# Best Practices for Avoiding Venous Stent Migration

## With Stephen A. Black, MD, FRCS(Ed), FEBVS, and Karem Harth, MD, MHS, RPVI


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Migration of venous stents is of significant clinical concern because the heart is a common site of migration and may result in surgical intervention for stent retrieval. A review of the available literature on venous stent migration was conducted in 2022 by Sayed et al, reporting that 82.6% of migrating stents were ≤ 60 mm in length, 93.6% were ≤ 14 mm in diameter, and 41.6% occurred ≤ 30 days from stent placement.[1] These findings are similar to reports of iliac vein stent migration within the FDA's MAUDE (manufacturer and user facility device experience) database. A total of 67 stent migration cases have been reported between March 2019 and May 2023.[2] Where data has been provided within the complaint, most of the MAUDE cases were in patients classified as May-Thurner/non-thrombotic iliac vein lesion (NIVL), more than half occurred with stents 60 to 90 mm in length, and all NIVL-related migrations occurred with stent diameters ≤ 16 mm. Of these, the only migrations reported with stents > 14 mm in diameter occurred in the subclavian vein and inferior vena cava (IVC). The fact that less than half occurred within 30 days is of further concern, indicating that later migration with poorly placed stents may be outside of traditional surveillance windows.

The growing link between stent migration and NIVL is not surprising. NIVL patients can be challenging to treat, and their condition is perhaps the least understood. There is no consensus on the hemodynamic significance of their focal lesion. Relative to postthrombotic patients, who would often require recanalization of occluded iliofemoral segments, NIVL patients have focal lesions that vary in degree of stenosis and may not all be fixed. In fact, various maneuvers may be required to confirm whether they are fixed and thereby more appropriate for stenting. Anatomically, NIVL patients may also have a fairly dilated prestenotic segment, which has implications for both venous stent landing and sizing (both length and diameter). These are some of the more subtle considerations an operator must consider when treating a NIVL patient compared to a postthrombotic syndrome patient. It is important for the clinician to be aware of these aspects in order to achieve success in their techniques and positive clinical outcomes.

**How prevalent is venous disease in your practice? What case mix or pathologies compose most of your venous stenting practice (eg, acute deep vein thrombosis [DVT] vs chronic/postthrombotic syndrome vs NIVL patients)?**

**Prof. Black:** My entire practice is dedicated to the treatment of venous disorders. We see a good mix of acute and chronic presentations and focus mostly on these pathologies. In our practice, we treat a minority of patients with NIVL pathology, and the bar to intervene is set quite high.

In our practice, the patient needs to have clear symptoms that fit with iliac compression—claudication or leg swelling involving the lower leg and thigh for example—as well as radiographic, venographic, and intravascular ultrasound (IVUS) findings of significant obstruction. The later findings are a stenosis of at least 60%, clear collaterals, and evidence of webs and trabeculations on IVUS. We also look to ensure the lesion is fixed (ie, no change on Valsalva maneuver). If in doubt, we take the view that no stent is better.

**Dr. Harth:** I have a mixed practice of both arterial and venous disease, with venous disease now comprising about 60% of my practice. Specific to my deep venous stent practice, in decreasing order of frequency, I treat acute DVT, postthrombotic/chronic venous disease, and NIVL lesions. In the latter two clinical scenarios, the most common indications for venous intervention include disabling venous claudication or active ulceration/recurrent healed ulceration. NIVL cases are few and far between, as most of my patients with edema or advanced venous disease respond well to management of their superficial venous disease as a first step.

**Recently, more venous stent migrations have been reported, yet only five (four in VIRTUS[3] and one in VIVO[4]) were reported from the investigational device exemption (IDE) venous stent trials. What might be contributing to the real-world reports of migration?**

**Dr. Harth:** It is very concerning to see such stark differences between trial data and real-world practice events. In trial-based studies, we have very controlled and selected patients and scenarios, with highly skilled operators doing the interventions. The unrestricted release of new FDA-approved devices opens up opportunities for use to a varied pool of operators who will have similarly varied results. Unfortunately, this will result in negative outcomes that are not evident in trial-based research. Additionally, venous stenting is fairly "new" to some operators. Inaccurate translation of arterial-based concepts and techniques into the venous space also leads to poor deployment and application of dedicated venous stents.

**Prof. Black:** IDE studies are, by nature, very tightly controlled with select centers. I think the real-world migration has by and large been in patients with possible NIVL lesions. In the cases of migration that I have reviewed, where we have had imaging to look, they almost always did not even have a clear lesion. I think the difference between the studies and so-called "real world" is predominantly an issue of appropriateness of treatment.

**Have you ever experienced a stent migration firsthand? If so, what were the circumstances? How did you manage the migration, and what techniques did you use to move the stent or secure the stent in place?**

**Prof. Black:** I have had one stent move in a NIVL patient marginally on implantation, but apart from that, I have not had any stent migrations. In that single case, I snared the end of the stent and repositioned it before extending it with an additional stent that locked the stent in the pelvis. The stent that moved was the contralateral stent of a case where we were placing parallel stents at the confluence to extend down both limbs. It was a technical error on my part.

**Dr. Harth:** I have not experienced any embolizations or delayed venous stent migrations. I have had one intraprocedural local migration of a dedicated venous stent in the setting of a complex redo reconstruction of a previously placed and thrombosed Wallstent™* endoprosthesis (Boston Scientific Corporation). This patient had prior kissing Wallstents, and one stent thrombosed due to poor outflow. After recanalization of the thrombosed stent, I proceeded with addressing the outflow and iliac confluence with dedicated kissing venous stent reconstruction. I placed a 12- X 100-mm stent into the right external iliac vein (EIV) with the plan to build up to a 14-mm stent based on IVUS imaging of the current Wallstent, which I was going to realign. The 12- X 100-mm stent deployed well, but when I advanced the 14-mm stent through it to complete the kissing stent portion and iliac confluence reconstruction, the 12-mm stent moved cephalad and migrated 3 to 4 cm. I addressed this by jailing it with the 14-mm stent cephalad and caudal and ultimately completed the reconstruction. In hindsight, I should have built down rather than up or maybe just used a 14-mm stent the entire way, as this would have given me better oversizing on the inflow side of things.

In general, avoiding any migration with good technique and thoughtful procedural maneuvers are most important. IVUS is mandatory to facilitate this, as well as proper sizing. The greatest challenge is in the NIVL patients. Some important technical points include (1) ensuring the lesion is fixed and not affected by respiratory maneuvers, hydration, or patient positioning; (2) avoiding short stents; and (3) landing a long single stent from the common iliac vein into the EIV to nail and secure the stent.

**What factors are most important for determining if a patient is an ideal candidate for venous stenting?**

**Dr. Harth:** The most important determining factors in deciding on the ideal candidate for venous stenting include the following:

- Clinical appropriateness/indication for venous stenting first and foremost
- Adequate anatomy
- Compliance with medical regimen (anticoagulation if postthrombotic/acute DVT)
- Compliance with follow-up/surveillance

I generally reserve venous stenting for patients with disabling venous claudication or active ulceration/recurrent healed ulceration. Edema is challenging and not very responsive to venous stenting. I will also rule out and treat superficial lower extremity venous disease first prior to any deep venous interrogation.

In my postthrombotic patients, I perform a detailed duplex evaluation of the profunda and femoral vein for inflow in addition to a diagnostic venogram. Anatomy must be suitable for endovenous reconstruction. I also tell patients that my procedures are only as good as their ability to follow through with the medications I prescribe and the follow-up/imaging I require to assure things are optimized long term. If a patient refuses anticoagulation or follow-up, then there is no point in proceeding with intervention.

**Prof. Black:** They need to have pathology that is related to the symptoms! If you search for compression in patients presenting with mild ankle swelling for example, you will massively overtreat. First, does the patient actually have venous outflow obstruction, and does the outflow obstruction explain the symptoms? Second, I want to ensure there is a good flow. This is never an issue in NIVL but is important in acute DVT and chronic cases where good inflow is likely the biggest determinant of success.

### What do you consider to be the key considerations for successful venous stenting, and how do device selection and stent sizing factor in the context of avoiding stent migration?

**Prof. Black:** Successful venous stenting starts with appropriate patient selection—treating patients, not lesions found on imaging. I am not sure that device selection is a huge factor. I think it is much more about getting the size right. The review we did shows that small and short stents migrate. I routinely use longer stents for NIVL that are well anchored in the pelvis (never < 120 mm in length). I therefore size predominantly on the inflow vessel, which is the EIV. I am not worried at all about covering the internal Iliac vein, nor do I think the "metal burden" that is mentioned is an issue, particularly so with open-cell, laser-cut nitinol stents where the material density is low.

**Dr. Harth**: To me, success is all about the clinical outcome. If there are no symptoms or mild/unimpressive symptoms, then there is no reason to treat/stent. If I have decided I have an indication to treat and proceed, then I eagerly await to see my patients to hopefully have made an impact in their clinical problem. Device selection is likely more of a user preference—as long as the device is used appropriately and where indicated. Focusing on NIVL and stent migrations, I use the EIV as my landing/sizing vessel to ensure good fixation of my stent.

### What protocol do you follow and recommend for optimal pre-, peri-, and postimaging?

**Dr. Harth:** The clinical indication and timing of imaging may vary across patient pathology. As an example, preprocedure imaging will be different for an acute DVT patient than for a postthrombotic patient. The main difference is in the preprocedural imaging for the postthrombotic patient. This requires a bit more interrogation as described above (detailed duplex ultrasound of inflow vessels and diagnostic venography). I will also obtain a CT scan depending on prior surgical history or the presence of an IVC filter. In NIVL patients, I will obtain a transabdominal pelvic venous duplex ultrasound to interrogate for the possibility of a NIVL lesion, and most of these patients also have a venous insufficiency study by nature of my algorithm. Procedurally, IVUS is mandatory to ensure the most accurate diameter is obtained, and I also use IVUS during intraprocedural maneuvers to understand if the lesion is fixed or dynamic. Postprocedurally, I see all patients at 1 month with an extremity duplex and a transabdominal pelvic duplex evaluation of the venous stents. At 3, 6, and 12 months and annually, I repeat the pelvic venous duplex ultrasound of the stents at the time of a clinical visit. I heavily rely on our vascular laboratory for a significant portion of venous stent imaging.

**Prof. Black:** Imaging is all about a combination of different modalities. Duplex ultrasound is the bedrock for both pre- and postvenous stenting. I combine duplex with cross-sectional imaging (MR venography) preoperatively, which gives me maximum anatomic information, and then use IVUS routinely intraoperatively in conjunction with venography. It is about combining the respective strengths of the different modalities to give a clear overall picture. They are completely synergistic.

In NIVL patients, you cannot base decisions purely on imaging. You need to be clear that there is a significant lesion. To do this, I combine imaging with ensuring the patient is hydrated, breath holds, and Valsalva maneuver and balloon pull through to ensure I am treating only lesions that are significant.

### Do you have any concluding remarks to share?

**Prof. Black:** I am sure we will see advances in diagnostic tests in the next several years that will allow us to choose patients better, but in the interim, we need to recognize that migration is a clinician problem, not a device-related problem. Stents placed properly in appropriate patients do not move. If we don't focus on proper patient selection and allow migration to become an issue, we will do all the patients who actually need treatment a disservice.

**Dr. Harth:** The availability of dedicated venous stents for patients with deep venous pelvic disease brings a new sense of excitement in the venous space. It is important that this excitement and enthusiasm is matched by a sense of personal responsibility to learn proper techniques and appropriate indications as one adopts these devices into practice. It is important to realize that techniques and devices will evolve and improve as well, and that also needs to be on our radars. ■

*Disclosures*
*Prof. Black: Consultant to Medtronic, BD, Cook, Boston Scientific Corporation, Surmodics, Veryan, Inari, and Philips.*
*Dr. Harth: Consultant to Medtronic, Boston Scientific Corporation, Cook, GE, and Inari.*

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