Review

Standards for recanalisation of chronic venous outflow obstructions

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Summary: Postthrombotic syndrome (PTS) is the most common complication after iliofemoral deep vein thrombosis. It reduces quality of life and increases deep vein thrombosis (DVT)-related costs. The clinical symptoms and severity of PTS may vary; the most common symptoms include edema, pain (venous claudication), hyperpigmentation, lipodermatosclerosis, and ulceration. PTS is based on the principle of outflow obstruction, which may be caused by venous hypertension and may lead to valvular damage and venous reflux or insufficiency. Recent technical developments and new stent techniques now allow recanalisation of even complex venous outflow obstructions within the iliac vein and the inferior vena cava. This manuscript gives an overview on the latest standards for venous recanalisation.

Keywords: postthrombotic syndrome; venous outflow obstruction; venous recanalisation standards; venous stents.

Introduction

Deep vein thrombosis (DVT) occurs at a rate of 1/1000 inhabitants per year in Western Europe [1]. Depending on the location and extent of DVT, 20–83 % of patients develop a postthrombotic syndrome (PTS) despite optimal anticoagulation [1, 2]. Iliac veins are involved in about 40 % of iliofemoral thromboses [3], while standard treatment fails to achieve sufficient recanalisation of these veins in about 70 % of cases [4]. Inadequate recanalisation of venous blood flow causes a persistent outflow obstruction with hemodynamic effects, inducing valve incompetence of the deep veins and subsequent valve failure of the saphenous veins of the affected lower extremity. The clinical symptoms include venous claudication and even venous ulcers. The general assumption that individually adjusted and systematic compression therapy can halt the disease process of a postthrombotic syndrome (PTS) was disproved recently in a randomized study [5, 6]. In order to limit clinical sequelae once PTS has been established, prompt recanalisation of a chronic venous occlusion is required.

Pathophysiology and clinical evaluation

Postthrombotic venous obstruction with increased outflow resistance, damaged venous valves with reflux, and fibrotic vein walls with reduced compliance lead to venous hypertension [7, 8].

Elevated pressure in the veins is passed on to the capillaries, which then become dilated and more permeable. This in turn leads to edema, inflammation, and pigmentation due to hemosiderin deposits – and eventually to characteristic alterations of the skin (lipodermatosclerosis) and venous ulcers. Venous hypertension also causes distension of the deep veins and aggravates valve insufficiency, which is passed on to the superficial venous system through the perforating veins (secondary varicosity). The resulting pathophysiological changes lead to capillary leakage in microvascular blood flow and subsequently destroy the capillary bed, culminating in a variety of clinical symptoms including venous ulcers.

Predisposing factors for the development of a postthrombotic syndrome are:

- Persistent proximal obstruction
- Axial reflux with a reflux volume >5 ml/s
- Combination of reflux and obstruction
- Recurrent DVT events
- Advanced age
- Obesity
- Poor compliance with treatment

Venous compression syndromes

Proximal venous outflow obstruction plays an essential role in the establishment and preservation of PTS. Outflow obstruction is particularly related to venous compression syndromes, of which the May-Thurner syndrome – due to anatomical conditions – is best known. The proximal left-sided common iliac vein is compressed between the 5th lumbar vertebra and the right-sided common iliac artery (Figure 1). As early as in 1851, Virchow described this form of venous compression and reported that a left-sided deep

https://doi.org/10.1024/0301-1526/a000696

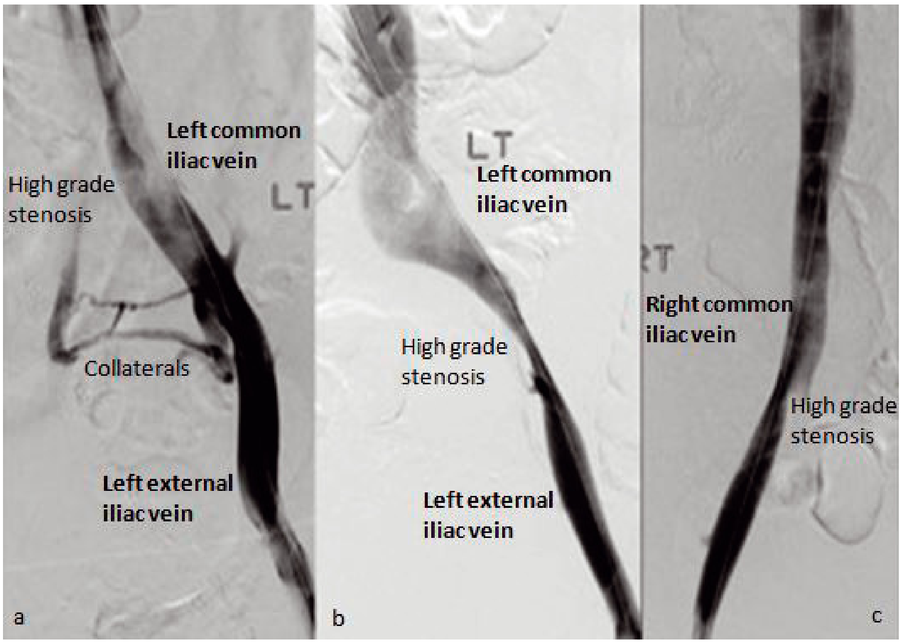


Figure 1. Significant left common iliac vein stenosis (May-Thurner syndrome) diagnosed by DSA venography (a, b, anterior-posterior projection). Compression of the right common iliac vein is shown in c (anterior-posterior projection).

leg vein thrombosis occurs about five times more frequently than a right-sided one [9]. In 1957, the pathologists May and Thurner published a detailed anatomical description of this pathology [10]. Cockett and Thomas continued the analysis initiated by May and Thurner and noted an evident clinical correlation between the described venous compression and a postthrombotic syndrome [11]. Thus, the May-Thurner syndrome and the Cockett syndrome are synonymous terms for the same type of venous compression. Cadaver investigations from the above-mentioned studies and more recent publications show that a pathological compression of the left-sided common iliac vein was present in 22–32 % of the examined cadavers. Clinically, the compression syndrome may go unnoticed for several years until it becomes symptomatic, usually because of external and internal circumstances (such as trauma, confinement to bed, or acquired diseases). One of the manifestations of this condition is an iliofemoral thrombosis. The significance of venous compression in patients with an iliofemoral thrombosis was confirmed by Oguzkurt et al. [12] in a study comprising 34 patients, who received a CT investigation for diagnostic clarification of a DVT in the corresponding region. Twenty-three of the 34 patients (68 %) had a minimum 70 % stenosis of the common iliac vein in the form of a May-Thurner syndrome. The mechanical alteration of the left-sided common iliac vein, which persists for several years, may then cause a marked thickening of the vessel wall, stenoses, scars, a local thrombus, or septation in the respective segment of the vein. Symptomatic patients frequently reveal unilateral swelling of the leg, pain in the groin, venous claudication, or a secondary chronic venous insufficiency.

In addition to venous compression syndromes due to anatomical conditions, there may be other reasons for an acute or chronic venous outflow obstruction:

Recommendation

In patients with clinical signs of venous hypertension of the leg, the clinician should rule out a venous outflow obstruction.

Intramural causes are:
- Deep leg vein thrombosis with postthrombotic changes
- Atresia of the inferior vena cava

Extramural causes are:
- External compression due to tumors, lymphoceles, retroperitoneal fibrosis, radiation or arterial aneurysms

Clinical evaluation of venous disease and indication for recanalisation

Patients with clinical symptoms in accordance with the CEAP classification 3–6 should be scheduled for revascularisation therapy when the clinician finds evidence of an iliac vein obstruction affecting the patient's hemodynamic condition. In addition to the CEAP classification, currently the rVCSS score, the CIVIQ-20 score, the VEINES-QoL score, and the Villalta score permit a much better classification of objective and subjective venous symptoms in the presence of chronic venous disease (a summary of the above-mentioned classifications and scores is available at http://www.veinforum.org/medical-and-allied-health-professionals/avf-initiatives/ceap-and-venous-severity-scoring/venous-severity-scoring). These validated and established scores should be used as standard procedures when following patients after surgery in order to assess their clinical progress. One limitation of the scores is that they do not register whether a patient has a venous claudication, which has a major impact on physical capacity, especially in young patients. In terms of clinical appearance, venous claudication does not differ from pain due to arterial causes. The duration of pain is usually longer after a stress phase and is an expression of high venous pressure in the lower leg under stress. A phlebodynamometry is performed to obtain objective evidence of elevated venous pressure; it should be preceded by a standard treadmill test (12 % elevation, 3 km/h) and a venous occlusion plethysmography.

Venous claudication is an indication for pelvic vein recanalisation.

A standardised stepwise diagnostic scheme was not established in the published literature. However, according to expert opinion the scheme could be as follows (Figure 2):

- Medical history (including rVCSS, CEAP, CIVIQ-20, and the Villata score)
- Treadmill investigation (venous claudication?)
- Duplex and Doppler ultrasound (linear venous flow without breath modulation, evidence of thrombosis, septa, aliasing, reflux, pathological compression ultrasound)
- Determination of ABI (to rule out arterial causes of the symptoms)
- Venous occlusion plethysmography (limited interpretation in cases of occlusions at several levels)
- A phlebodynamometry is only recommended for specific questions
- CT/MRI phlebography (see below)
- Ascending phlebography has no additional benefit over noninvasive examination methods
- Digital subtraction angiography (see below)
- Intravascular ultrasound (see below; the anticipated gold standard for invasive diagnostic investigation)

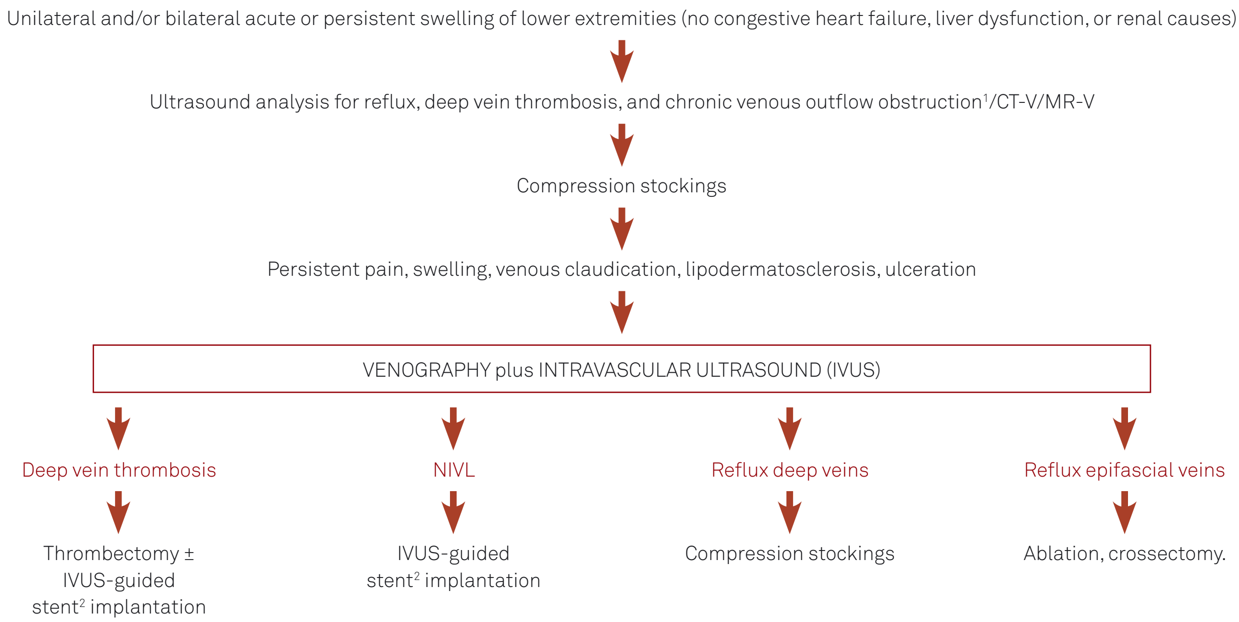
Doppler and duplex investigation

Doppler and duplex venous imaging is the imaging modality of choice in the diagnostic workflow for suspected venous outflow obstruction and reflux. It provides information about the underlying pathology and the anatomic extent of disease, but can be difficult to interpret in the iliac veins, especially in obese patients. However, pathologic venous Doppler examination can demand additional radiologic pelvic imaging to obtain information about the extent of the disease and also to exclude extravascular disease-causing venous outflow obstruction (Figures 3a and 3b).

Radiological diagnostic investigation

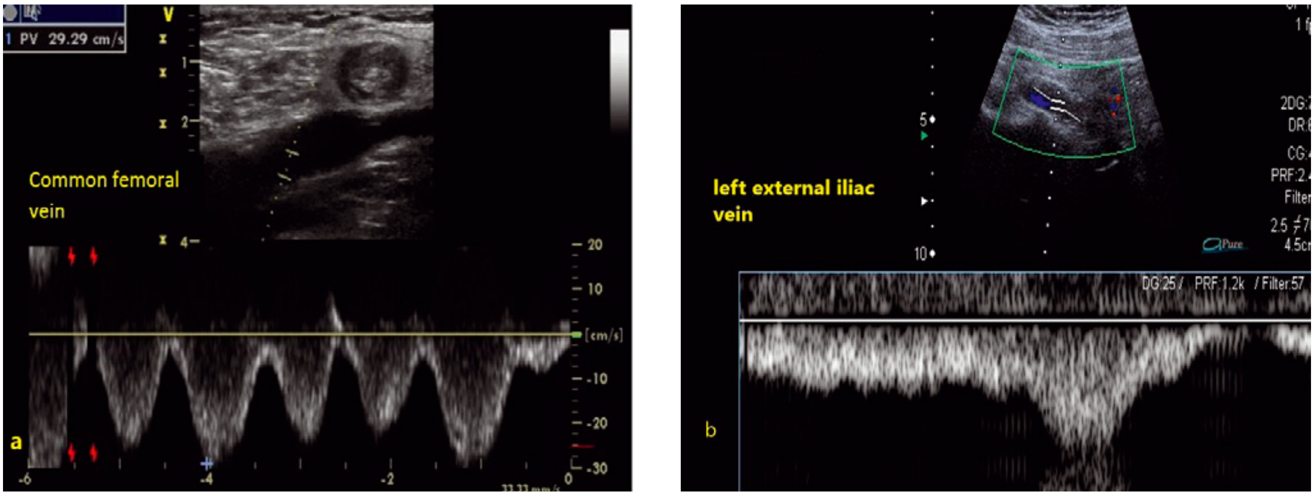
CT and MR venography

Non-invasive imaging prior to intervention is extremely helpful to underpin the clinical diagnosis and to plan the procedure. The modality of choice is characterised by high reproducibility, sensitivity, and specificity. Iliocaval obstructions and the accompanying pathological changes can be visualised by MR venography (MR-V) as well as CT venography (CT-V) [13, 14]. For example, both procedures can detect, with certainty, underlying compression pathologies such as the May-Thurner syndrome. Because such a hemodynamically significant iliac obstruction is present in



1) Consider further diagnostics to rule out compression by abdominal mass.
2) Only dedicated venous stents are recommended.
CT-V: CT Venography; MR-V: MR Venography

Figure 2. Diagnostic and therapeutic pathway for acute and chronic venous outflow obstruction.



Figures 3a and 3b. Different duplex and Doppler ultrasound flow of a left external iliac vein without outflow obstruction (3a) and proximal high-grade stenosis in the common iliac vein (3b). Physical breath dependent modulation of venous flow is documented in 3a. 3b shows the abnormal laminar flow of the external iliac vein which suspects venous outflow obstruction.

about 80 % of iliofemoral thromboses, MR-V or CT-V should be performed for diagnostic purposes prior to invasive treatment (especially in young patients) [12, 15, 16].

A recommendation of CT-V over MR-V remains difficult. Availability, scanning time, radiation exposure, iodinated contrast, and personal expertise all are important aspects to consider. Because the majority of patients with acute or chronic iliofemoral venous obstructions are relatively young females, limiting radiation exposure should be of high priority. Further, determining the (endovascular) options in patients with extensive postthrombotic obstruction by evaluating the common femoral vein is crucial. Preinterventional imaging should be efficient to exclude acute or chronic obstruction of the (deep) femoral veins hampering inflow. Although no comparative studies are available on the sensitivity of MR-V or CT-V for subtle postthrombotic trabeculations, intrinsic technical qualities seem to favor MR-V. Finally, MR-V may be helpful to predict the success of thrombolysis/thrombectomy by estimation of thrombus age.

In conclusion, in light of the superior diagnostic potential and safety profile, MR-V is the imaging modality of choice prior to deep venous intervention.

Recommendations for performing a DSA of a pelvic vein

- Ipsilateral access (the optimal access is through the femoral vein), minimum catheter size > 6F
- DSA mode
- High-pressure injection with a DSA contrast media injector
- DSA during an induced respiratory standstill
- Standard anteroposterior image plus at least two angulated images (90 degrees LAO/RAO)
- Follow-up and assessment of contrast outflow (filling of collaterals, reflux)

DSA phlebography

A DSA may not be adequate for an accurate diameter analysis of a pelvic vein or a venous obstruction. The impact of vessel diameter, various degrees of venous filling, breath-modulated diameters, and the structure of the vein wall are responsible for the elliptical shape of iliac veins. Because of this shape, it may be difficult to identify a lesion or quantify a stenosis, so that, in the presence of a parallel axis of the lesion and with a set angiography angle, even a high-grade stenosis may escape detection. Therefore, in addition to an anteroposterior image, one should obtain at least two angulated projections (90 degrees LAO and RAO). Care should be taken to ensure adequate filling with a high-molecular-weight contrast medium through an adequately large catheter lumen (8–10 F). Further, a DSA should be performed in the presence of an induced respiratory standstill. A bladder catheter inserted prior to the investigation or the recanalisation procedure prevents concealment of venous blood flow in pelvic veins due to a bladder filled with contrast medium; this is especially true of angulated images. Abscessed (lumbar) venous collaterals, collaterals of the internal iliac region to the contralateral pelvic vein (presacral) as well as the visualisation of a spontaneous suprapubic collateral (natural Palma) are urgent signs of a pelvic venous congestion with hemodynamic effects.

Intravascular ultrasound (IVUS)

Compared to a standard DSA for the evaluation of a venous congestion or lesion, IVUS offers the option of detecting a reduction in diameter as well as the much more significant reduction of area. Standardised use of IVUS permitted a much more accurate analysis of lesions (avoided false negative findings) and, in particular, oversizing the stent. A standard IVUS performed on a routine basis after stent implantation much more frequently revealed a residual stenosis that could then be dilated (Figure 3).

The recently published VIDIO (venography versus intravascular ultrasound for diagnosis of iliofemoral vein occlusive disease) study [17, 18] was a prospective multicenter investigation that clearly showed the advantages of diagnostic IVUS investigation over standard venography. A group of 100 patients with an iliac outflow obstruction underwent standard angiographies (anteroposterior, RAO 30 degrees, LAO 30 degrees). Based on this angiographic investigation, the examiners had to establish whether the patient had a venous stenosis affecting the patient's hemodynamic condition. The investigation was substantiated with an IVUS analysis, followed by a renewed assessment. In all a total of 300 vein segments were analysed. IVUS revealed a significant stenosis in 63 segments (21 %) that were not identified on venography. Furthermore, the grade of stenosis on IVUS was 11 % higher than that on the corresponding venography. Based on the IVUS analysis, the treatment plan was modified in 60 of 100 patients, and a stent implantation was performed.

This study is of enormous significance with regard to the quality requirements for venous interventions.

A sobering fact, however, is that the technical effort has not yet been mentioned in the current DRG system for 2017; the procedure involves substantial additional costs for the intervention centers.

Advantages of IVUS

- Dynamic measurement of area and the degree of stenosis
- Analysis of morphological changes in the vein (the formation of fibrosis, scars, thrombi)
- Dynamic evaluation of compression, such as in
- the presence of the May-Thurner syndrome
- No need for contrast medium in patients with kidney failure
- Reduced radiation exposure
- Exact determination of the diameter and length of the required vein stent
- Exact placement of the vein stent
- Luminal analysis after stent implantation

Treatment of chronic iliac vein obstruction

The following extents of chronic vein obstruction (CVO) should be established preoperatively:

1. Iliac CVO with or without common femoral vein confluence involvement
2. Iliac CVO with or without IVC involvement

This distinction has consequences on the choice of treatment. The first group can be treated only by endovascular procedures, while the second group may need a hybrid procedure involving surgical desobstruction and/or adjunctive artificial flow.

Technical details of recanalisation

Venous dilatation and stenting is painful and in some patients may take a considerable amount of time. Doing the intervention under local anesthesia should be confined to patients with circumscribed stenoses in the iliac region, such as those with the May-Thurner syndrome. General anesthesia or monitored conscious sedation is preferred in all other cases.

The femoral vein is a suitable access for iliofemoral and caval recanalisation. The popliteal vein, the right-sided internal jugular vein, and the contralateral common femoral vein may also be used. As a last resort, one may use the large saphenous vein or the deep femoral vein as the path of access.

The vein is punctured under ultrasound guidance. After introducing a sheath by Seldinger technique, a variety of wires or catheters may be used to pass through the stenosis. Once the wire has been introduced, the constriction or obstruction is dilated with a large-lumen balloon catheter. The vein should be predilated at least to the diameter and length of the stent to be inserted. Implantation of a venous stent is followed by postdilatation. The stent PTA procedure (Figures 3a and 3b) should be performed from one healthy segment to another healthy segment. In other words, PTA stenting covers the entire postthrombotic venous segment. A constriction in the common iliac vein should always be overstented. A control phlebography in two planes is mandatory. Successful recanalisation is followed by rapid outflow of contrast medium over the entire stented iliac flow region. Collaterals should no longer be seen [19].

Early thrombotic occlusions are nearly always unavoidable despite successful iliac stent PTA when there is no sufficient influx from the femoral veins and/or the large saphenous vein. In cases involving the common femoral vein, which is a sign of limited influx, it may be necessary to insert an arteriovenous (AV) fistula. This is performed either as a hybrid procedure during endovascular revascularisation or immediately thereafter.

Technical tips and tricks for recanalisation:

- Ultrasound-guided puncture
- Ipsilateral puncture is always better than the contralateral approach
- DSA in several angulated projections for the analysis of stenoses and obstructions
- Recanalisation of the chronic obstruction using a rigid 0.035-inch guidewire with a hydrophilic coating
- A supporting catheter may be needed for recanalisation in cases of chronic obstructions

Recommendation

Hybrid procedures with simultaneous endophlebectomy and/or the insertion of an AV fistula are recommended in cases of insufficient influx from the femoral vein.

A transjugular access is usually needed for recanalisation in obstructions of the inferior vena cava

Novel venous stents

Initially it was common practice to use arterial PTA stents (such as Wallstents or nitinol stents) for recanalising blood flow in the iliac veins. However, PTA stenting of a postthrombotic vein with intraluminal scarring – and frequently also with external compression – is *not* similar to an arterial PTA stenting in the presence of arteriosclerosis. Stents for venous recanalisation must fulfil their own standards. Therefore, special stents were developed for interventions in the iliac veins (Figure 5a, 5b and 6):

1. The diameter of veins is larger than the diameter of the corresponding arteries. Stents with a diameter of 14–18 mm are used for iliac vein recanalisation.
2. Longer stents are needed because the postthrombotic lesion is usually elongated. Using several overlapping stents does not adequately resolve this problem because it reduces flexibility.
3. Postthrombotic veins are often scarred over a longer area. Additional external compression may be present, such as the May-Thurner syndrome. Therefore, one needs stents with high radial force.
4. Venous recanalisation requires very flexible stents that can be aligned to the anatomical course of the veins even during movement – and not vice versa. Angulation is highest (ranging up to 90°) in the sitting position, especially in the iliac confluence, at the junction between the external iliac vein and the common iliac vein.

In summary, stents approved for the venous system are very flexible and possess a high degree of radial force.

There are currently six dedicated venous stents on the market in Europe: The sinus-Venous and sinus-Obliquus stents (OptiMed, Ettlingen, Germany), Zilver® Vena™ Venous Self-Expanding Stent (Cook Medical, Bloomington, IN), VENOVO™ Venous Stent System (Bard, Tempe, AZ), the VICI VENOUS STENT® (VENITI, Inc., Fremont, CA, USA), and the Abre™ venous stent (Medtronic, Minneapolis, Minnesota, USA). De Wolf and colleagues reported a 12-month cumulative primary patency rate of 92% for the sinus-Venous stent in patients with chronic VOO [21]. Stuck and colleagues evaluated the sinus-Obliquus stent in 20 patients with chronic and acute VOO, and found a primary patency rate of 92% at 6 months and 83% at 10 months [22]. The Zilver® Vena™ stent was shown by O'Sullivan et al. [23] to have a so-called "clinical" patency rate of 85% at a short-median follow-up of 55 days. This cohort included patients with acute ilio-femoral thrombosis (70%), and half of the patients had advanced malignancy.

No direct comparison exists between stents of different designs. It is difficult to compare stent patency rates from the various reports, because the patency rates are highly influenced by the aetiology and severity of the disease. Extensive postthrombotic occlusive disease with poor inflow to the stent system do worse than focal nonthrombotic iliac vein lesions. Therefore, it is important to know what type of patients are included in the studies reporting stent patency rates. Venous stent patency rates are markedly different in PTO and NIVL patients. In a study by Neglen et al. [24], primary, assisted-primary, and secondary cumulative patency rates in 303 patients with PTO and 302 patients with NIVL patients were 79%, 100%, and 100%, and 57%, 80%, and 86% at 72 months, respectively. That study used Wallstents® exclusively. A recent meta-analysis by Razavi et al. of 1,122 patients with NIVL and 1,118 patients with PTO showed a primary patency rate at 12 months of 96% and 79%, respectively [25]. Wallstents® were used in 78% of studies analysed. The cumulative primary and secondary patency rates remained higher in nonthrombotic patients than in the postthrombotic patients throughout 5 years (primary patency at 5 years approximately 90% and 65%, respectively).

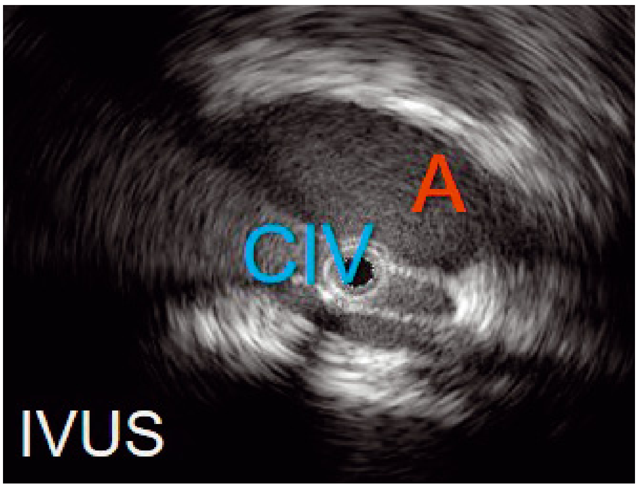


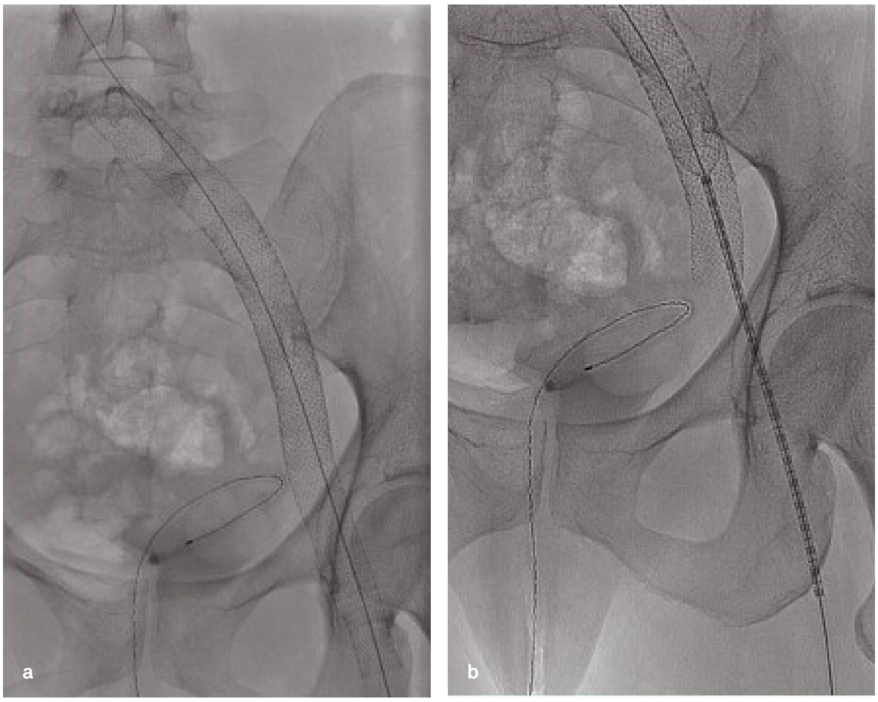
Figure 4. Intravascular ultrasound investigation of a symptomatic May-Thurner syndrome in a 23-year-old woman with a persistent swelling of the left leg with high-grade stenosis of the left common iliac vein (CIV) caused by arterial compression (A) of the right iliac artery.

Anticoagulation

Anticoagulant therapy started during the intervention is continued after the intervention, usually for 3 to 6 months. When using vitamin K antagonists for anticoagulation, the clinician should aim to achieve a target INR value of 2.5 to 3.5 (Table 1). When the value drops below the minimum, it is advisable to additionally administer low-mo-

Recommendation

Only approved vein stents should be used for venous recanalisation because only these fulfil the functional requirements of the procedure.



Figures 5a and 5b. Venous stent deployment (a) and implantation (b) from healthy segment (inferior caval vein) to healthy segment (common femoral vein) with 1–2 cm stent overlapping.

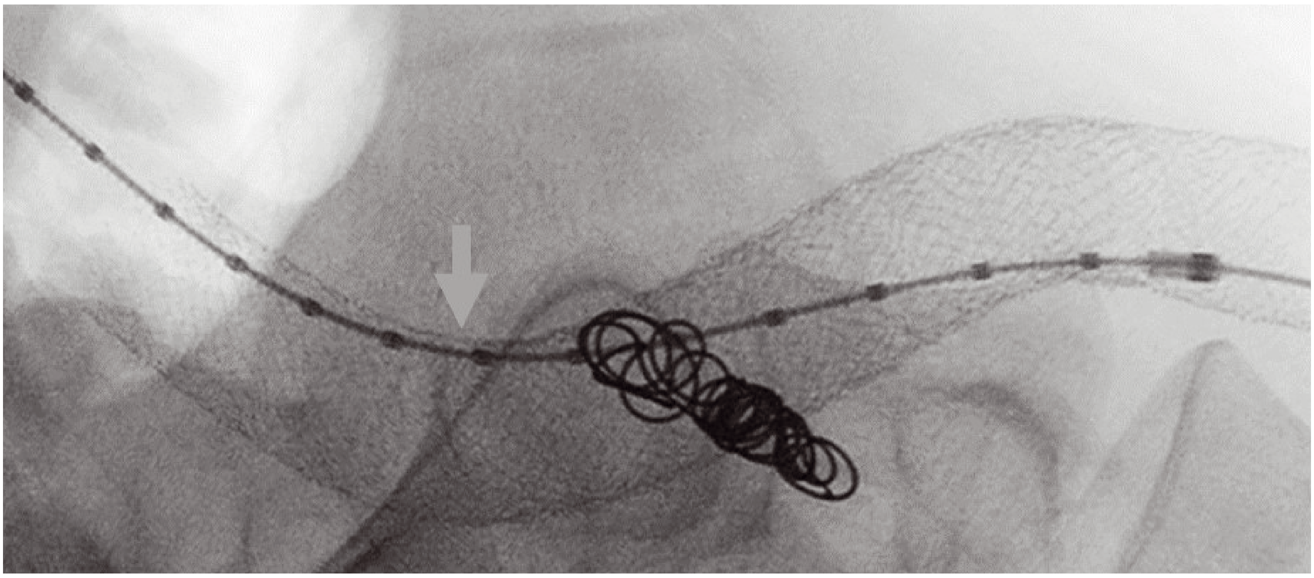


Figure 6. Venous stent follows the anatomical geometry of the common and external iliac vein without straightening or elongation of the vein. Arrow points on IVUS catheter that was used for postimplantation analysis of the stent.

Table I. Recommendation for postinterventional anticoagulation.

Nonthrombotic iliac vein lesion (May-Thurner syndrome without concomitant DVT)	Chronic postthrombotic syndrome with obstruction and/ or occlusion
Peri-procedure: – 5000 U heparin during procedure – Full-dose low-molecular-weight heparin after procedure – SCD compression/early mobilisation	Peri-procedure: – 5000 U heparin during procedure – Full-dose low-molecular-weight heparin after procedure – SCD compression/early mobilisation
Long-term: – Vitamin K antagonist 3–6 months after stent implantation – Lifelong anticoagulation per se not necessary	Long-term: – Vitamin K antagonist for 6–12 months – Consider lifelong anticoagulation as per conservative guideline (recurrent DVT, thrombophilia, etc.) – Consider lifelong anticoagulation in patients with IVC stenting

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lecular-weight heparin in a therapeutic dose. New oral anticoagulants are increasingly being used, but we presently lack sufficient experience with these agents [26].

Conclusions

Clinical signs of venous hypertension should be objectified by a combination of (non)invasive imaging modalities. Although venous claudication is a difficult diagnosis to establish, it should not be underestimated and rigorously scrutinised. Recanalisation with presently accepted venous stents suggests the highest probability of success. Adjunctive artificial flow is warranted for extensive PTS cases in which spontaneous venous influx is deemed insufficient. To further analyse safety, efficacy, and economic questions within venous revascularisation, a multicenter prospective nationwide registry will be soon started by the authors of this article.

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Manuscript submitted: 24.12.2017
Accepted after revision: 06.02.2018
Published online: 07.03.2018
Conflicts of interests: Michael Lichtenberg and Rick de Graaf received speaker honoraria from VENITI, Inc, CR Bard, Boston, Optimed, and Straub medical.

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