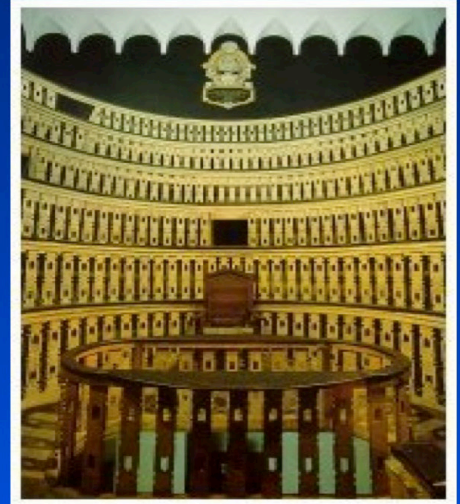


Paolo Prandoni Università di Padova

Razionale dello studio
APIDULCIS

Bologna, 01-02-2017



**Teatro Anatomico
Università di Padova**

Prandoni P, Noventa F, Ghirarduzzi A, Pengo V, Bernardi E, Pesavento R, Iotti M, Tormene D, Simioni P, Pagnan A

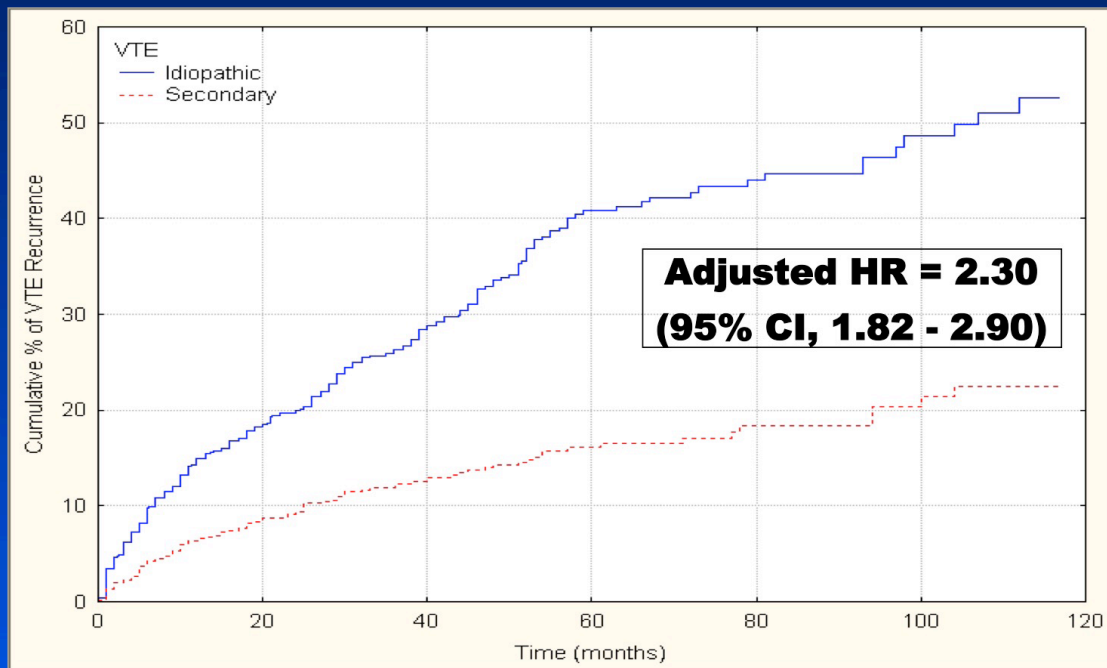
**The risk of recurrent VTE after discontinuing
anticoagulation in patients with acute proximal
DVT or PE**

Haematologica 2007; 91: 199-205

2° CONVEGNO DI ANTICOAGULAZIONE.it

scienza e pratica clinica per il management dei pazienti anticoagulati • AGGIORNAMENTI 2017
BOLOGNA, 1-2 FEBBRAIO 2017

The clinical course of 1626 patients with DVT and/or PE



Prandoni, Hematologica 2007

BMJ

2011, online first

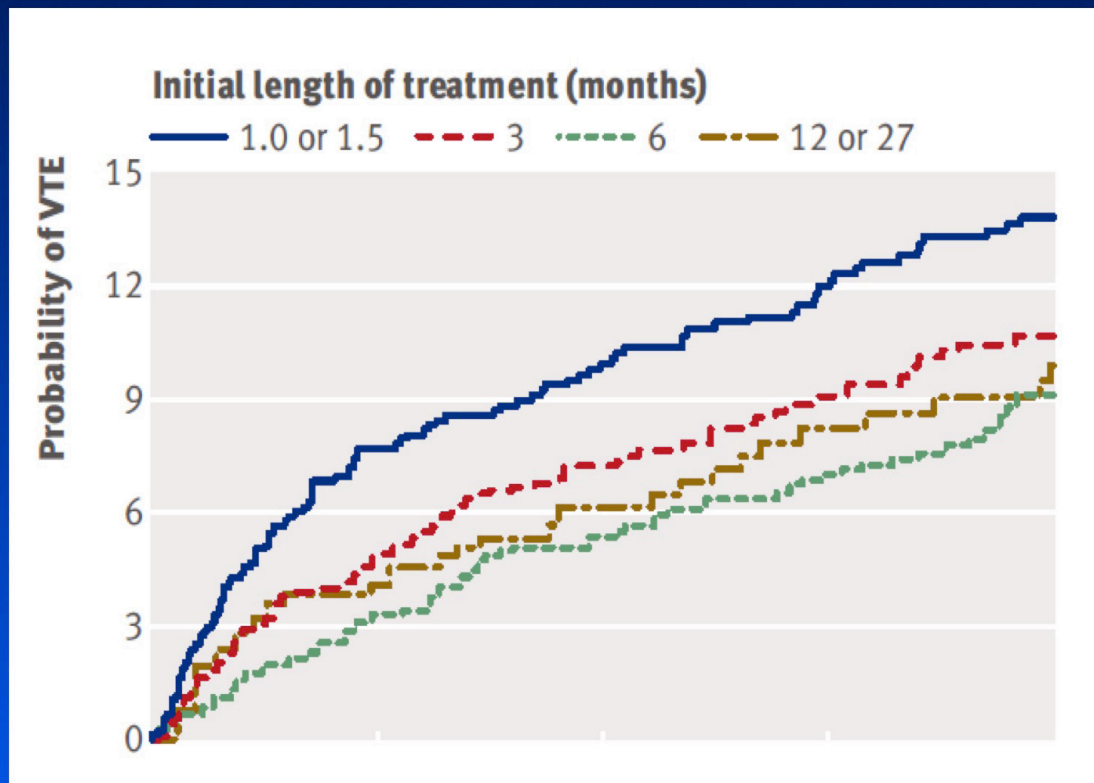
RESEARCH

Influence of preceding length of anticoagulant treatment and initial presentation of venous thromboembolism on risk of recurrence after stopping treatment: analysis of individual participants' data from seven trials

Florent Bouitrie, statistical investigator,¹ Laurent Pinede, investigator,² Sam Schulman, professor,^{3,4} Giancarlo Agnelli, professor,⁵ Gary Raskob, professor,⁶ Jim Julian, statistical investigator,⁷ Jack Hirsh, professor emeritus,⁴ Clive Kearon, professor⁴

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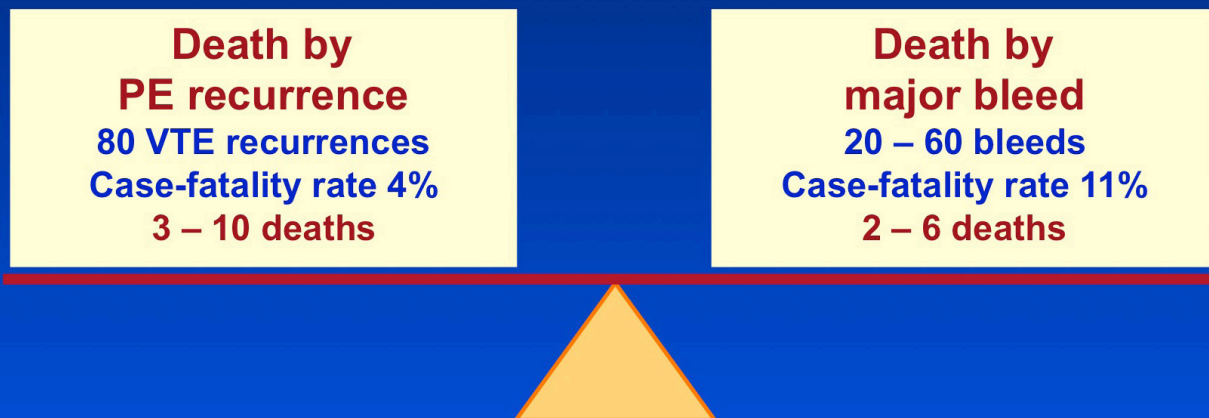


Optimal duration of OAT in patients with idiopathic VTE: 2016 ACCP guidelines

- In patients with a first VTE that is an unprovoked proximal DVT of the leg or PE and who have a low or moderate bleeding risk, we **suggest** extended anticoagulant therapy over 3 months of therapy **(Grade 2B)**

Extension of anticoagulant treatment beyond 3 to 6 months for VTE with the VKA

For 1,000 patient-years



Douketis JD, et al. *Ann Intern Med.* 2007;147:766-774.
Linkins LA, et al. *Ann Intern Med.* 2003;139:893-900.



Finite durations of anticoagulation Extending anticoagulation with VKA

Alternative scenarios?

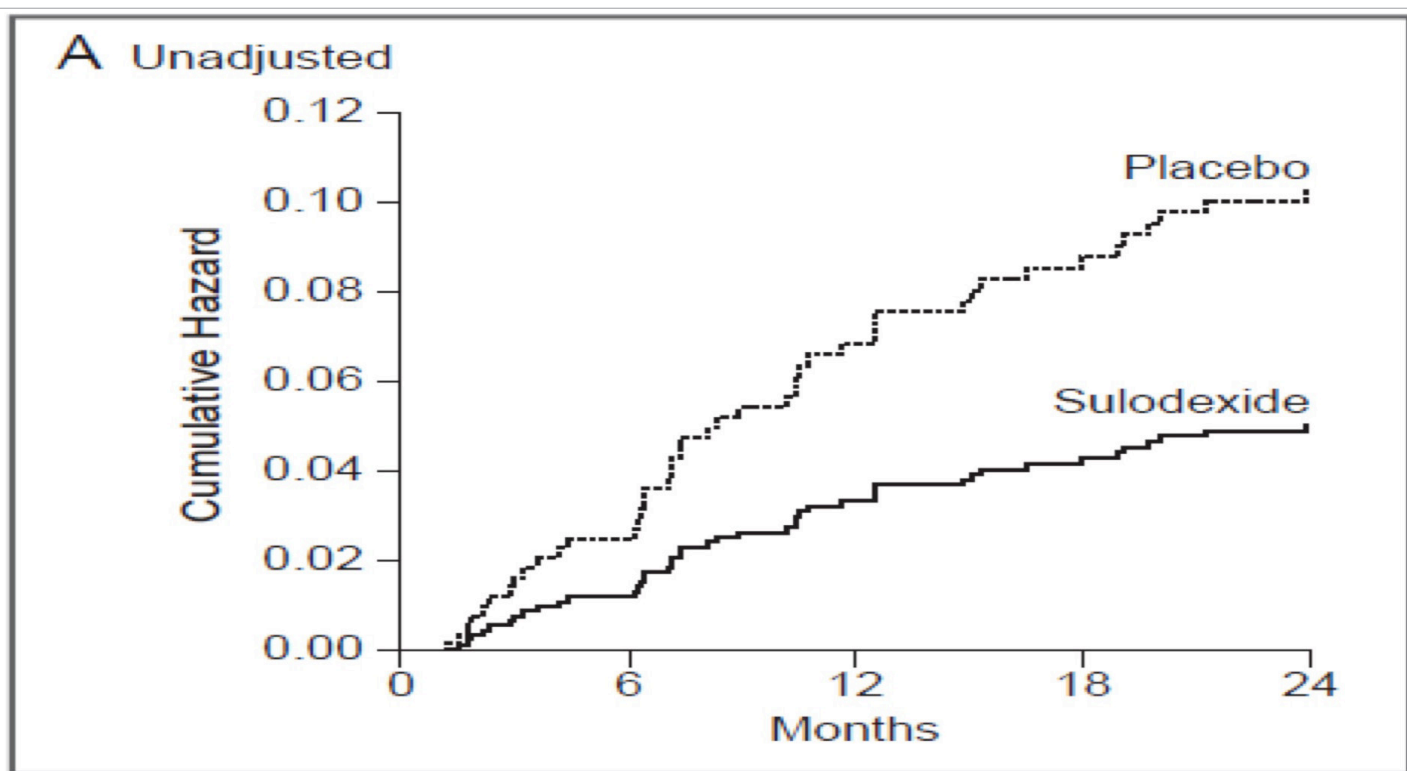
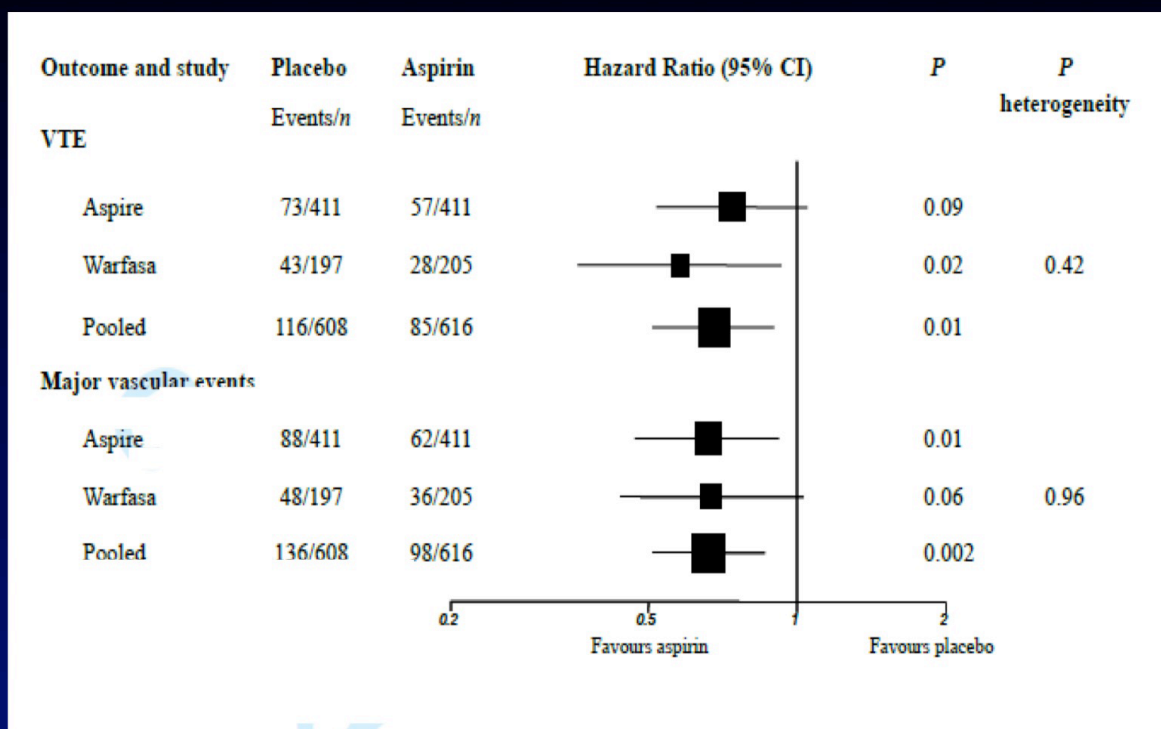
1. Aspirin or sulodexide

2. DOAC

3. Post-baseline parameters (RVT/DD)

Low-dose aspirin/sulodexide

Meta-analysis of the WARFASA and ASPIRE studies



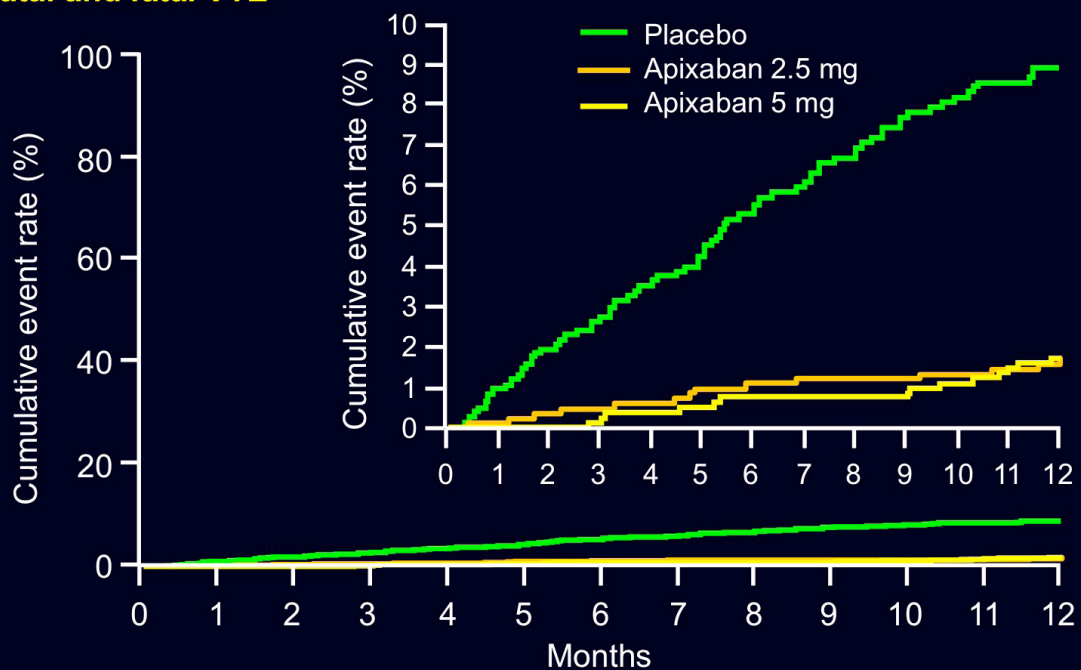
Andreozzi et al, Circulation 2015

2° CONVEGNO DI ANTICOAGULAZIONE.it

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BOLOGNA, 1-2 FEBBRAIO 2017

Amplify Extension

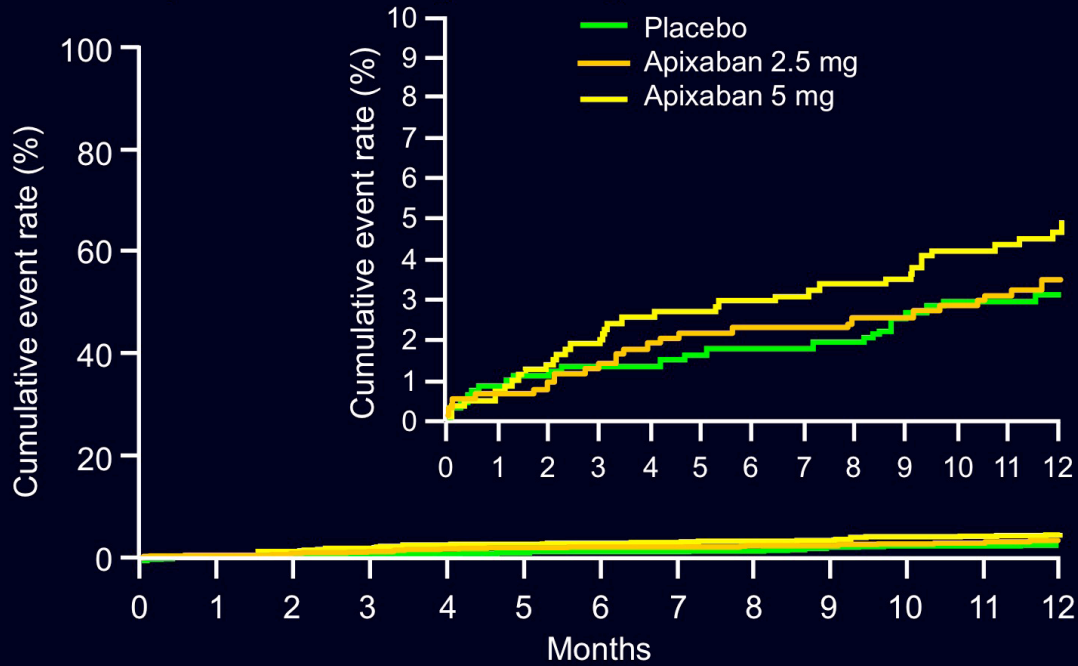
Kaplan–Meier: Non-fatal and fatal VTE



No. at risk	Baseline	Month 3	Month 6	Month 9	Month 12
Apixaban 2.5 mg	840	836	825	818	533
Apixaban 5 mg	813	807	799	791	513
Placebo	826	796	768	743	471

Kaplan–Meier:

Major or Clinically relevant non major bleeding



No. at risk	Baseline	Month 3	Month 6	Month 9	Month 12
Apixaban 2.5 mg	840	786	759	737	354
Apixaban 5 mg	811	751	716	689	331
Placebo	823	749	687	651	298

EINSTEIN CHOICE

Reduced dose rivaroxaban and standard dose rivaroxaban versus aspirin in the long-term prevention of recurrent symptomatic venous thromboembolism in patients with symptomatic deep-vein thrombosis and/or pulmonary embolism

Status 20.12.2016



Post-baseline variables

- **D-Dimer (in the whole spectrum of VTE presentation)**
- **Residual vein thrombosis (in the only patients with proximal DVT with or without concomitant PE)**

Combination of D-dimer and residual vein thrombosis

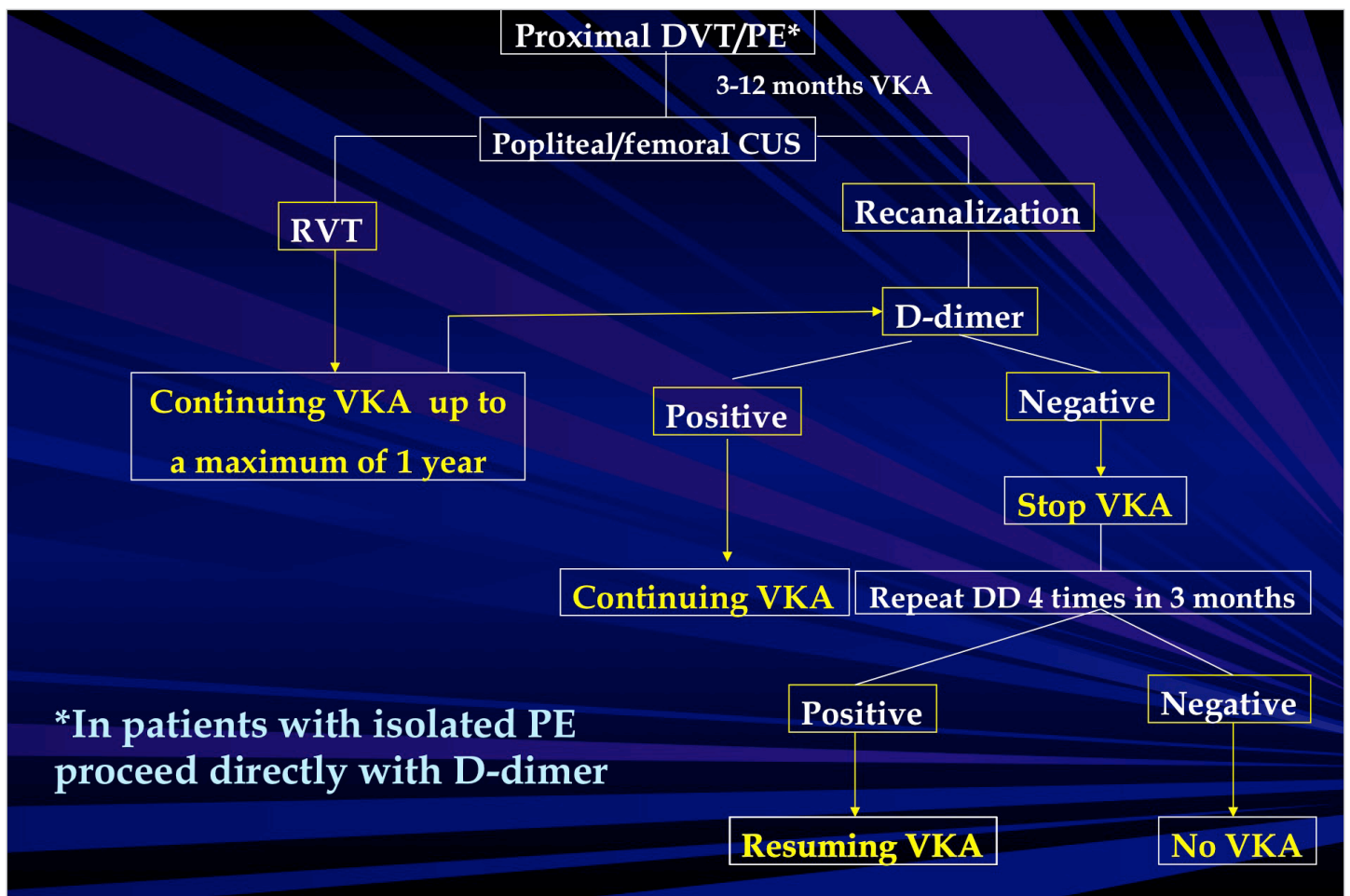
the DULCIS criteria

D-dimer to guide the duration of anticoagulation in patients with venous thromboembolism

A management study

Palareti G, Cosmi B, Legnani C, Antonucci E, Erba N,
Ghirarduzzi A, Poli D, Testa S, Tosetto A, Pengo V,
Prandoni P

Blood 2014



Main Study Results

- Proportion of subjects with persistently negative D-Dimer among eligible patients 51.2%
- Annual incidence of recurrent VTE in this patients' group (mean f-up, 2 years) 3.0%

**Sono maturi i tempi per incorporare i
risultati del Dulcis con quelli
provenienti dagli studi con basse dosi
di NOA**