
How do NOACs hold up in day to day practice? Looking at real life evidence

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LINC January 26th 2016

Disclosures

Speaker Name: Arne Kieback

Potential Conflicts of Interest:

Consulting: Bayer, Bristol-Myers Squibb

BACKGROUND

Rivaroxaban demonstrated to be non-inferior to warfarin in phase III trials

- Prevention of recurrent VTE in DVT patients (EINSTEIN DVT¹)
- Prevention of stroke/systemic embolism in AF patients (ROCKET AF²)

1) The EINSTEIN Investigators, N Engl J Med 2010;363:2499–2510

2) Patel MR et al. N Engl J Med 2011

XALIA – New Real World Evidence in VTE

Rivaroxaban vs Standard Anticoagulation as Therapy
in Deep Vein Thrombosis



Safety and effectiveness of oral rivaroxaban versus standard anticoagulation for the treatment of symptomatic deep-vein thrombosis (XALIA): an international, prospective, non-interventional study



Walter Ageno, Lorenzo G Mantovani, Sylvia Haas, Reinhold Kreutz, Danja Monje, Jonas Schneider, Martin van Eickels, Martin Gebel, Elizabeth Zell, Alexander G G Turpie

Summary

Background The efficacy and safety of the anticoagulant rivaroxaban for the treatment and secondary prevention of deep-vein thrombosis and pulmonary embolism has been shown in phase 3 trials. However, data about rivaroxaban use in routine clinical practice are needed.

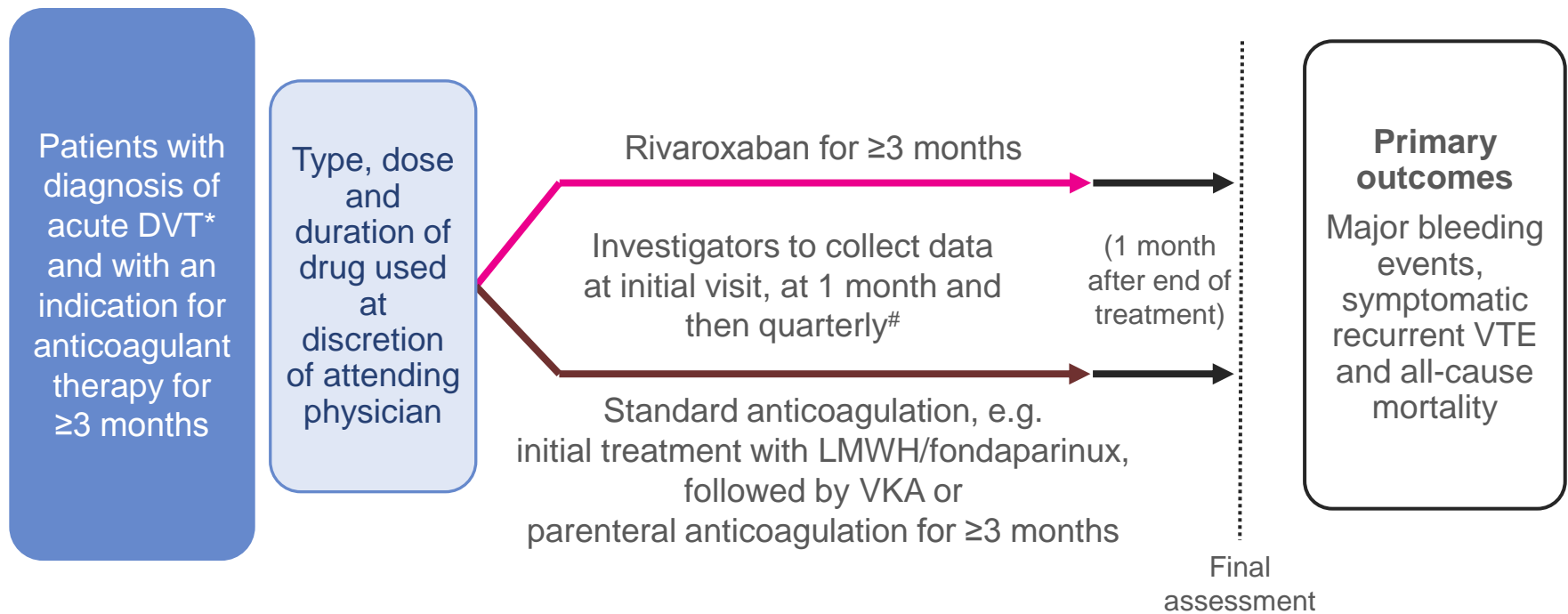
Lancet Haematol 2015

Published Online
December 7, 2015

<http://dx.doi.org/10.1016/>

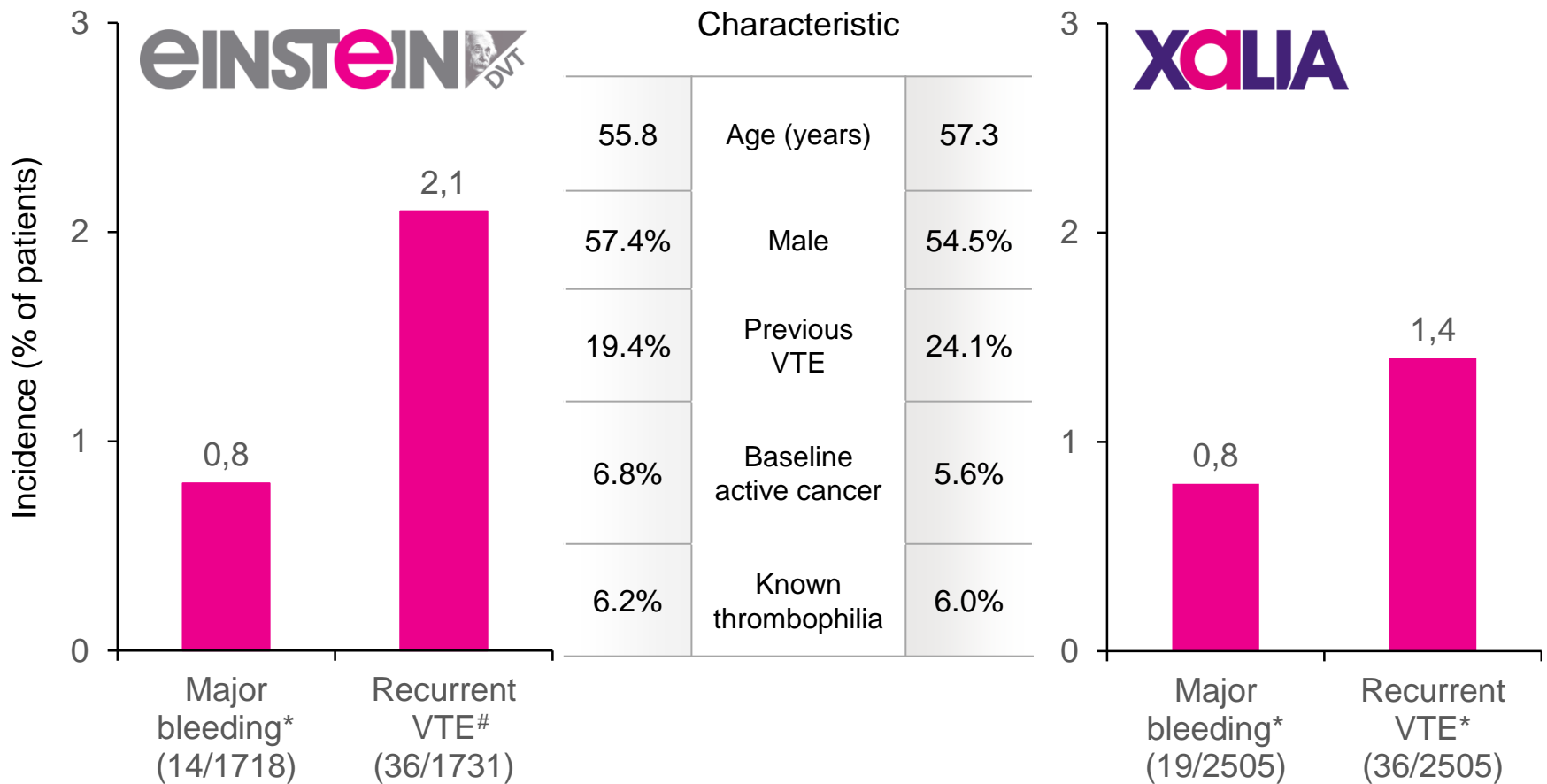
XALIA: A Prospective, Non-interventional Study

Objective: collect real-life data in patients with acute DVT treated with rivaroxaban or standard anticoagulation



ClinicalTrials.gov NCT01619007; *After PE EU licence, DVT with concomitant PE permitted; isolated PE excluded
#Data were collected at the initial visit and during routine follow-up visits or via mail, telephone, or email
Ageno W *et al*, *Thromb J* 2014;12:16

EINSTEIN DVT and XALIA: Rivaroxaban Outcomes



#ITT analysis; *Safety population (patients taking ≥ 1 dose of study drug);

Propensity-score: Carried out to balance covariates across treatment groups and minimize potential bias in the estimate of treatment effects

Real World Evidence for Rivaroxaban in SPAF

XANTUS

L.DE.MA.12.2015.0125

European Heart Journal Advance Access published September 1, 2015



European Heart Journal
doi:10.1093/eurheartj/ehv466

FASTTRACK
ESC Clinical Registry

XANTUS: a real-world, prospective, observational study of patients treated with rivaroxaban for stroke prevention in atrial fibrillation

A. John Camm^{1*}, Pierre Amarencu², Sylvia Haas³, Susanne Hess⁴, Paulus Kirchhof^{5,6}, Silvia Kuhls⁷, Martin van Eickels⁴, and Alexander G.G. Turpie⁸, on behalf of the XANTUS Investigators

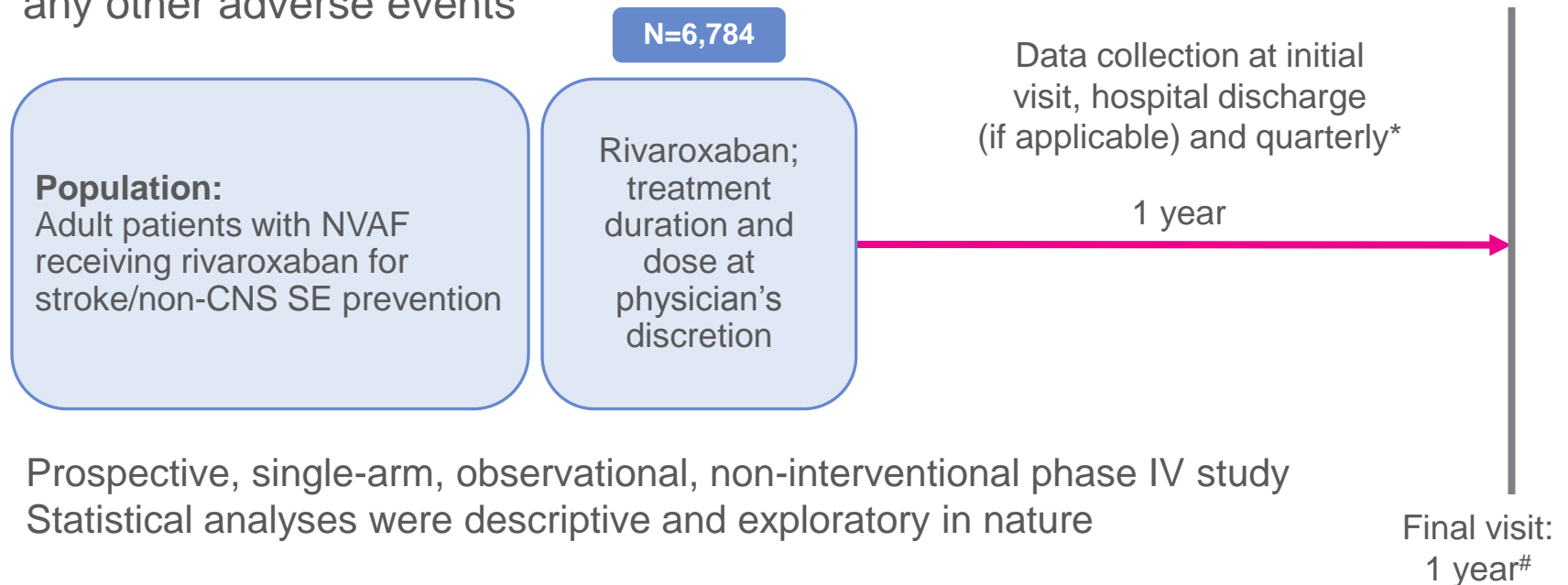
¹Cardiovascular and Cell Sciences Research Institute, St George's, University of London, Cranmer Terrace, SW170RE London, UK; ²Department of Neurology and Stroke Center, Paris-Diderot-Sorbonne University, Paris, France; ³Vascular Center, Munich, Germany; ⁴Global Medical Affairs, Bayer HealthCare Pharmaceuticals, Berlin, Germany; ⁵Centre for Cardiovascular Sciences, University of Birmingham and Sandwell & West Birmingham Hospitals NHS Trust, Birmingham, UK; ⁶Department of Cardiovascular Medicine, University of Münster, Münster, Germany; ⁷Global Integrated Analysis, Bayer HealthCare Pharmaceuticals, Wuppertal, Germany; and ⁸Department of Medicine, McMaster University, Hamilton, ON, Canada

Received 27 July 2015; revised 11 August 2015; accepted 20 August 2015

XANTUS: Study Objective and Design

To collect real world data on adverse events in patients with NVAF treated with rivaroxaban to determine the safety profile of rivaroxaban across the broad range of patient risk profiles encountered in routine clinical practice

Primary outcomes: major bleeding (ISTH definition), all-cause mortality, any other adverse events

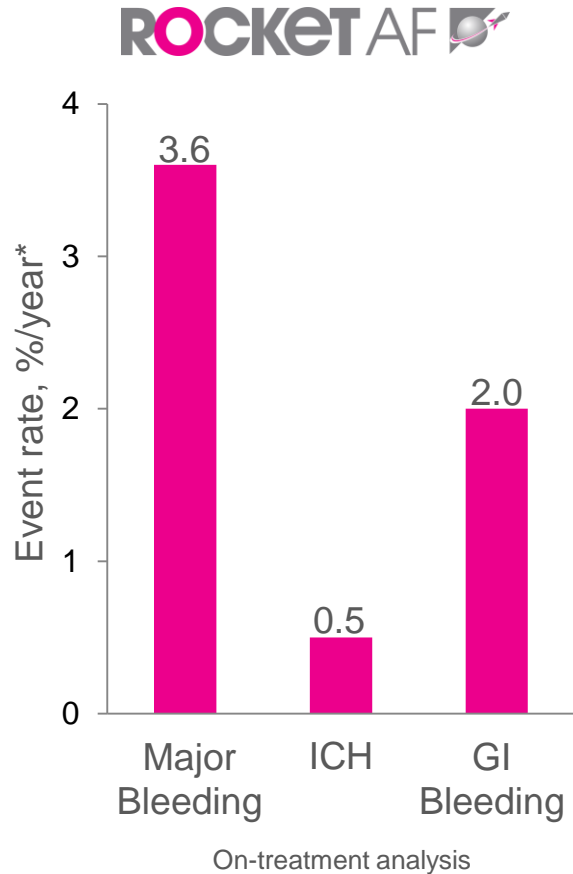


Prospective, single-arm, observational, non-interventional phase IV study
Statistical analyses were descriptive and exploratory in nature

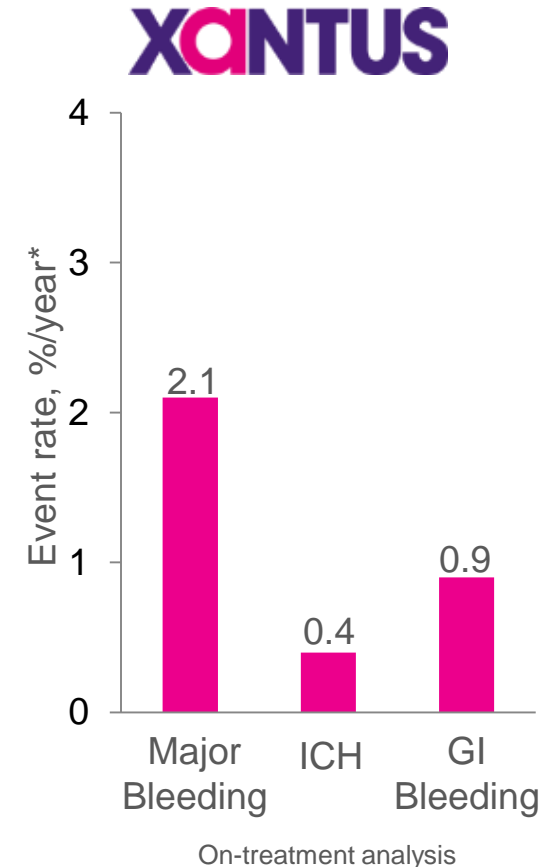
*Exact referral dates for follow-up visits not defined (every 3 months recommended); #for rivaroxaban discontinuation ≤ 1 year, observation period ends 30 days after last dose. Observational design means no interference with clinical practice was allowed

1. Camm AJ *et al*, *Vasc Health Risk Manag* 2014;10:425–434; 2. Camm AJ *et al*, *Eur Heart J* 2015; doi: 10.1093/eurheartj/ehv466

Rivaroxaban Provides Reassuring Safety, Reaffirmed in the Real World



ROCKET AF ²	Baseline	XANTUS ¹
3.5	CHADS ₂	2.0
0%	0-1	41%
13%	2	30%
87%	≥3	29%
63%	Heart Failure	19%
91%	Hypertension	75%
44%	Age: >75 years	37%
40%	Diabetes	20%
55%	Prior Stroke#	19%
17%	Prior MI	10%



Results are not intended for direct comparison

#Includes prior stroke, SE or TIA; *Events per 100 patient-years

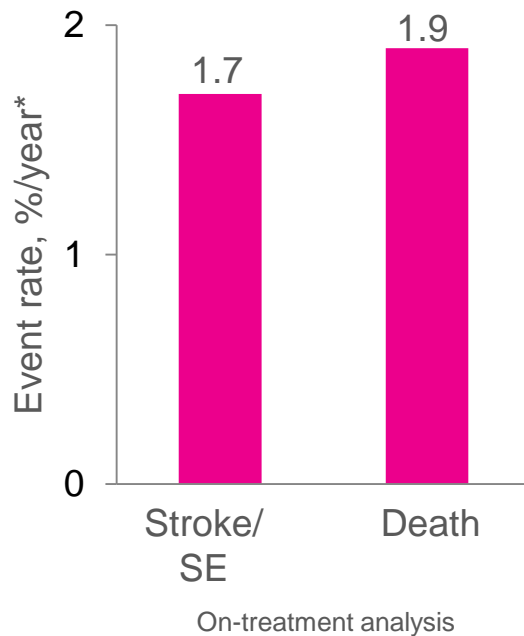
1. Camm AJ *et al*, *Eur Heart J* 2015; doi: 10.1093/eurheartj/ehv466;

2. Patel MR *et al*, *N Engl J Med* 2011;365:883–891

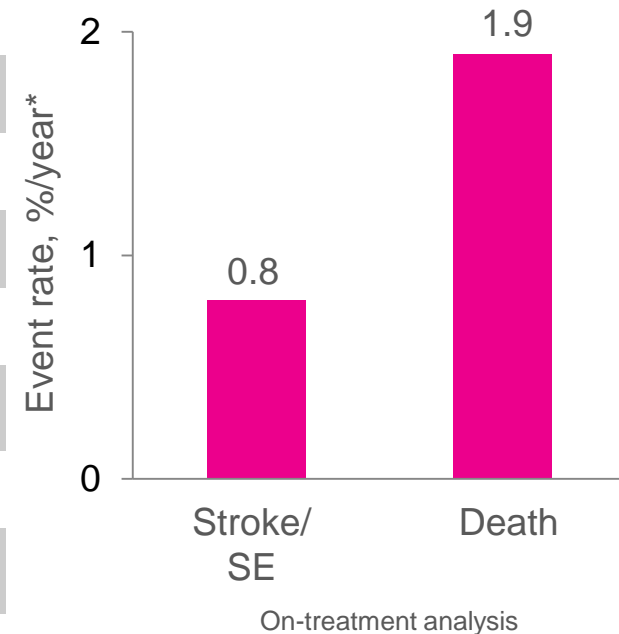
Rivaroxaban is Highly Effective in Both Randomized Clinical Trials and the Real World

ROCKET AF 

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XANTUS



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L.DE.MA.12.2015.0125

XANTUS

Conclusion

Phase IV studies

XALIA and XANTUS

confirm safety and efficacy of Rivaroxaban
which had been demonstrated in

Phase III trials

EINSTEIN DVT and ROCKET AF

Thank you for your attention!

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