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RECOMMENDATIONS

Venous recanalisation in the setting of post-thrombotic syndrome: An expert consensus from the French Society of Vascular Medicine (SFMV) and the French Society of Cardiovascular Imaging and Interventional Radiology (SFICV)

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KEYWORDS

Deep-vein thrombosis ;
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Imaging ;
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Summary Several aspects of the management of post-thrombotic syndrome (PTS) are still a matter of debate, or not yet addressed in international guidelines. The objective of this expert consensus from the French Society of Vascular Medicine (SFMV) and the French Society of Cardiovascular Imaging (SFICV) was to define the main elements of diagnosis and treatment of this syndrome, and to develop a proposal for its preoperative, procedural and follow-up management. In this consensus, the following issues were addressed: clinical and ultrasound diagnosis; pre-procedural workup; indications and contraindications to venous recanalisation; procedures; clinical and duplex ultrasound reports; follow-up; long-term treatment; management of great saphenous vein incompetency; anticoagulant and antiplatelet therapy after venous stenting.

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Introduction

Deep-vein thrombosis (DVT) represents a substantial burden in France with an incidence of 119.8 per 100,000 subjects/year [1]. In spite of optimal anticoagulant treatment, the first-line therapy recommended in the most recent guidelines [2], between 20 and 50% of patients develop a post-thrombotic syndrome (PTS), including all the symptoms and signs of chronic venous insufficiency secondary to DVT [3]. The pathophysiology of this disease comprises a combination of reflux due to valve incompetence and venous hypertension due to thrombotic obstruction [4,5].

Despite several published guidelines on the management of PTS, certain aspects of its clinical management remain unclear or have not yet been addressed [6]. The aim of this consensus of experts from the French Society of Vascular Medicine (SFVM) and the French Society of Cardiovascular Imaging (SFICV) was to analyse the diagnosis of PTS and approaches to its treatment, using a Delphi procedure. This paper summarises the consensus reached. The reader is encouraged to consult the full-text guidelines for additional guidance and details of PTS management, as this executive summary contains limited information.

The manuscript is divided into seven chapters: (1) clinical and ultrasound diagnosis; (2) pre-procedural workup; (3) indications and contraindications to venous recanalisation; (4) procedures; (5) clinical and duplex ultrasound (DUS) reports; (6) clinical and imaging follow-up; (7) long-term treatment (including management of great saphenous vein incompetency, as well as anticoagulant and antiplatelet therapy after venous stenting for chronic lesions).

Materials and methods

The recommendation was written according a Delphi method performed by a steering committee, online questionnaires evaluated by a grading committee and face-to-face meeting to evaluate the results and write the document.

Experts steering and grading committee

Thirty experts, from 13 centres across the France, were involved in the steering committee. Participants were selected from centres with high volume PTS patient management.

All participants were:

- either involved in the multidisciplinary management of PTS;
- or had at least five years' experience managing patients with PTS;
- or published on this topic;
- or for interventional radiologists had treated at least 50 patients with PTS by endovascular approach.

The steering committee was composed by 7 interventional radiologist and 8 vascular medicine physicians. This committee had the task to perform a review of the literature, create online questionnaires on identified issues concerning PTS management. The grading committee was composed by 30 experts, including vascular medicine physicians and interventional radiologist, in order to grade the proposals according to a Delphi method. The members of

the steering committee were not authorised to participate in the grading and evaluation group.

Delphi Method

The steering committee elaborated an online questionnaire on several priority topics in the diagnosis, evaluation and PTS management after a review of the literature. This proposal was discussed and reviewed during several face-to-face plenary sessions.

The resulting text was evaluated online by the grading committee that received the text and a link to register an online vote for each topic. Each expert indicated for each proposal if she/he:

- strongly agreed;
- agreed;
- neither agreed nor disagreed;
- disagree;
- strongly disagreed.

A commentary explaining the response was also requested to further document the grading. Consensus was calculated as percentage of respondent's agreement. All topics were evaluated with Likert scale questions and the consensus was considered achieved if the proposal attained at least an 80% rate of agreement (responses 1–2) or disagreement (responses 4–5). The percentage of consensus was evaluated according to the responses received, including the response "no opinion". Two rounds were conducted to obtain the consensus. If a consensus on a topic was not achieved, the text was revised by the steering committee, taking into account the commentaries forwarded by the grading committee, and was then subjected to a second vote.

The votes were recorded progressively and the manuscript was validated at a plenary face-to-face meeting of steering committee. Delphi process is summarized in Fig. 1.

Results

A total of 124 proposals were identified by the steering committee and submitted to the grading committee for evaluation. After a first round, 82 proposals (66%) achieved consensus. Forty-two (34%) proposals were revised by the steering committee in accordance with the grading committee's suggestions. The 42 new proposals were re-submitted for evaluation. At the end of the second round, consensus was reached on 100 proposals (81%) [7].

Recommendations and commentaries

Clinical and ultrasound diagnosis

The first step in PTS diagnosis is a clinical examination. Various clinical scores have been used to diagnose and assess the severity of PTS in patients. These include the CEAP (Clinical signs, Etiology, Anatomic distribution, Pathophysiological condition) classification, the Venous Clinical Severity Score (VCSS), the Widmer classification and the Villalta score [7]. The Villalta score is the most widely accepted score for

the diagnosis of PTS, its use facilitating comparisons between studies.

This score presents several advantages:

- it evaluates physical signs and symptoms of venous insufficiency;
- it permits a quantitative and qualitative evaluation of PTS;
- it can assess the temporal evolution of symptoms;
- it is correlated with patient quality-of-life scores;
- it shows good inter-observer agreement.

The main limitations of the Villalta score are the absence of an external prospective evaluation in clinical trials, the absence of a rating for healed ulcers and venous claudication, the absence of information on the mechanism of PTS (reflux and/or obstruction) and a lack of specificity.

Ultrasound (US) should be the first examination performed to evaluate venous insufficiency. It should include an anatomical and haemodynamic evaluation of the superficial and deep venous networks [8,9].

PTS should be diagnosed solely on clinical grounds, but a US examination nevertheless enables:

- evaluation of the mechanism of PTS [10];
- identification of the risk factors for severe PTS [11,12];
- guidance of treatment [13].

To improve the diagnostic evaluation of PTS, the expert consensus proposed the following advice.

Clinical evaluation should not be performed too early, as symptoms related to acute deep-vein thrombosis (DVT) may still be present and can mimic PTS symptoms. Thrombus involution and wall lesions are variables. No data concerning duplex ultrasound (DUS) of untreated patients are available. In clinical practice, post-thrombotic venous lesions are generally considered stable at 1 year [14].

1. We recommend that PTS should be evaluated on the leg affected by DVT and not before 6 months have elapsed since this event.

Delphi expert consensus: 95% agreement

2. We suggest that two separate assessments should be completed before venous recanalisation in the context of PTS.

Delphi expert consensus: 91% agreement

A bilateral US examination should be performed on the contralateral asymptomatic leg:

- to evaluate the presence of coexisting prior venous insufficiency;
- to diagnose PTS in patients with symptomatic venous insufficiency, without a history of DVT, but with asymptomatic venous DVT lesions [15].

3. We recommend performing, in both legs, a systematic search for clinical and US signs of an associated venous insufficiency, with comparison of these signs.

Delphi expert consensus: 100% agreement

Patients should always be evaluated at a regular time, preferentially in the afternoon, as signs of venous insufficiency

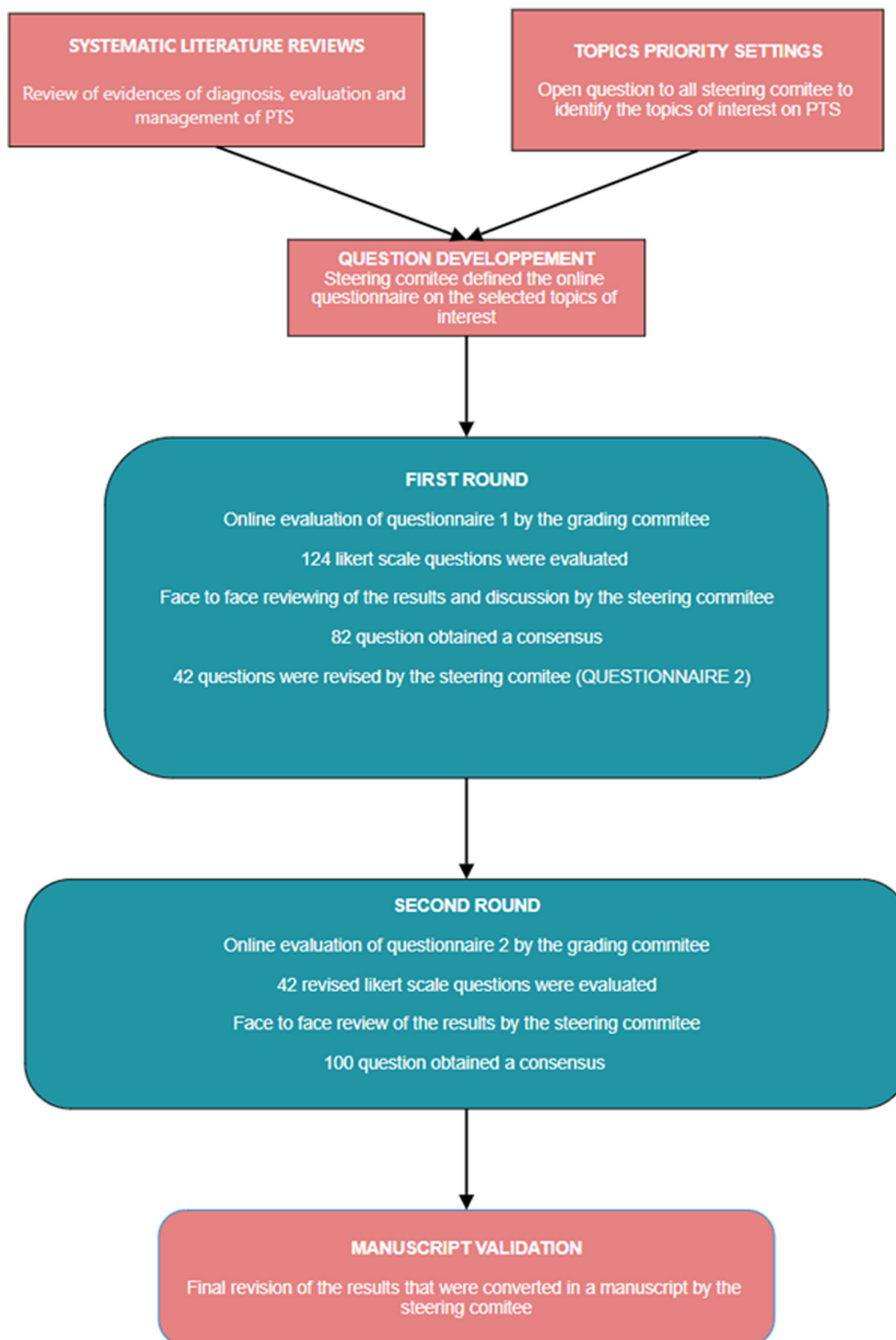


Figure 1 Delphi process flow chart.

ciency are more evident then. Moreover, elastic compression stockings should not be worn on the day of the assessment, to avoid underestimation of leg oedema [3].

In the presence of a proximal DVT (class III-IV in the Lower Extremity Thrombosis [LET] classification) [16], it is recommended to evaluate venous claudication, which may

be present in up to 44% of patients having experienced a previous iliac or femoral DVT [17]. Venous claudication is defined as painful muscular tension experienced while walking, located either above or below the knee, necessitating rest and not disappearing after rest when the patient is standing. Stair-climbing may provide a useful means of cha-

racterising the severity of this condition, using a graduated scale:

- mild: intermittent pain, or pain when climbing stairs;
- moderate: pain every day during intense efforts, rapid walking, or sports activities;
- severe: pain every day during normal walking or mild efforts.

4. We recommend searching for the presence of venous claudication.

Delphi expert consensus: 93% agreement

The presence of pelvic or abdominal varicose veins may be associated with PTS and can facilitate diagnosis.

5. We recommend checking for the presence of abdominal or pelvic varicose veins, or abdominal wall collateral veins.

Delphi expert consensus: 90% agreement

Neurological or rheumatological symptoms may also be associated with PTS. These symptoms may contribute to overestimation of this condition. Neuropathy could be caused by the venous disease and a dedicated treatment should be considered in the presence of associated symptoms. Neuropathic pain should be evaluated using the 4-point DN 4 score during the clinical evaluation of PTS [18].

6. We recommend excluding the presence of a concomitant neurological disease by use of the DN 4 score.

Delphi expert consensus: 95% agreement

For patients with a history of DVT, clinical signs of venous insufficiency and their impact on quality of life should be systematically assessed [17,19–21]. This evaluation can be accomplished using either generic quality-of-life scores, such as SF-36, EUROQOL, or EQ5D-3L [17,19,20], or quality-of-life scores specific to venous disease, such as VEINES-QOL or CIVIQ-20 [21].

7. We recommend assessing patient quality of life using either the generic SF36 quality-of-life score or the venous disease-specific VEINES – QOL or CIVIQ-20 scores.

Delphi expert consensus: 97% agreement

Pre-procedural workup

Thrombophilia testing

Venous thromboembolic disease (VTE), DVT, and pulmonary embolism (PE) are all chronic, recurrent, multifactorial diseases. The presence of a first-degree family history of VTE should be systematically assessed, particularly in the absence of triggering factors. Without clinical elements, the efficacy of systematic complementary examinations is poor [22]. In almost 50% of cases, patients with VTE do not present any risk factor or triggering condition. In these patients, a search for genetic or acquired thrombophilia may be considered in certain circumstances, in accordance with guidelines [2].

8. We suggest that preoperative testing for thrombophilia should not be mandatory for endovascular treatment of PTS. If a test for thrombophilia is envisaged, it should be performed according to dedicated guidelines.

Delphi expert consensus: 80% agreement

The search for hereditary biological thrombophilia should be performed according to dedicated guidelines, even if

anticoagulant therapy is anticipated in the context of endovascular treatment [23]. If venous recanalisation is scheduled, testing for thrombophilia should be performed exclusively in the following cases, according to dedicated guidelines:

- patients with a first unprovoked proximal DVT or PE, aged < 50 years and with a (first-degree) family history of thrombosis;
- patients with recurrent VTE (at least one proximal DVT or PE event before the age of 50 years);
- patients with unprovoked venous thrombosis in an atypical site (splanchnic, upper limb, cerebral);
- for patients not corresponding to any of the above situations, considering the complexity of clinical cases, an expert consensus evaluation is suggested following therapy.

The presence of hereditary thrombophilia should not be considered as a contraindication to interventional endovascular treatment of PTS. There are no data suggesting an increased risk of stent thrombosis in these patients [24]. The presence of hereditary thrombophilia may be useful in some cases for guiding the choice of an optimal anticoagulant treatment.

9. We suggest that the presence of hereditary thrombophilia is not a contraindication to endovascular treatment of PTS, given the absence of available data suggesting an increased risk.

Delphi expert consensus: 90% agreement

10. In patients with acquired thrombophilia (as in patients with antiphospholipid antibody syndrome [APLS]) the indication for endovascular treatment should be based on multidisciplinary evaluation.

Delphi expert consensus: 100% agreement

Ultrasound evaluation before endovascular treatment

Following DVT, DUS should be performed at the end of anticoagulant therapy and at least 6 months after DVT diagnosis [23]. A topographic lesion classification, mimicking the phlebographic LET score [16] should be used. This DUS examination should evaluate the type of lesion (residual venous obstruction, reflux, stenosis, collaterals), and also the presence of superficial venous insufficiency [8,9].

11. At the end of anticoagulant therapy and at least 6 months after DVT diagnosis, a DUS should be performed to evaluate chronic post-thrombotic morphological changes (residual clots/obstruction) and/or post-thrombotic haemodynamic alterations (stenosis, reflux, collaterals).

Delphi expert consensus: 96.6% agreement

Residual venous obstruction should be evaluated by measuring the antero-posterior vein diameter under compression using an US probe (pathological if ≥ 2 mm) [25]. The presence of a residual flow within the vessel should also be evaluated.

Post-thrombotic vein wall fibrosis may cause venous stenosis, resulting in a decrease in lumen diameter, an increase in systolic blood flow velocity, and a maximum velocity gradient before and at the lesion site. Upstream collateral development indicates a functional impact of the lesion.

Venous reflux should be evaluated by manual compression. It is considered pathological if it lasts longer than 0.5 seconds at the superficial level and 1 second at the deep level [15].

The analysis of collaterals should evaluate both their presence and the direction of blood flow (reflux).

The search for venous insufficiency should investigate:

- the presence of supplying venous circulation, valve normality, the degree of saphenous vein dilatation and the results of associated treatment (sclerotherapy, surgery, etc.);
- the presence of leak points and the persistence of residual varicose trunks in both legs to complete the superficial mapping.

12. We recommend performing a bilateral comparative DUS evaluation of the lower limbs and ilio-caval segments, including a systematic assessment of bilateral venous insufficiency/reflux.

Delphi expert consensus: 96% agreement

Preoperative cross-sectional imaging

Currently there are no guidelines on the use of cross-sectional imaging for diagnostic and preoperative PTS evaluation. The value of computed tomography (CT) or magnetic resonance imaging (MRI) has been demonstrated [26]. CT and MRI play a central role in vascular imaging, allowing analysis of the vascular network, collaterals, and the vessel wall.

Cross-sectional imaging should be considered in second line after DUS. Agreement between cross-sectional imaging and DUS findings is crucial for the planning and success of venous recanalisation [7,26].

The imaging included in the DVT workup is designed to reveal the presence of:

- a May-Thurner syndrome [27];
- an anatomical variation, ilio-caval venous hypoplasia, or agenesis [28,29];
- a venous compression factor, such as a pelvic mass.

The objectives of an imaging workup before an intervention are to evaluate the technical feasibility and planning of this intervention [7,26]. The following parameters may be assessed:

- the upper limit of the thrombosis;
- inferior vena cava (IVC) anatomy, patency and chronic lesions;
- healthy venous zones proximal and distal to the planned stenting;
- the upstream vein patterns.

Subsequently, cross-sectional imaging may be used in conjunction with fluoroscopy during recanalisation.

13. Before endovascular venous treatment, we suggest performing cross-sectional imaging.

Delphi expert consensus: 90% agreement.

Computed venography. Computed tomographic (CT) venography may be performed according to the two principal

techniques, namely direct or indirect venous injection [30,31]. In the indirect technique, a conventional contrast medium is injected into a peripheral vein of the upper arm, followed by late acquisition 2 minutes after injection. Venous enhancement is weak, generally below 200 Hounsfield units. This drawback limits the quality of the venogram as well as the possibility of reconstructions and volume rendering.

In the direct technique, diluted contrast medium is injected bilaterally into the pedal foot veins. Venous tourniquets should be applied at multiple sites, as well as balloon compression in the scarpa area. An ascending acquisition, from the feet up to the right atrium is then performed. This technique is technically more demanding, but enables complete visualisation of the venous network including collaterals and chronic venous lesions. The examination may be completed by volume rendering imaging.

14. Before endovascular venous treatment, we suggest performing cross-sectional imaging by direct CT venography.

Delphi expert consensus: 83% agreement

15. When considering endovascular venous treatment for PTS, we suggest CT venography using either the direct technique, with bipedal injection of diluted contrast medium into the veins of the dorsum of the foot, or the indirect technique, by injection of contrast medium into a peripheral vein of the upper limb and delayed acquisition.

Delphi expert consensus: 83% agreement

Phlebography. Phlebography is a complementary examination performed in addition to DUS for PTS management [8,9,14].

This examination comprises the injection of a contrast medium into the superficial dorsal foot vein in order to visualise the deep venous network of the leg. Nowadays, this approach may be replaced by cross-sectional imaging.

16. We suggest NOT to perform phlebography by pedal injection of a contrast medium at the beginning of a percutaneous venous intervention.

Delphi expert consensus: 91.7% agreement

Indications and contraindications to venous recanalisation

Both the American Heart Association (AHA) guidelines [32] and those of the European Society of Vascular Surgery [7] state that an endovascular intervention may be implemented in patients with severe PTS related to iliac or caval occlusion [33].

A review by Seager et al. [34] and other articles [35–39] concerning studies in various cohorts showed a high technical success rate, a low severe complication rate and a good patency rate of endovascular intervention at short-, mid- and long-term follow-up. However, the level of these scientific reports is low. The good outcomes obtained in these earlier studies may nevertheless encourage expansion of the therapeutic indications of this approach.

Indications according to clinical severity

Clinical severity should be evaluated in the preoperative workup, with investigation of multiple quantitative and semi-quantitative parameters. The Villalta score (a diagnos-

tic and severity score) is well accepted and widely used to evaluate PTS [40]. The severity of PTS is proportional to the score. Scores between 5 and 9 correspond to mild PTS, scores between 10 and 14 to moderate PTS and scores ≥ 15 , or the presence of ulcers, to severe PTS [32,40].

17. We recommend considering and assessing for venous recanalisation only patients with moderate to severe PTS (Villalta score ≥ 10).

Delphi expert consensus: 83.3% agreement

The Villalta score is nevertheless not perfect, as it does not consider all the complications of PTS. In particular, one symptom and one major sign of PTS are not taken into account in this score, namely venous claudication and healed ulcer. Clinical evaluation should also assess the increase in leg diameter and the presence of concomitant venous claudication evaluated according to walking distance and stair-climbing ability.

Improvement in patient quality of life should be the main goal of endovascular venous treatment and to a lesser degree, owing to the rarity of this complication, prevention of post-thrombotic ulcers.

The indication for this treatment should not be evaluated exclusively according to the Villalta score, but should also take into account the impact of symptoms and patient request.

Finally, the indication for treatment may exceptionally be assessed without considering clinical symptoms, exclusively with the aim of re-establishing venous access (for example, to permit endovascular treatment of cardiac pathologies or dialysis).

18. We suggest that endovascular venous treatment can be considered for patients with mild PTS symptoms (Villalta score 5–9) if the PTS has a substantial impact on their quality of life, or for the prevention of recurrent venous ulcers related to PTS, or in the case of a need for venous access.

Delphi expert consensus: 93.3% agreement

Indication according to radiological severity

An indication for therapy is typically considered in the presence of post-thrombotic iliac or ilio-caval occlusion.

19. We recommend that an indication for treatment should be considered in the case of symptomatic PTS with iliac occlusion.

Delphi expert consensus: 82.6% agreement

Certain patients present IVC occlusions that are regarded as “IVC agenesis” or “continuous azygos” without envisaging the diagnosis of PTS. Most of these patients probably experienced an early thrombosis on an atresia. True congenital atresia or agenesis is rare. Recanalisation may be considered for these symptomatic patients. Previous series showed good results of recanalisation, without increased risk, at this anatomical location [36,38,41–43].

The absence of visualisation of a venous segment (or agenesis) at the iliac or caval level should not be considered as a contraindication to recanalization, as a fibrous tract is frequently not visualised by cross-sectional imaging (venous CT scan, MRI or echography).

Extension of an above-knee occlusion has been reported to increase the risk of treatment failure [35].

20. We suggest that an iliac vein thrombosis extending to the vena cava should not be considered as a contraindication to venous recanalisation.

Delphi expert consensus: 86.7% agreement

21. We suggest that the absence of visualisation of an occluded vein (or agenesis), at the iliac or vena cava level, should not be considered as a contraindication to recanalisation after multidisciplinary evaluation taking into account both clinical and anatomical aspects.

Delphi expert consensus: 86.9% agreement

The same considerations apply to stenting extending below the inguinal ligament [39,44]. From a practical point of view, the extension of chronic femoral vein lesions should prompt caution with regard to the indication for recanalisation, and this indication should be supported by a detailed preoperative workup to characterise the venous flow.

22. We suggest that the extension of venous disease (i.e., the thrombosis) below the inguinal ligament should prompt caution with regard to the indication for endovascular treatment and that this should be supported by a rigorous pre-procedural workup with evaluation of inflow into the future stent.

Delphi expert consensus: 86.7% agreement

Occlusion of the vena cava, iliac or caval agenesis and disease extending below the inguinal ligament should be treated only by an experienced team, as treatment failure may compromise further therapy.

Specific conditions

Inferior vena cava (IVC) anomalies. There are various types of IVC anomaly, as reported in Table 1 [45].

Congenital anomalies of the IVC may lead to slowing or obstruction of blood flow into the right atrium, favouring venous thrombosis and PTS [46–49].

Owing to the rarity of these conditions, only case reports or small series have been reported in the literature [49].

As previously emphasised, it is crucial to differentiate between congenital agenesis of the IVC and complete IVC occlusion caused by a long-standing thrombosis. In the second case, long-term post-PTS fibrosis or stenosis of the IVC may be treated by recanalisation [50,51] with good outcomes (including a primary patency rate of 83% and a secondary patency rate of 93% for the IVC) [50]. An accurate anamnesis searching for a previous neonatal catheterisation at the umbilical level may be useful.

It is also crucial to identify the collateral network linked to the azygos and ascending lumbar veins in order to evaluate the impact of recanalization.

23. We suggest that the presence of an IVC atresia or agenesis does not constitute a contraindication to endovascular venous treatment subject to multidisciplinary evaluation considering both anatomical and clinical aspects.

Delphi expert consensus: 95.6% agreement

24. We suggest that the presence of congenital anomalies, such as duplicated IVC, left-sided IVC, or anomalous IVC drainage into the azygos vein, should not be considered as a contraindication to recanalisation, subject to a multidisciplinary evaluation taking into account both anatomical and clinical aspects.

Delphi expert consensus: 95.6% agreement

Table 1 Different types of inferior vena cava (IVC) anomalies.

Drainage anomalies	Developmental anomalies	Anomalies related to regression failure	Miscellaneous
IVC drainage into the left atrium	IVC interruption (rate 0.6%)	Duplicated IVC (prevalence 1–3%)	Left-sided IVC (prevalence 0.2–0.5%)
Abnormal IVC return	Agenesis of the hepatic or suprarenal segment with azygos continuation	Periaortic left renal vein (rate 1.5–16%)	Retrocaval ureter (rate 0.06–0.17%)
Abnormal type III pulmonary venous return to the IVC via a subdiaphragmatic vein	Absence of the infrarenal IVC		Retroaortic renal vein (rate 0.8–3.7%)
Portal vein drainage into the IVC			

Presence of an IVC filter. IVC filter occlusion may be isolated or associated with chronic lesions of the IVC and/or ilio-femoral veins. The rate of IVC filter occlusion determined in a previous study was 13% [52].

The outcomes of endovascular treatment of chronic IVC filter occlusion were reported in five published studies including a total of 65 patients [53–57].

Three other publications reported the results of endovascular treatment in a total of 192 patients presenting a combination of chronic and acute IVC filter occlusion [58–60]. In the series reported by Chick et al. [58] 48% of the patients manifested acute IVC filter occlusion and in 24% of these patients, concomitant ablation of the temporary filter was performed.

The reported recanalisation technique consisted in piercing the filter by means of a guidewire or needle, followed by balloon angioplasty and stenting or use of a self-expanding stent. The majority of the self-expanding stents used were Wallstents, in the context of various interventional setups (simple vena cava stenting, ilio-caval stenting, use of kissing stents or confluence stenting). Success rates ranged from 95 to 100% for chronic lesions, with permeability rates at 24-month follow-up of 75 to 100% and clinical improvement rates of 60 to 85%. In one series, the rate of major complications was 14% (two deaths due to cerebral haemorrhage) [58]. In another series, renal vein thrombosis and pulmonary embolism were reported as major complications [60]. No case of vena cava rupture has been reported.

25. We suggest that an occluded or patent IVC filter should not be considered as a contraindication to vena cava recanalization, subject to a multidisciplinary team meeting.

Delphi expert consensus: 86.9% agreement

Presence of a surgical interruption of the IVC. Surgical interruption of the IVC prior to implantation of a percutaneous vena cava filter has been reported in patients with extensive leg thrombosis [61].

Surgical occlusion of the IVC may be achieved by simple ligation, use of a caval clip or by partial interruption of the IVC using an Adams-DeWeese IVC clip. Three successful cases of endovascular IVC recanalisation have been reported in the literature [62], including one case of simple angioplasty using an Adams-DeWeese clip [63] and one using clip plicature of the IVC [64].

A recent article describing IVC canalisation in eight patients, reported a technical success rate of 100% with a primary patency rate of 100% at 2-year follow-up [65].

26. We suggest that a surgical interruption of the IVC does not constitute a contraindication to vena cava recanalization, subject to a multidisciplinary team meeting.

Delphi expert consensus: 86.9% agreement

Antiphospholipid syndrome (APS). Two case reports concerning venous recanalisation in patients with APS were published in 2018 [66,67].

Venous recanalisation should not be systematically considered in patients with APS in the absence of further data [68] and considering the high thrombotic risk of this disease [69], exposing the patients to stent thrombosis, and endothelial in-stent proliferation.

Patients with APS may be at different levels of risk depending on several variables [70]. Patients at higher risk include those with associated cardiovascular risk factors who are also positive for at least the circulatory anticoagulant test, or all three individual anticoagulant tests available (triple positivity = lupus anticoagulant + anticardiolipin antibodies + anti-B2 glycoprotein I antibodies), or who have previously experienced arterial thrombosis. These patients should not be considered for venous recanalisation in view of the severity of their symptoms and their high thrombotic risk.

27. We suggest that venous recanalisation should be considered with caution in patients with APS, in view of the absence of relevant data and the high risk of thrombosis.

Delphi expert consensus: 93.3% agreement

For patients with severe PTS, having a substantial impact on their quality of life but not associated with neuropathy, a multidisciplinary discussion of the benefit-risk ratio should be implemented. The risk of early stent-related thrombosis and in-stent thrombosis should be explained to the patient. Moreover, interruption of oral anticoagulant therapy in the context of venous recanalization could expose these patients to disease instability or worsening of APS particularly in higher risk patients (with triple test positivity, previous arterial thrombosis or organ failure). Moreover, bleeding complications are not uncommon in this population, as optimised antithrombotic treatment is not interrupted during the invasive intervention.

28. We suggest that for patients with severe PTS impacting their quality of life, who manifest stable APS under anticoagulant therapy, but not high-risk APS (as defined by triple test positivity, previous arterial thrombosis, or organ failure), the decision whether or not to perform venous recanalisation should be taken after multidisciplinary discussion (in a rare disease centre).

Delphi expert consensus: 83.3% agreement

Concerning anticoagulant therapy in the context of recanalisation, the choice is between a low-molecular-weight heparin and a vitamin K antagonist, as there are no data on the use of Direct Oral Anticoagulants (DOACs) in this population [23,71].

29. We suggest that in patients with APS, anticoagulant therapy should comprise a vitamin K antagonist or a low-molecular-weight heparin.

Delphi expert consensus: 80% agreement

Cancer. Endovascular treatment of patients with venous obstruction due to cancer has been studied only in the context of cancer-related ilio-caval compression or obstruction (post-surgery or post-radiotherapy) [72,73]. A total of 87 patients in three studies were treated for iliac-caval compression or obstruction due to cancer. The immediate clinical improvement rate ranged from 61 to 100% with a recurrence rate of 5 to 37%. A 10% rate of minor complications was reported.

With respect to patients receiving palliative treatment, the immediate efficacy of iliac-caval stenting was evaluated in 19 patients [74], although symptoms recurred in 37% of these patients. In this series, the 6-month mortality rate was 80%, highlighting the questionable value of venous recanalisation in patients with such a poor life expectancy [74]. The complications evidenced in this cohort comprised stent migration, embolism or re-thrombosis, death, cardiac rhythm disorders, acute heart failure, bleeding or haematomas, and arterial ischaemia related to arterial compression by the stent. Dedicated studies on peripheral venous stenting are mandatory to evaluate the impact of this procedure on this particular population category. Both cancer stability and life expectancy should be considered, and special attention should be focused on anticoagulant therapy following revascularisation.

30. We suggest that before considering venous recanalisation for a patient with a concomitant solid cancer, a multidisciplinary evaluation is needed to discuss aspects related to the patient, the procedure, and possible complications.

Delphi expert consensus: 86.6% agreement

31. We suggest that before envisaging venous recanalisation for PTS in the context of a concomitant solid cancer, functional impairment, bleeding risk, and life expectancy should be assessed to establish the feasibility of the procedure.

Delphi expert consensus: 93.3% agreement

32. We suggest that a concomitant solid cancer should not be considered as an absolute contraindication to vena cava or ilio-caval recanalisation.

Delphi expert consensus: 90% agreement

Myeloproliferative syndromes, non-solid cancers. So far, no article has been published on this topic.

In practice, from an empirical point of view:

33. We suggest a multidisciplinary evaluation before proposing venous recanalisation for a patient presenting a myeloproliferative disorder or a non-solid cancer.

Delphi expert consensus: 93.3% agreement

34. We suggest evaluation of the benefit-risk ratio, taking into account patient life expectancy, prognosis, autonomy, functional impairment and bleeding risk, before envisaging venous recanalisation for PTS in the context of a myeloproliferative disorder or a non-solid cancer.

Delphi expert consensus: 93.3% agreement

35. We suggest continuing anticoagulant therapy after venous recanalisation for PTS in the context of a myeloproliferative disorder or a non-solid cancer.

Delphi expert consensus: 93.3% agreement

Other conditions carrying a vascular risk: Behçet's disease and chronic intestinal inflammatory disease. Forty percent of patients with Behçet's disease may present an associated vascular disease. In a study comparing 78 patients having experienced prior lower leg venous thrombosis due to Behçet's disease to 50 control patients with the same condition due to other causes, patients with Behçet's disease showed more severe clinical signs, including an increased prevalence of bilateral thrombosis, or unsuccessful or incomplete recanalisation for more severe PTS. Effectively, 51% of patients with Behçet's disease had severe PTS and 32% presented venous claudication compared to 8% and 12%, respectively, in the control group. PTS before recanalisation was associated with interruption of anticoagulant therapy when immunosuppressor treatment was prescribed [75].

These patients constitute an appropriate population for venous recanalisation if their vasculitis is not in flare and is stable, as confirmed by follow-up. As Behçet's disease may cause vein wall abnormalities, caution is warranted when considering recanalisation [76].

In contrast, in a dedicated series focusing on patients with chronic bowel inflammatory disease, these patients did not show an increased frequency of PTS compared to controls. The risk of acute venous thrombosis is maximal during the acute inflammatory state [77]. No study concerning endovascular procedures in this patient population has been published.

In practice, from an empirical point of view:

36. We suggest that previous Behçet's disease or chronic inflammatory bowel disease should not be considered as a contraindication to venous recanalisation in the absence of flare and subject to a multidisciplinary decision.

Delphi expert consensus: 83.3% agreement

Women of childbearing age. Three studies have evaluated vascular interventions in women of childbearing age [78–80]. Hartung et al. [78] reported a follow-up of 62 women of childbearing age treated by venous stenting. In this study, eight pregnancies occurred during follow-up in six patients treated by left iliac venous stenting under low-molecular-weight heparin at prophylactic dose for 3 months during pregnancy. No acute venous thrombosis, pulmonary embolism or any other complication occurred during follow-up. Fifty-seven percent of the patients manifested signs of compression related to the fetus, which should be considered as a supplementary risk factor for thrombosis. Dasari et al. [79] described a cohort of 310 women of childbearing age.

ring age undergoing iliac stenting of whom 12 later became pregnant. The results confirmed that women of childbearing age may be treated by venous stenting without any complications. Marcelin et al. [80] described a cohort of 211 women of childbearing age undergoing ileo-femoral venous stenting to treat PTS, of whom 37 subsequently became pregnant. The French society of Radiology nevertheless recommends avoiding venous interventional procedures in pregnant women [81].

Based on expert consensus, taking into account published data:

37. We recommend verifying the absence of pregnancy in women of childbearing age, according to the French Radiology Society guidelines, prior to any venous recanalisation.

Delphi expert consensus: 100% agreement

38. We recommend that expected future pregnancy should not be considered as a contraindication to venous recanalisation.

Delphi expert consensus: 83.3% agreement

39. We recommend that women of childbearing age should be advised to use a method of contraception during anticoagulant therapy following venous recanalisation.

Delphi expert consensus: 80% agreement

40. We recommend that all women treated by venous recanalisation with stenting should undergo close clinical and ultrasound follow-up during pregnancy.

Delphi expert consensus: 86.7% agreement

41. We suggest that a history of previous venous recanalisation should not influence the indication for anti-coagulant treatment and the choice of anticoagulant in the case of future pregnancy.

Delphi expert consensus: 93.3% agreement

42. We suggest that in women having previously undergone venous recanalisation, venous DUS should be performed at the beginning of pregnancy to establish a baseline imaging profile that may be helpful in the case of suspected DVT.

Delphi expert consensus: 86.7% agreement

Procedures

Recanalisation and stenting techniques

In the absence of dedicated literature on the topic, the expert group proposes the following guidelines.

Vein puncture should be performed in a healthy zone, as identified by CT scan or DUS [82,83]. Permeability is effectively influenced by inflow and outflow. Any form of access that cannot allow complete treatment of the target lesion is not recommended. This proviso could justify various types of venous access (e.g., via the homolateral common femoral vein, internal jugular vein, or homolateral popliteal vein).

43. We suggest that the access point for venous recanalisation should be located in a healthy venous segment.

Delphi expert consensus: 100% agreement

44. We suggest that the vein should be accessed under US guidance.

Delphi expert consensus: 100% agreement

The entire length of the target lesion should be dilated to the nominal diameter of the planned stent [41].

45. We suggest that for venous recanalisation, the target vein should be predilated up to the diameter of the stent envisaged.

Delphi expert consensus: 100% agreement

Venous stenting is the final phase of venous recanalisation, its objective being to improve the long-term patency of the recanalized vein. Ideally, stenting should be performed from one healthy vein zone to another healthy vein zone [38], considering the location and diameter of the native vein [83,84]. Healthy status is evaluated according to the absence of stenosis and chronic venous lesions. The diameter of the iliac vein ranges from 14 to 16 mm, that of the IVC ranging from 18 to 24 mm. Stenting of the entire length of the lesion is recommended. Effectively, it may be challenging to evaluate on the basis of imaging the presence of persistent venous lesions (dissections or chronic lesions) and only complete stenting can guarantee good permeability. If multiple stents are used, these should overlap by at least 15 mm [83,85,86].

46. We suggest that the stent should cover all the target lesions.

Delphi expert consensus: 100% agreement

47. We suggest that the stent should cover all the target lesions, extending from one healthy vein zone to another.

Delphi expert consensus: 100% agreement

For stenting of the common iliac vein, the stent should traverse the IVC, covering the target lesion without obstructing the contralateral vein and without entering into contact with contralateral vena cava wall, as this could increase the risk of a contralateral thrombosis, evaluated at 2% in the meta-analysis performed by Seager et al. [34,87].

48. We suggest that if the lesion extends to the common iliac vein, the stent should cover the diseased area without reaching the opposite wall of the IVC or obstructing the contralateral common iliac vein.

Delphi expert consensus: 83.3% agreement

In the context of disease extending to the common femoral vein, the stent could be implanted below the inguinal ligament without any increase in fracture, restenosis or occlusion, as demonstrated by Neglen et al. [44], who evaluated retrospectively 177 patients treated with a femoral vein stent.

49. We suggest that if the lesion extends to the common femoral vein, the stent should be extended so as to cover the entire diseased area without reaching the opposite wall of the IVC or obstructing the contralateral common iliac vein.

Delphi expert consensus: 91.6% agreement

Recanalisation of the ilio-caval confluence may be challenging in view of the frequent association of bilateral lesions. Double, or triple access is frequently necessary, involving the jugular and femoral veins, unilaterally or bilaterally. Crossing of the lesion may be achieved by use of a guidewire in an ascending or descending direction. The "rendezvous" technique, consisting in externalization of the guidewire from a distal sheath, is frequently used to obtain sufficient support for advancing a balloon catheter.

In the case of bilateral iliac vein involvement, it is recommended to recanalise and dilate the contralateral side as well, before dilatation of the IVC. Once both guidewires are in place and have been advanced distally into the femoral

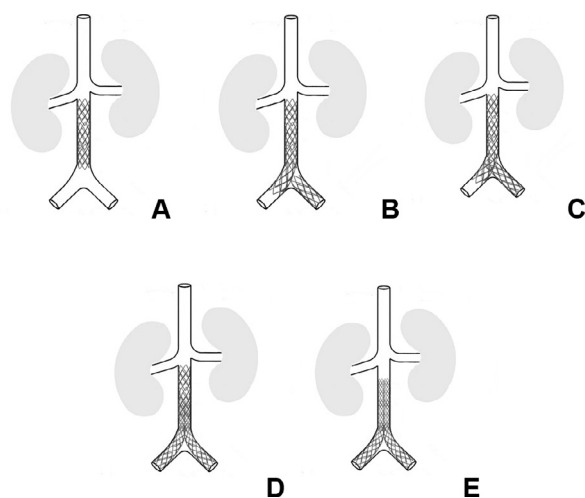


Figure 2 Different technique to treat inferior vena cava: simple stenting (A), affixing technique (B), Y inverted technique (C), confluence technique (D) and double barrel technique (E).

vein or the profunda vein, the most widely used technique is that described by Neglen et al. in 2010 [41], namely the double-barrel or kissing stent technique. After crossing the target lesion by means of two guidewires and balloon angioplasty, two self-expanding stents are released simultaneously in parallel, covering the pathological IVC. This procedure may be completed downstream by other stent implantations. Compared to those achieved by other available techniques (Fig. 2), such as that involving placement of an inverted Y stent after fenestration, the outcomes attained in 115 patients in this series, were better in the kissing stent group, whenever use of this technique was possible (in 39 patients, with primary and secondary patency rates of 77 and 100%, respectively, with an only 8% rate of reintervention). In comparison, the affixing technique (used in 38 patients) achieved a primary patency rate of 73% and a secondary patency rate of 100% with a 32% rate of reintervention, use of an inverted Y stent after fenestration (in 39 patients) attaining a primary patency rate of 41% and a secondary patency rate of 90%, with a 37% rate of reintervention.

The inverted Y stenting technique consists in placement of a stent covering the bifurcation after unilateral recanalisation and fenestration using contralateral stenting, with intentional long overlapping in the IVC. The affixing technique, used up to 2000 and currently used only in the event of fenestration failure, consists in the release of second stent as close as possible to the first stent, but leaving an uncovered area adjacent to the bifurcation. A recent alternative technique, reported in 2015 by Graaf et al. [38] is the confluence or Eiffel tower technique. After bilateral recanalisation using a kissing angioplasty balloon, an initial Nitinol self-expanding stent with a diameter corresponding to that of the IVC (24 mm) is released, if necessary covering the origin of the renal vein and downstream approaching as closely as possible the ilio caval confluence. The second guidewire is then withdrawn and re-advanced inside the IVC stent. Then two Nitinol stents (14–16 mm) are released in a kissing position towards the iliac veins, with an overlap of 20 mm with the caval stent, so as to recreate a harmonious confluence.

This step could be followed by the stenting of other lesions. Another option, used in 24 of 40 patients in the published series, consists in the use of a cobalt chromium balloon expandable stent in order to reduce the risk of an asymmetrical expansion of the two stents, sometimes observed on cone-beam CT imaging. The success rate in 40 patients was 100% with a permeability rate of 78% at the end of the 3-year follow-up, with primary and secondary patency rates of 85 and 95% respectively in the 26 patients treated only with self-expanding stents and 100% for 16 patients treated with balloon-expandable stents. This option was suggested by the authors for all patients except women of childbearing age. Effectively, pregnancy carries a risk of external compression.

50. In the context of caval bifurcation disease extending to the bilateral common iliac veins, we suggest using the confluence (Eiffel Tower) technique.

Delphi expert consensus: 100% agreement

When venous recanalisation was first practised, the stents used were the same as those used in arterial procedures [88]. The ideal stent for venous intervention should have a variable diameter ranging from 12 to 24 mm, should be long, and should have both good radial strength and good flexibility to reduce the risk of fracture. Recently, stents more specifically dedicated to venous procedures have been evaluated [37,89].

The recommended diameters for venous stents are:

- 18 mm or more;
- for the common iliac vein: 14–16 mm;
- for the external iliac vein: 12–14 mm;
- for the common femoral vein: 10–12 mm;
- for the profunda vein: 10 mm [83].

51. We suggest using a flexible Nitinol stent.

Delphi expert consensus: 100% agreement

Anaesthesia

Venous recanalisation may cause variable pain, sometimes severe, depending on the patient, the anatomical complexity and the disease extension. A preoperative visit should be performed systematically by the operator, to inform the patient about the procedure.

52. We suggest that if venous recanalisation is planned, the patient should first be seen by the interventional radiologist, in an outpatient setting.

Delphi expert consensus: 100% agreement

53. We suggest that a pre-interventional consultation with the anaesthetist should be scheduled with the patient at least 48 hours before the planned venous recanalisation procedure.

Delphi expert consensus: 90% agreement

Anaesthesia should be adapted to each situation in order to maximize patient comfort and security. Several cases of venous stenting under local anaesthesia [86,88,89], local anaesthesia with mild sedation [90,91], or general anaesthesia have been reported.

54. We suggest that for patients with chronic venous occlusion necessitating a prolonged stenting procedure, that this should be performed under general anaesthesia or sedation according to the centre.

Delphi expert consensus: 86.7% agreement

Antibiotic prophylaxis

No studies focusing on antibiotic prophylaxis during venous stenting interventions have been published and studies concerning this type of intervention have rarely reported antibiotic treatment. Guidelines on antibiotic prophylaxis were published in 2017 by the French Society of Anaesthesia in conjunction with several other societies, including the French Society of Radiology [92].

Certain contexts, such as femoral access and re-intervention may increase the risk of infection. Antibiotic prophylaxis should be instigated even if the patient is already under antibiotic therapy for leg ulcers [92].

If a stent is used, an initial intravenous dose of cefazoline 2 g is suggested as a single dose, unless the procedure is longer than 4 h, in which case a second dose of 1 g should be planned. As an alternative, cefamandole or cefuroxime may be used, as a single 1.5 g intravenous dose unless the procedure is longer than 2 h, in which case a second dose of 0.75 g should be envisaged. For patients allergic to penicillin, vancomycin 15 mg/kg/60 min as a single dose should be considered.

In patients with an implanted heart valve, including those having undergone Transcatheter Aortic Valve Implantation (TAVI), previous endocarditis or congenital cardiomyopathy, elimination of all potential septic sources two weeks before stent implantation is recommended. Antibiotic prophylaxis should be considered for these patients in the form of amoxicillin 2 g administered at least 30 min before the end of the intervention. In the case of penicillin allergy, clindamycin 600 mg should be considered, using the same administration schedule [93].

55. We suggest that usual care concerning antibiotic prophylaxis should be adapted for patients with a prosthetic heart valve, including those having undergone TAVI, as well as for patients having experienced previous endocarditis or with congenital cardiomyopathy.

Delphi expert consensus: 100% agreement

Peri-procedural anticoagulant therapy

Unfractionated heparin has been used in clinical practice since 1935. The goal of this treatment during endovascular procedure is to prevent clot formation on guidewires, balloons, other catheters and stents. There is a clear consensus on the use of efficacious anticoagulation during venous recanalisation, even though the guidelines issued by the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) in 2014 [83] did not include a specific protocol. In the meta-analysis published by Seager et al. [34], the issue of anticoagulation was not addressed, in contrast to the systematic review by Razavi et al. [94], which proposes a protocol based on a study in 1100 patients treated for chronic venous occlusion by stenting. In this protocol, unfractionated heparin is administered as an endovenous 4000–5000 IU bolus, adjusted during the procedure on the activating clotting time, with a cutoff value of 280–300 seconds. Recent publications concerning the use of stents not specifically designed for venous stenting, such as Wallstents or Nitinol stents [95–97], or dedicated venous stents [37], as well as articles focusing on the treatment of complex lesions, such

as IVC occlusion [38,41,98,99], describe the administration of unfractionated heparin with some variations on the initial protocol. In some cases, unfractionated heparin was injected at a fixed dose of 5000 IU without considering patient weight, in other cases at a weight-adjusted dose of 50 IU/kg. Doses were corrected during the procedure on the basis of activated clotting time, with a target value of 300 seconds, a complementary dose being injected if necessary.

56. In the preoperative phase of a planned venous recanalisation procedure, we suggest adherence to preoperative protocols for anticoagulant management.

Delphi expert consensus: 93% agreement

57. We suggest the use of periprocedural anticoagulation during endovascular venous recanalisation.

Delphi expert consensus: 100% agreement

58. We suggest administration of either an initial 5000 IU bolus or a weight-adjusted 50 IU/kg dose of unfractionated heparin during endovascular venous recanalisation.

Delphi expert consensus: 91.7% agreement

Intermittent pneumatic compression

Early walking after the procedure avoids the risk of early thrombosis. Up to now, the use of intermittent pneumatic compression has not been evaluated in any published study, even though some reports show a reduction in early thrombosis rate, particularly in patients not allowed to walk.

59. We suggest early ambulation after endovascular venous recanalisation.

Delphi expert consensus: 93.3% agreement

Periprocedural complications

Venous recanalisation for PTS is characterized by an absence of early deaths (at 1-month follow-up) and low levels of morbidity, according to the outcomes reported in a recent meta-analysis by Seager et al. including 2431 patients treated by venous stenting [34]. The reported complications are showed in Table 2.

The most frequent complications are haematoma at the puncture site, bleeding, iliac vein perforation and early thrombosis. These complications can generally be treated by a further intervention without major complications. Late complications comprise thrombosis and restenosis [100].

60. We recommend reporting adverse events according to the guidelines issued by the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR).

Delphi expert consensus: 93.3% agreement

Clinical and DUS reports

Patient care should include an outpatient visit and a detailed DUS report, focusing on anatomical lesions [25,34,83,94,95,101]. Published studies do not describe the data that should be included in this report. In the clinical report, symptoms, PTS score and quality of life should be considered. The operative report should describe the extent and site of chronic venous lesions, the main elements of the intervention (access point, stent characteristics, stent location in the vein, haemodynamic results and suggested postoperative therapy).

Table 2 Types of complications adapted from Seager et al.

Types of complications	217 patients
Short-term complications	
Puncture-site haematoma	22 (10%)
Haemothorax	1 (0.4%)
Retroperitoneal bleeding	2 (0.9%)
Pseudoaneurism	2 (0.9%)
Heparin-induced thrombocytopenia	2 (0.9%)
Early stent thrombosis	93 (43%)
Embolisation	1 (0.4%)
Iliac vein perforation	53 (24%)
Stent migration	9 (4%)
Stent kinking	2 (0.9%)
Stent fracture	1 (0.4%)
Arterial dissection	1 (0.4%)
Renal failure	1 (0.4%)
Late complications	
Late stent thrombosis	91 (42%)
Contralateral thrombosis	14 (6%)
Late restenosis	62 (29%)
Death	1 (0.4%)

In the absence of a specific classification, the DUS report preceding recanalisation should include a description of the lesion according to the LET classification [16].

61. We suggest that the clinical assessment of patients with chronic venous occlusion should include determination of the Villalta score and a quality-of-life assessment.

Delphi expert consensus: 96.7% agreement

62. We suggest that the report of the procedure for patients with chronic venous occlusion should include the location and extent of the chronic venous lesions.

Delphi expert consensus: 90% agreement

63. We suggest that the report of the intervention for patients with chronic venous occlusion should include the main elements of the procedure (venous access, number of stents, type of stent, and haemodynamic results).

Delphi expert consensus: 96.7% agreement

64. We suggest that the operative report for patients with chronic venous occlusion should include the proposed postoperative treatment.

Delphi expert consensus: 80% agreement

Clinical and imaging follow-up

Patients are frequently hospitalised after the venous recanalisation. During hospitalisation, clinical surveillance is suggested to evaluate pain and detect any complications. Pain in the lumbar region and inguinal fold is frequent and self-limiting within a few days. Walking and use of compression stockings should be encouraged. Follow-up visits at 1 day, 1 month and 3 months follow-up are useful to evaluate patient impressions, symptoms (pain reduction, feelings of heaviness, swelling, claudication, disappearance of collaterals), which may improve, remain stable or worsen. Published studies do not suggest any specific follow-up visits or improvement criteria. Definitive improvement may be appraised at the end of 6-month follow-up.

Recurrence of 56–58% of pre-intervention ulcers at 6 months is considered as failure of the intervention. Ulcers that have disappeared by the end of 6-month follow-up are considered as healed [102,103]. A publication by Meng et al. [104] reported an ulcer healing rate of 85% after treatment of stenosis or occlusion and varicose veins.

Results concerning oedema are more variable, healing rates ranging from 32 to 84%. The level and tolerability of compression stockings should be considered.

The need for reintervention may be assessed on the basis of clinical results [104]. The median time to reintervention is 15 months. The indication for treatment depends on residual or recurrent symptoms (69%), pain (10%), oedema (39%), pain and oedema combined (36%), as well as hypodermatitis and ulcers (15%). The decision to reintervene is generally taken on the basis of imaging.

Based on experience, multidisciplinary follow-up by a vascular medicine physician and radiologist should be implemented at 3 months, 6 months, one and 5 years.

65. After venous recanalisation, we recommend a comprehensive post-procedure clinical evaluation and repeated DUS examinations during the first year following this procedure.

Delphi expert consensus: 96% agreement

66. We suggest performing a clinical evaluation, including determination of the Villalta score and quality-of-life assessments, at the 6-month follow-up visit.

Delphi expert consensus: 86.7% agreement

67. We suggest that during patient follow-up, DUS data should be collected.

Delphi expert consensus: 96.7% agreement

68. We suggest that during patient follow-up, treatment data should be collected.

Delphi expert consensus: 100% agreement

DUS Follow-up

DUS is the first examination to be implemented during follow-up after venous recanalisation, owing to its non-invasive nature and performance. It should be performed systematically during follow-up.

In published studies, DUS was performed immediately (i.e., within the week) after the procedure, then at 1, 3, 6, 12 months and at the end of each following year [83]. Primary and secondary patency rates gradually diminish, justifying annual follow-up. A study in 194 patients treated with stenting for PTS demonstrated the efficacy of a follow-up program to prevent re-occlusion [105].

Pathological DUS semiology. Thrombosis is a frequent complication, particularly in stented vein segments. DUS should reveal the location and extent of thrombosis, partial or total obstructions, age and morphological and haemodynamic factors favouring thrombosis (such as inflow rate and residual stenosis). It is essential to try to date this thrombotic event on the basis of both DUS findings and questioning of the patient (to ascertain the date and context of symptom onset, and the level of therapeutic compliance).

Intrastent low flow evaluation is subjective in the absence of guidelines and is based on the assessment of velocities through DUS analysis, together with the quality of vein filling evaluated according to colour or energy modalities.

Slow flow is a factor of thrombosis, favoured particularly by persistence of chronic venous lesions at the entrance of the stent, chronic femoral vein lesions or a recent femoropopliteal DVT. Less frequent risk factors include persistence of an outflow stenosis, particularly at the IVC level. Venous flush tests can provide additional information on mobilisable flows.

Stent wall thickening may correspond to a wall thrombosis or to myointimal hyperplasia.

Failure of stent apposition, a rare complication, may induce flow turbulence related to stenosis caused by endoluminal material.

External compression, causing stent deformation, is frequently observed at the level of the left common iliac vein, if a Cockett syndrome has been inadequately treated (with insufficient radial force and with insufficient covering of the lesion by the stent) and may sometimes be observed at the inguinal or ileofemoral junction.

After venous stenting, we suggest performing:

69. A DUS on the day after the procedure.

Delphi expert consensus: 83.3% agreement

70. A DUS at 1-month follow-up.

Delphi expert consensus: 93.3% agreement

71. A DUS at 3-month follow-up.

Delphi expert consensus: 96.7% agreement

72. A DUS at 1-year follow-up.

Delphi expert consensus: 96.7% agreement

73. An exhaustive and repeated DUS follow-up during the first year.

Delphi expert consensus: 95.7% agreement

74. Urgent performance of a DUS in the event of suspected acute thrombosis or PTS symptom recurrence.

Delphi expert consensus: 100% agreement

75. Repeating the same evaluations (Villalta score, quality-of-life questionnaires) and examinations (measurements, photos) before and after treatment at each scheduled clinical assessment from the 6th month onwards.

Delphi expert consensus: 90% agreement

76. An evaluation of the treatment administered (antiplatelet therapy, anticoagulant treatment, compression stockings) and an evaluation of associated complications, tolerance and adherence to treatment at each clinical control visit.

Delphi expert consensus: 100% agreement

77. A DUS including detailed evaluation of the superficial and deep venous networks, collaterals, haemodynamic intrastent evaluation and assessment of deep and superficial reflux.

Delphi expert consensus: 90% agreement

78. A DUS evaluating the stented site, including vein diameter, filling and flow quality, with particular attention to the stent extremities.

Delphi expert consensus: 96.7% agreement

79. A DUS in the event of thrombosis, evaluating the site, age and diameter of the clot under compression, and searching for morphological or haemodynamic explanations for the thrombosis. We suggest referral of the patient to an expert centre in the event of a further thrombosis or symptom recurrence.

Delphi expert consensus: 96.7% agreement

Cross-sectional imaging follow-up

Follow-up examinations are required at regular intervals to evaluate stent restenosis and the need for re-intervention [103]. In general, the venous stents used for non-thrombotic lesions have a lower restenosis risk at 6 months and a better permeability at 3-year follow-up than the stents used for thrombotic lesions [106]. Abdul-Haqq et al. observed a primary patency rate of 73.7% for thrombotic lesions and 97.2% for non-thrombotic lesions in patients treated by stenting [107]. Consequently, a rigorous follow-up should be implemented. Neglen et al identified three risk factors for restenosis: thrombotic disease, thrombophilia and stenting below the inguinal ligament [108]. In practice, stent fracture and endoluminal calcifications that may justify radiography or a CT scan, are observed during long-term follow-up.

80. We suggest that DUS should be the first-line examination for venous stent follow-up.

Delphi expert consensus: 96.7% agreement

81. We suggest that in the presence of a suspected stent occlusion based on the DUS, a CT venogram (with direct or indirect contrast medium injection) should be performed to confirm the occlusion, its cause, and the extent of the thrombosis, and also to plan further treatment.

Delphi expert consensus: 90% agreement

82. To monitor patency after angioplasty or stenting, we suggest that post-procedural CT venograms at long-term intervals (at 3, 5 and 10 years) should be considered in order to check for stent fracture and the development of endoluminal calcifications.

Delphi expert consensus: 100% agreement

Management of re-occlusion

Even after successful recanalisation, clinical and haemodynamic outcomes according to DUS may be poor and necessitate a further intervention.

After successful recanalisation of post-thrombotic lesions with good clinical and haemodynamic outcomes, venous permeability progressively diminishes during follow-up. Recurrence of venous obstruction may be caused by two different physiopathological processes: in-stent restenosis and in-stent thrombosis. This decrease in patency has been reported in several studies [109] as well as in the metanalysis published by Qiu et al. [110]. In a recent French multicentre retrospective study, primary and secondary patency rates at a mean of 21 months of follow-up were respectively 80.4% and 92.2%. In the metanalysis reported by Qiu et al., primary and secondary patency rates were 83 and 94% at 1 year, 68 and 86% at 3 years and 63 and 82% at 5 years of follow-up. These data justify re-interventions to improve patency. The re-intervention rate is proportional to the severity of the post-thrombotic lesions [111]. Literature on this topic is limited and the following proposals reflect the expert consensus position.

Management of poor results

The results observed after recanalisation may appear haemodynamically inadequate on the initial DUS. If the quality of intra-stent flow is precarious, it is preferable to re-intervene early to improve the quality of the results and to avoid intrastent thrombosis. A CT venogram may add to

DUS analysis of stent deployment. Haemodynamic disorders may be related to insufficient proximal or distal stenting, residual stenosis, stent compression or kinking, or a bad release. Such poor haemodynamic results were observed in 13% of treated patients in the cohort study published by Raju et al. [103]. A further intervention may improve the long-term permeability rate.

Clinical results may be poor even if the haemodynamic results are good. In this situation, residual venous obstruction (in the femoro-popliteal veins) and superficial or deep venous reflux should be evaluated. Femoro-popliteal venous stenosis can be treated by simple angioplasty, and venous reflux by prolonged use of compression stockings or venous ablation. These conditions should be evaluated in a multidisciplinary discussion.

In-stent thrombosis. Acute in-stent thrombosis may be the consequence of:

- interruption or modification of anticoagulant therapy;
- discontinuous thromboprophylaxis;
- associated thrombophilia.

This form of thrombosis is generally symptomatic, even though its discovery may sometimes be incidental.

The occurrence of in-stent thrombosis should prompt a search for an associated haemodynamic problem (such as residual stenosis upstream or downstream of the stent, stent release failure, or compression) by means of a dedicated imaging workup. A CT venogram in conjunction with a DUS is advisable.

In-stent restenosis. The in-stent lumen may sometimes manifest restenosis, developing progressively and frequently involving calcification. The physiopathology of these lesions remains unknown. Raju et al. described both smooth and fibrous restenosis [103].

Neglen et al. reported restenosis revealed by systematic phlebography follow-up in 77% of patients, but only 15% presented symptoms [108]. The risk of restenosis is proportional to stent length [110]. Restenosis may be observed in the context of clinical recurrence or follow-up examinations. In the series described by Raju et al. [103] and Aboubakr et al. [112], 30 and 40% of patients with restenosis, respectively, were asymptomatic. Haemodynamic impairment should be checked by DUS. A CT scan may be useful to evaluate the presence of calcifications and stent anomalies. Endovascular treatment of haemodynamically significant restenosis should be envisaged, as the risk of poor blood flow increases the risk of thrombosis. Raju et al. [103] reported a secondary patency rate of 100% after re-dilatation or re-stenting.

83. In the event of poor haemodynamic results or recurrence (in the form of thrombosis or restenosis), we suggest a further endovascular intervention in order to improve mid- and long-term results.

Delphi expert consensus: 100% agreement

84. In the event of in-stent venous restenosis, we suggest performing a CT venogram, in conjunction with a DUS, before planning any new intervention.

Delphi expert consensus: 96.7% agreement

85. In the event of acute in-stent thrombosis, we suggest a pharmaco-mechanical treatment within 4 weeks following the thrombosis.

Delphi expert consensus: 86.9% agreement

86. In the event of stent thrombosis, we suggest a multidisciplinary evaluation of anticoagulant therapy duration.

Delphi expert consensus: 100% agreement

Long-term treatment

Postprocedural management (compression stockings, walking)

After the venous recanalisation, patients should wear compression stockings exerting pressure at the calf level (30–40 mmHg) during the 6 months following the procedure. Compression stockings should be worn for 80% of the day (ideally from getting up to going to bed). Adherence to the wearing of compression stockings is mandatory for their efficacy. Intermittent compression stockings could be used from the first night after the procedure. Early walking is recommended as soon as possible.

87. We suggest the wearing of calf compression stockings for 6 months after the procedure during at least 80% of the day.

Delphi expert consensus: 96.7% agreement

88. We suggest the continued wearing of calf compression stockings beyond 6 months after the procedure if signs of venous insufficiency are present.

Delphi expert consensus: 93.3% agreement

Management of great saphenous vein incompetence

Associated varicose and post-thrombotic chronic lesions may be managed only with respect to secondary veins and in the context of chronic venous insufficiency (CEAP 4 or plus) that is resistant to treatment or recurrent in the superficial network manifesting venous insufficiency.

Therapy addressing venous insufficiency may improve endovenous treatment of proximal venous obstructions, with beneficial effects on quality of life, rate of ulcer healing and recurrence rate [113].

Minimally invasive treatment, such as sclerosis and thermal ablation should be preferred to a surgical approach [114].

89. We suggest that in the context of superficial venous insufficiency associated with PTS, on condition that venous recanalisation is performed first, the treatment of venous insufficiency is not contraindicated in non-supplying venous circulation segments with reflux within areas showing cutaneous signs of chronic venous insufficiency (CEAP 4 and above), provided that the “inflow” of the de-obstructed vein is not impaired.

Delphi expert consensus: 83.3% agreement

Anticoagulant and antiplatelet therapy after venous stenting for chronic lesions

Anticoagulants. The American Heart Association recommends full anticoagulation after venous stenting (IIa; C recommendation), suggesting the use of an antiplatelet agent associated with an anticoagulant in patients at risk of re-thrombosis (IIb;C). However, there is no clear consensus on the choice and duration of anticoagulant therapy.

A recent consensus achieved using the Delphi method (involving 51 surgeons, 42 interventional radiologists and 13 haematologists) [115] reported the use of 12 different

anticoagulant regimens after ilio-femoral venous stenting. A third of these experts used long-term vitamin K antagonist therapy and 20% long-term direct oral anticoagulant therapy, 35% discontinuing this treatment after 6-month follow-up, and 25% used antiplatelet therapy following anticoagulant treatment.

The conclusions of this study were that:

- anticoagulant therapy is preferable to antiplatelet treatment after venous stenting (72% agreement);
- low-molecular-weight heparin is the treatment of choice for the first 2–6 weeks after this procedure (67% agreement);
- anticoagulant therapy should be discontinued after 6–12 months from the first DVT if the blood flow is satisfactory and the workup for thrombophilia is negative (87% agreement);
- anticoagulant therapy should be continued in the case of multiple DVT episodes (85% agreement).

Several comments are worth making as regards this Delphi study.

Among the various anticoagulant treatments, vitamin K antagonists were the most widely used, although 30% of the patients were treated with a direct oral anticoagulant, reflecting the evolution of clinical practice. Concerning the impact of the thrombophilia workup on the therapeutic decision, it is debatable whether it plays any role and no specification regarding the nature of this thrombophilia workup has been developed.

A particular case is the management of patients having undergone previous venous stenting during pregnancy. Hartung et al. [78] reported a small series of eight pregnancies in six patients having undergone venous stenting without anticoagulant therapy at the beginning of pregnancy. All these patients received enoxaparin 4000 U/day from the third month of gestation up to the week before delivery. No thrombosis or bleeding was reported. Dasari et al. reported a series of 12 women having undergone venous stenting during pregnancy under prophylactic low-molecular-weight heparin [79].

90. We recommend prescribing anticoagulant treatment after venous stenting for PTS.

Delphi expert consensus: 100% agreement

91. We suggest prescribing anticoagulant therapy with either low-molecular-weight heparin, warfarin or a direct factor Xa inhibitor after venous stenting for PTS.

Delphi expert consensus: 83.3% agreement

92. We suggest that after venous stenting, if a direct oral anticoagulant is used, to prescribe either rivaroxaban 20 mg/day or apixaban 5 mg twice a day, without a loading dose, irrespective of whether or not the patient had received anticoagulant treatment before the procedure.

Delphi expert consensus: 82.6% agreement

93. We suggest that the duration of anticoagulant treatment should be evaluated on the basis of patient characteristics, subject to good stent patency.

Delphi expert consensus: 90% agreement

94. We suggest long-term anticoagulant therapy for patients treated by venous stenting and presenting recurrent DVT.

Delphi expert consensus: 86.7% agreement

95. We suggest a multidisciplinary evaluation to determine the duration of anticoagulant therapy in patients treated by stenting after a first unprovoked DVT.

Delphi expert consensus: 86.7% agreement
Antiplatelet therapy. A retrospective study evaluated the effect of an antiplatelet regimen on permeability after ilio-caval stenting (62 patients) [116]. Previous DVT was reported in 54.8% of patients. After a median follow-up of 11.6 months, primary and secondary patency rates at 12 months were respectively 70% and 92.4%. After stenting, 97% of patients received an anticoagulant, 48.4% warfarin, 62.9% enoxaparin, 25.8% a direct factor Xa inhibitor and a mean of 35.5 other treatments. Thirty-eight patients (61.3%) received an associated antiplatelet treatment (aspirin in 41.9%, clopidogrel in 12.9%, and dual antiplatelet therapy in 6.4%). In the absence of an antiplatelet regimen, most cases of re-thrombosis occurred within the first months, up to the 15th month.

Six cases of bleeding were reported, including three cases of major bleeding, one during a switch from low-molecular-weight heparin to a vitamin K antagonist and the others under enoxaparin plus aspirin or rivaroxaban plus dual antiplatelet therapy.

96. We suggest the use of antiplatelet therapy in addition to anticoagulants after venous stenting.

Delphi expert consensus: 95.7% agreement

97. We suggest the use of aspirin 75–100 mg/day or clopidogrel 75 mg/day after venous stenting.

Delphi expert consensus: 82.6% agreement

98. We suggest that antiplatelet therapy should be prescribed for at least 1 month after venous stenting.

Delphi expert consensus: 91.3% agreement

99. We suggest considering the risk of bleeding when deciding whether or not to extend antiplatelet treatment beyond 1 month after venous stenting.

Delphi expert consensus: 86.7% agreement

100. We suggest not to continue antiplatelet treatment beyond 12 months after venous stenting.

Delphi expert consensus: 80% agreement

Conclusion

This expert consensus provides guidance for venous recanalisation in the setting of PTS in clinical practice. High quality studies remain to be conducted to improve the management of PTS treatment.

Disclosure of interest

The authors declare that they have no competing interest.

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