PANEL DISCUSSION

Venous Stent Maintenance: Improving Patency in Postthrombotic Patients

A comprehensive conversation about venous stent stenosis and occlusion, tackling why it's a problem and what causes it, the concept of "stent maintenance," when to intervene, next steps after crossing, and the role of medical management.

With Gerald O'Sullivan, MD; Kush R. Desai, MD, FSIR; Stephen A. Black, MD, FRCS(Ed), FEBVS; and Erin H. Murphy, MD, FACS

Gerald O'Sullivan, MD
Department of Interventional Radiology
University College Hospital
Galway, Ireland
gerard.osullivan2@hse.ie

Kush R. Desai, MD, FSIR
Associate Professor of Radiology, Surgery, and Medicine
Director, Deep Venous Interventions
Division of Interventional Radiology
Northwestern University Feinberg School of Medicine
Chicago, Illinois
kdesai007@northwestern.edu

Stephen A. Black, MD, FRCS(Ed), FEBVS
Professor of Venous Surgery
King's College London
Consultant Vascular Surgeon
Guy's and St Thomas' Hospital
London, United Kingdom
stephen.black@kcl.ac.uk

Erin H. Murphy, MD, FACS
Venous and Lymphatic Center
Sanger Heart and Vascular
Atrium Health
Charlotte, North Carolina
erin.murphy@atriumhealth.org

Why is venous stent occlusion problematic, and how is it similar to or different from arterial stent occlusion?

Dr. O'Sullivan: Veins are obviously fundamentally different from arteries, and venous stent occlusions are different in most ways from arterial occlusions as well. By its nature, the venous system is low pressure and often slow flow. Veins are much more compressible than arteries, and they still can be compressed even with a stent in place, by tumors for instance. The demands on veins are also much more severe than arteries. Typically, stents are placed in patients who are much younger and have a much longer life expectancy. It is quite a different proposition to place a venous stent in a 24-year-old female than to place an arterial stent in a 77-year-old man with diabetes and a lifelong history of tobacco use.

Dr. Desai: Postthrombotic venous obstructive disease is quite different than arterial occlusive disease on numerous fronts. The former affects a wider cross-section of society, including patients who are quite young. Therefore, the event horizon for issues to occur after deep venous stent placement is far longer than its arterial counterpart, and outcomes ideally would be durable for decades. However, both historical and current data suggest that stent obstruction for postthrombotic disease occurs at a high rate, with primary patencies in the high 60% to low 70% range in numerous contemporary trials. Thus, the risk of poor long-term durability, symptom/disability recurrence, and need for numerous reinterventions in some patients are significant.

Prof. Black: Venous stent occlusions present a unique challenge. Principally, this is because the biologic process results in formation of dense collagenous tissue within the stented segment if left for too long. The consequence is that we have very limited options to treat this. We lack tools to cross and to debulk. In essence, all we can do is repeat venoplasty (if you are able to cross), which does not provide a very elegant or efficacious solution.

Dr. Murphy: Managing chronic stent occlusions presents significant challenges, particularly in comparison to native vein occlusions and arterial stent occlusions. Initially, chronic stent occlusions are notably difficult to traverse. Arterial stent occlusions, while challenging, are often more manageable once the fibrous cap at the stent's edge is breached. In contrast, venous stent occlusions can exhibit a similar fibrous cap along the entire length of the stent.

Options for addressing stents that cannot be crossed transluminally are very limited. Venous stents occluded with dense scar tissue cannot be effectively managed with parallel pathway stents, a technique sometimes used in arterial cases. Additionally, bypass procedures have traditionally shown poor patency rates, especially in patients with poor inflow, which is common in this population.

Even when venous stents are crossable, the rubber-like scar tissue inside can complicate further intervention, as this tissue may not respond well to dilation. Unfortunately, beyond dilation, we lack optimized techniques or tools for removing extensive scar tissue from inside stents. The circumferential radial resistance of dense collagen scarring often exceeds the strength of stents available for relining previously occluded stents.

It is important to note that even with successful management of stent occlusion, there is often a decrease in long-term stent patency. Secondary thrombotic events can cause further damage and scarring to the stent inflow, compromising its function over time.

What kinds of issues cause stents to occlude?

Dr. O'Sullivan: Slow flow, low pressure, thrombophilia, extreme compression, and, most importantly, poor inflow.

Dr. Murphy: A review of stent occlusions from the ABRE investigational device exemption stent trial elucidated the primary causes of venous stent occlusions, which include incomplete treatment of diseased venous segments above the profunda/femoral confluence; inadequate inflow due to diseased femoral and profunda vessels; technical errors during the procedure; and issues with anticoagulation management, such as patient noncompliance or suboptimal medical decisions. Findings in clinical practice are very similar to the results we demonstrated in the trial. Overall, stent occlusions due to primary stent failure are rare with dedicated nitinol venous stents but can occur secondary to destabilizing stent fractures. Failures with Wallstents (Boston Scientific Corporation) can result from compression of the unsupported stent ends, which are weaker than the main stent body. Additionally, double-barrel Wallstents are susceptible to compression as they do not withstand sideloading well.

Prof. Black: I have previously written in *Endovascular Today* about reasons for stent failure—broadly, the main reasons are flow related, technical issues, and hematologic issues.[1] In our experience, the majority of cases are due to poor inflow. Houman Jalaie has created a classification of inflow disease, and this helps us understand the at-risk groups.[2]

Dr. Desai: The factors can be grossly separated into technical and nontechnical. Technical error occurs when an inflow lesion, most commonly in the common femoral vein, is not appreciated. The inflow into the stent is thus poor and the stent occludes. Similarly, when disease is incompletely bridged (ie, a stent is left short and does not cover a compression site), connection of "healthy inflow" to "healthy outflow" has not occurred. Under/oversizing of a stent can result in obstruction/persistent symptoms from inadequate luminal diameter or unrelenting back pain/neuropathy, respectively.

Nontechnical factors primarily center around issues in patient selection and management of antithrombotic therapy. There are times when the inflow is not suitable for stent placement at all, and a classification system is currently under review to aid operators in judging what type of inflow is likely suitable for a durable result.

In my opinion, the profunda/deep femoral vein is vital to a durable outcome, far more so than the femoral vein. Errors in antithrombotic therapy can be due to noncompliance or incorrect type/duration of anticoagulation (ie, direct anticoagulants in patients with antiphospholipid antibody syndrome). Working alongside our hematology and vascular medicine colleagues is vital to ensure that medical therapy is optimized.

How would you explain the concept of stent maintenance? Do all venous stents need to be maintained?

Dr. Murphy: Stent maintenance is a critical aspect of patient care that encompasses two key components: (1) Proper medical management, which often involves adequate anticoagulation for patients with thrombotic risk factors or high-risk stents; and (2) regular stent imaging surveillance, typically using duplex ultrasound, with axial imaging employed in select cases. Although maintenance protocols may vary based on individual patient factors, it is my professional opinion that all stents necessitate ongoing maintenance. This is particularly pertinent given our limited overall experience with newer stent products, which have only been available outside of clinical trials for the past 5 years.

Prof. Black: The major difference between arterial and venous patients is life expectancy after intervention. We know that venous patients are younger and therefore need to live for longer with a stent. Whatever we feel, it is naïve to believe that patients will not encounter problems over 40 to 50 years; even the perfect stent case may end up needing something. For this reason, I strongly believe we need to view treatment as a continuum.

We also need to remember that a stented vein is not a physiologic vein because it loses the ability for capacitance. Ultimately, we do not understand what impact this will have over the years. We therefore need to find better ways to treat the whole of the patient journey, not just focus on the stent.

Dr. Desai: The risk of stent occlusion is most significant in patients with postthrombotic disease. Fortunately, patients with stents for nonthrombotic disease have very high patency rates. As we will discuss, crossing and managing occluded stents is very challenging. Thus, we need to perform active surveillance to identify impending failures and intervene accordingly—ie, stent maintenance. There will be variability from patient to patient with regard to the amount of maintenance that might be necessary. For instance, a patient with inflow disease and genetic hypercoagulability may need more frequent maintenance than a patient with isolated postthrombotic iliac vein obstruction.

Dr. O'Sullivan: This is a fundamental concept because typically when we replace arterial stents, we put the patient on antiplatelets. Their wound should then heal or the claudication should improve, and we use those as surrogate markers for stent patency. However, in veins, symptoms can be more insidious, and abrupt swelling is relatively unusual. Patient often present 2 to 3 weeks after occlusion, or even longer. At that stage, recovering patency can be quite challenging.

Part of the issue with maintenance is making the patient aware that they need to take some ownership for the situation and contact you as their venous expert if they think they may have a problem.

When the patient comes in, you will take their history, complete a physical examination, and perform a color Doppler ultrasound. If the ultrasound is not definitive one way or another, then you need to perform another imaging test. Our go-to here would be CT venography. MRI has too much signal dropout to make it worthwhile, at least in my opinion.

When a stent is stenotic, when is intervention needed?

Dr. O'Sullivan: This is a very good question with no easy answer. Most people certainly do not have much interest in venous stenosis < 50%. However, if a patient is symptomatic with a 50% stenosis, this is at least as important as a 70% stenosis in an asymptomatic patient. It's a combination of the percentage of stenosis and the patient symptoms.

Dr. Desai: Early in my career, I tended to be cautious and would treat patients with significant buildup of scar material, primarily collagen, agnostic of symptoms. However, with experience, I have come to realize that unless symptoms recur when these "lesions" are identified, they may simply represent accommodation of the stent lumen to the diameter of the inflow. For example, if the inflow "column" is about 12 mm and the stent is 14 mm, a small rind of marginal scar may develop from areas where flow is nonlaminar. Currently, I only intervene if there is significant symptom recurrence that is attributable to the stenotic lesion, preferably demonstrated over longitudinal follow-up.

Dr. Murphy: Stent thrombosis becomes problematic when luminal narrowing is sufficient to cause recurrent symptoms or threaten stent patency. Any identifiable, correctable technical issues affecting stent inflow in the

presence of restenosis should be promptly addressed. In the absence of such specific technical concerns, reintervention often requires a judicious decision made in consultation with the patient on a case-by-case basis.

Prof. Black: The old adage was 50% stenosis, but this is really just a made-up number with no data backing it up. I now focus more heavily on patient symptoms. Some patients have a 60% stenosis but are fine; others start to get symptoms at 30%. We need a better understanding of what the critical level is.

What makes stent occlusions so difficult to cross? What are the needs in this scenario?

Dr. O'Sullivan: One might assume that stents should be easy to cross because the material typically isn't calcified as it may be in an artery. I think almost all of us found out that this is absolutely not the case. In fact, the contrary is true. There is a cap at the end of the occluded venous stent that is like grout you would use to seal a leak in your bathroom. It is extremely rubbery, quite hard, and really difficult to get through. Almost all of us have tried all sorts of very aggressive techniques, and getting through is difficult. For this reason, there is excitement about newer devices, such as the Traversa (VeinWay), which is specifically designed to cross these tough venous occlusions.

Once a wire does penetrate through this cap, it is also difficult to stay intraluminal within the stent. It's easier to stay intraluminal in a Wallstent than a newer, laser-cut option, as the wire may easily slip into the interstices.

Prof. Black: The material that builds up is extremely tough. We have done some studies that have shown it to be dense collagen, and as such, most devices have difficulty crossing. The challenge is to be within the stent, steer through the material, and be able to cross to the other side. I have tried multiple devices, and none have consistently worked. It is therefore gratifying to see the emergence of new technology like the Traversa.

Dr. Desai: When scar material builds up to the point that it results in complete luminal obstruction, it very challenging to cross these lesions. This material is dense, the anatomy is curved, and standard wire/catheter techniques are usually inadequate to cross these lesions. Operators have been using various needles for some time, and more recently, radiofrequency wires have shown some promise. The ideal tools would be able to safely and quickly navigate these obstructions by being steerable, rigid enough to pierce the material, and trackable once the lesion is crossed to facilitate completion of the intervention.

Dr. Murphy: Stent occlusions are often solid-core occlusions throughout compared to arterial occlusions that are easier to cross after the more difficult cap at the stent edge is traversed. Often, an approach from above and below the occluded stent is helpful. A support system is needed to traverse these occlusions. Lasers and radiofrequency ablation wires can be helpful. I find the larger cross-section of the laser technology to be more advantageous because the created lumen is larger and the laser is less likely to go through the stent struts.

You've gotten across the occluded stent: What do you do next? Do you place another stent, or is something else needed?

Prof. Black: Once across, you need to debulk. Again, this is where things fall short. None of the arterial devices work here, and we don't have a venous debulking tool. Simply ballooning and restenting leads to a worse problem in time. The density of the material prevents full stent expansion, and stents within stents create rigid pipes with no flexibility. This can prove to be an absolute disaster.

Dr. Desai: The natural reaction is to place another stent. However, this eventually leads to layers of alternating scar material and metal until the lumen becomes inadequate for venous flow. Until we see marked progress in the scaffold (stent) itself, we will need to focus on removal of scar material with devices that can effectively and safely remove or obliterate this tenacious material. Subsequently, local anti-inflammatory therapies to arrest the development of new scar may be of significant value.

Dr. Murphy: Once the occluded stent is crossed, body floss techniques can be advantageous. The response of occluded stents to dilation and restenting varies widely. Dilation alone can sometimes be effective, but this is typically more successful in stents that are patent and threaded rather than completely occluded. When stents are fully occluded, dilation remains the first-line option. However, the pathology becomes more complex, and the response to dilation is less predictable.

Stent relining is generally reserved for cases where stents can be dilated but may contain intraluminal chronic thrombus that requires smoothing. I do not recommend relining stents that cannot be dilated, as the stents themselves are weaker than noncompliant balloons and

cannot expand areas of disease that do not respond to dilation. Stent relining may also be indicated for primary stent failures from stent collapse or fracture.

What we urgently need are tools that can more effectively remove chronic scarring from inside the stents. Although current technology is progressing, in my opinion, it is not yet adequate for this purpose.

Lastly, after reopening an occluded stent, it is crucial to address any underlying issues that led to the occlusion. This may involve procedures to improve stent inflow or adjustments to postoperative anticoagulation regimens.

Dr. O'Sullivan: The next step here is to figure out what to do with all the debris inside the stent. At present, we are simply using balloon angioplasty, but most people have found that adding more metalwork is probably not a great idea. Personally, I aggressively and repeatedly balloon and try to avoid placing more stents.

Are there any medical management strategies to prevent stents from occluding in the first place?

Dr. Murphy: As previously mentioned, anticoagulation is a critical adjunct for stent maintenance in patients with thrombotic disease. Patients with post-thrombotic disease often retain risk factors for future recurrent events. These risk factors may include preexisting hypercoagulable disorders, residual inflow disease, limited mobility or reduced calf muscle pump function, cancer, and obesity. Therefore, it is essential to mitigate the risk of rethrombosis through appropriate anticoagulation management.

Prof. Black: There are a few ideas that involve the multimodal reason why stents block. It is not just about flow but also combating wall inflammation and the hematologic factors that drive thrombosis. We have seen good early data from the DEXTERITY studies showing a benefit of suppressing the inflammatory response, and Dr. José Diaz has spoken eloquently about the need for multipronged treatment. This may involve blood thinners in conjunction with statins, for example. I think the future is to work on a multipronged treatment strategy. It is not just the stent but all that needs to go around it.

Dr. O'Sullivan: I think that anticoagulation is key, and I prefer a twice-daily NOAC then a once daily. There's some evidence that adding antiplatelets may be a benefit, and there is also some evidence of some benefit with the introduction of anti-inflammatory medication. We've seen some benefit, at least in mice, in trials of Bullfrog (Mercator), where dexamethasone is injected into the wall of the vein. The preliminary data from a human trial (DEXTERITY-AFP) are also quite encouraging.

Ultimately, choosing your patient carefully and avoiding patients with poor inflow is probably the single biggest learning point.

Dr. Desai: Counseling a patient that they must be active participants in their care is of utmost importance. Compliance with anticoagulation is perhaps the most common cause of nontechnical failure that is not related to physician judgment. There is also exciting work being done in the realm of inflammation. We are seeing more routine use of high-dose statin therapies, and data are urgently needed to guide operators on optimal agent, dose, and duration. Beyond this, novel therapeutics that act upon the inflammatory cascade have significant future promise. ■

1. Black SA, Morris R. The unknowns of venous stenting: why do good cases go bad? Endovasc Today. 2019;18:65-66, 68-69.
2. Barbati ME, Avgerinos ED, Baccellieri D, et al. Interventional treatment for post-thrombotic chronic venous obstruction: progress and challenges. J Vasc Surg Venous Lymphat Disord. Published online May 20, 2024. doi: 10.1016/j.jvsv.2024.101910

Disclosures
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Dr. Desai: Speaker's bureau for/consultant to Cook Medical, Boston Scientific, Becton Dickinson, Medtronic, Penumbra, Tactile Medical, and Philips; consultant to W.L. Gore, Shockwave Medical, Asahi Intecc, Veryan, Cordis, Surmodics, Abbott, enVVeno, and Varian.
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