Silent brain infarction common after endovascular arch repair, STEP registry finds

Preliminary results from the STEP (Stroke from thoracic endovascular procedures) registry show that silent brain infarction following endovascular repair of the aortic arch is frequent, with postoperative diffusion-weighted magnetic resonance imaging (DW-MRI) demonstrating an incidence of 50%.

As a result of this main finding, Philippe Charbonneau (Hôpital Marie Lannelongue, GHPSJ, Paris, France) and colleagues write in an online European Journal of Vascular and Endovascular Surgery (EJVES) article that “innovative strategies to reduce the risk of embolisation need to be developed”.

The authors begin: “Over the last decade, thoracic endovascular aortic repair (TEVAR) has supplanted open surgery as the main repair technique for aneurysms of the descending thoracic aorta”. While TEVAR has an “early morbidity and mortality advantage,” they note, neurological complications following TEVAR remain a “significant periprocedural concern”.

Charbonneau and colleagues explain that cerebral solid and gaseous embolisation during aortic arch instrumentation is “debated to be the primary cause of perioperative stroke and silent brain infarction.” They note that silent infarct is defined as “image proven ischaemic brain injury without acute neurological dysfunction attributable to the lesion” and detail that it is identified as “an independent predictor of future stroke, cognitive impairment, and dementia”.

Considering the literature, the authors write that only a few studies have investigated the presence of silent brain infarction following TEVAR using cerebral DW-MRI, showing lesions in up to 81% of patients within the first week after TEVAR involving the aortic arch.

Charbonneau et al state that use of carbon dioxide flushing to replace trapped air in stent graft delivery systems has been introduced to reduce gaseous embolisation during TEVAR, but that “its impact on silent brain infarction has not yet been evaluated with cerebral imaging”.

According to the authors, the STEP registry is the largest study to evaluate the incidence and distribution of silent cerebral infarction following endovascular repair for disease of the aortic arch, and also the first cohort to include total endovascular arch repair and devices flushed with carbon dioxide.

The purpose of this work, Charbonneau and colleagues relay, was to quantify silent brain infarction in a patient population that underwent advanced endovascular aortic arch treatment. They specify that the study included total endovascular arch repairs, and carbon dioxide flushed devices as one embolic protection strategy.

Writing in EJVES, Charbonneau and colleagues detail that this multicentre retrospective cohort study included consecutive patients treated with an aortic endoprosthesis deployed in Ishimaru zone 0–3 and brain DW-MRI within seven days following the procedure. They state that DW-MRI was performed to identify the location and number of lesions assessed for disease of the aortic arch, and also the first cohort to include total endovascular arch repair and devices flushed with carbon dioxide.

The researchers performed a prospective cohort feasibility study between July and December 2018, recruiting patients undergoing either regular or complex endovascular aneurysm repair (EVAR) or endovascular peripheral lesion repair.
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Silent brain infarction common after endovascular arch repair, STEP registry finds

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of new silent brain infarctions and that all endografts were flushed with carbon dioxide prior to implantation. A total of 91 patients (mean age, 69 years; men, 64%) were included in the study. The authors relay that these patients were from two academic centres and were treated between September 2018 and January 2020, adding that the procedure was elective in 71 patients (78%).

In terms of aortic pathology, Charbonneau et al detail that treatment was performed for a dissection, degenerative aneurysm, or other aortic disease in 44 (49%), 34 (37%), and 13 (14%) patients, respectively. Finally, the authors specify that endografts were deployed in zone 0, 1, 2, or 3 in 23 (25%), 10 (11%), 47 (52%), and 11 (12%) patients, respectively. They detail that endografts were branched (25%), fenestrated (17%), or tubular (58%).

Key findings

At 30 days, Charbonneau and colleagues report that there were no deaths or clinical strokes. However, on cerebral DW-MRI, they identified a total of 245 silent brain infarctions in 45 patients (50%). They specify that lesions were in the left hemisphere in 63% of the patients (153/245), predominantly in the middle territory (94/245). On univariable analysis, the investigators identified some factors that were “significantly associated” with the presence of silent brain infarction, including deployment in zone 0–1 (p=0.026), placement of a branched or fenestrated endograft (p=0.038), a proximal endoprosthesis diameter ≥40mm (p=0.038), and an urgent procedure (p=0.005). They add that urgent procedure was found to be an independent predictor on multivariable analysis (binary logistic regression; p=0.002).

Results limited by selection bias, undetected strokes, and follow-up period

Charbonneau et al acknowledge some limitations of this retrospective study. For example, they recognise a selection bias in that the study cohort included non-consecutive patients who underwent TEVAR, and that two patients from the total population of nearly 100 patients who experienced ischaemic stroke during the study period were excluded from analysis, as the DW-MRI was not performed within the appropriate time window.

In addition, they note that specific neurocognitive examinations were not performed, meaning that “cognitive impairment cannot be judged,” and add that postoperative clinical evaluation was not routinely done with a neurologist, which “may have resulted in undetected relevant strokes”. Finally, they highlight that follow-up ended at 30 days following the repair.

Charbonneau and colleagues conclude that silent brain infarction is a common finding after endovascular arch repair, particularly in urgent procedures. They reiterate that this study is the largest cohort of patients evaluated by cerebral DW-MRI for the incidence of silent brain infarction following endovascular repair for disease of the aortic arch including total endovascular arch repair, and carbon dioxide-flushed devices. “Considering the long-term cognitive effect of silent brain infarction described in the literature,” they posit, “efforts should continue to identify and validate associated factors”. Also, they stress that “novel embolic protection strategies need to be developed to decrease the occurrence of those lesions”.

Cause of brain damage after TEVAR “too often accepted as fate”

Vascular News spoke to co-author Tilo Köhbel (University Heart and Vascular Centre, Hamburg, Germany), who commented on the significance of these results: “Stroke after TEVAR is the most feared complication risk of this otherwise game-changing minimally invasive treatment for thoracic aortic pathologies. The cause of stroke and other less obvious brain-damage such as silent brain infarction is meanwhile not sufficiently studied and too often accepted as fate due to our lack of knowledge. We have for too long focused solely on the advantages of endovascular aortic techniques, encouraged by the superior results compared to open surgery. “This blindness towards disadvantages and risks of new exciting technology is not surprising and normal human behaviour, but may prove a disservice to the endovascular and catheter-based revolution in cardiovascular therapy. Changing our research focus early towards the potential drawbacks of TEVAR, such as cerebral damage caused by the solid and gaseous embolisation, will eventually strengthen the technique as it will enable us to make progress and find new protective measures to improve our results. “Carbon dioxide flushing is a low-risk technique to reduce air embolisation from TEVAR devices used in leading aortic centres. Charbonneau et al present here a first proof of the potential efficacy of carbon dioxide flushing: in this high-risk selection of arch TEVAR cases, there is a lower rate of silent brain infarction (50%) compared with what has been reported so far for lower-risk procedures (80%). We see an increasing interest in this important research topic and look forward to see improved technology and devices in order to minimise the collateral damage of endovascular arch repair.”

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First-in-human study shows “feasibility and potential” of FORS technology

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Van Herwaarden et al used FORS guidance exclusively during navigational tasks, such as target vessel catheterisation or crossing of stenotic lesions. In EJVES, they write that three types of FORS-enabled devices were available: a flexible guidewire, a Cobra-2 catheter, and a Berenstein catheter. They note that devices were chosen at the physician’s discretion and could comprise any combination of FORS and non-FORS devices.

The primary study endpoint was technical success of the navigational tasks using FORS-enabled devices, and secondary endpoints were user experience and fluoroscopy time. The authors note that they enrolled 22 patients in the study, comprising 14 EVAR and eight endovascular peripheral lesion repair patients.

They detail that, owing to a technical issue during start up, the FORS system could not be used in one EVAR. However, they report that the remaining 21 procedures went ahead without device- or technology-related complications and involved 66 navigational tasks.

Van Herwaarden and colleagues add that in 60 tasks (90.9%), technical success was achieved using at least one FORS-enabled device. In terms of user experience, operators graded FORS-based image guidance “better than standard guidance” in 16 of 21 and “equal to standard guidance” in five of 21 procedures. Finally, regarding fluoroscopy time, the authors report that this ranged from 0 to 52.2 minutes, adding that several tasks were completed without or with only minimal X-ray use.

The authors acknowledge some limitations of the present study. For example, they communicate that, although the operators had experience with the system in preclinical studies, they went through a learning curve during clinical use. Van Herwaarden et al write: “The optimal visualisation settings (regarding viewing angle, magnification, mono- or biplane mode, and optimal overlay) had to be identified for the different types of procedure.”

In addition, they note that workflow improvements, like the optimal positioning of the system, to work from both the groin and the arm, had to be learned during the study. “In this first study, the technical success would probably have been higher if more than two differently shaped catheters had been available,” they posit.

Van Herwaarden and colleagues list a few more limitations for clinical use, including the limited working length of the catheters and guidewires available for this study and also the inability to backload the guidewires. “These issues will be addressed in future releases of the system,” they state.

Finally, they relay that there were technical issues with the FORS equipment during this study. The technology could not be used in one patient, they detail, and using two FORS devices at the same time was impossible in one other patient. They note that these factors “probably affected study results”.

The authors conclude that this exploratory study “demonstrates the feasibility and potential of this technology in clinical practice and forms a foundation for future clinical research.” However, they recognise that comparative studies are needed to “prove and quantify” the benefits and potential radiation reduction for all types of endovascular procedures.

EVAR not costlier than open repair for most routine AAA repairs, study suggests

A recent systematic evaluation of the costs of elective endovascular aneurysm repair (EVAR) and open infrarenal abdominal aortic aneurysm (AAA) repair implies cost equivalence. This is the conclusion of Ruth M A Bulder (Leiden University Medical Centre, Leiden, The Netherlands) and colleagues in an Editor’s Choice paper in the European Journal of Vascular and Endovascular Surgery (EJVES).

Cost equivalence for EVAR and open repair occurs at a device cost of €13,000 for EVAR.

Cost equivalence for EVAR and open repair occurs at a device cost

The authors conclude that this exploratory study “demonstrates the feasibility and potential of this technology in clinical practice and forms a foundation for future clinical research.” However, they recognise that comparative studies are needed to “prove and quantify” the benefits and potential radiation reduction for all types of endovascular procedures.

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Outpatient hospitalisation for endovascular repair of claudication not cost effective in France, RCT finds

According to the AMBUVASC randomised controlled trial (RCT), outpatient hospitalisation is not cost effective compared with inpatient hospitalisation for endovascular repair of patients with claudication at a €50,000/quality adjusted life year (QALY) threshold. Yann Gouëffic (Groupement Hôpital Paris St Joseph, Paris, France) warned against generalisation of their conclusion. “The findings depend on the specific organisation in France,” they state, “where the two procedures are performed within the same institution”.

The findings depend on the specific organisation in France, where the two procedures are performed within the same institution.

The authors report that rates of perioperative complications were 20% (15 events) and 18% (14 events) for the outpatient and inpatient arms, respectively (p=0.81). They add that overall costs (difference: €187.83, 95% confidence interval [CI] -275.68–651.34) and QALYs (difference: 0.00277; 95% CI -0.00237–0.00791) were higher for outpatients due to more readmissions than the inpatient arm.

Furthermore, Gouëffic and colleagues relay that the incremental cost effectiveness ratio was €67,741 per QALY gained for the base case analysis with missing data imputed using multiple imputation by predictive mean matching. Overall, the investigators found that the outpatient procedure was not cost effective for a willingness to pay €30,000 per QALY and the probability of being cost effective was only 59% for a €100,000/QALY threshold.

According to the authors, AMBUVASC was the first cost effectiveness analysis associated with a prospective randomised controlled trial in France that compared outpatient versus inpatient hospitalisation for the endovascular repair of LEAD. In the discussion of their findings, Gouëffic et al note that the cost differences were observed to be small, which “makes them sensitive to the precision of the estimation of hospital hotel costs (other than those of the intervention)”. They remark that this calls for further research to investigate the reasons for readmissions and to consolidate the estimation of the differences in initial hospital costs between outpatient and inpatient treatment before a definitive conclusion can be reached.

“Simple changes” enable vascular limb salvage clinic to maintain a service during COVID-19 peak

“The findings depend on the specific organisation in France, where the two procedures are performed within the same institution.”

The COVID-19 pandemic has had a “dramatic effect” on the provision of vascular services across the UK, Nickinson began. Focusing on hospitals in Leicester specifically, he detailed that, at the peak of the first wave, the University Hospitals of Leicester NHS Trust had over 200 inpatient cases on some days.

The rapid-access Leicester VaLS clinic opened in February 2018, and—before the pandemic—was open to referral from any healthcare professional, with the only referral criterion being suspicion of chronic limb-threatening ischaemia. With dedicated assessment and treatment protocols, the clinic was managing to revascularise patients within eight days of referral, Nickinson informed the audience.

“I think it is safe to say that a resource-intensive service like [VaLS] really does not mix with a global pandemic like COVID-19,” the presenter remarked, recalling that in March, the vascular ward was converted into a COVID-19 ward, a number of staff had to move on to emergency rotas or were shielding, and the clinic lost some theatre and interventional radiology capacity, reducing their ability to revascularise patients.

Nickinson relayed that, at the start of the pandemic, the team were concerned that they may have to completely shut the service. However, they decided early on that they wanted the clinic to continue, “at least in some form,” and “were willing to make changes and adaptations in order to survive”.

He outlined that they key change during this period was the implementation of a COVID protocol, which aimed to focus what limited resources they had available at the time on those patients at highest risk of amputation. Instead of trying to treat everyone, as they were doing before, the team used an objective clinical measure—the WiFi score (Wound, Ischaemia, Foot Infection)—in order to identify those patients who needed treatment the most.

In addition, he team incorporated VaLS into a broader vascular clinic and tried to maximise theatre capacity by shifting some wound debridements to a dedicated treatment room, to be performed under local anaesthetic.

Looking at the figures in the period from March to July, Nickinson told the VS ASM audience that the team assessed 166 patients, 84 (50.6%) of whom were diagnosed with CLI. Of those 84 patients, 55 (65.4%) underwent revascularisation, 24 (29.8%) were managed conservatively, and four (4.8%) had primary amputations.

Considering how the revascularisation rate changed from before COVID-19 to after the implementation of the COVID-19 protocol, Nickinson detailed that this dropped from 74.9% to 65.4%, and that the time from referral to revascularisation increased from eight to 10 days during the pandemic. “ Crucially,” Nickinson emphasised, “we managed to continue the vascular service, at least in some form, and managed to assess quite a few patients during the that time”.

Reflecting on the changes made in response to COVID-19, Nickinson acknowledged that the protocol is “probably too strict,” noting that the team revascularised more patients than they were expecting to between March and July. He added: “It is also important to say that, despite all the hard work and effort, it does not help those patients who had difficulty accessing community services in the first place; we expected a surge, which was not the case”. Nickinson believes the team have shown that small changes, primarily focusing on objective clinical measures, like the WiFi score, can allow an effective service to continue during the extremes of the pandemic.
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Network meta-analysis finds DCB angioplasty “significantly superior” to plain balloon angioplasty in failing AVFs with outflow stenosis

A recent network meta-analysis shows that, in failing arteriovenous fistulas (AVFs) with outflow stenosis, drug-coated balloon (DCB) angioplasty is “significantly superior” to plain balloon angioplasty, presenting an improved six-month failure rate. However, Gregory Tripsianis (Democritus University, Alexandroupolis, Greece) and colleagues stress that the effectiveness of DCB angioplasty in the long term “deserves further investigation”.

WHILE THE 2018 EUROPEAN Society for Vascular Surgery (ESVS) vascular access clinical practice guidelines recommend balloon angioplasty for the treatment of venous outflow stenosis to extend the use of AVFs, the authors note that its effectiveness compared to other endovascular modalities “remains unclear”. In fact, they state more generally that “there is currently uncertainty regarding the ideal treatment to salvage failing AVFs”.

Writing in an online Journal of Vascular Surgery (JVS) article, Tripsianis et al note that it was their intention in this study to investigate the comparative effectiveness of the different endovascular treatments in patients with failing autogenous AVFs with outflow vein stenosis.

The investigators detail that they searched Medline/PubMed and SCOPUS databases for studies that fit the criteria of being randomised controlled trials (RCTs), compared endovascular treatments of autogenous AVF stenoses—including plain balloon angioplasty, cutting balloon angioplasty, and DCB angioplasty—and provided six-month and/or one-year patency data for each group at follow-up.

Inclusion criteria were venous outflow, anastomotic or swing area stenosis, either de novo or recurrent, and exclusion criteria were central vein stenosis or RCTs including open surgical repair or stent/stent graft arms. Following the literature search, Tripsianis and colleagues performed a systematic review and network meta-analysis of RCTs investigating the effectiveness of plain balloon angioplasty, cutting balloon angioplasty, and DCB angioplasty in autogenous AVF vein stenosis. They write that they included eleven RCTs in the study, reporting a total of 814 patients, of whom 395 underwent plain balloon angioplasty.

According to the authors, their network meta-analysis showed that DCB angioplasty at six months was “significantly more effective” than plain balloon angioplasty (odds ratio [OR]: 0.39, confidence intervals [CI]: 0.18–0.81) and ranked as the best treatment option, but without having statistically significant difference when compared with cutting balloon angioplasty (OR: 0.65, CI: 0.2–2.12).

Writing in JVS, the investigators also report that statistical significance was not achieved at one year among treatments, and that additional conventional pairwise meta-analyses did not find significant differences at one year.

Tripsianis et al stress that the results of this review “should be interpreted with caution” due to some limitations. Firstly, they acknowledge that the network geometry did not provide any closed loops and write that “no direct comparison between DCB angioplasty and cutting balloon angioplasty existed, thus it was impossible to assess inconsistency between direct and indirect evidence”.

In addition, they note that there was “a considerable degree of heterogeneity” among the included RCTs and that confounding factors were present. They detail: “There was blending of various AVF configurations, de novo lesions with recurrent ones, high-pressure balloon use in a variable number, different brands of DCBs and paclitaxel dose, differences in patency reports (target lesion versus circuit patency), and difference in methodology of angioplasty regarding predilatation or post-dilatation following DCB angioplasty”.

Finally, they recognise that there was “a high risk of bias” among the included studies, especially those comparing plain balloon angioplasty with cutting balloon angioplasty. Tripsianis et al detail that most of the trials suffered from the “inherently high risk in the domain of blinding,” specifying that all but one of the included studies suffered from bias in blinding or personnel, as this is “almost impossible” in endovascular procedures. However, they note that there was some blinding of the outcome assessment in six studies.

COVID-related hypercoagulability linked to elevated malfunction rate in temporary haemodialysis catheters

Hypercoagulability in COVID-19 patients leads to an increase in the malfunction rate of temporary haemodialysis catheters—but heparin locking of the catheters is linked to decreased malfunction rates, a new study finds.

John J Kanitra (Ascension St John Hospital, Detroit, USA) and colleagues carried out a retrospective cohort study via chart review at their institution—a large urban hospital. Writing in the Journal of Vascular Surgery, they report that a total of 48 patients with a mortality rate of 71% were identified. Malfunction occurred in 31.3% of patients. Thirty-seven patients (77.1%) received heparin locking, 22 (45.8%) received systemic anticoagulation and 36 (79.1%) received venous thromboembolism prophylaxis. The overall rate of malfunction was lower at a trend level of significance with heparin versus saline locking (24.3% vs. 54.6%; p=0.058), Kanitra et al found. Meanwhile, systemic anticoagulation did not affect temporary catheter malfunction rate (p=0.240). Higher D-dimer levels were related to greater mortality (hazard ratio [HR] 3.28, 95% confidence interval [CI] 1.16–9.28; p=0.025), but were not significantly associated with temporary catheter malfunction (HR 1.79, 95% CI 0.42–7.71; p=0.434).

“There is currently uncertainty regarding the ideal treatment to salvage failing AVFs.”
PAVE trial finds “no evidence of a benefit” from paclitaxel-coated balloons in preserving AV fistula patency

There is no evidence of a benefit from additional paclitaxel-coated balloon use compared to standard balloon angioplasty alone in the context of preserving arteriovenous (AV) fistula patency for haemodialysis, according to as-yet unpublished data from the multicentre, randomised controlled PAVE (Paclitaxel-coated balloons and angioplasty of AV fistulas) trial, presented at the 2020 annual scientific meeting of the British Society of Interventional Radiology (BSIR; 1–3 December, online). Presenter Michael Robson (Guy’s and St Thomas’ Hospital and King’s College London, London, UK) reported no disclosures relating to the PAVE trial, but noted that BD provided the balloons used. BD played no other role in the investigation, he reported.

Contextualising the PAVE trial, Robson told BSIR attendees: “A fistuloplasty is a good treatment for a blocked arteriovenous fistula before haemodialysis; however, the benefits may be short-term, and a stenosis often occurs.”

The PAVE trialists conducted a double-blind, multicentre randomised controlled trial. Patients were unaware of treatment allocation, as were the majority of the clinical and research team. “It was not possible to blind the radiologists,” Robson explained, “because of the different appearances of the drug-coated balloon and the control balloon.” In total, 212 patients from 20 centres across the UK were recruited, randomised in a 1:1 ratio into the paclitaxel-coated balloon group or the control group, and followed up for a minimum of one year.

There was no statistically significant difference in time to end of target lesion primary patency, the study’s primary endpoint, between the two groups. To time of target lesion primary patency was measured when any of the following occurred: a clinically driven reintervention in the treatment segment; thrombotic occlusion that includes the treatment segment; surgical intervention that excludes the treatment segment from the access circuit; abandonment of the AV fistula due to an inability to re-treat the treatment segment.

Time to end of access circuit primary patency, one of the study’s secondary endpoints, was also not statistically significantly different between the paclitaxel-coated cohort and the control group.

Time to end of access circuit cumulative patency—when the fistula was abandoned—another secondary endpoint, was again not meaningfully different between the groups. Continuing the pattern, “there was no suggestion of a difference between groups” when the trialists looked at the angiographic secondary outcomes, late lumen loss and rate of binary restenosis.

Procedural success was “good” in both cohorts, according to Robson, with no difference between the treatment and control arms of the PAVE trial.

Randomised controlled trials prior to PAVE

In 2017, data from the first large-scale, randomised controlled trial investigating the clinical use and safety of a DCB catheter (Lutonix 035 AV; BD) for the treatment of dysfunctional AV fistulas and grafts were presented at the Leipzig Interventional Course (LINC; 24–27 January, Leipzig, Germany) and published in the Journal of Vascular and Interventional Radiology (JVIR). The eight-month data presented by Scott Torellota (Perelman School of Medicine of the University of Pennsylvania, Philadelphia, USA) at the time showed that the drug-coated balloon is linked with a significantly higher target lesion patency and far fewer reinterventions to maintain the opening in a wide variety of failing AV fistulas than standard angioplasty. Two-year data, also published in JVIR in 2020, corroborated this finding. However, the 180-day target lesion primary patency was not significantly different between the two treatment groups (p=0.06). As this was the primary endpoint, Torellota noted that it was not met, but clarified at the time that this was a “statistical blip” as the curves continue to clearly diverge by the 2-year mark.

In August 2020, the New England Journal of Medicine published the six-month results of a second large, randomised controlled trial—the IN.PACT AV access study, which used the IN.PACT AV balloon from Medtronic for the treatment of stenotic lesions in dysfunctional haemodialysis AV fistulas. In this study, DCB use was found to be superior to standard balloon angioplasty, and this difference was statistically significant: target lesion primary patency was 82.2% in the former group (n=170), and 59.5% in the latter (n=160; p<0.001).

“So why have we not shown a difference in the PAVE trial, whereas the IN.PACT AV access study did show a difference [at six months]?” Robson asked. “I have not got an obvious answer to that. I guess all I can say about the PAVE trial,” he continued, “is that we tried to deliver as robust a trial as we could. We did everything that we could to preserve blinding amongst participants and the research team.”

Differences between PAVE and IN.PACT AV

There were several differences between the PAVE trial and IN.PACT AV access study: only patients with a single lesion or with tandem lesions that could be treated with a single drug-coated balloon were included in the PAVE trial, whereas IN.PACT AV analysed data from patients with multiple lesions; AV fistulas with previous thrombosis were included in the PAVE trial, but not IN.PACT AV; more patients in PAVE were Caucasian, and fewer had had previous revascularisations. “Whether these explain the differing results I do not know,” Robson said.

Comment

James Gilbert (Oxford University Hospitals NHS Foundation Trust, Oxford, UK), president of the Vascular Access Society of Britain and Ireland (VASBI), gives his thoughts on the PAVE results: “I think there will be growing confusion around DCB use in a vascular access circuit given that we now have three large RCTs that have used a paclitaxel-coated balloon versus a standard balloon and all have shown different outcomes.

“Generally speaking, the data would suggest that there may well be a benefit of DCBs over standard balloons in some stenoses in an arteriovenous access circuit, despite the PAVE findings. And, the fact that a number of researchers have found benefit both in small and large studies should also be reflected. “Which intervention is used will come down to clinician experience and choice, but will include plain balloon angioplasty, DCBs, stenting, and revision procedures. The key thing clinicians must decide on is an intervention that will maintain patency for as long as possible and that will be driven by both the site of the lesion and how quickly it has recurred after previous interventions.

Gilbert adds: “My personal opinion on DCBs is that their use probably needs to be earlier rather than later on a lesion. The whole point of them is to try and arrest/slow the progression of the neointimal hyperplasia that has led to the stenosis in the first place.”

“The classic place that this occurs early is the perianastomotic stenosis area and it impacts on access maturation and functional patency. It would strike me that this site could benefit from DCB usage and it would be interesting for the PAVE and IN.PACT AV study groups to give a breakdown in outcomes in de novo stenosis at this point.”

Continuing the pattern, “there was no suggestion of a difference between groups” when the trialists looked at the angiographic secondary outcomes, late lumen loss and rate of binary restenosis.

Procedural success was “good” in both cohorts, according to Robson, with no difference between the treatment and control arms of the PAVE trial.

Robert L. Gilbert, BSIR president Ian McCafferty, presenter Michael Robson, session chair Raj Das, and fellow panellist Anna Belli watching live.
Risk of ischaemic steal syndrome and patency rate comparable for tapered and non-tapered AVGs

In their recent systematic review and meta-analysis, Venkata Sai Jasty (University of Arizona, Tuscon, USA) and colleagues found that the risk of ischaemic steal syndrome, “one of the most feared complications in vascular access,” and patency rate are comparable for both tapered and non-tapered prosthetic arteriovenous grafts (AVGs) in dialysis access.

**WRITING IN THE JOURNAL of Vascular Access (JVA), Jasty et al detail that end-stage renal disease (ESRD) “remains one of the leading causes of mortality and morbidity”. They note that there are currently three treatment options for ESRD—haemodialysis, peritoneal dialysis, and organ transplantation—but mention that a shortage of organ supply for a rising need has led to “a continued and increased call” for haemodialysis. Upper extremity arteriovenous access “remains the preferred vascular access for haemodialysis in ESRD patients,” the authors relay, detailing that an arteriovenous fistula (AVF) or AVG are generally favoured over a central venous catheter, “due to lower rates of infection, hospitalisation, cardiovascular events, and all-cause mortality rate.” They write that prior guidelines recommended arteriovenous fistulae (AVFs) as the initial choice for haemodialysis access due to more durability, higher patency rates, and lower morbidity and mortality compared to AVGs. However, “due to high failure rates of AVF from inadequate maturation and interventions required to achieve and maintain a functional AVF,” they stress that the latest guidelines from the National Kidney Foundation Kidney Disease Quality Outcomes Initiative (NKF KDQOI) “challenge the use of AVFs on certain populations” and recommend AVGs as the “preferable option” for haemodialysis.

Jasty et al note that one of the biggest complications of vascular access placement is ischaemic steal syndrome, where blood is diverted from the hand to the graft, leading to hand ischaemia. To mitigate this problem, they detail that tapered grafts were created. These grafts have a smaller diameter at the arterial anastomosis, they write, “which leads to decreased blood flow from the artery to the graft, thus lowering the risk of ischaemic steal”. “It is unclear whether tapered AVGs are superior to non-tapered AVGs when it comes to preventing upper extremity ischaemic steal syndrome,” Jasty and colleagues state, noting that this gap in the literature led them to evaluate the outcomes of both graft types using a systematic review and meta-analysis. The investigators performed a literature search in order to identify all English language publications from 1999 to 2019 that directly compared the outcomes of upper extremity tapered and non-tapered AVGs. They evaluated primary patency at one year (number of studies [n]=4), secondary patency at one year (n=3), and risk of ischaemic steal (n=5) and infection (n=4). Of 5,808 studies screened, Jasty et al identified a total of five studies involving 4,397 patients that met the inclusion criteria and were therefore included in the analysis. They write in JVA that the meta-analyses revealed no significant difference for the risk of ischaemic steal syndrome (pooled odds ratio [OR], 0.92; 95% confidence interval [CI], 0.29–2.91; p=0.12; I²=48%) between the tapered and non-tapered upper extremity AVG. In addition, they report that the primary patency (OR, 1.33; 95% CI, 0.93–1.9; p=0.12; I²=10%) and secondary patency at one year (OR, 1.49; 95% CI, 0.84–2.63; p=0.17; I²=13%), and rate of infection (OR, 0.62; 95% CI, 0.3–1.27; p=0.19; I²=29%) were also similar between the tapered and non-tapered AVGs. The authors acknowledge certain limitations of this meta-analysis, including a low number of studies, unknown reasons for surgeons’ preference for one graft over the other, and short follow-up. Jasty and colleagues conclude: “This meta-analysis does not support the routine use of tapered graft over non-tapered graft to prevent ischaemic steal syndrome in upper extremity access.” However, due to the small number of studies and sample sizes, as well as limited stratification of outcomes based on risk factors, they stress, “Future studies should take such limitations into account while designing more robust protocols to elucidate this issue”.

**VasQ device improves AVF creation in haemodialysis patients**

VasQ, a high haemocompatibility biosynthetic vascular device from Laminate Medical Technologies, could be protective against the haemodynamic modifications that occur during arteriovenous fistulae (AVF) creation, a recent article in The Journal of Vascular Access reports. Roberto Palumbo (Saint Eugenio Hospital, Rome, Italy) and co-authors caution that their results, which derive from their clinical experience and are thus representative of a “real-life setting”, should be considered preliminary.

**ACCORDING TO PALUMBO ET AL., THE VasQ device was designed “to improve the outcome of AVF [creation] by optimising the haemodynamics of the flow in the juxta-anastomotic region of the AVFs through tailored external support”. They continue: “The rationale for supporting the implantation of [the] VasQ device is based on the reduction of the turbulent blood flow through the anastomotic site and of the radial stretching of their venous wall, allowing a potential attenuation of hyperplasia and stenosis consequences and, finally, improving AVF-outcomes in haemodialysis patients.” To establish if the use of the VasQ device would help reduce these haemodynamic modifications, the investigators compared patients who underwent native radio-catheter AVF creation with and without implantation of the device at their institution between May and September 2019 (15 individuals in each group). Haemodynamic parameters were evaluated pre-operatively, and at one, three, and six months follow-up. At baseline, there was no significant difference between the treatment group and the control group in terms of mean preoperative arterial flow, vein diameter, preoperative ejection fraction, and cardiac output. Arterial diameter was greater in the treatment group (where the VasQ device was deployed) at baseline (3.4±0.8mm vs. 2.8±0.5mm), but Palumbo and colleagues dismiss this, writing: “Although the vessel radius is considered a major determinant of the vessel flow, this finding may have reflected only marginally in the clinical results achieved in the VasQ device implanted [in] patients”. While at one-month follow-up, there was no difference in mean arterial flow between the two cohorts, a significant difference was observed at three months (645±143mL/min in the VasQ group vs. 824±211mL/min in the control group; p=0.02) and six months (714±146mL/min vs. 810±194mL/min; p=0.05).

At six months follow-up, the cardiac output flow was lower in the cohort of patients implanted with the VasQ device: 4,458±928mL/min versus 5,599±1,355mL/min (p=0.05). Palumbo et al suggest that this could mean that the VasQ device “may provide a potential benefit in preventing haemodynamic modifications of the cardiovascular system and preventing the overload of the left ventricle by reducing the altered high cardiac output of haemodialysis patients associated with AVF creation”. “Of note, no VasQ device complications were recorded,” the authors write. “The VasQ has been well tolerated by the patients, and no patient had poor subcutaneous tissues at the anastomotic site. During surgery, no technical complication occurred.” At six months, primary patency was 73% in the treatment group and 80% in the control group, respectively. Cumulative patency was 80% and 86%, respectively, in implanted VasQ device patients compared to those in the control group.

Palumbo and colleagues conclude: “We confirmed the substantial safety and utility of [the] VasQ device in AVF creation. […] Our experience outlined that the implantation of [the] VasQ device during AVF creation compared to those [who underwent the] standard technique may allow a stabilisation of the high cardiac output of haemodialysis patients.”
“From pioneering times to a mature technology”: The evolution of bridging stents for FEVAR and BEVAR

There are several covered stents on the market that are used in an off-label setting as bridging stents for fenestrated and branched endovascular aneurysm repair (FEVAR). Currently, there is no consensus on when to use what—no gold standard, no proof, no evidence. According to three experts in the field, however, this is about to change. As trials take place and data begin to emerge, Vascular News speaks to Stéphan Haulon (Hôpital Marie Lannelongue, GHPSJ, Paris, France), Eric Verhoeven (Klinikum Nuremberg, Nuremberg Germany), and Tim Resch (Copenhagen Aortic Center, Rigshospitalet, Denmark), who express their views on the past, present, and future of bridging stents in FEVAR and BEVAR.

Considering the origins of bridging stents in these indications, Haulon explains that they have been used “for years”, but in an off-label sense. Nowadays, however, he relays that specific devices are being developed, and that trials are beginning to specifically evaluate bridging stents for FEVAR and BEVAR.

“I think it is important to stress that bridging stents for fenestrated endografts have different features to bridging stents for branched devices,” Haulon says. “The main difference is that we use bridging stents to connect the fenestration to the target vessel, but usually the fenestration is adjacent or close to the origin of the target vessel, so the bridging stent does not need to cross a large gap or a large aneurysm sac before going into the target vessel. In addition, it needs to be locked to the fenestration [...] so there is a flaring process, whereas in branches, you have a long overlap between the bridging stent and the branch, and you have a long gap in most cases to bridge the aortic device to the target vessel,” he explains.

Resch elaborates: “In many cases of fenestrated repair for pathologies such as juxtarenal and pararenal aneurysms, where you have wall apposition of the main body of the device, the fenestrated or branched stent per se is not much for seal, but for direction, to keep patency in these vessels.

“It means that [the] stent is much shorter and less subjected to difference forces, whereas oftentimes in a branch repair, you are actually traversing an aneurysmal space. It needs to create a whole different seal between the main body of the endograft and the target vessel and traverse a lot of space in between, so those stents are typically longer and need to display more varied properties. They have to be strong and flexible and to withstand forces of a different magnitude than bridging stents in fenestrated grafts,” he adds.

Within this context, Verhoeven highlights the fact that fenestrated and branched procedures require different types of stents. “In fenestrated grafts, or in grafts with fenestrations only, we use balloon-expandable covered stents that we can flare, while in branched grafts, we can use either self-expandable covered stents or balloon-expandable covered stents,” he states, adding that the next step in the branched setting is to have more flexible balloon-expandable covered stents to accommodate the angles between the branches and the target vessel.

Past: Expanding clinical goals and the changing role of industry

Historically, physicians did not have much choice about which stent to use, Verhoeven stresses. Resch echoes this lack of choice, recalling his experience from 15–20 years ago: “It was all about getting a graft in place, so we took whatever device we could regarding trackability and profile, and tried to get it in place.”

Nowadays, they emphasise that the aim is more focused on long-term outcomes. He explains: “Over the years, we have obtained more experience and data on what actually makes the device last, so our aim today is not just to get a device in place and get an aneurysm excluded, but to keep that aneurysm excluded over a long period of time.”

Regarding industry, Verhoeven notes that there used to be only a few companies who had the desire to develop these devices as it was a small market, but that this market has “continuously grown.”

Speaking on this changing role, Haulon remarks that, given the off-label use of these devices, the only way to get better was to combine experiences in order to try and find out which stent worked best in which indication, with little input from industry. “What is changing is that now industry is coming up with dedicated bridging stents and launching trials, so we will have real evidence,” he explains.

More specifically, Verhoeven details which devices he currently uses in his practice. “In fenestrations, we currently use the BeGraft [Bentley], which is a dedicated balloon-expandable covered stent for fenestrations, and we also use the Advanta V12/Cast [Gore], because that is the only balloon-expandable covered stent that comes in a length of 79mm.”

Present: Crucially different demands of FEVAR and BEVAR highlight need for trials

The interviewed physicians are keen to stress the importance of differentiating between FEVAR and BEVAR. Recognising the unique demands of the two procedures is “crucial,” according to Resch. “There is still some confusion with regards to that in the marketplace and among users, which sometimes leads to disastrous outcomes,” he explains, using the example of BeGraft (for fenestrations) and the BeGraft Plus (for branches) as examples, stressing that they are “two totally different devices that we use for two totally different things”.

In his consideration of why the two are confused, Haulon underlines the need for data and dedicated stents: “I think the main reason is that we do not have approved bridging stents for the technology. They are being used off-label and that is why we urgently need specific trials.” He elaborates that Bentley is currently actively supporting both a FEVAR and a BEVAR physician-initiated trial with the BeGraft and the BeGraft PLUS as bridging stents that he hopes will bring the data needed to support which stents work well for which indication.

Future: The journey from off-label to on-label continues

Resch sees the gathering of data for these indications as part of an essential part of a wider project. “We have worked on main body stent graft development for many years, and it feels like the mating stents were left a bit behind, so we are very happy now that we are finally taking on the whole package, because the repair itself and its durability is really dependent on the whole graft,” he comments.

“It has been a very long journey,” Haulon adds, noting that it “felt bad” to be using stents off label for so many years. “There was a huge learning curve for everyone, and it was a niche for companies for many years,” he recalls, but adds that the need for data is evident.

“We are moving from pioneering times to a mature technology,” Haulon concluded.

“...there was a huge learning curve for everyone, and it was a niche for companies for many years.”
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*Available to the US and EU markets only **Available worldwide
Large
Larger
Largest

BeGraft
aortic

available Ø 12 - 24 mm
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*max. diameter after post-dilation with an appropriate balloon catheter
**acc. to the IFU

www.bentley.global
In this arena, the BeGraft aortic stent is an off-label indication for use, under review.

We realised that it is an excellent solution for this indication. After the first few cases, we started to use balloon-expandable covered stents and noticed that the BeGraft aortic addresses the issue of overtreatment, thanks to its ability to be dilated to different diameters, allowing the physician to adjust the degree of therapy in order to match the extent of the disease.

Before we used this particular stent, one of the main challenges with this procedure was that standard infrarenal bifurcated grafts are designed to be used in large aneurysmatic aortas. Aortas with PAUs often have diameters of between 14 and 18mm, whereas self-expandable aortic stent grafts are made for large diameters of around 24mm.

Another issue was that an aortic aneurysm has more space to accommodate the bifurcation of the stent graft, whereas this is not the case in PAUs. In these patients, using iliac limbs of 12 or 16mm diameters in a narrow aortic bifurcation makes it very prone to occlusions. These were both challenges that have now been eliminated thanks to the BeGraft aortic.

Which anatomical conditions are needed in order for a balloon-expandable covered stent to provide good outcomes?
A basic condition is the ability to reach a healthy aortic segment. In addition, one needs to have a very localised lesion, as balloon-expandable stent grafts are not very long.

One should be aware of a tapered aorta. This is not an exclusion criterion, but one has to be cautious not to cause a rupture with a balloon-expandable stent due to extreme oversizing of the lower part of the aorta.

What made you decide to try out the BeGraft aortic for this indication?
I always thought that we were doing too much for too small a lesion.
Drawing on my experience with this balloon-expandable stent in other indications and getting to know it as a very reliable stent graft that can be inserted with a low-profile system of 9–11F, I thought it would be worth trying for PAUs. After the first few cases, we realised that it is an excellent solution for this indication.

What are the main advantages and limitations of using a balloon-expandable covered stent in a PAU?
I think the balloon-expandable covered stent offers very accurate positioning and also flexibility in terms of how much of the lesion you want to cover. In addition, it has a big advantage in terms of the sizes that are on offer.

It must be taken into account that one needs to develop techniques for how to deal with the challenges of using balloon-expandable covered stents in the aorta. We always use the lowest diameter of the aorta to start with and then, if we need to put in two stent grafts, we taper them instead of putting the bigger diameter stent into a smaller aorta. We do not measure to the proximal or largest diameter, but instead the distal, smaller diameter, and then balloon the proximal part, in order to get the proximal seal.

What are the long-term outcomes in patients you have treated?
The long-term reliability of a balloon-expandable stent in aorta that degenerates over time is a big concern. However, the pathology is a little bit different with PAUs than with the typical atherosclerotic aortic aneurysm that will evolve and develop. PAU patients have a very localised plaque rupture or have a local dissection—indications that require treatment, but these patients still have a relatively stable aorta. Nevertheless, I would always follow these patients extensively, especially at the beginning of our experience, with a standard protocol that is similar to the one we use for infrarenal aortic aneurysms.

A multicentre study led by our institution, which is now in the publishing process, found that use of the BeGraft aortic for the treatment of infrarenal PAU produces excellent results with low complications.

How many patients do you see with a typical PAU and how often do you treat them with an endovascular approach?
The indications for treating PAUs are not yet well defined, so while we are currently not treating a lot of patients, we are still seeing quite a few. In terms of approach, I was previously very cautious about treating a patient with a small aortic ulcer or a local dissection by using an aortoiliac stent graft, because I thought it to be an overtreatment. However, with localised, minimally invasive surgery, it is just like putting a covered stent in the iliac arteries, but instead you put it in the aorta. I now feel much more comfortable offering endovascular therapy to patients that present with these findings.

Computed tomography angiogram (CTA) of a symptomatic PAU

What are your key messages for treating PAU patients with this endovascular approach?
My main message is that we are able to treat a disease of its extent with the right tool, which is appropriate for the pathology. We no longer overtreat just because we do not have the right tools.

In addition, there are many centres that have now decided to use this technique, which shows how useful it is, and it is interesting to note that different centres have developed different tactics and strategies in order to deal with or to treat these patients with the BeGraft aortic. I think that it is an excellent tool and technique for this indication, and I believe that the more we learn from our experience, the better we will be able to understand the pathology and the further we will be able to extend the treatment options available.

References

DISCLAIMER The usage of the BeGraft aortic is an off-label indication for the treatment of PAU.
Julie Ann Freischlag

From her initial exposure to the field of vascular surgery as an intern to becoming the first female president of the Society for Vascular Surgery in 2013, Julie Ann Freischlag speaks to Vascular News about her career so far. Following her recent appointment as president-elect of the American College of Surgeons for 2020–2021, Freischlag contemplates her goals for the presidency, hoping to take forward some positive developments that have emerged during the COVID-19 pandemic—such as the use of telehealth—and also to continue the work of her predecessors on promoting vascular workforce diversity. Looking to the future, Freischlag predicts that prevention of vascular disease will improve, but stresses that patient education is needed in order for this to be successful.

What led you to pursue a career in vascular surgery?

My initial exposure to the field was as an intern—my first two months were on vascular surgery and Wesley Moore had just become the new division head. The operations were exciting and the other faculty—Ron Busuttil, Wiley Barker, Herb Machleder, and Denny Baker—were so fun to operate with and the new procedures were exciting to do. Plus, those vascular patients became your patients for life, which I loved. I also enjoyed the three-dimensional reconstruction of the arteries, such as the femoral or carotid bifurcation.

Who have been your professional mentors and what have they taught you?

I have had a number of professional mentors: Jon Towne, who taught me how to lead with passion and focus on the patient; Bob Hye, who showed me how to be the very best person every single day; Wesley Moore, who demonstrated how to be the best vascular surgeon in all aspects; Ron Busuttil, who taught me how to be technically excellent; Mike Zinner, who instructed me how to lead in adversity; and Ed Miller, who demonstrated how to be an institutional leader.

How have you seen the vascular field change over the course of your career?

The excellent outcomes we now can achieve in patency rates and low mortality rates are amazing, plus the endovascular revolution! We also know from the Vascular Quality Initiative (VQI) and other outcomes assessment whether a procedure works for a certain patient.

When I began my career in vascular surgery, we were doing some of the procedures, such as distal bypasses, for the first time, and we did not know patency rates or the incidence of complications. We learned over time as well about the cardiac complications that could occur, and how to predict and also treat them.

How do you anticipate the field might change in the next decade, and what developments would you most like to see realised?

One of the things I anticipate is better prevention of disease. We have seen improvements due to a decline in smoking, but better exercise and diet, and treatment of high cholesterol and high blood pressure will also yield positive results.

In addition, as our vascular patients are living longer and better lives, I expect to see improved longevity of endovascular devices, so that patients can enjoy them without reintervention.

In the last year, which new research paper has caught your attention?

The OVER trial by Frank A Lederle et al, published in May 2019 in the New England Journal of Medicine, of course, showing that the anatomy really matters in predicting long-term outcomes of endovascular treatment for abdominal aortic aneurysm (AAA).

What are your current areas of research?

Currently, my research is focused on outcomes for thoracic outlet syndrome patients utilising surgery, physical therapy, and botox injections. Additional areas of research involve work with a racial equity taskforce on how to improve the diversity of our pipeline of learners, and to improve access to healthcare for those who are disadvantaged due to their socioeconomic status. Through work with this taskforce, I am also part of a team aiming to be sure that everyone is comfortable taking the COVID-19 vaccine.

Furthermore, I am working with Dave McIntosh on bystander training and we are giving grand rounds nationally on our programme.

Finally, I am looking at bony abnormalities in those patients with thoracic outlet syndrome and reporting on our series at Wake Forest Baptist Health.

What advice would you give to someone starting their career in vascular surgery?

My advice would be to enjoy it along the way and always put your patient first, to always tell the truth and be open and transparent, to take time along the way to enjoy your family and friends, and to be kind to everyone, as they will then be kind back to you.

What are the biggest challenges currently facing vascular surgery?

I think one of the biggest challenges facing vascular surgery at the moment is preventing vascular disease; if we do not prevent it, we will have too many patients who need treatment. We need to be able to perform fewer procedures, as the cost and complexity of these interventions—although interesting and challenging—are making our health system unaffordable. Educating our patients so that they can participate with us in preventing and treating their vascular disease is really important.

How well do you think institutions are doing in assisting more women into following a career in vascular surgery, and could this be improved?

The number of women going into vascular surgery is increasing. One of the reasons for this is that students and residents see women vascular surgeons now and know that they too can pursue that career. The issues of work–life balance will always be there, but this exists for both women and men.

We do need to improve on the calling out of both micro- and macro-aggressions, most of which are aimed at women and others who are not white male surgeons. This is getting better, as the new generation is much more diverse in their thinking.

We also need to teach leadership in medical school. We can all lead and we all need to lead—whether it is in your division, your team in the operating room, your research laboratory, or your group practice—we all can lead and make the experience for our patients and co-workers better. Women need to ask for and take
Current positions

- 2018–present: Dean, Wake Forest University School of Medicine, Winston-Salem, USA
- 2007–present: Chief executive officer, Wake Forest University Baptist Medical Center, Winston-Salem, USA
- 2020–2021: President-elect, American College of Surgeons

Education

- 1976: BS, University of Illinois, Urbana-Champaign, USA
- 1980: MD, Rush University, Chicago, USA

Postgraduate training and fellowship appointments

- 1980–1986: Resident in general surgery, UCLA Medical Center, Los Angeles, USA

Could you tell us about one of your most memorable cases?

One of my most memorable cases is when I operated on an infected aortic graft in Milwaukee when I was seven months pregnant. We took out the infected graft and then took a break for pizza before we did the axillobifemoral. I remember sitting on a stool during the procedure feeling so tired. The patient did well and left the hospital in two weeks.

What do you hope to achieve as president of the American College of Surgeons?

I hope to be able to continue the work of J Wayne Meredith in racial equity for our patients and to increase the number of diverse individuals who become surgeons. Presently, 30% of vascular surgeons are women and only 2.5% of vascular surgeons are African American.

Also, I hope to lead post-pandemic in a way that makes us keep the good things we learned from the situation, such as virtual meetings, telehealth visits—especially for postoperative patients—and flexibility in all aspects of the workplace. We need to better understand the disparities in healthcare access and outcomes in order for us to be much better healthcare providers for all in the future.

How do you like to spend your time outside of work?

I like to spend my free time swimming, walking, reading fiction and leadership books, doing crafts, travelling—when we were able to—and sending gifts to my four grandchildren.
SWEDEPAD unplanned interim analysis shows no difference in all-cause mortality for paclitaxel devices

An unplanned interim analysis of the registry-based SWEDEPAD clinical trial, in which patients with peripheral arterial disease received treatment with paclitaxel-coated (drug-coated balloons or drug-eluting stents) or uncoated endovascular devices, “did not show a difference between the groups in the incidence of death” during one to four years of follow-up. This conclusion was published by Mårten Falkenberg, Joakim Nordanstig (Gothenburg University, Gothenburg, Sweden) and colleagues in the New England Journal of Medicine (NEJM).

Falkenberg et al relay that data for the analysis was from the multicentre, randomised, open-label, registry-based SWEDEPAD (Swedish drug elution trial in peripheral arterial disease) clinical trial. At the time of their analysis, the authors detail, 2,289 patients had been randomly assigned to treatment with either drug-coated devices (1,149 patients) or treatment with uncoated devices (1,140). They state that paclitaxel was used as the coating agent for all the drug-coated devices.

Falkenberg et al detail that randomisation was stratified according to disease severity on the basis of whether patients had chronic limb-threatening ischaemia (1,480 patients) or intermittent claudication (809 patients), and that the single endpoint for this interim analysis was all-cause mortality.

The authors communicate in NEJM that no patients were lost in the mean 2.49-year follow-up period, during which 574 patients died, including 293 patients (25.5%) in the drug-coated device group and 281 patients (24.6%) in the uncoated device group (hazard ratio, 1.06; 95% confidence interval, 0.92–1.22).

At one year, Falkenberg and colleagues write that all-cause mortality was 10.2% (117 patients) in the drug-coated device group and 9.9% (113 patients) in the uncoated device group. During the entire follow-up period, they found that there was “no significant difference in the incidence of death between the treatment groups” among patients with chronic limb-threatening ischaemia (33.4% [240 patients] in the drug-coated device group and 33.1% [243 patients] in the uncoated device group) or among those with intermittent claudication (10.9% [44 patients] and 9.4% [38 patients], respectively).

In the discussion of their findings, the authors acknowledge that this interim analysis “was not a prespecified part of the trial protocol”. They respond to this limitation by noting a twofold rationale behind publishing these total mortality data ahead of completion of the trial: “First, we sought to reduce patients’ and physicians’ concerns regarding the safety of paclitaxel-coated devices, and, second, we considered the data to be important to support completion of ongoing trials investigating the efficacy of such devices in peripheral arterial disease.” They add that this analysis was recommended by an independent data and safety monitoring committee “in order to alleviate patients’ and physicians’ concerns” surrounding paclitaxel safety.

Falkenberg and colleagues recognise a number of other limitations to their unplanned interim analysis. For example, they identify the use of “low-dose” (rather than “high-dose”) paclitaxel-coated devices being “relatively common” in the trial as another limitation, which “may have influenced” their results.

At the end of their discussion, Falkenberg and colleagues stress that the SWEDEPAD trial was “not primarily intended for analysis of total mortality,” pointing out that the main purpose was “to determine whether drug-coating technology ultimately improves the lives of patients with symptomatic peripheral arterial disease by preventing amputation and improving health-related quality of life”.

Because this interim analysis “does not show a significantly higher incidence of death resulting from the use of paclitaxel-coated devices,” the authors conclude with their belief that “equipoise remains,” detailing that recruitment has been resumed.

The authors write that the trial is funded by grants from the Swedish Research Council, the Swedish Heart-Lung Foundation, and Region Västra Götaland. They also communicate that “all the companies that provide drug-coated balloons and drug-coated stents for patients in Sweden with peripheral arterial disease are supporting the trial by providing price discounts on their devices”.

FDA Perspective in NEJM highlights need for continued clinical studies on paclitaxel devices

Following the publication of the SWEDEPAD interim analysis, Andrew Farb, Misti Malone, and William H Maisel, representatives of the Center for Devices and Radiological Health, US Food and Drug Administration (FDA), have authored a perspective piece in NEJM.

“The results of the SWEDEPAD interim analysis provide important and reassuring information on PCDs [paclitaxel-coated devices] used to treat femoropopliteal disease,” say Farb et al. “Furthermore, recent analyses of additional data from nonrandomised studies have not identified an increased mortality risk associated with PCDs.”

However, they also add that these newer analyses, “though comforting, are limited by the duration of follow-up”.

“Because of the demonstrated short-term benefits of the devices and the limitations of the available data, the FDA believes that clinical studies of these devices should continue and should collect long-term mortality data. Similarly, the FDA now routinely reviews longer-term data for PCDs for which market authorisation is being sought when they are intended to treat patients with PAD, and the agency requests that trials capture information on adjunctive antithrombotic therapy and medications indicated for patients with atherosclerosis,” they conclude.

This analysis was recommended by an independent data and safety monitoring committee ‘in order to alleviate patients’ and physicians’ concerns’ surrounding paclitaxel safety.”

At one year: the rate of all-cause mortality

**Drug-coated device group**

- 10.2% [117 patients]

**Uncoated device group**

- 9.9% [113 patients]
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The Lutonix™ 018 DCB brings the performance of the Lutonix™ drug coating technology to an 018 platform. Lutonix™ 018 offers a comprehensive size matrix to treat femoropopliteal lesions without the need to exchange to an .035" wire.

Lutonix™ 018
Drug Coated Balloon PTA Catheter

Balloon Diameter (mm) | Balloon Length (mm) |
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Looking back on the paclitaxel “debacle” at the 2020 Vascular Interventional Advances annual meeting (VIVA; 6–8 November, online), Peter Schneider (University of California San Francisco, San Francisco, USA) detailed key learnings from the last year and a half, pointed to forthcoming data, and praised the combined and ongoing efforts of researchers, societies, and regulatory bodies.

Schneider began by stressing the potency of paclitaxel in the femoropopliteal segment. At 12 months, the four randomised controlled trials (RCTs) of paclitaxel drug-coated balloons (DCBs) and drug-eluting stents (DESs) versus percutaneous transluminal angioplasty (PTA) that are currently approved in the USA—ILLUMINATE, IN.PACT SFA, Zilver PTX, and LEVANT—show a “significant improvement” in patency with DCB/DES use compared to PTA, he noted. Speaking to Vascular News, Schneider noted that, since then, the Eluvia DES and the Ranger DCB (both Boston Scientific), have also shown “excellent” results and been approved by the US Food and Drug Administration (FDA).

In December 2018, a meta-analysis of summary-level data was published, “which we all know about,” remarked Schneider, that suggested an increased risk of death with paclitaxel use in the femoropopliteal segment at two and five years. Here Schneider was referencing the 2018 Journal of the American Heart Association (JAH A) paper by Konstantinos Katsanos (University of Patras, Patras, Greece) and colleagues.

Highlighting the instant and enduring impact of this publication, Schneider commented: “Overnight, the use of paclitaxel-delivering devices diminished substantially, which means that overnight the value of our field diminished substantially, because now it takes so many more repeat revascularisations in order to keep our patients whole and to keep these arteries open.”

The meta-analysis relied upon three RCTs—Zilver PTX, THUNDER, and IN.PACT SFA—that were followed up to four or five years and encompassed “a little over 800 patients,” Schneider stated. Delving into the characteristics of the trials included, he noted that they were all powered for one-year patency, not long-term mortality, and that small control groups were used, leading to “unstable estimates.”

Key learning
As the meta-analysis pointed to causality between paclitaxel and mortality, Schneider stressed that it was necessary to assess whether or not there was a dose response. In the meta-analysis, dose was calculated as dose multiplied by time. Supposing a continuous, linear, and increasing exposure to paclitaxel over time is “quite an assumption,” said Schneider, detailing that tissue paclitaxel in pre-clinical models decreased over six months to nearly non-detectable levels and that time is disproportionately available for studies with longer-term follow-up.

When the FDA looked at the impact of dose response on mortality, Schneider recalled that “they found none,” specifying that the FDA included the LEVANT II, Zilver PTX, ILLUMINATE, and IN.PACT IDE trials in their assessment. Similarly, there was no dose relationship found in either the IN.PACT investigational device exemption (IDE) and Japan trials, or in the VIVA/North American Science Associates (NAMS A) individual patient data project, Schneider added.

The presenter stated that, along with dose response, it was also crucial to assess whether there was a clustering of deaths, as this would suggest a biological mechanism.

In the FDA analysis, Schneider relayed, there was no clustering of deaths. He elaborated: “There was an increase in deaths in the patients that had paclitaxel, but we also noted, and with cause, questioning the availability of a biological mechanism”. This led the FDA to issue a letter on 7 August 2019, stating that there was “no clear evidence of a paclitaxel dose effect on mortality, and no identified pathophysiological mechanism for the late deaths”.

“We know that these trials were powered for one-year patency, so what about the five-year mortality?” Schneider wondered, stressing that many of the paclitaxel RCTs had a considerable number of patients lost to follow-up or who had withdrawn by this time point.

Through a “Herculean effort” by both the clinical sites and by the study sponsors, “a dramatic number” of these patients were identified, located, and their vital status ascertainment found, Schneider detailed. He noted that a five-year point estimate by the FDA developed a risk of 1.72, which after vital status ascertainment was 1.57, showing a decrease of 21%. The same happened in the IN.PACT IDE and Japan trials, he added, where the hazard ratio decreased from 1.63 to 1.39 after vital status follow-up.

The third key point that Schneider addressed was the inconsistency of the mortality signal. In the IN.PACT SFA and the LEVANT II trials that were performed in both the USA and the European Union (EU), there was a “significant difference” in how the patients in the USA versus how those in the EU fared, with no apparent difference in mortality outside the USA, Schneider explained. “Why would this agent be more dangerous in one geography than another?” he asked.

“DCB and PTA patients are treated differently,” Schneider observed, adding that the difference in treatment is greater in the USA than in other geographies. Furthermore, he noted that the IN.PACT IDE and Japan trials, which were performed across different geographies using the same device, not only reveal this difference, but also show that PTA patients were more likely to follow up, with the biggest difference observed in the USA. “This really suggests that there may have been a treatment bias involved,” Schneider opined.

“When you include studies conducted outside the USA—I LLUMINATE EU, IN.PACT Japan, LEVANT I, and Lutonix Japan, for example—along with studies conducted on the same devices inside the USA—I LLUMINATE RCT, IN.PACT SFA, LEVANT II, and Zilver PTX—you see a significant drop in the hazard ratio,” he revealed.

Looking ahead
Summarising, Schneider noted that while paclitaxel is consistently efficacious, the mortality signal is not consistent. “There is no dose response and no biological mechanism, and the signal is not apparent so far in real-world data,” he communicated.

In addition, he told the VIVA audience that the signal is not consistent in the RCTs. The signal diminished with vital status ascertainment, and also when patients from outside the USA—where the signal was primarily observed—were included, he précised. “There is a possibility of treatment bias associated with trial design or practice patterns, which may help explain inconsistency of signal,” Schneider speculated.

The paclitaxel debacle is “crystallising” thanks to new data and teamwork, VIVA audience hears
Eighteen-year results provide insight into changing patterns of thoracic aortic disease

Based on data collected from 2002–2020, Dominic Howard (Oxford University Hospitals NHS Trust, Oxford, UK) spoke at the 2020 UK Vascular Societies’ Annual Scientific Meeting (VS ASM; 24–27 November 2020) on changing patterns of thoracic aortic disease. He stressed the significance of uncontrolled hypertension as a treatable risk factor for acute aortic dissection, predicted that dissections will increase “significantly” in the elderly over the next 30 years, and noted that further research is required to understand why women with aortic disease have poorer outcomes than men.

“Currently, there are very few data on risk factors, incidence, and outcomes of thoracic aortic disease,” Howard began, detailing that existing studies are mainly retrospective, restricted to certain cohorts, limited by age and gender, and have excluded out-of-hospital events and deaths, resulting in “potentially inaccurate” data. Howard and colleagues set up the Oxford Vascular study (OxVasc) in 2002. He informed the VS ASM audience that, over the last 18 years, the team has analysed a population of around 90,000 patients.

“The aim of OxVasc has always been to provide the most accurate data on incidence, risk factors, and outcomes for all vascular events,” the presenter explained, adding that the team have also extrapolated their incidence rates on to the UK population. Howard relayed that the team published 10-year results on acute dissection back in 2014, which showed that, firstly “a prospective, population-based methodology is far superior to HES [Hospital Episode Statistics] coding”. In fact, he stated that if HES coding is used to detect acute dissections, “you will miss approximately one-third of cases”.

The 10-year results also revealed that, overall, ruptured aneurysms—both thoracoabdominal and abdominal—have a higher incidence per 100,000 people than acute dissection, and that both of these conditions are more common in men than women. The team also observed that the age at index event for acute dissection is 72 years, compared to 79 years for an index ruptured aneurysm.

Howard mentioned that the 10-year results revealed a gender difference that is more significant with acute aneurysmal disease, with three-quarters of these events being in men, whereas for acute dissection, 60% are in men and 40% are in women.

Furthermore, Howard shared the finding that the first event in women for acute aortic dissection tends to be a decade later than the first even for men, whereas this is not the case for ruptured aneurysms, where both men and women can have their first event at a similar age.

Ten-year results confirmed that smoking status is the “driving” risk factor for ruptured aneurysms, Howard relayed, adding that current smokers tend to have their index event “approximately a decade younger than non-smokers,” whereas he stated that the main risk factor for acute aortic dissection is uncontrolled hypertension.

Looking at overall annual mortality for both acute aortic dissection and ruptured aneurysms, their results confirmed that these two conditions “have some of the worst outcomes of all cardiovascular events”.

Howard detailed that the team can now present the 18-year results of the OxVasc study. “First of all, we can show that ruptured abdominal aortic aneurysms continue to have the highest incidence of all aortic conditions, and are more common in men than women,” he revealed.

In addition, the team found that abdominal aneurysms are of a lower incidence and are as common in women as they are in men. Both type A and type B dissection increase in incidence with age, and both are slightly more common in men than women, “but this is not as marked as for aneurysmal disease”.

Considering the time trends in incidence over the last 18 years, Howard detailed that the team have confirmed ruptured aneurysms are slowly declining in incidence, which he said is most probably due to smoking cessation. He stated that acute aortic dissection is relatively stable in incidence, which is likely due to “ongoing, poorly-controlled” hypertension in the background population.

Going into more detail regarding ruptured aneurysm incidence, Howard pointed out that for ruptured abdominal aortic aneurysms, the incidence has slowly declined over the last 18 years, while for thoracoabdominal aneurysms the incidence has remained quite static, “but it is lower”.

Regarding type A and type B dissection, Howard reported that these have both slowly decreased in incidence. Based on UK population predictors from the Office of National Statistics (ONS), Howard detailed that by 2050, 40% of the UK population will be aged over 65. “Interestingly,” he stated, “since 1987, the number of people living over 90 has increased from around 200,000 to 600,000 currently”.

Therefore, when the OxVasc incidence rates are mapped by age for acute aortic dissection on to the UK population predictions, just under 4,000 are occurring per year currently, with the majority in men and women aged 65–75. However, by 2040, Howard stated that this number will increase to just under 6,000.

Primary care data on blood pressure elucidate role in aortic dissection

Howard explained that both ruptured aneurysm patients and acute dissection patients have a “similar profile” of risk factors. However, he noted that smoking status is more associated with aneurysmal disease. In particular, current smoking status is far more associated with ruptured aneurysms than it is with acute dissection.

The team wanted to investigate the relationship between blood pressure and aortic dissection in more detail, and so they went through the primary care data and collected all blood pressure measurements 15 years prior to index aortic dissection event. Howard reported that they managed to achieve this for 96% of patients. During the 15-year period, just under 50% had regular blood pressures of greater than 180 systolic, Howard reported.

In addition, they wanted to know how uncontrolled hypertension was associated with poor outcomes, and so looked at those patients with type A dissection and compared those who died immediately, at home, versus those who survived until after hospital admission. “We found that the age was similar in these two groups, but, interestingly, of those patients who died immediately, at home, far more were female, and also the blood pressure five years prior to the event was worse in those who had immediate death versus those who survived”.

Selected intervention “may be warranted” in type B dissection

Looking at five-year outcome data for mortality, the team observed that type A dissection has a “very high” up front mortality, “partly because over 50% of them die at home, before getting to hospital”. Type B has a lower 30-day mortality of around 15–20%. However, over a five-year period, the mortality increases for type B dissection due to ongoing cardiovascular events and aortic complications.

Regarding type B dissections in those who had early interventions versus those treated with medical therapy, although those who had early intervention had a higher 30-day and one-year mortality, at five years, this was potentially lower than those who had medical therapy. However, Howard noted that this analysis is biased by intervention selection, as often those who are intervened on have had a complicated dissection compared to those who are treated with medical therapy having uncomplicated dissections. Nevertheless, it does suggest that early intervention “may be warranted in selected patients”.

In terms of 10-year outcomes, Howard showed that ruptured aneurysms, both abdominal and thoracoabdominal, have a “very high” overall mortality, as does type A dissection, whereas type B has a gradual increase in mortality over a 10-year period.

Finally, when the team went on to look at whether there were any differences in outcome for women versus men, they found that for acute aortic dissection, immediate death, 30-day mortality, and five-year mortality were all “significantly higher” in women, and this is adjusted for age.

Summarising, Howard highlighted that uncontrolled hypertension is the “most significant, treatable” risk factor for acute aortic dissection.

In addition, he noted that type B dissection has a “significant” mortality at five and 10 years, and it is possible that selected intervention, even in those with uncomplicated dissection, may be necessary.

While observing that acute aneurysmal cases are declining, likely as a result of smoking cessation, the incidence of acute aortic dissection remains stable, probably as a result of uncontrolled hypertension in the background population. Due to the population ageing, dissections will increase “significantly” in the elderly over the next 30 years.”

“Due to the population ageing, dissections will increase significantly in the elderly over the next 30 years.”

Dominic Howard
Total endovascular aortic arch treatment shows promise in dissections, but secondary interventions remain the “Achilles’ heel”

Speaking at the Virtual Aortic Surgery How to Do It (HTDI) Highlights conference (17–18 December), Stéphan Haulon (Hôpital Marie Lannelongue, GHPSJ, Paris, France) discussed total endovascular treatment of the aortic arch in chronic dissections. Detailing global experience using three-vessel inner branch stent grafts for this procedure, Haulon highlighted good technical success and low morbidity and mortality rates. However, he also stressed that the high number of secondary procedures required remains the “Achilles’ heel” of the technique, and that larger experiences and longer follow-up are mandated.

HAULON NOTED THAT THE “evolution” of arch branch device design began a long time ago with fenestrated endografts, before surgeons moved towards using the single branch and subsequently the inner branched design. Honing in on this latest iteration, Haulon informed viewers: “The nice thing about [the inner branched] design is that you have a tapered portion in the middle where the branches are positioned, so you always have flow to the supra-aortic trunk.”

Focus on patients with chronic dissection sees drop in stroke rate
Haulon communicated that he and colleagues started using arch branch devices over 10 years ago to treat atherosclerotic aneurysms, noting that their initial experience was not good, with a 15% stroke rate. However, he added that better results have followed a switch from treating atherosclerotic aneurysms to treating chronic dissections—patients that had a prior type A repair who required a follow-up procedure due to false lumen evolution in the arch and in the descending thoracic aorta, he explained. “The main reason for getting a good outcome,” Haulon stated, “is that we now had a perfect landing zone, which in many of those patients is a long, proximal tube,” and no (or less) atherosclerotic plaque on the aortic wall. However, he added that some of those patients will have either a short or a kinked tube, meaning they cannot be treated.

In the specific anatomy of a chronic dissection of the arch, Haulon detailed that most patients are “perfect” candidates for the new arch branch device design—the three-branch endograft with a retrograde branch perfusing the left subclavian artery. Haulon then considered the outcomes of patients with a chronic dissection who have been treated with inner branched arch endografts following ascending open repair. In a retrospective international multicentre study published in the Annals of Surgery in 2019, Dorian Verscheure (Hôpital Marie Lannelongue, Paris, France), Haulon and colleagues looked at 70 patients across 13 vascular units in nine countries who obtained “unmatched” results—a combined in-hospital mortality and stroke rate of 4% and a “very high” technical success rate of 97%. “It was really interesting to see that, compared to the initial 15% stroke rate, we went down to 4% by focusing on those patients with chronic dissection,” he remarked.

Number of secondary procedures represents “Achilles’ heel”
Despite these improved results, however, Haulon stressed that there is an “Achilles’ heel” to this procedure—the number of secondary interventions required. He noted that most of these are due to persistent flow in the false lumen, requiring either coil embolisation in the false lumen or an extra-anatomic bypass of the supra-aortic trunk. Here Haulon referenced the work of Tilo Köhlbel (University Hospital Eppendorf, Hamburg, Germany), who advises getting a complete exclusion by implanting a candy-plug in the distal false lumen. Finally, Haulon referenced a presentation given at this year’s SVS ONLINE meeting (20 June–2 July) given by Emanual R Tenorio (Mayo Clinic, Rochester, USA) on a multicentre global early feasibility study that gathered all the three-branched data, including mainly patients with a dissection. He noted the technical success rate of 100%, a combined mortality and stroke rate of 8%, and a 5% 30-day mortality, but again, a high secondary procedure rate—around 60%.

Concluding, Haulon stressed that this multicentre global experience demonstrates the technical feasibility and safety of total endovascular aortic arch repair for aneurysms and chronic dissections using three-vessel inner branch stent grafts. Mortality and stroke rates compare favourably to reported outcomes of total open surgical arch replacement, he summarised, particularly among higher risk patients who had prior median sternotomies and ascending aortic repairs. However, Haulon reiterated that a limitation remains the high rate of secondary interventions, and—while these are planned in most cases—stressed that “this is something that needs to be shared with the patient”.

Pre-emptive embolisation of aneurysm sac side branches prevents post-EVAR type II endoleak, study finds

According to Daniela Branzan (University Hospital Leipzig, Leipzig, Germany) and colleagues, pre-emptive embolisation of aneurysm sac side branches for patients with abdominal aortic aneurysm (AAA) is “safe and effective” in preventing type II endoleak after endovascular aneurysm repair (EVAR) and results in aneurysm sac shrinkage.

W riting in the Journal of Vascular Surgery (JVS), Branzan et al write that type II endoleak is the most common endoleak after EVAR, yet its optimal management is hotly debated. They note that preliminary selective embolisation of aneurysm sac side branches has been adopted to prevent type II endoleak, and so the investigators’ goal with this study was to determine the rate of type II endoleak and diameter decrease of AAA after EVAR following pre-emptive embolisation of aneurysm sac side branches.

The authors detail that, between September 2014 and September 2019, 139 patients with AAA underwent percutaneous aneurysm sac side branch embolisation before EVAR. Imaging follow-up was performed at one and six months, and yearly thereafter. They state that endpoints included freedom from type II endoleak, AAA sac shrinkage, type II endoleak-related reinterventions, and all-cause mortality. After completion of embolisation, the authors report in JVS that 76.4% of initially patent aneurysm sac side branches were occluded, with no major procedure-related complications.

They note that follow-up imaging showed type II endoleak in seven (5%) of patients and that an increase of the aneurysm sac was seen in six of these patients. They also report that six type II endoleak-related reinterventions were performed during follow-up. Bransen et al add that the majority of patients (n=91, 86.7%) exhibited aneurysm sac shrinkage and that the mean diameter reduction was 9.2±7.7mm (p<0.001) in all patients with follow-up. Finally, they relay that one aneurysm-related death occurred within 30 days after EVAR.
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Patient reassurance and education needed to address drop in AAA surveillance engagement during pandemic

In a survey conducted by St George’s Vascular Institute (London, UK) on the willingness of patients in South London to attend abdominal aortic aneurysm (AAA) surveillance during the COVID-19 pandemic, just under 60% of patients said they would attend a scan in July, compared to a pre-COVID attendance rate of around 90%.

The research team cite fear of catching the virus and public transport concerns as key factors in patients’ reluctance. At this year’s UK Vascular Societies’ Annual Scientific Meeting (VS ASM 2020; 24–27 November, virtual), Will Selway, a trainee at the centre, outlined key findings from the study and considered ways to encourage attendance going forward.

Selway noted that the UK National Abdominal Aortic Aneurysm Screening Programme (NAASP) was suspended in March in line with the national lockdown. At the time, the survey was conducted in May, there were 667 men with small- to medium-sized aneurysms (3–5.4cm) under surveillance in South London, he reported, detailing that 271 of these men had had their scans postponed due to the lockdown, and that the remaining 354 had either been seen previously or were due scans later in the year after the initial lockdown was planned to end.

The St George’s team contacted 200 of the men from the postponed surveillance group and asked them five questions about attending surveillance scanning. Selway mentioned that the team had access to basic comorbidity information, which allowed them to produce a stratified risk score for COVID-19 infection.

Infection fears reduce likelihood of surveillance attendance

In answer to the question, “If you were invited for your surveillance appointment in July, how likely are you to attend?” 59% of the men confirmed that they would attend. Selway remarked that this represents “quite a drop” from the pre-COVID-19 89.8% level of attendance in South London. He reported that the team did not find any significant difference when they took into consideration aneurysm size.

The second question the team asked regarded patients’ main health concerns. When they reviewed the results using a stratified risk score, they found that 25.5% of patients across the risk categories were most concerned about their aneurysm, while 42.5% felt that catching COVID-19 was their main concern. When they looked at this again by aneurysm size, 45% in the small aneurysm cohort were most concerned about catching COVID-19, whereas in the medium-sized aneurysm cohort, there was equal concern of 38.2% between catching COVID-19 and their aneurysm.

In addition, Selway reported that only 20.6% of these patients received a letter from their GP advising them to shield, which would imply that they are in a high-risk group. However, the team’s risk scoring suggested that 74% of the men were in the high-risk group and therefore probably should have received advice to shield from their GP.

Regarding specific concerns about actually attending their screening appointment, the St George’s team found that 31.7% of the men were most concerned about having to use public transport, while 22.6% were concerned with having to wait in open waiting areas.

Finally, in terms of how far patients would be willing to travel if their local surveillance centre was not open, over half the men (56%) felt that they would only be willing to travel between one and three miles for their scan.

Concluding, Selway reiterated that there was 90% attendance before COVID-19 for surveillance in South London, and at the time their report was produced in May, about 60% of patients said they would attend surveillance. The presenter considered possible implications: “If this is mirrored in the uptake of initial screening inviations, then we are likely to see a drop there, and the worry is that if there is reduced engagement in both screening and surveillance scans, we may end up seeing an increase in the presentation of ruptured aneurysms and aneurysm-related mortality.”

“I think, going forward, it is important to reassess patients’ perceptions of risk as we learn more about managing and preventing COVID-19 infection,” he concluded.

Education and trust essential as knowledge of COVID-19 increases

Chair Richard Gibbs (Imperial College Healthcare NHS Trust, London, UK) remarked that the results are “quite depressing,” and asked what could be done to convince patients that “they are more at risk of their aneurysm rupturing than they are of dying of COVID-19”.

Selway responded: “I think it is partly about gaining their trust that it is safe to come for the scan,” he summarised that patient education was an important aspect of care, adding that aneurysms should be prioritised in a patient’s health concerns.

On the same topic, an audience member asked if Selway believes the risks that are posed to patients about COVID-19 have been exaggerated, and whether this has impacted attendance level. Selway remarked that early on the virus was an “unknown phenomenon” and that looking back there may well have been an exaggeration in terms of risk, and this likely did affect attendance.

Now that there is a better understanding and vaccinations are on the way, he stressed that reassessing patient perceptions was key to increasing their engagement.

One audience member was interested to know if the team had any data on whether there are differences in attendance depending on where the scans are taking place.

In the absence of hard data, the presenter speculated that so far as transport were concerned, in the more rural areas of the catchment, patients would be more likely to have a private vehicle, whereas in the city there is more likely to be a reliance on public transport. He also thought that if a patient is told to go to a large university teaching hospital that is looking after a lot of COVID-19 patients then this would likely deter them from going to the hospital. Conversely, if the patient is asked to go to much smaller facility with a scanner then, “that is more likely to be appealing”. He echoed that currently, however, the team does not have these data points available.

Study of AAA repair patients suggests screening guidelines may be inadequate

A retrospective study analysing approximately 55,000 patients undergoing abdominal aortic aneurysm (AAA) repair suggests current screening guidelines may be inadequate in detecting a significant number of new cases. The study patients were enrolled in the Vascular Quality Initiative between years 2003 and 2019.

The study was spearheaded by Jeffrey E. Index (Montefiore Einstein Center for Heart and Vascular Care, New York, USA) and results were published in the December 2020 edition of the Journal of Vascular Surgery (JVS).

Ruptured AAAs were responsible for close to 10,000 deaths in 2017 and represent the fifteenth leading cause of death in the USA. Screening guidelines derived from the 2005 US Preventive Services Task Force (USPTF) recommendations involve a one-time abdominal ultrasound examination only for men aged 65–75 with a history of smoking.

An update published in December 2019 added selective screening only for men aged 65–75 without a history of smoking. In 2018, the Society for Vascular Surgery (SVS) suggested including women aged 65–75 with a history of smoking. Additionally, the SVS expanded its criteria to include: first-degree relatives of those with an AAA, and anyone older than 75 with a history of smoking and who is fit for repair.

Amongst those cases, the percentage of patients that would have been captured via screening depended on the guidelines used—USPTF: 32% EVAR, 33% open; SVS: 38% EVAR, 45% open; expanded SVS: 72% EVAR, 66% open.

Thus, even when using the most liberal guidelines, 27% of EVAR and 33% of open cases would not have met any screening criteria.
First-in-human study finds novel laser technique “safe and effective” for embedded filter removal

The excimer laser sheath technique is safe and effective for removing embedded inferior vena cava (IVC) filters refractory to high-force retrieval, the investigators of a first-in-human escalation trial conclude in the Journal of the American Heart Association (JAHA).

“This technique may allow cessation of filter-related anticoagulation and can be used to prevent and alleviate filter-related morbidity,” they write.

THIS IS THE LARGEST STUDY TO DATE

supporting a new indication for endovascular laser use to remove a variety of embedded IVC filters, regardless of implantation length, according to lead author William T Kuo (Stanford University School of Medicine, Stanford, USA) and colleagues.

Over an 8.5-year period, 500 patients were prospectively enrolled into the study: 225 men and 275 women (mean age, 49 years; range, 15–90 years). Indications for retrieval included symptomatic acute inferior vena cava thrombosis, chronic inferior vena cava occlusion, and/or pain from filter penetration. Retrieval was also offered to prevent risks from prolonged implantation and potentially to eliminate the need for lifelong anticoagulation. In total, there were 140 physically symptomatic patients (28%; 140 of 500) with filter-related morbidity, 360 physically asymptomatic patients with filter-related anxiety (72%; 360 of 500), and 78 patients (16%; 78 of 500) receiving filter-related anticoagulation with no underlying thrombophilia.

After retrieval failed using standard retrieval force (6–7lb via digital gauge), treatment escalation was initiated by placing a laser sheath (Spectranetics) connected to a 308-nm XeCl excimer laser generator (CVX-300, Spectranetics), to attempt fibrotic tissue ablation. “We hypothesised that the laser-assisted technique would allow retrieval of more than 95% of embedded filters with less than 5% risk of major complications and with lower force,” Kuo et al put in their abstract.

Laser-assisted retrieval was successful in 99.4% (497 of 500; 95% CI, 98.3–99.9%). This was significantly higher than the 95% hypothesised by Kuo et al ahead of the study’s initiation (p<0.0001). Three cases that failed retrieval did so because of bulky calcified thrombus (refractory to thrombectomy) within cylindrical-shaped filter components, creating a volume that was too large to be captured within the bore of the existing laser sheath apparatus, the authors explain.

The mean filter dwell time was 1,528 days (4.2 years; range, 37–10,047 days [>27.5 years]), and the median dwell time was 569 days (interquartile range, 260–2,348 days). Successful filter retrieval alleviated filter-related morbidity in 98.5% of cases (138 of 140; 95% CI, 96.5–100%) and allowed cessation of anticoagulation in 98.7% of cases (77 of 78; 95% CI, 93.1–100%). Furthermore, the major complication rate was low: 2% (in 10 of 500 patients; 95% CI, 1.3–3.6%), with only 0.6% complications from laser. This is significantly less than the 5% threshold (p<0.0005). All complications were successfully treated with either medical management and/or percutaneous endovascular therapy without the need for open surgery.

Discussing the ten complications observed over the study period, Kuo et al say: “As a specialised centre receiving an IVC filter were also more likely to have evidence of right heart dysfunction on computed tomography pulmonary angiogram (CTPA) (61/359 [17%], p<0.001) and echocardiogram (26/144 [18.1%], p=0.003).

Finally, they note that, compared to patients without an IVC filter, the 30-day VTE recurrence rate was higher (4.7% vs. 11%) in patients with IVC filters (10/188 [5.3%], p=0.023).

Lun and colleagues acknowledge several limitations to the study, including its single-centre nature and their restricted data pool, comprising only PERT patients in Massachusetts General Hospital. They also recognise that, where IVC filter patients suffered higher rates of recurrent bleeding and VTE recurrence within the first 30 days’ post-PERT, “this may have been influenced by confounding by indication” and therefore “should be interpreted with caution.”

The authors detail that confounding factors included that patients who received an IVC filter were more likely to be from higher risk groups predisposed to recurrent bleeding and VTE regardless of IVC filter placement. In a single session may decrease overall expense by eliminating the high cost of multiple failed procedures routinely observed before successful laser retrieval.

The laser sheath apparatus is currently not FDA-approved for IVC filter removal; this is an experimental protocol—albeit one that has now been validated in a large cohort of patients.

VTE-related factors and elevated bleeding risk associated with IVC filter placement among PERT patients, study suggests

In a recent study, factors related with venous thromboembolism (VTE) severity—including pulmonary embolism response team (PERT) referral from the intensive care unit (ICU) and right ventricular dysfunction—and elevated bleeding risk were associated with inferior vena cava (IVC) filter placement among PERT patients.

Elizabeth Wen Yan Lun (Massachusetts General Hospital, Boston, USA) and colleagues write in the Journal of Vascular Surgery: Venous and Lymphatic Disorders that, while the use of IVC filters is “controversial,” the procedure is “widely performed for secondary prophylaxis patients with severe pulmonary embolism, including those treated by a pulmonary embolism response team”.

In the present study, the investigators collected data on all Massachusetts General Hospital patients who had a PERT activation from 1 October 2012 to 29 January 2019. They gathered information regarding demographics, medical history, pulmonary embolism (PE) characteristics, and treatment at the time of PERT activation, and prospectively for one year thereafter. They performed univariate and multivariable regression analyses to determine factors associated with IVC filter placement.

In this single-centre retrospective review of prospectively collected data, Lun et al identified 834 patients, of whom 91 (10.9%) had an IVC filter placed in the first seven days after PERT activation. They state that the majority of patients receiving an IVC filter were male (55/91 [60.4%], p=0.096) with a mean age of 65±15 years.

The authors detail that patients who received an IVC filter were less likely to have had a PERT referral from the emergency department (41/544 [7.5%], p=0.001) and more likely to have been referred from the ICU (24/107 [22.4%], p=0.001) compared to a floor referral. Lun et al add that patients who presented with syncope (15/16 [94.4%], p=0.04), a history of recent trauma (12/41 [29.3%], p=0.001), intracranial haemorrhage (11/39 [28.2%], p=0.002), a recent surgery or invasive procedure (30/188 [16%], p=0.012), recent surgery (29/160 [18.1%], p=0.001), and recent hospitalisation (38/250 [15.2%], p=0.009) were more likely to have an IVC filter placed.

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DIVERSITY trial finds adjusted dabigatran dosing algorithm appropriate for treatment of VTE in children

In a recent randomised controlled trial, an age-adjusted, weight-adjusted dabigatran dosing algorithm was found to be appropriate in children under 18 years old with venous thromboembolism (VTE). Writing in *Lancet: Haematology*, Jacqueline Halton (University of Ottawa, Ottawa, Canada) and colleagues report that dabigatran was non-inferior to standard of care in terms of efficacy—with similar pharmacokinetic–pharmacodynamic relationships as those seen in adults—and suggest that it might be a suitable alternative to the standard of care.

The authors detail that dabigatran etexilate is “a direct oral anticoagulant with potential to overcome the limitations of standard of care in children with VTE”. In this clinical trial, they aimed to study the appropriateness of a paediatric dabigatran dosing algorithm, and the efficacy and safety of dabigatran dosed according to that algorithm versus standard of care in treating children with VTE.

Halton *et al* describe the DIVERSITY (Dabigatran etexilate for the treatment of acute venous thromboembolism in children) study as a randomised, controlled, open-label, parallel-group, phase 2b/3 non-inferiority trial conducted in 65 centres across 26 countries. They write that the standard of care (low-molecular-weight heparins, unfractionated heparin, vitamin K antagonists, or fondaparinux) was compared with a paediatric oral dabigatran dosing regimen (an age-adjusted and weight-adjusted nomogram) in children younger than 18 years with acute VTE initially treated (5–21 days) with parental anticoagulation, requiring anticoagulation therapy for at least three months.

Patients were randomised 1:2 (standard of care:dabigatran) and stratified by age (12 to <18 years, 2 to <12 years, and birth to <2 years) via interactive response technology, the authors relay. Writing in *Lancet: Haematology*, Halton *et al* communicate that 328 children were enrolled in the study between 18 February 2014 and 14 November 2019, and that the median exposure to standard of care was 85 days (interquartile range [IQR] 80–90) and to dabigatran was 84.5 days (78–89). They report that similar proportions of children treated with standard of care and dabigatran met the composite efficacy endpoint (38 [42%] of 90 vs. 81 [46%] of 177; Mantel-Haenszel weighted difference, -0.04; 90% confidence interval -0.14–0.07; p=0.0001 for non-inferiority).

On-treatment bleeding events were recorded in 22 (24%) of 90 children receiving standard of care and 38 (22%) of 176 children receiving dabigatran (hazard ratio [HR] 1.15, 95% CI 0.68–1.94; p=0.61); major bleeding events were similar between the groups (two [2%] of 90 and four [2%] of 176; HR 0.94, 95% CI 0.17–5.16; p=0.95).

In addition, the authors mention that pharmacokinetic–pharmacodynamic curves showed a linear relationship between total dabigatran plasma concentration and diluted thrombin time and ecarin clotting time, and a non-linear relationship with activated partial thromboplastin time; curves were similar to those for adults. Finally, they relay that serious adverse events were reported for 18 (20%) of 90 children receiving standard of care and 22 (13%) of 176 children receiving dabigatran.

The most common severe adverse events were vascular disorders (standard of care three [3%] of 90, dabigatran two [1%] of 176), and gastrointestinal disorders (standard of care two [2%] of 90 and dabigatran five [3%] of 176).

One on-treatment death occurred in the standard to care group (retropertioneal bleeding, not considered treatment related by the study investigators). Considering the value of this study, the authors remark that DIVERSITY, “provides level II evidence that the efficacy and safety, and pharmacokinetic–pharmacodynamic relationships, of dabigatran are similar to those reported in randomised clinical trials evaluating dabigatran in adults with acute VTE”. The authors relay.

### Monitoring interface pressure “essential” during compression therapy, study suggests

In a study of interface pressure changes under compression bandages, Junjie Ning, Fedor Lurie (both Jobst Vascular Institute, Toledo, USA) and colleagues found that while pressure decreased over time under all studied bandages, the temporal pattern of pressure change varied among dressings. The authors conclude in the *Journal of Vascular Surgery: Venous and Lymphatic Disorders* that monitoring interface pressure is “essential” to maintain a desirable interface pressure during compression therapy.

Ning and colleagues detail that compression therapy is widely applied in the prevention and treatment of chronic venous disease. However, they note that its effectiveness “highly depends on the interface pressure,” which is often evaluated in the form of interface pressure at the ankle. “The consensus is that applying and maintaining a desirable interface pressure during treatment is an important goal of compression therapy,” the authors write. Pressure loss under compression bandages is a “well-known phenomenon,” Ning *et al* state, but they stress that the current standard of care does not include interface pressure measuring, monitoring, and adjusting of bandages if pressure drops.

Ning and colleagues write that this was a prospective, single-centre, open-label randomised trial, the aim of which was to investigate the change in pressure over time under three different compression bandages, and to compare the temporal patterns of pressure change between them.

They investigated four-hour change of interface pressure in 10 volunteers with no venous disease or leg swelling. In 20 patients with venous ulcers, the changes in the interface pressure was measured after four hours, one day, and seven days of wearing bandages. Ning *et al* detail that the three tested bandages were Smart Sleeve compression system (SSB; Carolon), Coban 2 (C2; 3M), and Profore Lite (PL; Smith & Nephew). The investigators measured pressure using PicoPress (Microlab) and Juzi Pressure Monitor (Juze).

The authors report that the mean pressure loss during the first four hours in the volunteers under SSB, C2, and PL were 4.5mmHg, 3.7mmHg, and 6.6mmHg, respectively. In addition, they found that there was no significant difference in pressure loss between the three bandages, whether in the supine (p=0.59) or standing position (p=0.47).

In patients with venous ulcers, pressure decreased gradually over seven days under C2. However, for SSB and PL, interface pressure maintained relatively stable during the first day but decreased significantly afterwards. At the seven-day time point, the mean pressure loss was 4.7mmHg (SSB), 7.7mmHg (PL), and 8.6mmHg (C2; p=0.017). Only SSB maintained a desirable mean pressure of higher than 30mmHg on the seventh day in venous ulcer patients.

In the discussion of their findings, the authors acknowledge two limitations of the present study. One of these limitations is that only four time points were selected, “which makes the analysis of temporal patterns impracticable,” they note, adding that this occurred because data from venous ulcer patients was collected during routine clinical visits, and it was impractical to ask patients to visit the clinic every day. They recognise that small sample size is also a limitation of the current study. However, they hope that this study, “might set the floor for larger and more rigorous studies with longer follow-up that investigate the clinical outcomes based on monitored interface pressure”.

The key take-home message from the study, Ning *et al* stress, is that different compression bandages loose pressure at different time periods. “Some bandages may need an adjustment after 24 hours of wearing, while other bandages loose pressure gradually and do not have a specific time point for adjustment,” they explain. For this reason, they highlight the importance of monitoring interface pressure in order to maintain a desirable interface pressure.
Clinical News

Centerline Biomedical launches MOTION study of IOPS technology

Centerline Biomedical recently announced completion of the first surgical case in the MOTION clinical study of the company’s intraoperative positioning system (IOPS) surgical navigation platform. The technology has been cleared by the US Food and Drug Administration (FDA) and is already being deployed in a controlled launch at Cleveland Clinic (Cleveland, USA) and other institutions in the USA. The MOTION study will be used to support the company’s submission for market clearance in Europe and other international markets.

First clinically deployed overseas in 2019, and with many cases completed in the USA in 2020, IOPS is used during endovascular procedures and allows navigation and placement of catheters and guidewires with reduced dependence on X-ray fluoroscopy, to which it serves as an adjunct, providing high-definition 3D colour image guidance using electromagnetic tracking much like a miniaturised form of GPS.

The primary objective of the MOTION study is to formally clinically evaluate the effectiveness and safety of the technology in providing accurate navigation during endovascular aneurysm repair (EVAR) procedures. The study will consist of 30 total cases divided among Cleveland Clinic and UNC Medical Center (Chapel Hill, USA).

This first case was performed at Cleveland Clinic’s Miller Family Heart, Vascular & Thoracic Institute by the principal investigator Francis Caputo. “This technology provides a promising future in endovascular aortic interventions. It not only provides accuracy as the aorta and its branches are navigated, but most importantly has the potential to reduce harmful radiation exposure to both surgeons and patients,” he commented.

The launch of this study is the latest in a series of significant milestones for the start-up, including deployment of IOPS at five leading US hospital systems. Company CEO Philip D Rackliffe noted that these achievements came despite challenges across the world—“it is one thing to have interest in a compelling new technology under normal circumstances, but it is entirely new to demonstrate success and sales in the midst of a pandemic,” he said.

“The demand for IOPS is grounded in the need for an endovascular surgical system. Company CEO Philip D Rackliffe commented, “The MOTION study will be used to support the company’s submission for market clearance in Europe and other international markets.”

First patient enrolled in Veryan Medical’s MIMICS-3 USA study

Veryan Medical recently announced that the first patient has been enrolled in the MIMICS-3 USA study by John H Rundback at NJ Endovascular & Aneurysm Prevention (Clifton, USA).

Nick Yeo, Veryan’s CEO commented, “The MIMICS-3 USA registry will grow our clinical database on BioMimics 3D use to more than 1,750 patients and will improve the opportunity for physicians across the world to have access to safety and effectiveness data on the BioMimics 3D vascular stent system, including those from a pivotal study with three-year follow-up.”

Rundback stated, “We have been invited to be involved in this study based upon the impressive clinical data for BioMimics 3D, and the unique helical configuration which creates a swirling flow pattern that promotes arterial healing after intervention. In addition, the truly biometric design addresses the unique physical challenges and mechanical stresses inherent in the femoropopliteal arteries. We look forward to continuing to collaborate with the Veryan team as we enrol patients to further enhance the real-world data on the value of the BioMimics 3D stent technology.”

The MIMICS-3 USA study will evaluate safety, effectiveness, and device performance of the BioMimics 3D stent within a real-world clinical population of patients undergoing femoropopliteal intervention. The study will enrol 500 patients from 40 sites within a two-year recruitment period and the three coordinating principal investigators are interventional cardiologist Sahil Parikh (Columbia University Medical Center, Columbia, USA), vascular surgeon Miguel Montero (Baylor College of Medicine, Houston, USA), and interventional radiologist Robert Beasley (Mount Sinai Medical Center, Miami, USA).

Terumo Aortic reveals midterm results with real-world use of the RelayPlus thoracic stent graft system

Terumo Aortic has announced the midterm results from the RelayPlus thoracic stent graft system post-approval study, revealing low operative mortality and morbidity—supporting its use as a “safe and effective” thoracic aortic aneurysm treatment.

The RelayPlus thoracic stent graft system is approved by the US Food and Drug Administration (FDA) to treat patients with thoracic aortic disease. The purpose of this multicentre, non-randomised, prospective study undertaken in the USA with novice implanters, was to report real-world outcomes of patients with thoracic aortic aneurysms and penetrating atherosclerotic ulcers (PAUs) undergoing thoracic endovascular aortic repair (TEVAR).

Over a three-year period, the RelayPlus stent graft was implanted in a total of 45 patients. Results showed 95.6% freedom from TEVAR-related mortality, 84% freedom from all-cause mortality, and 97.2% freedom from reinterventions. Only centres with no previous experience with this stent graft participated in the post approval study and confirmed 100% technical success and sustained freedom from TEVAR-related mortality in the mid-term. These results were published in the Journal of Vascular Surgery (JVS). In June, the lead author of the “RelayPlus in the USA” article, Mahmoud Malas, chief of vascular and endovascular surgery and vice chair of surgery for clinical research at the University of California (San Diego, USA), commented: “The RelayPlus system introduced a number of design improvements and innovations that facilitate the procedure for the physician; the questions were whether these elements could result in better clinical outcomes for the patient and whether those advantages persisted in the longer term. These results show a durable thoracic endovascular treatment at the mid-term follow-up of the study.”

The longer-term sustainability of these clinical outcomes with RelayPlus stent graft will be determined through five years of follow-up.

B Braun announces publication of 12-month LOCOMOTIVE EXTENDED results

B Braun has revealed that 12-month results from the LOCOMOTIVE EXTENDED study of the company’s Multi-Loc stent delivery system have been published in Vasa: European Journal of Medicine. The study authors, Kline Amendt (Diakonissenkrankenhaus Mannheim, Mannheim, Germany) and colleagues conclude that the Multi-Loc, “provides promising results concerning target lesions revascularisation and primary patency at 12 months”.

They add that use of the Multi-Loc stent system is both safe and effective for provisional repair of flow-limiting dissections or recoil following plain balloon angioplasty and drug-coated balloon angioplasty of the femoropopliteal artery.

The LOCOMOTIVE EXTENDED (Multi-Loc for flow-limiting outcomes after plain old balloon angioplasty and/or drug-coated balloon treatment in the infrarenal position, with the objective to implant multiple stent segments) study is a prospective, single-arm, multicentre observational study, in which B Braun’s Multi-Loc stent delivery system was used for provisional stenting of the femoropopliteal artery.

Amendt et al enrolled 357 patients with 449 femoropopliteal lesions and a mean age of 71±10 years. The mean lesion length was 169.9±7.4 cm. 44.5% of which were TASC II C/D lesions and 31.4% were chronic total occlusions.

At six and 12 months, the authors report that freedom from clinically-driven target lesion revascularisation was 95.5% and 88.7% and the primary patency rates were 88.7% and 82.3%, respectively.

At 12 months, significant improvements were noted in Rutherford categories and ankle-brachial indices, and in multiple regression analyses, both diabetes mellitus and no distal run-off vessel showed a trend toward worse target lesion revascularisation, while other factors such as drug-coated balloon predilection or the lesion length were not predictive.

Considering future research, Amendt and colleagues conclude: “Randomised controlled trials are needed to compare the focal stenting strategy to conventional interventions with long stents. Possibly, the efficacy of spot stenting could be further increased by combining it with additional preparation techniques, such as vessel scoring or debulking.”

First patient enrolled in Vesper Medical’s VIVID trial

Vesper Medical recently announced initiation of the VESPER USA Food and Drug Administration (FDA) investigational device exemption (IDE) study—VIVID (Venous stent for the iliofemoral vein investigational clinical trial using the Vesper Duo venous stent system).

The VIVID trial is a prospective, multicentre, single-arm study to evaluate the safety and efficacy of the Vesper Duo stent system in the treatment of patients with iliofemoral occlusive disease.

According to a press release, the Vesper Duo stent system is designed to be the next generation venous stent technology, uniquely engineered to address the challenges of deep vein obstruction.

The modular portfolio is intended to provide physicians clinical versatility with both the Duo Hybrid and Duo Extend stent options in a full range of lengths and diameters to customise therapy for each patient depending on their specific stenosis location within the iliofemoral vein.

“We were honoured to initiate this
clinical investigation which holds significant potential benefits for patients with deep venous occlusive disease,” said Jason Yoho of the Heart & Vascular Institute of Texas, New Braunfels, USA.

“Until now, we have not had a portfolio of stents that have been uniquely tailored to the venous anatomy and can be customised to meet each patient’s need.”

The study is led by lead principal investigator Mahmoud Razavi, director of clinical trials at St Joseph Heart and Vascular Center in Orange, USA, and European lead principal investigator Michael Lichtenberg, chief medical officer of the Angiography department at the Vascular Centre Clinic in Arnberg, Germany.

“Commencement of patient enrolment in the VIVID trial is a critical milestone in the development of the Vesper Duo stent system,” said Bruce J Shook, president and CEO of Vesper Medical. “The unmet need in the treatment of deep venous disease is enormous, and we are excited to bring the next generation in venous stenting technology to patients in need.”

The VIVID trial is a global study and will enrol up to 160 patients in up to 45 centres in the USA and Europe. It will assess freedom from major adverse events at 30 days post-procedure and primary efficacy of the stented segment at 12 months. Patients enrolled in the study will be followed for three years.

**ISABELLA trial for the treatment of failing AV fistulas in haemodialysis patients completes enrolment**

MedAlliance has announced completion of patient enrolment in the ISABELLA clinical trial with the Solution SLR 018 drug-eluting balloon (DEB) for the treatment of dysfunctional arteriovenous (AV) fistulas in end-stage renal failure patients undergoing haemodialysis.

Solution SLR (sustained limus release) is a novel sirolimus-eluting balloon that provides a controlled sustained release of drug, similar to a drug-eluting stent (DES).

ISABELLA (intervention with Solution SLR agent balloon for endovascular latent limus therapy for failing AV fistulas) is a prospective, single-centre, multi-investigator, non-blinded, single-arm trial investigating the safety and feasibility of the Solution SLR 018 DEB for the treatment of failing AV fistulas in 40 haemodialysis patients.

The objective of this study is to determine the safety and efficacy of the Solution SLR 018 DEB in the treatment of dysfunctional AV fistulas in end-stage renal failure patients undergoing haemodialysis. The anticipated clinical benefit is to improve the target lesion primary patency and reduce the number of reinterventions in stenotic AV fistulas of haemodialysis patients and hence manage this frail patient population compared to conventional balloon angioplasty.

The efficacy endpoint of interest is six-month target lesion primary patency and the safety endpoint is freedom from loss of access or systemic serious adverse events through 30 days that reasonably suggest the involvement of the AV fistula circuit.

The study has recently completed its 40-patient recruitment and will follow them up for a period of two years at Singapore General Hospital (SGH), which performs over 3,000 access salvage procedures annually.

“We are very excited at SGH and eagerly await the results from ISABELLA, which will be the first study to report clinical safety and efficacy data of sirolimus-eluting balloon (SEB) angioplasty using the Solution SLR DEB cather combined with high pressure conventional balloon angioplasty vessel preparation, for dysfunctional AVF circuits in Asian haemodialysis patients,” said lead principal investigator associate professor Tjun Tang, senior consultant vascular and endovascular surgeon at SGH.

“SEBs are a natural evolution of the current gold standard treatment option of conventional balloon angioplasty for salvaging failing and stenotic AV fistula circuits. Paclitaxel drug-coated balloons have been used with limited success and the data are far from conclusive.”

“The Solution SLR DEB provides therapeutic concentrations of drug within the vessel wall for at least 90 days post-angioplasty, which is a major advantage over other drug-coated balloons in dealing with the extended nature of the NIH [National Institutes of Health] process. Our plan is to follow up patients to two years to define the effectiveness of the studied therapy in the medium term.”

**Production news**

**Okami Medical announces FDA 510(k) clearance of the LOBO-5 vascular occluder**

Okami Medical has revealed the expansion of its LOBO vascular occlusion system product line with US Food and Drug Administration (FDA) 510(k) clearance of the LOBO-5 vascular occluder.

According to a press release from the company, the LOBO (Low-profile抱着ocluded occluder) system is uniquely designed to provide interventional physicians with a single-device, “one-and-done” solution for the occlusion of a wide range of peripheral arterial targets. The LOBO system combines neurovascular-derived HDBRAID technology with a patented design to create a highly occlusive structure for fast and efficient closure of blood vessels throughout the body.

LOBO-5, the second offering in the company’s product portfolio, is intended for use in 3-5mm diameter vessels. LOBO-3, the company’s first occluder, is intended for use in 1.5-3mm vessels.

“The FDA clearance of LOBO-5 marks another milestone in our mission to provide patients and physicians with access to advanced technologies that address the numerous unmet clinical needs in peripheral vascular occlusion,” said Bob Rosenbluth, president and CEO of Okami Medical.

He continued: “LOBO-3 and LOBO-5, to be followed by LOBO-7 and LOBO-9, are designed and built to enable fast, predictable and complete occlusion of a diverse set of vascular targets without the need for multiple embolic devices.”

**Corindus announces global launch of technIQ procedural automation series for CorPath GRX system**

Corindus has announced today global launch of a new set of automated robotic movements in the technIQ series designed for the CorPath GRX system. The company received 510(k) clearance from the US Food and Drug Administration (FDA) for new software automation that provides predictable and consistent movements to aid in advanced device manipulation during complex coronary and peripheral procedures.

Jean Fajadet, the co-director of interventional cardiology at Clinique Pasteur, Toulouse, France, performed the first-in-human coronary procedures using the new automated movements, which replicate manual techniques of interventionalists. The procedures demonstrated how the new movements can help to reduce procedure time associated with wire and device manipulation and drive standardisation in quality of care by offering advanced techniques to all physicians.

“This new software algorithm gives the operator new possibilities to advance and facilitate treatment, especially with complex lesions,” said Fajadet. “I am pleased with the success of using the automated moves and am honored to play a role in the advancement of robotic technology that will make interventional procedures more efficient and safer for our patients.”

In 2018, Corindus received CE mark and FDA clearance for an automated technique called Rotate on Retract (RoR). RoR was the first automated robotic movement in the techNIQ Series and has demonstrated the potential to significantly reduce wiring time.

The latest global introduction and FDA clearance for the techNIQ Series provides physicians with four additional automated robotic movements that aid with complex tasks such as crossing lesions, navigating tortuosity, and precisely measuring the anatomy for appropriate device size selection.

“The new techNIQ movements mark the next phase in the evolution of robotic-assisted intervention and a vital step toward the advancement of our technology,” said Wayne Markowitz, executive vice president and head of Corindus. “Automating more movements used in cardiovascular intervention will allow physicians to focus their attention on overall case strategy while equipping them with advanced techniques for navigating the vasculature.”

Corindus is a Siemens Healthineers company, following a merger in 2019.

**Penumbra continues to strive to bring innovative therapies to the medical community, and this is another important milestone that will help advance pulmonary embolism intervention,” said Adam Carney, senior vice president and chief executive officer of Penumbra. “COVID-19 has increased the awareness of the need for therapies that remove blood clots, and we are thrilled with the FDA clearance of the PE treatment indication for Lighting 12.”

The Indigo System Lighting 12 is the company’s newest generation aspiration system for peripheral thrombectomy. Lighting 12 combines the Indigo System CAT 12 aspiration catheter with lighting intelligent aspiration, enabling physicians to focus on optimising thrombus removal using the system’s unique clot detection mechanism.

CAT12 is a large-lumen aspiration catheter that incorporates novel laser-cut hypotube-based catheter engineering to provide deliverability and torqueability within the body. According to a press release, this combination of intelligent aspiration and large-lumen catheter engineering makes Lighting 12, Penumbra’s most advanced clot removal technology for the treatment of PE.
Alucent Biomedical adds to scientific advisory board, expands portfolio with AV fistula application

Alucent Biomedical has announced Stanford vascular surgeon Venita Chandra (Stanford University Medical Center, Stanford, USA) will join the company’s scientific advisory board. The news comes as Alucent seeks to expand its clinical trial portfolio and adapt its Natural Vascular Scaffolding (Alucent NVS) for the maturation and preservation of arteriovenous fistula (AVF) for haemodialysis.

Chandra is board certified in both general and vascular surgery. She is a clinical associate professor of surgery in the Division of Vascular Surgery at Stanford University Medical Center. She also serves as the co-medical director of the Stanford Advanced Wound Care Center and the program director of the Vascular Surgery Fellowship and Vascular Surgery Residency Programs at the Stanford University School of Medicine.

CMS creates new codes that establish specific payment for below-the-knee IVL

Shockwave Medical has announced that as part of the calendar year 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) final rule, the Centers for Medicare & Medicaid Services (CMS) has created four new codes for intravascular lithotripsy (IVL) procedures performed in below-the-knee (BTK) arteries in the hospital outpatient setting. These codes became effective 1 January 2021.

In creating the four new Healthcare Common Procedure Coding System (HCPCS) codes (C9772-C9775), CMS noted that, “resources associated with tibial and peroneal IVL procedures are higher than iliac, femoral and popliteal procedures.”Previously, in July 2020, CMS issued four codes C9764-C9767 to describe IVL performed in all lower extremity arteries. As part of the 2021 OPPS final rule, these initial codes have now been redefined to report IVL procedures performed in lower extremity arteries, except tibial and peroneal. There will now be four codes that pertain to below-the-knee IVL procedures and four that pertain to above-the-knee IVL procedures.

In addition, CMS assigned the new HCPCS codes to Ambulatory Payment Classifications (APCs) that determine hospital outpatient payment. These APC assignments are consistent with similar interventional procedures performed in the BTK arteries.

Also effective 1 January 2021, CMS added IVL procedures to the list of services covered in an Ambulatory Surgical Center (ASC) setting. “We appreciate CMS’s swift action in adding these new codes as they acknowledge the differentiation between above-the-knee and below-the-knee procedures and that complex BTK interventions involving IVL require more resources,” said Doug Godshall, Shockwave Medical president and CEO.

Calendar of events

25–29 January
LINC – The Leipzig Interventional Course
Virtual
leipzig-interventional-course.com

3–11 February
10th Management of Aortic Rupture Workshop Zurich (MARZ)
Virtual
new.usz.ch/veranstaltung/marz21/

7–8 March
24th European Vascular Course (EVC)
Virtual
vascular-course.com

19–22 April
19–22 April
CX 2021 Vascular and Endovascular Controversies Digital Edition
Virtual
cxsymposium.com

27–28 May
Pacific Northwest Endovascular Conference (PNEC)
Seattle, USA
pnc-seattle.org/

18–21 August
Society for Vascular Surgery (SVS) Vascular Annual Meeting
San Diego, USA
vascular.org

21–23 October
Paris Vascular Insights
Paris, France
paravascularinsights.com

16–20 November
VEITHsymposium 2021
New York, USA
veithsymposium.org

Registration is now open!
LINC 2021, 25–29 January 2021
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During these difficult times we are experiencing, LINC continues to be committed to provide a platform for an interdisciplinary exchange of latest scientific data and technical aspects of endovascular interventions amongst endovascular specialists from around the world.

While live case transmissions from renowned centers around the globe remain to be the main focus, the virtual LINC 2021 edition will feature especially designed Connect The World Sessions, Main sessions, Symposia, Company Learning Sessions, and Poster Sessions.

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The availability of custom-made devices is subject to local regulatory guidelines. Caution: Not available in the USA.