XXIV Congresso Nazionale SISET
Abano 9-12 Novembre 2016

Trombosi venose superficiali e trombosi venose distali

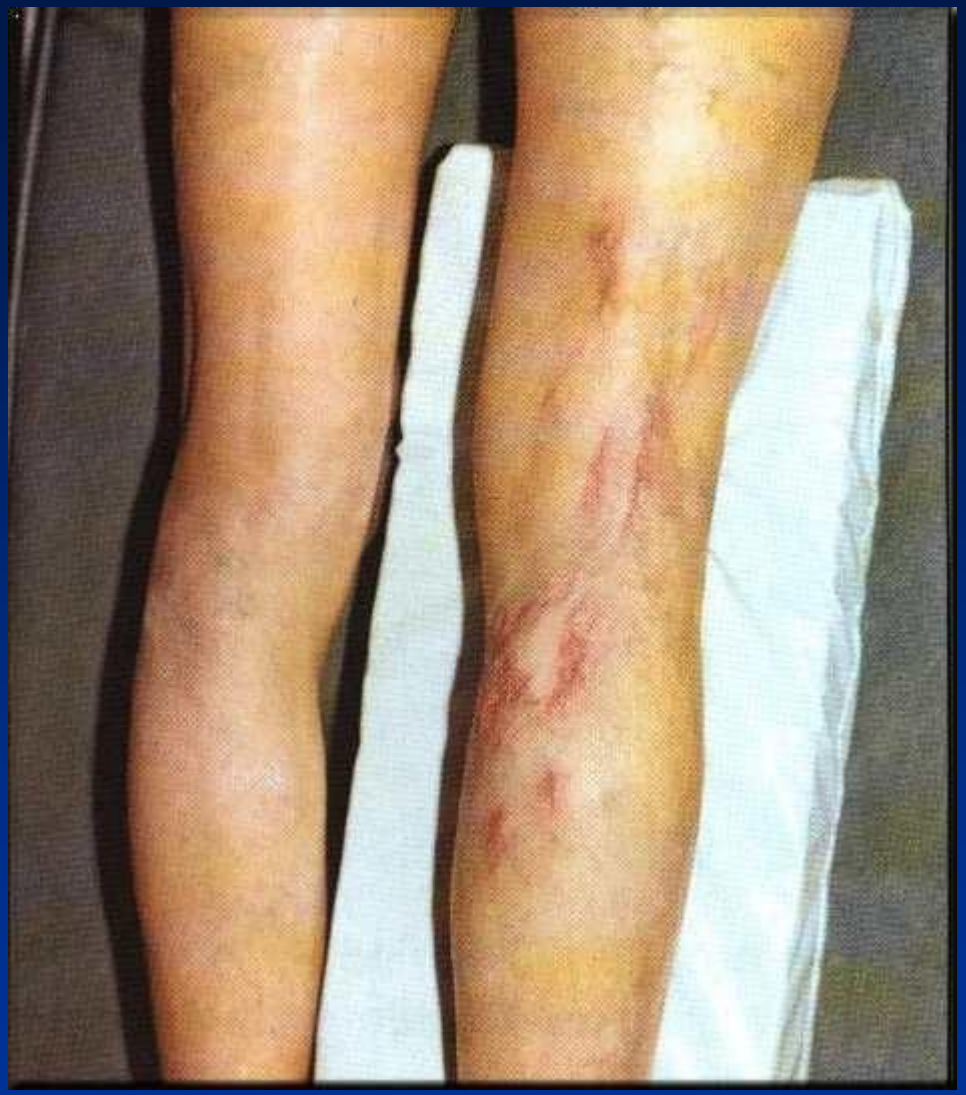
Gualtiero Palareti / Benilde Cosmi
Università di Bologna

Superficial vein thrombosis (SVT): definition

- thrombosis of the superficial vein system (suprafascial veins)

- several terms:
- superficial phlebitis or superficial thrombophlebitis
- varicose vein thrombosis
- Mondor’s disease
- Trousseau’s syndrome

- Most frequent sites: lower limbs
- Also upper limbs, neck, thorax



SVT:
traditionally considered to be a benign, self-limiting condition, distinct from thrombosis of the deep veins and
requiring only clinical diagnosis and symptomatic relief

(compression and NSAIDS)

Limited number of methodologically adequate studies for diagnosis and treatment

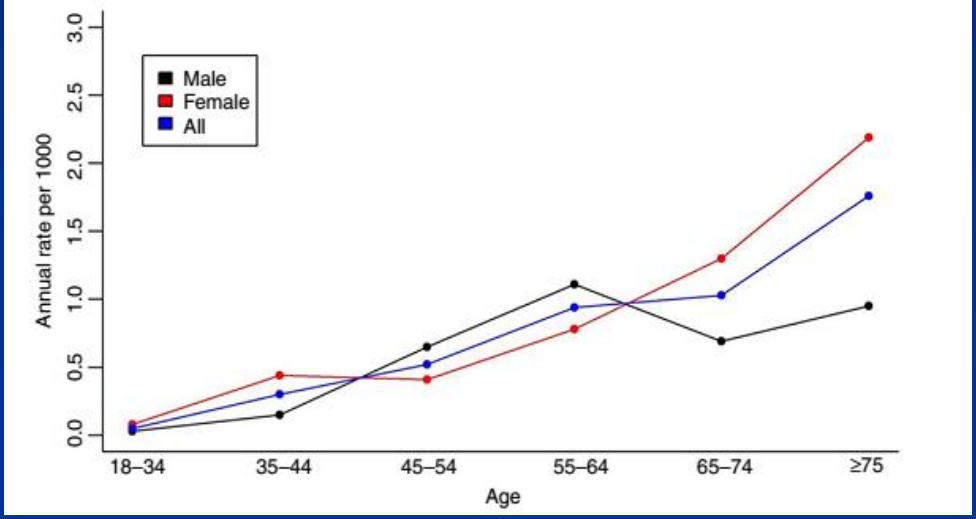
TVS: patologia sempre benigna?

Epidemiology of lower limb SVT

- in a primary care community of 265 687 people in France,

0.64 per 1000/year lower incidence than that of venous thromboembolism (VTE), which is estimated to be 1/1000/year

- Concomitant deep vein thrombosis (DVT) in 24.6% and pulmonary embolism (PE) in 4.7% of pts



Frappe P, et al STEPH study; J Thromb Haemost 2014; 12: 831

Prevalence of deep vein thrombosis and pulmonary embolism in patients with superficial vein thrombosis: a systematic review and meta-analysis

- Twenty-one studies (4358 patients) evaluated DVT prevalence
- 11 studies (2484 patients) evaluated PE prevalence in patients with SVT.
- At SVT diagnosis:
- DVT weighted mean prevalence 18.1% (95% CI: 13.9- 23.3%)
- PE weighted mean prevalence 6.9% (95% CI: 3.9-11.8%)

- Screening for a major thromboembolic event may be worthwhile in some SVT patients, in order to allow adequate anticoagulant treatment

- Other high-quality studies are warranted to confirm these findings

Di Minno et al J Thromb Haemost. 2016 May;14:964-72[6]

Pathogenesis and prognosis of lower limb SVT

- common risk factors with DVT:

advanced age
surgery
active cancer
pregnancy
hormonal therapy
obesity
autoimmune diseases (particularly Behcet's and Buerger's diseases)

- varicose veins main risk factor:

80–90% of cases (unlike in DVT)

Overall 3-month mortality:

- < 1% in SVT
- 5% in DVT
- 9–17% in PE , for the lower burden of comorbidities

Inherited and acquired thrombophilic alterations in patients with superficial vein thrombosis of lower limbs

Cristina Legnani; Michela Cini; Benilde Cosmi; Massino Filippini; Elisabetta Favaretto; Gualtiero Palareti

Thromb Haemost 2014

	N. affected/tested (%)		
	SVT patients (n=1294)	Healthy controls (n=1294)	DVT patients (n=1621)
Coagulation inhibitor deficiency #	25/1294 (1.9)	2/1294 (0.15) p < 0.001	38/1621 (2.3) p = 0.543 p < 0.001
Factor V R506Q Leiden mutation §	150/1294 (11.6)	56/1294 (4.3) p < 0.001	217/1621 (13.4) p = 0.170 p < 0.001
G20210A prothrombin mutation §	69/1294 (5.3)	57/1294 (4.4) p = 0.334	113/1621 (7.0) p = 0.075 p = 0.004
Antiphospholipid antibodies $	10/1294 (0.77)	4/1294 (0.31) p = 0.188	16 /1621 (0.99) p = 0.671 p = 0.049
Combined alterations &	20/1294 (1.5)	1/1294 (0.08) p < 0.001	49/1621 (3.0) p = 0.012 p < 0.001

SVT and cancer

Sorensen et al., Eur J Cancer 2012; 48: 586–593

Analysis of 7663 Danish SVT patients, the incidence ratio for the diagnosis of cancer within the first six months in patients after acute VTE was:

- 2.46 (2.10–2.86) in SVT
- 2.75 (2.60–2.90) in DVT
- 3.27 (3.03–2.52) in PE

Particularly strong associations with:
cancers of the liver, lung, ovaries and pancreas, non-Hodgkin's lymphoma

The risk declined after one year

Prandoni et al., Blood 2011; 118: 4719–4722

No association between SVT and subsequent diagnosis of cancer in retrospective study of 737 patients with SVT

SVT: superficial venous manifestation of a systemic process that is more commonly called VTE

	Reasons	Comments
Risk factors	1. Not an entirely benign disease	DVT, PE, fatality not rare
	2. Both SVT and VTE associated with similar clinical hypercoagulability (eg, trauma, surgery,pregnancy, immobility, obesity, advancing age, malignancy)	
	3. Incidence of thrombophilia enriched in both SVT and VTE patients	
Natural history	1. Coexistence of VTE at time of diagnosis of SVT	Averages 25%
	2. Progression of SVT to VTE	Averages 10%-20%/y
	3. Prior VTE a risk factor for future SVT	
	4. Prior SVT a risk factor for future VTE	
	5. No current plausible putative theory that justifies segregation of (local) SVT apart, different,and unique from (systemic) VTE	

Diagnosis of SVT

- No diagnostic gold standard

- straightforward clinical manifestations :
pain, tenderness, swelling, warmth, and erythema, with a palpable cord along the course of a superficial vein

- objective testing may not be considered mandatory for diagnosis (unlike for DVT).

Clinical diagnosis of lower limb SVT

- clinical assessment alone frequently underestimates the true extent of thrombosis, which may propagate from superficial into deep veins

- no data on sensitivity and specificity of SVT clinical diagnosis
- no scoring system based on those clinical features that make SVT more likely
- no validated diagnostic algorithms available

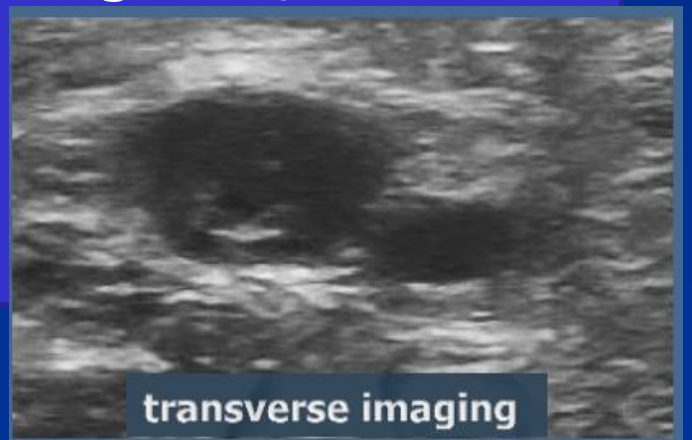
Objective diagnosis of SVT

Ultrasonography:
objective test of choice for confirming SVT clinical suspicion
superficial veins can be easily explored

same principles of DVT diagnosis:
compression ultrasonography (CUS):

lack of compressibility of a superficial vein segment, and impairment of blood flow

Also evaluation of SVT true extent and exclusion of concomitant DVT



Algorithm for the diagnosis of SVT

Clinically suspected SVT (any site)
(pain, erythema, warmth hardness along the course of superficial vein)
↓
Ultrasonography (CUS) within 24-48 hours (bilateral if lower limbs involved)
↓
(if high clinical suspicion for lower or upper limb SVT:
therapeutic doses LMWH while waiting for
ultrasonography to exclude concomitant DVT)

Cosmi B, JTH 2015

- scarcity of methodologically sound studies
- variable approach in clinical routine depending on local resources
- unlike for DVT diagnosis, need for testing unclear and it may still be considered to be neither mandatory nor urgent.

Aims of treatment of lower limb SVT

1-symptom relief

2-prevention of VTE, in relation to the thrombotic burden with different risks of thromboembolic complications

- No consensus on the optimal management of SVT (without DVT or PE) in relation to the thrombotic burden

- a small thrombus (< 4–5cm in length on ultrasonography):

minor, benign, and self-limiting, requiring only symptom relief

- significant thrombus burden (> 4–5 cm in length):

more aggressive treatment, for its higher risk of extension

Aims of treatment of lower limb SVT

- RCTs included patients with the most frequent locations of SVT, i.e. long and short saphenous veins
- higher risk of extension into the deep vein system through the saphenofemoral (SFJ)/saphenopopliteal junction
- SVT of a long saphenous vein with the thrombus head within 3 cm of the SFJ excluded from interventional studies
- equivalent to a DVT with regard to its high risk of progression (10–70%) and therapeutic anticoagulation is indicated

The NEW ENGLAND JOURNAL of MEDICINE
2010;363:1222-32

ORIGINAL ARTICLE

Fondaparinux for the Treatment of Superficial-Vein Thrombosis in the Legs

Hervé Decousus, M.D., Paolo Prandoni, M.D., Ph.D., Patrick Mismetti, M.D., Ph.D., Rupert M. Bauersachs, M.D., Zoltán Boda, M.D., Benjamin Brenner, M.D., Silvy Laporte, Ph.D., Lajos Matyas, M.D., Saskia Middeldorp, M.D., Ph.D., German Sokurenko, M.D., and Alain Leizorovicz, M.D., for the CALISTO Study Group*

Multicenter, randomized, double-blind, controlled vs placebo on efficacy and safety of Fondaparinux (Arixtra) for the treatment of SVT

Patients enroled : 3.002
Inclusion: SVT confermed with CUS, > 5 cm length
Exclusion: SVT < 3 cm from saphenous-femoral cross, thrombotic events < previous 6 months, active cancer, warfarin, NSAIDs, recent bleeds, platelets <100.000 plt/dl), Cr Cl< 30 ml/min

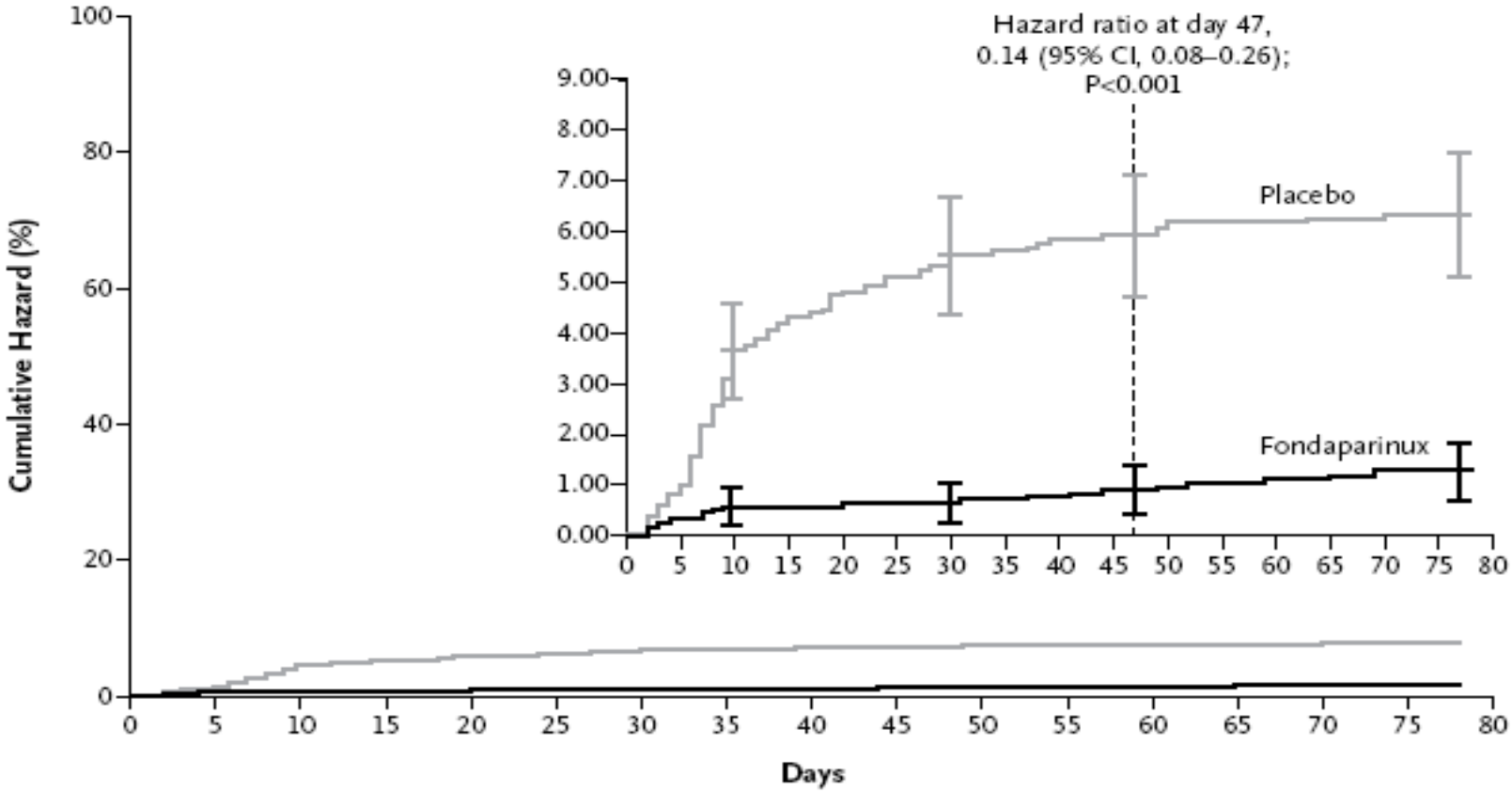
Treatments: Fondaparinux 2,5 mg or Placebo
Duration: 45 d
Follow-up: 1 month

Table 3. Efficacy Outcomes.

Efficacy Outcome	Fondaparinux (N=1502)	Placebo (N=1500)	Absolute Risk Reduction with Fondaparinux	Relative Risk with Fondaparinux	P Value*
	no. with event (%)		*percentage points (95% CI)*	*% (95% CI)*	
By Day 47					
Primary composite outcome†	13 (0.9)	88 (5.9)	−5.0 (−6.3 to −3.7)	0.15 (0.08 to 0.26)	<0.001
Death‡	2 (0.1)	1 (0.1)	0.1 (−0.2 to 0.3)	1.99 (0.18 to 21.87)	1.00
Pulmonary embolism§	0	5 (0.3)	−0.3 (−0.6 to 0.0)	Not calculated	0.03
Deep-vein thrombosis¶	3 (0.2)	18 (1.2)	−1.0 (−1.6 to −0.4)	0.17 (0.05 to 0.56)	<0.001
Extension of superficial-vein thrombosis to the saphenofemoral junction	4 (0.3)	51 (3.4)	−3.1 (−4.1 to −2.2)	0.08 (0.03 to 0.22)	<0.001
Recurrence of superficial-vein thrombosis	5 (0.3)	24 (1.6)	−1.3 (−2.0 to −0.6)	0.21 (0.08 to 0.54)	<0.001
Deep-vein thrombosis or pulmonary embolism	3 (0.2)	20 (1.3)	−1.1 (−1.8 to −0.5)	0.15 (0.05 to 0.50)	<0.001
Surgery for superficial-vein thrombosis	11 (0.7)	57 (3.8)	−3.1 (−4.1 to −2.0)	0.19 (0.10 to 0.37)	<0.001
By Day 77					
Composite outcome†	18 (1.2)	94 (6.3)	−5.1 (−6.4 to −3.7)	0.19 (0.12 to 0.32)	<0.001
Death‡	2 (0.1)	1 (0.1)	0.1 (−0.2 to 0.3)	1.99 (0.18 to 21.87)	1.00
Pulmonary embolism§	0	6 (0.4)	−0.4 (−0.7 to −0.1)	Not calculated	0.02
Deep-vein thrombosis	4 (0.3)	19 (1.3)	−1.0 (−1.6 to −0.4)	0.21 (0.07 to 0.62)	0.001
Extension of superficial-vein thrombosis to the saphenofemoral junction	5 (0.3)	54 (3.6)	−3.3 (−4.3 to −2.3)	0.09 (0.04 to 0.23)	<0.001
Recurrence of superficial-vein thrombosis	8 (0.5)	26 (1.7)	−1.2 (−2.0 to −0.4)	0.31 (0.14 to 0.68)	0.002
Deep-vein thrombosis or pulmonary embolism	4 (0.3)	22 (1.5)	−1.2 (−1.9 to −0.5)	0.18 (0.06 to 0.53)	<0.001
Surgery for superficial-vein thrombosis	15 (1.0)	61 (4.1)	−3.1 (−4.2 to −1.9)	0.25 (0.14 to 0.43)	<0.001

* P values were calculated with the use of Fisher's exact test.
† Some patients had more than one event.
‡ There were two deaths from cancer in the fondaparinux group and one death from acute heart failure in the placebo group.
§ No instance of pulmonary embolism was fatal.
¶ There were 11 cases of proximal deep-vein thrombosis: 1 in the fondaparinux group and 10 in the placebo group.

No difference for bleeding between treatment and placebo



No. at Risk	Day 10±2	Day 30±2	Day 45±2	Day 75±2
Placebo	1437	1399	1388	1330
Fondaparinux	1483	1477	1468	1410

Figure 1. Kaplan–Meier Estimates of the Probability of the Primary Efficacy Outcome, According to Study Group.

The primary efficacy outcome was a composite of death from any cause, symptomatic pulmonary embolism, symptomatic deep-vein thrombosis, or symptomatic extension to the saphenofemoral junction or symptomatic recurrence of superficial-vein thrombosis. Data from patients who were lost to follow-up were censored at the time of the last contact. I bars indicate 95% confidence intervals.

ORIGINAL ARTICLE

A randomized double-blind study of low-molecular-weight heparin (parnaparin) for superficial vein thrombosis: STEFLUX (Superficial ThromboEmbolism and Fluxum)

B. COSMI,* M. FILIPPINI,* D. TONTI,† G. AVRUSCIO,‡ A. GHIRARDUZZI,§ E. BUCHERINI,¶ G. CAMPORESE,** D. IMBERTI,†† and G. PALARETI,* ON BEHALF OF THE STEFLUX INVESTIGATORS[1]

*Department of Angiology & Blood Coagulation 'Marino Golinelli', S.Orsola-Malpighi University Hospital, Bologna; †Vascular Medicine Unit, Bufalini Hospital, Cesena; ‡Department of Angiology, S.Antonio Hospital, Padua; §Angiology Unit – Department of Internal Medicine, Arcispedale Santa Maria Nuova, Reggio Emilia; ¶Unit of Vascular Medicine and Angiology, Civic Hospital of Faenza, Faenza; **Unit of Angiology, University Hospital of Padua, Padua; and ††Department of Internal Medicine, G. da Saliceto Hospital, Piacenza, Italy

To cite this article: Cosmi B, Filippini M, Tonti D, Avruscio G, Ghirarduzzi A, Bucherini E, Camporese G, Imberti D, Palareti G, on behalf of the STEFLUX Investigators. A randomized double-blind study of low-molecular-weight heparin (parnaparin) for superficial vein thrombosis: STEFLUX (Superficial ThromboEmbolism and Fluxum). *J Thromb Haemost* 2012; **10:** 1026–35.

Prospective, randomized, double-blind placebo controlled multicenter study (16 centres)

TRATTAMENTI

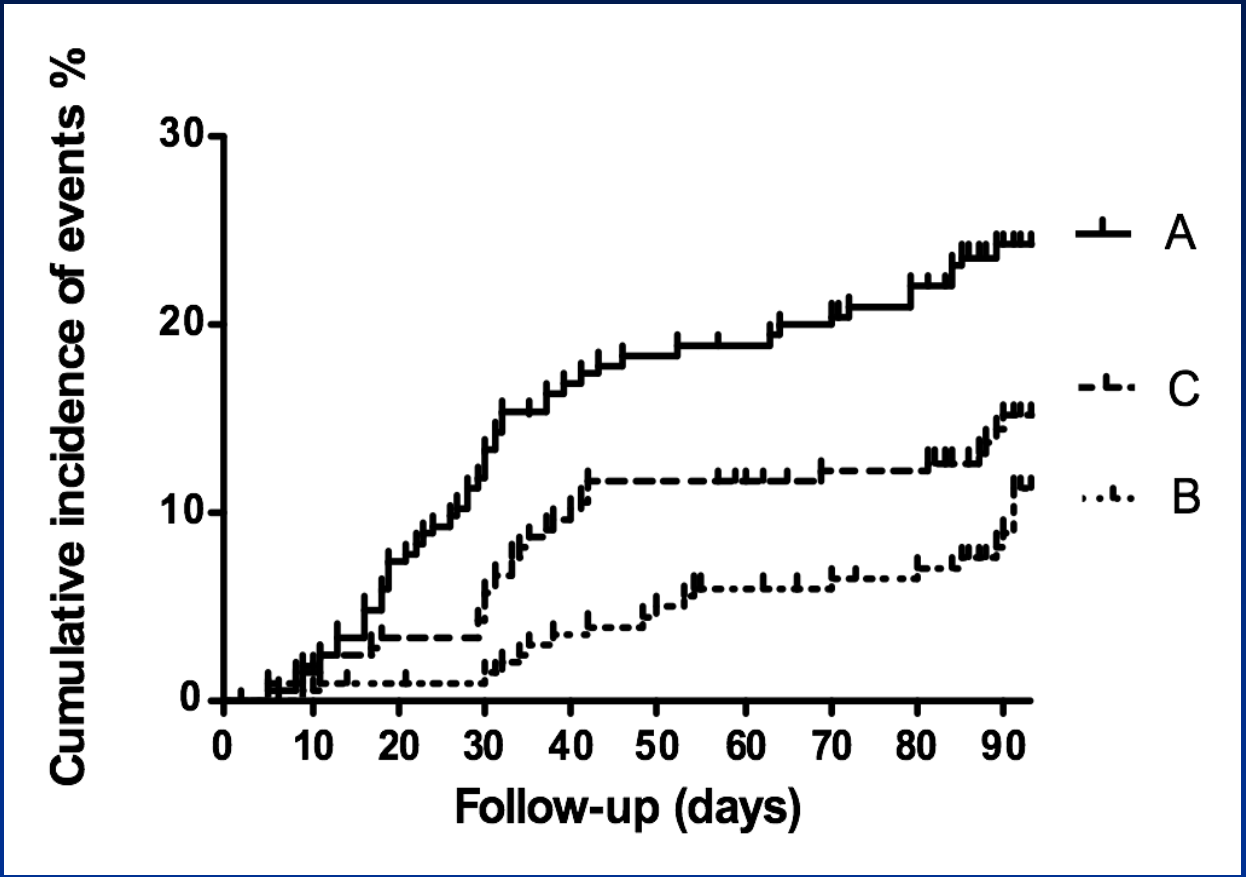
Consecutive outpatients were randomly assigned to receive in a double-blind fashion one of the following subcutaneous treatments with an allocation ratio of 1:1:1:

A Parnaparin 4250 UI aXa o.d. for 30 days (prophylactic dose of LMWH for 30 days).

B Parnaparin 8500 UI aXa o.d. for 10 days followed by 6400 UI aXa once daily for 20 days (intermediate dose of LMWH for 30 days).

C Parnaparin 8500 UI aXa o.d. for 10 days followed by placebo for 20 days (intermediate dose of LMWH for 10 days).

Cosmi et al.
JTH 2012



Cumulative incidence of events in the 33 days of treatment + 60 days of follow-up in the 3 groups Logrank test for trend P=0.0117
Log-rank (Mantel-Cox) Test p<0.0001
A VS B P<0.0001; B VS C P= 0.06; A VS C P=0.019

CONCLUSIONS

SVTs require anticoagulant treatment for at least 30 days
LMWH = relatively high dose
Fondaparinux = prophylactic dose
Class II elastic stockings

Some SVT still have late complications after 30 d of treatment
How to identify these patients?

Evaluation of individual risk factors

9th ACCP Consensus

(Kearon et al. Chest 2012)

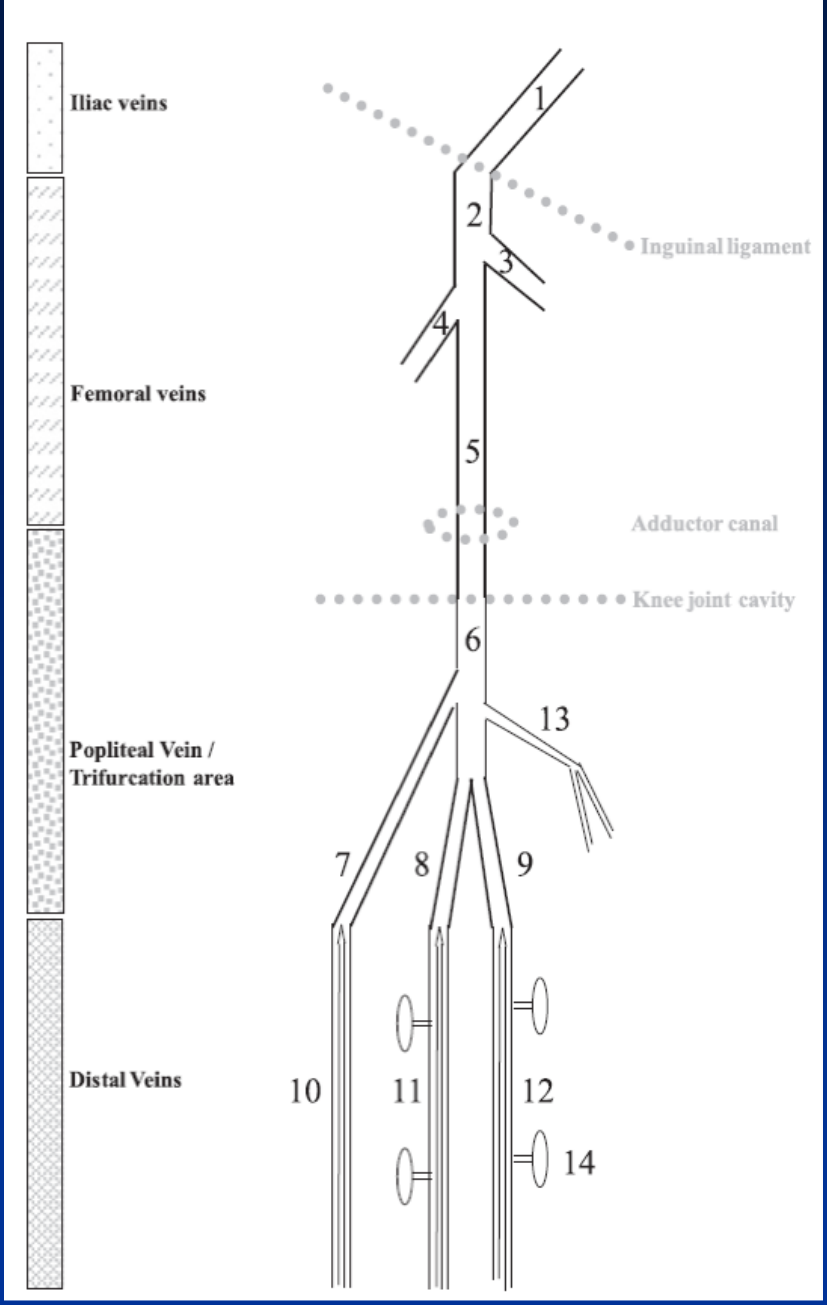
8.1.1. In patients with SVT ….of at least 5 cm in length, we suggest the use of a prophylactic dose of fondaparinux or LMWH for 45 days over no anticoagulation (Grade 2B) **.**

8.1.2. In patients with SVT who are treated with anticoagulation, we suggest fondaparinux 2.5 mg daily over a prophylactic dose of LMWH (Grade 2C)

Comments on SVT

- Complications are frequent, associated with or occurring after SVT
- Complications can be clinically important
- Risk factors are similar to those of DVT/PE
- Thrombophilic alterations are frequent and similar to those found in patients with DVT
- A limited course of AC is mandatory but does not always prevent complications

Trombosi venose distali



Schematic representation of leg veins

1, External iliac vein;
2, common femoral vein;
3, greater saphenous vein;
4, profound femoral vein;
5, (superficial) femoral vein;
6, popliteal vein;
7, anterior tibial confluent segment;
8, posterior tibial confluent segment;
9, peroneal confluent segment;
10, anterior tibial veins;
11, posterior tibial veins;
12, peroneal veins;
13, gastrocnemius muscle veins (medial head);
14, soleus muscle veins.

The OPTIMEV study: a French, multicenter, prospective, observational study of inpatients and outpatients referred to vascular medicine physicians for clinically suspected VTE and followed for 3 years
(Galanaud et al., JTH 2014)

DVT at baseline = 1643
- Proximal = 43.2%
- Distal = 56.8%

New Technologies, Diagnostic Tools and Drugs

Evolution of untreated calf deep-vein thrombosis in high risk symptomatic outpatients: The blind, prospective CALTHRO study

Gualtiero Palareti[1]; Benilde Cosmi[1]; Gianfranco Lessiani[2]; Giuseppina Rodorigo[1]; Giuliana Guazzaloca[1]; Carlotta Brusi[1]; Lelia Valdré[1]; Eleonora Conti[1]; Michelangelo Sartori[1]; Cristina Legnani[1]

Clinical evolution at 3 month follow-up				
	Simplified CUS 417	Calf DVT 64 (15.1%)	No calf DVT 359	p
Outcomes at 3 mo: 1 PE; 2 Prox. DVT; 2 Calf DVT	5 (1.2%)	5 (7.8%) [3 (4.7%)]*	3 (0.8%)	0.003

* excluding the 2 subjects in whom DVT was picked at the 2nd CUS

Accepted Manuscript

Antithrombotic Therapy for VTE Disease: CHEST Guideline

Clive Kearon, MD, PhD, Elie A. Akl, MD, MPH, PhD, Joseph Ornelas, PhD, Allen Blaivas, DO, FCCP, David Jimenez, MD, PhD, FCCP, Henri Bounameaux, MD, Menno Huisman, MD, PhD, Christopher S. King, MD, FCCP, Timothy Morris, MD, FCCP, Namita Sood, MD, FCCP, Scott M. Stevens, MD, Janine R.E. Vintch, MD, FCCP, Philip Wells, MD, Scott C. Woller, MD, Col. Lisa Moores, MD, FCCP

2016

The rationale for not routinely examining the distal veins:

(1) other assessment (e.g. low clinical probability; negative D-dimer);
(2) a repeat US of the proximal veins can be done after a week
(3) false-positive findings for DVT occur

Accepted Manuscript

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2016

In patients with acute IDDVT of the leg and
(i)without severe symptoms or risk factors for extension, we suggest serial imaging of the deep veins for 2 weeks over AC (Grade 2C),
(ii)with severe symptoms or risk factors for extension, we suggest AC over serial imaging of the deep veins (Grade 2C).

Accepted Manuscript

Antithrombotic Therapy for VTE Disease: CHEST Guideline

Clive Kearon, MD, PhD, Elie A. Akl, MD, MPH, PhD, Joseph Ornelas, PhD, Allen Blaivas, DO, FCCP, David Jimenez, MD, PhD, FCCP, Henri Bounameaux, MD, Menno Huisman, MD, PhD, Christopher S. King, MD, FCCP, Timothy Morris, MD, FCCP, Namita Sood, MD, FCCP, Scott M. Stevens, MD, Janine R.E. Vintch, MD, FCCP, Philip Wells, MD, Scott C. Woller, MD, Col. Lisa Moores, MD, FCCP

2016

If the calf veins are imaged and IDDVT is diagnosed,
two management options:
1)treat patients with AC therapy;
2)do not treat patients with AC therapy unless extension of their DVT is detected on a follow-up US examination (e.g. after one and two weeks)

Accepted Manuscript

Antithrombotic Therapy for VTE Disease: CHEST Guideline

Clive Kearon, MD, PhD, Elie A. Akl, MD, MPH, PhD, Joseph Ornelas, PhD, Allen Blaivas, DO, FCCP, David Jimenez, MD, PhD, FCCP, Henri Bounameaux, MD, Menno Huisman, MD, PhD, Christopher S. King, MD, FCCP, Timothy Morris, MD, FCCP, Namita Sood, MD, FCCP, Scott M. Stevens, MD, Janine R.E. Vintch, MD, FCCP, Philip Wells, MD, Scott C. Woller, MD, Col. Lisa Moores, MD, FCCP

2016

In patients with an IDDVT provoked by surgery or by a nonsurgical transient risk factor,
- we suggest treatment with AC for 3 months
over treatment of a shorter period (Grade 2C),
- we recommend treatment with AC for 3 months over treatment of a longer time-limited period (e.g. 6, 12 or 24 months) (Grade 1B),
- we recommend treatment with AC for 3 months over extended therapy (no scheduled stop date) (Grade1B).

Isolated distal deep vein thrombosis: efficacy and safety of a protocol of treatment. Treatment of Isolated Calf Thrombosis (TICT) Study

R. PARISI [1], A. VISONÀ [2], G. CAMPORESE [3], F. VERLATO [3], G. LESSIANI [4], P. L. ANTIGNANI [5], G. PALARETI [6] and Intersocietary Working Group on Distal Deep Vein Thrombosis

EVENTS DURING TREATMENT:

10/171 PTS (5.8%) had complications:

5 (2.9%) proximal DVT (all unprovoked IDDVT

the remaining extension of IDDVT

No major bleeding; 1.7% minor bleeding

EVENTS DURING 3 MO. FOLLOW-UP

5 complications: (3 developed cancer)

4 proximal DVT (3 had an unprovoked IDDVT)

Anticoagulant therapy for symptomatic distal DVT: the CACTUS randomized placebo-controlled trial

(Righini et al., XXV ISTH Congress Toronto, abstract)

- 126 pts received nadroparin (170 UI/kg) x 42 d.
- 133 " " placebo

- Outcomes: (at 42 d) nadro = 4 (3.3%); placebo = 7 (5.4%)
- Bleeds (M/NMCR): (at 42 d) nadro = 5 (4.1%) p= 0.03; placebo = 0

IDDVT treatment: current management in symptomatic pts

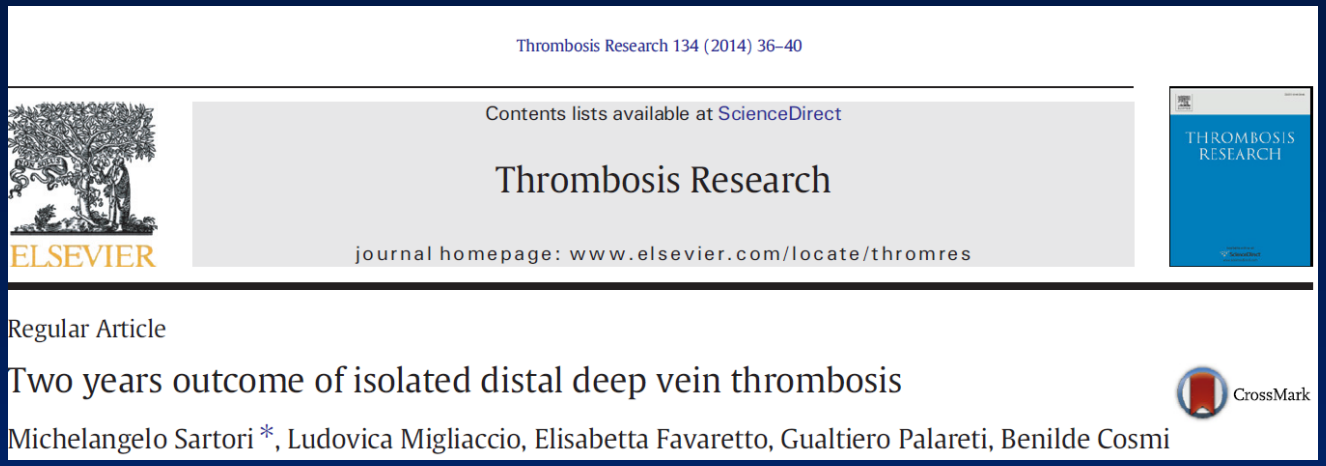
- Idiopathic IDDVT
  Therapeutic LMWH followed by oral anticoagulation (2.0-3.0 INR) for 3 months, elastic stocking
- Secondary IDDVT
  Therapeutic IDDVT for 1 week, half dose for 3 weeks, elastic stocking

The risk of recurrence after treatment of IDDVT

Galanaud
JTH 2014

Predictive factors and incidence of VTE recurrence after stopping anticoagulants

	Incidence of VTE recurrence, % PY (95% CI)
Age	
≤ 50 years (ref)	0.9 (0.3–2.3)
> 50 years	3.8 (2.6–5.5)
Gender	
Female sex (ref)	3.3 (2.2–4.9)
Male sex	2.0 (1.1–3.6)
Status at index event	
Outpatient (ref)	2.8 (1.9–4.1)
Inpatient	2.5 (1.2–5.3)
Risk factors associated with index DVT‡	
Major transient risk factor (ref)	1.44 (0.7–2.9)
Unprovoked DVT	3.8 (2.6–5.6)
Anatomical characteristics of index DVT	
Deep calf DVT (ref)	1.6 (0.7–3.9)
Muscular DVT§	1.7 (0.9–3.0)
Ultrasonographic characteristics of index DVT	
Number of venous segments thrombosed	
Single unilateral thrombosis (ref)	1.8 (1.1–2.9)
Multiple unilateral thromboses	4.9 (3.1–7.8)
Bilateral DVT	8.9 (3.7–21.4)
Clot diameter under compression	
≤ 7 mm (ref)	3.1 (2.1–4.5)
> 7 mm	2.2 (1.0–4.5)
Anticoagulant treatment > 90 days	–



Thrombosis Research 134 (2014) 36–40

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journal homepage: www.elsevier.com/locate/thromres

Regular Article

Two years outcome of isolated distal deep vein thrombosis

Michelangelo Sartori *, Ludovica Migliaccio, Elisabetta Favaretto, Gualtiero Palareti, Benilde Cosmi

Results: 90 patients (male 48.9%) enrolled.
At follow-up (24±2 months) = 17 events (18.9%)
3 PE (two in cancer), 4 proximal DVTs (one in cancer) and 10 IDDVT.

Associated with a higher risk of complications
- male sex (HR 4.73 CI95%: 1.55-14.5; p = 0.006)
- cancer (HR 5.47 CI95%: 1.76-17.6; p = 0.003)

Conditions or risk factors for complications after a first IDDVT (1)

Higher risk

- (Axial vs Muscular IDDVT)
- Previous VTE events
- Males
- Age >50 years
- Cancer
- Unprovoked IDDVT
- Secondary IDDVT with persistently hampered mobilisation
- IDDVT involving the popliteal trifurcation
- IDDVT involving >1 calf vein
- IDDVT present in both legs
- Presence of predisposing diseases (e.g. inflammatory bowel diseases)
- Known thrombophilic alterations

Conditions or risk factors for complications after a first IDDVT (2)

Lower risk

•IDDVT secondary to surgery or to other removable risk factors (plasters, immobilisation, trauma, long trip, etc), if complete mobilisation

•IDDVT occurring during contraceptive or replacement hormonal therapy (provided the therapy has been interrupted)

Rivaroxaban for the treatment of symptomatic IDDVT (RIDTS study)

Proposed by: Walter Ageno & Gualtiero Palareti

RIDTS study: Study design

All patients receive rivaroxaban, 15 mg BID for 3 weeks followed by open label rivaroxaban 20 mg OD for 3 weeks.

At the end of the first 6 weeks of treatment, all patients will be randomized to

A) Long treatment: rivaroxaban 20 mg OD for further 6 weeks

B) Short treatment: placebo for further 6 weeks

Randomization: using an IVRS system implemented to guarantee the balanced and blinded fashion of the two groups

Follow-up = 2 years

RIDTS study

Più di 30 centri hanno dichiarato la loro disponibilità allo studio

Grazie