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VENOUS

Venous Obstruction: Achieving Optimal Outcomes

With Stephen Black, MD, FRCS (Ed), FEBVS; Kush R. Desai, MD; and Paul Gagne, MD, FACS



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What are the most important factors you consider when diagnosing and preparing to treat a patient with venous obstruction?

Dr. Desai: It's about setting expectations. Venous disease remains a disease you manage. It's not something that you necessarily cure. Once you have identified what the pathophysiology is and what measures you need to take to treat the patient, you need to set the appropriate expectations. The diagnosis part is challenging, and we talk about it on a daily basis. But what I think is missed sometimes is making sure you set appropriate expectations, including that the patient needs to play an active role in their own care. They have to be compliant with their compression, compliant with their anticoagulation, and, when necessary, have to help you help them.

Prof. Black: I agree with Dr. Desai that it is important to manage expectations. We generally make patients better, but there are very few people who we make completely fine. We can't undo damage in its entirety. A stent in a vein is not natural; it overcomes a problem of obstruction, but it doesn't return a vein to what it was before. We're trying to improve people's symptoms and quality of life. As part of having a comprehensive practice, you need to look at every part of the venous system. There isn't a diagnostic test that says "yes" or "no" in a binary fashion. It's about putting history and diagnostics together in a way that makes sense to treat the venous obstruction first. However, there may be other things you might have to treat afterward or perhaps leave. If you have a comprehensive practice, you avoid a confirmation bias like, "It must be varicose veins."

Dr. Gagne: Taking a very careful history and physical is critical. It also helps to go down the checklist of a differential diagnosis. We know that the list of potential diagnoses for leg swelling is long. You can have skin damage and discoloration from a variety of pathologies that are not just venous related. So, appreciating the differential diagnosis of some of the key findings in both history and physical exam is important. Two diseases can look the same but are not the same. They share some similar characteristics. A careful history and physical exam, along with considering the differential diagnosis, helps you arrive at the right diagnosis more times than not.

For patients with deep venous obstruction, how do you gauge outcomes?

Prof. Black: We don't have a standard measure of outcome. There's so much variation in what people are using. We need a much more defined standard set of measures that quantifies what regulators, payers, and patients want. We're working with the International Consortium for Healthcare Outcomes Measurement to define a standard set of outcomes. We need an objective measure, such as vessel patency on duplex scan. If you don't have a patent vessel, then everything else falls apart. We also need a clinical scoring system like the Venous Clinical Severity Score (VCSS) or the Villalta score and a patient-reported outcome measure that includes quality of life. Then, we need everyone to report outcomes in a consistent fashion.

Dr. Gagne: Patency and quality of life are hallmarks, but I also look at durability. I don't want to have a patient who feels pretty good the month after their procedure and then 6 months later says, "I'm right back where I started." You either had a placebo effect, or you treated the wrong problem with the same persisting symptoms. I think durability is an important part of the equation. One of the benefits of tracking quality-of-life outcomes is that it gives us a point of discussion with payers. It helps us and the patients, and it helps the payers understand where to put their dollars.

Dr. Desai: Get the patient to that expectation that you helped set. We tell them we're going to improve their baseline level of function and make it easier to get through their day-to-day necessities. Of course, we're going to assess patency. However, we want the patient to say, "I'm so much better." Then, we can remind them that they must continue doing their part to make sure they stay better. We know that the quality of metrics is important because we know that research data are the building blocks to push the field forward. From the general practitioner's perspective,

they don't want to spend a lot of time collecting outcome measures. However, you want to get a keen sense of what measures are meaningful for the patient. I advocate that everybody uses VCSS and Villalta, which are important for tracking your own outcomes internally.

During the interventional procedure, what things are you most concerned about?

Dr. Gagne: The two things I'm most concerned about are proper sizing and creating good flow. Whether it's a compression lesion or a post-thrombotic syndrome (PTS) lesion, you need enough lumen and inflow to make sure the stent stays open. Aggressive ballooning of the lesions before stenting is important where there may be fibrosis. Then, the stent along with postdilation will give you the expansion you need. As far as sizing the stent properly, in long-segment PTS lesions, the stent tends to be sized to the size of the balloon. With vein recoil, those stents are well fixed and don't embolize. For compression lesions, the vein on the contralateral side has too much variation. Instead, it's important to have the concept of anchoring to prevent migration. It's all about proper sizing, and intravascular ultrasound is probably the best way to do that.

Dr. Desai: One of the things I think about is why stents fail. They fail because of poor inflow and incomplete coverage of the disease. You want to ensure that inflow is sufficient to support a stent which crosses through the diseased iliofemoral segment; this is a more significant issue in post-thrombotic obstruction relative to non-thrombotic obstruction. Sizing is critical in non-thrombotic iliac vein lesions (NIVLs) because migration can be an issue, so you need to be diligent about how you size your stents and ensure you place stents on the longer side. As we're about to see from the work Prof. Black, I, and others have done, short and small-diameter stents can migrate. This is something that turns an outpatient procedure into a potentially catastrophic procedure. You also need to be aware of fracture and other complications to ensure you've optimized your procedure to the greatest extent possible and minimize those issues from occurring.

Prof. Black: The sizing decision is about risk mitigation. For acute and chronic patients, extensive scar tissue often holds the stent in place. I'm not that worried about migration. I'm trying to create a lumen that is big enough to compensate for the symptoms of the patient. In chronic PTS patients with long occlusions, I've ended up using 14-mm stents the majority of the time. My matrix has changed from using predominantly 16- to predominantly 14-mm-diameter stents. It's normal for us to take a 14-mm stent all the way from the groin to the confluence. There

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are no data to support that, but the risk of migration is not high. Our primary driver is creating a lumen that matches inflow vessels as much as possible and has smooth drainage of the leg.

With NIVL patients, the predominant risk is migration. I size those patients on the normal segment of the external iliac vein (EIV). I think the biggest conceptual problem is choosing a size based on the prestenotic dilation of the common iliac vein. Aortic disease is the analogy for me. We never size grafts for aneurysms based on aneurysm size. Why don't we do that in veins? According to the first principles of vascular surgery, I size the stent for the normal segment of vein, and we get a good anchoring point in the EIV. In practice, we end up with 16 mm for most NIVL patients. If you need an 18- or 20-mm stent, you have to ask yourself if this is genuinely an NIVL. If you can pass a 16-mm balloon through the lesion, I don't see how that causes significant venous outflow obstruction, even with a 50% stenosis.

What do you think are the most important factors in achieving optimal outcomes?

Dr. Desai: I split it up into non-thrombotic and post-thrombotic patients. In non-thrombotic patients, the most important factor is ensuring you've excluded other causes and that compression is probably the cause of their symptoms. Treating non-thrombotic patients is pretty straightforward. On the post-thrombotic side, patient compliance is a big factor. The two other important things are proper inflow to the stent and complete coverage of the disease. When you have all three, the patient will probably do a lot better for a lot longer.

Dr. Gagne: When talking about inflow and outflow, I don't think there's much difference between venous and arterial. In the venous system, you're going from a small vessel to a big vessel. In the arterial system, you're going from a big vessel to a small vessel. It's really about resistance to flow. If there is no resistance into and out of your stent, you typically have a successful, durable reconstruction. On the venous side, I think outflow is less spoken about because it's usually fixable. You can even extend up through an occluded vena cava to the level of the renal veins. On the other hand, inflow is not always fixable.

Prof. Black: For acute thrombotic and chronic post-thrombotic patients, it is flow, flow, flow. If you have good inflow, stents do well. All the data we have and all the publications say that if you have a relatively normal common femoral vein and good inflow, stents will do well. For non-thrombotic patients, the two most important factors are

(A) getting a diagnosis and diagnosing correctly so you don't stent patients who don't need stents, and (B) avoiding stent migration because it's literally the only thing that can go wrong. That's why stent sizing is important, because flow is not an issue. If a stent is placed for the right indications and properly sized and anchored, you will get great results.

Why do you think Zilver Vena (Cook Medical) is well suited to treat your patients?

Dr. Gagne: I like Zilver Vena in part because of its flexibility. Some stents do a good job of gaining lumen but also distort the veins because they're relatively stiff and want to get straight, rather than allowing for flexibility and conformability. Zilver Vena seems to be adequate for doing the job I ask it to do and not cause new or other headaches. That is where I've found it to work very well for my patients.

Dr. Desai: I take a lot of solace in the VIVO-US trial data,¹ which reflected a true, heterogeneous venous population. The trial included acute deep vein thrombosis, PTS, and NIVL, which reflects what comes in my door on a day-to-day basis. The trial showed outcomes in all three patient subsets. I can use that to not only consult patients but also know what kind of outcomes I can expect. Zilver Vena is a flexible stent that comes in a variety of lengths, allowing me to minimize the number of devices I need to place. From an economic standpoint, this also very compelling.

Prof. Black: We're dealing with a heterogeneous patient population. The data from the trials showed that all of the stents performed equally in a heterogeneous population. We need to improve at making decisions about why we choose different qualities of stents for different areas. There are pros and cons to the different devices. Having stents that are more flexible and less rigid and stents that are stronger and less flexible gives you choices when looking at different types of patients. If you have a patient with post-thrombotic disease in the groin who is an athlete and will be exercising a lot and stressing the stent, then you want something more flexible. Zilver Vena allows us to have that very flexible stent to focus on that group of patients who will benefit from greater flexibility. ■

1. U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED): Zilver Vena venous self-expanding stent. Accessed September 8, 2021. http://www.accessdata.fda.gov/cdrh_docs/pdf20/P200023B.pdf

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