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RECOMMENDATIONS

Unresolved questions on venous thromboembolic disease. Therapeutic management of superficial vein thrombosis (SVT). Consensus statement of the French Society for Vascular Medicine (SFMV)

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Summary Superficial vein thrombosis (SVT), a manifestation of venous thromboembolism (VTE), is a common condition, yet of all the types of VTE, it has been the least well studied. Recent studies have challenged the conception that SVT is a benign disease, showing that its risk factors overlap with those of deep-vein thrombosis (DVT) and that it is frequently associated with DVT or pulmonary embolism (PE). In 2010, the CALISTO trial demonstrated the benefit of treatment with fondaparinux at the dose of 2.5 mg (one injection per day) for 45 days for lower limb SVT. Prior to CALISTO, the treatment of SVT was based on venous compression therapy, nonsteroidal anti-inflammatory drugs (NSAID) and anticoagulation using various therapeutic regimens. Surgery could also be envisaged in certain cases. In CALISTO, the inclusion criteria designed to obtain a homogeneous population meant that numerous questions remained unanswered with respect to SVT occurring in other locations and under other circumstances, notably in pregnant women, patients with renal insufficiency, and patients with recurrent SVT or superficial vein thrombosis less than 5 cm long. The aim of this section is to review the current state

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of knowledge of SVT and to propose or recommend therapeutic strategies for the management of SVT according to the clinical context, the location of the thrombosis, and the presence of particular risk factors.

The challenge

Superficial vein thrombosis (SVT), a manifestation of venous thromboembolism (VTE), is a common condition. Yet, it has been less well studied than any other type of VTE. Few clinical trials have focused on this condition and relevant published data are relatively scarce [1]. SVT is regarded as a relatively benign disease, yet recent studies have challenged this concept by showing that its risk factors overlap with those of deep-vein thrombosis (DVT) and also that it is frequently associated with DVT or pulmonary embolism (PE) [2]. Its progressive and often recurrent nature is also problematic.

Several observational studies have indicated a link between SVT and DVT, revealing that around 25% of patients with symptomatic SVT also present DVT, a frequency justifying an early complete diagnostic work-up [3,4]. However, the incidence of SVT remains unclear. Several retrospective studies have suggested an incidence higher than that of DVT, but a recent French study conducted in a community-based general population showed an incidence closer to that of PE [2,5]. SVT is usually diagnosed on the basis of clinical findings, but the diagnosis should be systematically confirmed by an ultrasound examination allowing detection of any associated deep-vein thrombosis. In 2010, the CALISTO trial demonstrated the benefit of treatment with fondaparinux at the dose of 2.5 mg (one injection per day) for 45 days for lower limb SVT, in preventing the extension and recurrence of SVT, the clinical safety of this treatment being good [6]. Prior to CALISTO, the treatment of SVT was based on venous compression therapy, nonsteroidal anti-inflammatory drugs (NSAID) and anticoagulation using various therapeutic regimens [7]. Surgery could also be envisaged in certain cases. In CALISTO, the inclusion criteria designed to obtain a homogeneous population meant that numerous questions remained unanswered with respect to SVT occurring in other locations and under other circumstances, notably in pregnant women and patients with renal insufficiency, as well as in patients with recurrent SVT and SVT less than 5 cm in length.

In the context of suspected SVT, we recommend in the first instance a complete venous ultrasound examination of the lower limbs to detect any associated DVT.

Place of anticoagulants in the treatment of superficial vein thrombosis

An anticoagulant treatment should be envisaged for all patients presenting SVT. Based on the results of CALISTO, fondaparinux was granted a marketing authorisation (MA) for the treatment of acute, symptomatic, spontaneous superficial vein thrombosis of the lower limbs in adults not presenting associated deep-vein thrombosis [6]. International guidelines therefore propose treating lower limb SVT of more than 5 cm in length with fondaparinux at the dose of 2.5 mg or with low-molecular-weight heparins (LMWH) rather than no treatment (grade 2B recommendation), suggesting the use of fondaparinux in preference to LMWH (grade 2C recommendation) [8]. Prior to CALISTO, the recommendations issued by the French Medicines Agency (AFSSAPS) in 2009 were of low grade, suggesting low-dose anticoagulation for 7 to 30 days associated with venous compression (based on professional consensus) and NSAID administered topically rather than systemically (grade C recommendation) [9]. The use of anticoagulants at curative dose was not recommended for SVT (grade C recommendation) with the exception of SVT extending to the saphenofemoral junction. If treatment with fondaparinux or a LMWH is implemented, continuation of this treatment for 7 to 30 days was suggested (based on professional consensus). The role of surgery was limited, as this was not recommended as an initial treatment (grade C recommendation), although it could be considered for SVT extending to the saphenofemoral junction. The indication of fondaparinux for the treatment of SVT is based on the results of the CALISTO trial, which showed a lower incidence of symptomatic thrombotic events in patients receiving fondaparinux, based on a composite endpoint comprising DVT recurrence, PE or extension of SVT to within less than 3 cm of the saphenofemoral junction, as well as SVT recurrence. The incidence of this endpoint was 1.2% in the fondaparinux group versus 6.3% in the placebo group at the end of a 2.5-month follow-up after the diagnosis of isolated SVT. Of note, treatment with Fondaparinux was as safe as the placebo, the incidence of major bleeding being identical in the two treatment groups at the end of this period [6].

The results of CALISTO therefore justify current guidelines, which recommend treating symptomatic SVT involving thrombosis more than 5 cm long and located more than 3 cm from the saphenofemoral junction for 30 to 45 days. Recent French inter-society guidelines and a meta-analysis suggest choosing fondaparinux 2.5 mg for 45 days to treat SVTs meeting the CALISTO criterion. This choice is based on the results showing that this molecule is associated with a lower risk of recurrence and good clinical tolerance. The other treatments are less validated, which is why they are not proposed [10,11].

Although one therapeutic trial (SURPRISE TRIAL) tested rivaroxaban 10 mg daily for 45 days in patients with SVT with an additional risk factor, this non-inferiority study lacks power to make a recommendation [12].

However, numerous questions remain unanswered and we shall discuss these in the following sections.

Unprovoked or provoked nature of superficial vein thrombosis

SVT may be characterised as unprovoked if examination of the patient reveals no evidence of any readily identifiable risk factors likely to have triggered this condition. Provoked SVT shares numerous risk factors with DVT, namely age above 65 years, obesity, active cancer, history of thromboembolism, pregnancy, use of oral contraceptives or œstro-progestative therapy, recent surgery, and certain rare diseases, such as Behçet's disease and Buerger's disease. Varicose veins constitute the principal risk factor for lower-limb SVT, being present in 80 to 90% of cases. Typically, SVT occurs in elderly women with a high body mass index (BMI) and chronic venous insufficiency. SVT may therefore be considered to be unprovoked if it occurs in the absence of the associated risk factors cited above [13—15].

Definition of unprovoked and provoked SVT

Unprovoked SVT is defined by the absence of any evident triggering factor.

Provoked SVT is defined by the presence of risk factors (immobilization, cancer, surgery, etc.).

The presence of varicose veins is a risk factor for SVT.

Duration of treatment for SVT

No data have been published supporting prolonged treatment (beyond 45 days) of patients presenting unprovoked SVT. The principal risk factors identified in the POST and OPTIMEV studies, evaluating thromboembolic recurrence at three months, were: male sex and hospitalisation (OPTIMEV multivariate analysis). In the Optimev study, mortality at three months was higher in the group of patients whose SVT was located in a ''healthy vein'' than in the group presenting SVT in a varicose vein, but association with DVT was more frequent in the ''healthy vein'' group and may be a confounding factor [4].

In the POST study, history of thromboembolism, male sex, presence of cancer and absence of varicose veins were risk factors for recurrence. Published data therefore provide no argument in support of increasing the duration of treatment in patients presenting unprovoked SVT. A search for cancer, an inflammatory disease or, depending on the context, thrombophilia associated with antiphospholipid antibody syndrome (APLS) may be justified in certain cases [3]. SVT has a similar risk of recurrence as DVT, although the recurrence phenotype is different since SVT often recurs as SVT and DVT [16].

Similarly, no published data confirm the value of increasing the doses of the treatment administered in order to enhance resolution of the thrombosis [17]. In a French observational study, most SVTs were treated with fondaparinux or LMWH for 45 days or more at the recommended doses [18].

Based on the current state of knowledge, it is premature to propose treating SVT with a direct oral anticoagulant. Although one therapeutic trial tested rivaroxaban 10 mg daily for 45 days in patients with SVT with an additional risk factor, this non-inferiority study lacks the power to make a recommendation [12].

With regard to recurrent SVT, available epidemiological data provide no information concerning the risk of recurrence beyond the second episode.

There is no justification for long-term treatment of patients experiencing recurrence of unprovoked SVT. The risk factors potentially associated with recurrence are principally male sex, history of VTE, and cancer. In the presence of these factors, particularly cancer, a specific treatment should be envisaged (see below). With regard to other risk factors, a longer treatment may be considered on a case-by-case basis. Finally, the data concerning venous thrombosis in a non-varicose vein are contradictory and do not provide a basis for any specific treatment proposal. There are no data supporting adjustment of anticoagulant doses to achieve greater efficacy. In a French observational study, most SVTs were treated with fondaparinux or LMWH for 45 days or longer at recommended doses [18].

For patients experiencing an initial episode or a first recurrence of isolated symptomatic SVT with a thrombus over 5 cm long located more than 3 cm from the saphenofemoral junction (the CALISTO criteria), and no risk factor, we recommend anticoagulant treatment with fondaparinux 2.5 mg (one injection per day) for 45 days.

There is no justification for administering a loading dose, or for increasing the duration of treatment.

For patients presenting symptomatic SVT in a non-varicose vein, with no associated risk factor, we recommend the same treatment.

From the third recurrence of SVT onwards, the benefit of prolonged treatment is uncertain and should be discussed with the patient, taking into account the patient's risk of bleeding and life choices.

Superficial vein thrombosis and active cancer according to ISTH criteria

In patients experiencing an onset of SVT in the context of cancer, the rate of SVT recurrence following discontinuation of anticoagulant treatment is around 10%, justifying the pursuit of this treatment as long as the cancer is active, provided that the risk of bleeding is acceptable [3,4,19,20]. A French retrospective study shows that practitioners willingly prescribe LMWH in patients hospitalized with cancer and SVT in the absence of DVT for at least three months [21]. The attitude is identical for superficial venous thrombosis of the upper limb associated with cancer, for example after placement of a venous catheter. Depending on the context, prophylactic or curative treatment is suggested because the risk of recurrence in this population remains

about 10% at 3-month follow-up, whether in the upper or lower limb [21,22].

For SVT occurring in the setting of cancer, we suggest treatment for 3 to 6 months. For patients with active cancer and without any increased risk of bleeding, prolonged anticoagulant treatment may be proposed. Treatment beyond 3 months is advisable, but the patient's wishes should also be taken into account, as the risk of embolism associated with SVT in this population is largely unknown.

By analogy with proximal DVT and PE, an initial treatment with a LMWH or Fondaparinux without any relay treatment should be envisaged for SVT.

For patients experiencing SVT in the context of cancer, we suggest considering on a case-by-case basis prolongation of anticoagulant treatment beyond 45 days.

In the event of symptomatic extension of SVT, objectively confirmed by ultrasound, in a patient receiving anticoagulant treatment at prophylactic dose, we suggest continuing anticoagulant treatment at curative dose for 3 months. In patients with cancer, we suggest using a LMWH at curative dose or Fondaparinux for 3 months without switching to an oral anticoagulant.

If there is a risk of bleeding, or the risk of thrombotic complications is low, we suggest using a prophylactic dose.

Superficial vein thrombosis and identified risk factors (apart from cancer)

We suggest respect of the recommended duration of treatment in view of the substantial risk of recurrence if treatment is discontinued prematurely.

We suggest refraining from emergency treatment of varicose saphenous veins on diagnosis of SVT.

Once the acute episode has resolved, and if no particular risk factor is present, we suggest proposal of ablation of the affected varicose veins after the occurrence of SVT.

Superficial vein thrombosis less than 5 cm in length

SVT involving a small thrombus, defined empirically as being less than 5 cm long, are considered as benign and require only symptomatic treatment. SVT exceeding 5 cm in length necessitate the treatment specified above. These data are based on the STENOX trial [23] in which the length of 5 cm was arbitrarily chosen to define a clinically relevant thrombosis. The same threshold thrombus length was adopted in the CALISTO trial [6].

For thrombosis less than 5 cm long, we therefore suggest topical treatment. However, this therapeutic strategy may be reconsidered if the thrombus is located close to a perforating vein or to the saphenofemoral or saphenopopliteal junction, in which case the risk of extension into the deep venous system is greater. The therapeutic strategy may also be adapted according to the risk factors presented by the patient, notably in the case of cancer [3,4,13].

We suggest that anticoagulants should not be used to treat SVT if the thrombus is less than 5 cm in length.

For thrombosis less than 5 cm long, we therefore suggest topical treatment.

For patients with SVT involving a multisegmented thrombus or bilateral thrombi less than 5 cm long, in the absence of cancer, we suggest initiating anticoagulant treatment at prophylactic dose.

Thrombosis located less than 3 cm from the saphenofemoral junction

Few studies have specifically focused on SVT extending to the saphenofemoral or saphenopopliteal junction and patients presenting such thrombosis have often been excluded from clinical trials. Nevertheless, various findings indicate their potential for serious consequences as a result of extension of the thrombosis into the deep venous system [3]. The pooled results of the POST and OPTIMEV trials show that involvement of the saphenofemoral or sapheno popliteal junction increased the risk of DVT and PE at 3 months (univariate analysis) [4]. Several other studies have also described extensions of the thrombus into the common femoral vein, in approximately 50% of patients. The management of these SVT remains controversial: ligation of the saphenofemoral junction has been proposed by North-American teams, whereas in Europe, the tendency is to suggest anticoagulant treatment for 3 months [15]. A major distinction is whether or not the thrombus extends to the preterminal valve, which may determine recourse to surgery. A systematic review published by Sullivan and colleagues showed that surgery is associated with a risk of extension to the deep venous system, and in particular a risk of PE similar to that associated with no treatment [24]. Recent guidelines suggest exclusively medical treatment [8].

In the absence of confirmed scientific data, we suggest that sapenofemoral ligation should be avoided.

We suggest anticoagulant treatment at curative dose for at least 3 months for SVT involving a thrombus located less than 3 cm from the saphenofemoral junction in the absence of any bleeding risk.

Asymptomatic superficial vein thrombosis

Data concerning asymptomatic SVT are scarce, as most SVT are accompanied by clinical symptoms, frequently major, which facilitate their diagnosis.

In the absence of validated data, we suggest refraining from anticoagulant treatment.

In the setting of cancer, SVT are generally symptomatic. However, if an asymptomatic SVT is detected in a patient with cancer, prescription of anticoagulant treatment at curative dose may be envisaged without supportive clinical evidence. In all other cases, anticoagulant treatment is not advised.

Specific situations

Superficial vein thrombosis, pregnancy and estro-progestative contraception

As pregnant women are excluded from interventional clinical trials, few data are available concerning SVT in this population. A Danish nationwide cohort study [25] found a SVT incidence rate of 0.6 per 1000 person-years (95% CI: 0.5—0.6) in the antepartum and postpartum periods combined. This incidence increased from the first trimester to the postpartum period, from 0.1 per 1000 person-years to 1.6 per 1000 person-years respectively. Women who developed SVT during pregnancy had a significantly higher risk of subsequent VTE during the same pregnancy or in the postnatal period, with a cumulative incidence of 13.0% (95% CI: 8.3—20.0).

On the basis of the recommendations issued by the Canadian Society of Obstetricians and Gynaecologists [26], treatment with LMWH at prophylactic dose may be suggested for patients presenting SVT during pregnancy. The duration of treatment is more difficult to establish. Most authors concur in proposing durations ranging from 1 to 6 weeks, favouring a longer treatment duration for patients presenting bilateral or highly symptomatic thrombosis, or thrombosis located in proximity to the deep venous system. For more limited or smaller SVT, Canadian recommendations suggest clinical evaluation comprising an ultrasound examination repeated after one week. Given the difficulty of patient selection and the low risk of bleeding, a six-week treatment may be considered necessary taking into account also the postpartum risk of thromboembolism. A recent French retrospective study in two hospitals shows that practitioners prefer anticoagulant treatment with LMWH in pregnancy to treat SVT and that this treatment is continued during the postpartum period if needed [21].

For SVT occurring after the use of œstro-progestative contraceptives, treatment with fondaparinux at 2.5 mg (one injection per day) for 45 days is proposed. Guidelines suggest discontinuation of œstro-progestative contraception during anticoagulant treatment and immediately following its discontinuation, with a subsequent switch to a non-thrombogenic mode of contraception [27].

For SVT occurring during pregnancy, we suggest anticoagulant treatment at prophylactic dose using a LMWH.

We suggest that the increased risk of thromboembolism during the postpartum period should be taken into account.

By analogy with DVT, we suggest considering on a case-by-case basis the prolongation of anticoagulant treatment beyond 45 days, throughout the postpartum period.

In the event of a documented extension of SVT during anticoagulant treatment at prophylactic dose, we suggest envisaging the use of curative doses with regular clinical monitoring.

In view of the mode of administration (subcutaneous injections during a long period), we suggest giving preference to a once-a-day injection regimen.

We suggest refraining from regular platelet monitoring in patients receiving a LMWH for SVT.

In the case of SVT occurring in the context of œstro-progestative therapy, we recommend treatment with fondaparinux at 2.5 mg for 45 days.

We suggest replacing oestro-progestative contraception by a method of contraception not associated with an increased risk of thromboembolism.

SVT in the context of anticoagulant treatment

For SVT occurring during oral anticoagulant treatment at prophylactic dose, we suggest switching to treatment with a LMWH or fondaparinux at curative dose.

Risk of bleeding

We suggest refraining from anticoagulant treatment if the patient is at significant risk of bleeding or is experiencing active bleeding, suggesting instead clinical and ultrasound monitoring. The ultrasound examination should be performed at weekly intervals.

We recommend avoiding placement of a vena cava filter in this context.

If the risk of bleeding is lower, recourse to anticoagulation should be decided on a case-by-case basis, taking into account particularly the presence of additional risk factors for thrombus extension.

Elastic compression therapy for SVT

Prescription of elastic compression stockings is standard for patients with SVT, both to reduce oedema and as a

symptomatic treatment for pain associated with SVT. In general, this therapy is proposed for one week or even two weeks. Furthermore, as the wearing of elastic stockings is an integral part of treatment for venous insufficiency associated with varicose veins, and SVT is often a complication of varicose veins, this therapy is widely prescribed. Data concerning the value of elastic compression therapy in the context of SVT are scarce, but a recent clinical trial showed no improvement of symptoms, no increase in patency, no reduction of thrombosis, no improvement in quality of life, and no decrease in analgesic consumption in 80 patients presenting a SVT less than 5 cm long [28]. The wearing of elastic compression stockings may nevertheless be suggested, in the absence of any contraindication, in order to relieve symptoms or to continue the management of superficial venous insufficiency in the context of SVT, without any expectation of benefit in terms of recanalisation or prevention of thrombus extension. This therapy may be prescribed as a complement to anticoagulant treatment if necessary.

A *Cochrane* meta-analysis did not sufficiently differentiate data concerning the use of compression therapy alone for any conclusions to be drawn, although the benefit of this therapy as a complement to anticoagulant treatment was noted [29].

Despite the absence of convincing data on the benefit of compression therapy on recanalisation or the risk of recurrence, we suggest that elastic compression stockings should be worn for the purpose of analgesia, in the absence of any contraindication.

Superficial vein thrombosis of the upper limbs

Venous thrombosis occurs in approximately 40% of hospitalized patients fitted with an intravenous catheter. The benefit of anticoagulant treatment in these patients has not been established and available data suggest that symptomatic treatment should be prescribed rather than anticoagulant therapy [30]. However, in patients presenting unprovoked upper-limb SVT, a condition analogous to unprovoked lower-limb SVT, an etiological assessment should be envisaged. In patients with cancer, upper limb SVT may expose the patient to recurrence and discussion of curative therapy may occur sometimes if the bleeding risk is low.

For SVT following peripheral vein puncture, topical treatment is sufficient (except in the context of cancer).

For unprovoked upper-limb SVT, the treatment is the same as for SVT of the lower limbs.

Superficial vein thrombosis after thermal ablation of varicose veins

No recommendation has been issued in favor of systematic thromboprophylaxis in patients scheduled to undergo thermal ablation of varicose veins. A control ultrasound examination is generally recommended after thermal ablation to detect any clinically relevant thrombotic complications. The incidence of such thromboembolic complications is nevertheless low, these complications occurring in less than 1% of patients after thermal ablation procedures [31]. The benefit of treatment with a LMWH or an anticoagulant treatment at curative dose has not been established. However, for documented SVT meeting CALISTO criteria, treatment with fondaparinux 2.5 mg per day for 45 days may be envisaged, although it is important to differentiate SVT from vein induration following the thermal ablation procedure.

Following thermal ablation of varicose veins, treatment with fondaparinux 2.5 mg per day for 45 days may be envisaged for symptomatic SVT involving a thrombus exceeding 5 cm in length, and not situated in the veins treated with thermal ablation.

Following thermal ablation of varicose veins, there is no indication for treating a thrombus that does not extend beyond the saphenofemoral junction.

Mondor's disease

The data concerning the etiology and treatment of Mondor's disease are contradictory, as this condition does not correspond to a true thrombotic episode, but more likely to an inflammatory episode or to thickening and local inflammation of the vein concerned. The efficacy of anticoagulant treatment has not been established.

We suggest that anticoagulant treatment should not be prescribed for patients with Mondor's disease, as this condition does not correspond to venous thrombosis.

Severe renal insufficiency

Patients with severe renal insufficiency are systematically excluded from clinical trials, while in the cohorts enrolled in observational studies focusing on SVT, patients with severe renal insufficiency are generally too few for any conclusions to be drawn concerning therapeutic strategies [3,4].

Patients aged over 80 years

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

For patients with severe renal insufficiency (creatinine clearance according to the Cockcroft-Gault formula < 30 mL/min), we suggest solely clinical and ultrasound monitoring in the first instance.

With regard to patients with additional risk factors:

- for those with severe renal insufficiency (creatinine clearance according to the Cockcroft-Gault formula < 30 mL/min), we recommend that fondaparinux 2.5 mg should not be prescribed;
- for those with a creatinine clearance of 20—30 mL/mL, we suggest replacing fondaparinux by LWMH at prophylactic dose;
- for those with severe renal insufficiency (creatinine clearance according to the Cockcroft-Gault formula < 15 mL/min) we suggest that enoxaparin should not be prescribed in view of the lack of specific data concerning VTE and we recommend that other LMWH should not be used.

For patients over 80 years old, we suggest the same therapeutic strategy as for younger patients, in the absence of any particular risk of bleeding unrelated to age.

Informed consent and patient's details

The authors declare that the work described does not involve patients or volunteers.

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CRediT authorship contribution statement

M.-A. Sevestre: conceptualization, formal analysis, investigation, methodology, resources, software, validation, visualization, writing — review & editing. M. Talbot: formal analysis, investigation, validation, writing — original draft. L. Bertoletti, D. Brisot, P. Frappe, J.-L. Gillet, P. Ouvry: conceptualization, formal analysis, investigation, methodology, validation.

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L. Bertoletti reports personal fees and non-financial support from Viatris; grant, personal fees and non-financial support from Bayer; personal fees and non-financial support from BMS-Pfizer; personal fees and non-financial support from Leo Pharma; grants, personal fees and non-financial support from MSD; non-financial support from Johnson and Johnson; outside the submitted work.

D. Brisot, J.-L. Guillet, P. Ouvry, P. Frappe declare that they have no competing interest.

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