

**Security and efficacy of Rivaroxaban in real life in
the prevention of the stroke in non valvular AF
patients: presentation of the results of the
international study Xantus**



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THE FIRST 100 YEARS OF THE HISTORY



1905-1915

*Oral
Inhibitors*

Xabans i.v.

1980-2008

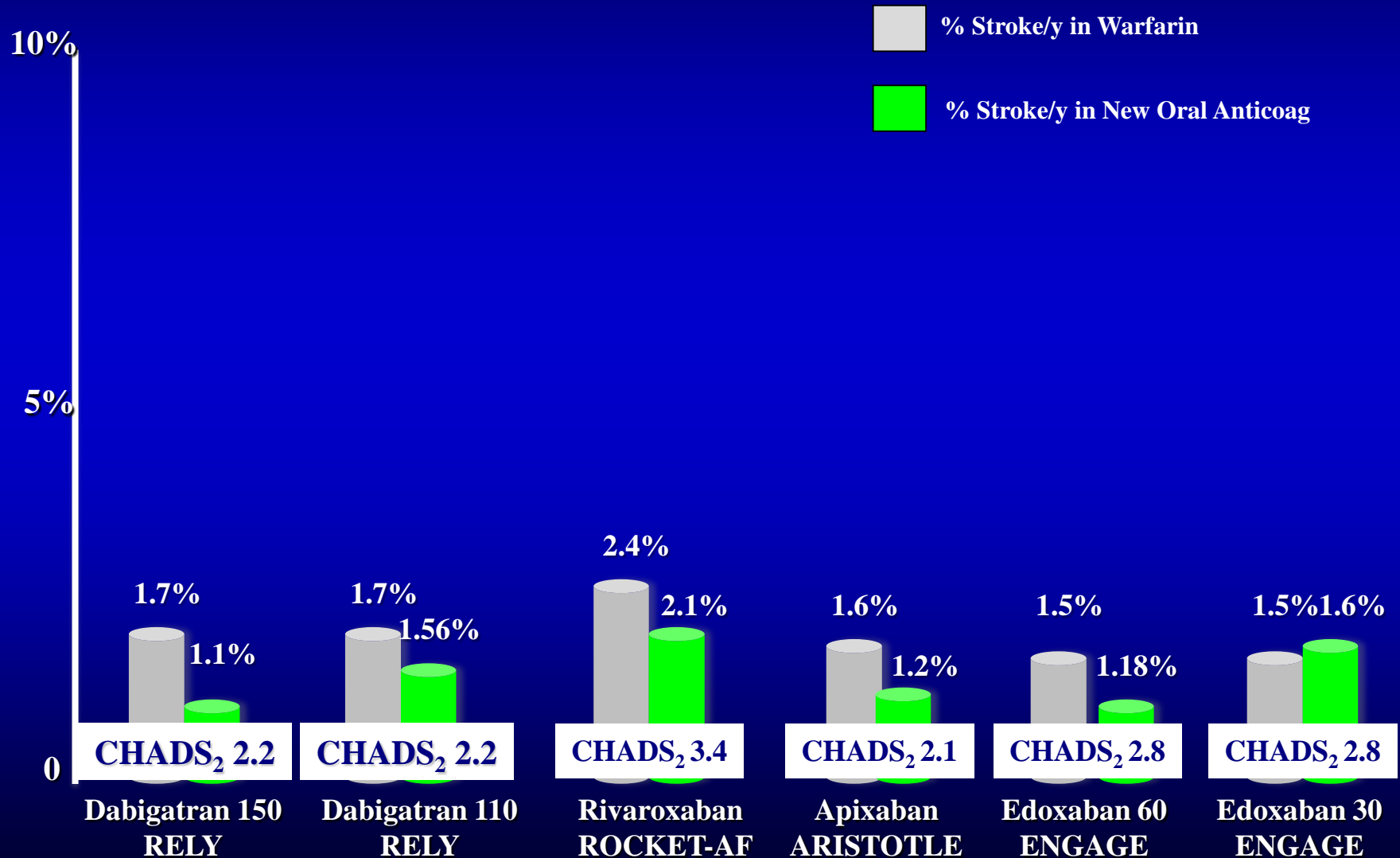
**FDA
PROGRESSIVLY
APPROVES NOACs**

**RELY, ROCKET-AF,
ARISTOTLE, ENGAGE-AF**

2009-2014

Efficacy of NOACs: data from Trials

Warfarin vs **New Oral Anticoagulants**

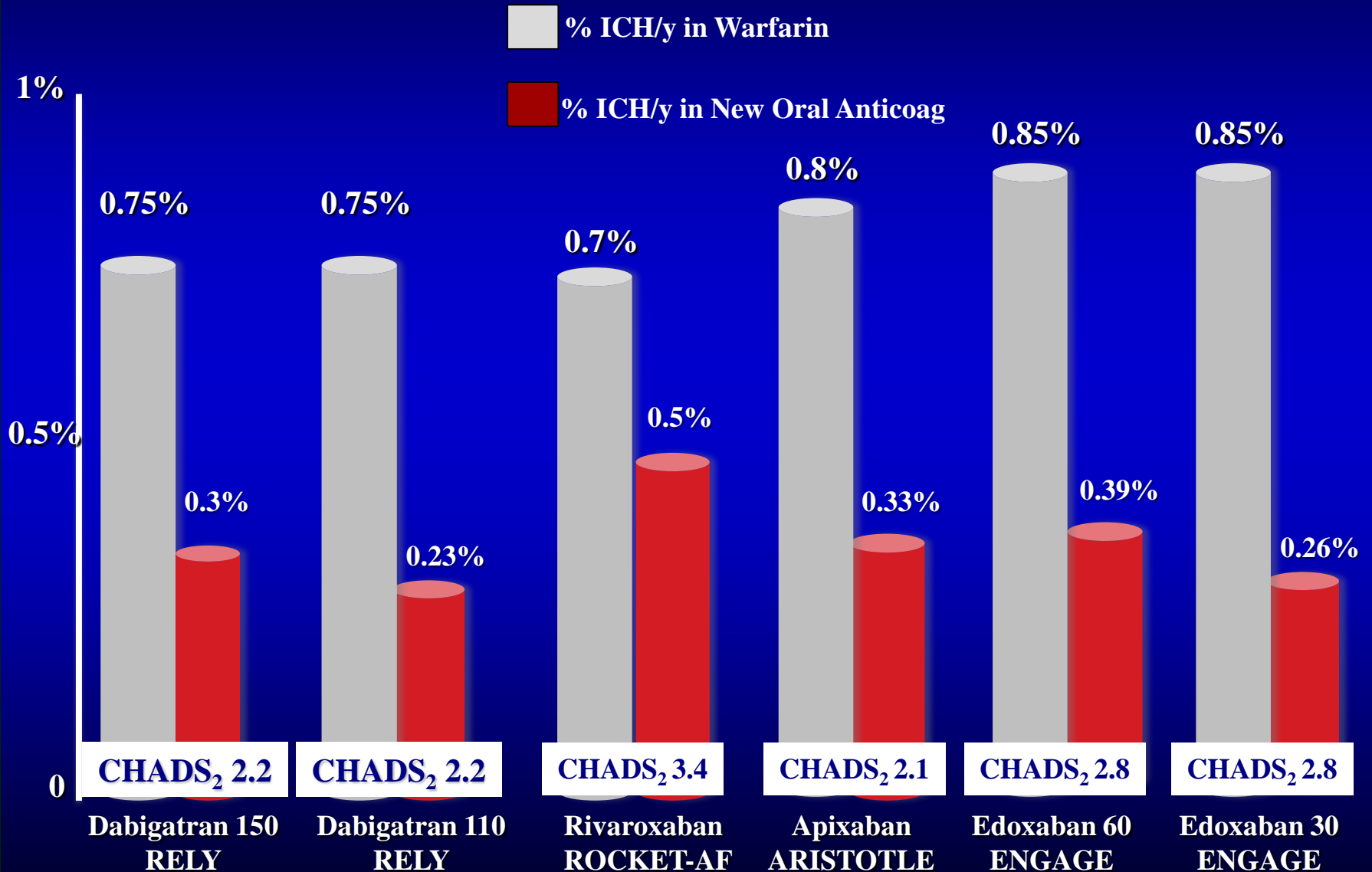


SECURITY of NOACs

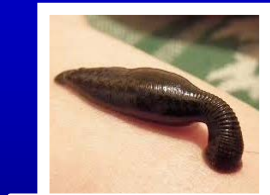
Drug	Any bleeding	Major bleeding
Warfarin (data from NOACs trials)	18,1%/year (mean)	3.4%/year (mean)
Dabigatran	16.4%/year	3.11%/year
Rivaroxaban	14%/year	3.6%/year
Apixaban	18.1%/year	2.13%/year
Edoxaban	14.1%/year	2.75%/year

Security of NOACs: data from Trials

Warfarin vs New Oral Anticoagulants



THE FIRST 100 YEARS OF THE HISTORY



*Hirudin and
Antistasin*

1905-1980

Xabans i.v.

1980-2008

*Oral
Inhibitors*

2009-2014

**RELY, ROCKET-AF,
ARISTOTLE,
ENGAGE-AF**

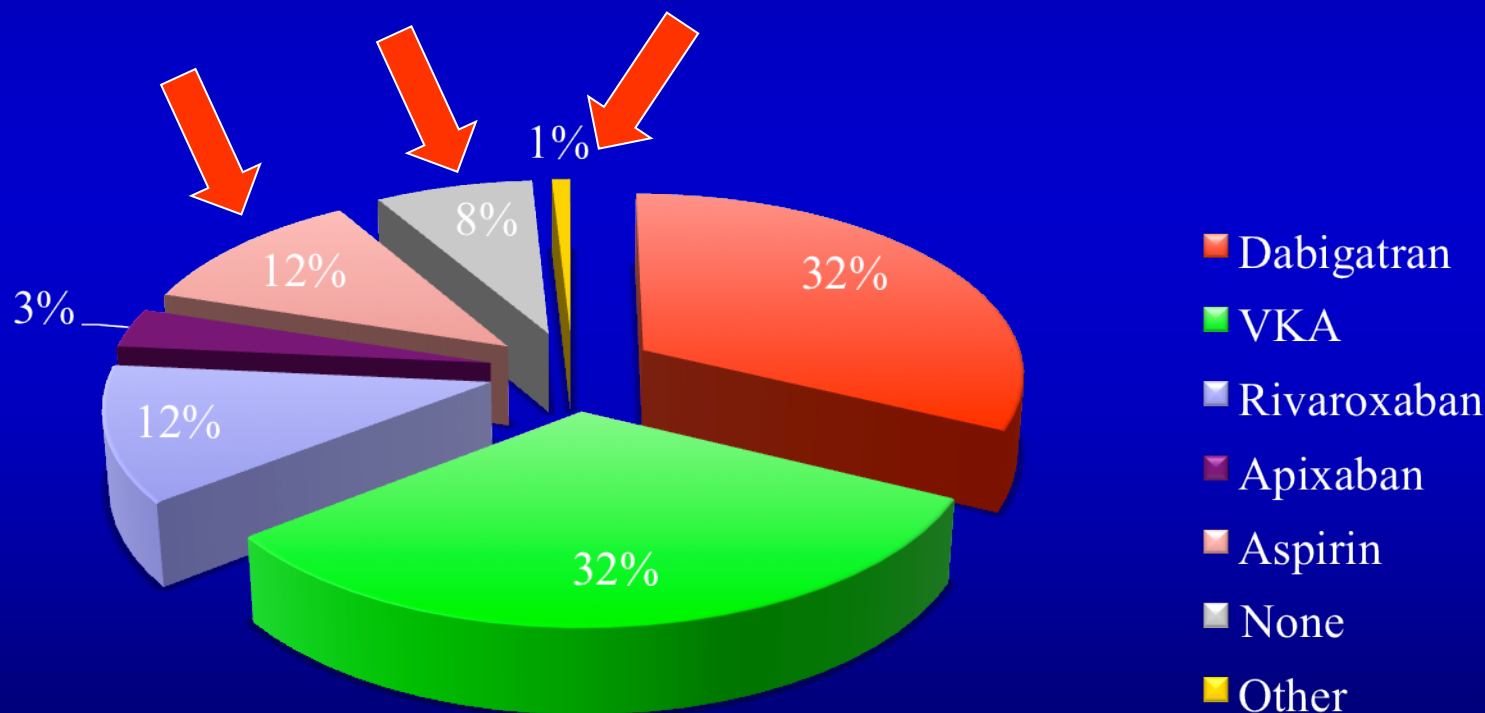
**FDA
PROGRESSIVELY
APPROVES NOACs**

The real life:
REGISTRIES

2015

GLORIA-AF

10,675 non valvular AF pts enrolled from 2011 until 2014 in 736 Centers – 92% CHA₂DS₂VASC score \geq 1



Representativeness of the dabigatran, apixaban and rivaroxaban clinical trial populations to real-world atrial fibrillation patients in the United Kingdom: a cross-sectional analysis using the General Practice Research Database

83898 NVAF pts

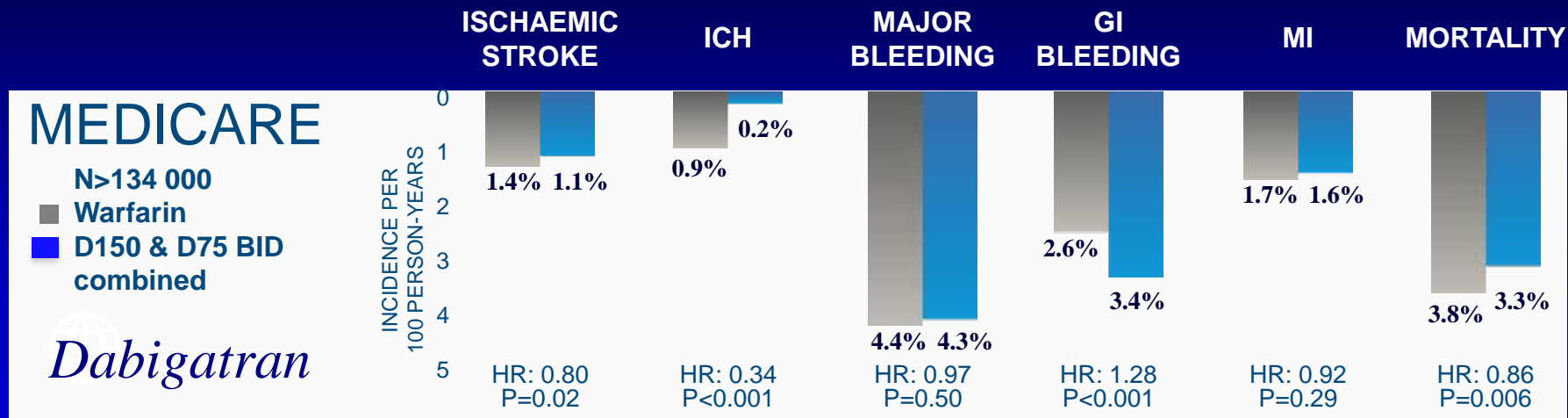
Using the CHA₂DS₂VASC score, % of eligible pts for inclusion into:

- **RE-LY** → 68%
- **ARISTOTLE** → 65%
- **ROCKET** → 51%

Using the CHADS score, % of eligible pts for inclusion into:

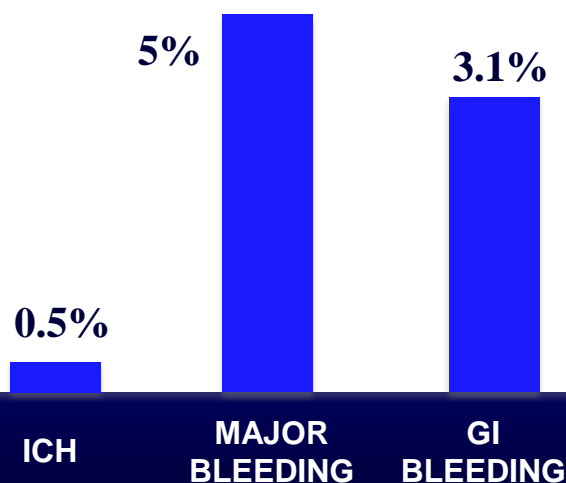
- **RE-LY** → 74%
- **ARISTOTLE** → 72%
- **ROCKET** → 56%

Security and Efficacy of NOACs: data from Registries



Graham DJ et al. Circulation 2015;131:157

Preliminary data
 N. 8785 pts
Apixaban

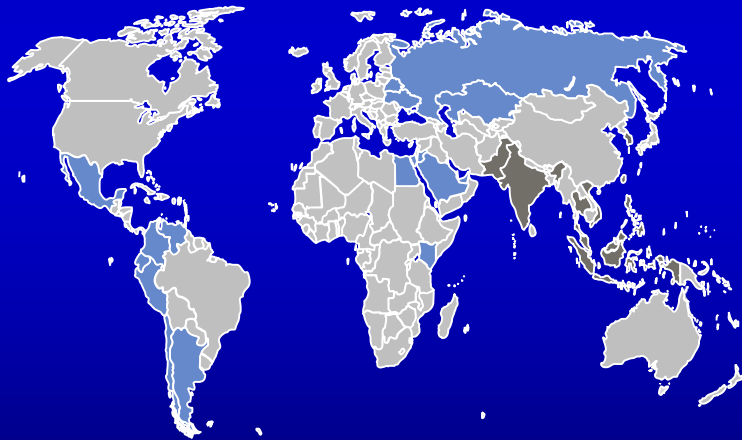


Tepper et al. ESC 2015 Poster Section

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

Prospective, single-arm, observational, non-interventional phase IV study

6784 Pts enrolled from June 2012 to December 2013,
311 centres Europe and Canada - *Follow up 1 year*

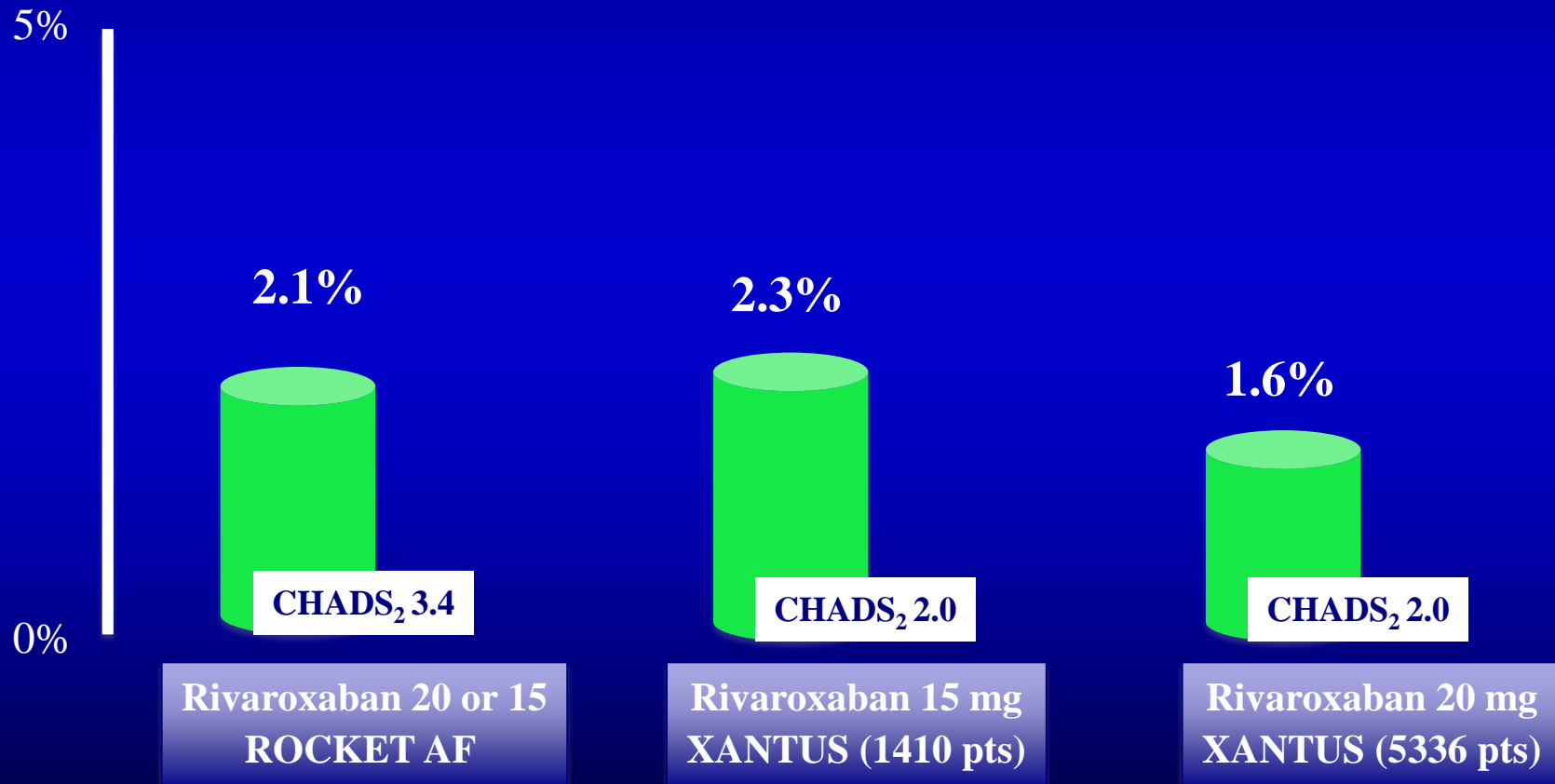


- **XANTUS EL** study in Eastern EU, Middle East, Africa and Latin
- **XANAP** study in Asia

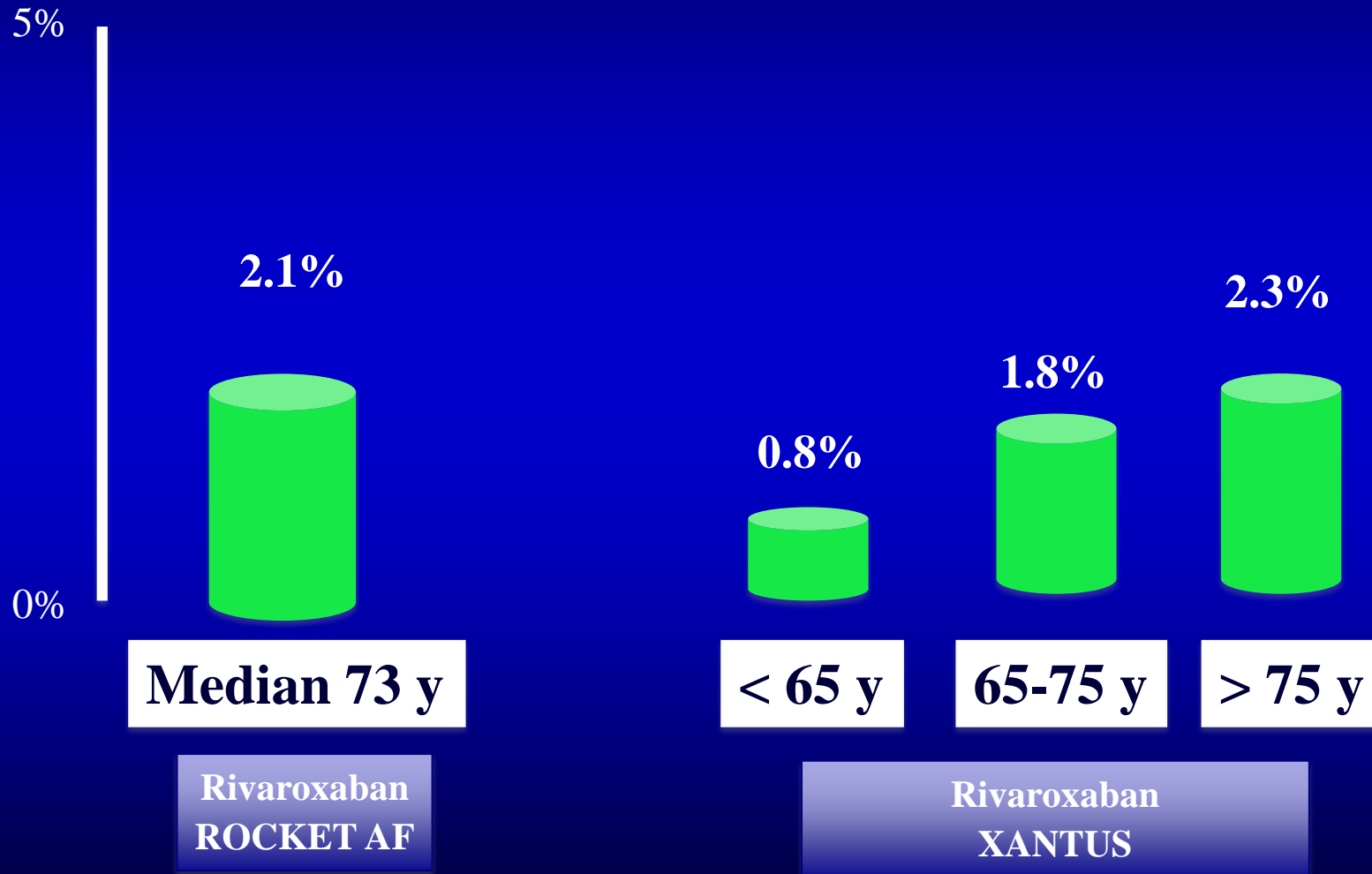
**Primary outcomes: major bleeding, all-cause mortality,
any other adverse events**

Clinical Characteristics	ROCKET (N=7131)	XANTUS (N=6784)
Age (years, mean)	73	71
Gender (male): n (%)	4300 (60.3)	4016 (59.2)
AF type, n (%)		
Paroxysmal	1345 (18.9)	2757 (40.6)
Persistent	5786 (81.1)	923 (13.6)
Permanent	-	1835 (27.0)
Hypertension	6436 (90.3)	5065 (74.7)
Diabetes mellitus	2878 (40.4)	1333 (19.6)
Prior stroke/non-CNS SE/TIA	3916 (54.9)	1291 (19.0)
Congestive HF	4467 (62.6)	1265 (18.6)
Prior MI	1182 (16.6)	688 (10.1)
Mean CHADS₂ score	3.48±0.94	2.0±1.3
Mean CHA ₂ DS ₂ -VASC score	-	3.4±1.7
VKA experienced	4443 (62.3)	3089 (45.5)

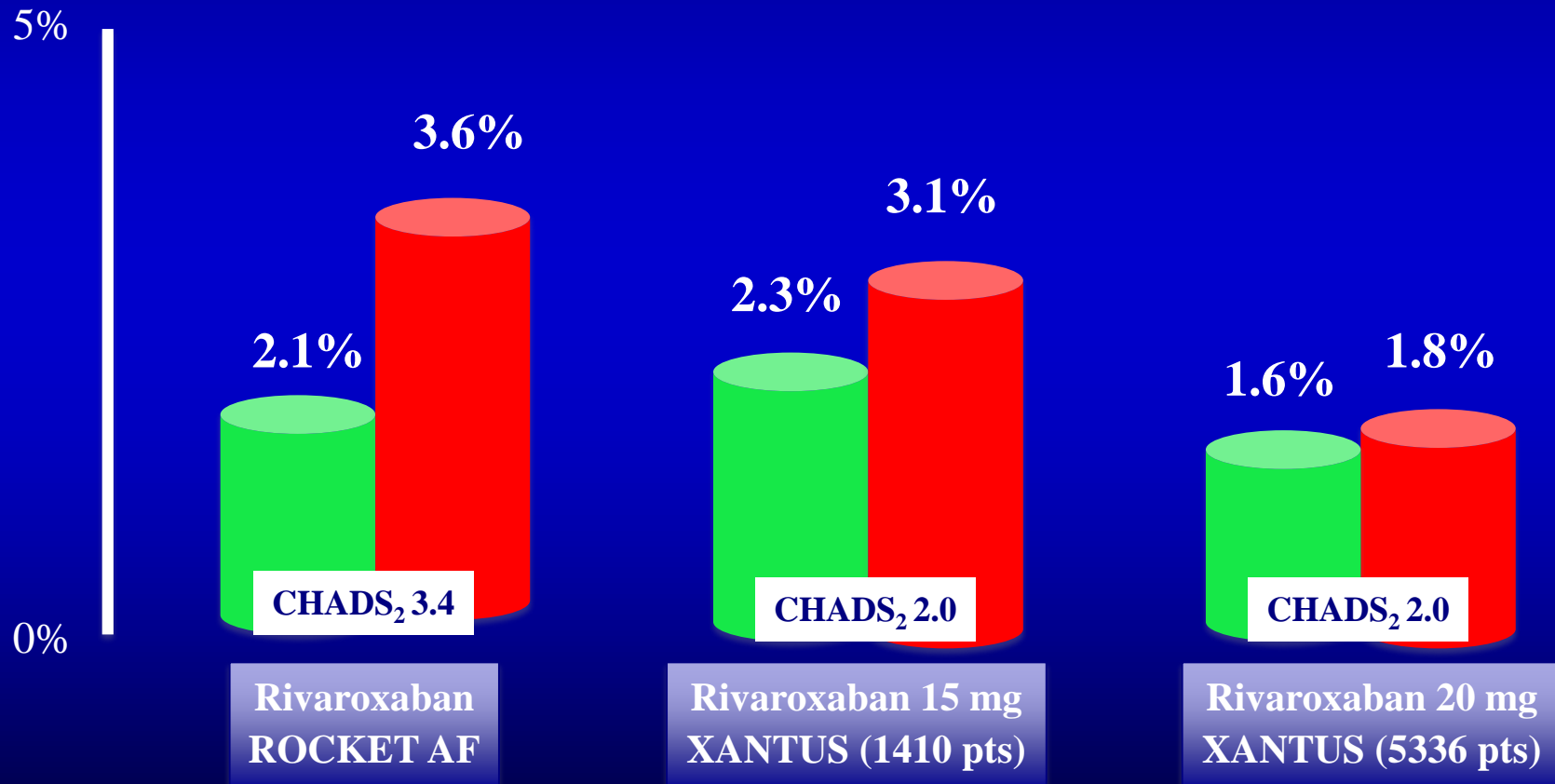
Thromboembolic events according to dosing (events/100 pts/year)



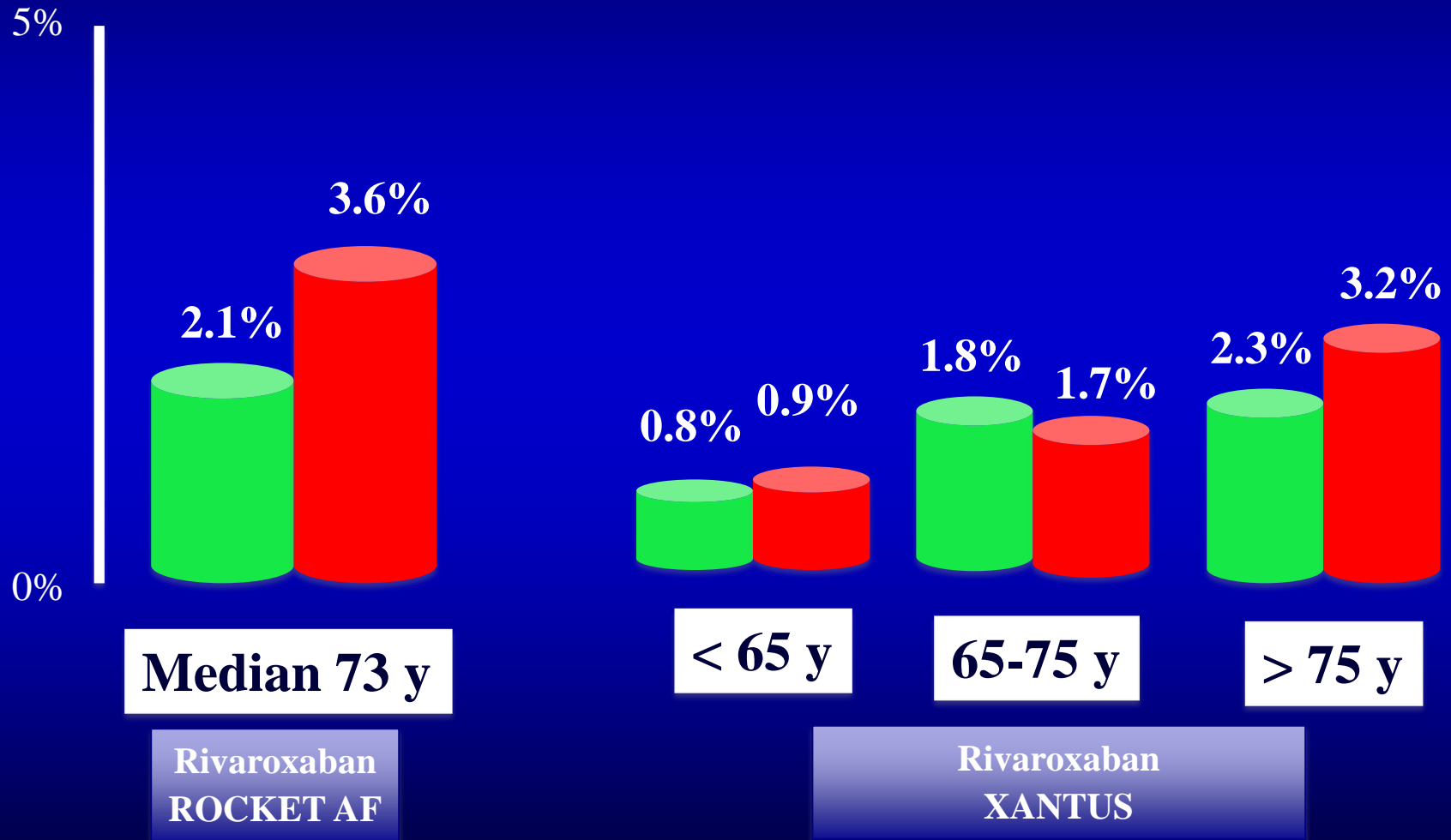
Thromboembolic events according to age (events/100 pts/year)



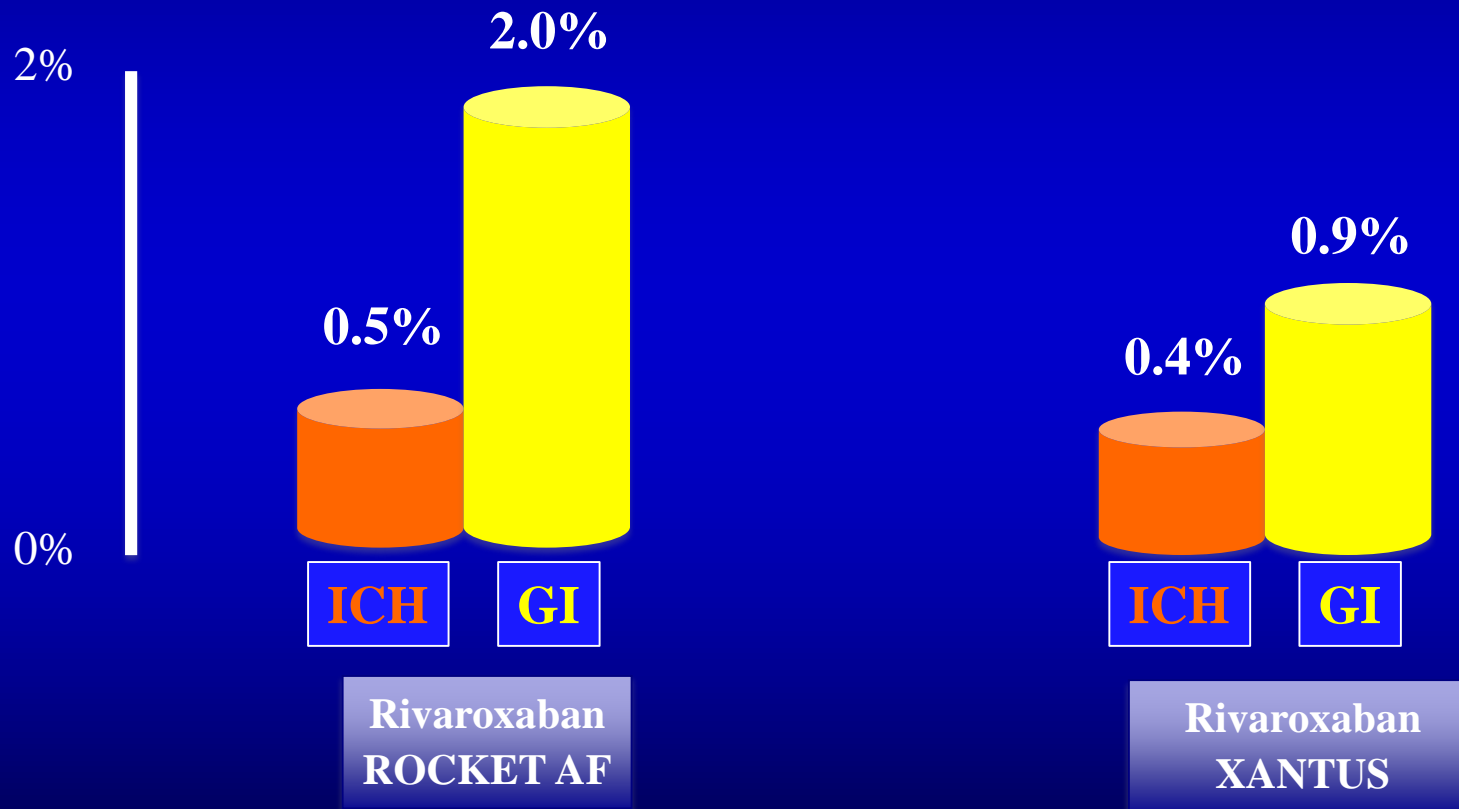
Thromboembolic events and major bleedings according to dosing (events/100 pts/year)



Thromboembolic events and major bleedings according to age (events/100 pts/year)



**Major bleedings (events/100 pts/year):
Intracranial (ICH) and Gastrointestinal (GI)**



BLEEDINGS MANAGEMENT

ROCKET AF

Major bleeding was mostly treated using conservative methods:

- 2.6% of patients (n=184) received transfusions of ≥ 2 units of packed RBCs or whole blood

The use of non-specific reversal agents was low:

- PCC \rightarrow in 4 patients
- Tranexamic acid \rightarrow in 2 patients

XANTUS

Major bleeding was mostly treated using conservative methods:

- 0.8% of patients (n=53) received transfusions of ≥ 2 units of packed RBCs or whole blood

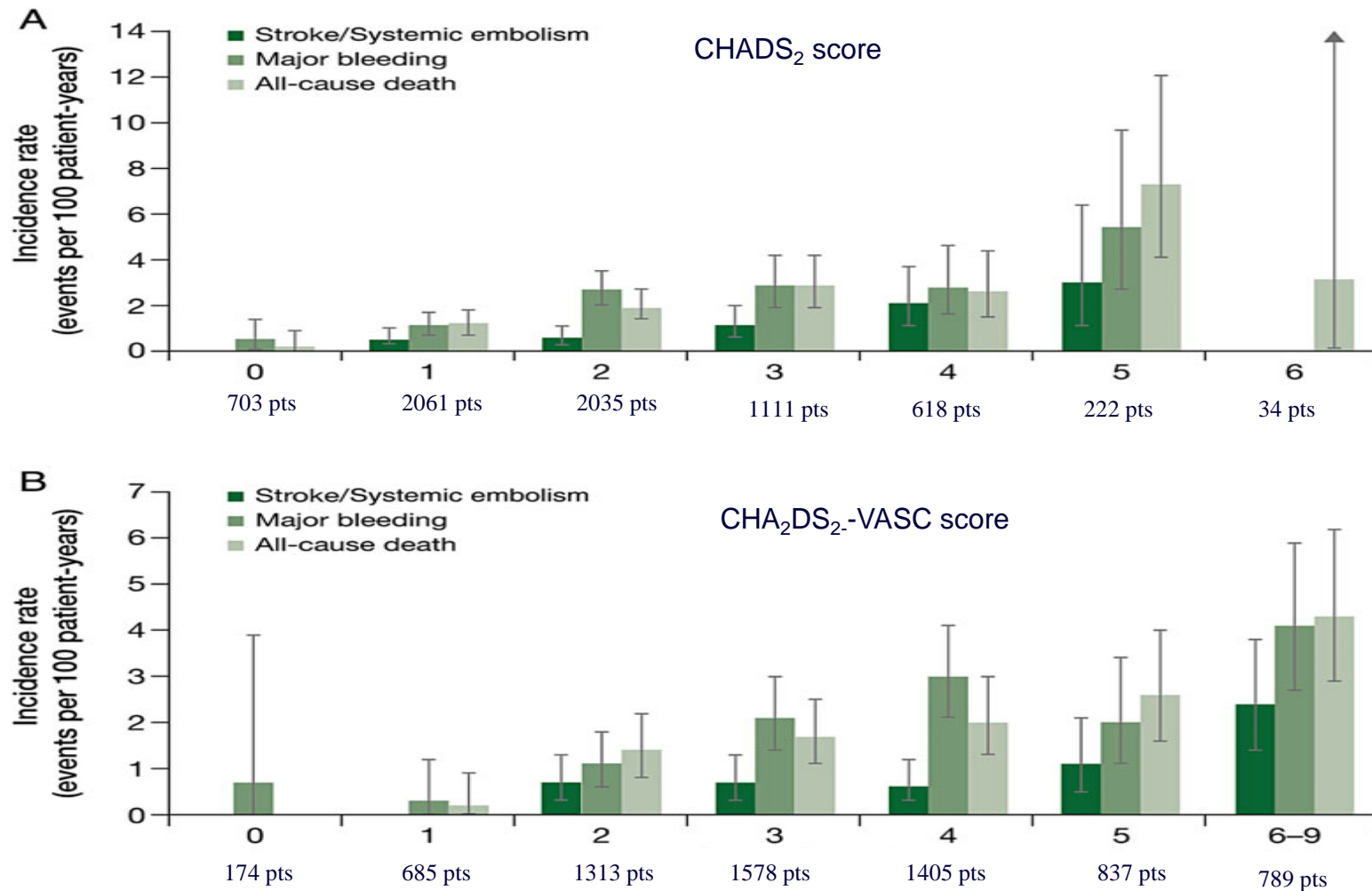
The use of non-specific reversal agents was low:

- PCC \rightarrow in 2 patients
- Tranexamic acid \rightarrow in 3 patients

All-cause mortality

	ROCKET AF (N=7,061)	XANTUS (N=6,784)
Endpoints	n (% per year)	n (% per year)
All-cause mortality	208 (1.9)	118 (1.7)
Vascular death	170 (1.5)	49 (0.7)
Non-vascular death	21 (0.2)	60 (0.9)
Unknown cause	17 (0.2)	9 (0.1)

Thromboembolic events, major bleedings and all-cause death according to risk scores (events/100 pts/year)



Conclusions

In a real world population, rivaroxaban demonstrated low rates of stroke and major bleeding, including intracranial and GI bleeding for both dosages

Incidences of these outcomes increased with age and generally with higher risk scores

Major bleeding was mostly treated conservatively; reversal agents were rarely used

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and

GREAT INNOVATIONS IN CARDIOLOGY

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UNIVERSITÀ DEGLI STUDI DI TORINO



From Caliper to Catheter



JOINT MEETING
OF CARDIOLOGY

Thank You for your Attention!

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