**A clinical guide to Deep venous stenting for chronic iliofemoral venous obstruction**

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**Abstract**

Introduction: An increase in endovenous interventions for deep venous pathologies has been observed. This article aims to provide an overview of the role of venous stenting in the management of chronic conditions affecting the deep venous system of the lower limbs, with a focus on intervention relating to the vena cava and iliofemoral venous segments.

Method: An overview of literature on the minimally invasive venous stenting procedures that are being increasingly used in management of chronic conditions affecting the deep venous system of the lower limbs.

Results: We discuss key areas of interest to a venous specialist practicing in this area, including: diagnostic imaging in chronic deep venous disease, with a focus on the use of intravascular ultrasound in this context; treatment of chronic venous outflow obstruction, including the rationale and structural indications for stenting, current guidance regarding stent placement, and fundamental points to consider during decision-making (endophlebectomy and stenting, stenting across the inguinal ligament, optimal sizing of venous stents, extension of venous stenting to beyond the common femoral vein confluence, the role of thrombolysis useful in chronic venous disease, and arteriovenous fistulae); outcomes and initial reports of stenting; and the future of venous stents.

Conclusion: Deep venous stenting has become a key treatment option for chronic (thrombotic or non-thrombotic) obstructive venous disease. Dedicated venous stents and intravascular ultrasound represent important technological advances in the minimally invasive treatment of symptomatic chronic deep venous obstruction, which previously required open surgical reconstruction.

**Keywords**

DVT, endovenous, catheter-directed lysis, thrombolysis, venous stent, post-thrombotic syndrome, May-Thurner syndrome

**Introduction**

Deep venous stenting has grown in popularity over recent years and is now an accepted treatment strategy for patients with both acute and chronic venous obstruction, as well as patients with manifestations attributable to compression of the iliac vein (non-thrombotic iliac vein lesion [NIVL], May-Thurner compression1 or Cockett’s syndrome) which is frequently described; compression the left common iliac vein occurring where it crosses posterior to the right common iliac artery is the most common variant. Presence of chronic, repetitive compression at this site causes fibrosis of the vein, with intraluminal synechiae and spurs that result in stenosis or occlusion of the lumen9.

Where intervention is indicated, although open surgical strategies exist, endovascular techniques in treating venous outflow obstruction resulting from NIVL are currently felt to be more appropriate in the majority of these patients2.

The chronic sequelae of deep venous thrombosis (DVT), known as post-thrombotic syndrome (PTS), include persistent pain, swelling or ulceration that occurs in almost half of patients within 1-2 years3,despite adequate anticoagulation therapy3,4, and carries significant negative impacts on quality of life5 and on the economy6.

The underlying pathophysiology of PTS is elevated ambulatory venous pressure that develops as a consequence of persistent venous obstruction and/or reflux7. A proportion of occluded vein segments in the lower extremities will at least partially recanalize with time. This recanalization process results in the creation of a new channel(s) through the thrombus, re-establishing a proportion of pre-DVT blood flow through this venous segment7. Given the important relationship between the radius of a channel and the flow within it, partially recanalized thrombus and collaterals often afford insufficient venous flow. Complete recanalization has been documented in approximately 53% of patients with lower extremity venous thrombosis by 3 months after presentation of the acute episode8.

Unlike balloon angioplasty within arteries, when the residual venous stenosis resulting from a post-thrombotic process is treated by balloon venoplasty alone, there is resistance to dilatation with a high rate of recoil and recurrence3. This is an important consideration in the management of venous outflow obstruction, highlighting that venoplasty alone appears suboptimal and indicating the role of stenting to maintain venous patency following venoplasty.

May-Thurner syndrome is a key example of a NIVL and is frequently described; compression the left common iliac vein occurring where it crosses posterior to the right common iliac artery is the most common variant. Chronic, repetitive compression at this site causes fibrosis of the vein, with intraluminal synechiae and spurs that result in stenosis or occlusion of the lumen9.

The available literature shows that the cumulative experience of venous stent placement in patients with chronic obstructive lesions (NIVL or PTS) continues to increase, however the evidence, particularly with regards to randomised controlled trials, supporting this practice remains limited11.

This article aims to provide an overview of the management options which are now available to patients with chronic venous disorders, with particular emphasis on the minimally invasive venous stenting procedures that are being increasingly used in management of chronic conditions affecting the deep venous system of the lower limbs, with a focus on intervention relating to the vena cava and iliofemoral venous segments. In addition, infrainguinal lesions involving popliteal and tibial veins are beyond the scope of this paper, however are mentioned as important in relation to maintaining venous inflow and hence patency of more cephalad venous stents. Moreover, it provides a brief overview of intravascular ultrasound (IVUS) imaging that is often used to guide endovenous stent procedures.

Dedicated venous stents are available on the market (Figure 1), however, clinical trial comparison between different stent types are lacking51.. A number of venous stents have received approval from the Food and Drug Administration (FDA) for use in the USA [e.g., **Vici Venous Stent®** (Boston Scientific, Marlborough, MA, USA, **Zilver® Vena TM** (Cook, Bloomington, IN, USA), **VenovoTM Venous Stent** (BD, Franklin Lakes, NJ, USA)], while others have received approval for use in Europe [e.g., **Vici Venous Stent®** (Boston Scientific, Marlborough, MA, USA, **Zilver® Vena TM** (Cook, Bloomington, IN, USA), **Sinus Venous** (Optimed, Ettlingen, Deutschland), **VenovoTM Venous Stent** (BD, Franklin Lakes, NJ, USA)].

In general, dedicated venous stents have been designed to incorporate and allow good visibility, flexibility and expandability, permitting appropriate management of most complex venous lesions through endovascular means12. However, because of the perceived trade-off between stent flexibility and radial force/crush resistance, some believe that a single “perfect” deep venous stent does not currently exist and that, alternatively, the type of stent used should be tailored to the needs of the specific situation. Some cases and anatomical locations require more flexibility, others (for example crossing the inguinal ligament) there is a risk of stent fracture, with some demanding increased crush resistance and, hence, stents designed with these characteristics in mind can be selected accordingly.

**Diagnostic imaging in chronic deep venous disease**

*Duplex ultrasound*

Venous duplex imaging is the first line imaging method in the diagnostic workup of chronic venous insufficiency (CVI). It provides information about the type (reflux with or without obstruction) and anatomic extent of disease.

*Tomographic imaging*

Additional pelvic imaging studies, such as CTV or MRV imaging, are needed to assess the extent of disease in the iliocaval segment especially in the case of inadequate information from duplex ultrasound (for example when not able to adequately visualize the iliocaval segment due to overlying bowel gas or the presence of a pelvic mass)14. In addition CTV/MRV are obtained to exclude extravascular disease-causing obstruction, such as neoplasms or retroperitoneal fibrosis14.

*Intravascular ultrasound*

Intravascular ultrasound (IVUS) imaging has emerged as a promising intraoperative diagnostic tool35 because the inaccuracy of transfemoral venography in the delineation of the iliac venous outflow obstruction has been increasingly recognized36. The extent and severity of obstructive lesions appear greater on IVUS as compared with venographic findings, and even severe obstructions may go undetected with venography, giving IVUS a higher sensitivity and greater diagnostic yield1,37. The use of IVUS imaging is not only important for diagnosis but is also essential for accurate stent placement.

*Clinical guidance for the use of IVUS*

In 2011, the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) provided their practical guidance regarding the care of patients with varicose veins and associated chronic venous diseases41. They suggest that IVUS should be used selectively in those patients with suspected or confirmed iliac vein obstruction. IVUS is an important imaging tool in assessing the morphology of the vessel wall, identifying lesions such as trabeculations, spurs, synechia, frozen valves, mural thickness, and external compression that are not visualised with conventional contrast venography. Furthermore, it provides measurements permitting accurately assessment of the degree of any stenosis. At present, IVUS is felt to be the gold standard and should be used generously in symptomatic patients in whom outflow obstruction is suspected42. The presence of a morphologic obstruction resulting in a reduction in flow lumen area of more than 50% measured by IVUS has arbitrarily been chosen as criteria to consider proceeding to deep venous stenting43,44. Limiting workup of patients with significant chronic venous disease to duplex ultrasound alone will not suffice, especially when views of the deep venous system are limited cephalad to the inguinal ligament42.

Not only is IVUS an invaluable diagnostic tool, its use is also essential at the point of stent insertion to determine the extent of the lesion for appropriate stent placement42. The diseased vein segment is frequently more extensive on IVUS than indicated by venography45,46, this being important as the success of deep venous stenting relies upon stenting from healthy vein segment to healthy vein segment.

*Clinical results of IVUS*

In the study reported by Neglén and Raju (2002)38 and involving 304 limbs in 294 patients, the authors reported that “in a comparison with IVUS as the gold standard, venography had a poor sensitivity (45%) and negative predictive value (49%) in the determination of a venous area stenosis of >70%.” Similarly, the stenotic area was significantly more severe when measured with IVUS when compared with venography. They concluded that determination of morphologically significant stenosis using IVUS appears to be the best available method for the diagnosis of clinically important chronic iliac vein obstruction. In another study by the same authors39, venography was only 66% sensitive, with 34% of venograms appearing ‘normal’, whereas IVUS had a diagnostic sensitivity of >90%. In a recent prospective multicentre international cohort study (VIDIO Trial)40, IVUS was found to be more sensitive than multiplanar venography for diagnosis of iliofemoral venous obstruction. Moreover, IVUS imaging resulted in a change in treatment plans in 57 of 100 patients in the study, from no endovascular intervention based on venography alone to a stenting procedure. The authors recommend the use of IVUS to both diagnose iliofemoral venous obstructions and plan endovascular treatment.

**Treatment of chronic venous outflow obstruction**

*Rationale and structural indications for stenting in CVI*

Compression therapy is the basis of management of CVI in many cases. We would advocate that an initial 6 month trial of conservative management with appropriate compression therapy should be initiated in the first instance and that, should this not be successful in meeting the patient’s goals of therapy, deep venous intervention can be explored14.

One issue to overcome when treating obstructive venous lesions is to withstand the compression by adjacent structures (e.g. the right common iliac artery in May-Thurner syndrome) or intraluminal fibrosis, which can be extensive. Stenting of the iliac veins can be considered in symptomatic CVI patients in with presence of non-thrombotic obstructive venous lesions in the iliofemoral and caval segments with a degree of stenosis of more than 50%, often in the presence of venous collaterals14,15.

Many of endovenous procedures for the deep venous system are performed under general anaesthesia as patients cannot tolerate multiple painful venoplasties in complex iliocaval lesions and to avoid increased postoperative pain, in addition, these procedures can be lengthy, unless if there is localised stenosis so the patient could be done under local anaesthesia with use of moderate sedation.

*Current guidance regarding stent placement in the context of CVI*

Recent European and American guidelines recommended endovenous stenting for severe

obstructive venous disease14,26 but recognise that the evidence supporting these recommendations is weak 20. The American Heart Association (AHA) gives a weak recommendation for endovascular treatment (recommendation class IIb, evidence level B)16. However the 2017 European Society of Vascular Surgery (ESVS) guidance recommends that stent placement after percutaneous transluminal venoplasty be considered for patients with chronic deep venous obstruction (recommendation class IIa, evidence level C)35.

Regarding deep venous stenting procedure, an open-label, assessor-blinded, multicentre, randomized controlled trial (the Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy (C-TRACT) Study47) was launched in May 2018 to compare catheter based-endovascular therapy with no-endovascular therapy in 374 patients presenting with disabling iliac-obstructive PTS. We hope that the C-TRACT trial will contribute robust data in this area.

*Fundamental points to consider during decision-making*

Deep venous stenting is currently the first interventional option in the management of both thombotic and non-thrombotic chronic venous obstruction. However, it is important to emphasize a number of fundamental points to consider during the decision-making process when managing patients with CVI due to venous obstructive lesions in lower limbs:

1. Endophlebectomy and stenting

The decision as to whether endophlebectomy (surgical disobliteration with removal of synechiae and septae from within the occluded venous segment) is necessary is principally related to whether a common inflow can be maintained into the stent system from the profunda and femoral veins. The decision to proceed to endophlebectomy is often based on IVUS in addition to the pre-operative imaging, intra-procedural venography and patient factors (e.g. hostile groin) 27. The principal question is whether a sufficient landing zone for the stent can be identified (however small), which will allow the inflow vessels from the lower limb to run into the stent. Furthermore, evaluation needs to assess whether any trabeculations, once stented, will be pushed away or toward the profunda confluence. In the latter scenario, this will compromise inflow, and the patient may then require an endophlebectomy.

If a common luminal channel is identified, stenting the entirety of the diseased venous tract is feasible with the aim of landing the caudal stent as precisely as possible just cephalad to the profunda vein origin. On the other hand, if a common inflow channel cannot be identified and trabeculations are clearly extending into both the femoral and profunda veins, an endophlebectomy may be necessary27. Moreover, presence of severely impaired inflow from both PFV and SFV should be excluded as a possible contraindication for consideration of any kind of invasive treatment (with or without endphlebectomy), as even ‘perfect’ CFV and iliac veins will not improve lower limb drainage if the PFV and SFV are severely impaired31.

Endophlebectomy can be accompanied by a temporary arterio-venous fistula formed in the groin with a loop fistula28. There are reported complications with endophlebectomy including a significant rate of groin wound infection up to 30%29.

*Table 1: Results of deep venous stenting studies for chronic venous disease.*

1. Stenting across the inguinal ligament

Stenting across the inguinal ligament is another controversial topic. In the arterial system, the published literature traditionally did not recommend stenting across joints, because of increased risk of in-stent focal neointimal hyperplasia and compression or fracture of the stent by joint motion with decreased long-term patency25. This view has been relaxed to some extent with the availability of arterial stents engineered for use in such circumstances, e.g. the popliteal artery at the level of the knee joint. Therefore, there is a concern that such issues would arise when stents are placed under similar circumstances in the venous system and, thus, negatively affect outcomes. However, experience obtained from arterial stenting may not necessarily be transferable to the venous system25. In contrast, Neglen et al25reported that it is safe to extend stenting across the inguinal ligament when the obstructive lesion involves the common femoral vein; failure to do so in this situation will frequently result in early occlusion of the stent. The cumulative patency rate was not significantly different in limbs stented cephalad and caudal to the inguinal ligament (7% and 11%, respectively, P = 0.6393)37. The study concluded that the patency rate is not related to the length of stented area or the placement of the stent across the inguinal ligament, however is dependent upon the aetiology and whether the treated post-thrombotic obstruction is occlusive or non-occlusive. In recent study reported by Black et al15, a durable secondary patency rate (82% and 87% at 1 and 2 years follow up, respectively), with substantial symptomatic resolution has been reported in patients with chronic post-thrombotic occlusions. In addition, no significant differences were found in clinical and stent outcomes in patients with stenting terminating above or below the inguinal ligament, suggesting that stenting across the inguinal ligament is not a significant factor in patency and clinical outcomes15.(Table1)

1. Optimal sizing of venous stents

Iliac vein stents should be of a size that provides outflow with low resistance to normalize the elevated venous pressure in the extremity. The ‘optimum’ stent size is more difficult to determine than it would seem with Raju49 recently reporting different methods including, duplex scan data from healthy volunteers, patient IVUS data, Poiseuille equation and Young’s scaling rule. Table 2 summarises Raju’s recommendations. Raju49 recommended grading the severity of stenosis on the basis of this optimal calibre, rather than contralateral lumen as a comparator. Moreover, he recommended over-sizing the stent by 2 mm beyond the recommended calibre, with post dilatation restricted to the optimum outflow calibre for the segment. Under-sizing a stent is more harmful than slight over-sizing as this may become a cause of a permanent iatrogenic stenosis that is not easily corrected. Raju49 concluded that the optimal stent size is unknown but should match the normal calibre at a minimum. Currently there is no evidence to suggest the optimal option and it should be guided by the discretion, experi­ence and expertise of the vascular interventionalist. But according to our experience, Sinus venous XL flex stent is usually used for IVC and VICI Veniti stents are used for iliac and femoral venous segments.

*Table 2: Recommended stent diameters and post-stent IVUS areas for different vein segments49.*

1. Extension of venous stenting to beyond the common femoral vein confluence

Stenting caudal to the common femoral vein confluence offers further challenges and most guidelines discourage stenting below the inguinal ligament, more specifically beyond the common femoral confluence14,30. This is in part owing to the presumed risk of stent-related complications, i.e., fracture or kinking. First experience with dedicated venous stents highlighted some favourable characteristics, making caudal stenting a feasible option32. There is also concern regarding compressing or ‘jailing’ the profunda vein, negatively impacting on inflow into the stent. Moreover, after failure of primary surgical treatment, the only remaining option may be distal stent extension to preserve inflow. Lastly, there is also a concern regarding stenting of veins with small calibres.

The aim of a study reported by De Wolf et al32 was to investigate whether secondary venous stenting into one inflow vessel caudal to the common femoral vein is feasible and clinically effective after primary endophlebectomy for deep venous recanalization fails. It concluded that stenting through the femoral confluence into a single inflow vessel is a feasible bailout option if primary hybrid intervention fails. Results indicate that relative high patency rates and clinical improvement were obtained where primary, assisted primary and secondary patency were 60 %, 70% and 70%, respectively at 12 months follow up period. Furthermore, Villalta score reduced by 6.1 points (p < 0.001), and venous clinical severity score by 2.7 points (p = 0.034)32. Actually, many interventionists have abstained from stenting below the inguinal ligament, even in cases where the common femoral vein is involved in the disease25. However, stenting below the inguinal ligament should be considered and is supported by a recently reported study by Black et al15.

1. Is thrombolysis useful in chronic disease?

Catheter directed thombolysis is used in the treatment of acute iliofemoral DVT33, particularly considered with symptoms of less than 14 days duration. Successful clearance of thrombus drops precipitously after 3-4 weeks’ symptom duration2. Outcomes of thrombolysis in the context of chronic DVT, with the aim of dissolving any fibrinous strands present in a chronically obstructed vein or treating any superimposed acute venous thrombosis, have been disappointing with a technical success rate of 66.7% of patients prior to endovascular reconstruction with balloon venoplasty and stents2. This likely due to the fact that, in chronic DVT, thrombus is replaced by synechiae and septae with a significant type I collagen content, which are not amenable to clearance by thrombolysis. In general, recommendation from our experience is against considering thrombolysis during deep venous stenting procedure.

1. Are arteriovenous fistulae required to maintain patency of iliac venous stents?

Although some centres have used arteriovenous fistulae as a temporary adjunct to increase flow through stented segments34, the results are not sufficiently superior to recommend their routine use2. Nazarian et al reported primary, assisted primary and secondary patency for stented patients with adjunctive arteriovenous fistula of 20 %,71 % and 100%, respectively if compared to those without adjunctive fistulae 62%, 67% and 74% at 12 months follow up period34. Arteriovenous fistulae may, however, be used selectively in those with poor inflow and/or in the context of endophlebectomy. In addition, the decision to create an adjunctive arterio-venous fistula is based on the completion imaging, specifically the clearance of contrast following venography with a slow hand injection of contrast and appearances on IVUS.

*Example algorithm for management of patients with chronic deep venous occlusive disease*

An example algorithm which illustrates a current treatment protocol for patients with chronic thrombotic and non-thrombotic iliac lesions (NIVL) is presented in Supplementary Figure 1.

**Outcomes and initial reports of stenting for CVI related to deep vein obstruction**

The first large study on the subject of stenting for CVI was in 2000 by Neglén et al1 reviewing the results of percutaneous transfemoral recanalization of the iliac venous outflow tract by means of stent venoplasty. Since then, endovascular interventions in deep venous occlusive disease have come into wider use16.

Published in 2009, Hartung et al17 explored patency rates in 89 patients with non-malignant obstructive iliocaval disease and found that there was a 98% technical success rate for patients treated with balloon venoplasty and stenting. Primary, assisted-primary and secondary patency rates, in terms of intention to treat, were 83%, 89% and 93%, respectively, at 3 and 10 years, with a median venous disability score (VDS) of 129.

A large study in 2007 by Neglén et al18 reflected on long-term outcomes of stenting in 982 non-malignant obstructive lesions of femoroiliocaval veins. At 72 months, primary, assisted-primary, and secondary cumulative patency rates were 79%, 100%, and 100% in non-thrombotic disease and 57%, 80%, and 86% in thrombotic disease, respectively. Cumulative rate of severe in-stent [restenosis](https://www.sciencedirect.com/topics/medicine-and-dentistry/restenosis) (>50%) occurred in 5% of limbs at 72 months (10% in thrombotic limbs, 1% in non-thrombotic limbs)18.

A meta-analysis by Wen-da et al in 2015 looked at 14 studies exploring the use of stents in chronic venous disease related to deep vein obstruction19. They reported that venous stenting may be a relatively effective and safe approach for PTS and NIVL patients because of the low incidence of perioperative complications and satisfactory long-term patency. A further systematic review reported primary patency rates following venous stenting in PTS and May-Thurner syndrome ranging between 32% and 98.7%, and secondary patency rates of 66% to 96%20. Moreover, another systematic review reported the median primary, assisted primary, and secondary patency rates were 71%, 89%, and 91%, respectively, at median follow-up period of 23.5 months. In this study, an overall primary patency of 78.8% at 12 months, with lower patency seen in post-thrombotic (73%) versus compressive (96%) disease, and a low overall major complication rate (<1%)22.

Moreover, systematic reviews have shown low complication rates (0%–8.7%) and high rates of technical successes (up to 98%) for deep venous stenting20,21. Reviews also show a relief of oedema and pain in up to 64%–68% and 82% of patients, respectively. One systematic review reported a potential positive impact on quality of life following endovenous stenting in CVI patients20. Although these reviews show favourable results, the outcomes are mainly based on retrospective, single-centre, cohort studies (Table 1).

In a large follow-up study by Neglén et al in 200716, 982 patients (464 of these with PTS), with prior stent venoplasty of the iliac outflow tract, were recruited. There were no reported mortalities in this study. Among the patients with PTS, the primary patency rate after 72 months was 57% and the secondary patency rate was 86%. Ulcer healing was achieved in 58% of 148 ulcerated limbs.

Despite the widespread recommendation14,26 for the use of endovenous stenting in CVI related to outflow obstruction from post-thrombotic changes or NIVL, one systematic review dedicated to the topicfailed to report guideline standards due to lack of highly evident studies to be able to issue robust recommendations20.

**Future of venous stents**

Dedicated venous stent technology is advancing at a rapid pace alongside the increased undertaking of endovascular deep venous stent reconstruction in the management of iliofemoral and caval venous pathologies (including common femoral vein). Considering these together, it is likely that endovenous stenting will become more commonplace. However, sustained development work on stent technology and the techniques related to their use are needed, such as venous confluence devices, venous stents for use at inguinal ligament level, and drug-eluting venous stents to prevent in-stent stenosis and thrombosis.

**Conclusion**

Deep venous stenting is safe and effective in chronic venous outflow obstruction and has high patency rates with acceptable complication rates. In addition, the use of intravascular ultrasound (IVUS) imaging is not only important for diagnosis but also for the guidance of accurate stent placement. Further studies, including randomised and non-randomised trials with long term follow-up, will strengthen the evidence available to reinforce the ongoing use of deep venous stent reconstruction in clinical practice.

**Contributorship**

Mohamed A H Taha researched literature and wrote the first draft of the manuscript. All authors critically reviewed and edited the manuscript and approved the final version of the manuscript.

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**Conflict of interest**

None.

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