



XI congresso nazionale

simeu

ROMA 24-26 MAGGIO 2018

Terapia Anticoagulante Oggi: Il Valore Aggiunto Dei Noacs
Versus La Terapia Standard; Gli Eventi Avversi In PS

Noemi Renzi PS/OBI NOA (MS); ATNO. Consiglio Regionale SIMEU Toscana



Stato dell'arte..

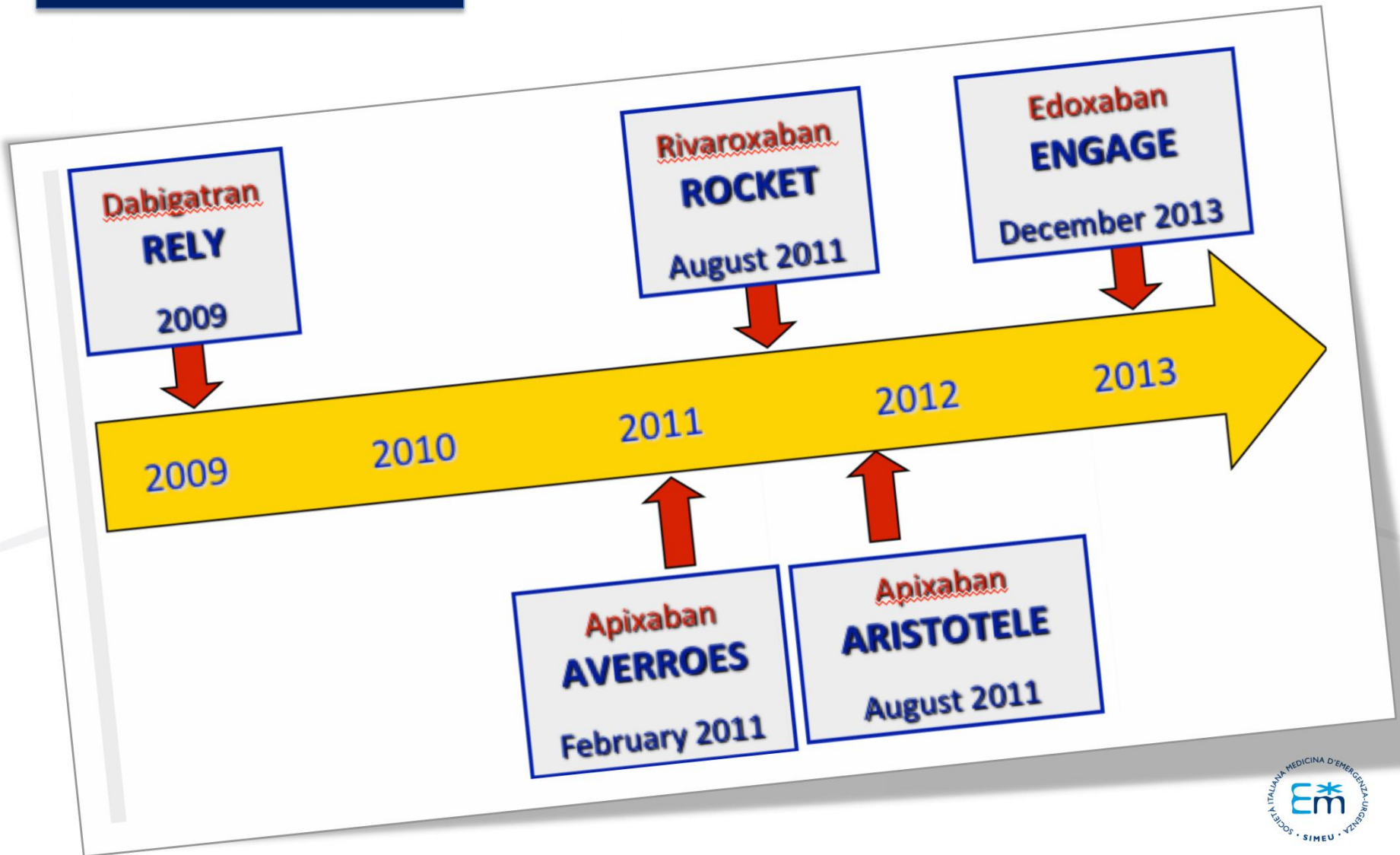


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La storia



RELY

Dabigatran versus Warfarin in Patient with Atrial Fibrillation

Dabigatran
110 mg BID
vs. warfarin



Margin=1.46

Non-inferiority
P value

<0.001

Superiority
P value

0.30

Dabigatran
150 mg BID
vs. warfarin

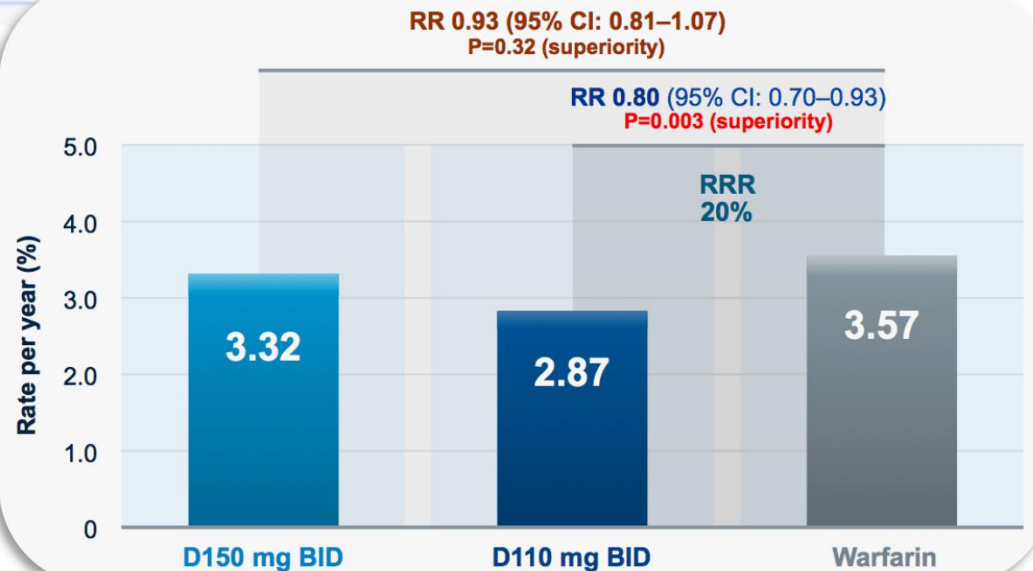


<0.001

<0.001

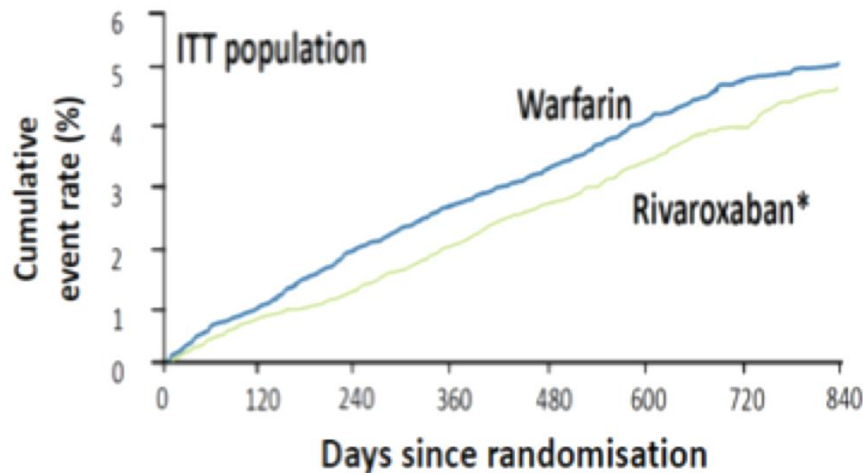
Stroke or Systemic Embolism

Major Bleeding



ROCKET-AF

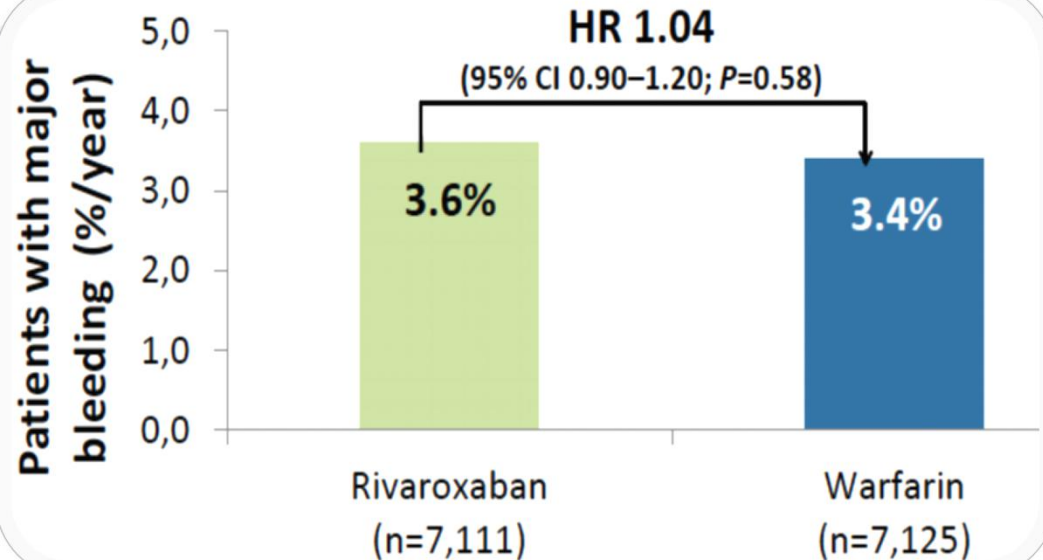
Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation



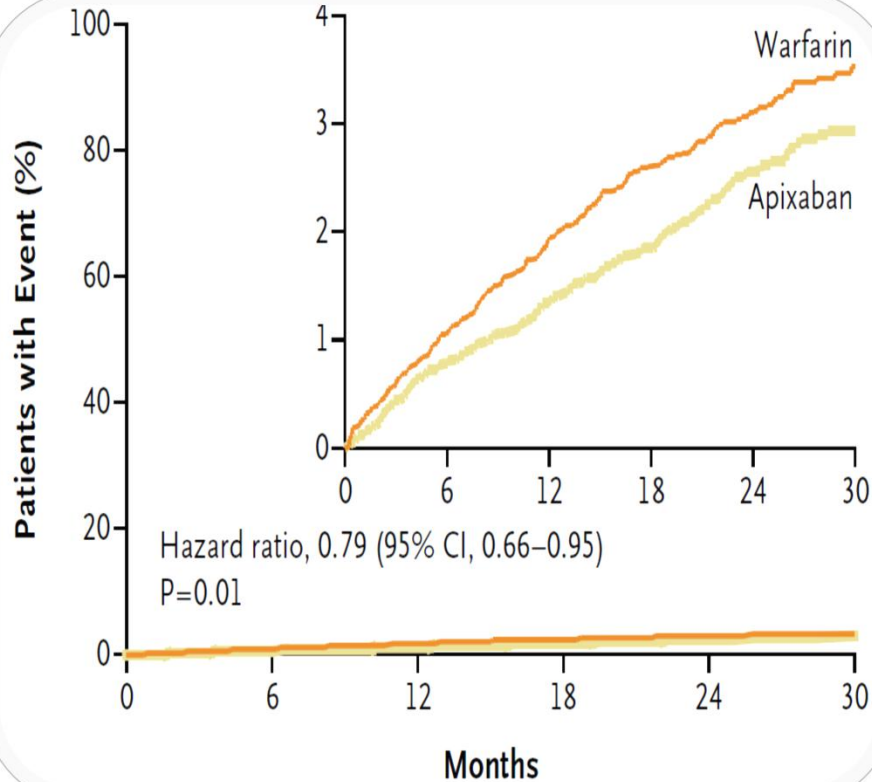
HR 0.88 (95% CI: 0.74–1.03)
 $P < 0.001$ for non-inferiority
 $P = 0.12$ for superiority

Stroke or Systemic Embolism

Major Bleeding



Stroke or Systemic Embolism



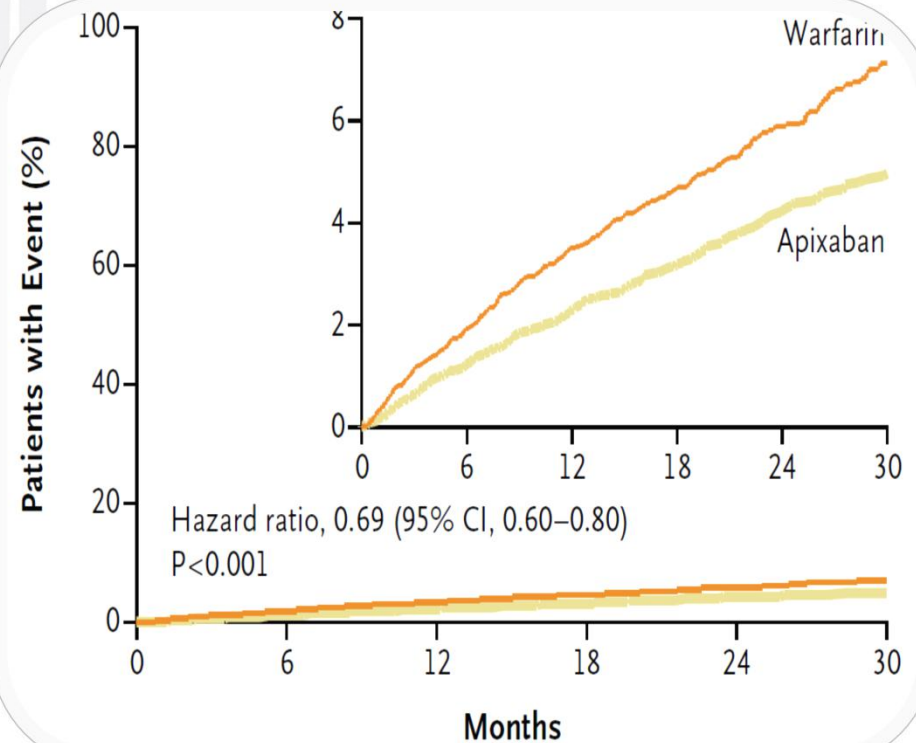
Major Bleeding

HR= 0.69 (95% CI= 0.60-0.80)

ARISTOTELE

Apixaban versus Warfarin in Patients with Atrial Fibrillation

HR= 0.79 (95% CI= 0.66-0.95)

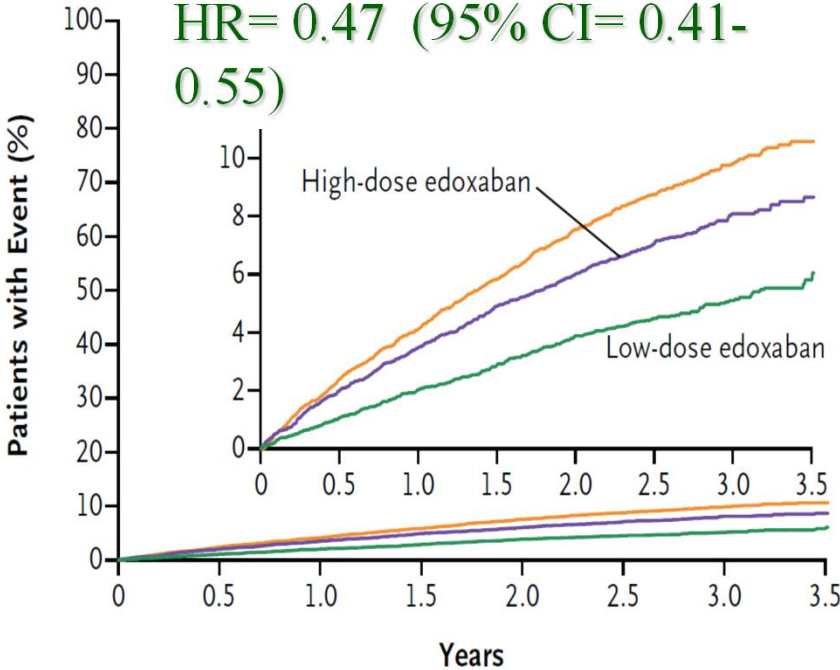


ENGAGE

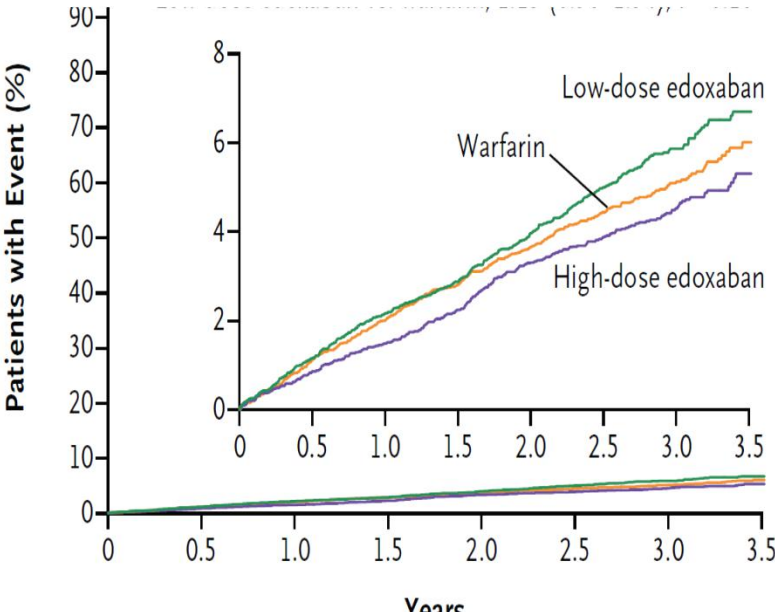
Edoxaban versus Warfarin in Patients with Atrial Fibrillation

Stroke or Systemic Embolism

HR= 0.80 (95% CI= 0.71-0.87)
 HR= 0.47 (95% CI= 0.41-0.55)



HR= 0.87 (95% CI= 0.73-1.04)



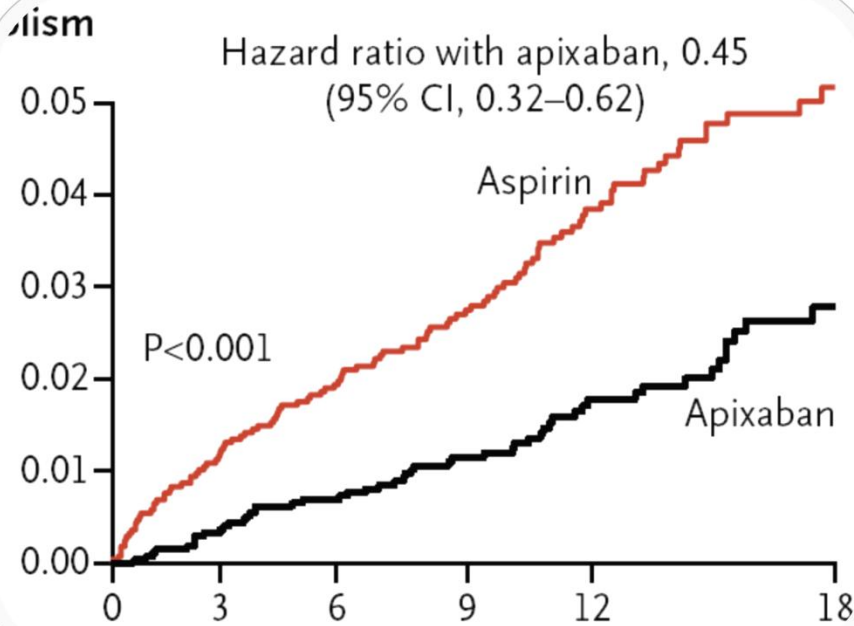
HR= 1.13 (95% CI= 0.96-1.34)

Major Bleeding

Event rate	
EDOXYBAN 60 mg	2.75 % / yr
EDOXYBAN 30 mg	1.61 % / yr
WARFARIN	3.43 % / yr

AVERROES

Apixaban in Patients with Atrial Fibrillation Stroke or Systemic Embolism



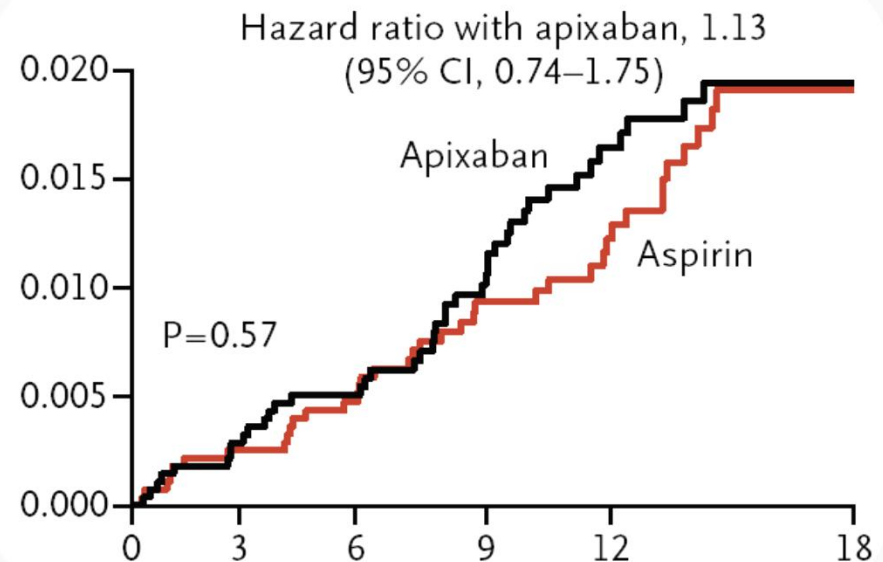
Major Bleeding

HR=1.13

Event rate	
APIXABAN (5 mg bid)	1.4 % / yr
ASPIRIN (81-324 mg)	1.2 % / yr

Event rate	
APIXABAN (5 mg bid)	1.6 % / yr
ASPIRIN (81-324 mg)	3.7 % / yr

HR=0.45



VTE Treatment Trials With NOACs

According to the ACCP 2012 guidelines, the framework of anticoagulation for VTE treatment includes initial (0 to ~7 days), long-term (~7 days to ~3 months) and extended treatment (~3 months to indefinite)¹

Initial 5 Days
of DVT
therapy

(Si...
ap...)

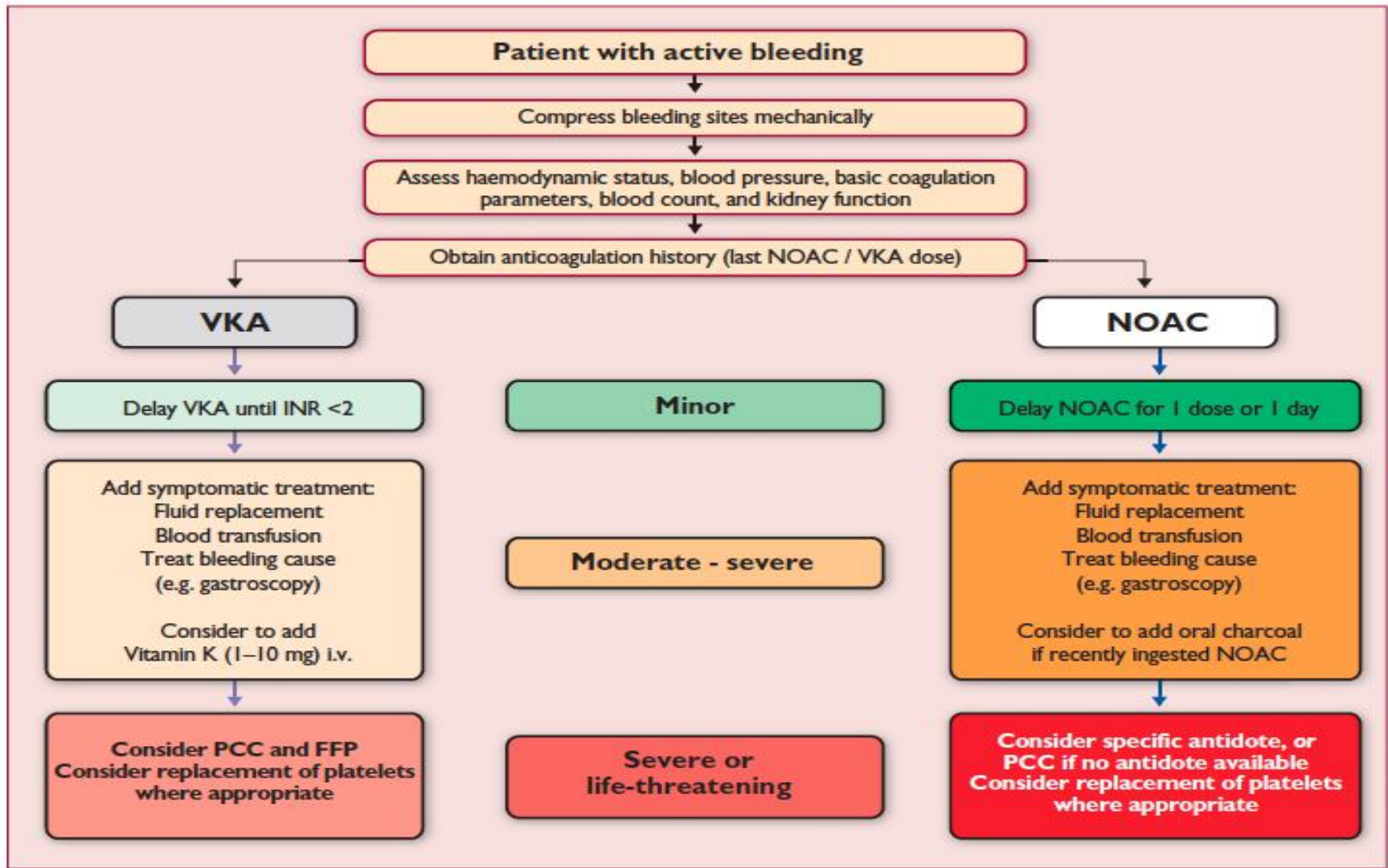
***2. In patients with DVT of the leg or PE and no cancer, as long-term (first 3 months) anticoagulant therapy, we suggest dabigatran, rivaroxaban, apixaban, or edoxaban over vitamin K antagonist (VKA) therapy (all Grade 2B).** [/journal.publications.chestnet.org/](http://journal.publications.chestnet.org/) on 03/24/2016

Yes	Dabigatran	RE-COVER ⁵	RE-MEDY ⁹
	Edoxaban	RE-COVER II ⁶	RE-SONATE ⁹
		Hokusai-VTE ⁷	—

ACCP=American College of Chest Physicians.

1. Kearon et al. *Chest*. 2012;141(2):e419S-e494S.
2. Agnelli G et al. *N Engl J Med*. 2013;369:799-808.
3. Bauersachs R et al. *N Engl J Med*. 2010;363:2499-2510.
4. Büller HR et al. *N Engl J Med*. 2012;366:1287-1297.

5. Schulman S et al. *N Engl J Med*. 2009;361:2342-2352.
6. Schulman S et al. *Circulation*. 2014;129:764-772.
7. Büller HR et al. *N Engl J Med*. 2013;369:1406-1415.
8. Agnelli G et al. *N Engl J Med*. 2013;368:699-708.
9. Schulman S et al. *N Engl J Med*. 2013;368:709-718.



FFP = fresh frozen plasma; INR = international normalized ratio; i.v. = intravenous; NOAC = non-vitamin K antagonist oral anticoagulant; OAC = oral anticoagulation; PCC = prothrombin complex concentrates; VKA = vitamin K antagonist.



REAL WORLD



TRIALS

TRIALS



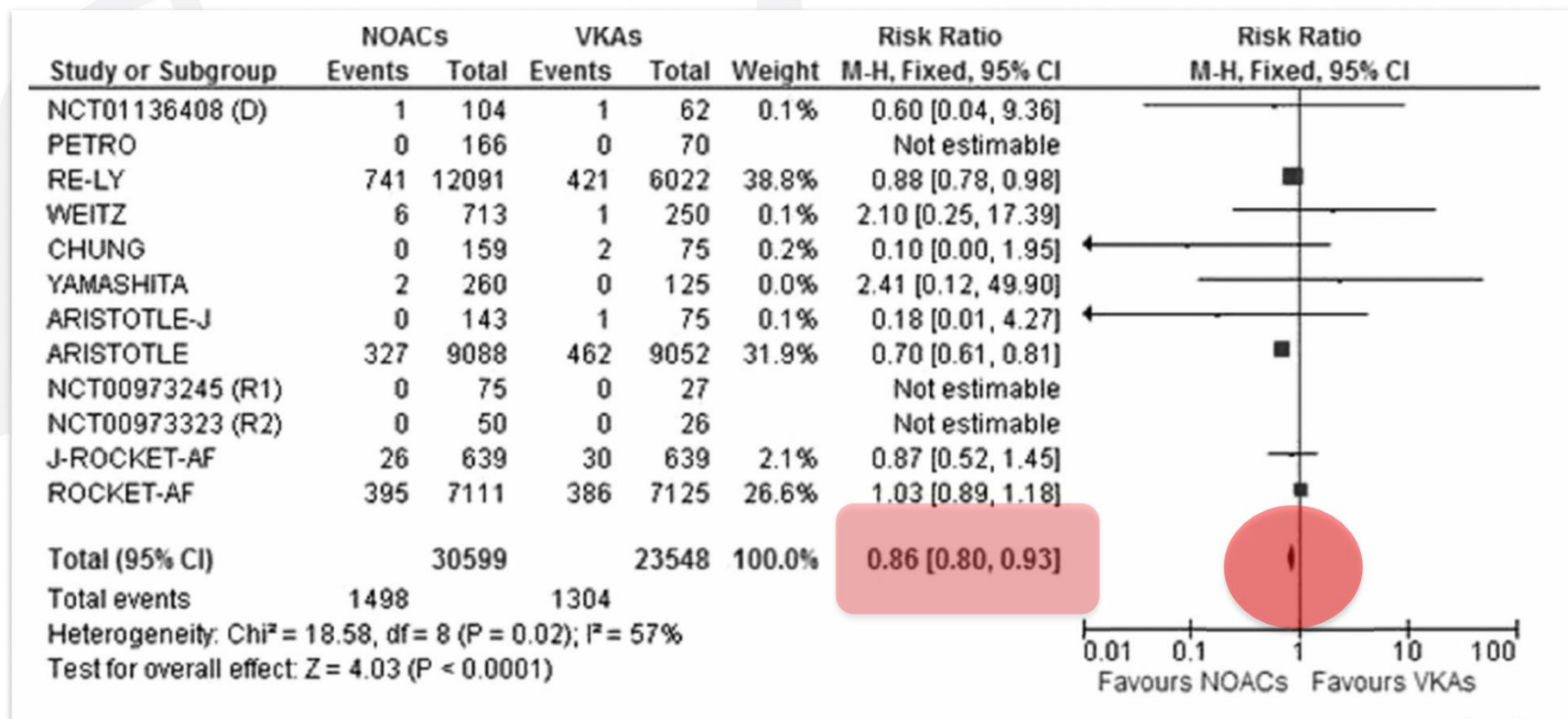
REAL WORLD



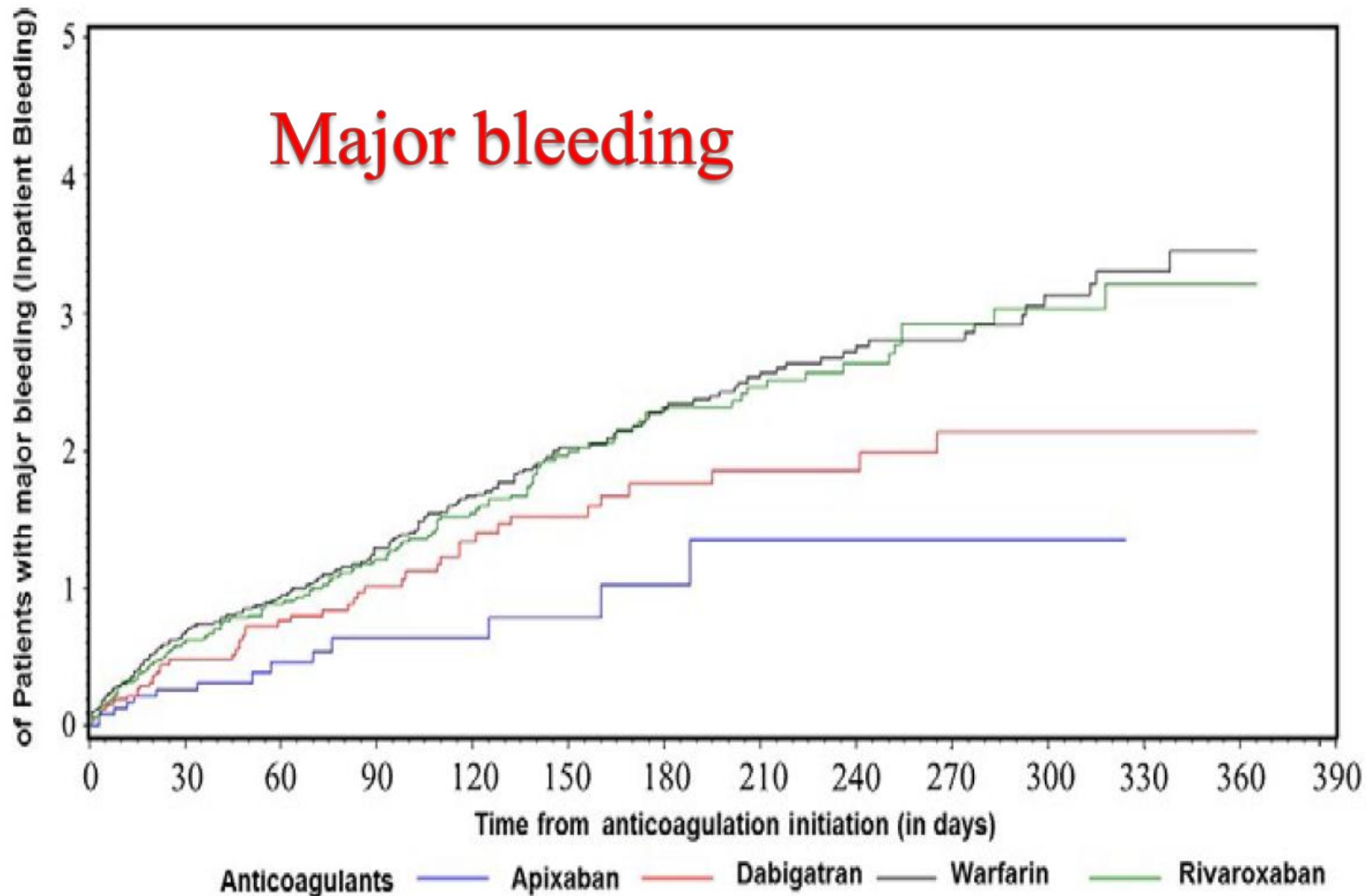
Efficacy and Safety of the Novel Oral Anticoagulants in Atrial Fibrillation

A Systematic Review and Meta-Analysis of the Literature

Major Bleeding

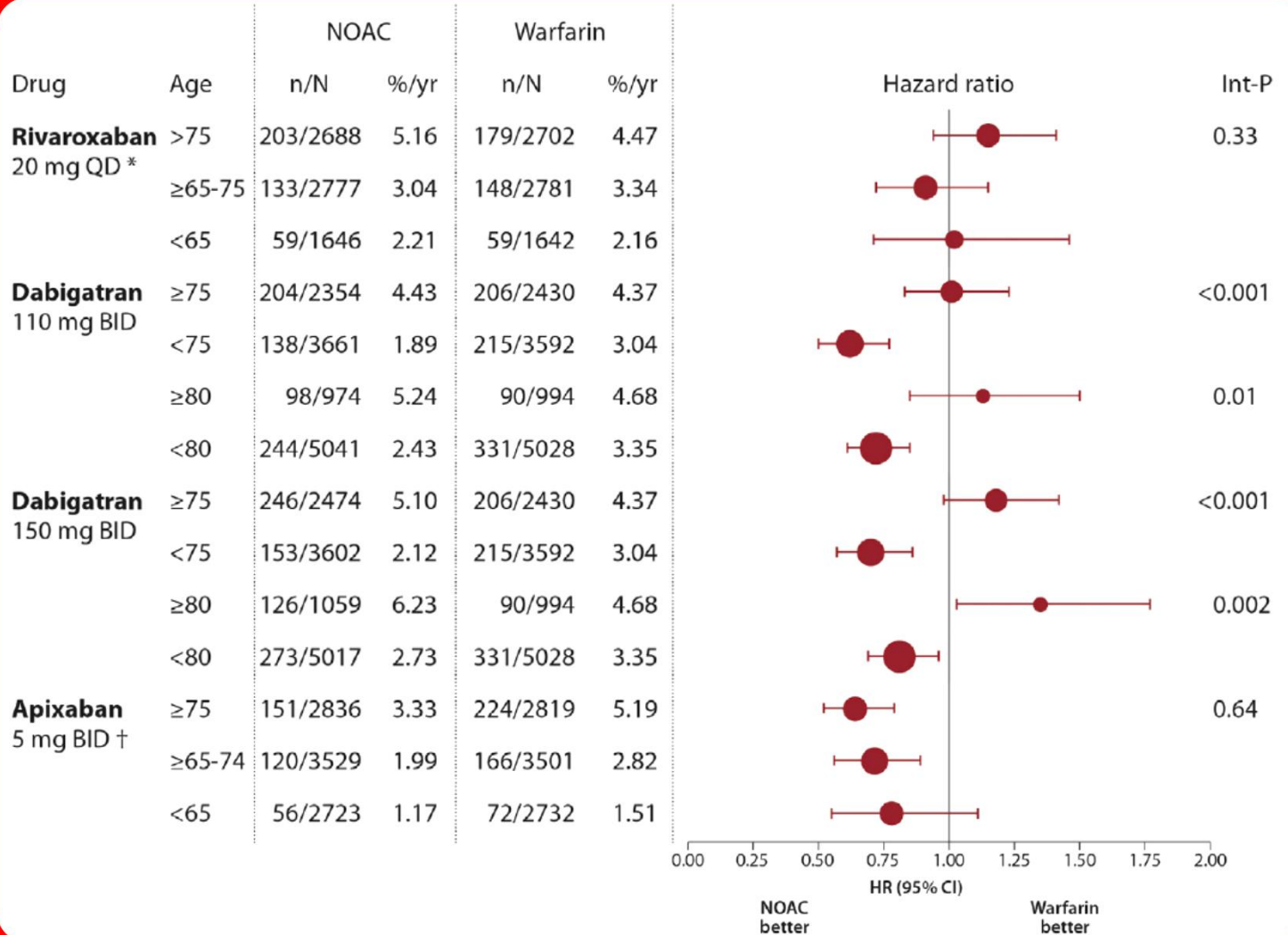


Major bleeding risk among non-valvular atrial fibrillation patients initiated on apixaban, dabigatran, rivaroxaban or warfarin: a “real-world” observational study in the United States



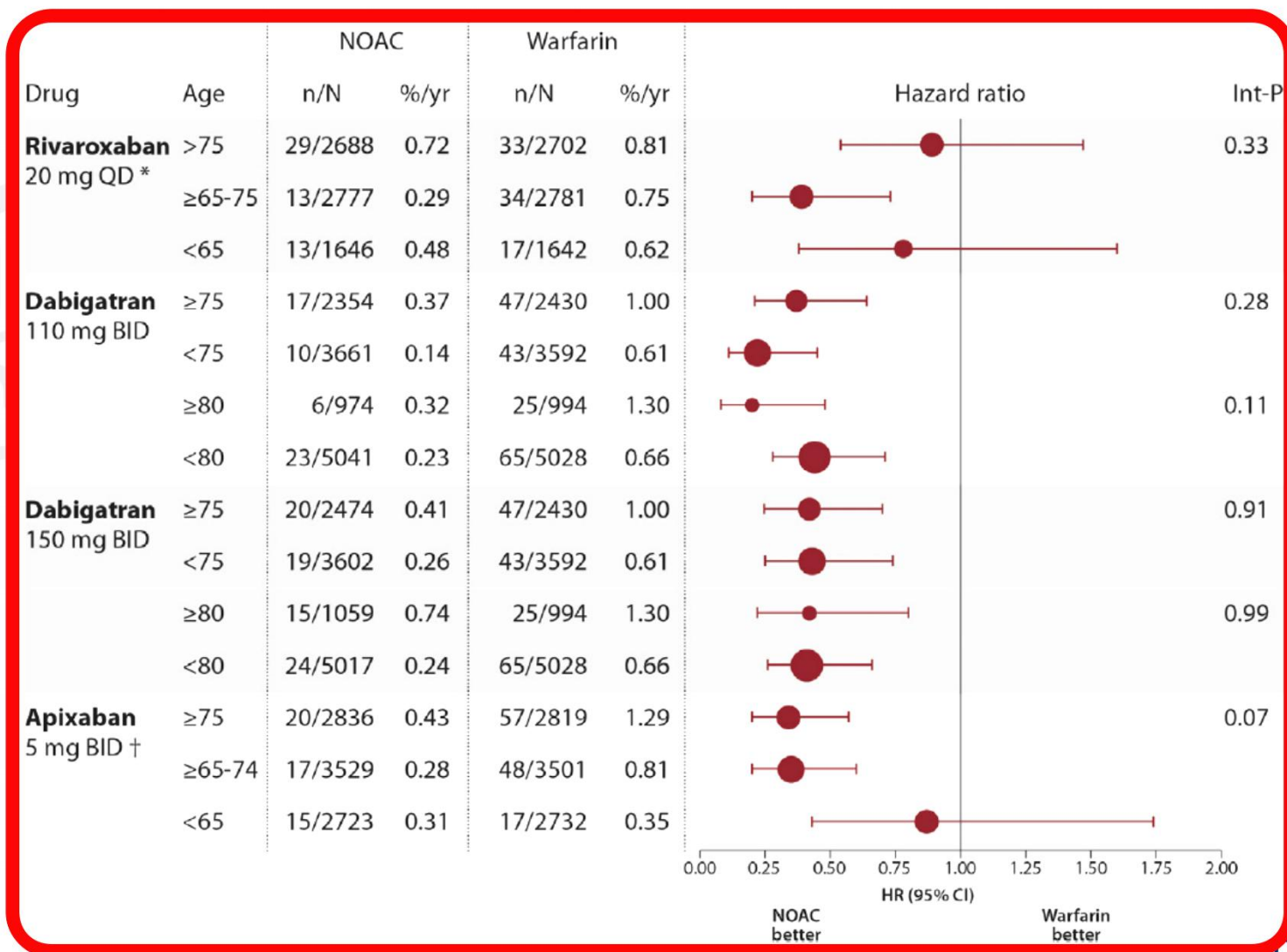
New oral anticoagulants in elderly patients

Major bleeding



New oral anticoagulants in elderly patients

Intracranial bleeding

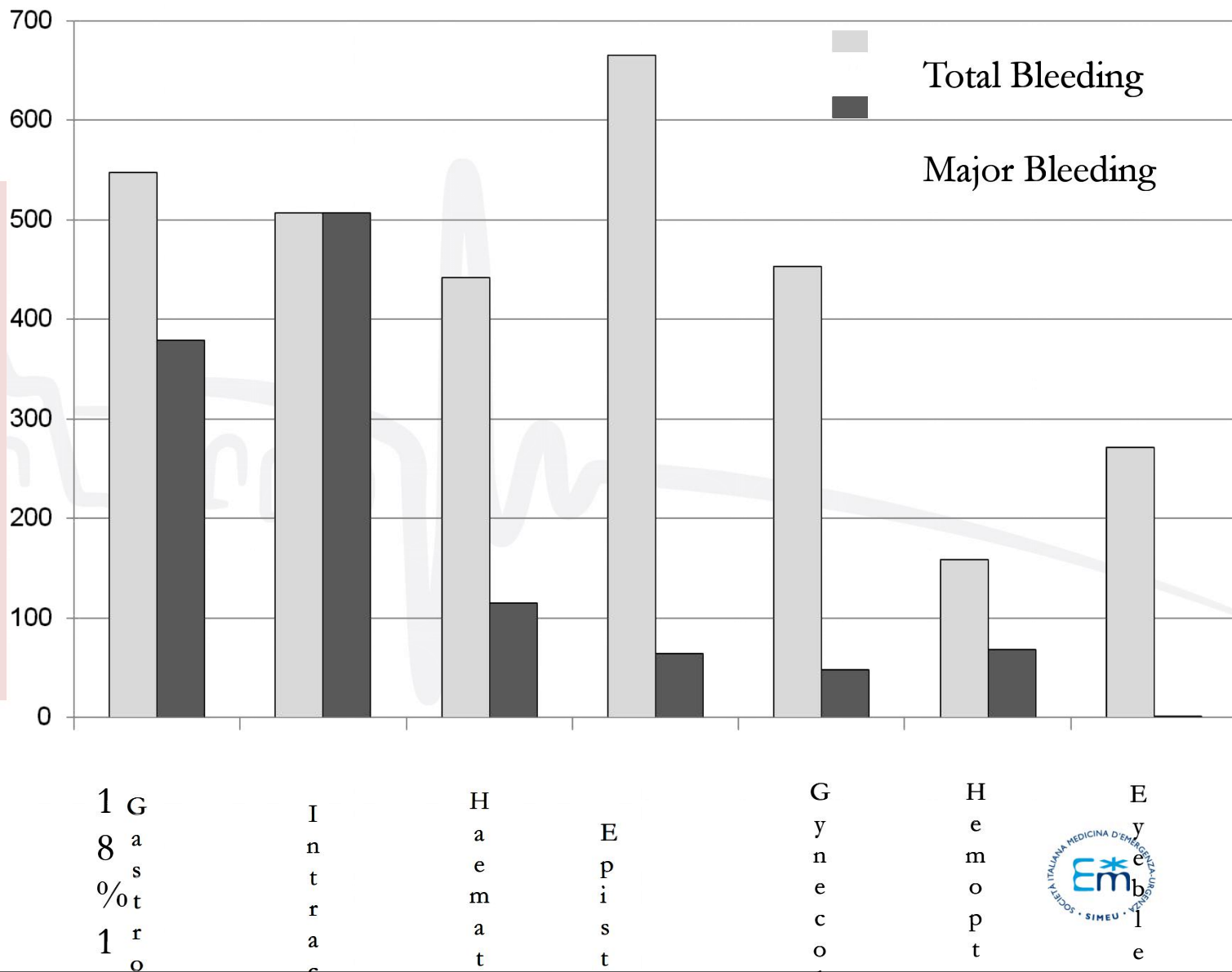


Gli eventi avversi in PS

Survey 2015-2016

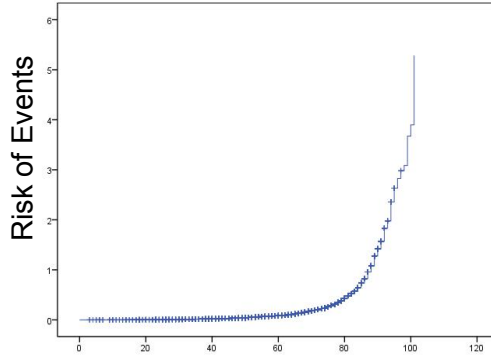
3.048 pazienti
con
eventi emorragici

PS
Ospedale
Apuane

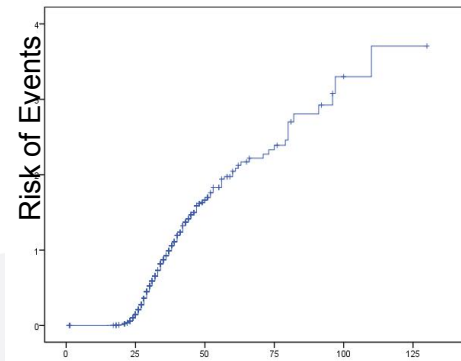


Cumulated risk of events about variables of Major clinical interest on presentation according to Kaplan-Meier analysis.

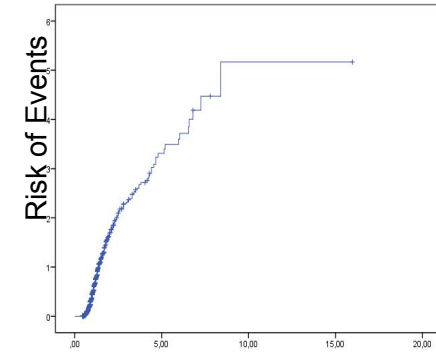
Age



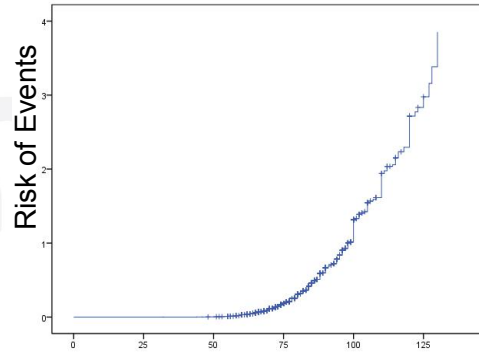
Partial Thrombin Time



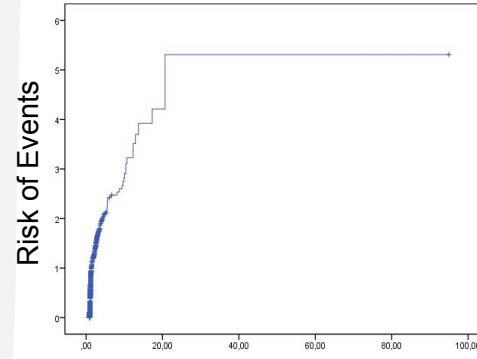
Creatinine



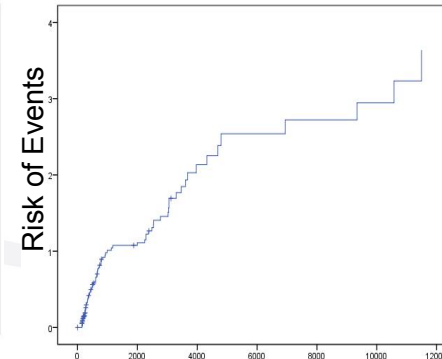
Heart Rate



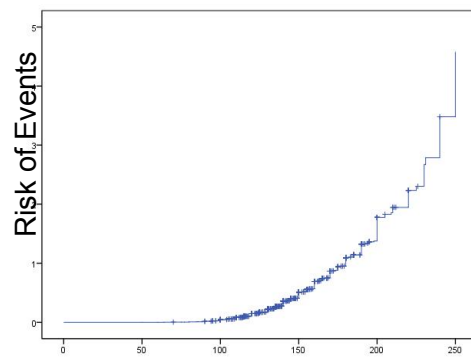
International Normalized Ratio



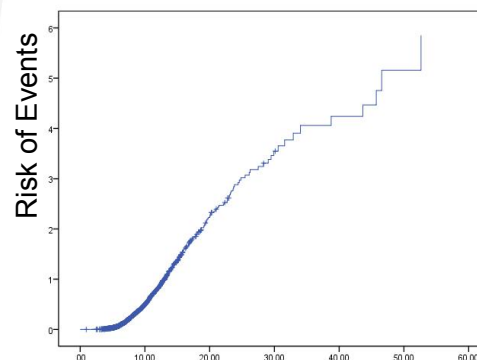
D-Dymer



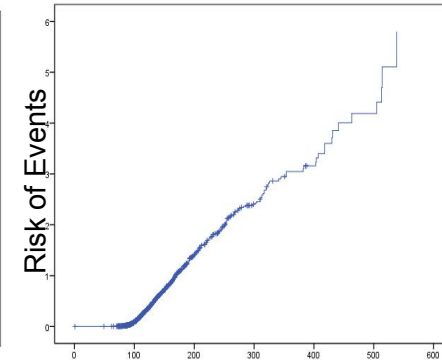
Systolic Arterial Pressure



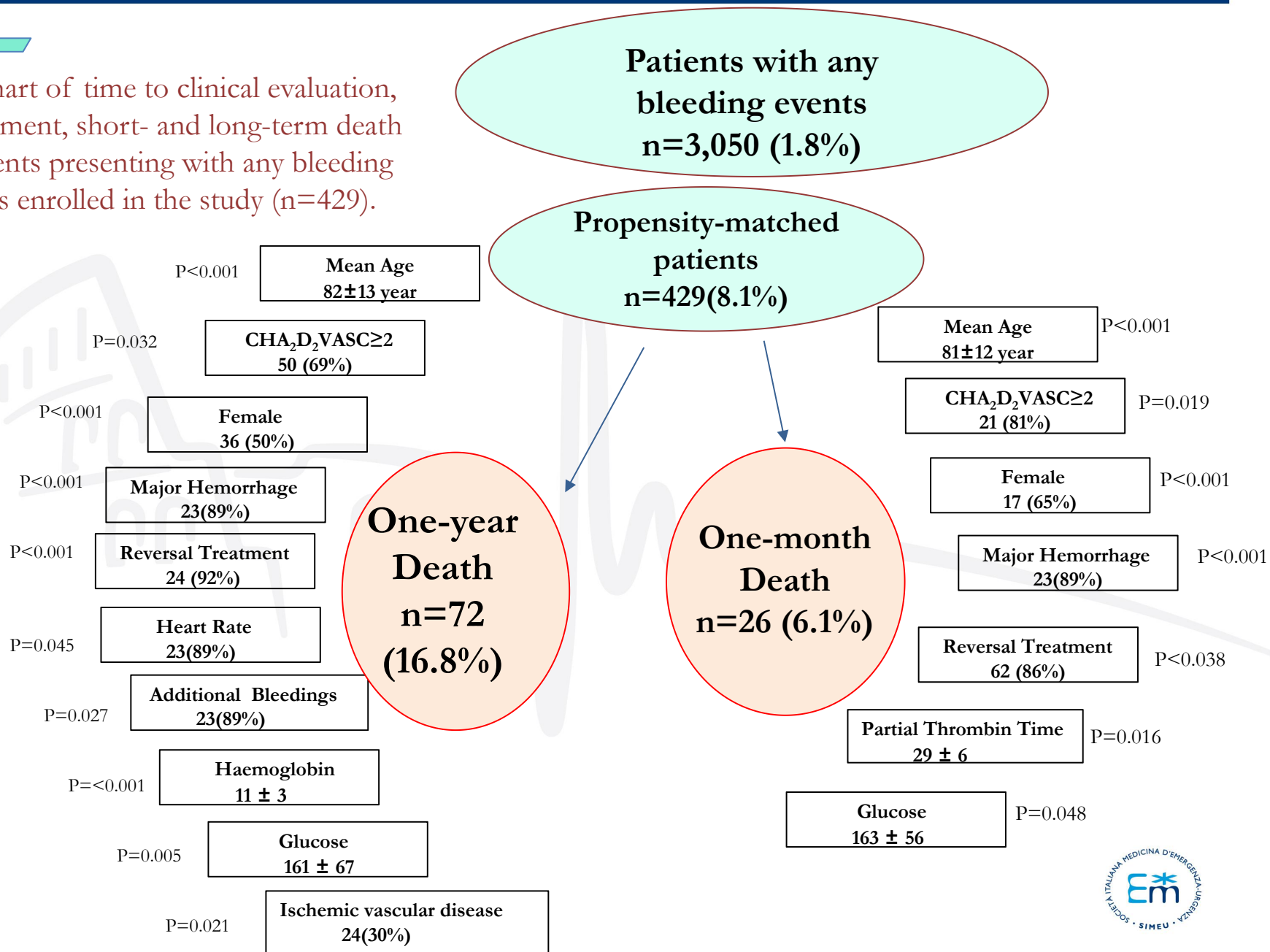
White Blood Cells



Glucose



The chart of time to clinical evaluation, management, short- and long-term death in patients presenting with any bleeding events enrolled in the study (n=429).



Thaca
 CHA₂D₂VASc score ≥2 p < 0.001
 382 (64%)

Anticoagulants
 287 (24%)

Ischemic Vascular
 Disease
 329 (28%)

Antiplatelets
 388 (33%)

Kidney
 Disease
 76 (6%)

Low Molecular Weight
 Heparin
 127 (11%)

Pulmonary Embolism or
 Deep Venous Thrombosis
 75 (3%)

Warfarin
 130 (11%)

Chronic Obstructive
 Pulmonary Disease
 128 (11%)

Direct Oral
 Anticoagulants
 33 (3%)

Major Bleeding
 1.185 (39%)
 Out of 3.048 patients
 with any bleeding
 events to the
 Emergency
 Department

Dilated Cardiomyopathy
 90 (8%)

Aspirin
 307 (26%)

Cancer
 204 (17%)

Clopidogrel
 118 (10%)

Reversal Treatment
 130 (1.1%)

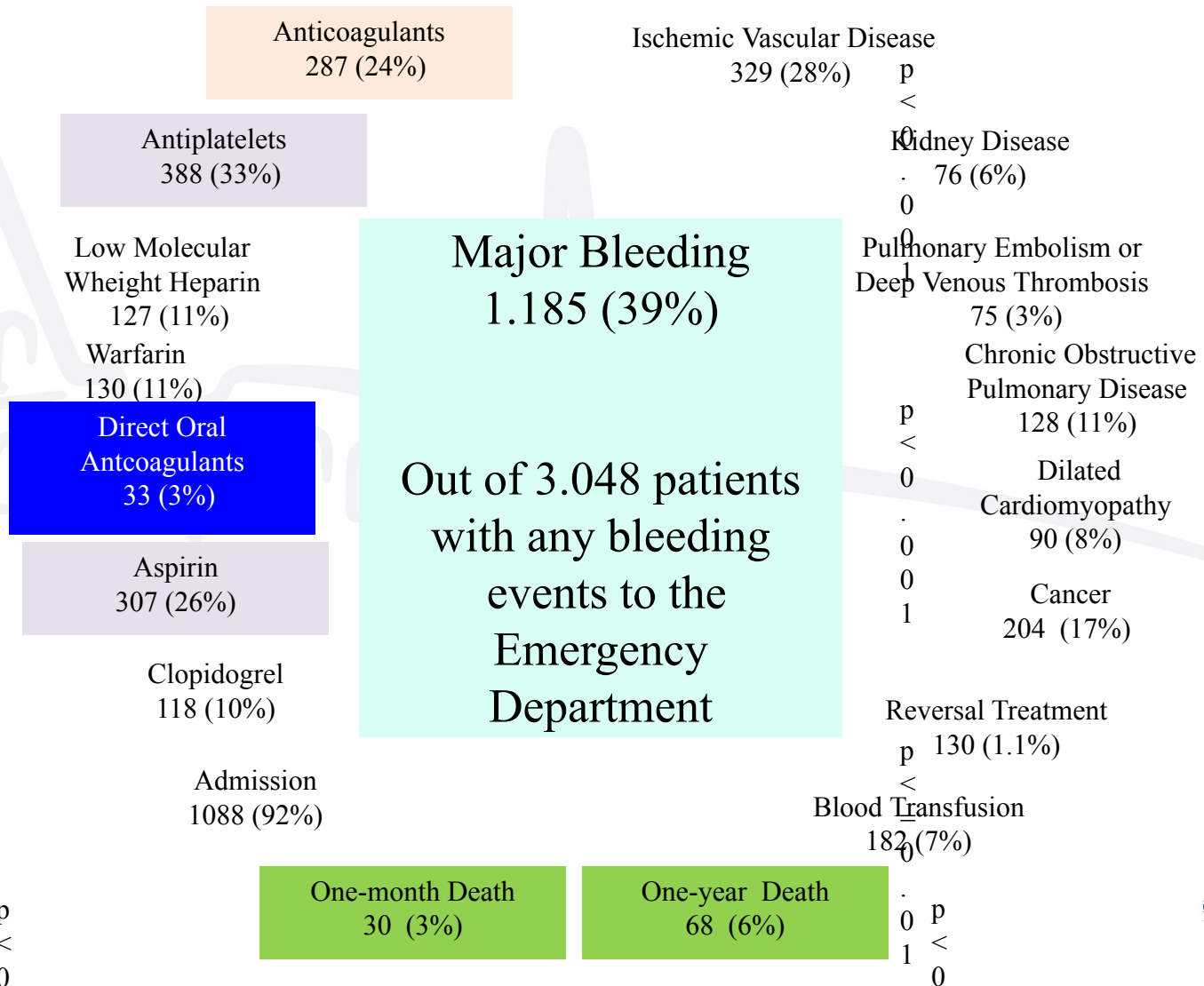
Admission
 1088 (92%)

Blood Transfusion
 182 (7%)

One-month Death
 30 (3%)

One-year Death
 68 (6%)

CHA₂D₂VASc score ≥2
 382 (64%) p < 0.001



p < 0

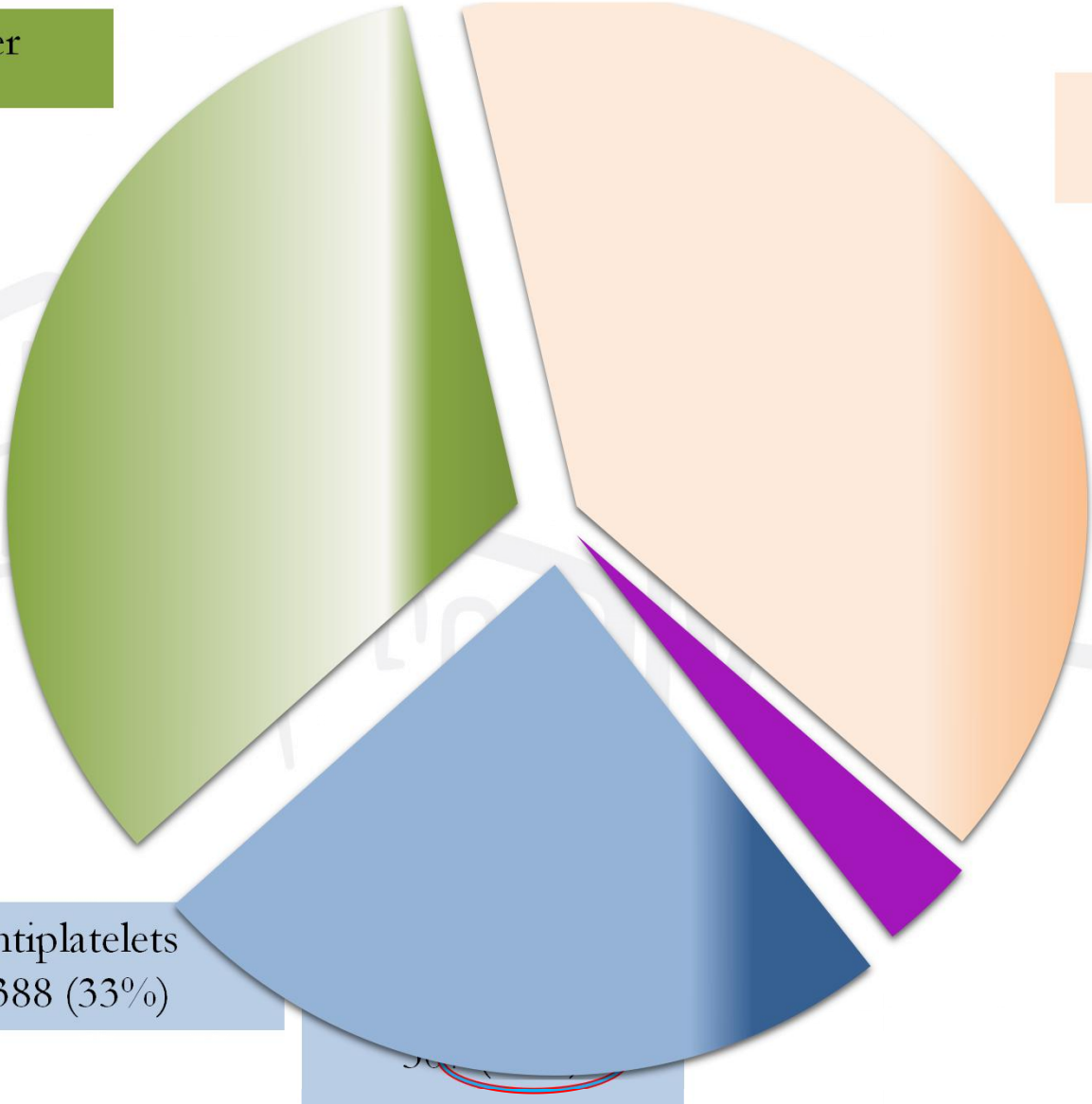


Other

Anticoagulants
287 (24%)

Direct Oral
Antcoagulants
33 (3%)

Antiplatelets
388 (33%)



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YAJEM-56753; No of Pages 6

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Short and long-term mortality of patients presenting with bleeding events to the Emergency Department☆☆☆

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^a North-West District Tuscany HealthCare, Apuane General Hospital, Emergency Department, Massa-Carrara, Italy

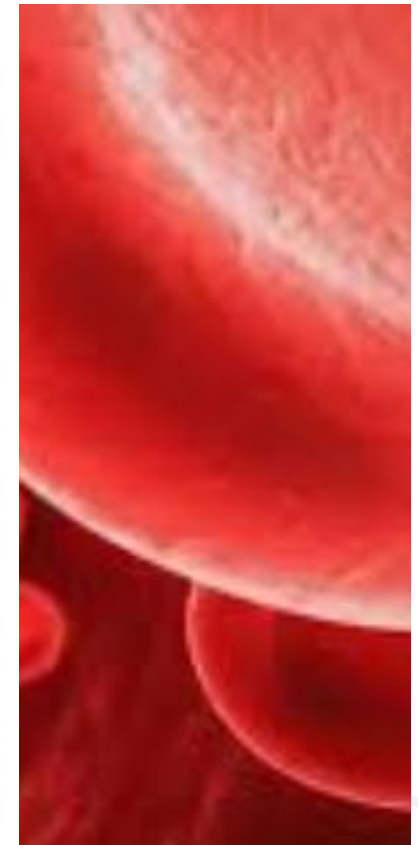
^b North-West District Tuscany HealthCare, Versilia and San Luca General Hospital, Emergency Department, Viareggio-Lucca, Italy

^c North-West District, Tuscany HealthCare, Spedali Riuniti Livorno, Emergency Department, Livorno, Italy

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Conclusions

Bleeding events to the emergency department accounts for 2% visits in a population based large survey. Death rate was substantially high at short- and long-term. Death rate was driven by major bleeding, female gender, white blood cells on short-term and older age on long-term, regardless of any treatment strategy. Patients presenting with gastrointestinal bleeding, intracranial bleeding or haematuria were more likely to die at one-month. Among dead patients mortality was approximately 40% on one-month; up to 60% in older patients, and up to 80% in female gender associated with CHA2D2VASC-score ≥ 2 .



Grazie per l'attenzione