EUROPEAN HEART HOUSE

Anti-Thrombotic Therapy – Update 2016

Thursday 23 February – Saturday 25 February, 2017

Course Directors:
Raffaele De Caterina (IT), Erik Grove (DK), Steen D. Kristensen (DK), Marco Zimarino (IT)

Faculty :
Giancarlo Agnelli (IT), Jean-Philippe Collet (FR), Kurt Huber (AU), David J. Moliterno (USA), Franz-Josef Neumann (GE), Giuseppe Patti (IT), Bianca Rocca (IT), Helmut Schühlen (GE), Robert F. Storey (UK)

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Warfarin or NOACs
Lessons from real-life data in different countries

Giuseppe Patti
Campus Bio-Medico University of Rome

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	Efficacy (CRTs)	Effectiveness (Real-world data)
Objective	Efficient and safe under ideal, highly controlled circumstances	Efficient and safe under usual circumstances
Setting	Relatively small set of pts over a short time period	Very large set of pts over a long time period
Centers	Highly dispersed	Localized
Purpose	Regulatory approval	Safety in populations
Type of intervention	Fixed, pre-determined regimen	Flexible regimens (considering doctor's and patient's choice)
Subjects	Homogeneous/highly selected	Heterogeneous/Any subjects
Cost-efficiency evaluation	No	Yes

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ARISTOTLE vs Real world data

	N	OR	95% CI	P	% Api	NNT
ARISTOTLE	18,201	0.69	0.60-0.80	<0.001	2.1%	100
Lip et al.	29,338	0.52	0.30-0.89	0.018	1.4%	48
ARISTOTLE	18,201	0.71	0.68-0.75	<0.001	18%	13
Lin et al.	35,757	0.75	0.63-0.88	<0.05	7.2%	22
ARISTOTLE	18,201	0.79	0.65-0.95	0.01		
Amin et al.	5,573	0.74	0.68-0.81	<0.001		

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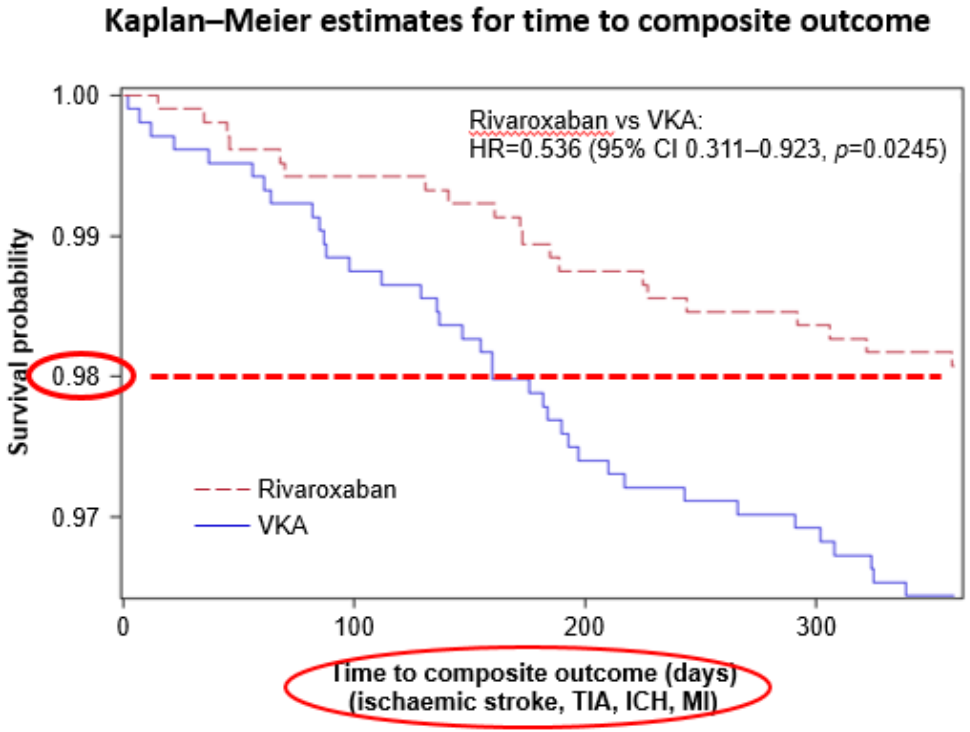
RELIEF Survival Analysis in German Primary Care Setting Suggests Favourable Effectiveness Versus VKA Treatment (N=2,078 pts)



Coleman CI et al., Int J Cardiol 2015

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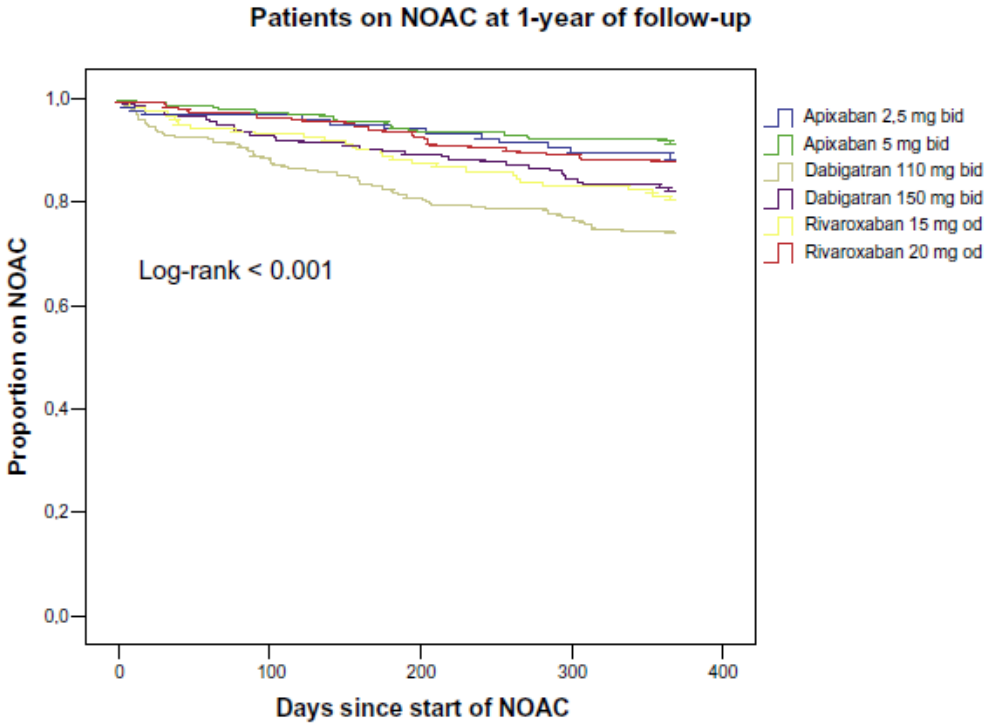
NOACs adherence in an Italian real-world setting (N=1,305 AF patients)



Vedovati et al. Int J Cardiol 2017

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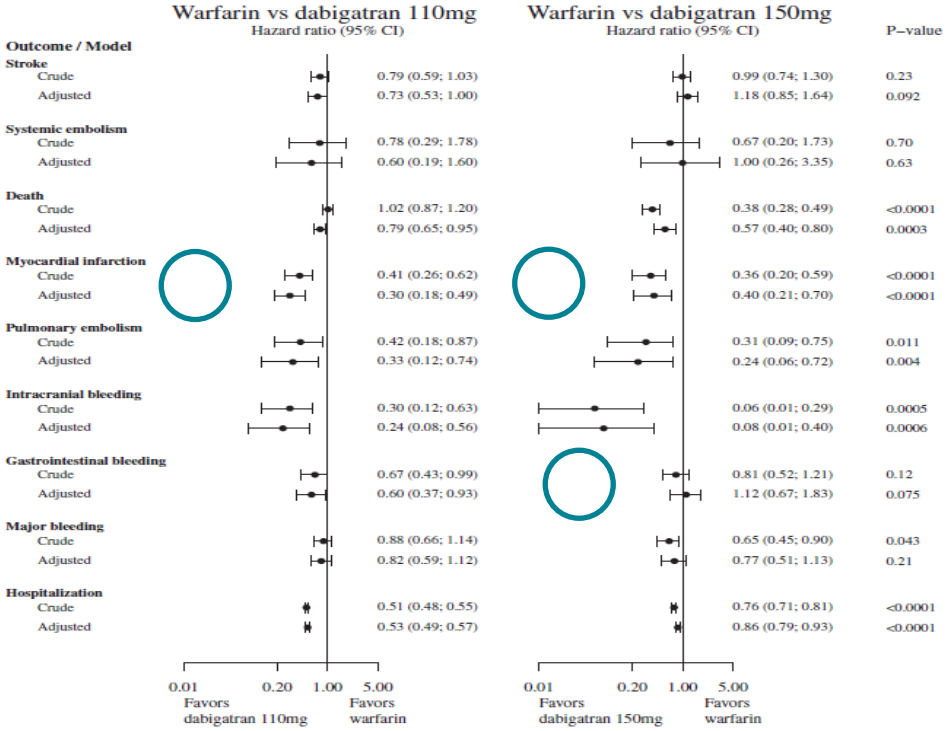
Efficacy and Safety of Dabigatran Etexilate and Warfarin in "Real-World" Patients With Atrial Fibrillation

A Prospective Nationwide Cohort Study

Torben Bjerregaard Larsen, MD, PhD,*† Lars Hvilsted Rasmussen, MD, PhD,†
Flemming Skjøth, MSc, PhD,* Karen Margrete Due, MSc,* Torbjörn Callréus, MD, PhD,‡
Mary Rosenzweig, MSc,‡ Gregory Y. H. Lip, MD†§

Aalborg and Copenhagen, Denmark; and Birmingham, United Kingdom

Larsen TB et al. JACC Vol. 61, No. 22, 2013 June 4, 2013:2264



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The Prospective RE-LY Atrial Fibrillation Registry (164 sites in 46 countries; N=15,400)

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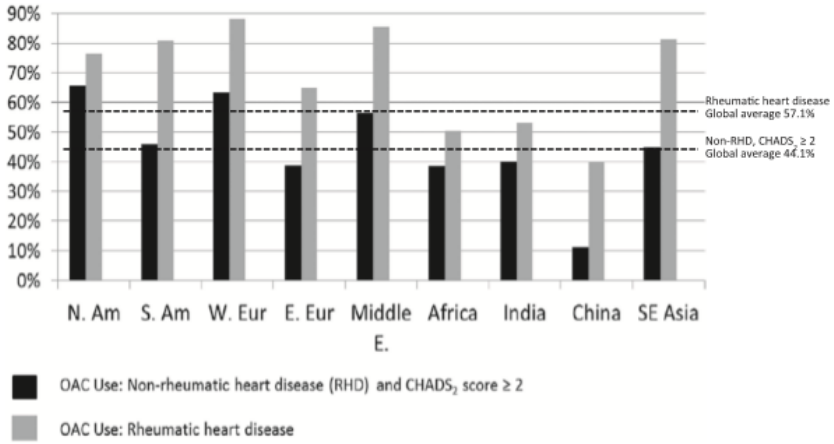
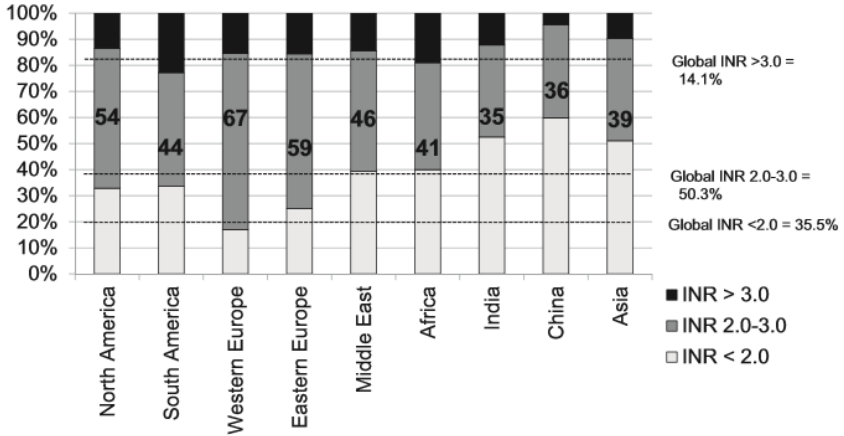
Prevalence of AF patients receiving OAC at ED presentation



INR control before ED presentation



Oldgren J et al. Circulatyion 2014

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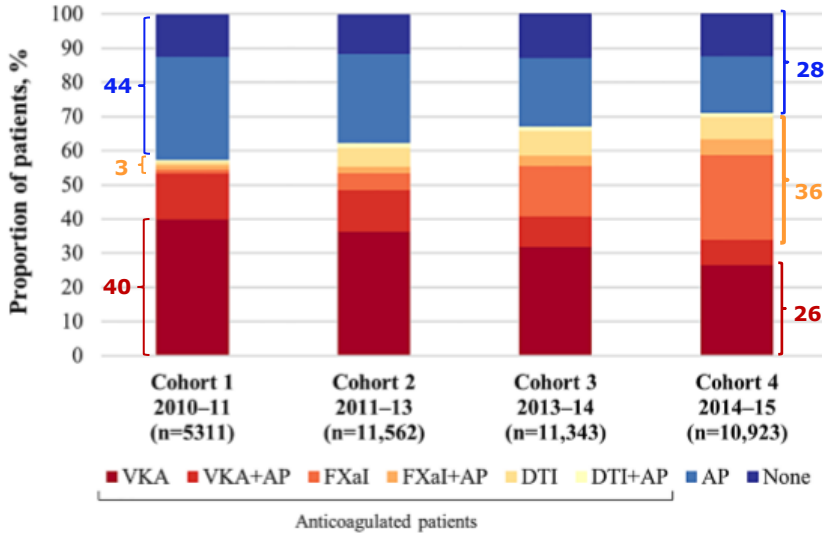
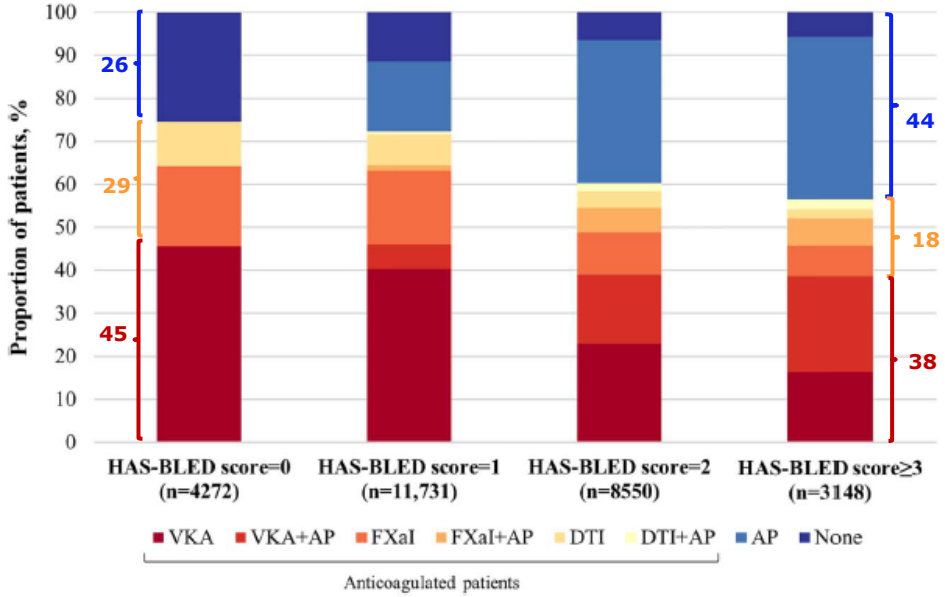
Antithrombotic strategies before and after NOACs diffusion – The GARFIELD AF Registry



Camm AJ et al. Heart 2014

Antithrombotic strategies according to bleeding risk The GARFIELD AF Registry

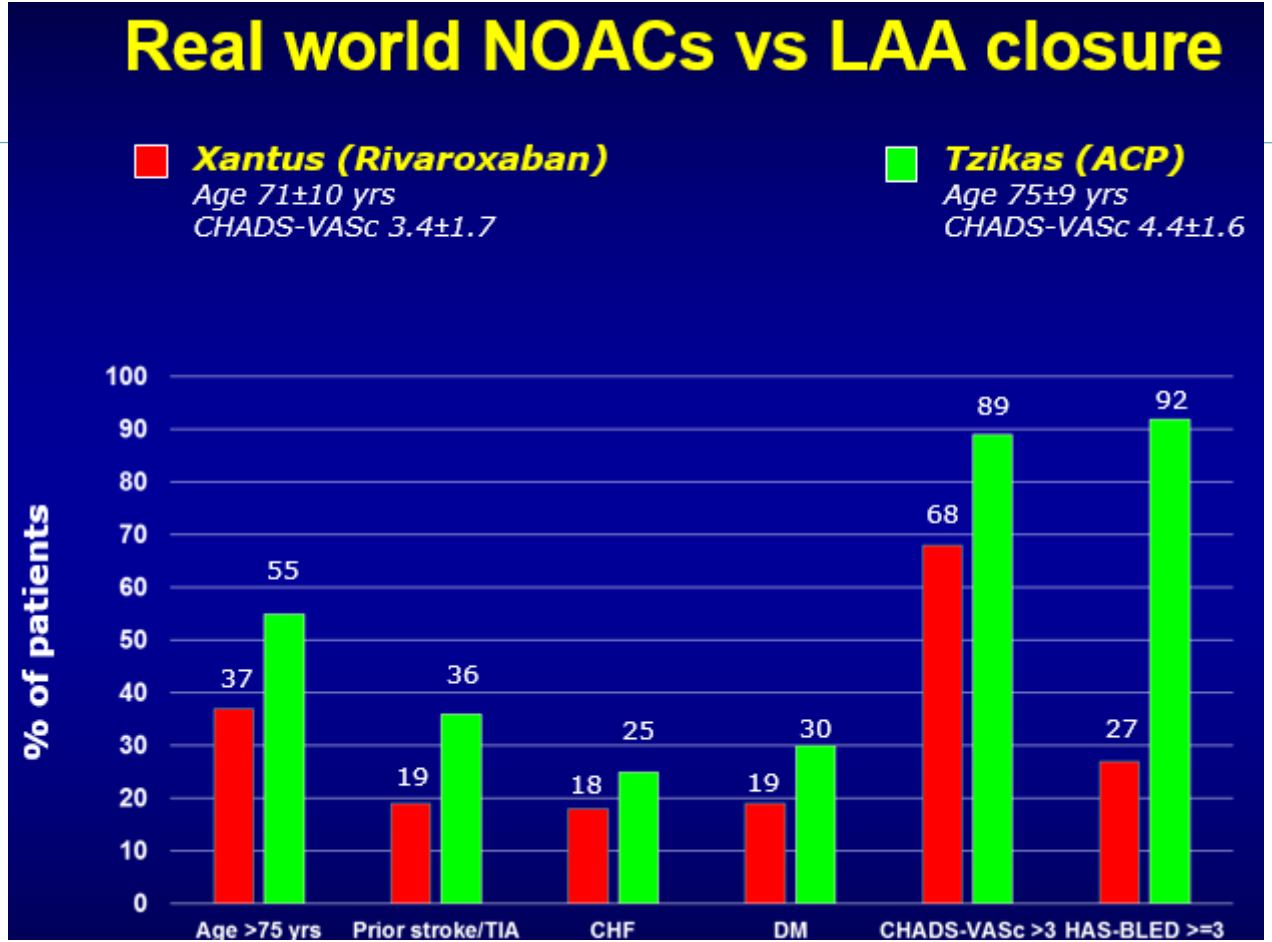


Median CHADS-VASc score of NOAC pts: 4 in C1 .....3 in C4!
Median HAS-BLED score of NOAC pts: 2 in C1 .....1 in C4!

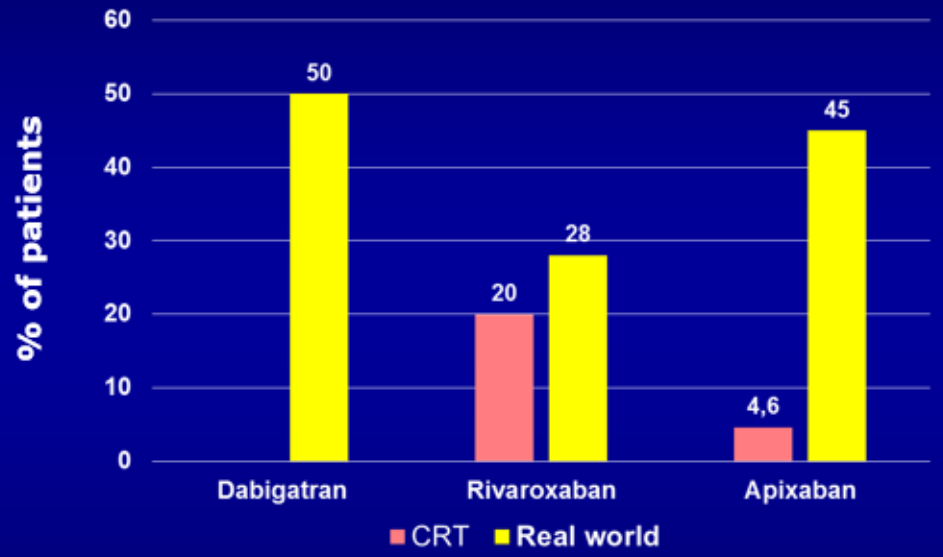
With NOACs diffusion there was a great proportion of patients at low TE risk (score 0-1) treated with these agents

Camm AJ et al. Heart 2014

Real world NOACs vs LAA closure



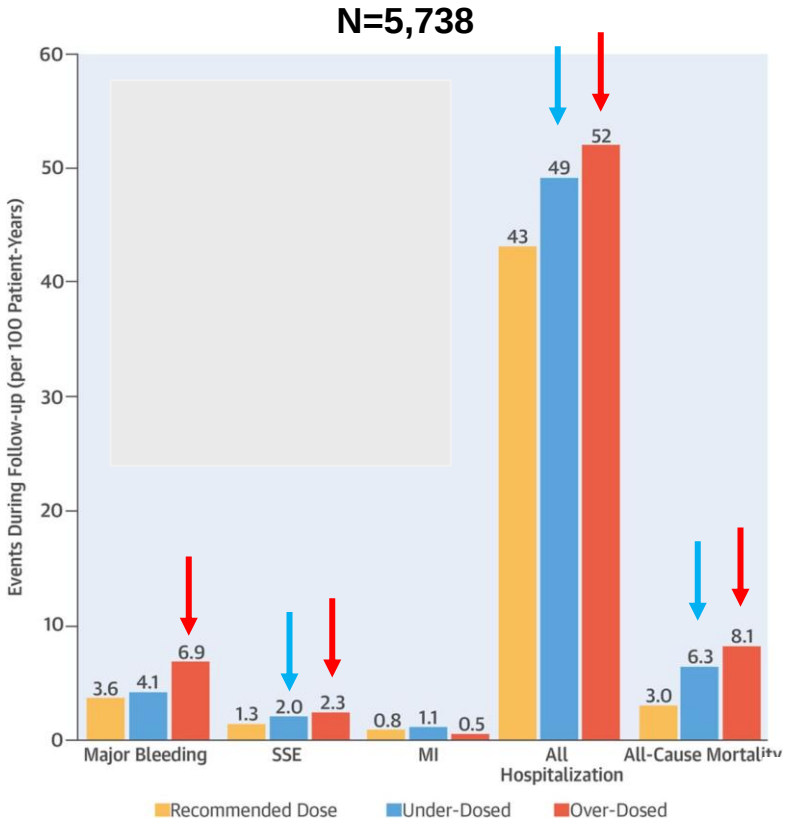
Prevalence of NOACs use at low doses in CRTs and European real world registries



ROCKET: dose reduction of Rivaroxaban from 20 mg to 15 mg if Cr Cl 30-49 ml/min

***ARISTOTLE: dose reduction from 5 to 2.5 mg if** at least 2 of:*
age ≥80 years, Cr ≥1.5 mg/dL, weight ≤60 kg

Off-Label Dosing of Non-Vitamin K Antagonist Oral Anticoagulants and Outcome
The ORBIT-AF II Registry - J Am Coll Cardiol, December 2016



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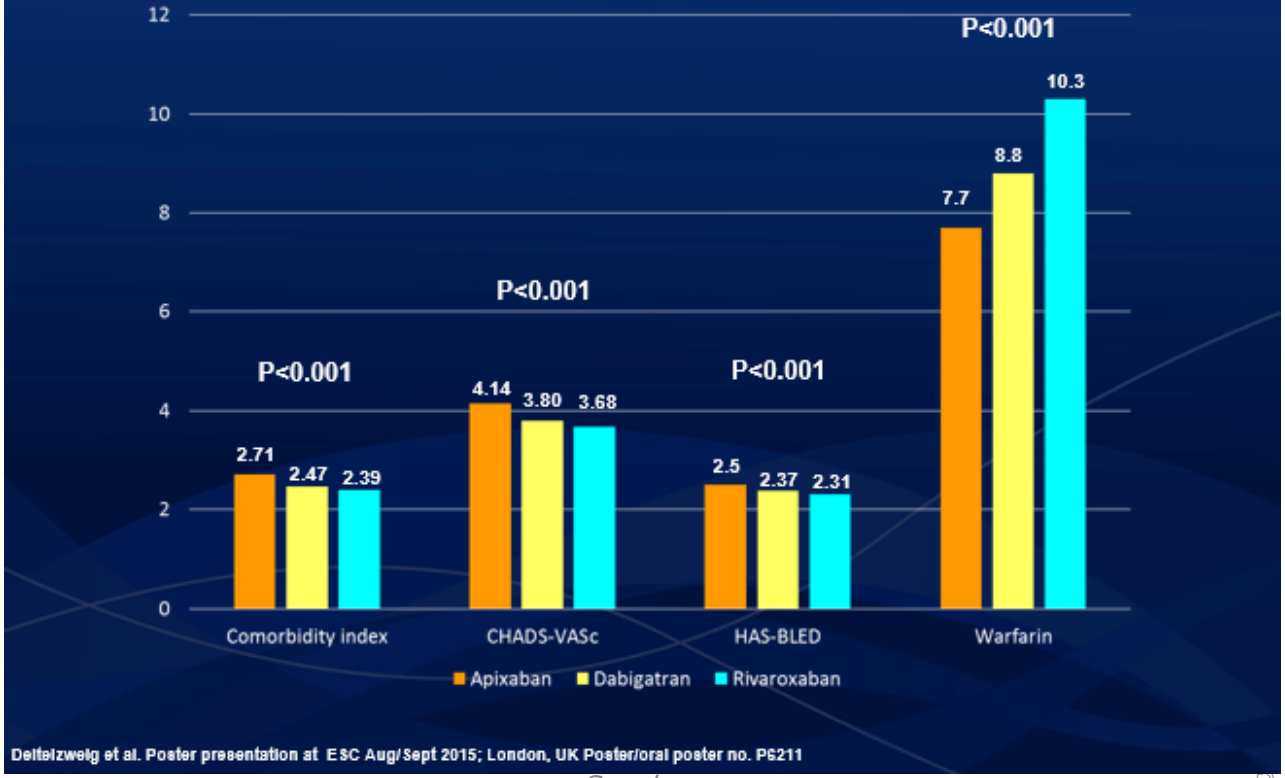
Risk profile of pts receiving different NOACs in the real world



Deitelzweig et al. Poster presentation at ESC Aug/Sept 2015; London, UK Poster/oral poster no. P6211

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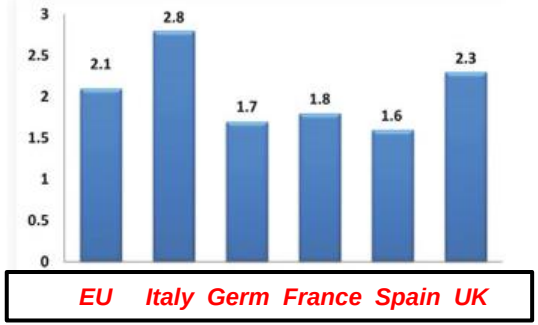
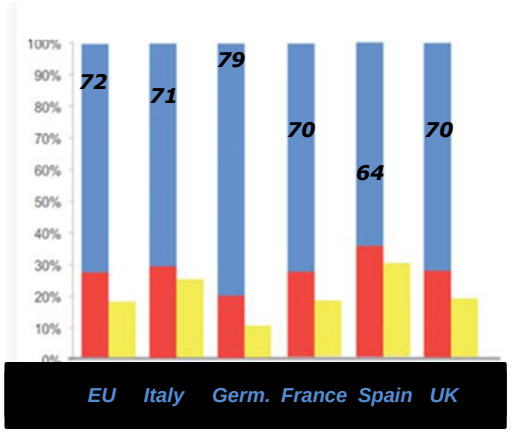
PREFER in AF Registry (N=7,243)

	Total	France	Germany	Italy	Spain	UK
Vitamin K antagonists (VKAs)	78.0	86.0	79.1	71.4	80.0	75.1
Combination therapy (VKA + AP)	9.9	10.1	7.7	8.8	10.3	14.7
Novel oral anticoagulants (NOACs)	6.1	6.0	11.6	0.3	11.2	3.7
Antiplatelet agents (AP) monotherapy	22.1	16.9	17.2	27.0	18.7	30.7
No anticoagulants or antithrombotic therapy	6.5	4.1	5.0	10.4	5.7	6.5





Le Heuzey et al. Thromb Haemost 20014