CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 25-27 2018

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER, PARIS, FRANCE

An Update On The American Venous Forum Guidelines For Deep Vein

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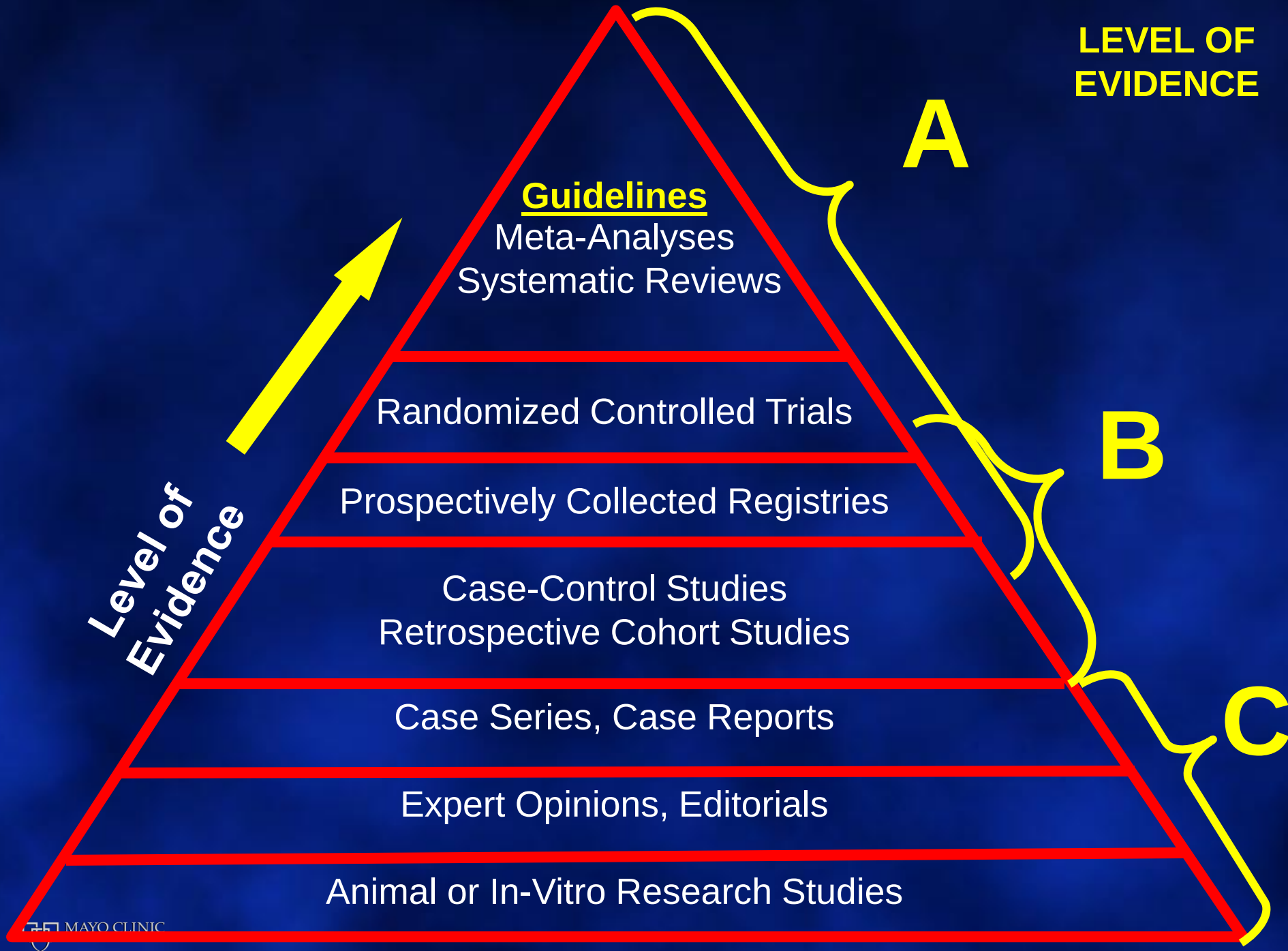
Disclosure

Speaker name:

Peter Gloviczki.....

- ☐ I have the following potential conflicts of interest to report:
- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☒ **I do not have any potential conflict of interest**


LEVEL OF EVIDENCE
A
B
C
Guidelines
Meta-Analyses
Systematic Reviews
Randomized Controlled Trials
Prospectively Collected Registries
Case-Control Studies
Retrospective Cohort Studies
Case Series, Case Reports
Expert Opinions, Editorials
Animal or In-Vitro Research Studies
Level of Evidence
MAYO CLINIC

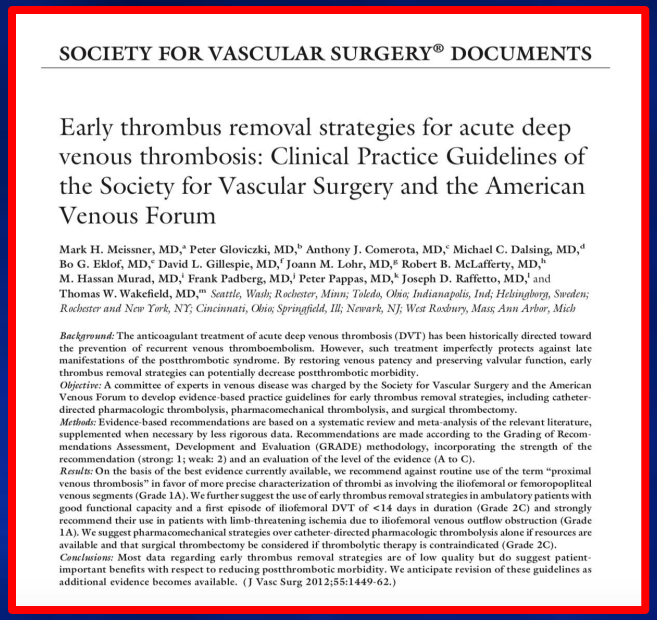
Evidence Based Guidelines

Grade of Recommendation	Grade of Evidence
1 = strong (Recommend) 2 =weak (Suggest) Risk and burdens vs. benefits	A: High quality B: Moderate quality C: Low or very low quality

Guyatt G et al. **Grading strength of recommendations and quality of evidence in clinical practice guidelines: report from an American College of Chest Physicians task force.** Chest 2006;129:174-81

Society for Vascular Surgery and American Venous Forum Guidelines

Acute DVT



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*

Background: The anticoagulant treatment of acute deep venous thrombosis (DVT) has been historically directed toward the prevention of recurrent venous thromboembolism. However, such treatment imperfectly protects against late manifestations of the postthrombotic syndrome. By restoring venous patency and preserving valvular function, early thrombus removal strategies can potentially decrease postthrombotic morbidity.

Objective: A committee of experts in venous disease was charged by the Society for Vascular Surgery and the American Venous Forum to develop evidence-based practice guidelines for early thrombus removal strategies, including catheter-directed pharmacologic thrombolysis, pharmacomechanical thrombolysis, and surgical thrombectomy.

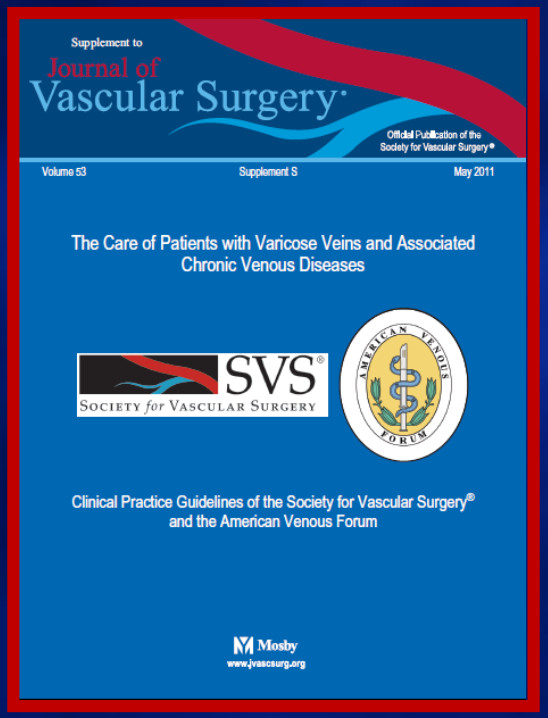
Methods: Evidence-based recommendations are based on a systematic review and meta-analysis of the relevant literature, supplemented when necessary by less rigorous data. Recommendations are made according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, incorporating the strength of the recommendation (strong: 1; weak: 2) and an evaluation of the level of the evidence (A to C).

Results: On the basis of the best evidence currently available, we recommend against routine use of the term "proximal venous thrombosis" in favor of more precise characterization of thrombi as involving the iliofemoral or femoropopliteal venous segments (Grade 1A). We further suggest the use of early thrombus removal strategies in ambulatory patients with good functional capacity and a first episode of iliofemoral DVT of <14 days in duration (Grade 2C) and strongly recommend their use in patients with limb-threatening ischemia due to iliofemoral venous outflow obstruction (Grade 1A). We suggest pharmacomechanical strategies over catheter-directed pharmacologic thrombolysis alone if resources are available and that surgical thrombectomy be considered if thrombolytic therapy is contraindicated (Grade 2C).

Conclusions: Most data regarding early thrombus removal strategies are of low quality but do suggest patient-important benefits with respect to reducing postthrombotic morbidity. We anticipate revision of these guidelines as additional evidence becomes available. (J Vasc Surg 2012;55:1449-62.)

J Vasc Surg 2012

Chronic Venous Disease



J Vasc Surg 2011

Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum

Endorsed by the American College of Phlebology and the Union Internationale de Phlébologie

Thomas F. O'Donnell Jr, MD, Marc A. Passman, MD, William A. Marston, MD, William J. Ennis, DO, Michael Dalsing, MD, Robert L. Kistner, MD, Fedor Lurie, MD, PhD, Peter K. Henke, MD, Monika L. Gloviczki, MD, PhD, Bo G. Eklöf, MD, PhD, Julianne Stoughton, MD, Sesadri Raju, MD, Cynthia K. Shortell, MD, Joseph D. Raffetto, MD, Hugo Partsch, MD, Lori C. Pounds, MD, Mary E. Cummings, MD, David L. Gillespie, MD, Robert B. McLafferty, MD, Mohammad Hassan Murad, MD, Thomas W. Wakefield, MD, and Peter Gloviczki, MD

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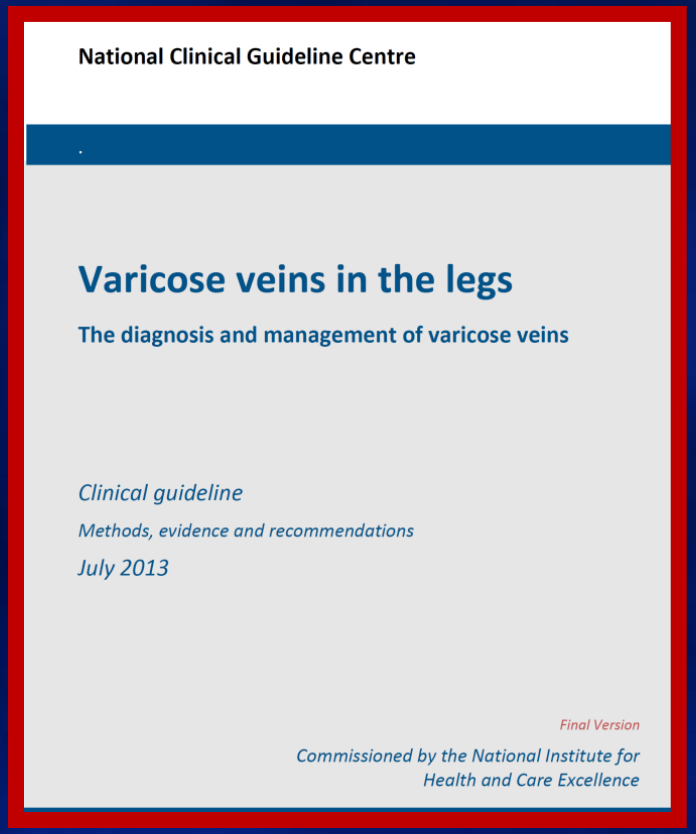
Author conflict of interest: none.
J Vasc Surg 2014;60:3S-59S
0741-5214/$36.00

http://dx.doi.org/10.1016/j.jvs.2014.04.049

J Vasc Surg 2014

The UK NICE and the European Guidelines



National Clinical Guideline Centre

Varicose veins in the legs

The diagnosis and management of varicose veins

Clinical guideline

Methods, evidence and recommendations

July 2013

Final Version

Commissioned by the National Institute for Health and Care Excellence

Eur J Vasc Endovasc Surg (2015) 49, 678–737

Editor's Choice – Management of Chronic Venous Disease

Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)

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Keywords: Chronic venous disease, Venous disease, Varicose veins, CEAP, VCSS, Villalta, AVVQ, Vein QoI Sym, Duplex ultrasound, Plethysmography, Phlebography, MRV, CTV, Wound dressings, Compression, Ambulatory compression, Sclerotherapy, Thermal ablation, Non-thermal ablation, Laser, Radiofrequency ablation, Stripping, High ligation, Phlebectomy, Stenting, Endophlebectomy, AV fistula, Recurrent varicose veins, Venous malformation

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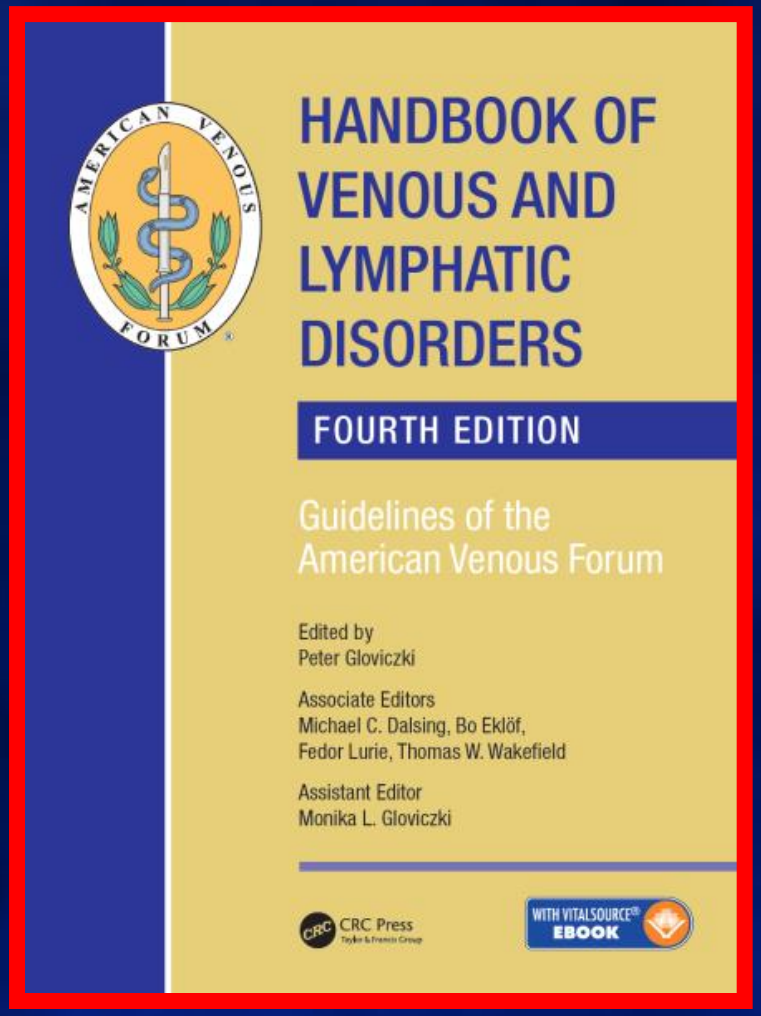
http://dx.doi.org/10.1016/j.ejvs.2015.02.007



2017

300 Guidelines
68 chapters
118 authors

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Conclusions: Most data regarding early th
important benefits with respect to reducing
additional evidence becomes available. (J

1. a. first episode of DVT
   b. symptoms <14 days
   c. low risk of bleeding
   d. good functional capacity and life expectancy

   2 (weak) C (low level of evidence)
2. Phlegmasia cerulea dolens

   1 (strong) A (high level of evidence)

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Technique

1. **percutaneous catheter-based techniques (pharmacologic or pharmacomechanical) as first-line therapy (2 C)**
2. **pharmacomechanical thrombolysis over catheter-directed pharmacologic thrombolysis alone if expertise and resources are available (2 C)**
3. **self-expanding metallic stents for treatment of chronic iliocaval compressive or obstructive lesions that are uncovered (2 C)**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pharmacomechanical Catheter-Directed Thrombolysis for Deep-Vein Thrombosis

S. Vedantham, S.Z. Goldhaber, J.A. Julian, S.R. Kahn, M.R. Jaff, D.J. Cohen, E. Magnuson, M.K. Razavi, A.J. Comerota, H.L. Gornik, T.P. Murphy, L. Lewis, J.R. Duncan, P. Nieters, M.C. Derfler, M. Filion, C.-S. Gu, S. Kee, J. Schneider, N. Saad, M. Blinder, S. Moll, D. Sacks, J. Lin, J. Rundback, M. Garcia, R. Razdan, E. VanderWoude, V. Marques, and C. Kearon, for the ATTRACT Trial Investigators*

ABSTRACT

BACKGROUND

The post-thrombotic syndrome frequently develops in patients with proximal deep-vein thrombosis despite treatment with anticoagulant therapy. Pharmacomechanical catheter-directed thrombolysis (hereafter "pharmacomechanical thrombolysis") rapidly removes thrombus and is hypothesized to reduce the risk of the post-thrombotic syndrome.

METHODS

We randomly assigned 692 patients with acute proximal deep-vein thrombosis to receive either anticoagulation alone (control group) or anticoagulation plus pharmacomechanical thrombolysis (catheter-mediated or device-mediated intrathrombus delivery of recombinant tissue plasminogen activator and thrombus aspiration or maceration, with or without stenting). The primary outcome was development of the post-thrombotic syndrome between 6 and 24 months of follow-up.

RESULTS

Between 6 and 24 months, there was no significant between-group difference in the percentage of patients with the post-thrombotic syndrome (47% in the pharmacomechanical-thrombolysis group and 48% in the control group; risk ratio, 0.96; 95% confidence interval [CI], 0.82 to 1.11; P=0.56). Pharmacomechanical thrombolysis led to more major bleeding events within 10 days (1.7% vs. 0.3% of patients, P=0.049), but no significant difference in recurrent venous thromboembolism was seen over the 24-month follow-up period (12% in the pharmacomechanical-thrombolysis group and 8% in the control group, P=0.09). Moderate-to-severe post-thrombotic syndrome occurred in 18% of patients in the pharmacomechanical-thrombolysis group versus 24% of those in the control group (risk ratio, 0.73; 95% CI, 0.54 to 0.98; P=0.04). Severity scores for the post-thrombotic syndrome were lower in the pharmacomechanical-thrombolysis group than in the control group at 6, 12, 18, and 24 months of follow-up (P<0.01 for the comparison of the Villalta scores at each time point), but the improvement in quality of life from baseline to 24 months did not differ significantly between the treatment groups.

CONCLUSIONS

Among patients with acute proximal deep-vein thrombosis, the addition of pharmacomechanical catheter-directed thrombolysis to anticoagulation did not result in a lower risk of the post-thrombotic syndrome but did result in a higher risk of major bleeding. (Funded by the National Heart, Lung, and Blood Institute and others; ATTRACT ClinicalTrials.gov number, NCT00790335.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Vedantham at Washington University in St. Louis, Mallinckrodt Institute of Radiology, 510 S. Kingshighway Blvd., St. Louis, MO 63110, or at vedanthams@wustl.edu.

*A complete list of investigators in the ATTRACT trial is provided in the Supplementary Appendix, available at NEJM.org.

This article was updated on December 7, 2017, at NEJM.org.

N Engl J Med 2017;377:2240-52.
DOI: 10.1056/NEJMoa1615066

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N Engl J Med 2017;377:2240-52.
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venousnews

Jan 18

Published ATTRACT data call into question validity of the Villalta scale

Following the publication of the ATTRACT trial in the New England Journal of Medicine (NEJM) in December 2017, Venous News spoke to experts in the field to analyse the data and formulate future research questions. One of the interesting points raised was whether the Villalta scale is an altogether valid measure of post-thrombotic syndrome, even though its use is recommended by international guidelines. The Villalta scale is considered the gold standard for the diagnosis and classification of post-thrombotic syndrome, when combined with a venous disease-specific quality-of-life questionnaire.

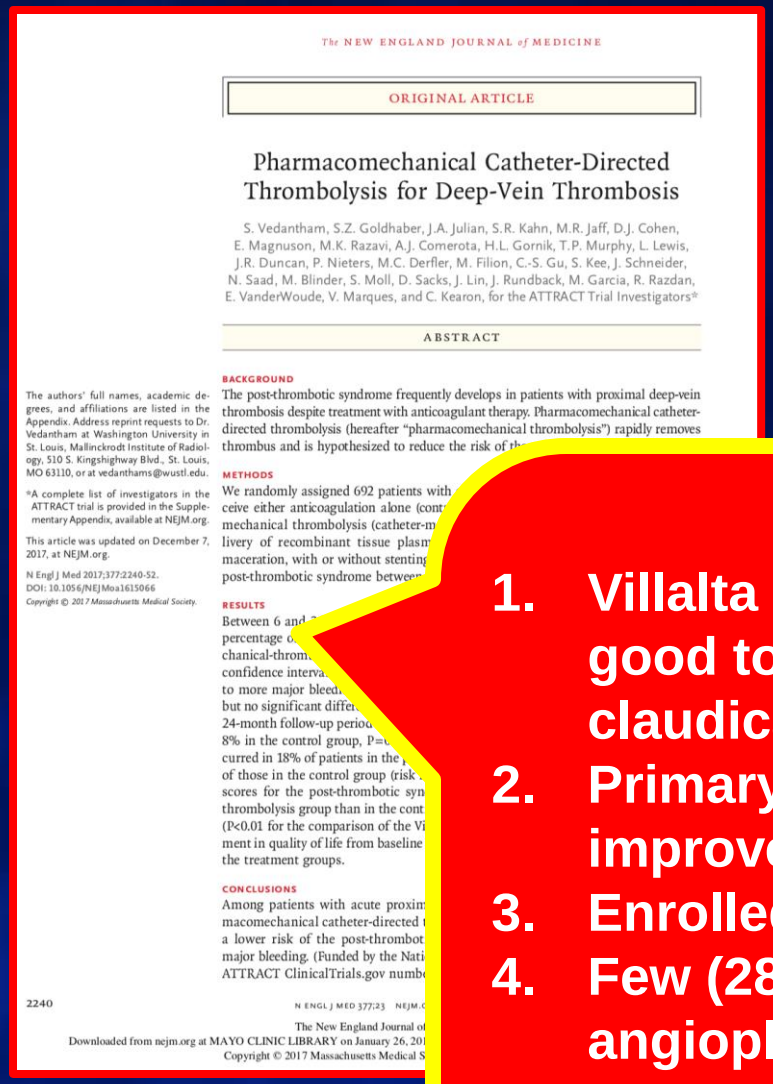
The ATTRACT (Acute venous thrombosis: Thrombus removal with adjunctive ...er-directed thrombolysis) ...ts set out to assess the treat-...ffect obtained by adding ...comechanical thrombolysis ...llary measures including ...s aspiration/maceration, ...ithout balloon angio-

Johann C Ragg: Percutaneous valvuloplasty

Armando Mans... Profile

Nicholas Os... VQI Varic... Registry

Brave Drean... finds venop... "safe, but l... ineffective"



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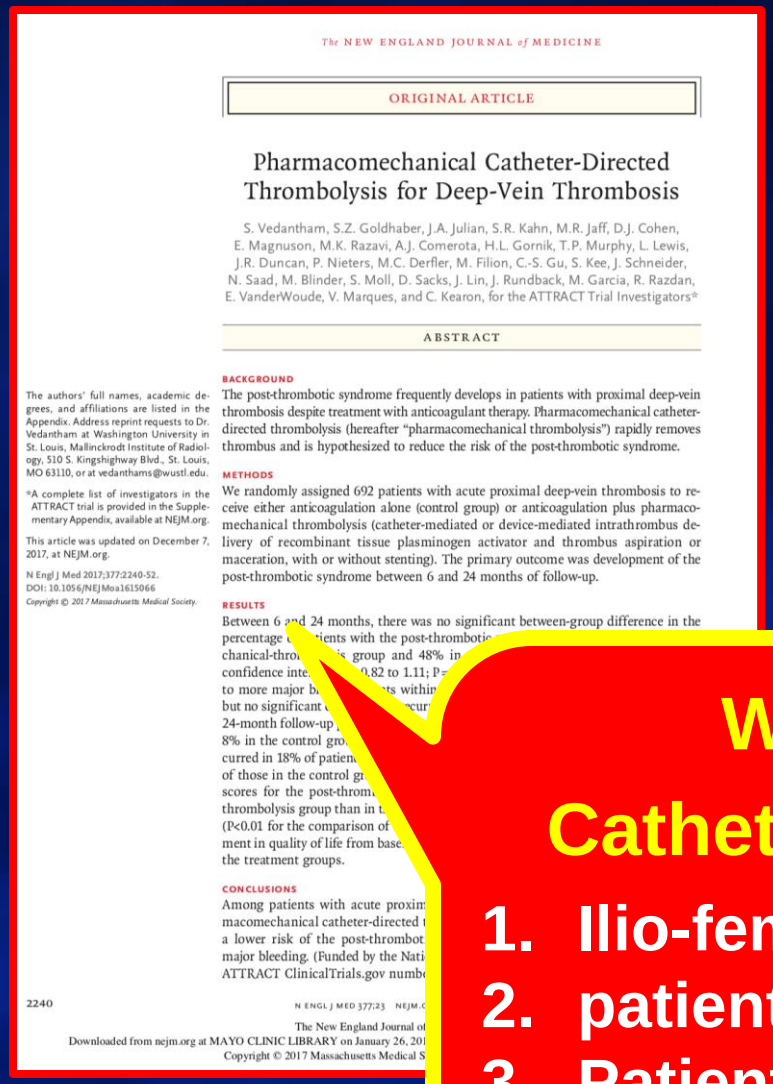
Problems

1. Villalta Scale (imperfect, subjective scale, not good to measure changes in venous claudication)
2. Primary endpoint (did not focus on symptom improvement)
3. Enrolled femoropopliteal DVT patients (43%)
4. Few (28%) iliac vein stenting (62% balloon angioplasty!
5. IVUS/Multiplanar venography was not in the clinical protocol



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pharmacomechanical Catheter-Directed Thrombolysis for Deep-Vein Thrombosis

S. Vedantham, S.Z. Goldhaber, J.A. Julian, S.R. Kahn, M.R. Jaff, D.J. Cohen, E. Magnuson, M.K. Razavi, A.J. Comerota, H.L. Gornik, T.P. Murphy, L. Lewis, J.R. Duncan, P. Nieters, M.C. Derfler, M. Filion, C.-S. Gu, S. Kee, J. Schneider, N. Saad, M. Blinder, S. Moll, D. Sacks, J. Lin, J. Rundback, M. Garcia, R. Razdan, E. VanderWoude, V. Marques, and C. Kearon, for the ATTRACT Trial Investigators*

ABSTRACT

BACKGROUND

The post-thrombotic syndrome frequently develops in patients with proximal deep-vein thrombosis despite treatment with anticoagulant therapy. Pharmacomechanical catheter-directed thrombolysis (hereafter "pharmacomechanical thrombolysis") rapidly removes thrombus and is hypothesized to reduce the risk of the post-thrombotic syndrome.

METHODS

We randomly assigned 692 patients with acute proximal deep-vein thrombosis to receive either anticoagulation alone (control group) or anticoagulation plus pharmacomechanical thrombolysis (catheter-mediated or device-mediated intrathrombus delivery of recombinant tissue plasminogen activator and thrombus aspiration or maceration, with or without stenting). The primary outcome was development of the post-thrombotic syndrome between 6 and 24 months of follow-up.

RESULTS

Between 6 and 24 months, there was no significant between-group difference in the percentage of patients with the post-thrombotic
chanical-thro group and 48% in
confidence inte 0.82 to 1.11; P=
to more major b ts within
but no significant
24-month follow-up
8% in the control gro
curred in 18% of patien
of those in the control gr
scores for the post-throm
thrombolysis group than in t
(P<0.01 for the comparison of
ment in quality of life from base
the treatment groups.

CONCLUSIONS

Among patients with acute proxim
macomechanical catheter-directed
a lower risk of the post-thrombot
major bleeding. (Funded by the Nati
ATTRACT ClinicalTrials.gov numb

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Vedantham at Washington University in St. Louis, Mallinckrodt Institute of Radiology, 510 S. Kingshighway Blvd., St. Louis, MO 63110, or at vedanthams@wustl.edu.

*A complete list of investigators in the ATTRACT trial is provided in the Supplementary Appendix, available at NEJM.org.

This article was updated on December 7, 2017, at NEJM.org.

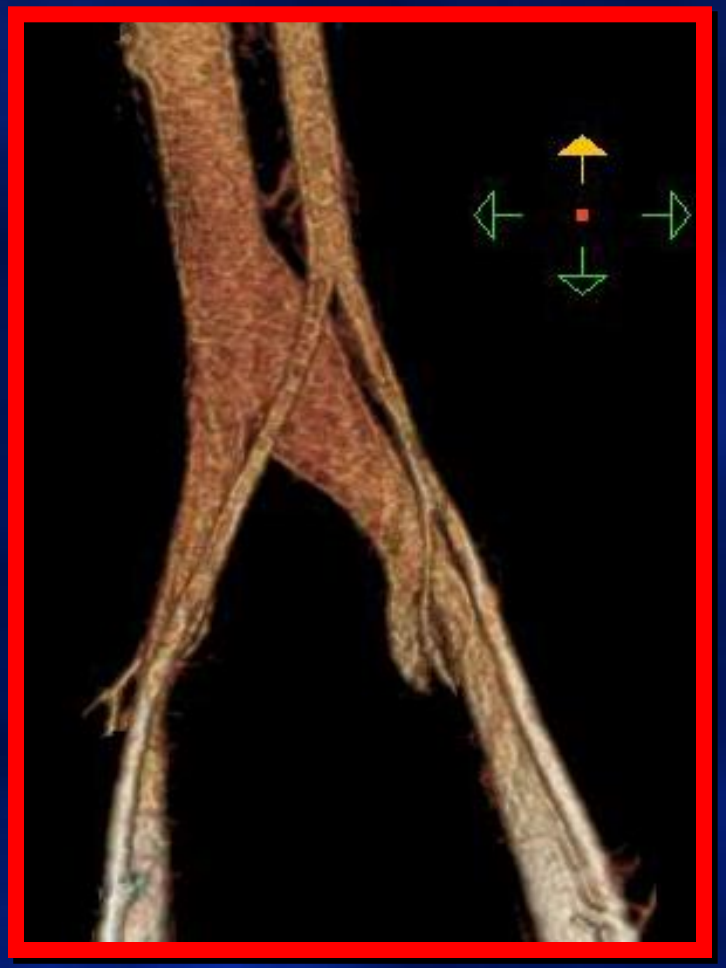
N Engl J Med 2017;377:2240-52.
DOI: 10.1056/NEJMoa1615066

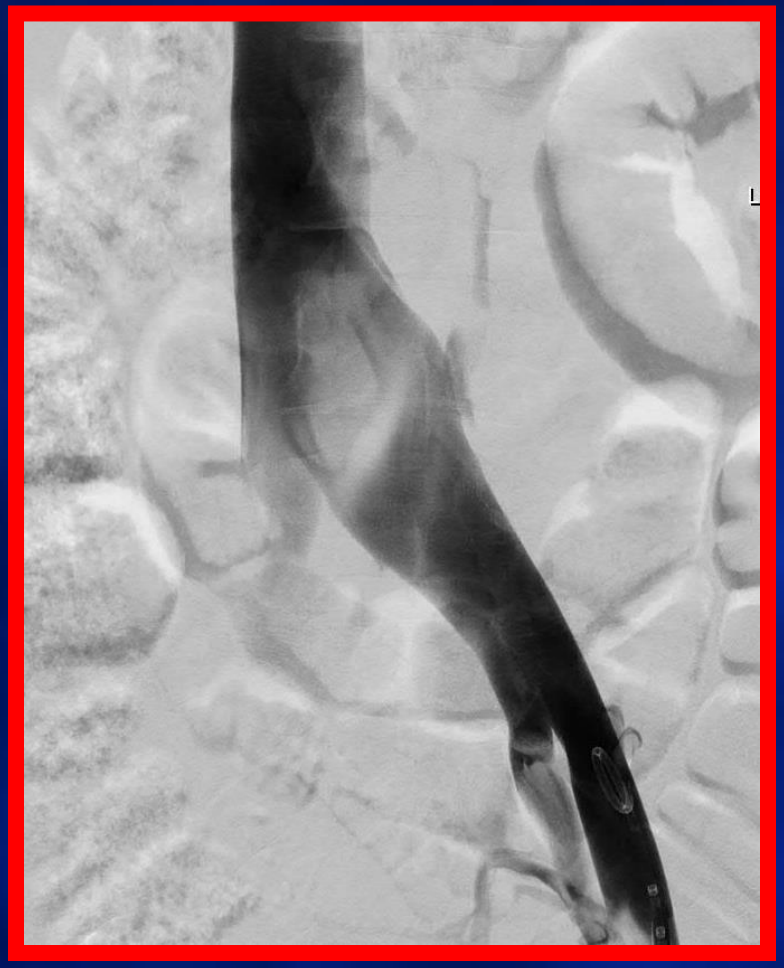
Who may benefit from Catheter Directed Thrombolysis

1. Ilio-femoral DVT
2. patients with more severe symptoms
3. Patients <70 years of age
4. Low risk of bleeding

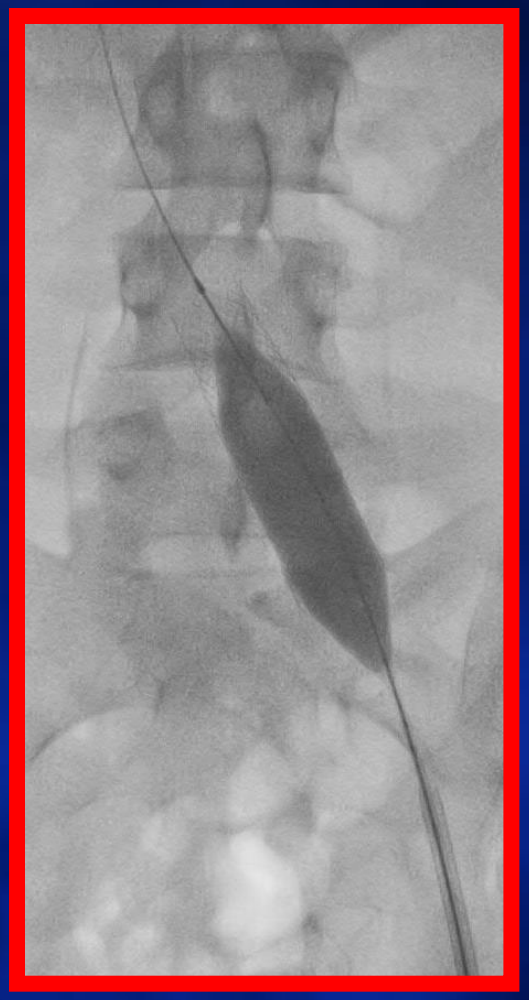
GUIDELINES FOR CHRONIC VENOUS DISEASE

Non-thrombotic obstruction of the iliac veins





Balloon Angioplasty and Stenting of Left Common Iliac Vein



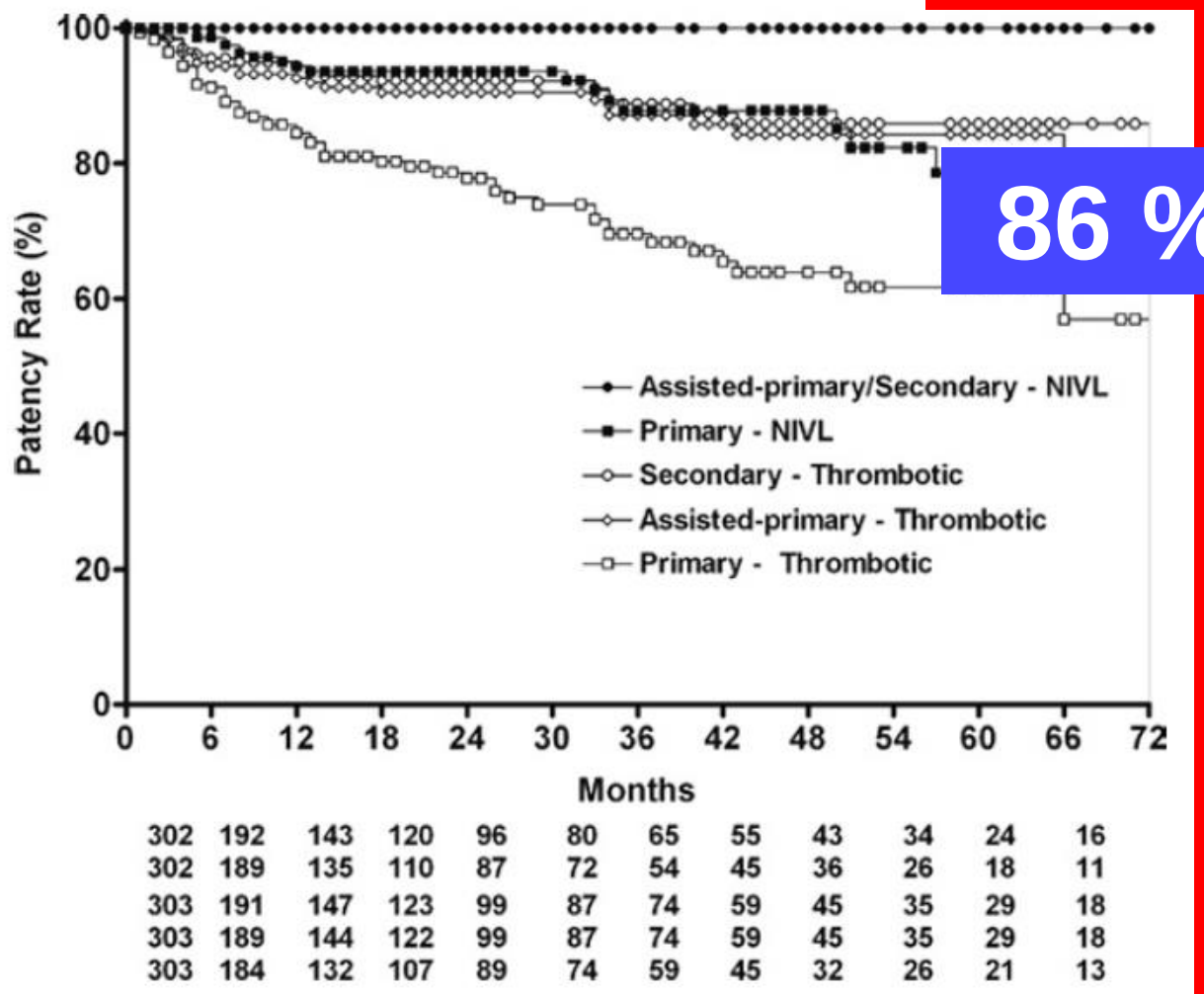
Stenting of the venous outflow in chronic venous disease: Long-term stent-related outcome, clinical, and hemodynamic result

Peter Neglén, MD, PhD,[a] Kathryn C. Hollis, BA,[a] Jake Olivier, PhD,[b] and Seshadri Raju, MD,[b]
Jackson, Miss

Background: Stenting of chronic nonmalignar
sets are now available to perform long-term ar
intervention.
Materials: From 1997 to 2005, 982 chronic
under intravascular ultrasound guidance. Me
2.6:1, and left/right limb symptoms, 2.4:1. C
primary/secondary etiology was 518:464.
recurrent stenosis), clinical outcome, quality o
Questionnaire (CIVIQ), and hemodynamics
Result: Monitoring for 94% of patients lasted
no mortality (<30 days) and low morbidity.
days) and during later follow-up (3%). At 72
were 79%, 100%, and 100% in nonthrombo
Cumulative rate of severe in-stent restenosis (
in nonthrombotic limbs). The main risk fa
thrombotic disease; thrombophilia by itself w
significantly poststent. Severe leg pain (visual
present to 11% and 18% poststent, respectiv
62% and 32%, respectively, and ulcer healing
categories. Mean hand-foot pressure differen
limbs with no concomitant reflux. The hemo
superficial reflux in subsets of patients with a
Conclusions: Venous stenting can be performe
rate of in-stent restenosis. It resulted in maj
consistently reflected in any substantial he
clinical outcome occurred regardless of pres
obstruction. (J Vasc Surg 2007;46:979-90.)

100 %

86 %



Safety and Effectiveness of Stent Placement for Iliofemoral Venous Outflow Obstruction

Systematic Review and Meta-Analysis

Mahmood K. Razavi, MD; Michael R. Jaff, DO; Larry E. Miller, PhD

Background—E[illegible] recanalization of iliofemoral stenosis or occlusion with angioplasty and stent placement has been increasingly used[illegible]ng-term venous patency in patients with iliofemoral venous outflow obstruction. The purpose of this systematic re[illegible]lysis was to determine safety and effectiveness of venous stent placement in patients with iliofemoral venous [illegible]

Methods and Results—We s[illegible] placement in patients [illegible] nonthrombotic, acute th[illegible] complications, sympto[illegible] reporting 45 treatmen[illegible] patients (nonthrombot[illegible] success rates were con[illegible] among groups for maj[illegible] mortality, and from 1.[illegible] year, primary and seco[illegible] and 94% for chronic p[illegible]

Conclusions—Stent plac[illegible] complication rates re[illegible]

CIRCINTERVENTI[illegible]

37 studies, 2869 patients

(non-thrombotic, 1122; acute thrombotic, 629; and chronic post-thrombotic, 1118)

- **Periprocedural mortality: 0.1% - 0.7%**
- **Early thrombosis: 1.0% to 6.8%**
- **Major bleeding: 0.3% - 1.1%**
- **Primary patencies: 79-96% at 1 year**

Eur J Vasc Endovasc Surg (2016) 51, 100–120

REVIEW

Editor's Choice — A Systematic Review of Endovenous Stenting in Chronic Venous Disease Secondary to Iliac Vein Obstruction

M.J. Seager, A. Busuttil, B. Dharmarajah, A.H. Davies *

Department of Surgery and Cancer, Imperial College London, Charing Cross Hospital, London, UK

WHAT THIS PAPER ADDS

This review demonstrates that quality of evid
chronic venous disease is weak. However
that it should be considered as an acce
vascular teams are aware of this, and

Objectives: Deep endovenous stenting
non-thrombotic iliac vein obstruction is
reported systematic reviews on the top
analysis of the available data, reported
Analyses guideline.
Methods: MEDLINE, EMBASE, and the
references were searched.
Results: Sixteen studies were included
case series)
thrombotic limb
were significant imp
of life. Persistent ulcer he
management. Primary and s
major complication rate ranged
of the evidence for five outcomes t
Conclusions: The quality of evidence t
currently weak. The treatment does how
a treatment option while the evidence b

Article history: Received 7 June 2015, Accepted 2 September 2015, Available online 14 October 2015
Keywords: Venous insufficiency, Iliac vein compression syndrome, Post-thrombotic syndrome, Stents, Angioplasty, Systematic review

- **Evidence from 16 studies to support the use of stenting venous obstructions is weak**
- **Stenting is safe, promising and should be considered acceptable treatment for proximal venous obstruction**

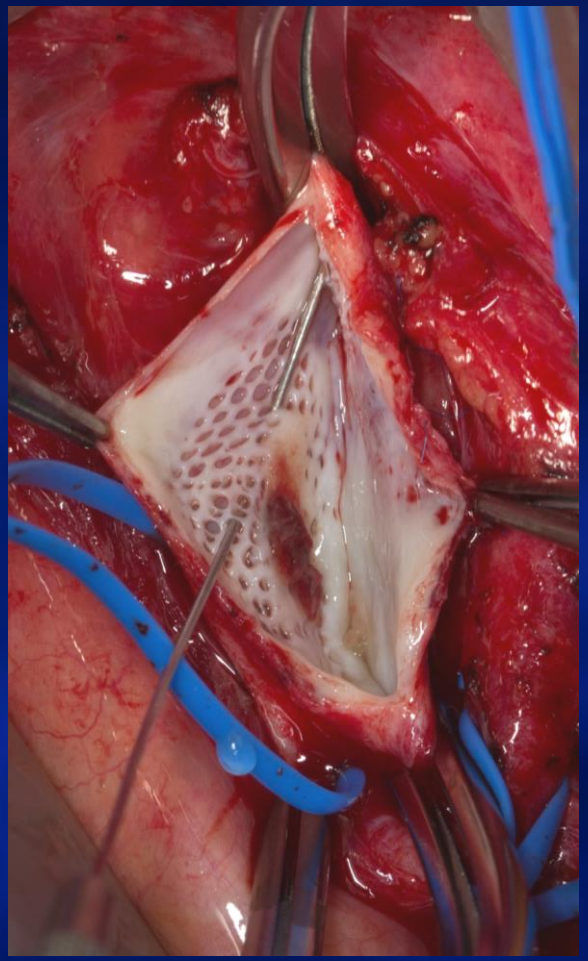
Guidelines of the American Venous Forum on Endovascular Reconstruction for Iliac Vein Obstruction

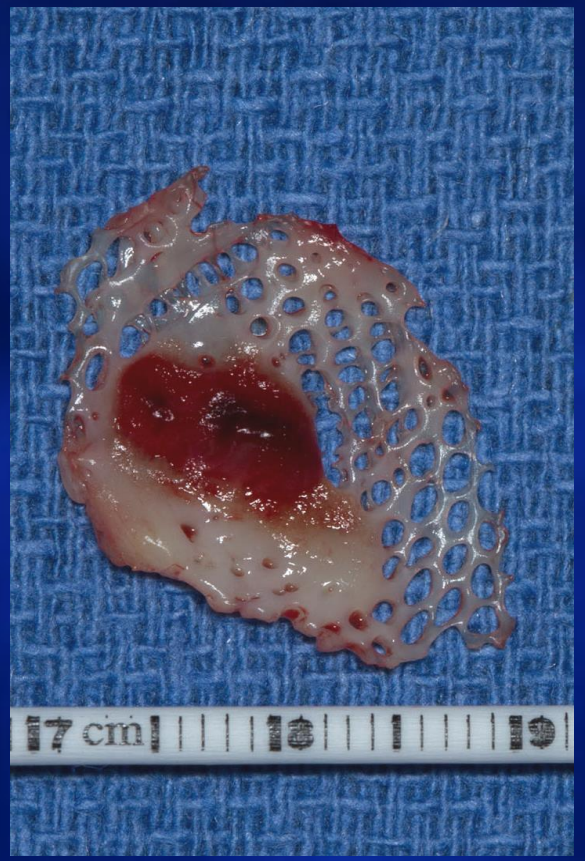
Guideline No.		*GRADE of recommendation*	*Level of evidence*
4.17.1 4.18.1	We recommend endovenous stenting as the current "method-of-choice, " for treatment of symptomatic primary and post-thrombotic iliac vein obstruction	1	B

Challenges for iliofemoral stenting

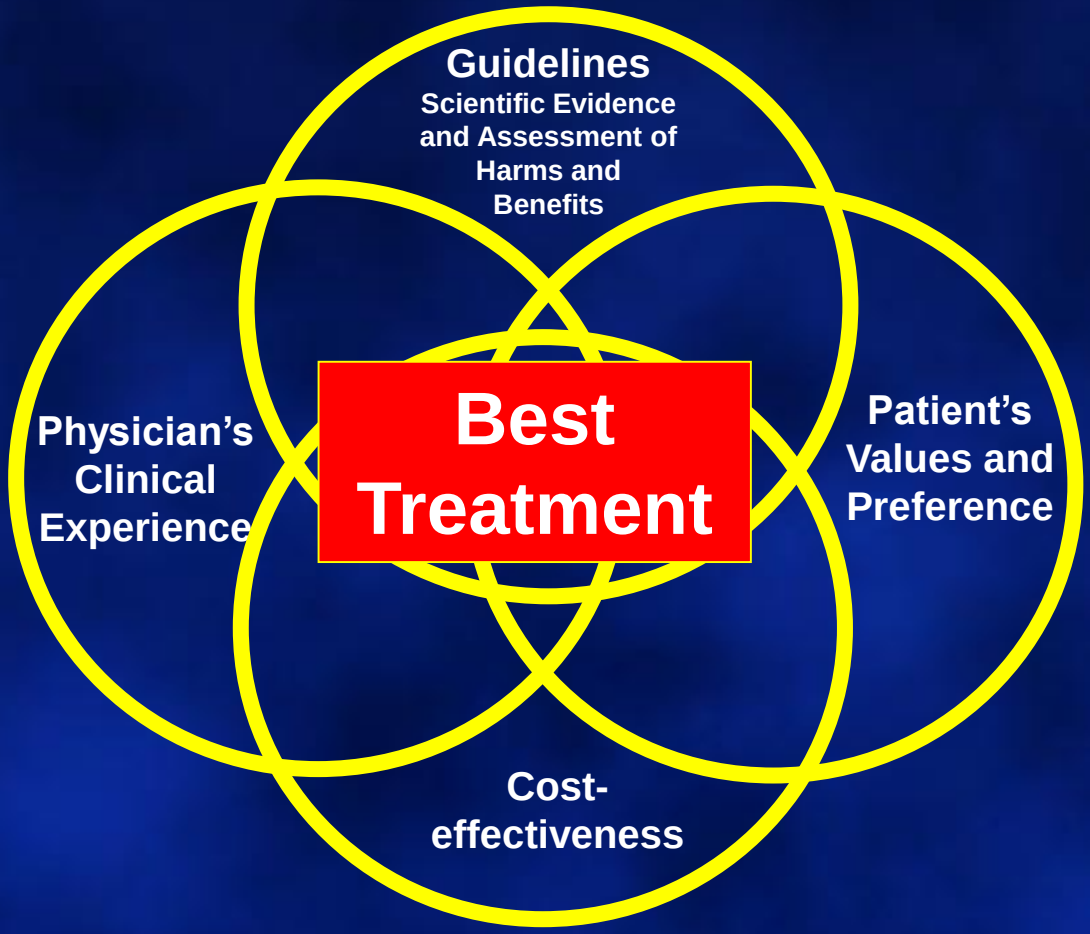
- Poor inflow – poor result (consider femoral endophlebectomy)
- Size with IVUS, avoid undersizing or excessive oversizing of stents

Avoid covering the contralateral iliac vein!

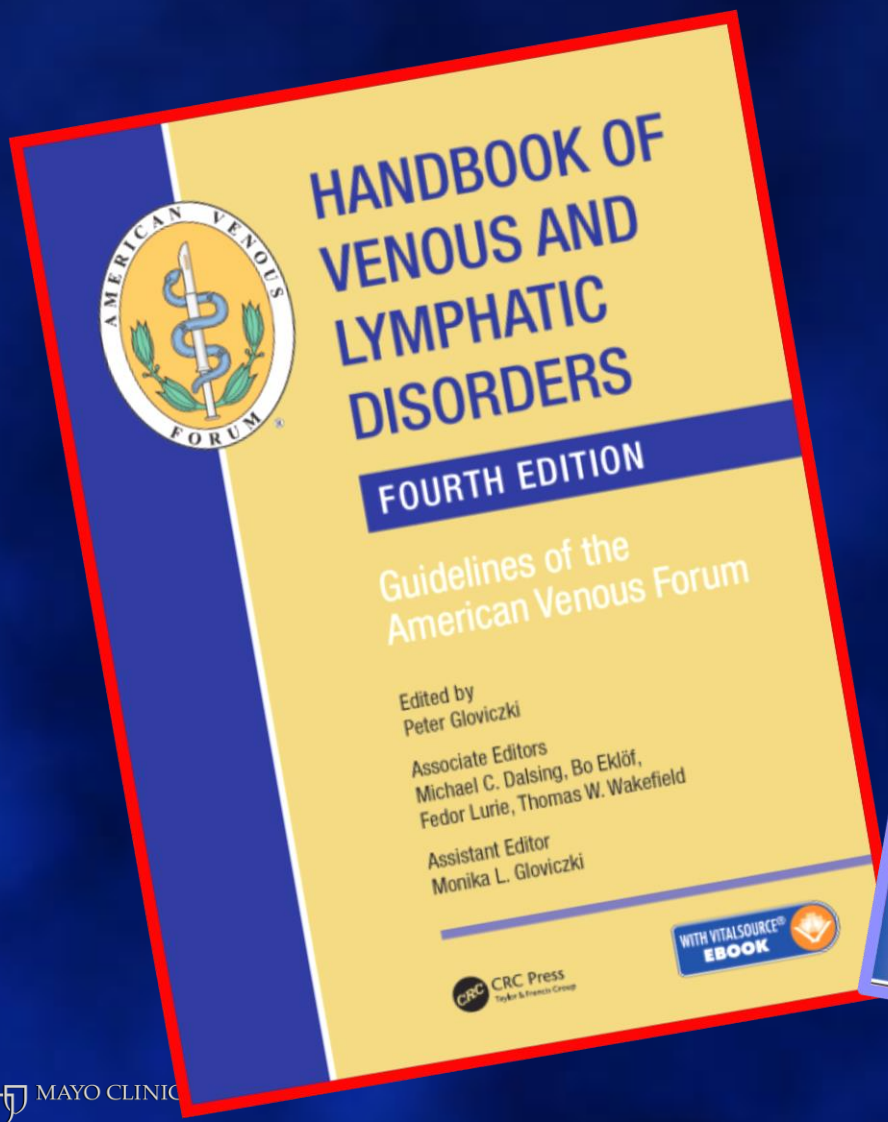


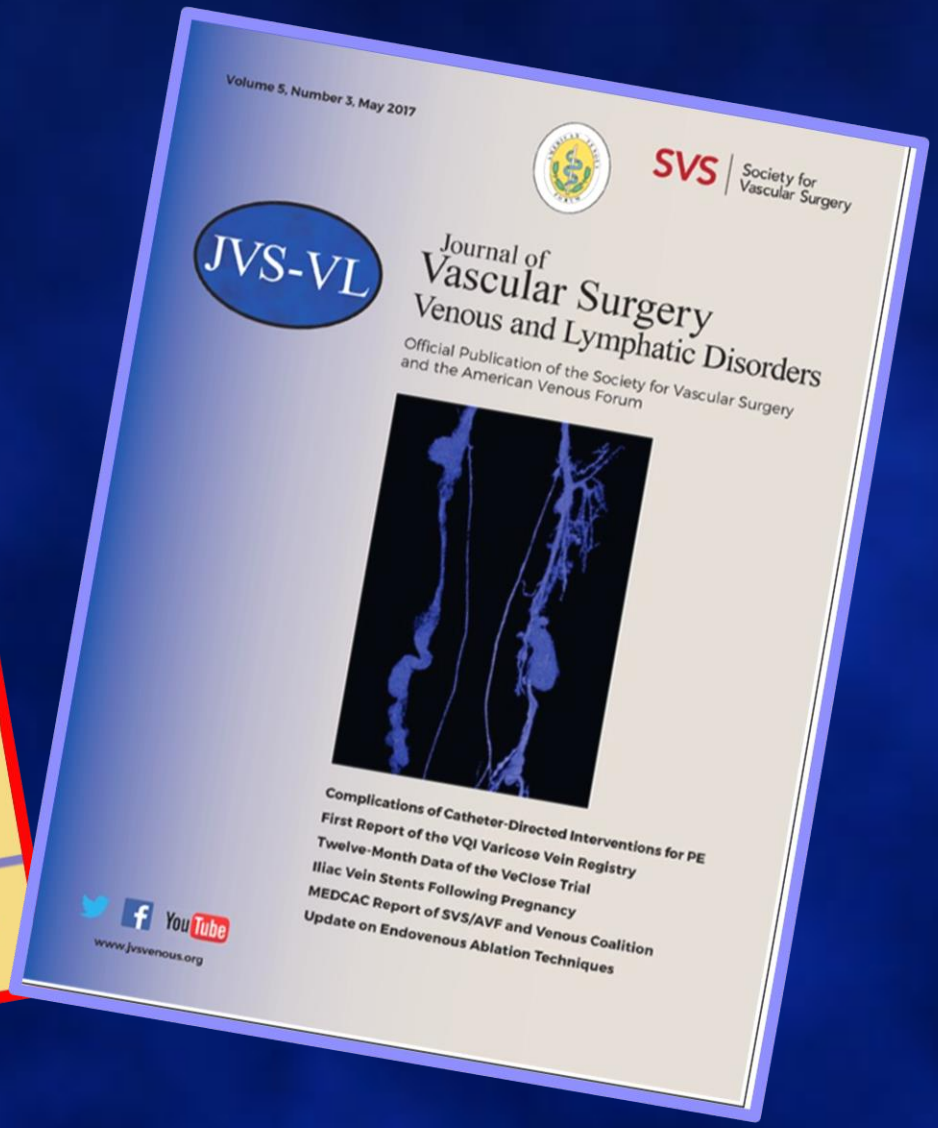


SCIENTIFIC EVIDENCE FOR BEST TREATMENT?



Thank You!


AMERICAN VENOUS FORUM
HANDBOOK OF VENOUS AND LYMPHATIC DISORDERS
FOURTH EDITION
Guidelines of the American Venous Forum
Edited by
Peter Gloviczki
Associate Editors
Michael C. Dalsing, Bo Eklöf,
Fedor Lurie, Thomas W. Wakefield
Assistant Editor
Monika L. Gloviczki
WITH VITALSOURCE® EBOOK
CRC Press


Volume 5, Number 3, May 2017
SVS Society for Vascular Surgery
JVS-VL
Journal of Vascular Surgery
Venous and Lymphatic Disorders
Official Publication of the Society for Vascular Surgery and the American Venous Forum
Complications of Catheter-Directed Interventions for PE
First Report of the VQI Varicose Vein Registry
Twelve-Month Data of the VeClose Trial
Iliac Vein Stents Following Pregnancy
MEDCAC Report of SVS/AVF and Venous Coalition
Update on Endovenous Ablation Techniques
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