEMS adopts European Training Requirements in Phlebology

The European Board of Phlebology has announced that the European Union of Medical Specialists (UEMS) has adopted the European training requirements presented by Jean-Jérôme Guex, president of the newly created Board. The development is the result of a European inter-speciality co-operation as the latest step in a process that started in 2015 with a meeting of the Multidisciplinary Joint Committee in Phlebology at the initiative of several UEMS specialties, including vascular surgery, vascular medicine, dermatology, radiology and general surgery, to elect a board of Phlebology.

The European Board of Phlebology was formed in October 2016, and the European Training Requirements in Phlebology were published and presented to the UEMS' general council in Brussels, Belgium. Following the presentation of the proposed training requirements, the general council voted for adoption with 22 votes in favour, two opposed, and five abstentions.

The European training requirements in Phlebology define a "competency degree" in complete Phlebology as well as competency degrees in phlebology procedures, certifying physicians' competencies in one or several phlebological procedures, including endovenous thermal ablation, ultrasound-guided foam sclerotherapy, duplex ultrasound mapping, surgery and venous angioplasty.

Although the Board state that phlebology "is not a specialty and does not intend to become one", they state that it is practiced by vascular physicians, vascular surgeons, surgeons, dermatologists, radiologists and other healthcare professionals, and therefore requires an structure of validation and certification of training.

An official validation of training is especially necessary due to the number of venous patients increasing with the population aging. New technologies which challenge older ones, as well as new methods which are often released and used before publication of recommendations, also pose an issue for the standard and importance of training. The fact that such training is often only provided by industry, as well as the lack of overall quality control, are problems which the newly formed European Board of Phlebology aim to change by providing validation and accreditation tools for training centres, creating a certification authority for trainees.

Calendar of events

4–8 February
UIP 2018
Melbourne, Australia
W uip2018.com

21–23 February
American Venous Forum Annual Meeting
Tucson, USA
W www.veinforum.org

2–4 March
IMAP 2018—International Meeting on Aesthetic Phlebology
Sao Paulo, Brazil
W www.imap.med.br/en

5–7 April
Venous Symposium New York
New York, USA
W www.venous-symposium.com

16–17 April
EVF HOW Plus—Deep Valve Repair
Modena, Italy
W www.evfvip.com

19–21 April
International Vein Course
Miami, USA
W ivcmiami.com

24–27 April
Charing Cross Symposium—40 Years of Looking Forward
London, UK
W www.cxsymposium.com

7–8 May
EVF HOW Plus—Stenting of the Femoro-Ilio-Caval Outflow
Modena, Italy
W www.evfvip.com

28–30 June
European Venous Forum
Athens, Greece
W europeanvenousforum.org

17–18 July
Venous Imaging Masterclass
Paris, France
W www.anatomy-masterclass.com

4–5 November
THE VEINS
Las Vegas, USA
W vivaphysicians.org

8–11 November
ACP 2018
Nashville, USA
W Phebology.org

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