Diagnosis and treatment of superficial vein thrombosis

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Keywords
Superficial vein thrombosis, review, epidemiology, diagnosis, treatment

Summary
Superficial vein thrombosis (SVT) is a common disease, characterized by an inflammatory-thrombotic process in a superficial vein. Typical clinical findings are pain and a warm, tender, reddish cord along the vein. Until recently, no reliable epidemiological data were available. The incidence is estimated to be higher than that of deep-vein thrombosis (DVT) (1/1000). SVT shares many risk factors with DVT, but affects twice as many women than men and frequently occurs in varicose veins. Clinically, SVT extension is commonly underestimated, and patients may have asymptomatic DVT. Therefore, ultrasound assessment and exclusion of DVT is essential. Risk factors for concomitant DVT are recent hospitalization, immobilization, autoimmune disorders, age > 75 years, prior VTE, cancer and SVT in non-varicose veins. Even though most patients with isolated SVT (without concomitant DVT or PE) are commonly treated with anticoagulation for a median of 15 days, about 8% experience symptomatic thromboembolic complications within three months. Risk factors for occurrence of complications are male gender, history of VTE, cancer, SVT in a non-varicose vein or SVT involving the sapheno-femoral junction (SFJ). As evidence supporting treatment of isolated SVT was sparse and of poor quality, the effect of fondaparinux on symptomatic outcomes in isolated SVT. This study showed that, compared with placebo, 2.5 mg fondaparinux given for 45 days reduced the risk of symptomatic thromboembolic complications by 85% without increasing bleeding. Based on CALISTO and other observational studies, evidence-based recommendations can be made for the majority of SVT patients. Further studies can now be performed in higher risk patients to address unresolved issues.

Schlüsselwörter
Oberflächliche Venenthrombose, Übersicht, Epidemiologie, Diagnostik, Behandlung

Zusammenfassung
Epidemiology and complications

Epidemiology and risk factors for the occurrence of SVT

Population-based incidence and prevalence data are lacking, but SVT has been reported in 3 to 11% of the population (5, 6, 23), and its prevalence could be more than twice that of DVT and PE combined (6, 10), 6% of men and 14% of women having a history of prior SVT (41, 42). Similar frequencies were observed among patients consulting general practitioners (Fig. 1) (10). The transient and chronic risk factors for SVT are similar to those for DVT or PE, including

- immobilization,
- trauma,
- recent surgery,
- hormonal contraceptives or hormonal replacement therapy,
- pregnancy, puerperium,
- cancer,
- autoimmune disease,
- obesity,
- thrombophilia and
- a personal or family history of VTE.

An exception to this general rule is the higher prevalence of varicose veins in SVT patients, as more than 75% of SVT occur in these veins (18). Another difference is the predominance of women, who constitute two-thirds of the patients presenting SVT (Fig. 1, Tab. 1).

The long saphenous vein or other superficial veins being implicated in the remainder. SVT itself is also a risk factor for the development and recurrence of DVT or PE (23, 38), the risk of DVT being increased about sixfold and that of PE about fourfold in patients with prior SVT, as shown in the population-based, case-controlled MEGA study (38).

In a recent countrywide analysis of 7663 Danish SVT patients, the standardized incidence ratio for the diagnosis of cancer within the first six months in patients after acute SVT was 2.46 (2.10–2.86), compared to 2.75 (2.60–2.90) in DVT patients and 3.27 (3.03–3.52) in those with PE, respectively (33). Particularly strong associations were found for cancers of the liver, lung, ovaries and pancreas as well as for non-Hodgkin’s lymphoma. Interestingly, the risk of developing malignancies declined after one year (33). However, no association between SVT and subsequent diagnosis of cancer was found in a retrospective study of 737 consecutive patients with isolated SVT not involving the sapheno-femoral junction (SFJ) (29).

Finally, all-cause mortality at three months among patients with SVT is about 1%, lower than that in patients with DVT, which may reach 5%, and substantially lower than that in patients with PE, which ranges from 2 to over 15% (5, 21).

Risk of concomitant DVT and/or PE in patients presenting with SVT

In historical retrospective studies, about 3% (1.5–13%) of patients with SVT were found to have symptomatic PE (5, 16, 17, 25), and asymptomatic PE was present in about 30% (20–33%) (27, 28, 39) of SVT patients.

An exception to this general rule is the higher prevalence of varicose veins in SVT patients, as more than 75% of SVT occur in these veins (18). Another difference is the predominance of women, who constitute two-thirds of the patients presenting SVT (Fig. 1, Tab. 1). The long saphenous vein is affected in about two-thirds of SVT cases.

The largest (n = 844) observational study in patients with SVT to date was the French POST study (8), a prospective, multicentre, observational study, which recruited both inpatients and outpatients, and provided data on patient characteristics and occurrence of complications during treatment. The similar OPTIMEV study, performed in France by physicians specialized in vascular medicine (14), prospectively included 788 patients with SVT. At initial presentation, concomitant symptomatic PE and/or symptomatic or asymptomatic ultrasonographically detected DVT was observed in 24.9% of the patients enrolled in POST (8), of whom 9.7% had proximal DVT and 3.9% had symptomatic PE. Similarly, in the OPTIMEV study, concomitant DVT and/or PE was found in 29.4% of patients at presentation (14). Risk factors for the presence of concomitant DVT or PE in SVT patients at first presentation are summarized in (Fig. 2) (14, 31).

Risk of subsequent thromboembolic complications in patients with isolated SVT at presentation

Patients suffering from SVT without concomitant DVT or PE at first presentation are considered to have “isolated SVT”. The characteristics of patients with isolated SVT in a pooled analysis of the POST and OPTIMEV studies are summarized (Fig. 1) (13).

The 3-month outcome of patients with isolated SVT was analyzed in the combined population of the POST and OPTIMEV studies, and risk factors for the occurrence of symptomatic thromboembolic complications during follow-up were identified.
It is important to recognize that these complications occurred while the majority of patients were receiving antithrombotic treatment:

- 84% received anticoagulant drugs, and
- 81% received full therapeutic anticoagulant doses for a median duration of 15 days (interquartile range: 10–61 days).

Compression stockings were prescribed in 70% of the patients. Approximately 11.2% (132/1178) of patients were considered at high risk of thromboembolic complications (due to the presence of cancer or involvement of the SFJ). These patients received anticoagulant treatment more often (89% vs. 83%, p=0.06), at higher doses (full therapeutic dose: 90% vs. 82%, p=0.02) and for a longer duration (median of 31 days vs. 15 days, p < 0.01) compared to patients with neither of these two risk factors (13).

In spite of this anticoagulant treatment, 3.9% of the overall population experienced thromboembolic complications. Of these, 8.3% occurred in varicose veins and 9.7% in non-varicose veins. Of SVT patients, 1.7% developed DVT or PE and 3.3% developed symptomatic SVT extension into the SFJ. These patients may be less specific. The clinical diagnosis of SVT may be unreliable and extension of SVT is often underestimated clinically.
Clinically, it is important to consider differential diagnoses of SVT, particularly:
- erysipelas,
- cellulitis,
- chronic dermatitis,
- lyme disease,
- erythema chronicum migrans and
- other cutaneous manifestations of immunological or rheumatological disorders.

### Treatment

Several options have been proposed for the treatment of SVT, including local measures, such as:
- topical application of non-steroidal anti-inflammatory drugs (NSAIDs),
- elastic compression stockings, or
- excision of a local thrombus,
- systemic NSAID therapy to reduce pain and inflammation, and
- anticoagulant agents, including:
  - low-molecular-weight heparins (LMWH),
  - unfractionated heparin (UFH), prescribed at various dosages and for various treatment durations, or
  - vitamin K antagonists (VKA) (9, 11).

Compression stockings are frequently recommended, and surgical therapy (ligation or stripping of the affected veins) may be performed, mostly as an emergency procedure in patients with SVT extending into the SFJ or the deep venous system.

Unfortunately, even though SVT is a common disease, until recently only about 20 studies had been conducted to investigate its treatment. These included only a few small, randomized controlled trials of anticoagulant agents in SVT patients, of which only two were placebo-controlled studies (▶Tab. 4). These trials suggested that both prophylactic (low) and therapeutic (high or intermediate) doses of anticoagulant treatment reduced the extension and recurrence of SVT in comparison to placebo, while topical treatments appeared to improve local symptoms. In 2007, the evidence for the treatment of SVT was summarized in a Cochrane-Review (11). The methodological quality and size of the studies was considered poor, with several questions remaining unresolved, particularly the:
- optimal dose and
- duration of anticoagulant treatment.

Accordingly, national and international guidelines on the treatment of SVT at that time varied substantially and provided only weak recommendations, although the majority favoured the use of anticoagulant treatment (1, 3, 4, 19, 20, 40). Consequently, the treatment of patients with SVT in routine practice varied widely, as reflected by the heterogeneity of treatment practices shown in the POST and OPTIMEV observational studies (8, 14). Adequately designed studies of sufficient size

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**Tab. 2**

<table>
<thead>
<tr>
<th>Risk factors for concomitant DVT or PE at initial presentation of patients with superficial-vein thrombosis (14, 31)</th>
<th>odds ratio [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>extension of SVT into a perforating vein</td>
<td>17.6 [9.6–32.3]</td>
</tr>
<tr>
<td>recent hospitalization and/or immobilization</td>
<td>13.0 [6.9–24.7]</td>
</tr>
<tr>
<td>autoimmune disorder</td>
<td>6.1 [1.6–22.8]</td>
</tr>
<tr>
<td>age ≥75 years</td>
<td>2.8 [1.7–4.8]</td>
</tr>
<tr>
<td>active cancer</td>
<td>2.5 [1.5–4.2]</td>
</tr>
<tr>
<td>prior VTE</td>
<td>0.2 [0.1–0.4]</td>
</tr>
<tr>
<td>SVT in a varicose vein</td>
<td>0.2 [0.1–0.4]</td>
</tr>
<tr>
<td>SVT in a non-varicose vein</td>
<td>1.8 [1.1–2.7]</td>
</tr>
</tbody>
</table>

CI: confidence interval; SVT: superficial vein thrombosis; VTE: venous thromboembolism

**Tab. 3**

<table>
<thead>
<tr>
<th>Risk factors for the occurrence of DVT or PE during a three-month follow-up in patients with isolated SVT at initial presentation (13)</th>
<th>risk of DVT/PE</th>
</tr>
</thead>
<tbody>
<tr>
<td>age &gt; 62 years</td>
<td>1.90 [0.76–4.74]</td>
</tr>
<tr>
<td>male gender</td>
<td>3.45 [1.35–8.84]</td>
</tr>
<tr>
<td>personal history of VTE</td>
<td>1.21 [0.51–2.89]</td>
</tr>
<tr>
<td>cancer</td>
<td>2.08 [0.67–6.50]</td>
</tr>
<tr>
<td>SVT in a non-varicose vein</td>
<td>2.02 [0.80–5.11]</td>
</tr>
<tr>
<td>recent travel</td>
<td>4.01 [1.32–12.23]</td>
</tr>
<tr>
<td>involvement of the sapheno-femoral junction</td>
<td>2.42 [0.92–6.36]</td>
</tr>
<tr>
<td>initial anticoagulant treatment</td>
<td>4.08 [0.54–30.77]</td>
</tr>
</tbody>
</table>

HR: Hazard ratio; CI: confidence interval; SVT: superficial vein thrombosis; VTE: venous thromboembolism; *p < 0.05

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**Fig. 2** Clinical aspects of superficial vein thrombosis with an inflamed, red, warm, tender area along a superficial vein

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were called for to clarify the role of the different treatment options for SVT (11).

### The CALISTO trial

Initiation of the randomized, placebo-controlled, double-blind CALISTO study was prompted by the lack of sufficient evidence for the treatment of SVT (7). This trial, with clinical endpoints, compared the use of fondaparinux at low (prophylactic) dosage to placebo over 45 days. As the risk-benefit ratio of any treatment was then unclear in patients with SVT, a placebo-controlled trial was necessary and justified. To assess clinical outcomes, the sample size had to be much larger than those of previous trials using surrogate endpoints. A total of 3002 patients with an acute symptomatic SVT at least 5 cm long in the leg were included in the CALISTO study. Patients requiring anticoagulation at therapeutic doses, such as those with DVT or symptomatic PE and those with an extension of the SVT such that the head of the thrombus was ≤3 cm from the SFJ were excluded (7). As the trial was placebo-controlled, high-risk patients were also excluded, such as those with a history of DVT or PE within the last six months or a history of SVT within the last three months, those with active cancer, and those with an indication for surgical treatment in the investigator’s view. The primary efficacy outcome was the composite of adjudicated and confirmed symptomatic events up to day 47, comprising all-cause death, symptomatic PE and those with an extension of the index SVT to ≤3 cm from the SFJ, and recurrence of SVT. All patients had an ultrasound test at inclusion to exclude DVT or extension into the SFJ.

The primary safety outcome was major bleeding up to Day 47 in all randomized patients having received at least one dose of study treatment. All outcomes were confirmed by objective tests and adjudicated as such by an independent central adjudication committee. Permitted concomitant medications included topical NSAIDs (41.6%), analgesics (28.1%), and aspirin or other anti-platelet agents (22.0%). Use of

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Tab. 4  Studies investigating antithrombotic treatment in patients with superficial-vein thrombosis

<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>design</td>
<td>randomized, open-label</td>
<td>randomized, double-blind vs. placebo</td>
<td>randomized, double-blind vs. placebo</td>
<td>randomized, double-blind vs. placebo</td>
<td>randomized, double-blind vs. placebo</td>
<td>randomized, double-blind vs. placebo</td>
<td>randomized, double-blind vs. placebo</td>
</tr>
<tr>
<td>n =</td>
<td>117</td>
<td>444</td>
<td>60</td>
<td>84</td>
<td>427</td>
<td>164</td>
<td>276</td>
</tr>
<tr>
<td>treatment</td>
<td>nadroparin vs. naproxen</td>
<td>UFH + VKA vs. nadroparin + VKA</td>
<td>“low-dose” UFH vs. “high-dose” UFH</td>
<td>enoxaparin vs. surgery</td>
<td>enoxaparin (low dose/high dose) vs. tenoxicam vs. placebo</td>
<td>enoxaparin (low dose/high dose) vs. tenoxicam vs. placebo</td>
<td>dalteparin 10 000 vs. placebo</td>
</tr>
<tr>
<td>treatment duration</td>
<td>6 days</td>
<td>3 months</td>
<td>30 days</td>
<td>4 weeks</td>
<td>8–12 days</td>
<td>4 weeks</td>
<td>14 days</td>
</tr>
<tr>
<td>duration of follow-up</td>
<td>8 weeks</td>
<td>3 months</td>
<td>6 months</td>
<td>6 months</td>
<td>12 weeks</td>
<td>12 weeks</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

Tab. 5  Main efficacy and safety results of the CALISTO study (7)

<table>
<thead>
<tr>
<th>outcome by day 47</th>
<th>fondaparinux n (%)</th>
<th>placebo n (%)</th>
<th>relative risk (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>efficacy n</td>
<td>1502 (9.9)</td>
<td>1500</td>
<td>0.15 (0.08 to 0.26)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>primary composite outcome</td>
<td>13 (0.9)</td>
<td>88 (5.9)</td>
<td>1.99 (0.18 to 21.87)</td>
<td>1.000</td>
</tr>
<tr>
<td>death</td>
<td>2 (0.1)</td>
<td>1 (0.1)</td>
<td>not calculated</td>
<td>0.031</td>
</tr>
<tr>
<td>pulmonary embolism</td>
<td>0 (0.0)</td>
<td>5 (0.3)</td>
<td>not calculated</td>
<td>0.031</td>
</tr>
<tr>
<td>DVT</td>
<td>3 (0.2)</td>
<td>18 (1.2)</td>
<td>0.17 (0.05 to 0.56)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>extension of SVT to ≤3 cm from the sapheno-femoral junction</td>
<td>4 (0.3)</td>
<td>51 (3.4)</td>
<td>0.08 (0.03 to 0.22)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>recurrence of SVT</td>
<td>5 (0.3)</td>
<td>24 (1.6)</td>
<td>0.21 (0.08 to 0.54)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DVT or pulmonary embolism</td>
<td>3 (0.2)</td>
<td>20 (1.3)</td>
<td>0.15 (0.05 to 0.50)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>surgery for SVT</td>
<td>11 (0.7)</td>
<td>57 (3.8)</td>
<td>0.19 (0.10 to 0.37)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**DVT**: deep-vein thrombosis; **SVT**: superficial vein thrombosis
graduated compression stockings was encouraged and these were worn by 83.1% of patients.

The results (Tab. 5) showed a reduction in the risk of the primary efficacy outcome from 5.9% with placebo to 0.9% with fondaparinux, corresponding to an absolute risk reduction (ARR) of 5% (95% confidence interval [CI]: 3.7 to 6.3, \( p < 0.001 \)), and a relative risk reduction (RRR) of 85.2% (95% CI: 73.7 to 91.7) \( p < 0.001 \). No rebound phenomenon was observed after the end of treatment (Fig. 3), all symptomatic secondary endpoints showed consistent risk reductions (Fig. 4), and the treatment effect was consistent within each of the studied subgroups (7).

Safety outcomes included one case of major bleeding (0.1%) in each group, clinically relevant non-major bleeding in 5 (0.3%) patients treated with fondaparinux vs. 8 (0.5%) patients in the placebo group, and minor bleeding in 9 (0.6%) patients receiving fondaparinux vs. 6 in the placebo group (0.4%). No fatal bleeding occurred in either group.

One component of the primary efficacy endpoint was “symptomatic extension of SVT”, which by definition required not only symptoms reported by the patient, but also an extension of the SVT to ≤3 cm from the SFJ, i.e. an extension that normally calls for full-dose anticoagulant therapy or surgical ligation of the SFJ according to most guidelines (1, 3, 4, 19, 20, 40). Other symptomatic extensions (with the head of the thrombus >3 cm from the SFJ), confirmed by objective tests and adjudicated by an independent central committee, also occurred during the study. Fondaparinux also significantly reduced the rate of such extensions from 3.7% (56/1500) to 0.8% (12/1501) at day 77 (\( p < 0.01 \)) (22). Taking into account these extensions, the total rate of symptomatic thromboembolic events recorded on day 77 was 9.4% in the placebo group vs. 1.9% in the fondaparinux group (22).

**Current evidence concerning the management of SVT**

A recently updated Cochrane review summarized the available evidence relating to the treatment of SVT (12) in order to assess the efficacy and safety of local or systemic medical treatment or surgery in patients with SVT of the legs. A total of 26 studies including 5521 participants were reviewed and again the methodological quality of the studies was considered to be poor. Therapeutic modalities ranged from local treatment to systemic treatment with fondaparinux, LMWH, UFH or NSAIDs or surgery. In a placebo-controlled RCT trial (7), fondaparinux achieved a significant reduction in symptomatic VTE (RR 0.15 (0.04 – 0.50)) with comparable rates of major bleeding (RR 0.99 (0.06 .15.86)) relative to placebo. Both prophylactic and therapeutic doses of LMWH (RR 0.40 (0.22 – 0.72)) and [RR 0.42 (0.23 – 0.75)], respectively, and NSAIDs [RR 0.41 (0.23 – 0.75)] reduced extension and recurrence of SVT in comparison to placebo, with no significant effects on symptomatic VTE or major bleeding. Overall, the authors concluded:

1. Topical treatments improved local symptoms, but no data were provided on VTE and SVT extension with such treatments.
2. Surgical treatment combined with graduated compression stockings was encouraged and these were worn by 83.1% of patients.

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3. Fondaparinux given for six weeks appears to be a valid therapeutic option for SVT of the legs.
4. Further research is required to assess the role of new oral anticoagulants (NOACs), LMWH and NSAIDs, the optimal doses and duration of treatment, and whether combination therapy could be more effective than single treatment.
5. Adequately designed and conducted studies are required to clarify the respective roles of topical medical and surgical treatments (12).

**Outlook**

The two main criticisms of the CALISTO study were that the incidence of the most clinically relevant thromboembolic endpoints was low in the placebo group, and that no treatment-related effect on mortality was seen (15). DVT or PE occurred in only 1.3% of the placebo patients, so almost 99% percent of patients who received no antithrombotic treatment did not experience VTE. This low rate of symptomatic endpoints raised the question of whether SVT requires treatment at all. However, it should be noted that an escalation of treatment towards full therapeutic dose anticoagulation was necessary according to today’s clinical practice norms in more than 5% of the patients in the placebo group by day 77. In addition, surgical treatment was decided for 61 patients (4.1%) in the placebo group (mostly ligation of the SFJ). Finally, due to the placebo-controlled design of the CALISTO study, high-risk patients, e. g. those with underlying cancer, those with SVT closer than 3 cm to the SFJ, or those having experienced DVT or PE within the previous six months, were excluded for ethical reasons.

The results of the pooled analysis of the POST and the OPTIMEV studies showed that the VTE complication rate was higher in patients that would have been excluded from the CALISTO study, based on their high-risk profile, compared with those who would have been eligible for inclusion in this study (▶Fig. 6) (13). PE or DVT occurred at a rate of 4.7% in the former patient population even though the great majority (84%) of these patients received anticoagulant treatment (13). This 4.7% rate is much higher than the VTE recurrence rate observed in patients treated for DVT or PE, challenging the safety of a “no anticoagulant treatment approach, unless conservative measures fail to resolve symptoms or deep-vein thrombosis develops” as proposed on the basis of the CALISTO results (15).

The available data from the CALISTO study now allow the implementation of active-controlled trials with inclusion of high-risk patients, to compare fondaparinux at prophylactic doses with other treatment modalities, for instance NOACs. One ongoing trial (the SURPRISE study) is comparing the fondaparinux treatment regimen used in CALISTO with rivaroxaban 10 mg once daily. Trials like this have the potential not only to show whether other antithrombotic approaches are effective for the treatment of SVT, but...
Superficial-vein thrombosis in the clinical practice

Practical management

After the results of the CALISTO study became available, fondaparinux was licensed in Europe at the dose of 2.5 mg per day (1.5 mg for patients with a creatinine clearance of 20–50 ml/min) for the treatment of · acute, symptomatic, spontaneous SVT of the legs, · at least 5 cm in length and · with the head of thrombus at least 3 cm away from the deep venous system (SFJ), · in the absence of concomitant DVT or PE.

The treatment should be continued for at least 30 days, up to a maximum of 45 days.

- Patients with SVT extending into the deep venous system (or less than 3 cm from the SFJ) should receive the standard anticoagulant treatment administered for DVT. In addition, patients should · wear compression stockings, · stay mobile and · may additionally be prescribed local anti-inflammatory treatment.

- Patients presenting with a small SVT (less than 5 cm in length) should receive thromboprophylaxis, if, and for as long as, there is a risk of thromboembolism (Fig. 5).

Recommendations

1. In patients presenting with a SVT > 5 cm, a compression ultrasound examination should be performed, first to confirm SVT and to document the extension of the thrombus relative to the SFJ, and second to exclude the presence of DVT. Signs and symptoms of PE should also be routinely assessed in these patients.

2. Once daily 2.5 mg fondaparinux for 30 to 45 days should be administered to patients with a symptomatic isolated SVT, at least 5 cm long, in the absence of any contraindication.

3. Symptomatic treatment such as topical NSAIDs can be used; concomitant use of systemic NSAIDs is discouraged.

4. Compression stockings have been routinely used in studies of SVT to alleviate symptoms, even though their effectiveness has not been demonstrated in controlled trials.

5. Patients with SVT extension into the SFJ and patients with DVT or PE should receive full-dose anticoagulant treatment.

6. Patients with a small SVT (less than 5 cm long) should receive symptomatic treatment and, in those at risk of thromboembolism, additional thromboprophylaxis, e.g. fondaparinux 2.5 mg once daily, for as long as the risk persists.

also to ascertain thromboembolic complication rates in high-risk patients.

Conflict of interest

Prof. Bauersachs was member of the Steering Board of the CALISTO study, and of the DAPS study on superficial vein thrombosis.

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