vascularnews
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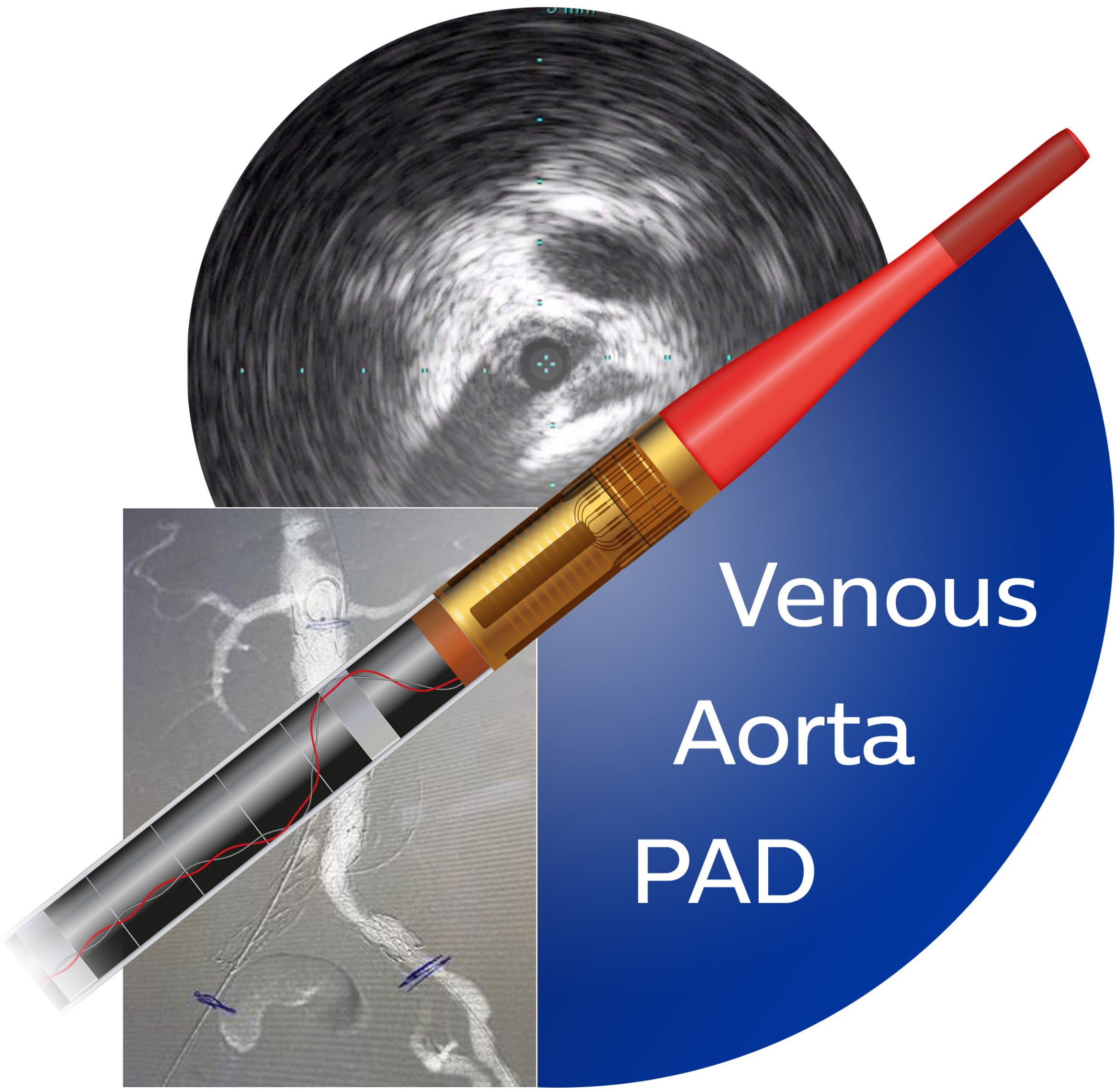
See clearly. Treat optimally.

The value of IVUS in Endovascular Procedures



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IVUS enables advances in "historically inadequate" venous disease treatment

Paul Gagne explains how intravascular ultrasound (IVUS) can be used to guide the treatment of chronic venous disease, discussing the various pathologies and patients in which the benefits of IVUS imaging are "irrefutable". "The ability of IVUS to detect and guide safe treatment of iliofemoral vein occlusive disease has led to a revolution in the care of these patients," he writes.

WORLDWIDE, UNTREATED CHRONIC venous hypertension results in patients suffering from persistent leg swelling, heaviness, pain, or ulceration. Treatment of the underlying chronic venous disease (CVD) has historically been inadequate for many patients. Additionally, clinically severe venous hypertension affects all demographics of the population. Unlike peripheral arterial disease, which typically affects the elderly, smokers, and diabetics, severe venous disease can afflict adults of any age. Many young adults without modifiable risk factors suffer a markedly diminished quality of life if their CVD is not addressed through invasive means. To date, there is no medical cure for CVD.

Treatment for symptomatic CVD includes leg-elevation and compression. Though helpful to some patients, it is impractical and inadequate for many. Elevation and compression are not equally effective for the myriad of venous system abnormalities that can cause severe symptoms. Venous valvular insufficiency (VVI) of the superficial, perforator, and deep veins, as well as deep vein occlusive disease due to extrinsic compression or intraluminal or intramural scarring from prior acute deep vein thrombosis (DVT), can all lead to significant leg complications. Chronic venous ulcers (VLU) and venous claudication are the most severe presentations. These patients typically have VVI and occlusive disease in multiple vein segments. Compression therapy is often inadequate and uncomfortable, with limited compliance in patients with deep vein occlusive disease. Younger patients are particularly unsatisfied with elevation and compression as life-long therapy, and benefit from more direct venous interventions.

Superficial vein ablation has proven beneficial for clinical CEAP (Clinical, Etiology, Anatomy, Pathophysiology) 1, 2 and 3 CVD patients, and in selected patients accelerates the healing of venous ulcers[2] and decreases VLU recurrence.[3] However, for the majority of patients with clinical CEAP 4–6 disease, treatment of existing deep vein disease (DVD) may be the only path to cure.

Treatment of DVD starts with an accurate diagnosis of the pathophysiology. You cannot treat what you cannot see! Venography has historically been the diagnostic imaging of choice for detecting iliac and common femoral vein (i.e. iliofemoral vein) occlusive disease. The VIDIO trial[4] compared multiplanar venography and IVUS, and showed that IVUS is more accurate than venography for identifying iliofemoral vein occlusive disease and is the imaging of choice for assessing DVD in clinical CEAP 4-6 patients. This includes patients with non-thrombotic iliofemoral vein lesions (NIVL) and post-thrombotic scar, either intraluminal or intramural. Intraluminal disease is detected with IVUS as a scar on the wall of the vein, or scar across the lumen of the vein or webs (Figure 1). Intramural scar presents as diffusely small diameter veins with patent but small cross-sectional area lumens.

The VIDIO trial also showed that IVUS was the best guide for deep vein interventions.[5] IVUS-guided stent placement better predicts clinical improvement at six months, based on a decrease in the revised Venous Clinical Severity Score of at least four points than interventions based on multiplanar venography. Subsequently, IVUS has become a necessary and integral part of deep vein stenting worldwide.

There are three requirements for successful deep vein reconstruction. These are: a) adequate inflow, b) adequate outflow, and c) adequate stent coverage and expansion. IVUS is important to ensure reproducible success in this. IVUS best identifies all deep vein occlusive disease so that all significant disease is stented. Unaddressed occlusive disease in the inflow or outflow veins may limit flow through the stented segments resulting in stent thrombosis. IVUS also measures the size of normal deep vein segments to allow proper balloon selection. Balloon size is critical for adequate pre-stent vein dilation, stent expansion and lumen gain. Inadequate lumen gain may increase stent thrombosis. Conversely, adequate lumen gain after stenting predicts clinical improvement at six months.[5] IVUS measured vein diameter allows proper stent size selection within the manufacturer's instructions for use to ensure venous stents are adequately anchored and do not embolize to the heart and lungs.

The majority of patients with iliofemoral vein DVT will have chronic DVD identified once the acute thrombus is removed. IVUS-guided stenting of chronic deep vein stenosis is necessary to prevent recurrent DVT and achieve satisfactory clinical improvement.

Many patients suffer from Pelvic Congestion Syndrome (PCS). The clinical symptoms and findings of PCS are numerous and the underlying pathophysiology is varied. A pending classification scheme will help guide systematic study of this clinical entity and proper treatment. What is currently clear is that iliofemoral vein occlusive disease contributes to the pathophysiology in a subset of patients. IVUS is necessary for identifying these occlusive lesions and should be used routinely in the diagnostic workup. Further study is necessary to understand when IVUS-guided stenting of these lesions is appropriate.

> **"The ability of IVUS to detect and guide safe treatment of iliofemoral vein occlusive disease has led to a revolution in the care of these patients."**

Procedure selection for treating CVD is becoming increasingly more complex as more options become available. Patients with advanced CVD of the leg often have both deep and superficial vein disease. Deciding which to treat first can be a clinical dilemma. I have found that the more severe the clinical presentation, the more likely the

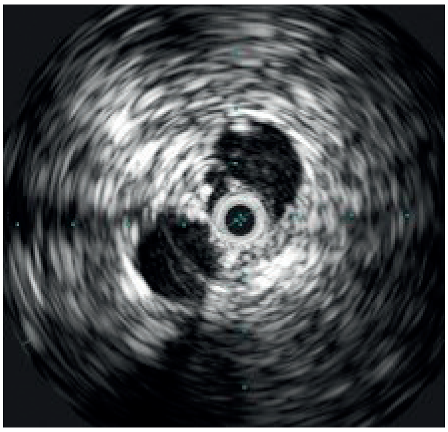

Figure 1. Multiple hyper echoic wall irregularities protruding into the vein lumen across from and around the IVUS catheter due to scar from prior DVT.

Figure 2. Focal skin damage in the distribution of a dilated greater saphenous vein with significant venous valvular insufficiency can resolve with GSV ablation alone.

Figure 3. Chronic skin damage such as hemosiderin deposition and lipodermatosclerosis that involves 180 degrees or more of the circumference of the leg may indicate central vein occlusive disease. Treatment may require intervention for both superficial and deep vein disease if present.

Figure 4. Diffuse skin ulceration, damage and induration involving most or all of the circumference of the leg often indicates the presence of deep vein occlusive disease. Diffuse deep vein valvular insufficiency can have a similar presentation.

patient will require treatment of both the deep and superficial vein pathology. Patients with clinical CEAP 2 or 3 disease generally respond well to superficial vein ablation. Focal skin damage in the distribution of superficial vein VVI (Figure 2) also responds to superficial vein ablation. When skin damage starts to involve the circumference of the ankle or calf (Figure 3) or large VLUs (Figure 4) occur, it is often necessary to treat both deep and superficial vein disease. Further investigation to develop exact treatment algorithms is needed.

Recent treatment of DVD has largely focused on treating occlusive disease. Active research into interventions to address deep vein valvular insufficiency is ongoing. The exact and detailed imaging provided by IVUS is considered integral to this clinical research and ultimate clinical implementation. IVUS provides essential information regarding the deep vein wall integrity and lumen diameter. IVUS will expand in use in parallel to progress in treating VVI.

Intravascular ultrasound has enabled advances in treating CVD patients suffering from the most disabling forms of this disease. The ability of IVUS to detect and guide safe treatment of iliofemoral vein occlusive disease has led to a revolution in the care of these patients. Though there is still much to learn about the treatment of CVD in general and DVD specifically, the necessity of IVUS imaging to detect and treat DVD, especially with stents, is irrefutable.

***Paul Gagne** is a vascular surgeon in Darien, USA.*

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IVUS "makes a real difference" in venous procedures

Stephen Black (Guy's and St Thomas' National Health Service Foundation Trust, London, UK) speaks to *Vascular News* about his experience using intravascular ultrasound (IVUS) in venous procedures. He advocates for its consistent use, saying: "I use IVUS in every case. […] You need to use it all the time to start to recognise all the different subtleties of anatomy. I genuinely do not believe it is possible to be selective anymore."

When did you start using IVUS in venous procedures?

I started using IVUS in 2013. I spent quite a lot of time asking clinicians at conferences if I needed it, and all I got was "It is great, but expensive". I never got any negative feedback, so it seemed that cost was the only obstacle. I discovered that my cardiology colleagues had two IVUS towers in the hospital, and so began using their systems. Initially, for me the catheter volume I used was so small that no one noticed it in the overall cardiology budget, so it was easy to make it standard of care under the radar, so to speak.

When you first started, did you perceive it as difficult, and what did you do to become more proficient?

I was already quite proficient in ultrasound, so looking at images was OK, but the orientation took a while to become familiar with. In the beginning, I used IVUS on a few 'normal' patients. Once I had the opportunity to become familiar with what normal anatomy looked like, I could begin to recognise what abnormal looks like. I think this is an often neglected step.

In 2013, there was little in the way of online support and so forth, so it just took a bit of time to become totally comfortable. It is for this reason I use IVUS in every case. I have seen so-called experts use IVUS in a truly incomprehensible way. You need to use it all the time to start to recognise all the different subtleties of anatomy. I genuinely do not believe it is possible to be selective anymore.

Do you use IVUS in all your venous procedures?

Yes. As above, I cannot see a reason not to. It eliminates radiation and contrast exposure, and you cannot predict before-hand which cases you may not need it in. I have been surprised many times by IVUS findings in cases which otherwise look great. It makes a small difference in every case, and it is these marginal gains that start to improve the overall results.

In your opinion, what is the greatest value of IVUS?

IVUS is additive. In many respects, it is the sum of all the parts that is greater than the individual bits. You visualise the intra-luminal pathology far more directly, and it makes the technical aspects far more precise. The under-recognised but important reduction in radiation dose I believe will prove to be the greatest advantage.

Do you believe IVUS has been an important tool for you to achieve the results you are seeing today with vein stenting? In other words, do you believe that without IVUS those outcomes would have been less good, and why?

Yes. I do totally. Small errors can really destroy otherwise good cases. Missed inflow disease. Stent compression. All these together have to be perfect. In particular, treating chronic iliac outflow obstruction is unforgiving. I do believe it has allowed me to be more aggressive with stenting and to avoid endophlebectomy, as I can be really precise in landing stents on the confluence and be sure of inflow.

> **"The under-recognised but important reduction in radiation dose [associated with IVUS] I believe will prove to be the greatest advantage."**

Can you describe a case or situation where IVUS really helped you in your treatment strategy?

As above in question five, it is most helpful in those cases where you think inflow may be questionable. I remember a case where I got Rick De Graaf (Clinic of Friedrichshafen, Friedrichshafen, Germany) over, who is an outstanding interventional radiologist, to do the first case I ever did using Sinus venous stents (OptiMed). We stented a lady with truly bad common femoral vein disease, and to be honest I think Rick thought I had stitched him up with the case selection. She had a really tight landing zone, but we landed the stent perfectly, and she is still doing well five years later.

Many—mostly smaller centres—place venous stents without using IVUS. Do you believe their results will be suboptimal because of that?

I do not think we have the evidence to say that categorically, and we have to be careful. Do I believe it improves results? Yes. But there are many excellent interventionalists who have got good results using it sparingly. However, in my opinion, based on the errors I have made over the years, it was often IVUS that revealed them, and as I have got better with IVUS, I have got much better at avoiding mistakes. I think in non-thrombotic iliac vein lesion (NIVL) patients, you can get away without IVUS—but why get away with something? I think we undoubtedly need to build the evidence base to ensure that personal opinion or anecdote are backed up.

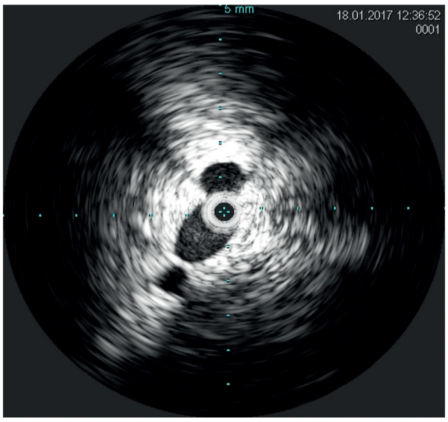
If you had to choose the procedure or indication where IVUS would have the biggest benefit, which would that be?

In patients with chronic disease extending below the inguinal ligament—this is where IVUS makes a real difference.

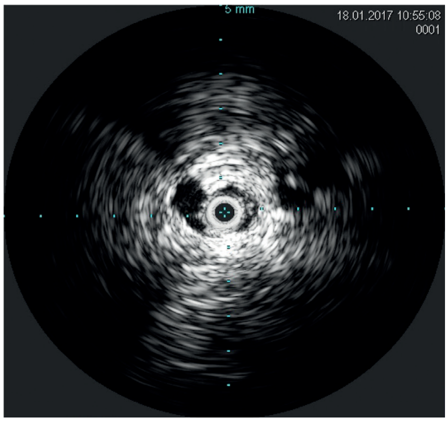
Last but not least, what will be your one golden tip for centres starting with IVUS in venous procedures?

Just do it. Do a lot of cases. Use IVUS in normal cases. Look repeatedly—in other words, spend time looking at the patient before and after you place the stent, and take the time to familiarise yourself with the anatomy and the orientation. You will then start to trust it and forget what contrast is!

Picture showing in stent thrombus within a stent but stent is well expanded



Picture showing stent with compression at the inguinal ligament



Do we need IVUS in PAD procedures?

Considering the addition of intravascular imaging to angiography in peripheral arterial disease (PAD) procedures, **Michael Lichtenberg** and **Konstantinos Stavroulakis** write that it has a number of benefits. They conclude, therefore, that IVUS "should be available in all major interventional centres".

DIGITAL ANGIOGRAPHY HAS BEEN instrumental in allowing major technical advances in endovascular therapy, and to most of us angiography is still considered the 'gold standard' for peripheral interventions.

Choice of device, diameter and length decisions are generally based upon two-dimensional lumenograms without objective information of what is going on inside the vessel. Especially in situations with large plaque burden, relying solely on angiography will inevitably lead to underestimation of the true vessel size, with potential suboptimal outcomes as a result.[1] Buckley and colleagues have demonstrated that utilising IVUS as an adjunct to iliac angioplasty and stenting improves iliac artery patency rates.[2,3] In the group that was treated with both angiographic and IVUS assessment, 41% of patients were found to have underdeployed stents by IVUS, even though they appeared to be adequately apposed based on angiography.

Indeed, the acute result, as confirmed by angiography, may actually look very good, however we are all familiar with reinterventions that result from either the inherent complexity and progression of disease, poor medication compliance, or—let us be honest—a potential suboptimal initial procedure. While the first two causes reside largely beyond our control, we should continuously be looking for ways to improve our outcomes after the initial procedure. In a recent literature review, albeit heterogeneous, IVUS-guided intervention was reported to have potential beneficial effects on re-intervention rates, without significant peri/postoperative IVUS related complications.[4] In that respect, in our hands, complementing angiography with intravascular ultrasound has been found to not only improve our understanding of what is really going on, but more importantly has frequently led to a change in initial treatment strategy.

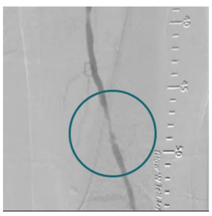


Figure 1a. Angiogram of disease distal SFA

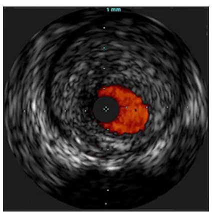


Figure 1b. Corresponding IVUS image showing 6.5mm vessel with >80% plaque burden

The added value of IVUS in PAD procedures can be summarised in a framework, called the FOUR PILLARS of IVUS. The first pillar refers to vessel size: vessel diameter, lumen diameter, and plaque burden can be reliably assessed using IVUS, while it also identifies stent apposition and expansion. Using IVUS, we discovered large diameter differences compared to angiographic estimates in the leg, most pronounced in below-the-knee arteries, where differences >1mm were observed.[5] The second pillar is plaque morphology: soft, fibrotic, thrombus, or calcium—IVUS can help differentiate between these, thereby facilitating choice of appropriate interventional technique. The third pillar refers to plaque geometry: IVUS will show the eccentricity of plaque and location, so again, the optimal interventional tool can be selected. Especially dissections can be easily identified using IVUS and we have found major dissections that were not visible on single-plane angiography. The fourth and last pillar is guidewire position. IVUS can show whether the guidewire is in the true lumen or subintimal. Again, this information is extremely helpful to help guide your interventional strategy.

In conclusion, the addition of intravascular imaging to angiography in PAD procedures allows for more accurate sizing, better understanding of the extent of disease, shows the presence and severity of dissections, and confirms stent apposition, and therefore should be available in all major interventional centres.

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***Konstantinos Stavroulakis** is a consultant of vascular and endovascular surgery at St Franziskus Hospital Münster, Münster, Germany.*

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The value of IVUS in CLTI revascularisation

The patient

A 57-year-old man with a history of type 2 diabetes mellitus, chronic obstructive pulmonary disease, coronary artery disease, hypertension, hyperlipidaemia, obesity, and current smoker. The patient was referred from another centre for additional complex revascularisation when the referring physician was unable to obtain antegrade access to revascularise the anterior tibial (AT) artery and the pedal loop. The patient presented with a non-healing transmetatarsal amputation (TMA) of the left foot with dehisced wounds and infection at the site of the anastomosis of the plantar and dorsal skin with gangrenous changes (Rutherford 6). This type of chronic limb-threatening ischaemia (CLTI) case is complex. Historically, technologies prohibited operators from reconstructing distal tibial and pedal arteries, preventing the revascularisation of patients in a state clearly leading toward amputation. This case demonstrates the advantages of current technologies and details how to use them to plan revascularisation when faced with a complex body habitus and occluded tibial and pedal arteries.

The case

This limb salvage case was started by obtaining ultrasound-guided retrograde access to ensure the arteriotomy was secure above the profunda-superficial femoral artery (SFA) bifurcation and distal enough from the inferior epigastric artery. Figure 1a shows the mini Omni Flush (Angiodynamics) in position to advance the antegrade wire into the SFA or the profunda. In Figure 2, the wire is advanced into the profunda with the Omni Flush pulled back into the sheath. The sheath is then reversed and advanced over its dilator into the profunda (Figure 3).

Once the wire is deep into the SFA, the profunda wire is removed, the dilator is advanced over the SFA wire, and the sheath is advanced into the SFA. With the sheath in the right position, the procedure is initiated as an antegrade revascularisation. Tibial pedal angiography showed significant disease, including total occlusion of the AT and posterior tibial (PT) arteries, and a desert foot due to lack of distal blood flow (Figures 4–5).

The AT artery, where our referring physician had encountered difficulty crossing, teetered off distally. We used extravascular ultrasound (EVUS) to follow the dorsalis pedis (DP) artery, and looked for a quick turn of the DP medially just above the ankle. This is consistent with anomalous take off of the AT and DP from the peroneal artery (Figure 6).

Information from EVUS directed the revascularisation. We engaged the peroneal artery, and used it as our primary target to cross into the DP, hopping from there into the pedal loop. We used a triaxial support system, deploying a Navicross 0.035” angled support catheter. Inside this, we placed a Spex 0.014” catheter, which crossed the distal peroneal occlusion and advanced the wire into the DP, further into the pedal loop, and back up into the lateral plantar artery (Figure 7).

This was a unique change of events from historic records. We changed our approach and proceeded with intravascular ultrasound (IVUS) over the course of the wire. IVUS showed the peroneal AT junction was occluded with a high burden of elasto-calcinosis and calcium (Figure 8).


Jihad Mustapha

The rest of the IVUS showed severe disease involving the entirety of the peroneal artery and tibial peroneal trunk (TPT), with variation in vessel size from 3.5–5mm. Importantly, our IVUS findings enabled us to perform proper balloon-to-artery sizing. The proximal peroneal artery is 5mm (Figure 9a). Many of us may think twice before using a 5mm balloon in the proximal peroneal artery. However, IVUS measurements support this action, which is the most reasonable next step in providing the patient a second chance of regaining ambulation. Not following IVUS measurements may lead to under-sizing, poor outcomes, and potential amputation.

Figure 9b shows a large distal popliteal artery with eccentric plaque and elasto-calcinosis. The TPT appeared smaller than expected; most likely because the IVUS measurements excluded the majority of the actual vessel (Figure 9c). This case is an example of the disease involving not just the lumen, but the wall of the artery. The overall percentage of stenosis was 95%.

Having looked at the TPT, peroneal, and AT, one can extrapolate that the DP most likely is going to be large as well. We obtained an IVUS image that showed the expected large DP artery at 4mm (Figure 9d).

We then used a 1.5mm, solid crown orbital atherectomy device on low and medium speeds throughout the length of the diseased segment, from the TPT to the DP artery. We then performed sequential balloon angioplasty with tapered balloons, starting with 3x2.5x210mm from the DP to the AT, then 3.5x3x210mm from the AT to the peroneal, then 4x3.5x210mm from peroneal to the TPT.

Repeat angiography showed unsatisfactory results of the flow in the AT and DP, and 100% occlusion of the junction between the peroneal and the AT (Figure 10). We used IVUS-driven measurements and increased to 3.5mm and 4mm balloons in the DP and AT/peroneal junction. The angiographic images (Figure 11a–d) show the initial resistance of the balloon to break through the high plaque burden. As the 4mm balloon comes in, proper sizing of 1.1:1 shows the value of luminal gain of the artery. The 4mm balloon in the DP artery under ultrasound demonstrates the value of EVUS and proper sizing post-IVUS imaging (Figure 11d). The balloon is sitting comfortably in the vessel at a 1.1:1.0 ratio.

After this intense revascularisation, selective angiography showed excellent flow in the peroneal, AT, and DP arteries, and a plantar flow in the medial and lateral planters (Figure 12a–b). Figure 13a–b show the pedal loop completely intact. We opened the PT artery from both a retrograde and an antegrade approach with pedal loop balloon angioplasty; the final results show beautiful branches coming off the DP and plantar arteries. The most important part for healing in this patient is getting a reconstructed pedal loop with sufficient branches supplying the non-healing wound area.

To ensure ongoing perfusion to obtain wound healing, we stuck to our IVUS findings and followed a 1.1:1 ratio for balloon inflations in the TPT and proximal peroneal arteries, with excellent results (Figure 14). With proper imaging modalities such as IVUS, we no longer have to fear proper balloon sizing (or 6mm balloons when indicated in the tibial arteries). Use and apply IVUS and EVUS data to obtain safe and effective results for best patient outcomes.

At two-weeks follow-up, healing of the left TMA site has progressed. The foot is warm to the touch, with brisk capillary refill and biphasic PT and DP pulses. The patient is on dual antiplatelet therapy, and continues to visit podiatry and the wound clinic.

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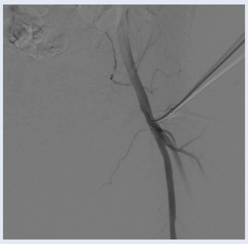
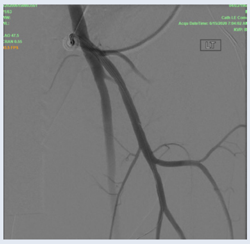
1a: Retrograde angiogram with mini Omni Flush in place.



1b: Retrograde image with oblique view showing the retrograde sheath arteriotomy above the SFA/ peroneal bifurcation.

2: Sheath tip is reversed from retrograde to antegrade.

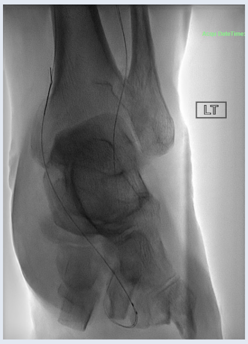


3: Using the profunda to anchor the support wire.

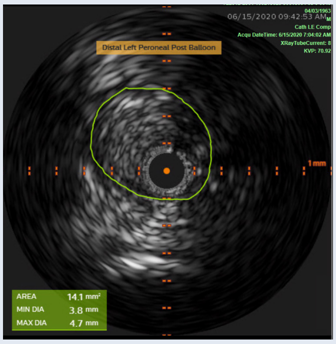
4: Selective antegrade angiogram.

5: Desert foot.

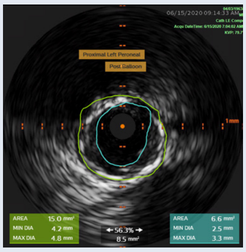
6: Anomalous take off of the AT and DP from the peroneal artery.



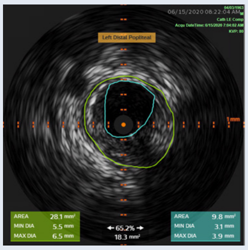
7: Pedal loop engaging the peroneal, AT, DP, and lateral plantar arteries.



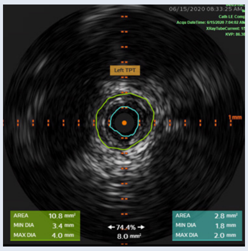
8: Pre-percutaneous transluminal angioplasty (PTA) IVUS peroneal/AT junction.



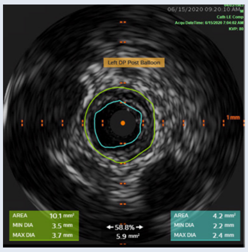
9a: Intravascular ultrasound (IVUS) directed PTA with 5mm balloon.



9b: IVUS demonstrating eccentric plaque.

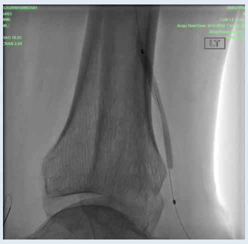


9c: Where does the disease start and where does it end?



9d: Left dorsalis pedis post balloon recoil.

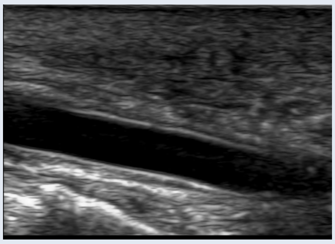
10: Anomalous AT take off demonstrating peroneal artery is still 100% occluded.



11a: 3.5mm balloon.

11b: 4mm balloon at four ATMs in the peroneal/AT junction.

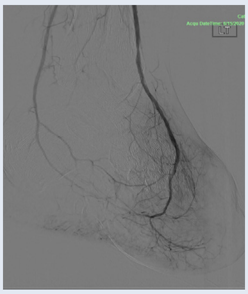
11c: 4mm balloon at six ATMs in the peroneal/AT junction.



11d: 4mm balloon in the dorsalis pedis artery as shown by extravascular ultrasound (EVUS).

12a: Post revascularisation angiogram of the peroneal, AT, and DP arteries.

12b: Post revascularisation angiogram of the AT, DP, and plantar arteries.



13a–b: Demonstration via angiography of intact complete pedal loop.

14: 1.1:1 ratio balloon ratio (utilising 6mm balloon) in the TPT and proximal peroneal arteries with excellent results.

Disclosures: Consultant to BD Bard Peripheral Vascular, Boston Scientific, Cardiovascular Systems, Medtronic, Philips, and Terumo.

IVUS-guided EVAR and TEVAR for maximum radiation reduction

In this article, **Jörg Tessarek** provides a step-by-step procedural guide to using intravascular ultrasound (IVUS) in endovascular aneurysm repair (EVAR) and thoracic endovascular aortic repair (TEVAR) procedures.

Jörg Tessarek

RADIATION EXPOSURE OF staff members and patients is a challenging problem with the permanent progress of imaging-guided therapies in the aortic field.[1] Renal function impairment as a preexisting risk factor, the patient's comorbidities, the aortic disease, and repetitive application of iodinated contrast media represent another menace for early complications, costs, and worsened overall outcome of EVAR and TEVAR.[2] IVUS guidance has for a long time been known as a more effective and less invasive method for endovascular imaging, even in the coronaries and the aortoiliac pathologies. In 2002, a prospective randomised trial comparing contrast free IVUS versus angiographic guidance of EVAR could demonstrate the superiority of IVUS with 0% vs. 7% mortality.[3] Recently published results from a comparative study could demonstrate equal long-term results three years after IVUS- or angiographic-guided EVAR.[4] Beside the renal benefit, the most obvious advantage of IVUS guidance is the significant reduction of radiation dose to both patients and staff.

The data so far demand further evaluation of combined approaches with IVUS and the recent generation of angiography systems, including dedicated software solutions for radiation reduction.

Further efforts have to be undertaken. In our hospital, IVUS has become the preferred guidance tool for T/EVAR under fluoroscopy avoiding contrast media application.

Technical aspects of IVUS

The ceiling mounted C-arm in our hybrid room, an Allura FD 20 (Philips), has a 38cm flat screen detector. In combination with the ClarityIQ software, the system was able to achieve significant radiation reduction from 45–75%, without loss of imaging quality, increase of procedural length, or use of higher amounts of contrast in several prospective studies.[5–10] A retrospective analysis of our EVAR cases prior to ClaityIQ implementation and afterwards could show a BMI-adjusted reduction of 45.6% for complete angiographic guidance of the procedures.

Since 2016, we have been using IVUS for T/EVAR for aneurysms and dissections. The IVUS system, with an 8.2F aortic catheter (Visions PV.035 Digital IVUS Catheter, Volcano/Philips) requires a minimum 8.5F sheath and offers a 60mm imaging diameter with excellent resolution. This offers complete control into any landing zones for standard or complex aortic dissection and aneurysm repair. The three-dimensional imaging with 360° circumference allows for mapping of the aortic wall or the different lumen and intimal flaps in dissections, as well as the sidebranch orifices with their surrounding plaques morphology.[11] Surface structures can be evaluated very accurately prior to and after device placement with better long-term outcomes.[12] The 25 radiopaque markers on the shaft facilitate on-table longitudinal measurements, while the whole system requires an area of only 60x60cm and fits to any endovascular workflow.

Operative setting and procedural steps

The procedural workflow of T/EVAR with IVUS guidance does not differ from angiographic guidance in terms of patient and C-arm position or choice of anaesthesia.

In our setting, the C-arm position and monitoring tools for T/EVAR are positioned cranial, with the IVUS console on the left side of the patient, opposite the operator and directly under the X-ray monitor. All table-mounted radiation protective tools are placed before sterile draping, while the mobile ceiling-mounted protection glass shield (Figure 1) is placed, sterile, by the operator themselves. Further individual radiation protection includes a full body lead apron, as well as a thyroid shield and head protection with 180° glass shield (lev 0,1Pb).

Arterial access is performed percutaneously with duplex ultrasound using the pre-suturing technique. Two extra stiff wires are placed for IVUS imaging and target vessel definition to have congruent intraluminal pathways for the catheter and graft. In dissection treatment, the wire is cautiously guided into the arch with IVUS to achieve a safe position in the true lumen.

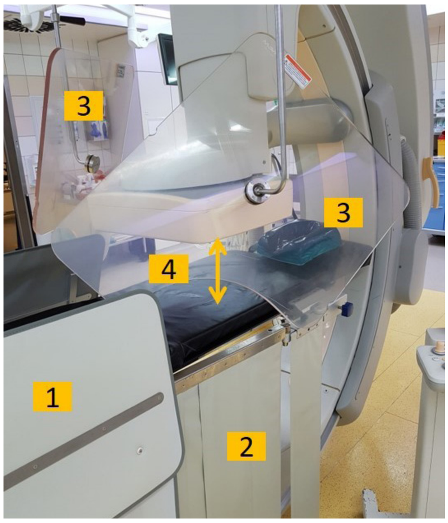


Figure 1. Optimal setting for passive radiation protection tools: (1) main working area lead shield; (2) flexible lead curtain; (3) lead glass shield; (4) minimum achievable source detector distance.

Collimation is used to minimise the radiation field, leaving the measuring chambers of the detector uncovered for automatic boost prevention.

The IVUS measurements, independent from the region of interest, are performed with a slow bilateral pullback through the aortic pathology and the vicinity segments with continuous video documentation. The crosswise position of the infrarenal wires and the wire position at the outer arch curve allow for the maximisation of imaging accuracy and of parallaxis effects. For top and bottom end definition, the orifices of the target vessels are marked on the diagnostic X-ray screen with single frame fluoroscopy (Figure 2).

The table and C-arm are kept in a stable position and the IVUS catheter remains at the level of the relevant target vessels as a steady and reliable marker until partial deployment of the main body. After complete deployment of all components in the standard manner, completion IVUS—instead of angiographic imaging—is performed, including the same segments as prior to graft placement. The high resolution enables the operator to evaluate the grafts wall apposition, expansion, and distance to the target vessels without radiation use. If unacceptable crimping, infolding, or stenosis are visible,

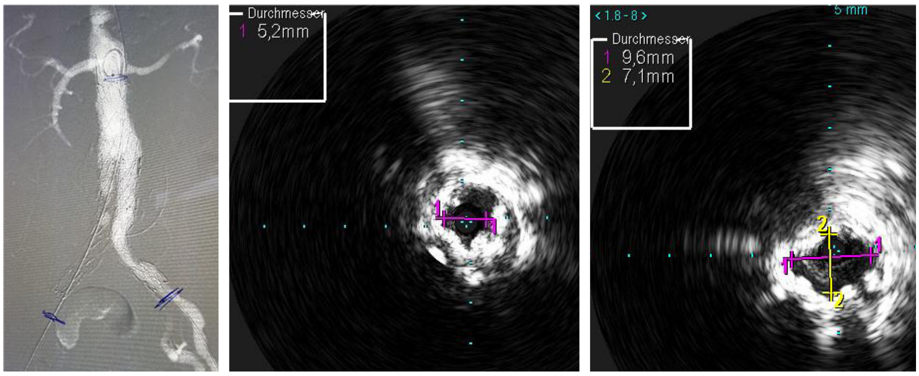


Figure 2. Photography of the diagnostic screen shows the carbondioxid angiography after IVUS guide EVAR (2017) with postdilatation of the left limb for severe stenosis. The markers on the screen show the exact placement of the device without relevant loss of top or bottom landing zones or target vessels. Flow in the right iliac was reduced due to the main body sheath still in place. This table position with ap-projection was maintained for the whole procedure. The middle and right image shows the crimping of the left iliac climb during completion IVUS in the calcified artery and the diameter gain after postdilatation.

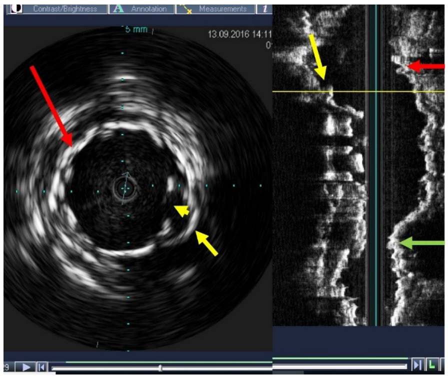


Figure 3. Left: accommodation of the thoracic graft to the wall (red arrow) while a gap remains (short yellow arrow indicates fabric, long arrow indicates wall). Right: longitudinal reconstruction with the gap (yellow arrow) and a stenosis in the distal thoracic aorta (green arrow).

further actions can be taken (Figure 2). For troubleshooting, angiography is not forbidden. The procedure is completed by closure of the access vessels in a standard manner.

How IVUS makes a difference

Aortic IVUS allows the surgeon to perform T/EVAR treatment with zero contrast, avoiding any of the associated risks, which are contrast-induced nephropathy or other organ damage. Avoiding high-energy radiation for angiography reduces the patient and staff dose significantly. With clarityIQ an average reduction of the dose area product (DAP) for 45.6% compared to the pre-Clarity era EVAR. With the use of IVUS and angiographic control a further reduction of 55.36% was seen. With IVUS guidance under a strict collimation regime and fluoroscopy only, we achieved a further reduction of 95.56% compared to pre-clarity era.

During the whole EVAR procedure, the table and the C-arm remain in a stable position avoiding oblique projections, which would cause a significant increase of skin entrance dose and scattered radiation. Accordingly, the radiation protection tools can also remain in the optimal position with maximum effect for the staff.

The high resolution of the IVUS live images can show Ia/b endoleaks indirectly when incomplete graft apposition or fabric movements are present. Irregularities, such as malpositioning, infolding, stenosis, or crimping (Figure 3) can also be detected very clearly in a single run through without radiation. After 80 EVAR cases with complete or partial IVUS guidance and a follow-up of up to 36 months, there are no safety concerns in terms of missed Ia/b endoleak. The type II endoleaks in the 30-day baseline CT or enhanced duplex examination were clinically irrelevant. These findings are supported by Pecoraro *et al.*[4] One graft showed migration due to inappropriate sizing.

Parallaxis and artefacts, such as bowel gas or vertebral implants and the BMI, are neglectable with the IVUS catheter being very close to the lumen centerline and very close to intimal flaps or dissection membranes.

With pullback, the catheter tends to rotate, which requires reliable marker structures for orientation. Therefore, it is mandatory to start either in the supravisceral segment or the ascending arch to have full right-left orientation using the position of the side branches and the renal vein. Without contrast injection, the risk of embolic events should be reduced, because pressure injection of oily contrast with a procedure immanent risk of debris or bubble embolisation is avoided.

Conclusion

IVUS is an easy to use and reliable imaging tool which has proven superiority to angiographic guidance in many ways:

- Radiation dose reduction for patient and staff
- Avoidance of renal complications by using zero iodinated contrast
- Better long-term outcome for dissections[13]
- Facilitated orientation in dissection without flow measurement[11,12]
- With the expected increase of the interventionist's work life radiation dose, the stochastic risk of radiation-associated diseases will further increase[1,14]

IVUS in combination with software mediated radiation reduction represents the only logical solution for this problem showing an 83–95% radiation reduction and zero contrast risk.

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From simple tool to "important instrument": IVUS in EVAR and TEVAR procedures

Based on evidence in the literature and their own clinical experience, **Fabrizio Fanelli** and **Gianmarco Falcone** detail key advantages of intravascular ultrasound (IVUS), including how the technology has come to be considered a "valid and safe tool" in the endovascular treatment of thoracic and abdominal aortic pathologies.

IN THE LAST FEW YEARS, intravascular ultrasound (IVUS) has gained more and more popularity in the evaluation of the peripheral vessel morphology. From a simple diagnostic tool, IVUS nowadays can be considered an important instrument to guide endovascular procedures in the thoracic and abdominal aorta.[1]

In fact, IVUS provides immediate and dynamic imaging of the thoracic and abdominal aorta as well as of their pathologies.

At the beginning, IVUS was commonly used for accurate sizing of the aorta and to perform an accurate morphological evaluation especially in case of dissections.[2]


Fabrizio Fanelli


Gianmarco Falcone

Operators are able to select the most appropriate treatment strategy

Several advantages are correlated with the use of IVUS. First of all, it allows a clear visualisation of the vessel lumen from inside with correct evaluation of the lumen diameter, lesion extension, and aneurysm diameter. Moreover, IVUS allows the evaluation of the plaque morphology and plaque geometry. In particular, in the case of thoracic and abdominal aortic aneurysms, IVUS permits to correctly analyse: diameter and length of the proximal neck, diameter of the aneurysm sac, diameter and length of the distal neck, patency of the aortic visceral branches, and diameter and length of the iliofemoral axis. In the case of a thoracic dissection, IVUS will provide useful information such as the location of the primary entry tear, other communications between the true (TL) and false (FL) lumens and re-entry sites.

On the basis of the data collected, IVUS operators are able to select the most appropriate treatment strategy.

In addition, IVUS provides real-time images of the dynamic environment of the aorta, which is important, as the aorta, especially in the thoracic segment, is going to expand significantly following heart beat. At the level of the abdominal aorta, the changes of the vessel diameter are less evident due to the major distance of this segment from the "pump". However, 30–40% of endovascular aneurysm repair (EVAR) patients have been found to require a stent graft with a different diameter; this modification, either in the thoracic aorta or in the abdominal aorta, might lead to an incorrect sealing and a consequent type I endoleak (Figure 1).[3]

Moreover, it is also known that the diameter of the thoracic aorta decreases significantly during blood loss. Images obtained before fluid resuscitation in patients with a ruptured thoracic aorta and severe blood loss may result in the incorrect measurement of the aortic diameters that do not represent the correct fully expanded calibre.

Using IVUS, it is pretty easy to follow and analyse the correct aortic diameters in all the different phases of the cardiac cycle.

The use of IVUS might therefore lead to optimal stent graft selection. It is known that once the stent graft is inserted, it cannot be modified, so a correct evaluation of the aortic morphology and diameters is crucial to achieve a final technical success.

Another advantage of IVUS over other imaging techniques is that it can be used directly in the angiosuite during the endovascular procedure. For example, during the deployment of an aortic stent graft, given the real-time images IVUS provides, the most optimal site for proximal and distal landing zones of the stent graft can be chosen.

IVUS is also able to clearly visualise the branches of the thoracic and abdominal aorta and might help in preventing unintentional coverage of side branches, which in turn improves the stent-graft sealing and fixation to the aortic wall.

Landing zone visualisation is particularly beneficial in tortuous anatomy

As a guidance to treatment, the advantages of using IVUS are more evident in case of tortuous anatomy. In fact, to better visualise the landing zone at the level of the proximal neck, using conventional subtraction angiography (DSA), several oblique projections are required. With IVUS, however, thanks to the intraluminal visualisation, a clear representation of the take-off of the branch vessels is always

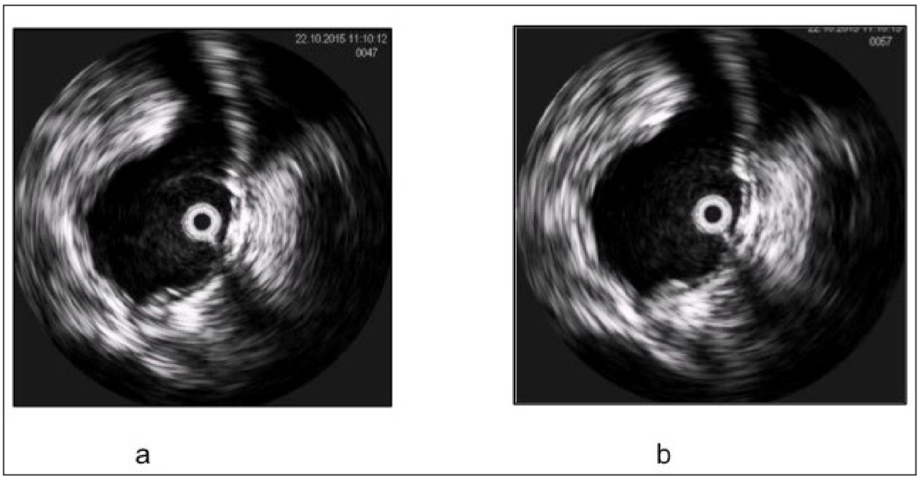

Figure 1. IVUS images acquired at the same level of the abdominal aorta (origin of the superior mesenteric artery) in the dyastolic (a) and systolic (b) phase. A different diameter was measured (23.2mm dyastolic, 25.6mm systolic).

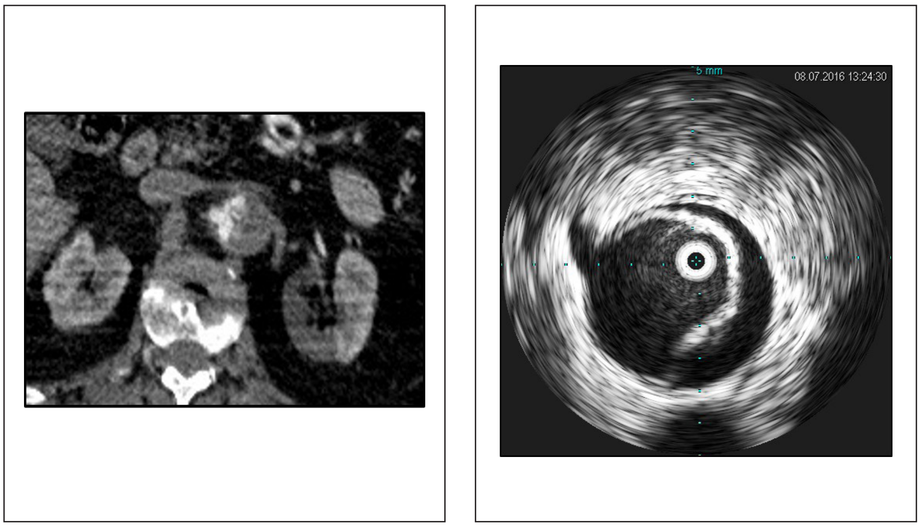

Figure 2. IVUS evaluation of type B chronic dissection. The aortic morphology is equivalent between CTA (a) and IVUS (b). Moreover, IVUS confirms the presence of the catheter inside the TL.

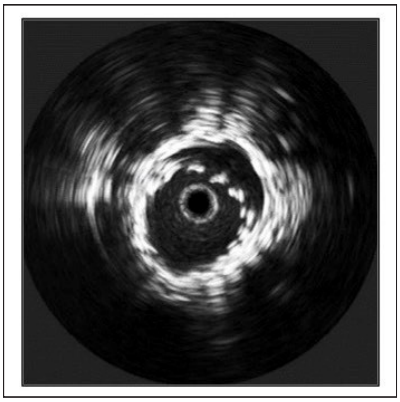

Figure 3. IVUS evaluation performed at the end of an EVAR procedure. The presence of a type I endoleak is evaluated with IVUS and shows an incorrect wall apposition of the stent graft.

possible. This allows a tremendous reduction in the amount of contrast media and of the radiation dose.[4]

It is well known that up to 30% of patients with an abdominal aortic aneurysm (AAA) suffer from chronic renal insufficiency with a high risk of developing contrast-induced nephrotoxicity (CIN). For this reason, several methods have been studied to reduce or avoid the use of contrast media such as carbon dioxide (CO^2), duplex-ultrasound as additional guidance, and intraoperative contrast-enhanced ultrasound. However, each modality has significant limitations especially when compared with IVUS.[5]

IVUS also has clinical utility in terms of its ability to define the often confusing series of entry and re-entry sites during treatment of aortic dissections.

Recognising the true lumen in an aortic dissection is one of the key steps during thoracic endovascular aortic repair (TEVAR) procedures, but confirmation of correct placement of the different instruments in the true lumen is always very challenging using only DSA. Conventional angiography alone has been shown to be inaccurate in confirming the presence of the guidewire within the true lumen.[6] IVUS allows real-time imaging to first ensure wire access in the true lumen, but also to ensure that one stays within the true lumen. For this reason, we routinely perform a full IVUS evaluation of the whole aorta prior to deploy a stent-graft in the setting of dissection to confirm its correct placement in the true lumen (TL; Figure 2).

Von Segesser demonstrated in a prospective study demonstrating that a dedicated programme of IVUS-only deployment of endografts was comparable to angiographic deployment in terms of technical success and mortality.[7]

Clinical experience shows reduced fluoroscopy time with IVUS

This is also confirmed in our clinical experience where 35 patients underwent EVAR under fluoroscopic and IVUS guidance avoiding the use of contrast media and reducing the radiation dose, not only for the patients, but also for operators. This group of patients was compared with a same number of patients with AAA who underwent conventional EVAR with fluoroscopic guidance plus contrast media injection. No differences in technical success were observed between the two techniques as well as in procedural time (mean IVUS 57.9 minutes vs. 49.3 minutes for the standard technique, p=0.1). On the contrary, a marked difference was observed for the fluoroscopy time (mean value 17.5 minutes for IVUS vs. 30 minutes for DSA; $p<0.05$) and radiation dose (patients: 700 mGy IVUS vs. 1.2 mGy DSA; operators: 0.021 mSv IVUS vs. 0.045 mSv DSA). Regarding contrast media injection, using IVUS, EVAR was conducted with no contrast, while a mean volume of 125ml was used in the conventional EVAR technique ($p<0.05$).

A final evaluation using IVUS after EVAR or TEVAR procedures will be important to confirm the correct wall apposition of the stent-graft without evidence of a type I endoleak (Figure 3).

Limitations

Despite the several advantages IVUS in TEVAR and EVAR procedures, some limitations are still present, such as the learning curve, increased procedural time, and costs. As is the case with all technologies, reimbursement for IVUS varies according to the country in which the procedure is performed. Moreover, as flow evaluation is not possible, IVUS does not allow for an evaluation of an endoleak.

Conclusion

An overall evaluation of IVUS confirmed that it can be considered as a valid and safe tool to guide all endovascular procedures in the thoracic and abdominal aorta.

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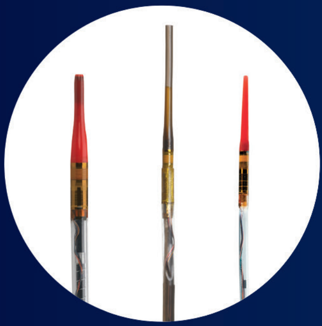

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