

Antithrombotic therapy following stent reconstruction for PTS

Real world practice and the planned ARIVA trial

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Disclosure

Speaker name: Tim Sebastian

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Real World Practise

Case Scenario

- 40 y male
- 2 DVTs in last 10 years
- Now left venous leg ulcer (PTS)
- Dx: Left iliac vein obstruction
- Undergoes venous stent recanalization

Antithrombotic therapy?

Current Practise

Eur J Vasc Endovasc Surg (2018) 55, 537–544

Antithrombotic Therapy Following...
Con...
VKA or DOAC?
Life-long therapy OR time limited therapy?
Include antiplatelets?

London, UK
London Postgraduate School of Surgery and Imperial College London, London, UK
Imperial College Healthcare NHS Trust and Imperial College London, London, UK

32%: VKA (life-long)
25%: VKA (limited duration)

19%: DOAC (life-long)
15%: DOAC (limited duration)

9%: Others:

45%: Antiplatelet therapy

25%: After AC was stopped
13%: In combination with AC
7%: Single use without AC

[Chest](#). 2016 Feb;149(2):315-352. doi: 10.1016/j.chest.2015.11.026. Epub 2016 Jan 7.

Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report.

[Kearon C](#)¹, [Akl EA](#)², [Ornelas J](#)³, [Blaivas A](#)⁴, [Jimenez D](#)⁵, [Bounameaux H](#)⁶, [Huisman M](#)⁷, [King CS](#)⁸, [Morris TA](#)⁹, [Sood N](#)¹⁰, [Stevens SM](#)¹¹, [Vintch JRE](#)¹², [Wells P](#)¹³, [Woller SC](#)¹¹, [Moore L](#)¹⁴.

+ Author information

Erratum in

Correction to Grade in: Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. [Chest. 2016]

No recommendation on antithrombotic therapy for patients with venous stent implants available

The Postthrombotic Syndrome: Evidence-Based Prevention, Diagnosis, and Treatment Strategies A Scientific Statement From the American Heart Association

Susan R. Kahn, MD, MSc, FRCPC, Chair; Anthony J. Comerota, MD;
Mary Cushman, MD, MSc, FAHA; Natalie S. Evans, MD, MS; Jeffrey S. Ginsberg, MD, FRCPC;
Neil A. Goldenberg, MD, PhD; Deepak K. Gupta, MD; Paolo Prandoni, MD, PhD;
Suresh Vedantham, MD; M. Eileen Walsh, PhD, APN, RN-BC, FAHA; Jeffrey I. Weitz MD, FAHA;
on behalf of the American Heart Association Council on Peripheral Vascular Disease, Council on
Clinical Cardiology, and Council on Cardiovascular and Stroke Nursing

Consider use of balloon angioplasty and stent for selected patients, but no recommendation on antithrombotic management

Practise guidelines

CIRSE STANDARDS OF PRACTICE GUIDELINES

CIRSE Standards of Practice Guidelines on Iliocaval Stenting

Andreas H. Mahnken · Ken Thomson ·
Michiel de Haan · Gerard J. O'Sullivan

“**Continuous** anticoagulation with **warfarin** ... is strongly recommended, although there is **no evidence** from controlled studies on this issue.”

“The relative importance of antiplatelet agents versus anticoagulants has **never been evaluated** in clinical trials.”

Swiss Venous Stent Registry

Subgroup of 121 patients treated for postthrombotic syndrome

- 35 (29%) with IVC stents
- 119 (98%) with iliac stents
- 86 (71%) stent below the inguinal ligament
- 36 (30%) bilateral interventions

Mean follow-up 796 days

Continued vs. discontinued anticoagulation therapy?

VKA vs. DOACs?

Swiss Venous Stent Registry

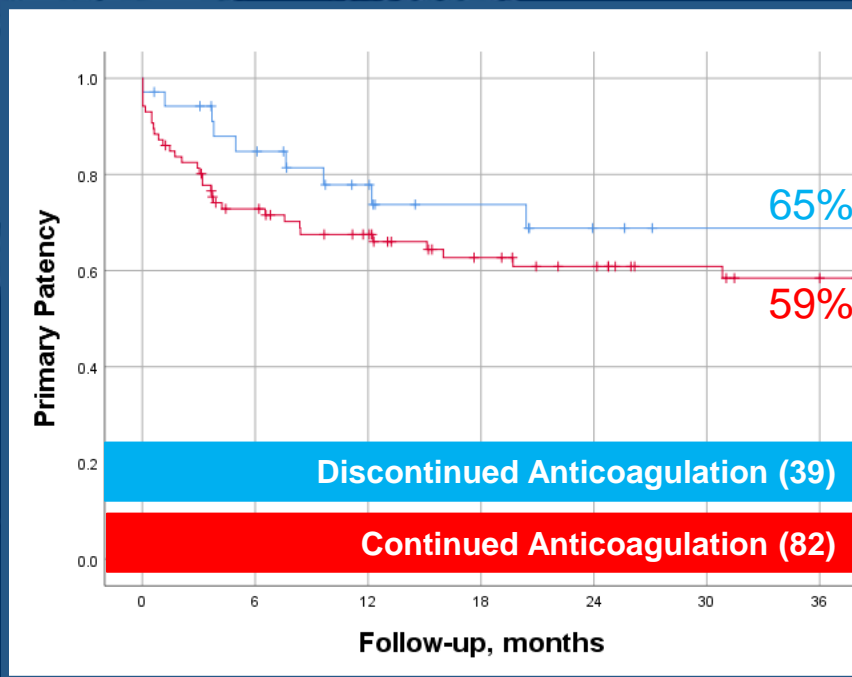
Baseline	Continued AC (82)	Discontinued (39)
Age	46 years	39 years
Women	29 (35%)	29 (74%)
Recurrent VTE	34 (42%)	8 (21%)
Obesity	34 (42%)	3 (8%)
May Thurner Anatomy	19 (23%)	24 (62%)

Swiss Venous Stent Registry

Antithrombotic therapy	Continued AC (82)	Discontinued (39)
Vitamin K	23 (28%)	7 (18%)
DOAC	46 (56%)	30 (77%)
Switch (VKA, DOAC)	11 (13%)	0
Enoxaparin	2 (2%)	2 (5%)
Initial therapy with antiplatelet agent	15 (18%)	5 (13%)
Mean duration of therapy, days	723 days	393 days

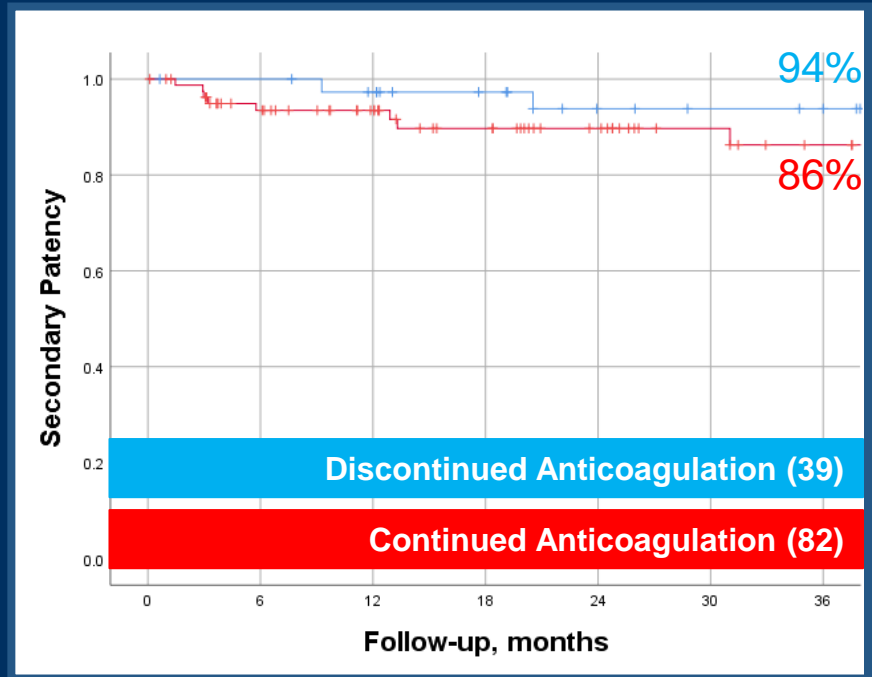
Discontinued vs. continued AC

Primary Patency Rate



Long Rank (Mantel-Cox): $p = 0.61$

Secondary Patency Rate



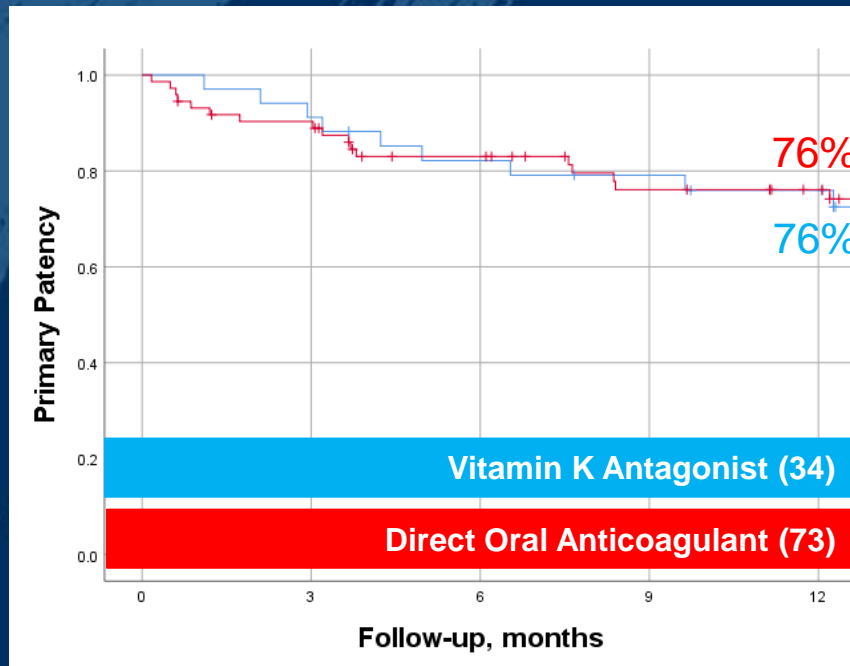
Long Rank (Mantel-Cox): $p = 0.26$

VTE EVENTS in DISCONTINUED GROUP

- 3 patients stent thrombosis before cessation
- 5 patients with stent thrombosis after cessation
- 1 patients with PE, 1 patients with contralateral DVT after cessation

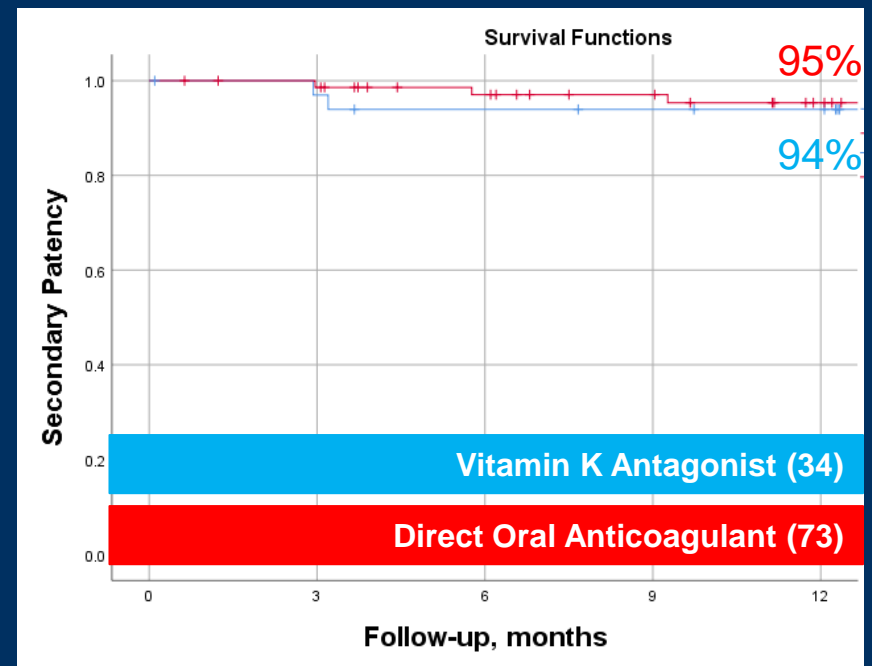
Vitamin K antagonist vs. DOAC

Primary Patency Rate



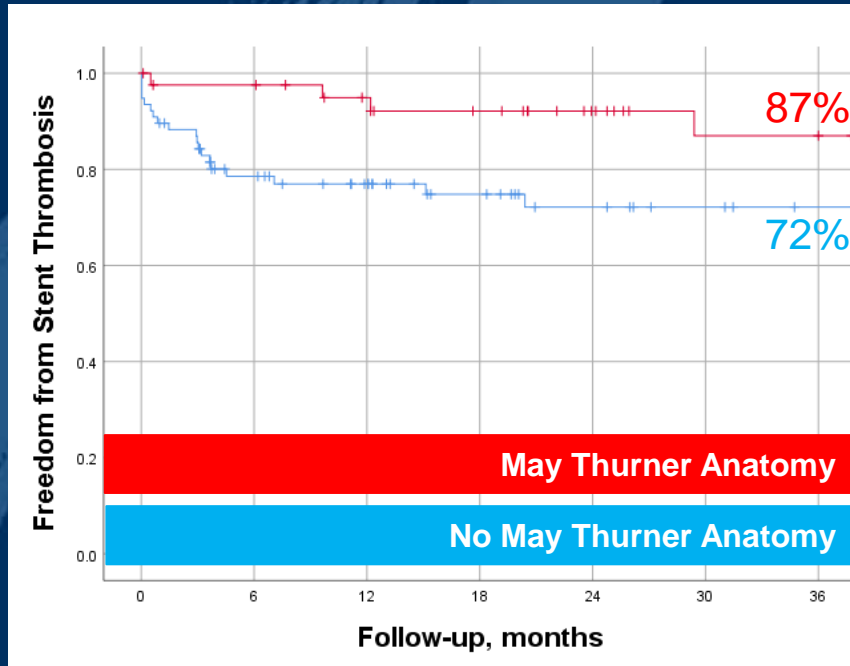
Long Rank (Mantel-Cox): $p = 0.57$

Secondary Patency Rate



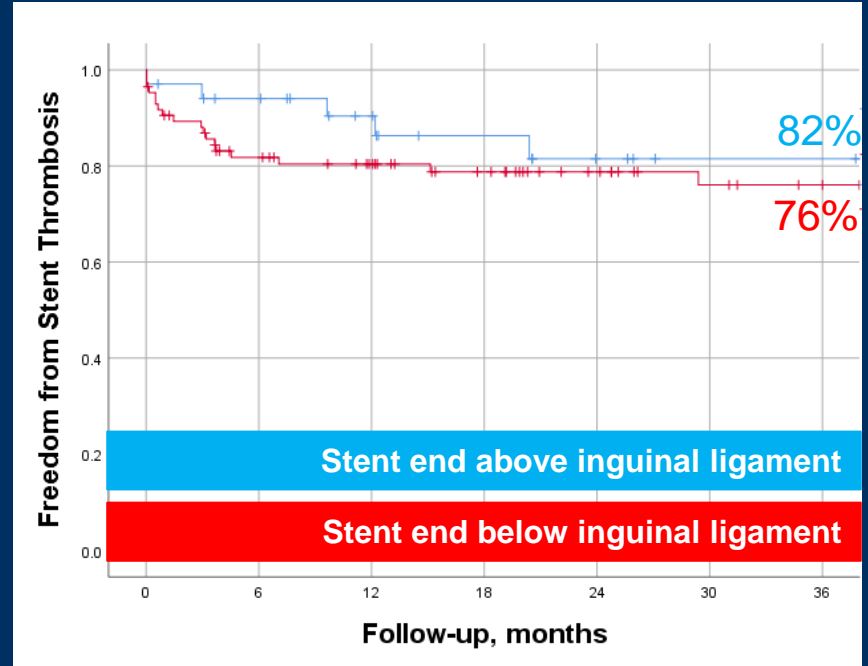
Long Rank (Mantel-Cox): $p = 0.95$

May Thurner Anatomy



Long Rank (Mantel-Cox): $p = 0.03$

Stenting below Inguinal Lig.



Long Rank (Mantel-Cox): $p = 0.77$

PERMANENT STENT FAILURE

- 5/10 patients with stents below CVF

Benefit of Additional Antiplatelet Agents?

Cardiovasc Intervent Radiol (2018) 41:1691–1698
<https://doi.org/10.1007/s00270-018-2062-5>



CLINICAL INVESTIGATION

VENOUS INTERVENTIONS

Antiplatelet Therapy is Associated with Stent Patency After Iliocaval Venous Stenting

Masayuki Endo¹ · Younes Jahangiri¹ · Masahiro Horikawa¹ · John A. Kaufman¹ ·
Ryan C. Schenning¹ · Kenneth J. Kolbeck¹ · Robert E. Barton¹ · Yasufumi Ohuchi² ·
Keng Wei Liang¹ · Khashayar Farsad¹

Retrospective, 62 patients with iliocaval stent procedures, 38P treated with antiplatelet agents. **Antiplatelet medication predicted a significant decreased risk of stent malfunction (HR 0.23, p=0.007)**

Use of AP in VTE disease no stents

WARFASA: 403 patients

- Pat. with first unprovoked DVT and completed anticoagulation therapy
- Randomized to aspirin or placebo

ASPIRE: 822 patients

Recurrence rate per year

6.6% **aspirin** vs 11.2% **placebo**

HR 0.58 (95% CI: 0.36-0.93)

p = 0.02

4.8% **aspirin** vs 6.5% **placebo**

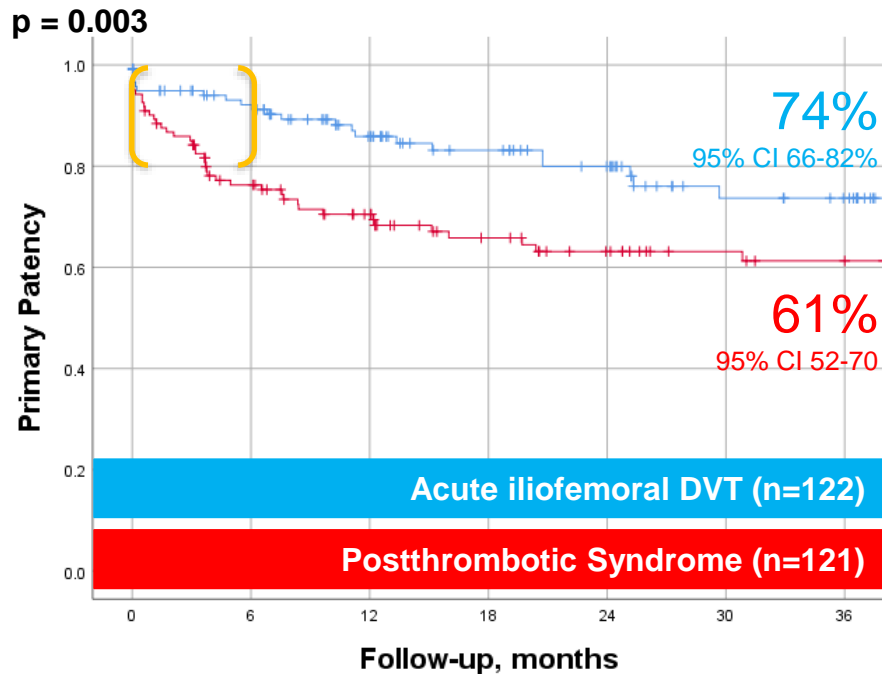
HR 0.74 (95% CI: 0.52-1.05)

p = 0.09

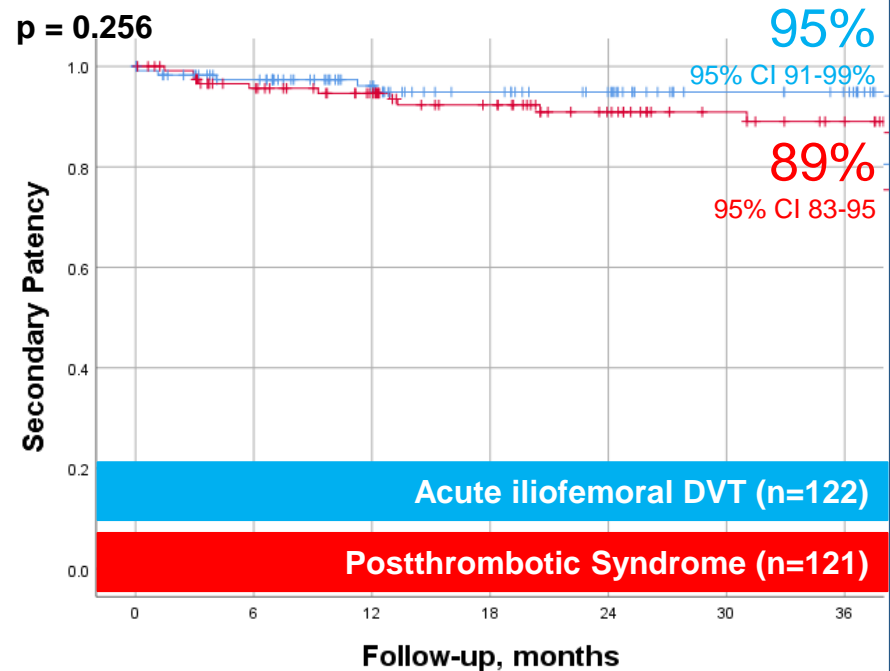
Swiss Venous Stent Registry

Patients with venous stent implants

Primary Patency Rate



Secondary Patency Rate



Need for more aggressive treatment in PTS patients in the early phase?

Is there a place for antiplatelet therapy in addition to oral anticoagulation?

Aspirin plus rivaroxaban
versus
rivaroxaban alone

**for the prevention of venous stent thrombosis in
patients with post-thrombotic syndrome**

Study design

- Multi-center
- International (Austria, Germany, Switzerland)
- Randomized
- Open-label (aspirin on top of rivaroxaban)
- Controlled (rivaroxaban alone)

Study design

Main inclusion criteria

- › Confirmed diagnosis of PTS (Villalta score > 4 pts)
- › Patients scheduled for stent recanalization IVC, iliac veins, common femoral vein
- › Patients either on active treatment with rivaroxaban or patients planned for treatment with rivaroxaban after procedure

Main exclusion criteria

- › Previous procedures in target vessel
- › Ongoing antiplatelet therapy, or antiplatelet therapy within the previous 7 d
- › Acute thrombosis (< 3 mo prior to procedure)
- › Pre-existing coagulopathy
- › Malignant growth (relapse free >5 y)

Study design

Primary Endpoint

- › Primary patency rate after 6 mo

Main Secondary Endpoint

- › Assisted primary and secondary patency rate after 6 mo
- › Primary sustained clinical success after 6 mo (def. Villalta < 5 pts and absence of repeated procedures)
- › Difference of limb circumference of affected leg in comparison to contralateral leg at 6 mo CTB
- › CIVIQ-20 (quality of live) at 6 mo CTB
- › Villalta / rVCSS scores at 6 mo CTB
- › Adverse events: stent thrombosis, recurrent VTE any site, stent compression/ fracture, bleeding

Schedule

284 patients planned to be included

First Patient IN: Q2 2019

Last Patient OUT: Q4 2021

Centers in with more than 20 PTS interventions per year **are invited to participate** in this trial

Summary

- Currently, antithrombotic management of PTS patients with stents is experienced-based rather than evidenced-based.
- We see a shift from the use of VKA to DOACs, but no evidence on efficacy available.
- It might be safe to withdraw selected patients from anticoagulation therapy. Those need to be followed-up to detect late events.
- The ARIVA trials might be able to provide insight whether anticoagulation therapy combined with aspirin is beneficial to prevent early stent failure.

Thank you for your attention!



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