saint 2017

12. Symposium für angewandte interventionsradiologische Techniken

RADIOLOGISCHE INTERVENTIONEN

BECKENVENENTHROMBOSE - ENDOVASKULÄRE BEHANDLUNG WANN UND WIE ?

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Interessenkonflikte

Forschungsunterstützung: Biotronik, Boston Scientific, Veniti, Veryan, Straub medical

Vortragstätigkeit: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan

Beratertätigkeit: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan

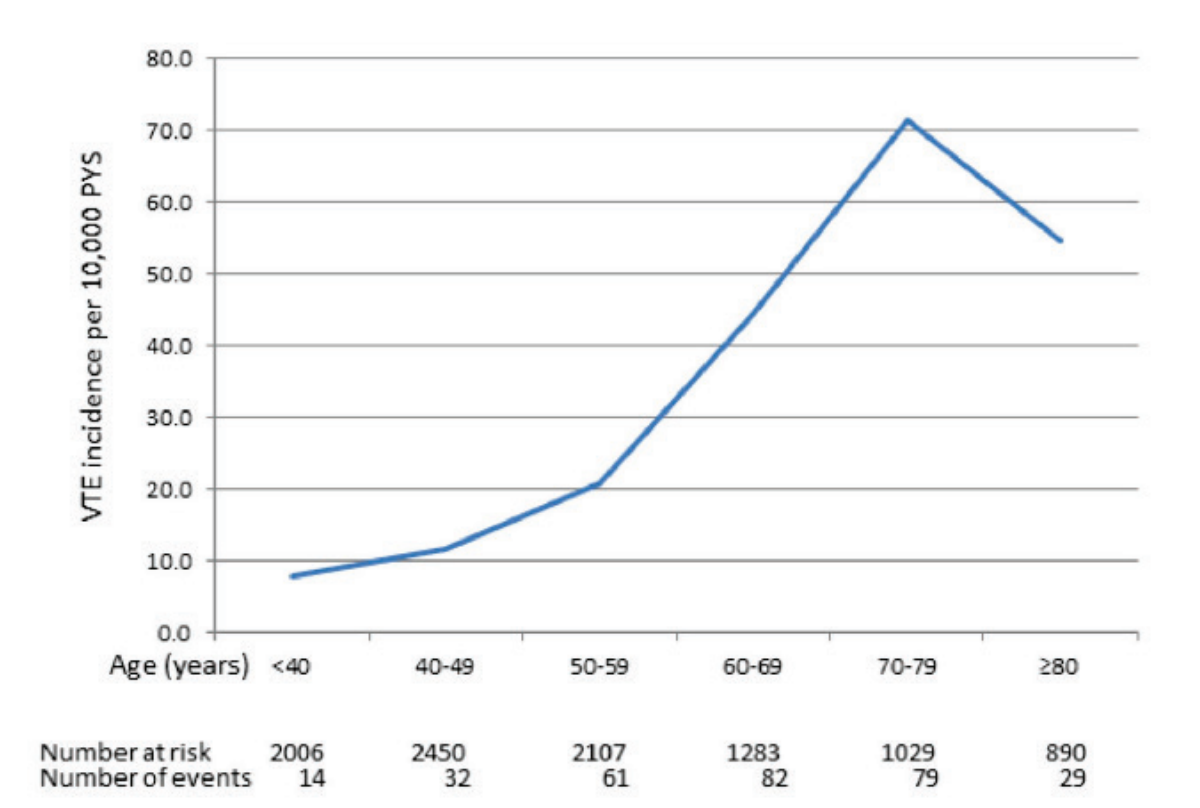
Venous thromboembolism (VTE) in Europe. The number of VTE events and associated morbidity and mortality

Thromb Haemost. 2007 Oct;98(4):756-64

	Outpatient	During hospital stay	Total
VTE			
Deep vein thrombosis	200.482	265.233	465.715
Pulmonary embolism	86.511	209.471	295.982
VTE associated death	108.535	261.477	370.012
Patient on anticoagulation	8.124	18.349	26.473
Patient not on anticoag.	63.541	153.853	217.394
Sudden death	36.870	89.275	126.145
Chronic complications			
Postthrombotic Syndrome[b]	177.236	218.437	395.673
Pulm. Hypertension	1.173	2.961	4.135

Ereignisse pro Jahr in 6 europäischen Ländern

VTE Incidence Framingham cohort



1995-2014:

104,091 person-years

297 incident VTE (PE+DVT)

IR: 20.3/10,000

Thromb Res. 2016 September ; 145: 27–33. doi:10.1016/j.thromres.2016.06.033.

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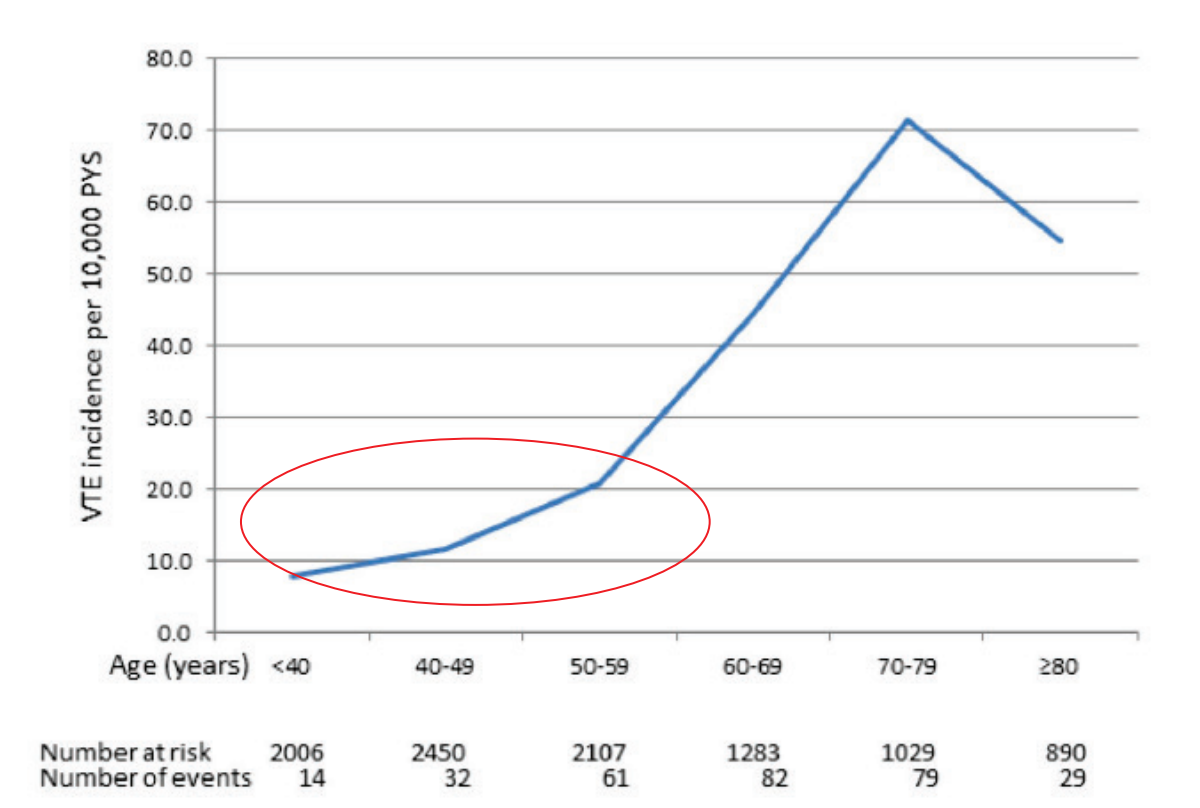

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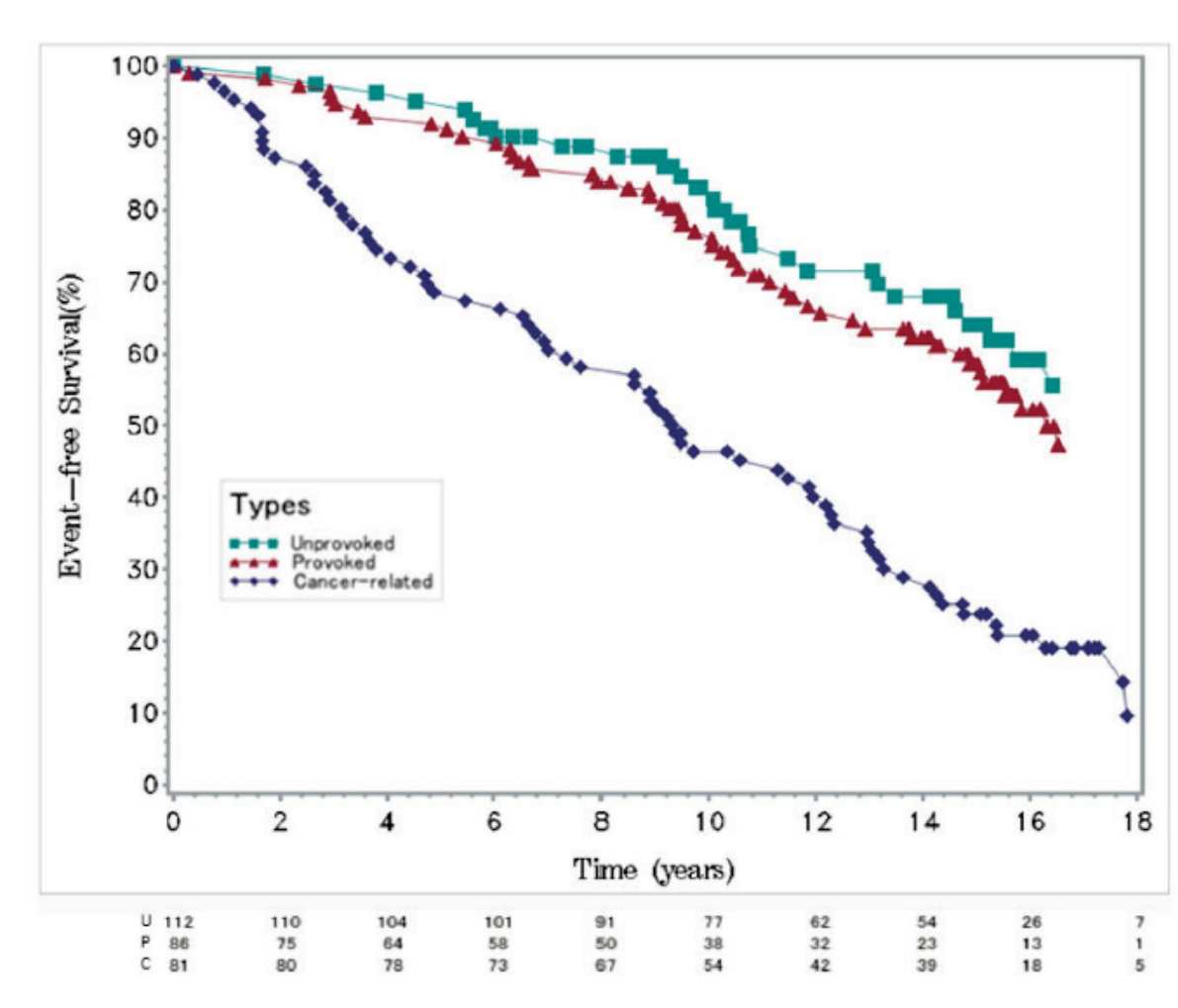
Mortality rates



Thromb Res. 2016 September ; 145: 27–33. doi:10.1016/j.thromres.2016.06.033.

Kahn S. et al. Determinants of health-related quality of life during the 2 years following deep vein thrombosis. Journal of Thrombosis and Haemostasis 2009, 6: 1105-1112

QOL measure	Variable*	Parameter estimate	*P*-value
SF-36 PCS	Post-thrombotic syndrome	− 7.1	< 0.0001
	Age (per year)	− 0.14	0.0009
	Proximal (vs. distal) DVT	− 2.9	0.01
	Inpatient (vs. outpatient) at time of DVT diagnosis	− 2.6	0.04
SF-36 MCS	Post-thrombotic syndrome	− 1.8	0.11
	Age (per year)	0.10	0.008
VEINES-QOL	Post-thrombotic syndrome	− 4.4	< 0.0001
VEINES-Sym	Post-thrombotic syndrome	− 5.2	< 0.0001

PTS Raten in Studien VILLALTA Score > 4

Study	Mean follow-up	Type study/study arm (RCT)	PTS, % (n)				PTS ulcer, % (n)
			Overall	Mild	Moderate	Severe	
Reverse [17] Galanaud (2012)	6 months	Cohort	31.6 (116)	79.3 (92)	15.5 (18)	5.2 (6)	1.7 (2)
VETO [28] Kahn (2008)	2 years	Cohort	≈50 (NA)	≈69.8 (NA)	≈23.3 (NA)	≈7.0 (NA)	~1.3 (5)
Ten Cate-Hoek (2010) [16]	2 years	Management cohort study	29.6 (37)			7.5 (3)	~0.8 (1)
SOX trial [10]	2 years	ECS arm (n = 410)	51.3 (185)	67.6 (119)	17.0 (30)	15.3 (27)	4.4 (17)
Kahn (2014)		Placebo ECS arm (n = 396)	51.4 (178)	66.1 (111)	22.0 (37)	11.9 (20)	4.1 (16)
CaVenT trial [11]	2 years	CDT arm (n = 90)	41.1 (37)			0 (0)	0 (0)
Enden (2012)		Standard arm (n = 99)	55.6 (55)			1 (1)	0 (0)
Octavia trial [29]	2 years (after DVT)	Continue ECS arm (n = 262)	13 (34)	91 (31)	6 (2)	3 (1)	0.4 (1)
Mol (2016)		Stop ECS arm (n = 256)	19.9 (51)	84 (43)	16 (8)	0 (0)	0 (0)
ELATE [26] Kahn (2005)	2.2 years	RCT	37 (n = 55)			11 (4)	~1.4 (n = 2)
CANANO [90] Prandoni (2012)	3 years	Below-knee ECS arm (n = 132)	35.6 (47)			6.4 (3)	
		Thigh-length ECS arm (n = 135)	32.6 (44)			6.8 (3)	
Prandoni (2004) [53]	2 years up to 5 years	ECS arm (n = 90)	25.7 (23)			13.0 (3)	2.2 (2)
		No ECS arm (n = 90)	49.1 (44)			22.7 (10)	6.7 (6)
Edith study [91] Delluc (2010)	51 months	Cohort	28.4 (27)			0 (0)	0 (0)
van Dongen (2005) [30]	4.9 years	Cohort	33 (81)	90.1 (73)		9.8 (8)	2.0 (5)
EINSTEIN trial [20] Cheung (2016)	5 years	Rivaroxaban arm (n = 162)	29 (45)	89 (40)		11 (5)	2 (1)
		Warfarin arm (n = 174)	40 (66)	91 (60)		9 (6)	6 (4)
CaVenT trial longterm follow-up [19] Haig (2016)	5 years	CDT arm (n = 87)	42.5 (37)	83.8 (31)	5.4 (2)	10.8 (4)	2.3 (2)
		Standard arm (n = 89)	70.8 (63)	77.8 (49)	20.6 (13)	1.6 (1)	1.1 (1)
Prandoni 1996 [54]	Up to 8 years	Cohort	29.1 (NA)			~32 (NA)	

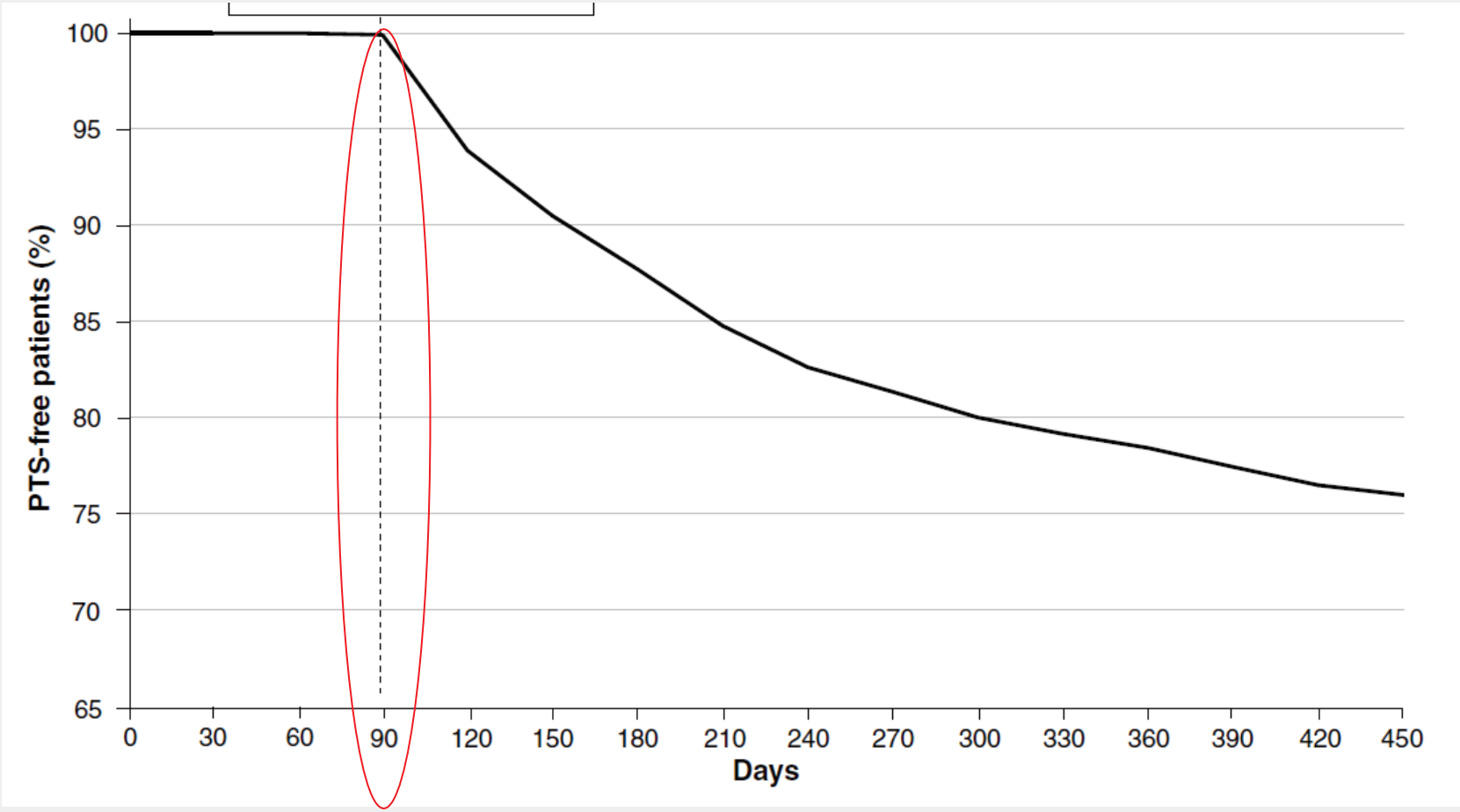
PTS nach Venenthrombose (TULIPA)

Hach-Wunderle et al (2013) J Vasc Surg: Venous and Lymph. Dis. 1: 5-12

PTS-Schweregrad (Villalta-Score)	PTS - Kohorte		
	alle N=135*	**proximale TVT** N=71 (=52.6%)	**distale TVT** N=64 (=47.4%)
PTS, n, % (95%VI)			
nein (<5)	**102, 75.5** (68.3-82.8)	**48, 67.6** (56.7-78.5)	**54, 84.4** (75.5-93.3)
ja (>5)	**33, 24.5**	**23, 32.4**	**10, 15.6**
mild (5-9)	**23, 17.0** (11.1-24.5)	**16, 22.5** (13.5-34.0)	**7, 10.9** (4.5-21.3)
moderat (10-14)	**8, 6.0** (2.6-11.3)	**6, 8.5** (3.2-17.5)	**2, 3.1** (0.4-10.8)
schwer (≥15)	**2, 1.5** (0.2-5.3)	**1, 1.4** (0.04-7.6)	**1, 1.6** (0.04-8.4)

Fazit: PTS-Rate 24.5%, dabei signifikant häufiger bei proximaler (32.4%) vs. distaler (15.6%) TVT (p=0.024)

Wann treten Symptome eines PTS auf ?



Am J Health-Syst Pharm—Vol 63 Oct 15, 2006 Suppl 6

Economic burden of deep-vein thrombosis, pulmonary embolism, and post-thrombotic syndrome

Annualized Resource Utilization and Costs for Patients in Post-Thrombotic Syndrome Subanalysis[a]

Group	PTS (n = 624)			No PTS (n = 1781)		
	Mean	S.D.	Median	Mean	S.D.	Median
Resource utilization (number)						
Pharmacy claims	49.4	54.2	33.8	40.4	43.2	27.0
Related outpatient claims	30.3	27.6	26.5	22.4	24.8	16.0
Other outpatient claims	107.4	128.7	70.4	71.7	88.7	45.9
Hospital admissions						
Index event	0.7	0.5	1.0	0.7	0.4	1.0
Other admissions	1.2	2.0	0.0	0.7	1.4	0.0
Length of stay (days)						
Index event	7	14	5	7	11	5
Other admissions	11	27	0	6	16	0
Health care costs (U.S. $ × 1000)						
Pharmacy costs	3.7	8.4	1.5	3.3	8.2	1.0
Related outpatient costs	1.4	2.9	0.9	0.9	2.1	0.4
Other outpatient costs	10.1	18.7	4.8	6.5	13.3	2.6
Inpatient costs						
Index event	16.6	40.5	5.5	14.7	37.4	6.3
Other admissions	24.0	69.2	0.0	12.0	36.1	0.0
Total costs	55.8	101.1	20.6	37.4	66.1	15.8
Total costs (adjusted)	47.6			35.9		

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Other outpatient claims	107.4	128.7	70.4	71.7	88.7	45.9
Hospital admissions						
Index event						1.0
Other admissions						0.0
Length of stay (days)						
Index event						5
Other admissions						0
Health care costs (U.S. $ × 1000)						
Pharmacy costs	3.7	8.4	1.5	3.3	8.2	1.0
Related outpatient costs	1.4	2.9	0.9	0.9	2.1	0.4
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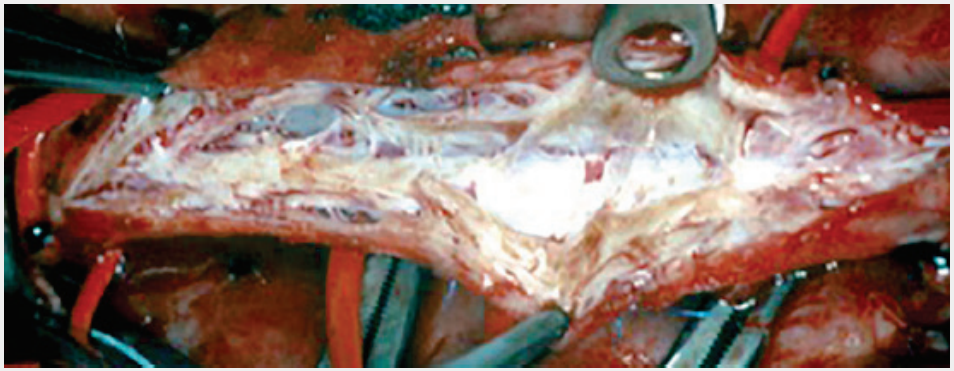
Anually costs
PTS: 20.569 $
No PTS: 15.834 $

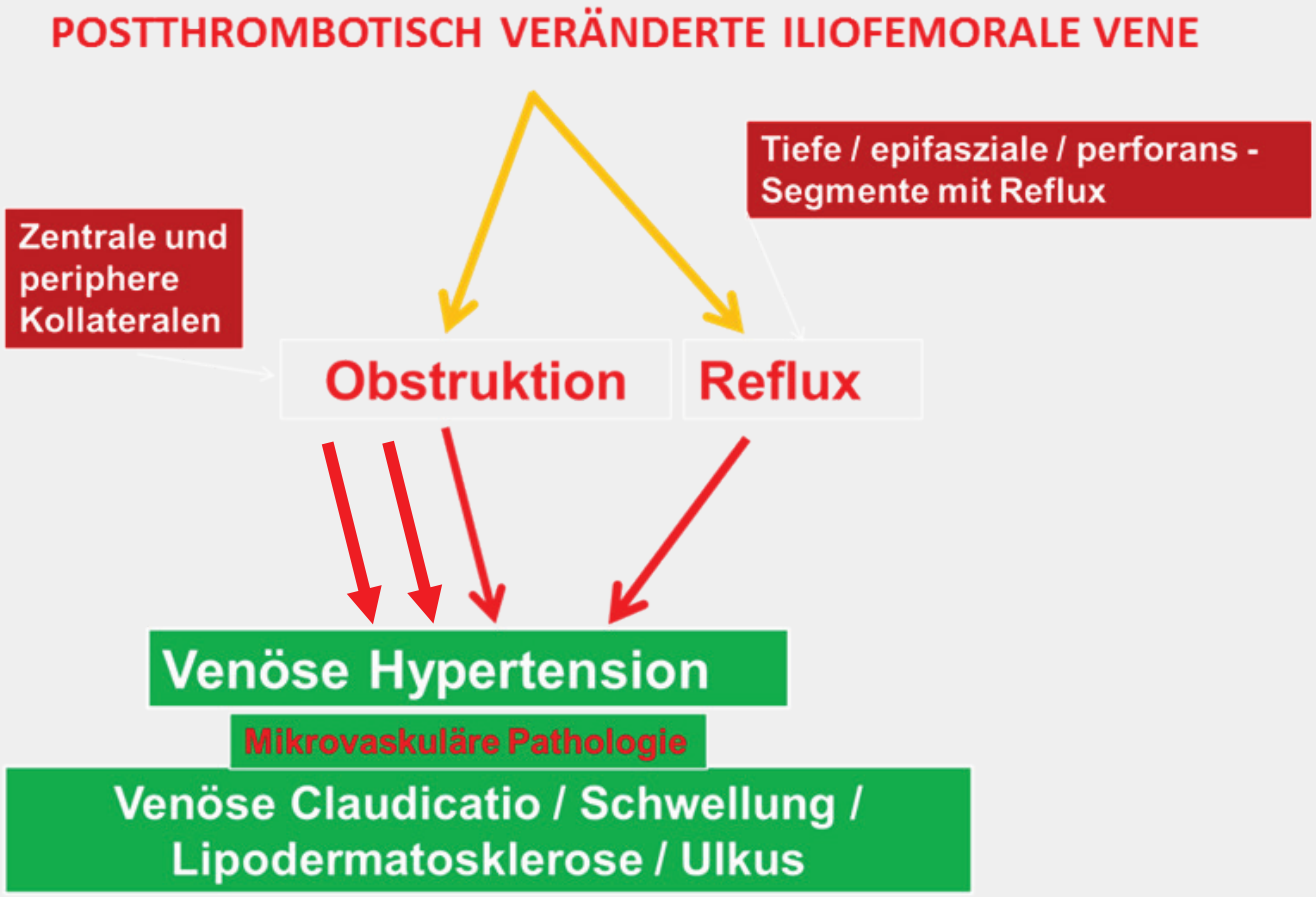
Am J Health-Syst Pharm—Vol 63 Oct 15, 2006 Suppl 6

Behandlungsziele TVT

- **Verhinderung einer Lungenembolie**
- **Akute Beschwerdelinderung**
- **Verhinderung eines VTE-Rezidivs**
- **Verhinderung eines postthrombotischen Syndroms**

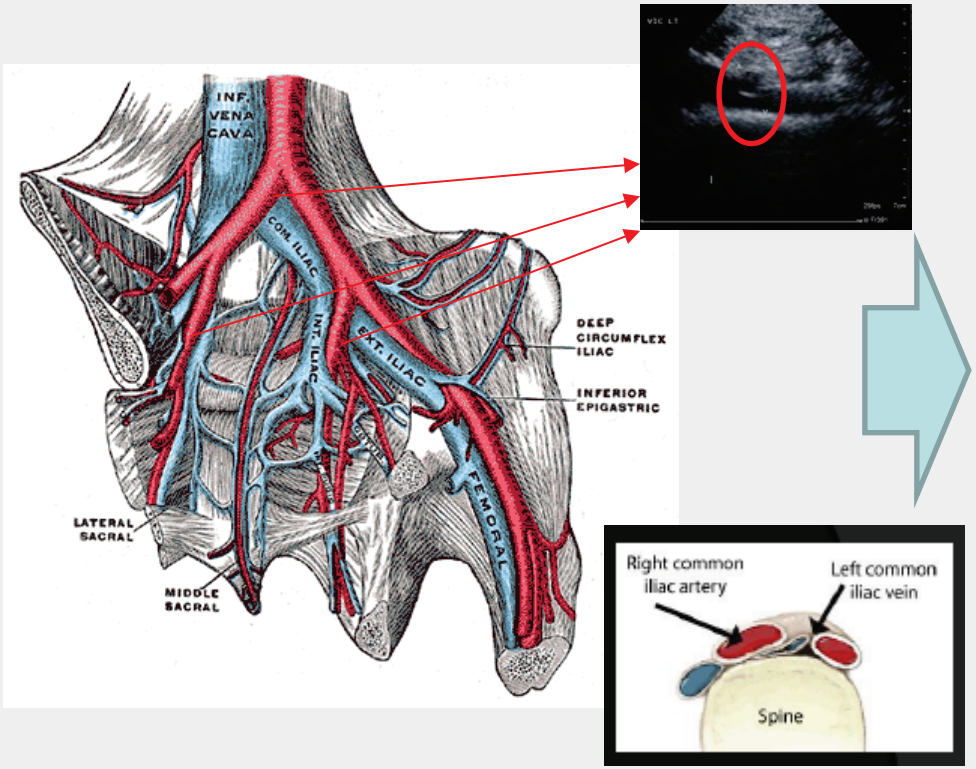


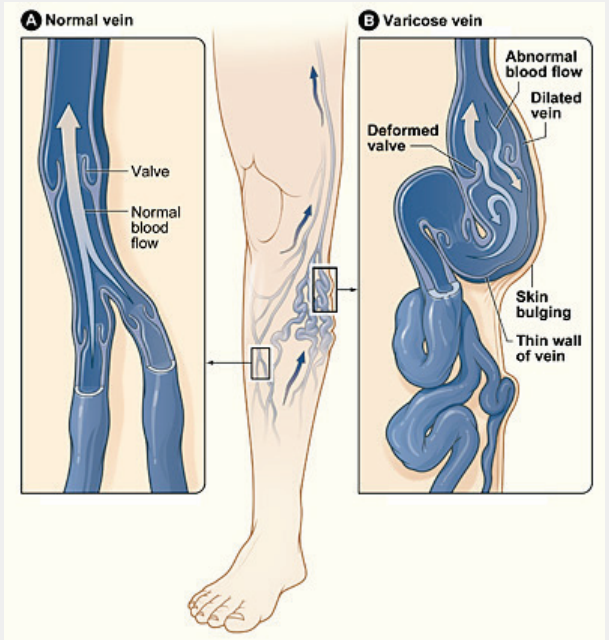
Pathophysiologie des postthrombotischen Syndroms



Klinikum Arnsberg
Karolinen-Hospital

Beckenvenenanatomie und Pathologie





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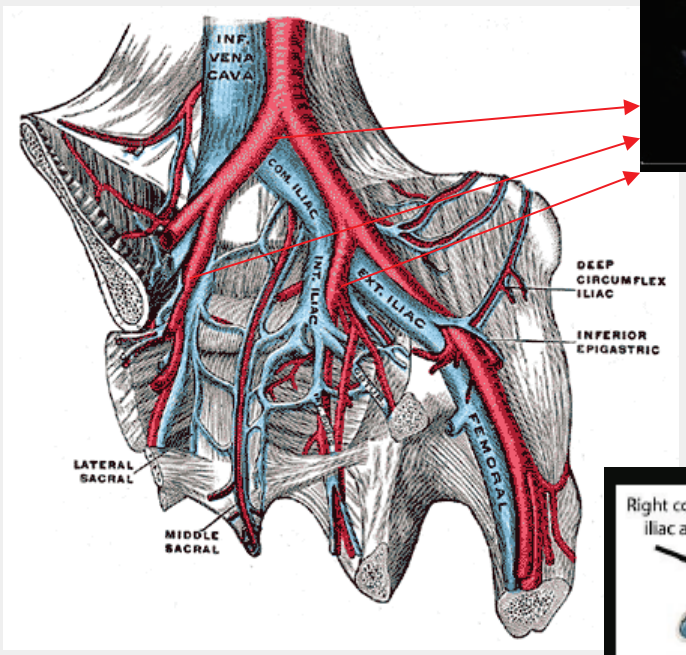
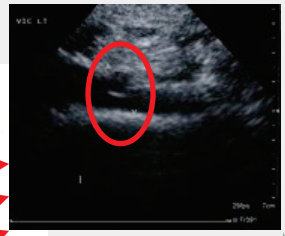
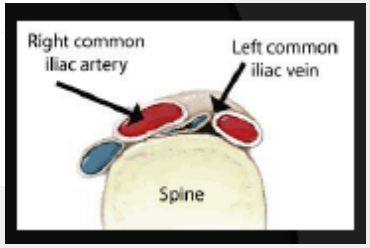
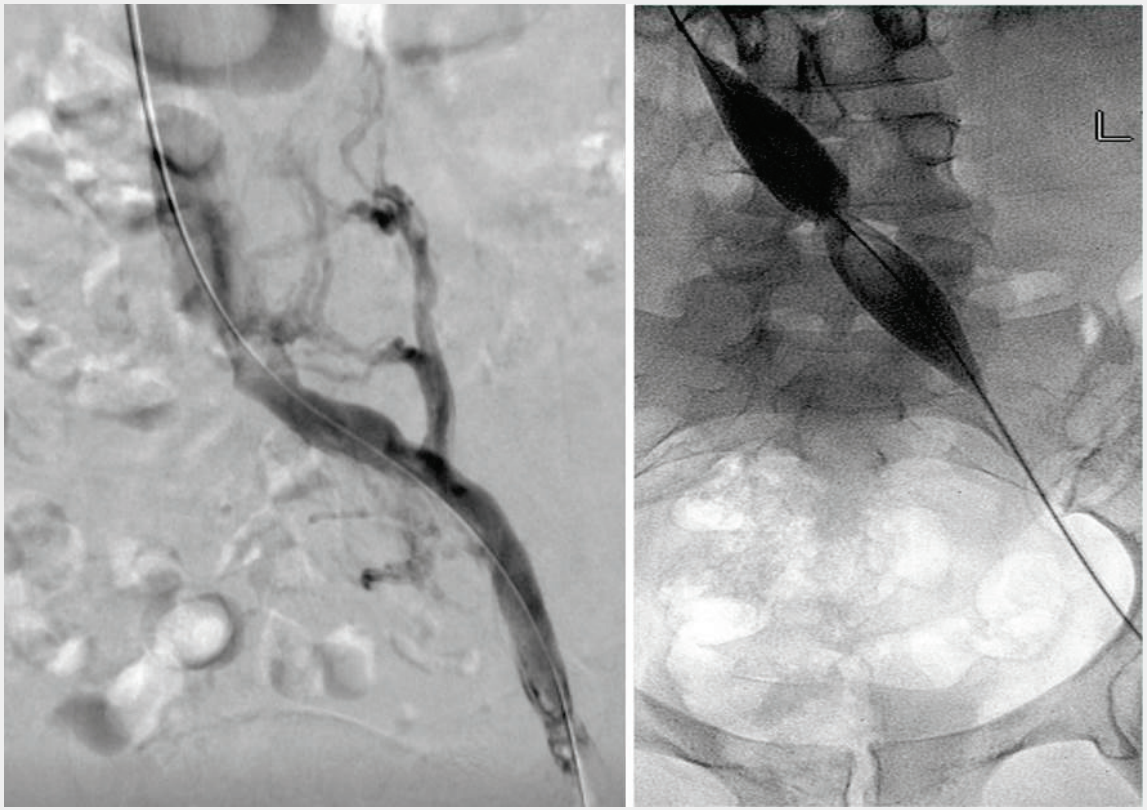






Klinisches Beispiel



Quelle: M. Lichtenberg

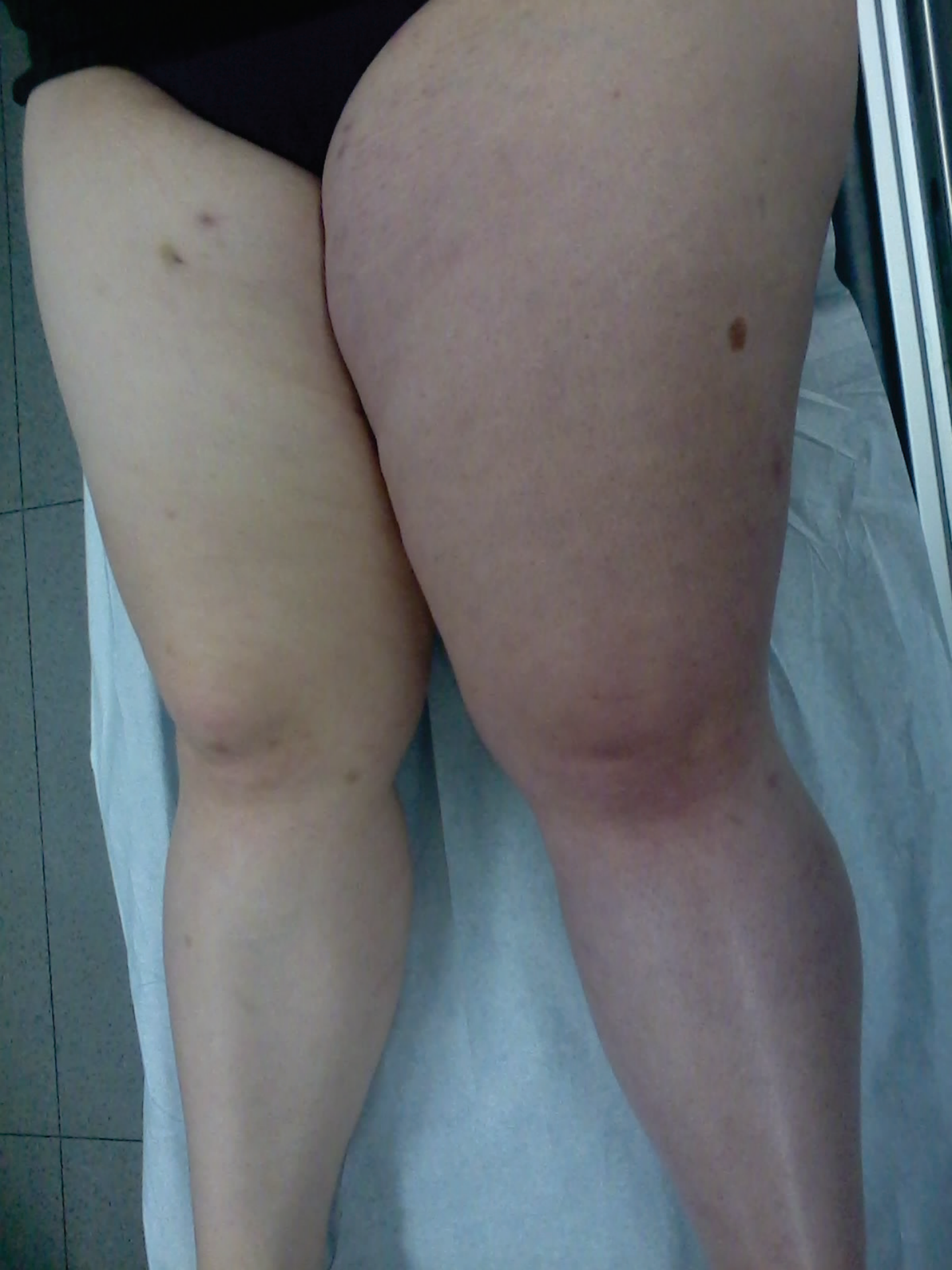
American College of PHLEBOLOGY
advancing vein care

PRACTICE GUIDELINES
Chronic Deep Venous Obstruction

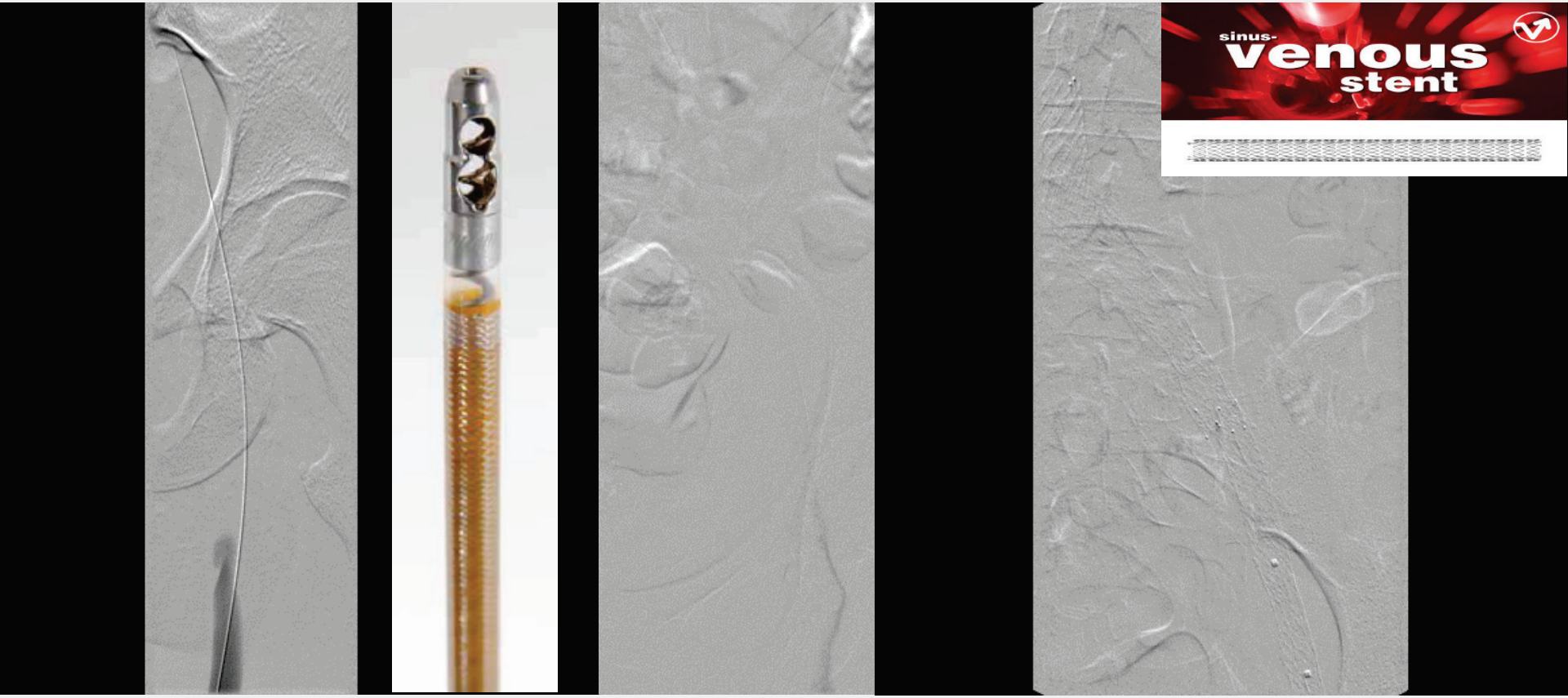
American Venous Forum
Promoting venous and lymphatic health

SOCIETY FOR CLINICAL VASCULAR SURGERY

the IVC. Eighty percent of iliofemoral DVTs, DVTs that involve the iliocaval segment in addition to the veins below the inguinal ligament, have an underlying iliac vein compression. This compression is thought to be a lesion which increases the risk of iliofemoral DVT, especially in individuals who have other risks for thrombosis including oral contraceptive use.[22] For

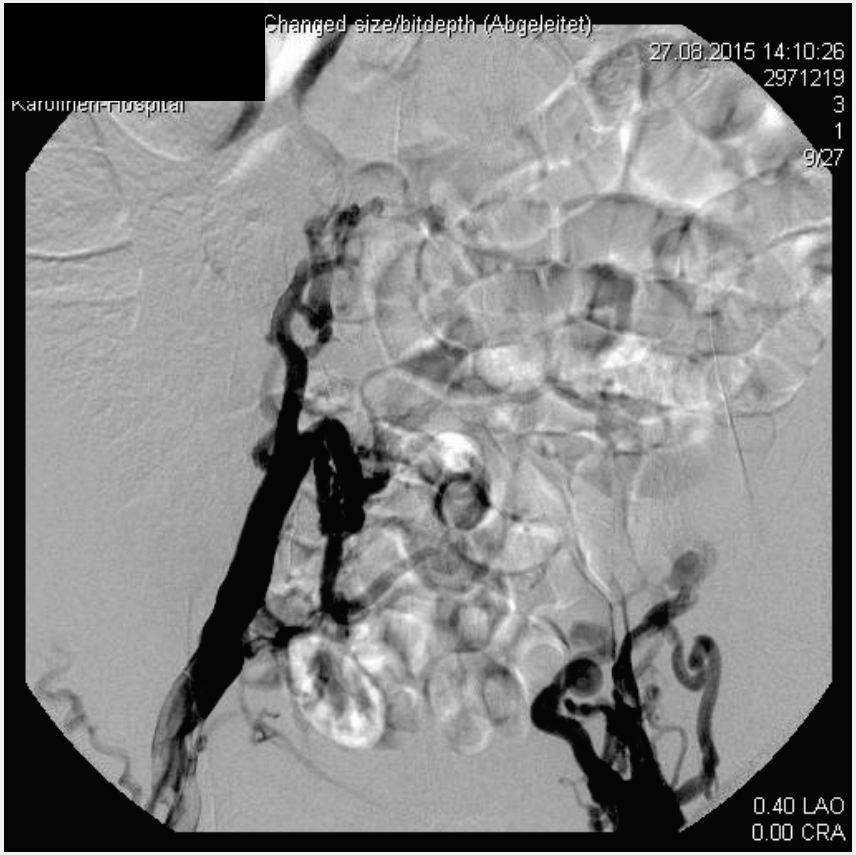


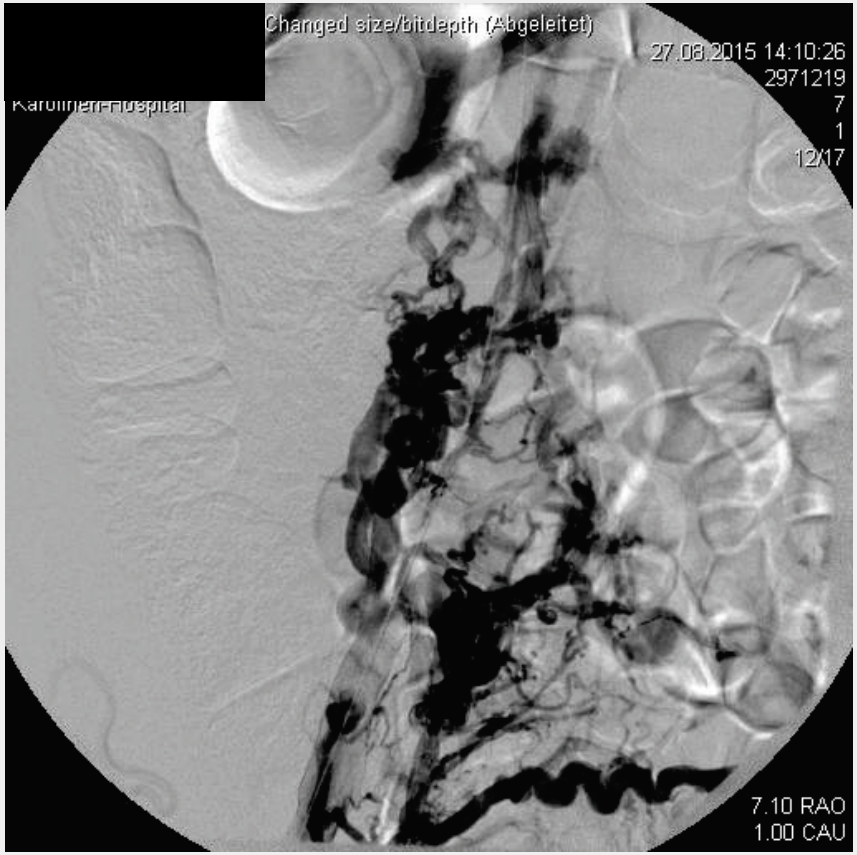
21 y, female, descending DVT in May – Thurner syndrome. Transpopliteal access, 10 F Aspirex®



8 F: blood volume aspiration up to 75 ml/min
10 F: blood volume aspiration up to 130 ml/min

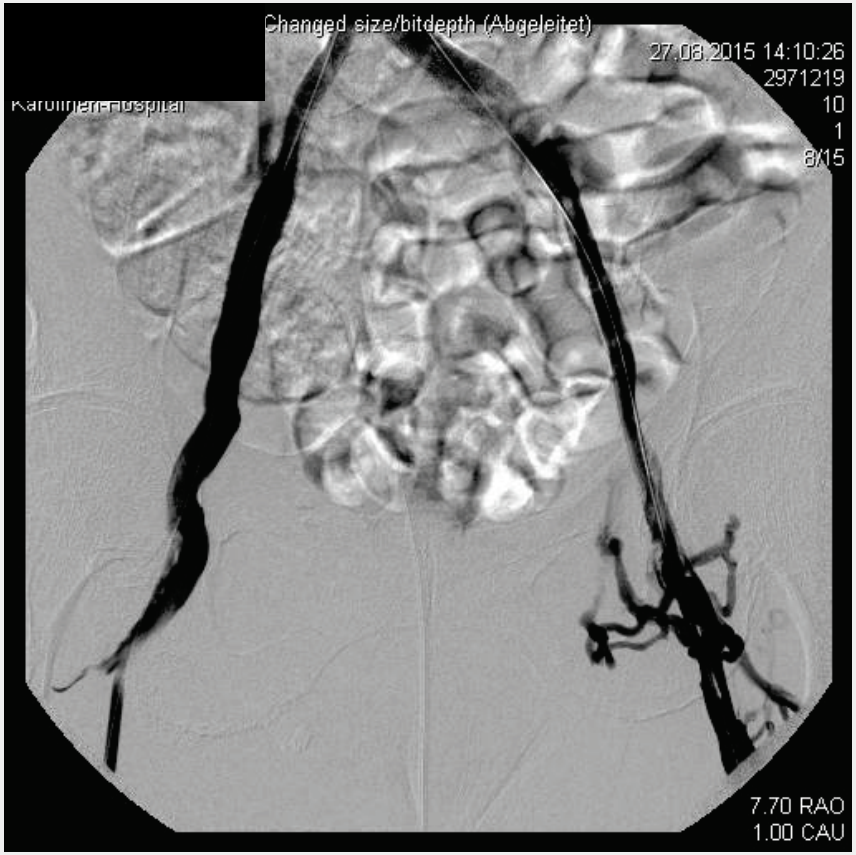
C6 Stadium, 58 Jahre, Z.n. peripartaler Thrombose vor 30 Jahren

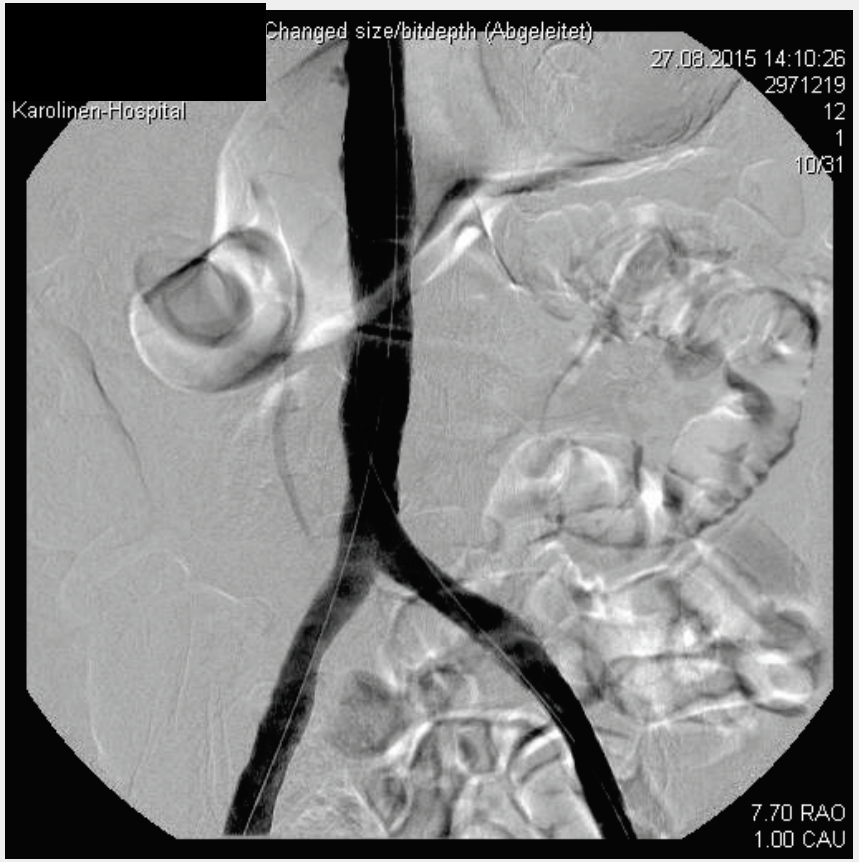




Quelle: M. Lichtenberg

Sinus XL Stent (22 x 80 mm)
4 x Veniti Stent (16 x 120 mm + 14 x 60 mm)





Quelle: M. Lichtenberg

Therapie der akuten TVT

Intervention	Indikation	Ziel	Probleme
Systemische Antikoagulation	Gold Standard	Verhinderung der Apposition und LAE	Keine! Thrombusauflösung Blutungen, PTS
Systemische Lyse	Keine Indikation für DVT aber für LAE	Verstärkte Thrombusauflösung	Blutungen, ITS-Aufenthalt
Chirurgische Thrombektomie	Last chance!	Thrombusentfernung	Narkose, Blutungen, hohe Morbidität und Mortalität
CDT („lokale Katheterlyse)	Deszendierende DVT von iliakal	Lokale Lyse des Thrombus	ITS-Aufenthalt, auch systemische Wirkung, Blutungen 5-11 %
Mechanische Thrombektomie	Kontarindikation Lyse	Mechanische Thrombektomie	In wenigen Fällen Dissektion, kaum Daten
Pharmakomechanische Thrombolyse	Kombination Lyse plus Thrombektomie	Pharmakomechanische Thrombektomie	Blutungen, Hämolysegefahr

Chest. 2016;149(2):315-352.
doi:10.1016/j.chest.2015.11.026

EST

Antithrombotic Therapy for VTE Disease

CHEST Guideline and Expert Panel Report

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 A. Morris, MD, FCCP; Namita Sood, MD, FCCP; Scott M. Stevens, MD; Janine R. E. Vintch, MD, FCCP; Philip Wells, MD; Scott C. Woller, MD; and COL Lisa Moores, MD, FCCP

PODCAST

Catheter-Directed Thrombolysis for Acute DVT of the Leg

16. In patients with acute proximal DVT of the leg, we suggest anticoagulant therapy alone over CDT (Grade 2C).

Remarks: Patients who are most likely to benefit from CDT (see text), who attach a high value to prevention of postthrombotic syndrome (PTS), and a lower value to the initial complexity, cost, and risk of bleeding with CDT, are likely to choose CDT over anticoagulation alone.

DVT. Although the quality of the evidence has improved, the overall quality is still low because of very serious imprecision. Unchanged from AT9, we propose that the patients who are most likely to benefit from

CDT have iliofemoral DVT, symptoms for <14 days, good functional status, life expectancy of ≥1 year, and a low risk of bleeding (Tables 14 and 15, e-Table 15). Because the balance of risks and benefits with CDT is

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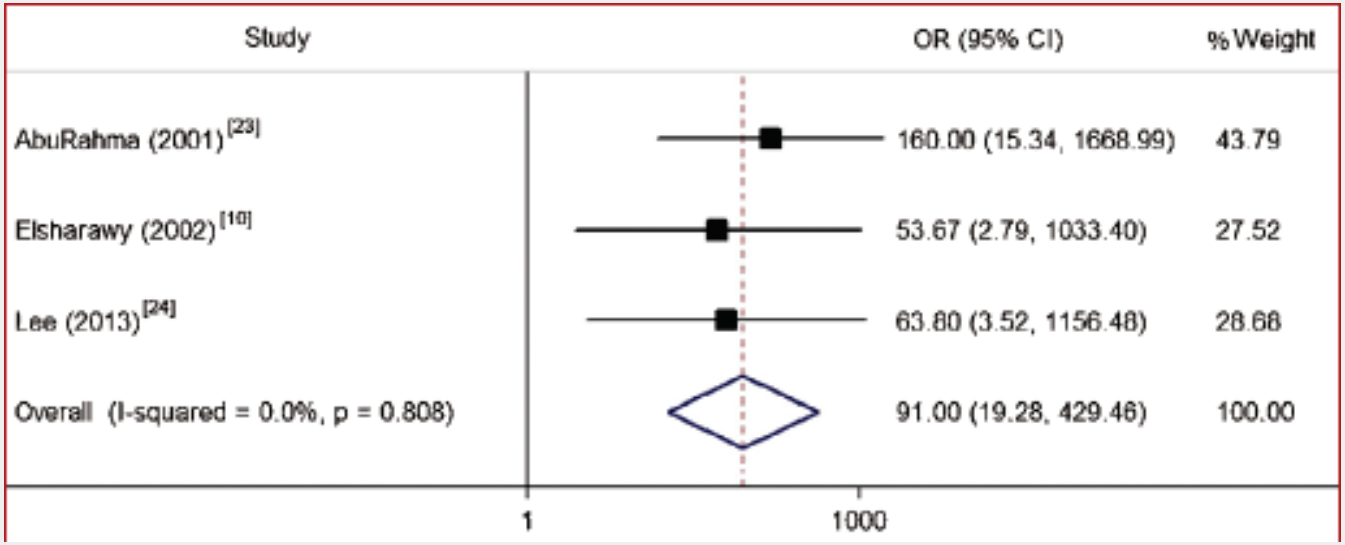
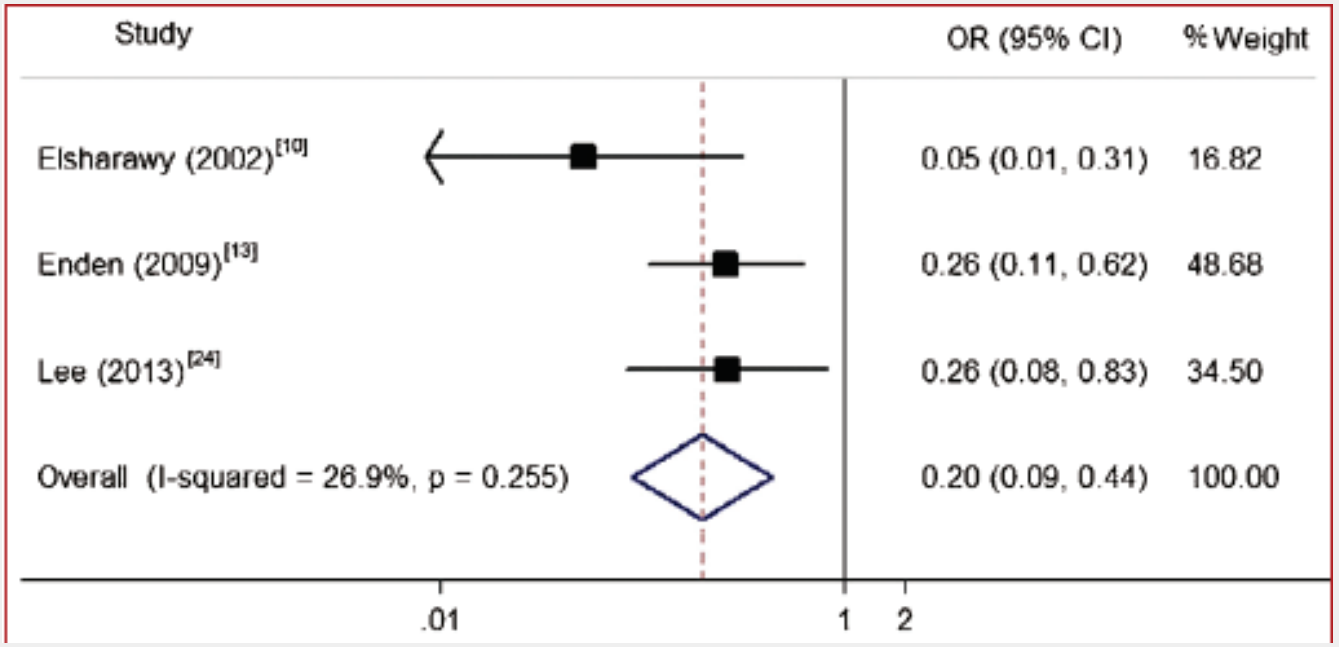
Catheter-directed thrombolysis plus anticoagulation versus anticoagulation alone in the treatment of proximal deep vein thrombosis - a meta-analysis

Du et al., Vasa 2015 May;44(3):195-202

Study	Design	Region	Mean age (year)	Male (%)	Compared groups (no.)	Thrombolytic agent	Clinical outcomes	Duration of follow-up
AbuRahma et al., 2001[23]	Prospective	USA	47	39	CDT + AA (18) vs. AA (33)	Urokinase, rtPA	Patency rate, long-term symptom resolusion, major complications	5 years
Elsharawy et al., 2002[10]	RCT	Egypt	46	31	CDT + AA (18) vs. AA (17)	Streptokinase	Patency rate, venous function, major complications	6 months
Enden et al., 2009[13]	RCT, multicenter	Norway	52	62	CDT + AA (50) vs. AA (53)	Alteplase	Patency rate, venous function, major complications	6 months
Enden et al., 2012[6]	RCT, multicenter	Norway	52	63	CDT + AA (90) vs. AA (99)	Alteplase	Patency rate, major complications, PTS, recurrent DVT	2 years
Lee et al., 2013[24]	Retrospective	Taiwan	62	51	CDT + AA (27) vs. AA (26)	Urokinase	Patency rate, major complications, PTS, venous function, recurrent DVT	15 months
Bashir et al., 2014[11]	Retrospective	USA	53	51	CDT + AA (3594) vs. AA (3594)	NA	Mortality, major complications	6 years



Iliofemorale Offenheitsrate nach 6 Monaten



Persistierende venöse Obstruktion im Follow-up

Du et al., Vasa 2015 May;44(3):195-202

Standardbehandlung vs. CDT

Enden et al., Lancet. 2012 Jan 7;379(9810):31-8.

Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial

Tone Enden, Ylva Haig, Nils-Einar Kløw, Carl-Erik Slagsvold, Leiv Sandvik, Waleed Ghanima, Geir Hafsahl, Pål Andre Holme, Lars Olaf Holmen, Anne Mette Njaastad, Gunnar Sandbæk, Per Morten Sandset, on behalf of the CaVenT Study Group

	Additional catheter-directed thrombolysis (n=90)		Standard treatment only (n=99)		p value*
	n	% (95% CI)	n	% (95% CI)	
Post-thrombotic syndrome at 24 months†	37	41·1% (31·5–51·4)	55	55·6% (45·7–65·0)	0·047
Iliofemoral patency at 6 months†‡	58	65·9% (55·5–75·0)	45	47·4% (37·6–57·3)	0·012
Post-thrombotic syndrome at 6 months§	27	30·3% (21·8–40·5)	32	32·2% (23·9–42·1)	0·77

Post-thrombotic syndrome defined as Villalta score of 5 points or higher. *χ^2 test. †Co-primary outcomes. ‡Five patients had inconclusive patency assessments and one was lost to follow-up at 6 months. §Secondary outcome.

Table 2: **Short-term and long-term outcomes**

Standardbehandlung vs. CDT

Enden… …ncet. 2012 Jan 7;379(9810):31-8.

Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial

…Nils-Einar Kløw, Carl-Erik Slagsvold, Leiv Sandvik, Waleed Ghanima, Geir Hafsahl, Pål Andre Holme, Lars Olaf Holmen, …Per Morten Sandset, on behalf of the CaVenT Study Group

STENT RATE

17 %

= Patienten haben weiterhin eine hämodynamisch relevante Stenose

Post… syn…		
Ilio… 6 months†‡		
Post-thrombotic syndrome at 6 months§	27	30 …

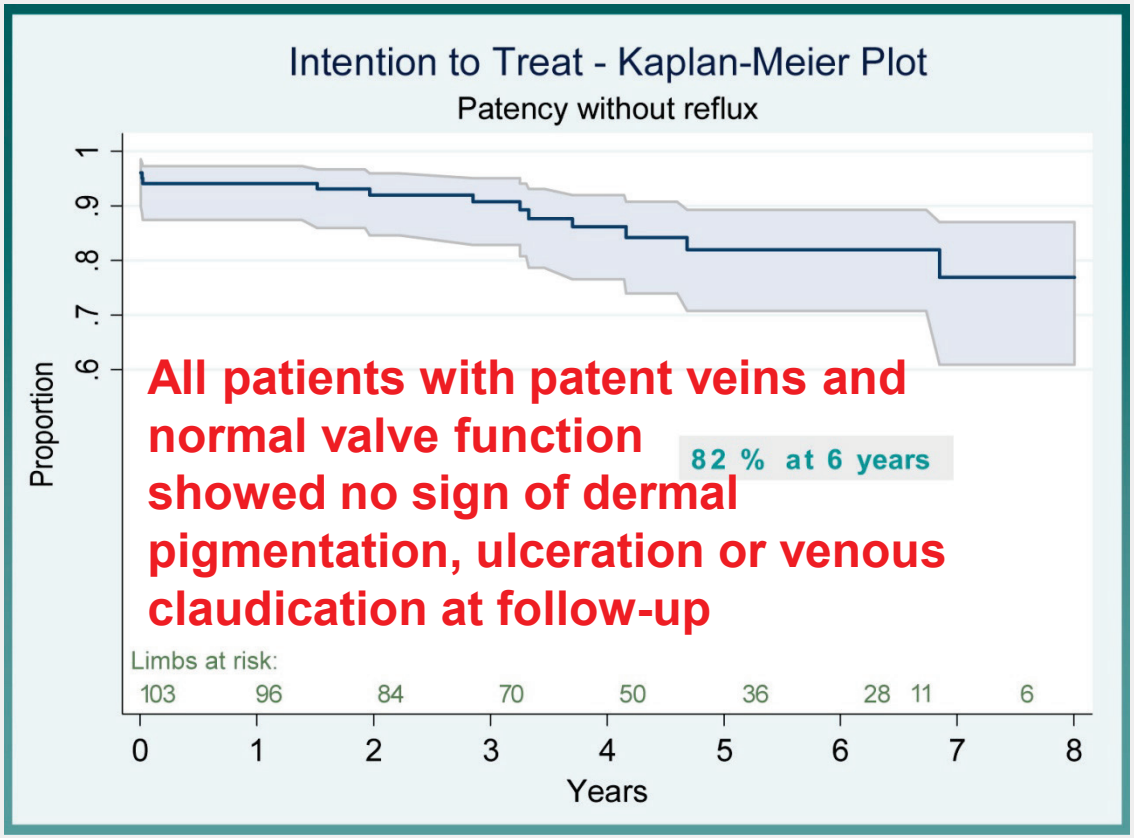
Post-thrombotic syndrome defined as Villalta score of 5 points or higher. *χ^2 test. †Co-primary … patients had inconclusive patency assessments and one was lost to follow-up at 6 months. §Secondary outcome.

Table 2: **Short-term and long-term outcomes**

Long-Term Results using Catheter-directed Thrombolysis in 103 Lower Limbs with Acute Iliofemoral Venous Thrombosis

N. Bækgaard, R. Broholm, S. Just, M. Jørgensen, L.P. Jensen

European Journal of Vascular and Endovascular Surgery **, Volume 39, Issue 1, Pages 112-117 (January 2010)**



1 major bleeding complication

Long-Term Results using Catheter-directed Thrombolysis in 103 Lower Limbs with Acute Iliofemoral Venous Thrombosis

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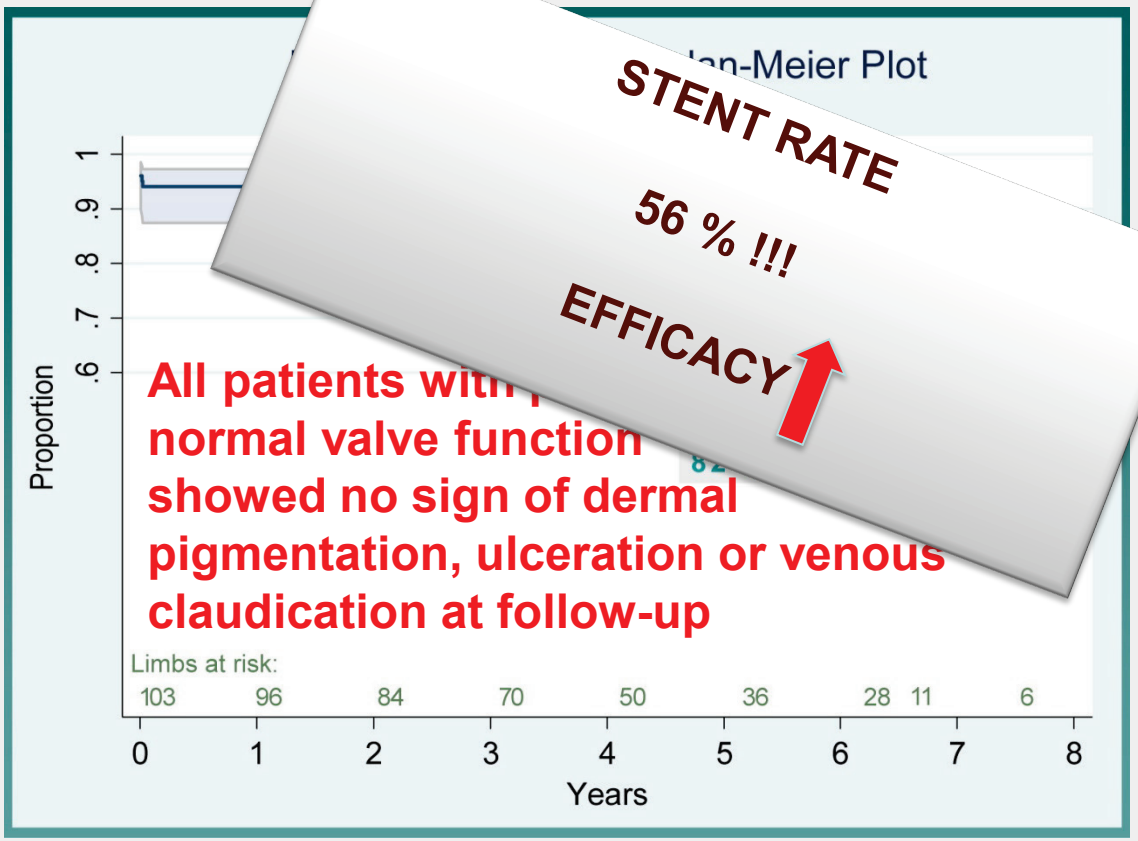


STENT RATE

56 % !!!

EFFICACY

All patients with [illegible] normal valve function showed no sign of dermal pigmentation, ulceration or venous claudication at follow-up

1 major bleeding complication

Original article

Stenting of iliac vein obstruction following catheter-directed thrombolysis in lower extremity deep vein thrombosis

MENG Qing-you, LI Xiao-qiang, JIANG Kun, QIAN Ai-min, SANG Hong-fei, RONG Jian-jie, DUAN Peng-fei and ZHU Li-wei

Keywords: deep venous thrombosis; catheter-directed thrombolysis; stent

Background Catheter-directed thrombolysis (CDT) for deep venous thrombosis (DVT) of the lower extremity has good effect, but whether iliac vein stent placement after thrombolytic therapy is still controversial. The goal of this study was to evaluate the efficacy of stent placement in the iliac vein following CDT in lower extremity DVT.

Methods This was a single-center, prospective, randomized controlled clinical trial. After receiving CDT, the major branch of the distal iliac vein was completely patent in 155 patients with lower extremity DVT, and 74 of these patients with iliac vein residual stenosis of >50% were randomly divided into a control group (n=29) and a test group (n=45). In the test group, stents were implanted in the iliac vein, whereas no stents were implanted in the control group. We evaluated the clinical indicators, including patency of the deep vein, C in CEAP classification, Venous Clinical Severity Score (VCSS), and Chronic Venous Insufficiency Questionnaire (CIVIQ) Score.

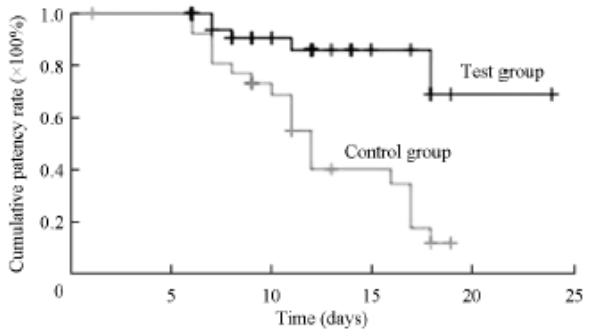


Figure 1. Comparison of cumulative patency rates.

Groups	CEAP C classification	
	Pre-procedure	Post-procedure
Test	3.13±0.50*	1.61±0.23*,‡
Control	3.11±0.06†	2.39±0.23†,‡

*,†P <0.001. ‡P <0.01.

Table 3. Comparison of VCSS pre- and post-procedure in the two groups

Groups	Pre-procedure	Post-procedure
Test	8.61±0.20*	1.04±0.19*,‡
Control	1.90±0.24†	6.56±0.23†,‡

*,†P <0.001. ‡P <0.01.

American Venous Forum
Promoting venous and lymphatic health

Society for Clinical Vascular Surgery

SOCIETY FOR VASCULAR SURGERY® DOCUMENTS

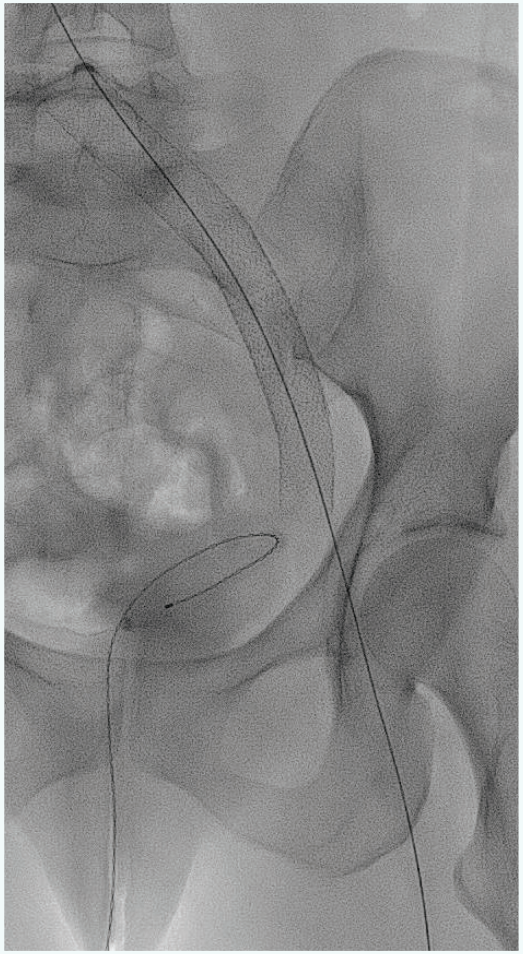
Early thrombus removal strategies for acute deep venous thrombosis: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum

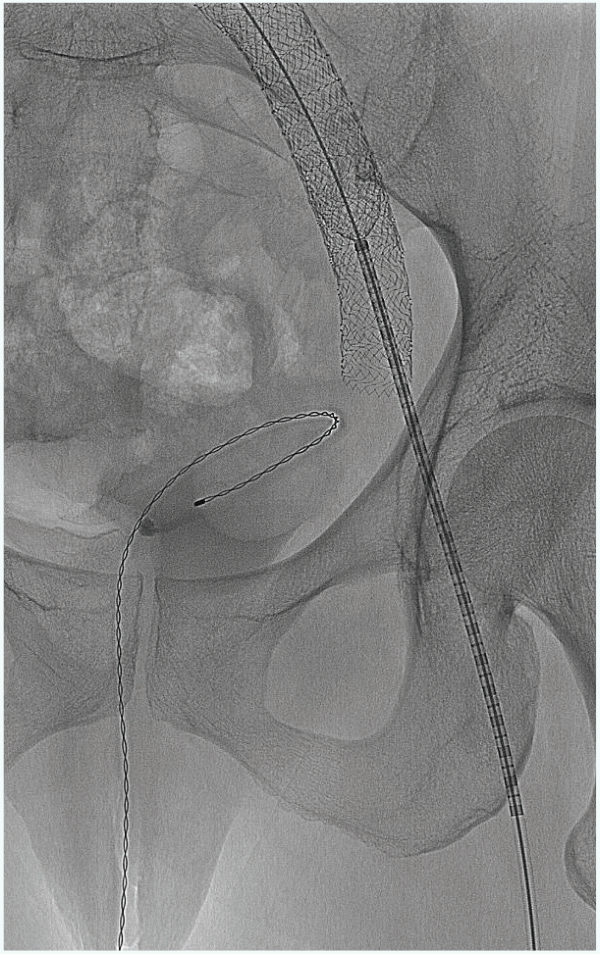
Mark H. Meissner, MD,[a] Peter Gloviczki, MD,[b] Anthony J. Comerota, MD,[c] Michael C. Dalsing, MD,[d] Bo G. Eklof, MD,[e] David L. Gillespie, MD,[f] Joann M. Lohr, MD,[g] Robert B. McLafferty, MD,[h] M. Hassan Murad, MD,[i] Frank Padberg, MD,[j] Peter Pappas, MD,[k] Joseph D. Raffetto, MD,[l] and Thomas W. Wakefield, MD,[m] *Seattle, Wash; Rochester, Minn; Toledo, Ohio; Indianapolis, Ind; Helsingborg, Sweden; Rochester and New York, NY; Cincinnati, Ohio; Springfield, Ill; Newark, NJ; West Roxbury, Mass; Ann Arbor, Mich*

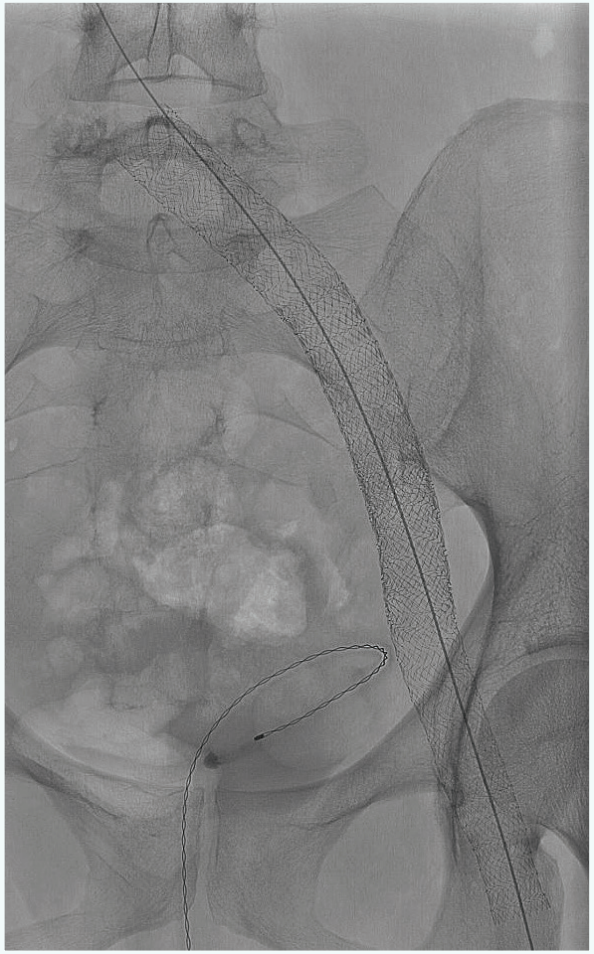
- **2. Indications for early thrombus removal**
  - **2.1. We suggest a strategy of early thrombus removal in selected patients meeting the following criteria:**
    - **(a) a first episode of acute iliofemoral deep venous thrombosis**
    - **(b) symptoms <14 days in duration**
    - **(c) a low risk of bleeding**
    - **(d) ambulatory with good functional capacity and an acceptable life expectancy (Grade 2C)**

5.1. We recommend the use of self-expanding metallic stents for treatment of chronic iliocaval compressive or obstructive lesions that are uncovered by any of the thrombus removal strategies (Grade 1C). and

Beispiel überlappende Stents







Quelle: M. Lichtenberg

Diagnostik und Therapie
der Venenthrombose
und der Lungenembolie

Datum der Verabschiedung: 10. Oktober 2015
Gültigkeitsdatum: 09. Oktober 2020

Federführende Fachgesellschaft:
Dt. Gesellschaft für Angiologie – Gesellschaft für Gefäßmedizin

Fazit für die Klinik und Praxis

Eine primäre rekanalisierende Maßnahme kann bei ilio-femoraler Thrombose eingesetzt werden und soll - wenn indiziert – so früh wie möglich durchgeführt werden.

Das Ziel rekanalisierender Maßnahmen zusätzlich zur Antikoagulation ist die Verringerung von Häufigkeit und Schwere des postthrombotischen Syndroms (PTS) [Strandness, Jr. et al. 1983].

Die Behandlung sollte baldmöglichst nach Diagnosestellung erfolgen, um längerfristig ein PTS zu vermeiden bzw. zu minimieren. Eine effektive Entfernung des thrombotischen Materials reduziert das Risiko eines PTS [Kuo 2013].

Eine Behandlung durch Thrombektomie, kathetergestütze Verfahren und Thrombolyse sollte spezialisierten Zentren mit ausreichender Erfahrung vorbehalten sein [Baldwin et al. 2004], [Blaettler et al. 2004], [Eklof et al. 2000], [Largiader et al. 2002], [Plate et al. 1997],

Interdisziplinäre Stellungnahme

Deutsches Ärzteblatt | Jg. 113 | Heft 17 | 29. April 2016

ENDOVASKULÄRE THERAPIE DER ILIOFEMORALEN THROMBOSE

Effektiv, sicher und leitliniengerecht bei richtiger Indikationsstellung

Dr. med. Dipl. oec. med. Michael Lichtenberg
Klinik für Angiologie, Klinikum Arnsberg
Dr. Rick de Graaf MD, PhD
Department of Radiology, Maastricht University Medical Centre, Maastricht
Dr. med. Houman Jalaie
Klinik für Gefäßchirurgie, Universitätsklinikum der RWTH Aachen, Aachen
Prof. Dr. med. Ralf Kolvenbach
Klinik für Gefäßchirurgie und Endovaskuläre Therapie, Augusta Krankenhaus, Düsseldorf
Prof. Dr. med. Bruno Geier
Chirurgische Klinik III, Stiftung Krankenhaus Bethanien für die Grafschaft Moers, Moers
Prof. Dr. med. Viola Hach-Wunderle
Krankenhaus Nordwest, Sektion Angiologie, Frankfurt a. M.

Schlussfolgerung

- Eine Thrombus entfernende Therapie wird bei einer iliofemoralen Venenthrombose zur Verhinderung eines postthrombotischen Syndroms nach den zunehmend günstigen Effektivitäts- und Sicherheitsdaten immer mehr zum Standard werden; das gilt vor allem für die pharmakomechanischen und rein mechanischen Verfahren.
- Die Therapie sollte dabei spezialisierten Zentren vorbehalten bleiben.
- Die Indikation besteht dabei insbesondere für junge und mobile Patienten mit kurzer Anamnesedauer und niedrigem Blutungsrisiko.
- Eine konstruktive Diskussion mit einer fachübergreifenden Konsensusfindung sollte wissenschaftlich fundiert im Rahmen von weiteren interdisziplinären Leitlinienprozessen stattfinden.

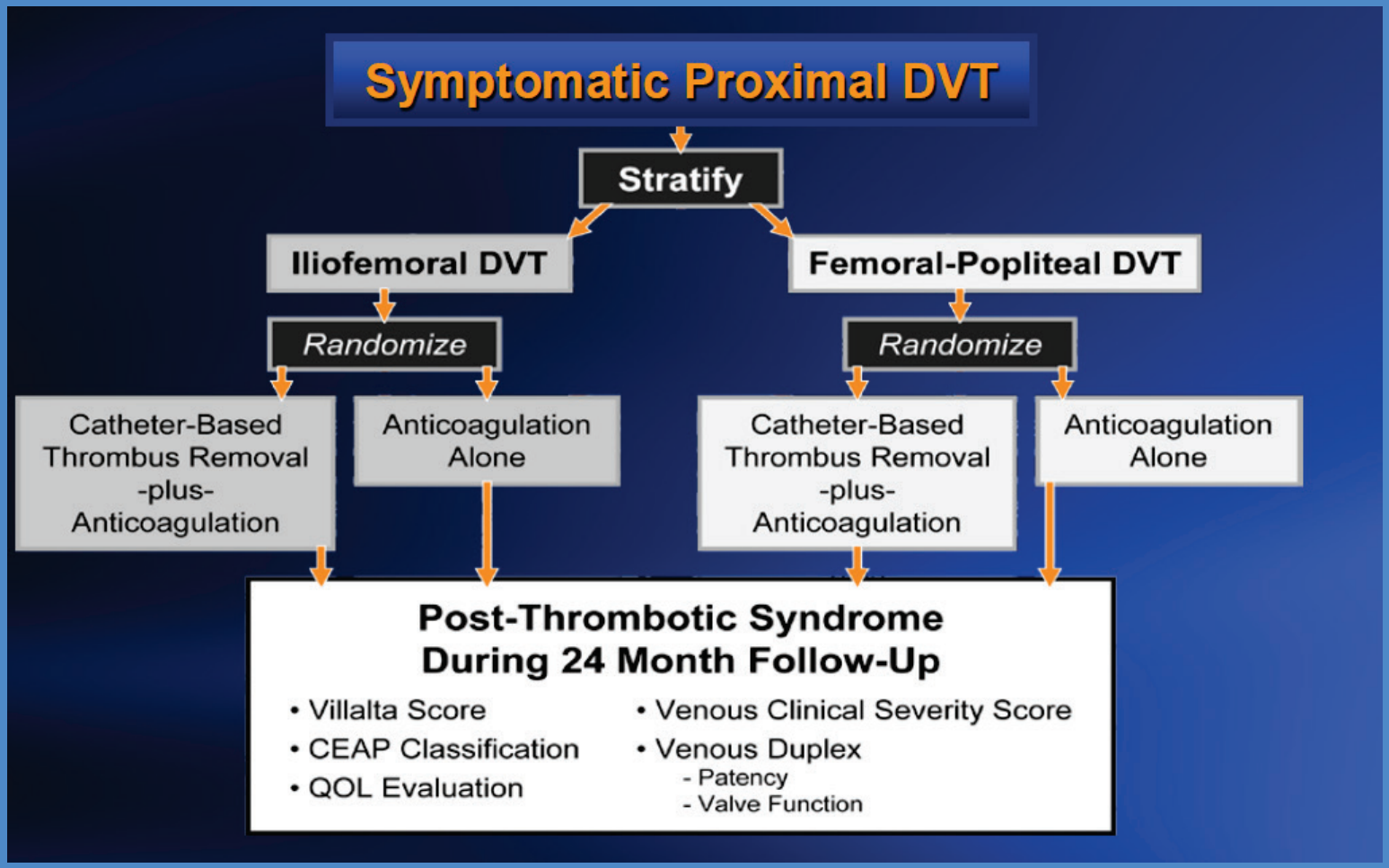
- Eine Indikation zur Thrombektomie sollte bei Beckenvenenthrombose überprüft werden
- …insbesondere bei jungem, gesunden Patient mit kurzer Anamnesedauer

Attract Trial: 6.3.2017

The ATTRACT Trial

- **Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis**
  - NHLBI-funded, Phase III, open-label, multicenter Randomized control trial
  - Pharmacomechanical Catheter-Directed Thrombolysis plus Conventional Therapy VS. Conventional Therapy Alone
  - 692 patients with symptomatic, acute proximal DVT
  - 28 U.S. Centers, enrollment began 1st quarter 2010
  - PI = Dr. Suresh Vedantham (Washington University)
  - Study Chair = Dr. Samuel Z. Goldhaber (Harvard)

ATTRACT TRIAL



PCDT Treatment

Treatment Arm
5 days heparin concurrent with PCDT procedure – then warfarin

- Trellis™-8
- AngioJet™ System
- Catheter-Directed Thrombolysis

Initial Treatment
Maximum 25 mg rt-PA

If **good** inflow to popliteal[a]

- **AngioJet™ System** (PowerPulse Thrombolysis), **or**
- **Trellis™-8** (Isolated Thrombolysis)

If **poor** inflow to popliteal

Catheter-Directed Thrombolysis

Adjunctive Options

- **Additional rt-PA** (total max 35 mg)
- **Balloon maceration**
- **Aspiration/mechanical thrombectomy**

Treatment Discontinuation

- **≥90% thrombus removed and flow restored, or**
- **Maximum rt-PA dose or infusion time reached, or**
- **Overt bleeding or complication requiring cessation of therapy**

[a]Lower half of the popliteal vein and ≥1 major calf vein tributary are free of occlusive thrombus.
rt-PA, recombinant tissue plasminogen activator; PCDT, pharmacomechanical catheter-directed thrombolysis

Vedantham S, et al. Rationale and design of the ATTRACT Study: a multicenter randomized trial to evaluate pharmacomechanical catheter-directed thrombolysis for the prevention of postthrombotic syndrome in patients with proximal deep vein thrombosis. Am Heart J. 2013;165(4):523-530.e3

ATTRACT trial

Outcome (24 mo)	PCDT (n=336)	no PCDT (n=335)	P value
Any PTS	**46,7 %**	**48,2%**	**0.56**
Recurrent VTE	12,5%	8,5%	0.09
Generic QOL (SF-36 PCS)	11,8	10,1	0.37
VENOUS QOL (VEINES)	27,7	23,5	0.08
Moderate or Severe PTS	17,9%	23,7%	0.035
MS-PTS IFDVT	18,4%	28,2%	
MS-PTS FPDVT	17,1%	18,1%	
Major bleed	1,7%	0,3%	0.049
Any bleed	4,5%	1,7%	0.049

PTCD less effective in patients ≥65 years (p = 0.038)

SIR, Washington 6.3.2017

ATTRACT trial

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SIR, Washington 6.3.2017

Performance of PCDT

INITIAL PCDT METHOD

- Trellis (Technique A)
  - 50 Patients (15%)
- Angiojet (Technique B)
  - 75 Patients (23%)
- Infuse-First (Technique C)
  - 194 Patients (59%)

ADJUNCTIVE PROCEDURE

- Balloon maceration (56%)
- Balloon angioplasty (56%)
- Angiojet (55%)
- Aspiration (19%)
- Trellis (14%)
- Stent placement (30%)

IVUS: NO !!!

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- Angiojet (55%)
- Aspiration (19%)
- Trellis (14%)
- Stent placement (30%)

No definitions when to stent and where to stent in the protocol

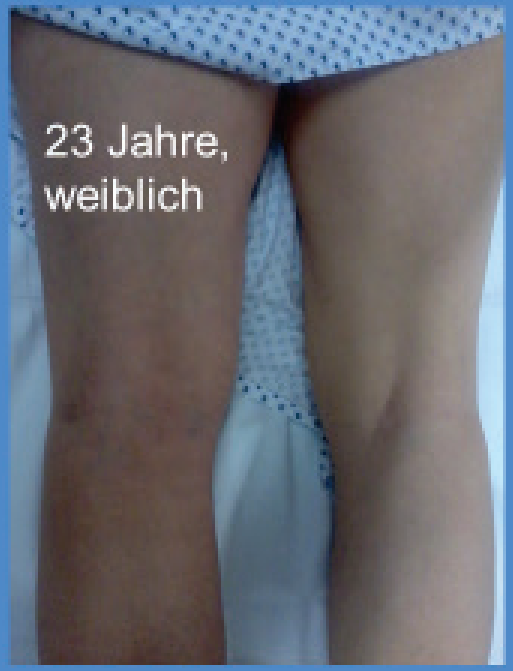
IVUS: NO !!!

Differences between treated DVT patients from Bern, ATTRACT and CaVenT

Courtesy N. Kucher

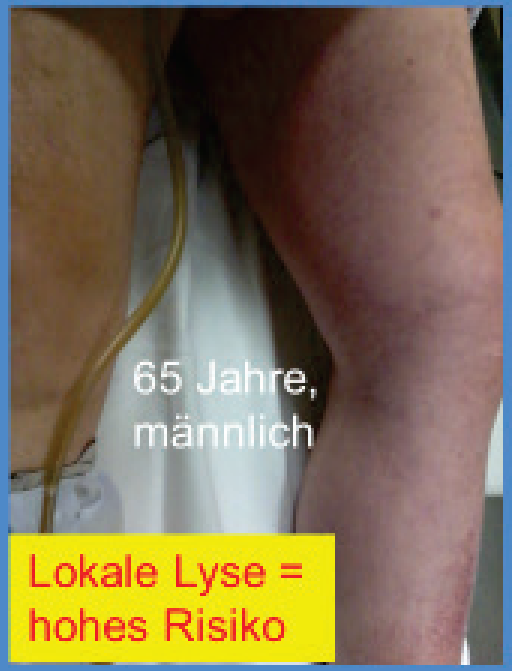
	BERN	CaVenT	ATTRACT
N	119	90	337
Control group without treatment	NO	YES	YES
Age, years	47	53	53
Symptom duration, days	<30	<21	<14
Ascending femoropopliteal DVT	**0 %**	**52 %**	**43%**
Descending iliofemoral DVT	**100%**	**48%**	**57%**
Mean tPA dose, mg	20 (fixed)	55 (variable)	21 (max 35 mg)
Mean tPA duration	15 h (fixed)	2,5 d	17 h
Major bleeding	1.0%	9.0%	1.7%
Definition of criteria for stenting	YES	NO	NO
Dedicated venous stents	YES	NO	NO
Stenting rate	**80%**	**17%**	**30%**
Overall PTS 12-24 mts (Villalta <5 pts)	**6%**	**41%**	**47%**
Patency rate	**94% (1y)**	**75% (2y)**	**Not evaluated**

Patienten mit Indikationen zur Thrombektomie



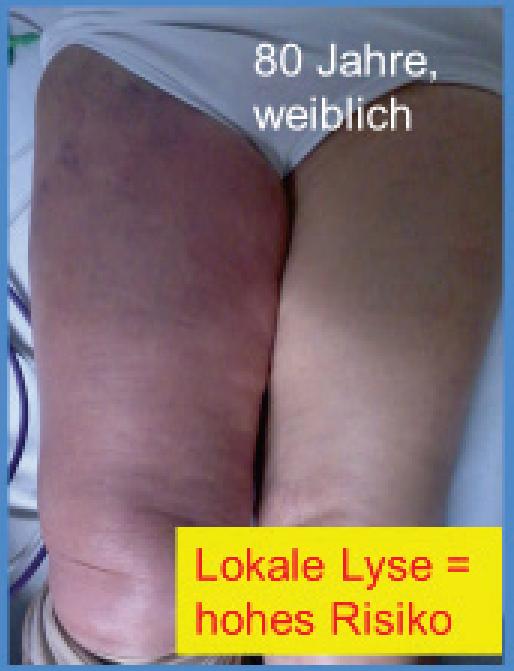
Junger, aktive Patientin,
Deszendierender TVT

May-Thurner Syndrom



Phlegmasie, Cavathrombose

Metastasiertes Colon-CA



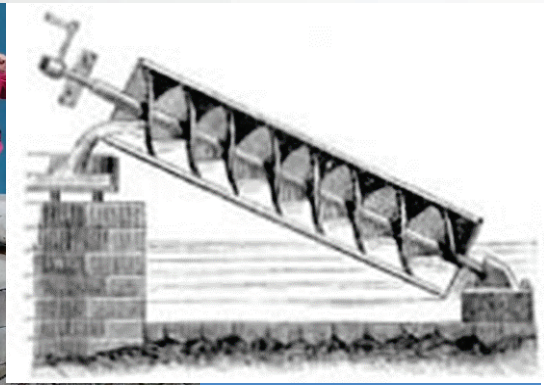
Stenosis Vena ilica externa

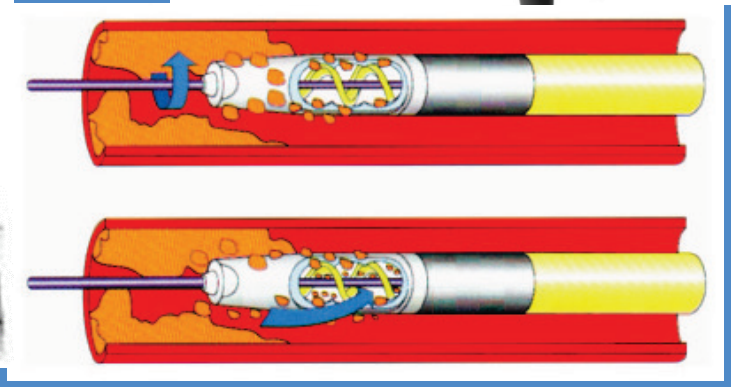
Lymphozelenkompression

Klinikum Arnsberg
Karolinen-Hospital

Rotational thrombectomy (Aspirex®)

6 – 10 French





M. Lichtenberg (Hrsg.), C. Tiefenbacher, M. Katoh, P. Minko, E. Minar, C. Wissgott, A. Storck, B. Hailer: Thrombektomie: medikamentös, mechnisch, operativ. Uni-med Verlag, 20

Clinical retrospective follow-up study with the ASPIREX®S Endovascular System to investigate safety and effectiveness in treatment of iliofemoral DVT patients

- ARNSBERG ASPIREX REGISTRY -

Responsible principal investigator (PI): M. Lichtenberg, R. de Graaf

Study sponsored by **Vascular Clinical Research Department, Arnsberg**

Klinikum Arnsberg
Akademisches Lehrkrankenhaus
Westfälische Wilhelms-Universität Münster

ARNSBERG ASPIREX REGISTRY

Das Ziel dieser Studie ist die Erfassung von Behandlungsdaten zur Sicherheit und technischen/medizinischen Leistung der Medizinprodukts ASPIREX®S unter Routineanwendungs-bedingungen in der klinischen Praxis.

Die erhobenen Daten werden für die klinische Bewertung nach MEDDEV 2.7.1. Rev 4. (2016) verwendet und sollen auf Fachkongressen präsentiert und in einem Fachjournal publiziert werden.

Patient Demographics

	Retro-ASPIREX
Total N (%)	**56 (100 %)**
Age Mean (Median [Range]) in years	52 (51 [17 - 89])
Female N (%)	37 (66 %)
Male N (%)	19 (34 %)
General Medical History	**N (%)**
Smoking status (valid observations)	**55 (100 %)**
Current	9 (16 %)
Former	4 (7 %)
Hypertension	**56 (100%)**
Yes	28 (50 %)
Immobilisation (valid observations)	**55 (100 %)**
Yes	4 (7 %)
Malignancy	**56 (100 %)**
Current active	4 (7 %)
Condition post	5 (5 %)
Oral contraceptive	**56 (100 %)**
Yes	21 (38 %)
No	35 (62%)

Study is sponsored by Klinikum Arnsberg

Diagnostic details (contd.)

	N (%)
Type of occlusion	**56 (100 %)**
Acute	40 (71 %)
Subacute	13 (23 %)
Chronic	2 (4 %)
Acute / Chronic	1 (2 %)
D-Dimer test positive	**56 (100 %)**
Not done	37 (66 %)
Yes	17 (30 %)
No	2 (4 %)
Underlying lesion	**56 (100 %)**
May Thurner	25 (45 %)
Not determined	14 (25 %)
Cancer	5 (9 %)
Post-thrombotic alterations	5 (9 %)
Benign prostate hypertrophy	1 (2%)
Factor V	1 (2 %)
May Thurner / Condition after surgical intervention	1 (2 %)
May Thurner / Protein C deficiency	1 (2 %)
Mechanical (e.g. V. cava clip)	1 (2 %)
Peripartal	1 (2 %)
Thoracic outlet syndrome	1 (2 %)

Study is sponsored by Klinikum Arnsberg

Diagnostic details

	N (%)
Diagnosis	**56 (100 %)**
Deep vein thrombosis (DVT)	44 (78 %)
Subacute thrombosis	6 (11 %)
In-stent restenosis	5 (9 %)
Subclavial thrombosis	1 (2 %)
Diagnostic	**56 (100 %)**
Ultrasound (DUS) / Venography	20 (36 %)
Ultrasound (DUS) / Venography / Angio-CT	8 (14 %)
Ultrasound (DUS) / CT / Venography	6 (11 %)
Ultrasound (DUS) / IVUS / Venography	5 (9 %)
Ultrasound (DUS)	4 (7 %)
Ultrasound (DUS) / IVUS	4 (7 %)
Other combinations (≤5% patients each)	9 (16 %)
Clinical Symptoms	**56 (100 %)**
Swelling / Pain	20 (36 %)
Swelling only	12 (21 %)
Swelling / Pain / Lividity	6 (11 %)
Other combinations (incl. Dyspnoea, Feeling of tension, Hyperthermia, Erysipelas, Wounds and Significant thoracic problems	18 (32 %)

Study is sponsored by Klinikum Arnsberg

Diagnostic details (contd.)

	N (%)
Location of occlusion (vessel)	**56 (100 %)**
Left complete pelvic veins including com. femoral vein, left sup. femoral vein (may also include profunda femoral vein and distal part of IVC)	42 (75 %)
Left common iliac vein only	7 (13 %)
Left common iliac vein / Left external iliac vein without com. femoral vein	3 (5 %)
Right complete pelvic veins	4 (7 %)
Length of occlusion [mm] N=56 (100 %)	**Statistics**
Mean (SD)	156.6 (72.0)
Median (Range)	150.0 (60 – 410)

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Aspirex treatment

	N (%)
Approach / Access	**56 (100)**
Left popliteal vein	27 (48 %)
Left superficial femoral vein	12 (21 %)
Left / Right superficial femoral vein	5 (9 %)
Left femoral communis vein	3 (5 %)
Right popliteal vein	3 (5 %)
Right superficial femoral vein	3 (5 %)
Left / Right popliteal vein	1 (2%)
Right brachial vein	1 (2 %)
Right saphena parva vein	1 (2 %)
Aspirex size	**56 (100 %)**
10	47 (85 %)
8	8 (15 %)
Sheath size	**56 (100 %)**
10	31 (55 %)
11	16 (29 %)
8	7 (12 %)
12	2 (4 %)

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Aspirex treatment (contd.)

		N (%)
Heparin [IU]		**56 (100)**
5,000		50 (89 %)
10,000		3 (5 %)
7,000 **OR** 7,500 **OR** 9,000 (1 patient each)		3 (5 %)
Thrombolysis		**56 (100 %)**
No		52 (93 %)
Yes		4 (7%)
Technical success	Yes	**56 (100 %)**
Number of implanted stents		**56 (100 %)**
1		22 (39 %)
2		19 (34 %)
3		8 (14 %)
4		3 (5 %)
5 **OR** 6 (1 patient each)		2 (4 %)
0		2 (4 %)
		Statistics
Mean (SD)		1.9 (1.2)
Median (Range)		2 (0 – 6)
Treatment duration [min] N=34		
Mean (SD)		94.2 (44.8)
Median (Range)		81.5 (27.0 – 238.0)

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Outcome

		N (%)
Follow up [years]		**56 (100 %)**
0		14 (25 %)
0.5		14 (25 %)
1		13 (23 %)
1.5		4 (7 %)
2		7 (12 %)
3		2 (4 %)
4		2 (4%)
Improvement of acute DVT symptoms on FU	Yes	**56 (100 %)**
Time to improvement on FU (days after procedure)		**56 (100 %)**
1		54 (96 %)
2		2 (4 %)
Patency on FU month 1 (valid observations)		**47 (100 %)**
Yes		44 (94 %)
Patency on FU month 6 (valid observations)		**37 (100 %)**
Yes		35 (95 %)
Patency on FU month 12 (valid observations)		**26 (100 %)**
Yes		24 (92 %)

Patency rate including scondary patency rate after 12 months 92 %

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Outcome (contd.)

	N (%)
Time on intensive care unit [days]	**56 (100 %)**
0	53 (95 %)
1	2 (3 %)
2	1 (2 %)
Post-thrombotic syndrome	**53 (100 %)**
low PTS (CEAP Score < 3, rVCSS Score < 3)	34 (64 %)
moderate/severe PTS (CEAP Score > 3, rVCSS Score > 3)	19 (36 %)

Prevention of moderate and severe PTS in 64 % of patients

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Safety

		N (%)
Patients (N=56) by number of adverse events (non device related but procedure related)		
no		45 (80 %)
yes (hematoma, puncture site infection, bleeding complication)		11 (20 %)
Patients (N=56) by number of serious adverse events (non device related but procedure related)		
no		48 (86 %)
yes (rehospitalization, re-occlusion of target vein, prolonged hospitalization because AV-Fistula operation or operation of access site complication)		8 (14 %)
Device malfunction reported Aspirex	**None**	**56 (100 %)**
Complaints reported on Aspirex	**None**	**56 (100 %)**

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Venous Thrombus Treatment Options:
Proactive Endovascular Treatment

- *Anticoagulation & Compression Stockings only*
- ***Catheter Directed Thrombolysis (CDT)***
  - *Enhanced CDT (eg, ultrasound)*
- ***Pharmacomechanical Thrombectomy***
- ***Mechanical Thrombectomy***

Verständigung notwendig

- **Zielpopulation**
  - **Aszendierende TVT mit Beckenbeteiligung**
  - **Deszendierende Becken-TVT**

- **Bewertung Schweregrad PTS**
  - **Jegliches?**
  - **Behinderndes?**
  - **Ulcus?**
  - **Andere Klassifikation?**