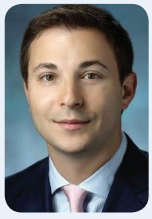
ROUNDTABLE DISCUSSION

Venous Stenting Perspectives: Current Best Practices, Trial Experiences, and Device Designs

WITH STEVEN D. ABRAMOWITZ, MD; STEPHEN A. BLACK, MD, FRCS(Ed), FEBVS; MICHAEL D. DAKE, MD; ERIN H. MURPHY, MD, FACS; GERARD O'SULLIVAN, MD; AND MAHMOOD K. RAZAVI, MD, FSIR, FSVM



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What are your most important tips for success in iliac vein stenting?

Dr. Dake: For the best outcomes, I find these practices to be most helpful:

- Strive for optimal thrombolysis of acute clot prior to stent placement.
- Take time to carefully evaluate the true size of the vein, accounting for residual disease of the vein, not only the luminal diameter prior to stenting; this is most accurately evaluated with intravascular ultrasound (IVUS).
- Treat all of the disease from good vein to good vein, even if this requires extending the stented segment below the inguinal ligament and/or into the inferior vena cava (IVC).
- Strongly consider the use of a dedicated venous stent.
- Avoid stent jailing of the contralateral iliac vein, if possible.
- Pay keen attention to tailored anticoagulation management intra- and postprocedure.

Dr. Razavi: I am sure my other esteemed colleagues will go over the important "dos" of venous stent placement, so I am going to focus on a few "do nots" of venous stenting:

- Nonthrombotic iliac vein compression is very common, but symptomatic obstruction is rare, so do not stent every venous compression you see. The decision regarding when to stent or when not to stent has to be data driven. Not every venous narrowing needs to be stented.
- None of the "rules of thumb" for what constitutes a clinically significant venous obstruction have been validated, including the 50% area reduction. Focus on symptoms and ask if an obstruction could be a causative factor before stent placement, especially if a narrowing is borderline.
- Do not undersize or oversize stents in veins. The misconceptions of "go big" and "go generously into the IVC" are based on a different era of venous stenting. You do not necessarily need to do either. Normal to normal is a good rule to live by.
- If you are used to Wallstents (Boston Scientific Corporation), do not assume nitinol stents behave the same (and vice versa). Performance characteristics of stents should be matched to the lesion characteristics.
- Lastly, please do not refer to venous in-stent obstruction as neointimal hyperplasia or venous intimal hyperplasia. Venous in-stent growths are usually thrombotic, so let's just call it in-stent growth until more pathologic confirmation of its nature becomes available.

Dr. O'Sullivan: As we have so many experts here, I am certain there will be some overlap, but my "essentials" include:

- Accurate preoperative imaging. Become familiar and preferably expert in CT venography (CTV)/magnetic resonance venography (MRV), IVUS, and transvaginal and abdominal ultrasound.
- Determine inflow accurately. The number of times I see postthrombotic patients who had the initial procedure performed through the common femoral vein (which itself is involved in the disease process and therefore must be avoided) is depressing. Get on the highway through some other route and stent from normal to normal.
- Adequate anticoagulation before, during, and after the procedure. Again, bleeding is far less of an issue than rethrombosis, so I want patients on full anticoagulation before, during, and after the procedure. Don't stop anticoagulation before the procedure. We use low-molecular-weight heparin preoperatively, intravenous heparin intraoperatively to achieve an activated clotting time of 250 to 350 seconds, and then low-molecular-weight heparin again postoperatively for 2 weeks. If the patient is reliable, then novel oral anticoagulants are OK (I like apixaban 5 mg twice daily); if you are uncertain, use warfarin. If there is an early thrombosis on warfarin and the international normalized ratio is 1.5, you have your cause right there—it's much harder to be sure with a novel oral anticoagulant.

Dr. Murphy: My tips include:

- Proper patient selection. Treat the patient, not the lesion.
- Use of IVUS to guide all steps of the procedure
- Stent from good inflow to good outflow without jailing the profunda or contralateral iliac vein
- Predilation with noncompliant balloons to the size of intended stents
- Use of adequately sized stents that mirror normal iliac anatomy. Keep in mind, sizing for nitinol stents is different than with Wallstents
- Proper postoperative care, including early anticoagulation and close follow-up

Dr. Abramowitz: Iliac vein stenting can provide immense relief for patients with a relatively low complication risk. To optimize patient outcomes, I advise keeping a few general tips in mind:

- Successful treatment of iliac lesions begins with preoperative imaging that allows for access site selection and intervention planning. Poor access choice can easily complicate or end a case.

- While performing the procedure, the careful use of IVUS both before and after stent deployment can eliminate many technical errors that can result in stent failure.
- Ensuring that the lesion is treated means the stented segment extends from healthy vein to healthy vein.
- When intervening from an infrainguinal approach, place your wire tip above the heart to avoid unintentional stent embolization.

Mr. Black: As always, case selection is vital. Patients with decent inflow, especially those with a relatively disease-free common femoral vein, will do better. Attention to detail is also vital, both in terms of technical aspects and medical management. On the technical side, the most common issue is not achieving good inflow and outflow. In particular, untreated inflow disease (residual scarring in the common femoral vein) leads to stent occlusion. On the medical management side, it is important to get the anticoagulation strategy right. One must ensure that patients are fully anticoagulated from the time the stent is placed. We confirm an activated clotting time of at least 200 seconds and then have a very clear anticoagulation strategy from day 1. Finally, patients are followed up with regular scans in the first 6 weeks. If stent thrombosis is quickly detected, it is much simpler to address.

What are your standard imaging practices in a case involving venous stenting?

Dr. Murphy: Intraoperatively, I use venography to provide a roadmap of the anatomy and develop an overall assessment of the patient's pelvic blood flow. I then rely on IVUS for an assessment of the degree of stenosis, to determine stent sizing, and the precise location of the iliac confluence and profunda femoral vein, and to decide on the cranial and caudal landing zones for stent placement. After stenting, I use IVUS to confirm stent expansion and apposition. A final venogram is obtained to assess flow.

Mr. Black: Imaging is divided into preprocedural and intraprocedural. In our practice, preprocedural workup is built on duplex ultrasound and MRV. During the procedure, I really rely on IVUS and believe that virtually all of the essential decisions, from a technical standpoint, depend on it. Venography is helpful at the end of the procedure to get an impression of how good the flow is and whether collaterals are still filling primarily.

Dr. Razavi: Preprocedural duplex ultrasound is standard in our practice, regardless of the indication for venous stenting (acute thrombotic, chronic postthrombotic, or nonthrombotic obstructions). If the iliac veins and/or IVC are not visualized on ultrasound, we would move to other cross-sectional imaging such as CTV or MRV in cases of chronic or suspected chronic iliocaval occlusions.

Intraprocedurally, catheter venography is supplemented with IVUS, which is performed for accurate sizing of balloons and stents, as well as to check the final results. IVUS is also very helpful in determining the extent of involved segments and where to and where not to stent.

Dr. Abramowitz: Preprocedure, I use ultrasound on each patient to assess the extent of disease, which is a critical step in determining appropriate venous access for the case. For almost all patients, I also perform indirect CTV or MRV. This is particularly important in patients with bilateral symptoms, those with ultrasound results showing common femoral vein involvement, a concern for an occlusive May-Thurner lesion, and those with a history of iliofemoral or iliocaval deep vein thrombosis (DVT) or IVC filter insertion.

During the procedure, I always use IVUS in addition to venography. In addition to improved lesion identification demonstrated by the VIDIO trial, IVUS also helps me minimize radiation exposure, size for stent selection, assess for inflow lesions, and confirm appropriate stent deployment. In particularly challenging iliocaval reconstruction cases, I have also used cone-beam CT to confirm wire location and stent deployment.

Dr. O'Sullivan: Preoperatively, I use direct CTV in chronic cases and indirect CTV in acute cases. Otherwise, I fully agree with Dr. Razavi. In essence, CTV is harder to make a mess of. MRV is very operator dependent. I routinely get sent 20 to 30 sequences in an MRV, and perhaps two have any useful diagnostic information. If the MRI center you use for your arterial work thinks they can use the same techniques, they are just plain wrong. Intraoperatively, I use fluoroscopy, with more and more IVUS, because it uses less radiation, is repeatable, and very accurate. Postoperatively, I use color Doppler ultrasound at day 1, CTV at 6 weeks, and clinical evaluation thereafter.

Dr. Dake: Preprocedurally, I use CTV or MRV as appropriate to provide overall regional evaluation of venous disease. Intraprocedurally, I use fluoroscopy, conventional catheter venography, IVUS, and cone-beam CT, if appropriate. Postprocedurally, I use ultrasound at day 1, CTV at 4 to 6 weeks, and ultrasound at 2, 6, and 12 months or as indicated.

What is the ideal role and timing of IVUS in optimizing outcomes?

Dr. Abramowitz: First, IVUS can prevent overstenting in this patient population. Without validated cross-sectional area reduction standards for stenting nonthrombotic iliac vein lesions, interpractice standards and use of IVUS can prevent unnecessary stenting and consistent delivery of care.

When stenting is performed, predeployment IVUS allows for a more accurate assessment of vessel diameter and lesion length. The operator can also identify important anatomic landmarks, such as the iliocaval confluence. When treating chronic venous occlusive lesions, it will also verify appropriate intraluminal wire presence and prevent accidental stent deployment in collateral vessels. Postdeployment IVUS confirms suitable stent-vein wall apposition, appropriate luminal shape, and correct stent-to-stent overlap. Judicious IVUS use during each stage of the procedure can improve the likelihood of achieving uncompromised technical success. This, and the added benefit of lower radiation exposure and contrast utilization, can only improve patient outcomes.

Dr. O'Sullivan: For me, IVUS is best utilized in only two situations: (1) landing a stent precisely in the common femoral vein, femoral vein, and/or profunda femoris vein; and (2) after stent placement to ensure adequate dilatation.

Dr. Murphy: IVUS should be utilized for all decision making in deep venous stenting cases. With proper use and understanding of the images obtained, the vast majority of complications can be avoided.

Dr. Dake: Without a doubt, the value of IVUS for guiding venous stent procedures in iliac veins is now widely recognized. IVUS contributes unique and valuable information apart from conventional venography and does more than simply confirm contrast venography findings. It provides the most accurate diagnostic evaluation of disease burden, vein size, and geometry; location of collateral veins preintervention; and poststent placement, it identifies untreated segments of disease, degree of stent expansion, and any areas of focal stent distortion or compression that may need to be addressed.

The use of IVUS involves cost considerations, but experts find that the incremental information IVUS offers is often responsible for adjustments in procedure planning, proper stent selection, and valuable endpoint assessment information poststent deployment, which may indicate the need for further treatment to achieve an optimal result.

Mr. Black: IVUS has value in the diagnostic workup where there are clear features of chronic venous hypertension but standard imaging is inconclusive. All the imaging modalities are complimentary and I do not depend entirely on one. Principally, in our practice, IVUS guides accurate stent placement, evaluation of the inflow, and ensures that stents are fully expanded with no residual compression at completion.

Dr. Razavi: Although use of IVUS is common and helpful in venous stent placement as previously mentioned, it is important to point out that we have not yet proven that its use changes or optimizes outcomes. Having said that, IVUS is a useful imaging modality to assess venous dimensions and also distinguish involved versus uninvolved venous segments (hence, its use to determine the size and extent of stents). In cases of venous compression, radial dimensions of the vein are often difficult to accurately determine with catheter venography, and IVUS is then used. We have also found IVUS to be useful in interrogating the poststent lumen for residual narrowing or presence of clot.

What is one key lesson you have learned from a suboptimal outcome, either your own case or a vicarious experience?

Dr. Razavi: Stents without adequate inflow and compromised outflow are doomed to occlusion. Most failures in venous stents are thrombotic events; hence, optimal anticoagulation is also critical in acute and chronic postthrombotic occlusions. In patients with hypercoagulable conditions, I prefer an initial regimen of low-molecular-weight heparin to oral anticoagulation for 4 to 8 weeks before switching to oral medications. I should clarify that the latter is based on anecdotal experience rather than on robust data.

Mr. Black: I believe it is a failure to not base one's knowledge solely on those who have gone before. Primarily, this stems from the belief that arterial techniques could simply be transposed to the veins. They are entirely different. Spend time learning from others and make only novel mistakes—then teach!

Dr. Dake: In my experience, one of the most critical determinants of procedural success and clinical benefit for patients is complete treatment of disease, not only the most obvious critical focal lesions. Undertreatment for fear of placing too much metal or because of an underappreciation of disease severity or the full extent of disease, is a harbinger for postprocedural problems.

Dr. Murphy: Strict adherence to detailed operative technique and proper stent configuration during the initial operation is key to success. Failure to do so can result in suboptimal clinical outcomes and a higher risk of postoperative stent occlusion. In turn, stent occlusion secondary to technical failures or attempts at complex stent configurations gone wrong (eg, double barrel, Y configurations) can be extremely difficult or impossible to fix. This can leave patients with permanent discomfort and various levels of disability. In summary, these cases must be done the right way, with attention to detail the first time for optimal results.

Dr. O'Sullivan: It is important to trust your gut. If the inflow isn't perfect, it will fail; if the stent doesn't look right, it will fail. In many ways, the standard is higher than in arterial work.

Overall, where do you see the most significant potential pitfalls in this procedure? How are they best avoided?

Dr. Razavi: Here are a few pitfalls, the first in the list being the most important in my opinion:

1. Lack of proper procedural planning prior to the procedure. The operator needs to determine the anatomy and flow patterns before the procedure. In other words, which veins are patent and which ones are diseased, how low or high the disease extends, what would the potential flow patterns look like after stent placement, and what is the best venous access given the venous map in any particular patient.
2. Wire passage through collaterals rather than the occluded lumen in chronic occlusions. Various projections may be necessary to ensure intraluminal wire passage. Avoid collaterals, especially in the iliocaval occlusions, some of which may communicate with the epidural venous plexus, a place you don't want to be.
3. Venous access into a diseased common femoral vein. This prevents adequate treatment of the inflow, leading to a higher likelihood of stent failure. Access should be in the femoral vein (my preference), the internal jugular (when the common femoral vein is diseased and the femoral vein is occluded), or the contralateral groin (my least favorite).
4. The assumption that venous recanalization and stenting are simple. I think enough said.

Dr. O'Sullivan: Not being aggressive enough with ballooning before and after stent implantation.

Dr. Abramowitz: Issues with stent sizing and stent deployment are often the root cause of many stenting-related complications. The Wallstent has design elements that have shaped stenting techniques to date. Dedicated venous stents may alter technical considerations and procedural steps even for experienced operators. Predilatation of lesions to achieve appropriate stent expansion becomes more important in deploying the first generation of self-expanding venous stents. Additionally, significant oversizing may lead to stent-related complications such as erosion, arterial compression, and vein wall deformation at the proximal or distal landing zone, impairing patency. Previous confluence stenting techniques, such as extending the stent into the cava or placing a Gianturco stent within a Wallstent, may no longer be required. It will be important for each operator to consider the stenting technology they are using and adjust their approach accordingly.

Mr. Black: The biggest potential pitfall is failing to work together as a group and ensuring that we collect appropriate data and rigorously evaluate our outcomes. If we genuinely believe that these treatments work, we need to prove it with robust data (which report both technical outcomes but also quality-of-life and health economic outcomes) to show it. If we can't, we should stop until we can improve.

Dr. Murphy: The greatest pitfall in venous cases is the false assumption that these cases are easy. This leads to technical failures resulting from a lack of diligence. Venous cases require an attention to detail to ensure good, sustainable results. This includes following the recommendations discussed earlier in the panel. Adequate predilation is mandatory. Further, stents must be sized sufficiently but accurately. The nitinol stenting experience differs here compared to Wallstent use. Nitinol stents need to be precisely sized and cannot tolerate generous oversizing the same way that Wallstents can. The most common pitfall I see is reliance on venography for procedural guidance. This technology is inaccurate in determining the degree of underlying disease. In addition, it is falsely reassuring when determining the location of the confluence cranially or the health of the vessel at the caudal stent landing zone. This mistake underlies many stenting complications. It is important to understand that there is no level of provider proficiency that overcomes the shortcomings of venography. These shortcomings are not with the provider but with the technology.

What do you see as the most common technical error in venous stenting procedures?

Dr. Dake: The best way to avoid failure is to pay close attention to accurate pre- and intraprocedural

imaging to assess the full extent of disease and to focus on the poststent appearance at the completion of the procedure and within the first 24 hours postprocedure to ensure complete coverage of disease without residual narrowing.

Mr. Black: The most common error I see is either failing to stent beyond the May-Thurner compression point and leaving the stent short or failing to treat to obtain good inflow.

Dr. Abramowitz: Failure to stent the entire diseased segment is the most common technical error I encounter. The stent should extend proximally and distally into a normal flow segment of vein. In instances of postthrombotic syndrome or long occlusive lesions, this may require stenting across the inguinal ligament into the common femoral vein. Care should be taken to reposition the sheath or catheter well proximal to the stented lesion for completion ascending venography and IVUS to ensure appropriate identification of any potentially missed inflow lesions. Anticoagulation or antiplatelet therapy will not maintain patency in a stent with poor flow.

Dr. Murphy: The most common technical error that I see is failure to properly use IVUS to identify stent landing zones. Failure to do so is essentially a violation of one of the key principles of vascular surgery, namely the need to ensure good inflow and outflow. Venography is inadequate in this regard and is falsely reassuring for both identification of the iliac confluence as well as for identification of a distal healthy landing zone. Misidentification of the iliac confluence can result in landing stents too low and missing more cranial disease, while landing them too high can risk jailing the contralateral iliac vein with eventual risk of contralateral DVT in a small subset of patients. An improper distal landing zone is one of the most common reasons for early stent occlusion. In the majority of referrals I get for occluded stents, there is evidence of chronic disease in the 1 inch or so below the stent that likely explains the occlusion. Distally, stents need to be landed in the largest and least diseased segment above the profunda. It is OK to cross the inguinal ligament. Importantly, landing zones should be selected based on IVUS prior to venoplasty.

Dr. Razavi: An inadequate overall approach and stent strategy (or mis-strategy) is the most common technical error in these procedures. This includes over- or undersizing of balloons/stents, stented segments being too short or too long, insufficient stent overlap (when needed), or stenting a location that would not help (no inflow, for example). A wrong strategy usually emanates from an incomplete understanding of patients' symptoms and anatomy.

Dr. O'Sullivan: The selection of undersized stents and balloons seems to be most common, as well as puncturing the common femoral vein.

What are you generally looking for in a venous stent? Envisioning a future scenario in which multiple, unique platforms are available in your clinic, which anatomic/case-based factors would most influence device selection? In other words, how would you match stent features to patient needs?

Mr. Black: We need stents that provide strength at compression points and flexibility at the ligament. This may well come down to a closed-cell design above the ligament and open-cell/braided design to cross beneath the ligament and extend below into the common femoral vein. There are no data to support this yet, but I am sure selection will improve as we analyze the data and evaluate the patterns of stent failure. In addition, we need to understand whether there will be any value for stent coatings and what those should be.

At the moment, we do not have enough detailed information about the causes of stent thrombosis/stenosis to know what we need to add (if anything). Hopefully, we can utilize the roadmap of evolution in the coronaries and arterial intervention to innovate quickly and appropriately.

Dr. Razavi: The easy answer is the obvious one—stents with adequate radial force and crush resistance that come in appropriate sizes. But, this may prove to be an oversimplification of the requirements for venous stents. It took us awhile to realize the optimal performance characteristics of stents for the arteries, and as such, I have no doubt that the same will be true in the veins. Although crush resistance may be the most important characteristic in the common iliac or renal veins, radial force and flexibility may be more desirable in the chronic occlusions of common femoral or external iliac veins. Presently, we do not have enough robust hypothesis-driven studies to judge.

The results of the recently completed and currently ongoing venous stent trials may shed some light on these and other questions such as: what is the influence of lesion length or location; does chronic outward force matter (similar to arteries); given that nitinol stents tend to open to their nominal diameter, would gross oversizing cause penetration into adjacent organs

over time (similar to IVC filters); what is the impact of stent fractures; should venous stents be coated and with what; do stents prevent or improve superficial venous reflux disease; and should an 18-year-old with benign iliac vein compression get a stent? If you think you know the answers, stay tuned. We will probably be proven wrong in many aspects of venous stents.

Dr. Murphy: The ideal venous stent should be specifically designed to address the needs of venous lesions in the venous system. Importantly, these needs are not arterial. The stents need to provide both radial force to resist the scarring seen in postthrombotic disease, as well as crush resistance to withstand external forces that may be exerted by crossing vessels or other external structures. Further, the stent has to be flexible and durable enough to withstand the bending, shortening, compression, and torsion that occurs with hip flexion, as the majority of the stents are required to cross the inguinal ligament. Easy and precise deployment is a necessary improvement in the venous stenting technology to allow predictable landing with preservation of the femoral and iliac confluences. Lastly, stent sizes and lengths need to match the needs in the venous system, including stents that are large enough to mirror normal anatomy (≥ 14 mm) and long enough to prevent stent migration (generally ≥ 80 mm).

Dr. Dake: There is general consensus that the ideal venous stent would incorporate the best blend of flexibility, radial force, scaffold coverage, and deployment accuracy. However, that is a lot of variables, so the perfect dose of each ingredient may vary from one interventionalist to another depending on the particular application or lesion treated. Indeed, it may be that the precise recipe for the ideal venous stent is elusive, and different stent designs may prove necessary to best manage the range of iliac venous lesions.

One thing is for sure, the recent heightened attention of the field to the desirability and potential benefits of dedicated venous stents has allowed investigators to evaluate a wide range of improved device designs that promise to provide a welcome addition to the management of iliac venous obstruction.

Dr. Abramowitz: A lot has been said about the need for the first generation of dedicated venous stents to be more accurate in deployment with improved flexibility, high radial force, and high compression resistance. However, iliofemoral venous obstruction encompasses a vast array of lesion locations and characteristics. A "one size fits all" stent may not apply in venous stenting, and simple changes in these design elements can result in significant differences patient outcomes. Dr. Murphy's analysis of outcomes compared with stenting techniques at the confluence has demonstrated this.

Ideally, we should see a variety of pathology-specific stents engineered to meet these needs. For instance, large-diameter stents designed for use in the IVC to treat caval occlusive lesions will require high radial force and crush resistance but may not necessarily need the flexibility required to traverse the curves of the pelvis. The ideal stent for treating confluence lesions may have an open-celled, beveled shape, which would come at the expense of the necessary strength required to prevent fracture upon repeated flexion of crossing the inguinal ligament. Stents designed to resist focal compression in isolated nonthrombotic iliac vein lesions may not be produced with the same size matrix as those of long, tapered stents idyllic for treating long postthrombotic syndrome lesions. Needless to say, it will be important to continue to compare and evaluate outcomes related to stent design and anatomic location.

What updates can you provide on the progress of any trials you are currently participating in?

Dr. Razavi: The 12-month data collection and analysis are complete in the VIRTUS trial.

Mr. Black: I have been involved in the VERNACULAR trial studying the Venovo venous stent (BD Interventional) and VIRTUS trial on the Vici venous stent (Veniti, Inc), both of which have now completed recruitment. I am currently a Principal Investigator (together with Dr. Murphy) for the ABRE investigational device exemption study (Abre stent, Medtronic), which has recruited well, and so far, I am delighted with the progress. It looks likely that this study will complete recruitment ahead of schedule. Hopefully, once this study is completed, we will be able to utilize the data, together with other studies, to evaluate which patients have good outcomes and where the issues have been and to better shape our future understanding of when and how to treat these patients.

Dr. Murphy: As Mr. Black mentioned, we currently serve as Coprimary Investigators for the ABRE stent trial, sponsored by Medtronic. The study is designed to evaluate the use of the Abre stent in individuals with iliofemoral venous outflow obstruction. The study is set to enroll 200 patients across 35 different study sites in the United States and Europe. Many of these sites, including mine, are currently enrolling. ■