Current Considerations in Venous Obstruction and Stenting

Key elements in recanalization and stenting in the chronically occluded IVC and iliac vein systems.

TIPS FOR SUCCESSFUL VENOUS OCCLUSION INTERVENTION

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The key to successful inferior vena cava (IVC) and iliac vein recanalization is to understand the anatomy. One must take into account the overall anatomic situation, inflow and outflow, or more precisely, the health of the common femoral veins and feeding veins (profunda and femoral), as well as the cephalic extension of the obstruction. It is therefore crucial to have good cross-sectional imaging for planning purposes. I have relied on CT venography with formatting in the coronal and sagittal view, but I also feel very comfortable using MRI. If the disease extends far proximal into the IVC to the level of the renal veins or even the hepatic veins, cross-sectional imaging will provide information regarding the renal vein patency and the hepatic veins. I also perform a duplex ultrasound examination of the lower extremity veins, which will give a better indication of the health of the common femoral vein and display prognostic indications on how widespread the postthrombotic changes are in the deep veins of the entire limb.

Procedures that only involve the iliac veins can be performed using local anesthesia and intravenous sedation, but IVC recanalization typically requires the use of propofol. For IVC recanalization, a urinary catheter is also placed, as these procedures can be prolonged. Patients are fully anticoagulated during the procedure with unfractionated heparin, with a target activated clotting time of approximately 300 seconds.

HOW TO CHOOSE THE ACCESS SITE

I select my approach based on the preprocedural imaging evaluation. For isolated iliac vein recanalization, my primary access choice is the right internal jugular vein, although I also like to have the ipsilateral groin prepped in case I cannot recanalize from the IVC. The reason for the jugular vein (remote) approach is that if there is involvement of the common femoral vein, profunda femoral, and femoral vein, I can more easily dilate the inflow vessels from above, as coming from below is much more challenging. The remote approach also gives you distance from the diseased area and allows for more precise distal stent placement. The challenge with the jugular vein approach is precise proximal stent placement (at the bifurcation), especially with stents that foreshorten significantly during deployment.

For the more complicated bilateral iliac vein and IVC occlusions, I typically have both groins prepared, along with the right neck. I then make my first puncture in the common femoral vein, where there is the least amount of disease present, and I will perform the recanalization all the way through the iliac veins and the IVC from there. I typically dilate the IVC and the ipsilateral iliac veins from that access and then puncture into the right internal jugular vein and place a 45-cm-long, 10-F introducer. I then recanalize the contralateral iliac venous system from the jugular vein access, which allows for inflow angioplasty on the more diseased side, and stents are placed accordingly.

CHOOSING EQUIPMENT

For stent selection, I have gone back to using Wallstents (Boston Scientific Corporation) for all of the iliac veins and the IVC procedures. I typically use stents no larger than 14 or 16 mm dilated to the nominal diameter in the iliac veins and 20- or 22-mm stents in

the IVC. I will typically dilate the IVC to 20 mm. For many years now, I have been using Gianturco stents (Cook Medical) inside of the Wallstents at the bifurcation, with the Gianturco stent (20 mm in diameter) extended approximately half a stent (1.7 cm) beyond the Wallstent. This opens up the bifurcation and helps with bringing the iliac vein stent into the bifurcation without compromising the lumen.

If the central iliac stents are compromised, I place 15-mm diameter Gianturco stents inside the proximal iliac stents, extending into the IVC stent from both sides. Proximally, I occasionally place 20-mm Gianturco stents extending proximal to the Wallstents if I think I need to support the lower border of the renal vein or hepatic vein inflow.

Recanalization and stenting of the chronically occluded IVC and iliac veins is a challenging procedure. It requires significant planning and preparation. Placing stents in an anatomic situation where either inflow or outflow is inadequate should be avoided. A successful procedure is gratifying, as most patients will experience significant improvement in symptoms and usually is lifestyle changing for the patient, making it possible for the patients to return to a more normal lifestyle.

EQUIPMENT CHOICE FOR CHRONIC VENOUS OCCLUSION

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The treatment of chronic venous occlusions is rapidly expanding, which means that we are increasingly trying to treat patients who we may have previously considered untreatable and are testing current equipment to the limit. I believe there are three broad areas that we have to consider.

CROSSING THE LESION

For most patients, it is possible to cross the occlusion with a combination of straight or curved stiff/semistiff Glidewires (Terumo Interventional Systems) and appropriate catheters; however, there are some lesions in which the occlusion does not allow for this. This becomes particularly challenging when crossing lesions that extend into the IVC. On many occasions, using the back end of a Glidewire may help gain access to a channel that can subsequently be crossed. In crossing venous occlusions, it is important to remember that unlike arteries, if you are not making progress, it is acceptable to pull the wires right back and try again. Rick de Graaf, MD, PhD, taught me that administering a regular, small-volume contrast injection as you make progress often allows direct visualization of a path across the lesion that may not be obvious on initial venograms.

On occasion, when there is wire access from both cranial and caudal ends, it may be impossible to connect the wires into a common lumen. In these instances, a technique described to me by Nils Kucher, MD, has been useful. An Outback catheter (Cordis/Cardinal Health) is passed from the caudal access point end and positioned adjacent to the cranial access wire. An Atlas balloon (14- or 16-mm diameter; Bard Peripheral Vascular, Inc.) is then passed from the cranial end and inflated adjacent to the Outback catheter. The Outback catheter is then manipulated into position, and the crossing needle is deployed until it bursts the balloon. Without withdrawing the needle, a 0.014-inch wire can be passed through so it coils in the balloon, which is then slowly withdrawn while advancing the 0.014-inch wire. This allows the wire to be advanced and then snared for through-and-through wire access.

STENTING COMPLEX LESIONS

The stenting of complex lesions involving both iliacs and the IVC is currently a challenge. Multiple stents need to be used to recreate a bifurcation, and this may lead to problems at the bifurcation when one or more stents compete and "crush" the contralateral stent. This issue may be overcome by simultaneously deploying the newer nitinol stents from both sides (Vici Verto [Veniti, Inc.] or Zilver Vena [Cook Medical]). A trouser configuration can also be constructed using balloon-expandable stents, as described by de Graaf et al.[1] It is important to recreate the bifurcation slightly higher (2–3 cm) than the natural confluence to avoid excessive angulation of the limbs (particularly the left) as they pass into the common iliac vein.

KEEPING THE STENTS PATENT

Stent patency is multifactorial and frequently related to flow or hematologic issues and not related to stent failure. In many cases, the stent is still at its nominal diameter, but the lumen has started to thrombose. Provided this is addressed early, it is possible to perform venoplasty in the lumen, using high-pressure balloons, which may need to be repeated a few times until the patient stabilizes. We are still lacking an optimal technique for dealing with this, as this repeated inflation is slightly crude and may lead to stent fracture. In addition, no large-diameter, high-pressure cut-

ting balloons exist. One of my colleagues, Athansios Diamantopoulos, MD, PhD, EBIR, has used a technique in which a buddy wire is placed alongside a high-pressure balloon, creating a virtual cutting balloon. This seems to be effective, but we certainly need better options for removing this thrombus buildup. Treating occluded stents is a real challenge if the window for early intervention has been missed.

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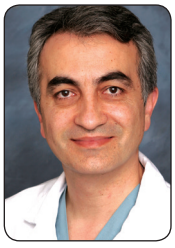
KEY QUESTIONS IN CANDIDACY FOR VENOUS STENT PLACEMENT



MAHMOOD K. RAZAVI, MD, FSIR, FSVM

As the role of venous obstructive lesions in various pathologies becomes better recognized, the importance of stents in alleviating the related symptoms comes into a much sharper focus. The correlation between venous stent placement and improved venous patency after catheter-directed thrombolysis for deep vein thrombosis has long been recognized.[1] Similarly, stent-supported restoration of outflow in patients with superficial venous disease and chronic venous insufficiency is gaining more acceptance.[2] As a result, there has been a steady growth in the number of patients undergoing venous stent placement in recent years. Thus, the pendulum of venous stenting is in motion, and as treating physicians, we must guard against overenthusiastic utilization of the procedure.

One of the major problems in the treatment of central venous obstructions is that we do not completely understand how to determine if a lesion detected on noninvasive imaging or in a recumbent patient undergoing catheter venography is hemodynamically significant. Complete occlusions in symptomatic patients excluded, defining the contribution of venous "stenoses" to patient symptoms remains a dilemma. It is well known that there is poor correlation between catheter venography and accurate determination of the degree of venous obstruction. Although the use of intravascular ultrasound largely overcomes this limitation of venography, there are inadequate criteria to determine hemodynamically "significant" stenoses on either intravascular ultrasound or contrast venography. The suggested 50% cross-sectional area reduction is neither widely accepted nor based on rigorous data.

Although it may seem logical to stent all apparent lesions, given the excellent patency and low procedural complications seen with venous stents,[3] there are potential drawbacks to the use of stents. Importantly, not all venous narrowings are hemodynamically significant. Thus, the placement of the stent may have no therapeutic benefit while adding to the cost. The benefits of stenting in nonthrombotic low-grade lesions await confirmatory studies. Furthermore, use of the new generation of large-diameter, high-radial-strength stents may expose patients to unknown risks, such as stent erosion into the venous wall or an increased predisposition to deep vein thrombosis in nonthrombotic patients. Therefore, until the data from the ongoing pivotal studies of dedicated venous stents become available, prudence dictates the avoidance of overzealous venous stent placement solely because it is the new thing to do.

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2. Raju S, Darcey R, Neglén P. Unexpected major role for venous stenting in deep reflux disease. J Vasc Surg. 2010;51:401-408.
3. Razavi MK, Jaff MR, Miller LE. Safety and effectiveness of stent placement for iliofemoral venous outflow obstruction: a systematic review and meta-analysis. Circ Cardiovasc Interv. 2015;8:e002772.

VENOUS-SPECIFIC STENT DESIGN CONSIDERATIONS

ERIN H. MURPHY, MD

The use of iliac vein stents for the treatment of iliofemoral or iliocaval obstruction has revolutionized the treatment of patients with chronic venous disease. Intervention can now provide substantial relief of severe chronic symptoms. However, despite the dramatic clinical advancements, technologic advancements have lagged. To date, there has been a relative paucity of technologic attention to the specific needs of venous stenting.

Currently, the Wallstent, designed for use in the biliary system, continues to be the most commonly implanted stent in the venous system. This stent performs well overall, with good flexibility and minimal risk for stent fractures, even across the inguinal ligament. However, there are several important limitations, namely weak radial force at the ends of the stents, inability for precise landing, and the closed-cell design, which all leave opportunities for improvement in venous stent design. In addition, there is a growing need to appropriately address obstructive disease extending into the iliac confluence and IVC, which, in our practice, is currently approached with multiple interlocking tracheobronchial Gianturco Z-stents.

Several dedicated venous stents are now in various stages of development and approval in the United States. It is clear that stents designed specifically for the venous system have unique requirements compared to arterial stents. Specifically, large stent diameters are required (up to 25 mm or greater in the IVC) with increased radial force throughout the stent length to address the significant recoil and fibrous nature of thrombotic veins. Ideally, a stent that combines this radial force with the strength to handle repeated flexion at the inguinal ligament over time without stent fracture is highly desirable. Improvements in deployment precision are also needed. To address the iliac confluence, open-cell designs may allow for increased flexibility in stent placement.

Ultimately, the development of a bifurcated device that functions similarly to a modular abdominal aortic stent graft might address the confluence more gracefully. Although in-stent restenosis is a pervasive problem after iliac vein stenting, the role for covered stents in the venous system is tentative, given the proclivity for thrombosis, especially in a patient population with increased rates of hypercoagulable disorders and often substantially compromised inflow. I think the possibility for antiproliferative agents delivered via drug-coated balloons or drug-eluting stents is intriguing, even promising, but unclear. Overall, venous technology is ripe for improvement, and I look forward to the pending advancements.

ENDOVASCULAR AVF TECHNIQUES TO FACILITATE TREATMENT OF DEEP VENOUS OBSTRUCTION

RICK DE GRAAF, MD, PHD

Endovascular repair of unilateral iliac vein obstructions has proven to be a successful treatment strategy with a low complication risk. However, stenting below the inguinal ligament into the common femoral vein is associated with lower technical and clinical success. This is mainly caused by extensive disease involving the common femoral vein tributaries. Postthrombotic sequelae, like fibrotic trabeculations and webs, may impede spontaneous venous inflow, compromising short- and long-term stent patency. This can be managed endovascularly by a stent extension into a single inflow vessel, increasing stent length and blocking several femoral vein branches, potentially affecting thrombogenicity. Alternatively, surgical desobstruction of the common femoral vein and orifices of the profunda branches is advocated in some centers; the flow through the stented track is optimized by an arteriovenous fistula (AVF), typically with a 6-mm PTFE graft. Major downsides of this "hybrid" procedure include groin incision, infection, lymph leakage, and early restenosis due to surgically induced scar tissue. Furthermore, primary patency is uncomfortably lower than endovascular recanalization in our experience. An endovascular method to enhance inflow might therefore provide an attractive alternative. Recently, novel endovascular AVF techniques have been introduced for different indications.

The Coupler device (Rox Medical, Inc.) creates a permanent, fixed-size anastomosis between the external iliac artery and vein and is being investigated for the treatment of structural hypertension, as well as other chronic disorders (Figure 1). The shunt, with a fixed

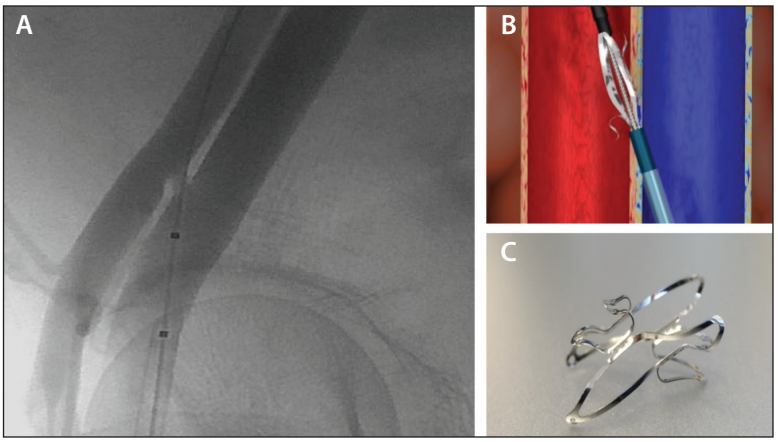

Figure 1. Angiographic representation (A) and illustration (B) of an AVF created by the Coupler device (C).

4-mm diameter, creates a fixed-volume shunt of 800 to 1,000 mL/min, resulting in an immediate reduction of effective arterial volume and total systemic vascular resistance, causing a clinically significant immediate and durable reduction of blood pressure. The diameter and volume of the conduit do not change over time. A recent randomized controlled trial of the Coupler device in well-matched therapy-resistant hypertension patient populations demonstrated an immediate and sustainable reduction in blood pressure upon device deployment.[1]

Another device, the everlinQ system (TVA Medical, Inc.), gained CE Mark approval in 2014 and is used to create a percutaneous fistula for hemodialysis access in the forearm (Figure 2). Specifically, a 4-mm fistula is created through the delivery of focal radiofrequency energy between two parallel catheters positioned in the ulnar artery and vein. Blood is transferred to the superficial venous system through a perforator vein. It has been shown to create a durable AVF without significant complications.[2] Naturally, alternative indications for endovascular AVF creation (eg, venous bypass surgery) are waiting to be scrutinized. The previously mentioned endovascular AVF techniques may be used to enhance flow through the recanalized iliofemoral vein tract, although, currently, there is no approval for this indication.

The location of an endovascular AVF should probably be found in one of the profunda branches. The superficial femoral vein should principally be neglected, because peripheral ischemic complications due to AVF creation must be avoided. However, the profunda vein anatomy is quite variable, and not all anatomically possible sites may be appropriate for an endovascular AVF. Endovascular AVF creation is limited by the extent of postthrombotic disease, thus an adequate-diameter profunda branch free of trabeculations should be chosen. Adequate cross-sectional imaging should be performed prior to identifying the ideal location (Figure 3).

Side-to-side anastomosis similar to those created by the Coupler device and the everlinQ system have favorable flow and wall shear stress characteristics that may limit intimal hyperplasia. Nevertheless, one-third of patients who had implants developed iliac venous stenosis at the side of the Coupler implant, presenting with discrete upper leg swelling and apparent loss of the desired blood pressure reduction benefits. A potential downside of endovascular AVF might be the necessity to perform a stent extension and to close the AVF sometime during follow-up.

In our experience, the surgically created PTFE-AVF loop is closed with an endovascular plug 6 weeks after primary surgery to prevent excessive restenosis or other complications. Specific closure devices to occlude an endovascular AVF are not available at the moment, so the most likely option would be to close the AVF with a covered stent, which increases costs and the risk of complications. Finally, the devices currently available to create an endovascular AVF are not specifically designed to enhance flow after recanalization of chronic iliofemoral

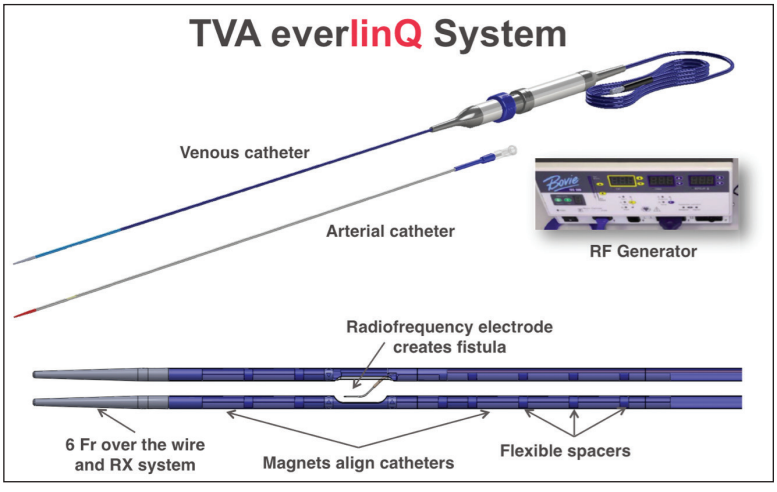

Figure 2. The everlinQ system.

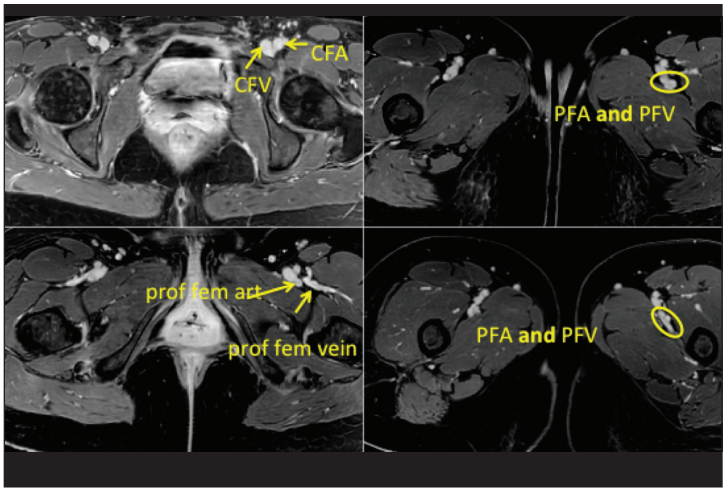

Figure 3. Magnetic resonance venography at the level of the groin showing the orientation of the common femoral artery (CFA), common femoral vein (CFV), profunda femoral artery (PFA), and profunda femoral vein (PFV) at different levels.

obstructions. Dedicated features might be needed to facilitate optimal AVF creation in deep venous obstruction treatment. For example, recent advances were made to the everlinQ system that include downscaling to 4-F catheters with increased length for better workability, which would also facilitate endovascular AVF creation in treating deep venous obstructions.

In conclusion, this exciting new endovascular AVF technology may further expand the indication for endovascular strategies to treat deep venous obstruction. Moreover, it might improve technical and clinical success, while at the same time lowering the risk of complications. ■

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