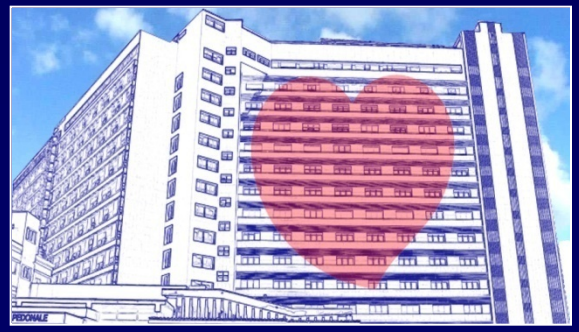
LA GESTIONE DEL PAZIENTE CON FIBRILLAZIONE ATRIALE

Convegno Associazione “G. Dossetti: i Valori”
“Fibrillazione Atriale e Ictus Cardioembolico:
Misure legislative, strategie di prevenzione, accesso alle cure”

Roma, 15 Maggio 2013

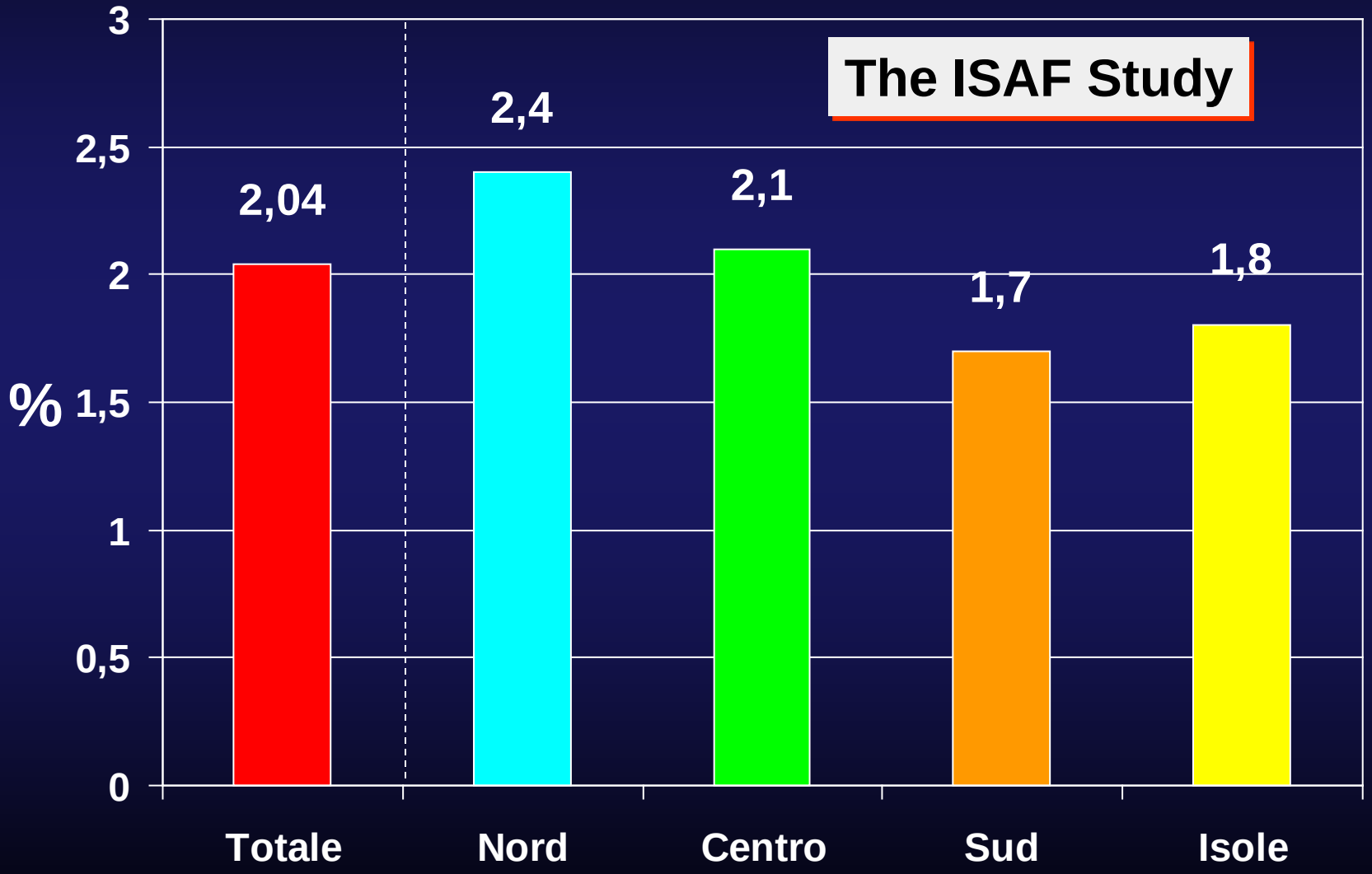
Giuseppe Di Pasquale
Direttore Dipartimento Medico ASL Bologna
Direttore Unità Operativa Cardiologia
Ospedale Maggiore, Bologna



Giuseppe Di Pasquale Disclosures

- **Member of the Steering Committee of the RELY and PALLAS trials**
- **Member of Advisory Board of Dabigatran, Rivaroxaban, Apixaban, Dronedarone**
- **Consulting fees / honoraria**
  - Boehringer Ingelheim
  - Bayer AG
  - Sanofi Aventis
  - BMS / Pfizer

Prevalenza della Fibrillazione Atriale in Italia (Nei soggetti di età ≥ 15 anni assistiti da MMG)



Zoni-Berisso M et al. Am J Cardiol 2013;111:705-711

Studio FIRE

Il peso della FA/fa sull'attività del Pronto Soccorso

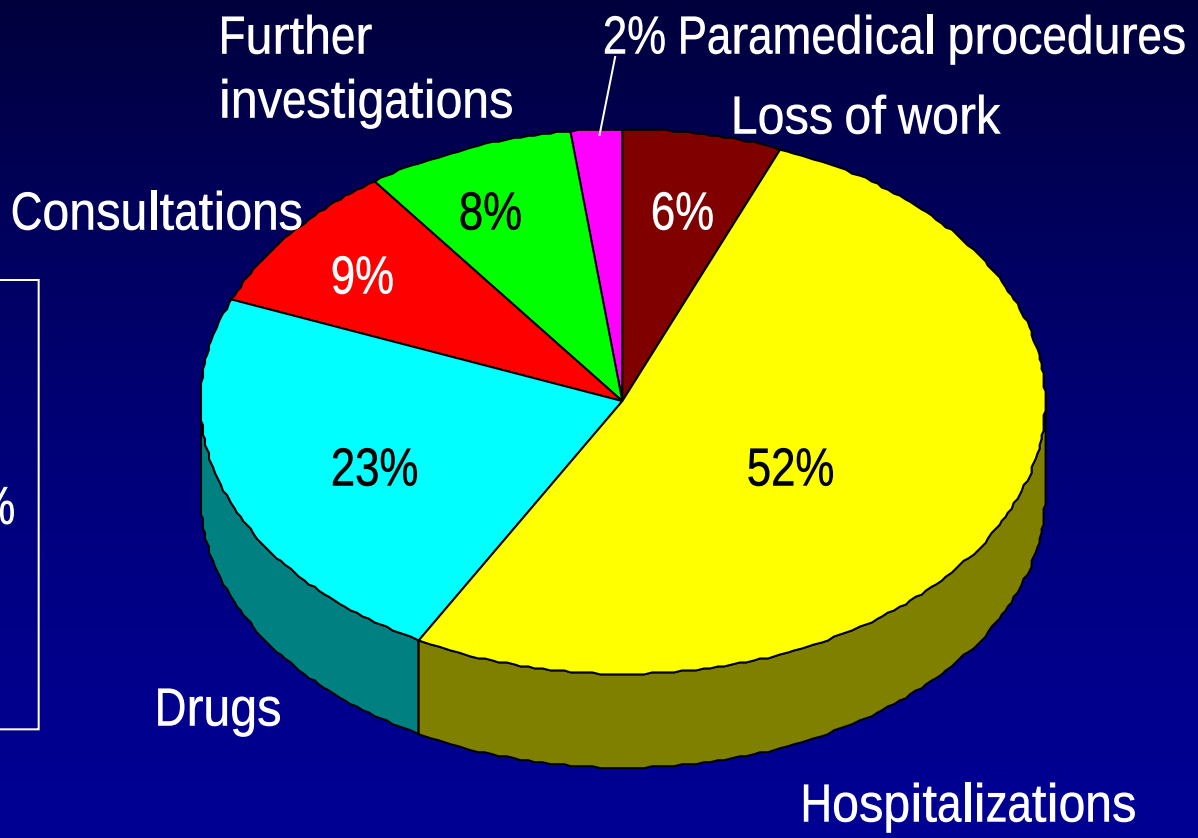
	Totali	Per FA/fa	
Numero accessi al PS	308.191	4.570	1,5%
Ricoveri ospedalieri	86.603	2.838	3,3%
	28,1%	61,9%	

I pazienti con FA o fa hanno un tasso di ospedalizzazione doppio rispetto a tutti gli altri

Santini M et al., Ital Heart J 2004; 5(3): 205-13

Distribution of Costs of Care in Atrial Fibrillation in the Societal Perspective: The COCAF Study

- 671 pts
- Mean age 69 yrs
- Paroxysmal AF 46%
- Persistent/permanent AF 54%
- Follow-up 1 year
  - death 21 (3%)
  - hospitalization 210 (31%)



Le Heuzey JY et al. Am Heart J 2004; 147: 121-26

European Heart Journal (2010) 31, 2369–2429
doi:10.1093/eurheartj/ehq278

Guidelines for the management of atrial fibrillation

The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA)†

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: A. John Camm (Chairperson) (UK)*, Paulus Kirchhof (Germany), Gregory Y. H. Lip (UK), Ulrich Schotten (The Netherlands), Irene Savelieva (UK), Sabine Ernst (UK), Isabelle C. Van Gelder (The Netherlands), Nawwar Al-Attar (France), Gerhard Hindricks (Germany), Bernard Prendergast (UK), Hein Heidbuchel (Belgium), Ottavio Alfieri (Italy), Annalisa Angelini (Italy), Dan Atar (Norway), Paolo Colonna (Italy), Raffaele De Caterina (Italy), Johan De Sutter (Belgium), Andreas Goette (Germany), Bulent Gorenek (Turkey), Magnus Heldal (Norway), Stefan H. Hohloser (Germany), Philippe Kolh (Belgium), Jean-Yves Le Heuzey (France), Piotr Ponikowski (Poland), Frans H. Rutten (The Netherlands).

European Heart Journal
doi:10.1093/eurheartj/ehs253

ESC GUIDELINES

2012 focused update of the ESC Guidelines for the management of atrial fibrillation

An update of the 2010 ESC Guidelines for the management of atrial fibrillation
Developed with the special contribution of the European Heart Rhythm Association

Authors/Task Force Members: A. John Camm (Chairperson) (UK)*, Gregory Y.H. Lip (UK), Raffaele De Caterina (Italy), Irene Savelieva (UK), Dan Atar (Norway), Stefan H. Hohnloser (Germany), Gerhard Hindricks (Germany), Paulus Kirchhof (UK)

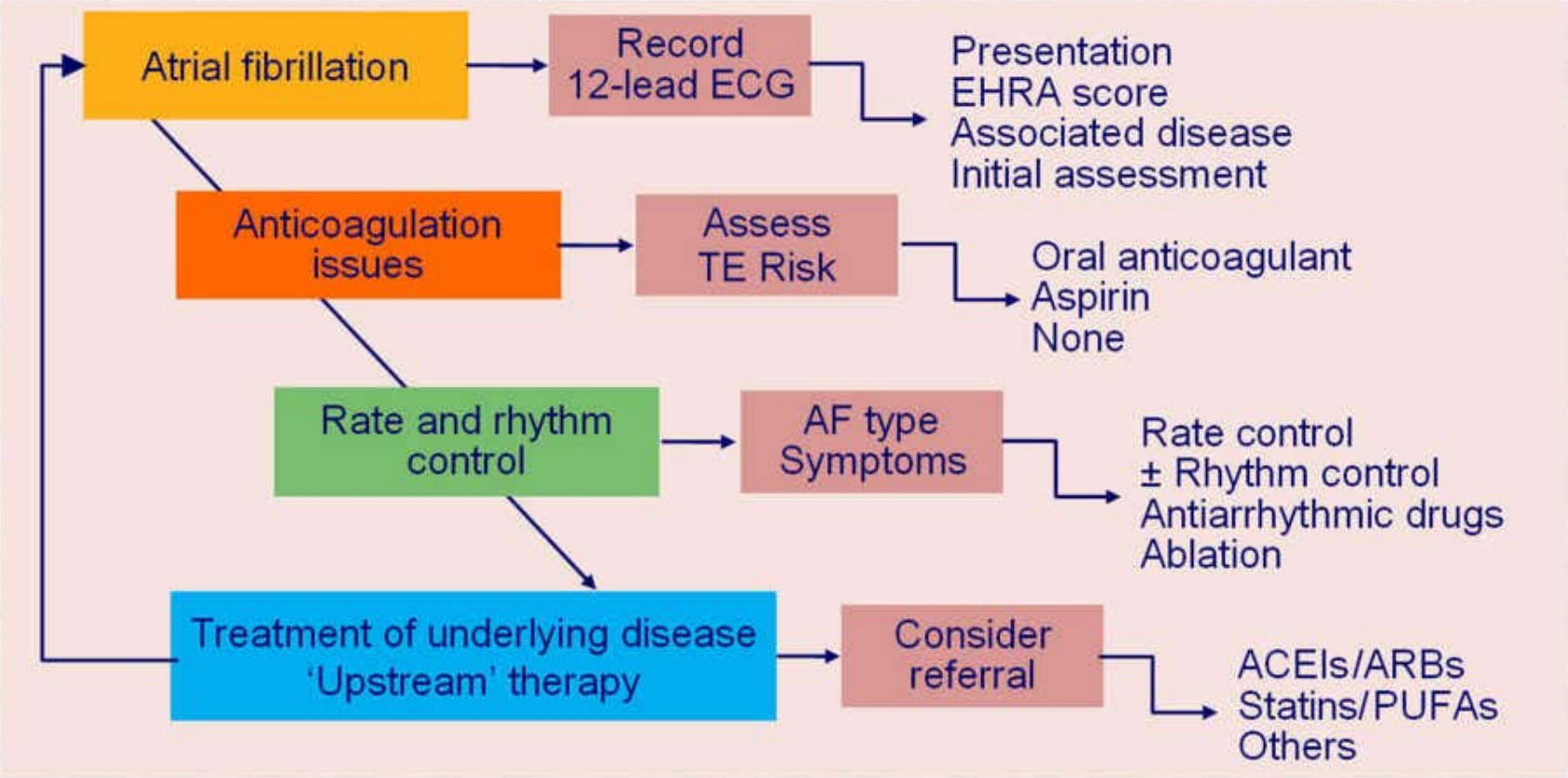
Eur Heart J August 2012

Linee guida AIAC per la gestione e il trattamento della fibrillazione atriale. Aggiornamento 2013

Antonio Raviele (Chairman)[1], Marcello Disertori[2] (Co-Chairman), Paolo Alboni[3], Emanuele Bertaglia[4], Gianluca Botto[5], Michele Brignole[6], Riccardo Cappato[7], Alessandro Capucci[8], Maurizio Del Greco[2], Roberto De Ponti[9], Matteo Di Biase[10], Giuseppe Di Pasquale[11], Michele Gulizia[12], Federico Lombardi[13], Sakis Themistoclakis[14], Massimo Tritto[15]

G Ital Cardiol 2013; 14 (3): 215 - 40

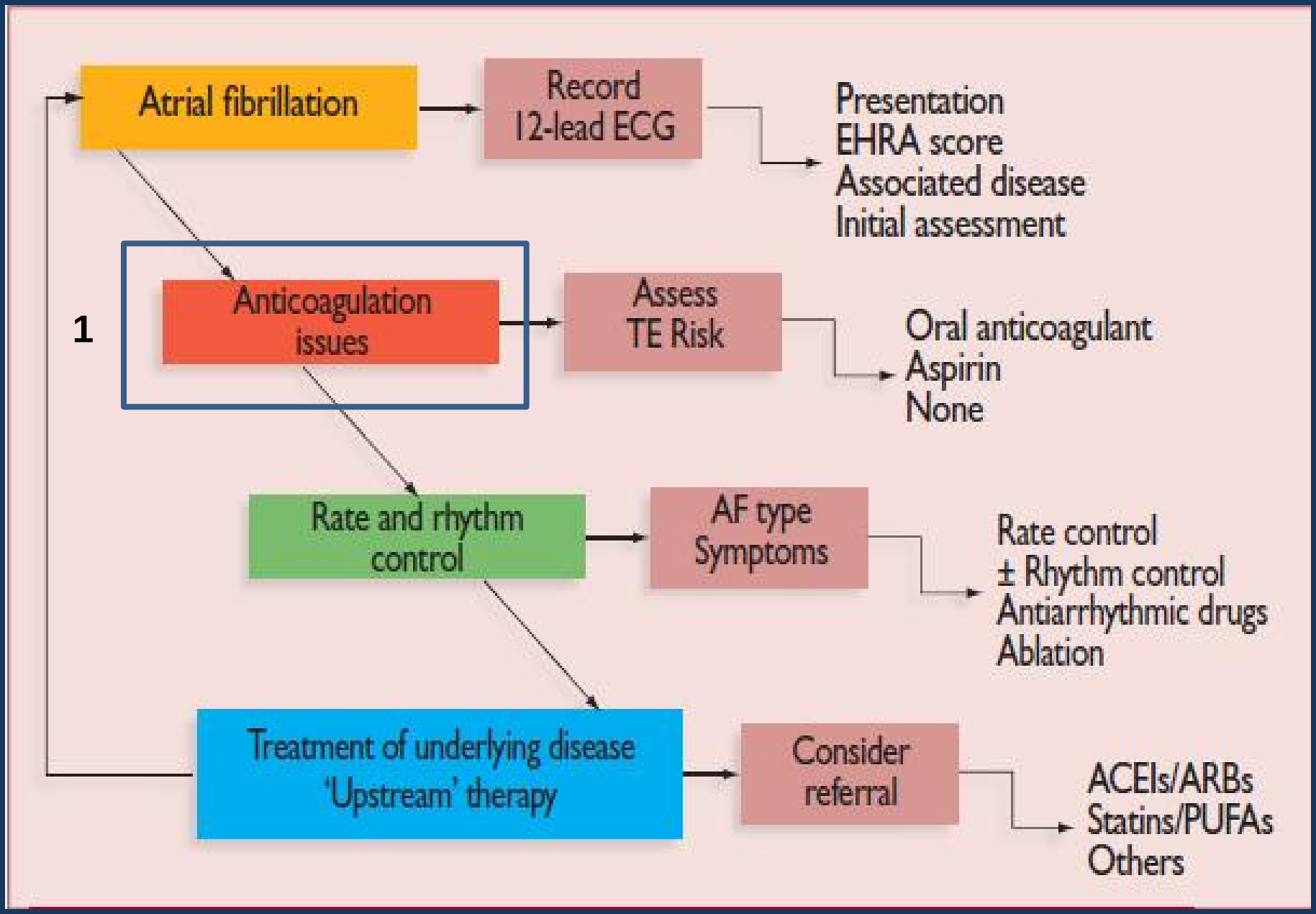
The management cascade for patients with AF



ACEI = angiotensin-converting enzyme inhibitor; AF = atrial fibrillation; ARB = angiotensin receptor blocker; PUFA = polyunsaturated fatty acid; TE = thrombo-embolism.

European Heart Journal (2010) 31, 2369-2429

EUROPEAN SOCIETY OF CARDIOLOGY®


Atrial fibrillation
Record 12-lead ECG
Presentation
EHRA score
Associated disease
Initial assessment
1
Anticoagulation issues
Assess TE Risk
Oral anticoagulant
Aspirin
None
Rate and rhythm control
AF type
Symptoms
Rate control
± Rhythm control
Antiarrhythmic drugs
Ablation
Treatment of underlying disease
'Upstream' therapy
Consider referral
ACEIs/ARBs
Statins/PUFAs
Others

$CHADS_2$ Score

Risk Factor	SCORE
CHF / LV dysfunction	1
Hypertension	1
Age > 75 years	1
Diabetes mellitus	1
Stroke / TIA	2

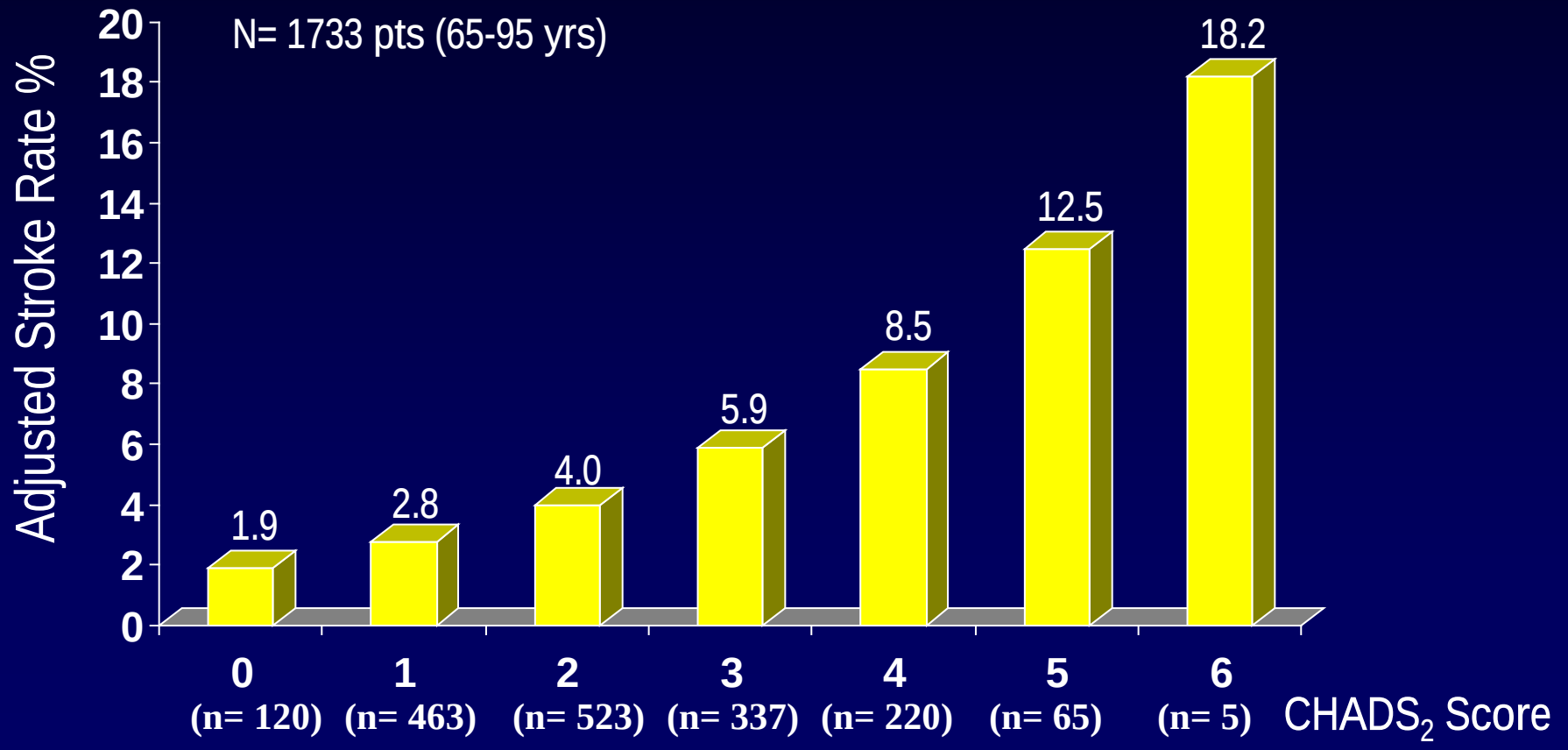
Gage BF et al. JAMA 2001; 285: 2864-70

$CHADS_2$ Score: Validation for Predicting Stroke

US National Registry of AF

- AFI scheme
- SPAF scheme

$CHADS_2$ index



1 point: recent CHF, hypertension, age ≥ 75 years, diabetes mellitus

2 points: prior stroke or TIA

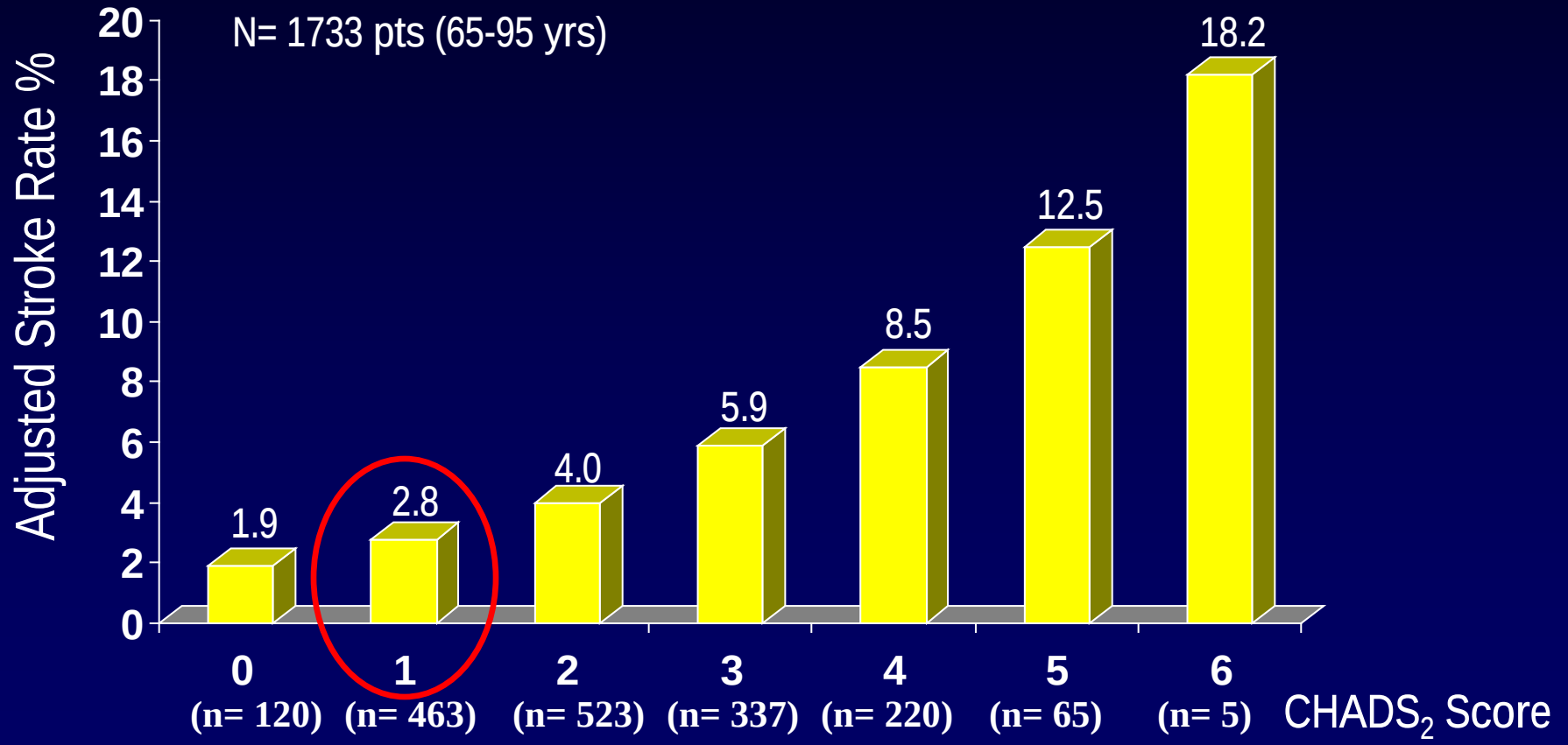
Gage BF et al. JAMA 2001; 285: 2864-70

$CHADS_2$ Score: Validation for Predicting Stroke

US National Registry of AF

- AFI scheme
- SPAF scheme

$CHADS_2$ index



1 point: recent CHF, hypertension, age ≥ 75 years, diabetes mellitus

2 points: prior stroke or TIA

Gage BF et al,. JAMA 2001; 285: 2864-70

CHEST

Original Research

THROMBOEMBOLISM

Refining Clinical Risk Stratification for Predicting Stroke and Thromboembolism in Atrial Fibrillation Using a Novel Risk Factor-Based Approach

The Euro Heart Survey on Atrial Fibrillation

Gregory Y. H. Lip, MD; Robby Nieuwlaat, PhD; Ron Pisters, MD; Deirdre A. Lane, PhD; and Harry J. G. M. Crijns, MD

CHEST 2010; 137(2):263–272

CHA_2DS_2 - VASc Score

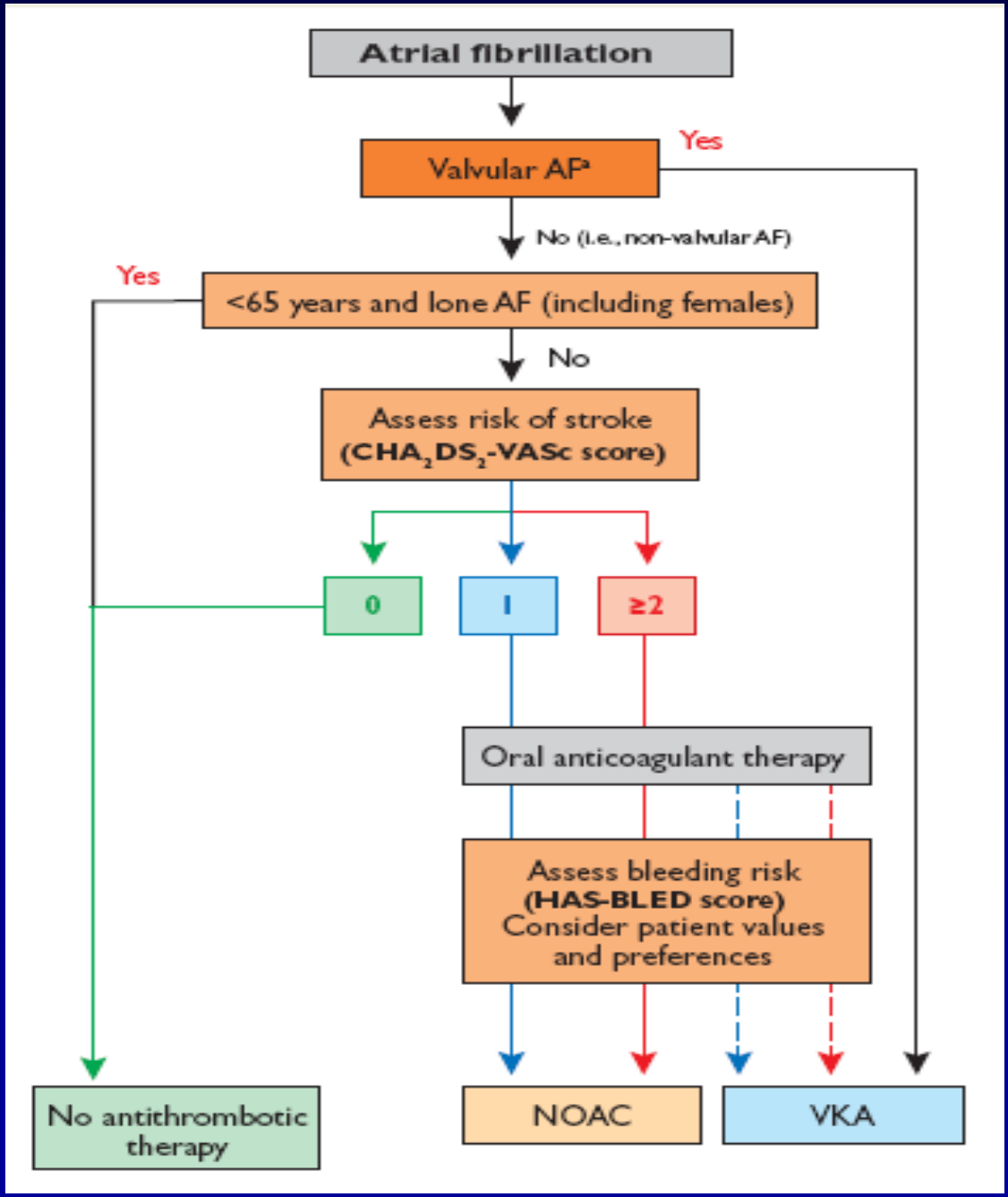
Risk Factor	Score
Congestive heart failure / LV dysfunction	1
Hypertension	1
Age ≥ 75 y	2
Diabetes mellitus	1
Stroke / TIA / systemic embolism	2
Vascular disease (prior myocardial infarction, peripheral artery disease or aortic plaque)	1
Age 65 - 74 y	1
Sex category (ie female gender)	1

Lip GYH et al. Chest 2010;137(2): 263-72

Relationship between AF scores and stroke rate

$CHADS_2$	Adjusted stroke rate % year
0	1.9 (1.2-3.0)
1	2.8 (2.0-3.8)
2	4.0 (3.1-5.1)
3	5.9 (4.6-7.3)
4	8.5 (6.3-11.1)
5	12.5 (8.2-17.5)
6	18.2 (10.5-27.4)

CHA_2DS_2-VASc	Adjusted stroke rate (% year)
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7
6	9.8
7	9.6
8	6.7
9	15.2



Eur Heart J Aug 2012

Bleeding Risk

… an assessment of bleeding risk should be part of the patient assessment before starting anticoagulation…

ESC AF GUIDELINES 2010

HAS-BLED Bleeding Risk Score

H	1 point	Hypertension
A	1 or 2 points	Abnormal renal and liver function
S	1	Stroke
B	1	Bleeding
L	1	Labile INRs
E	1	Eldery (e.g. age > 65 years)
D	1 or 2 points	Drugs or alcohol

Maximum 9 points

Pisters R et al. Chest 2010

CMAJ RESEARCH

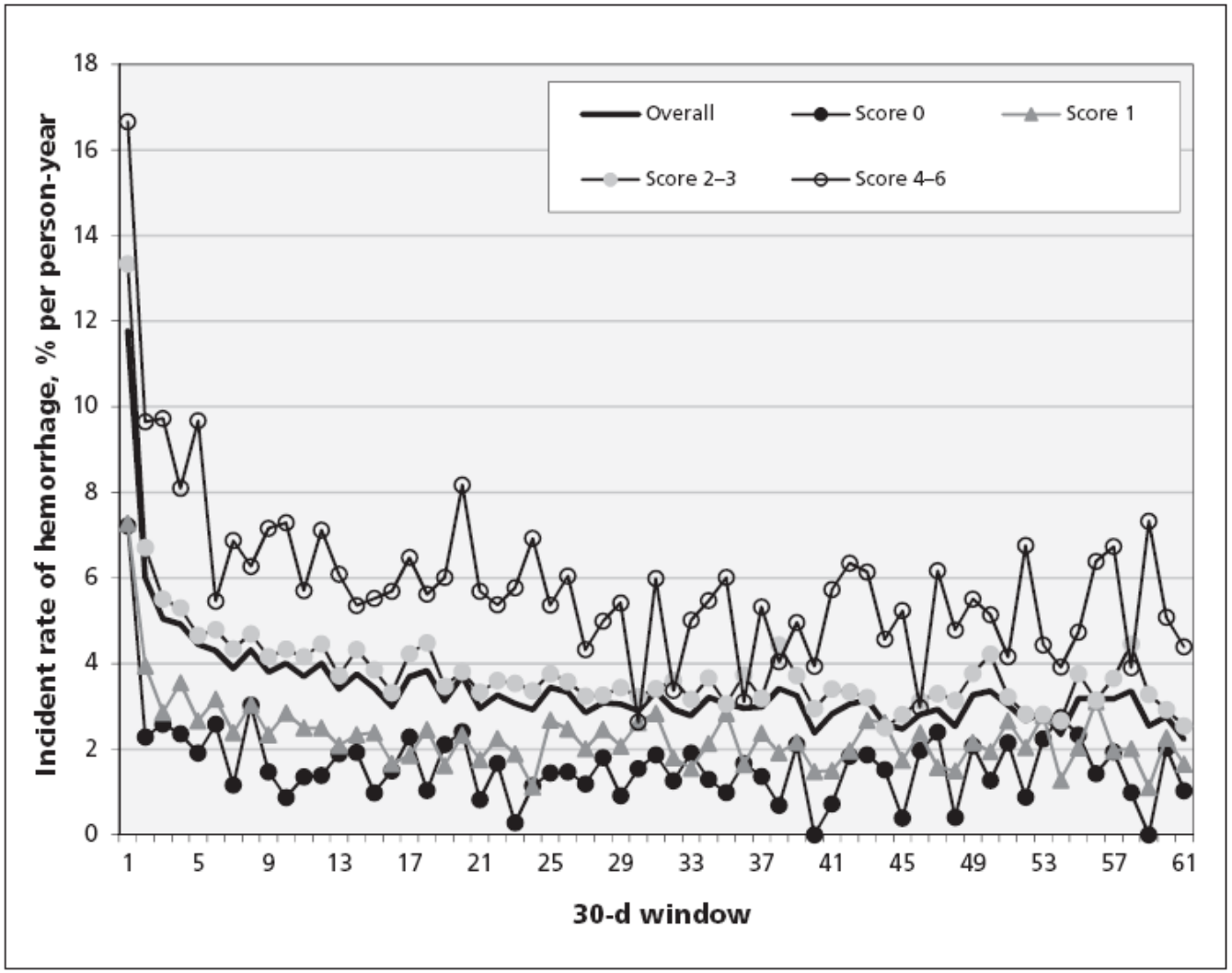
Rates of hemorrhage during warfarin therapy for atrial fibrillation

Tara Gomes MHSc, Muhammad M. Mamdani PharmD MPH, Anne M. Holbrook MD PharmD, J. Michael Paterson MSc, Chelsea Hellings MSc, David N. Juurlink MD PhD

- 125 195 patients with AF who started treatment with warfarin
- rate of hemorrhage = 3.8% per person-year
- risk of major hemorrhage highest during the first 30 days of Rx with rate of hemorrhage during 5-yr follow-up = 11.8% per person-year

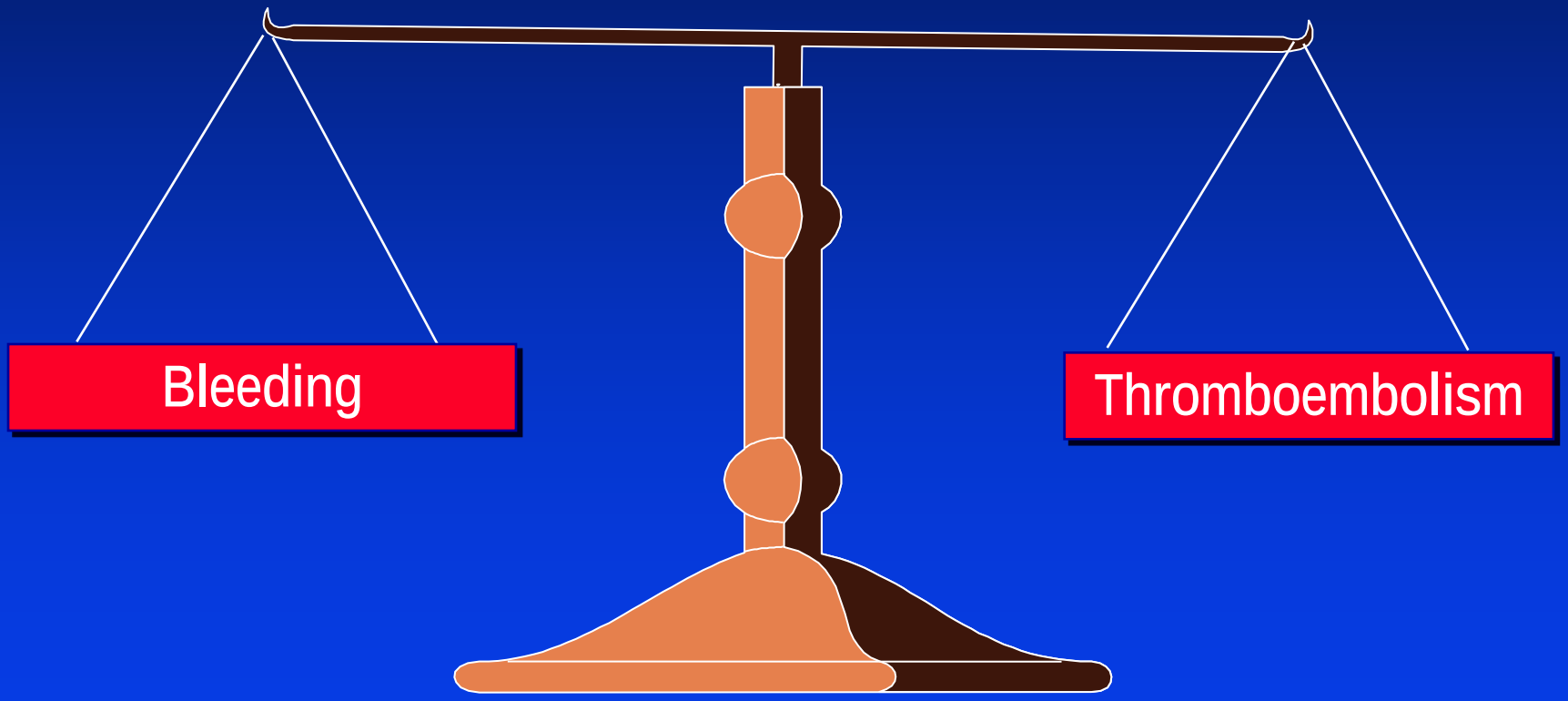
CMAJ 2013;185(2): E121-E127

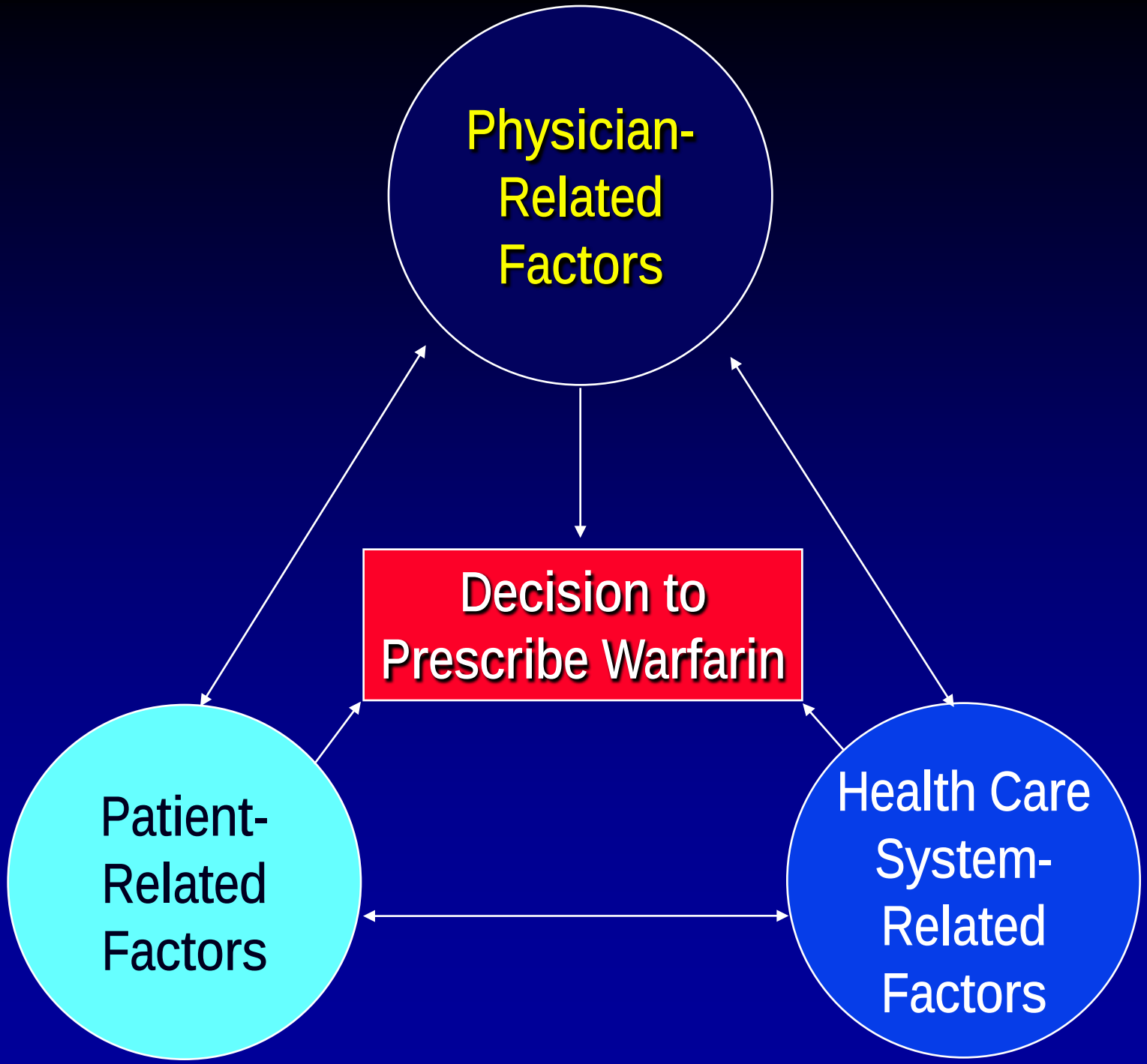
Incident rate of visits to hospital with hemorrhages in 30-day after the start of warfarin among patients with AF stratified by $CHADS_2$ score



CMAJ 2013;185(2): E121-E127

NET CLINICAL BENEFIT OF ORAL ANTICOAGULANT TREATMENT IN ATRIAL FIBRILLATION




Physician-Related Factors
Decision to Prescribe Warfarin
Patient-Related Factors
Health Care System-Related Factors

Differences between perspectives of physicians and patients on anticoagulation in patients with atrial fibrillation: observational study

P J Devereaux, David R Anderson, Martin J Gardner, Wayne Putnam, Gordon J Flowerdew, Brenda F Brownell, Seema Nagpal, Jafna L Cox

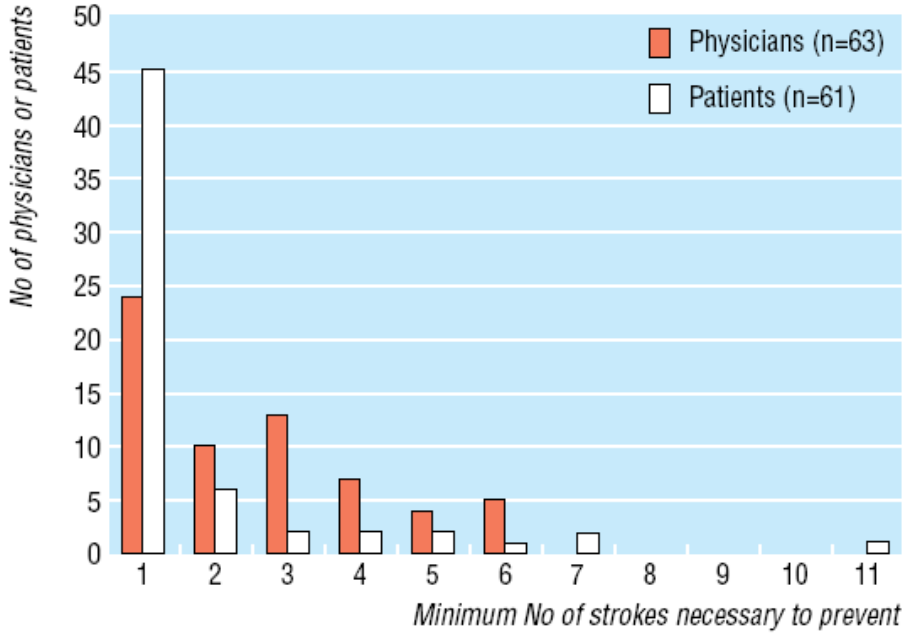


Fig 3 Stroke thresholds for warfarin

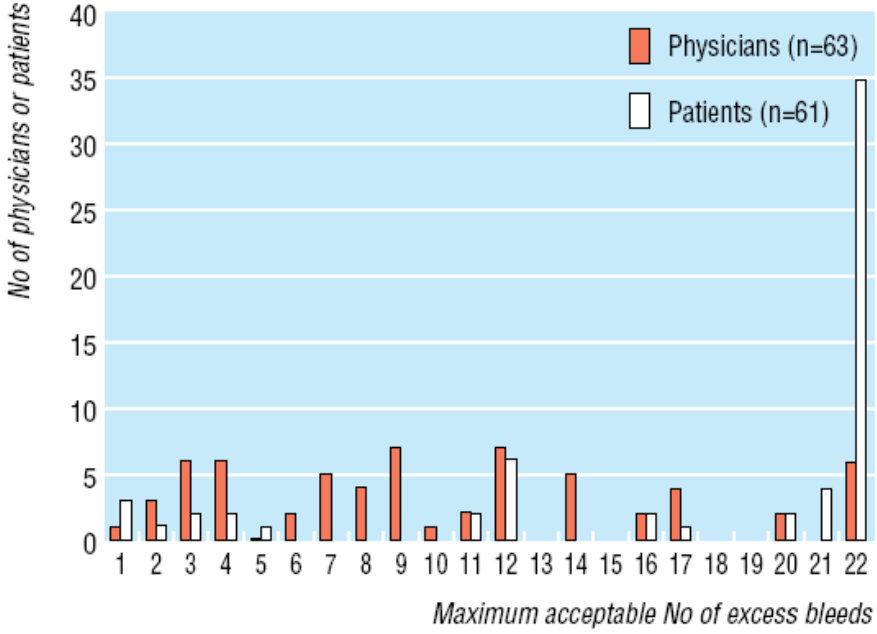
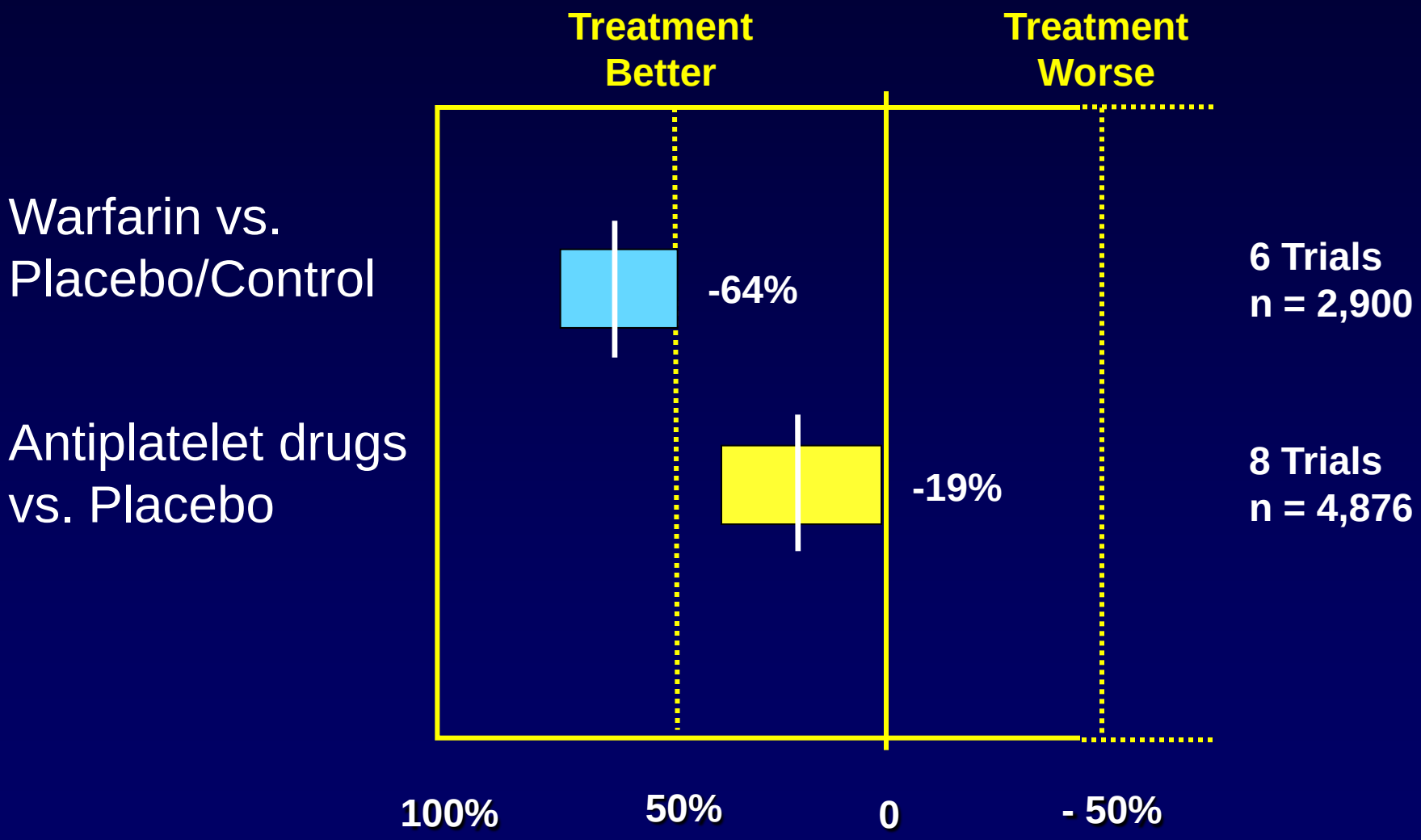


Fig 5 Bleeding thresholds for warfarin

Br Med J 2001;323:1-7

Antithrombotic Therapy for AF

Stroke Risk Reduction



Hart RG et al. Ann Intern Med 2007;146:857

Limiti della terapia con antagonisti della Vitamina K

- Risposta non prevedibile
- Finestra di trattamento stretta (INR range 2-3)
- Monitoraggio routinario dei fattori della coagulazione
- Lente insorgenza/termine d'azione

La terapia con antagonisti della vitamina K presenta diversi limiti che ne rendono difficoltoso l'impiego nella pratica clinica

- Frequenti aggiustamenti della dose
- Numerose interazioni alimentari
- Numerose interazioni con altri farmaci
- Resistenza al Warfarin

1. Ansell J, et al. *Chest* 2008;133;160S-198S; 2. Umer Ushman MH, et al. *J Interv Card Electrophysiol* 2008; 22:129-137; Nutescu EA, et al. *Cardiol Clin* 2008; 26:169-187.

Limiti della Terapia Anticoagulante Orale

Conseguenze nella FA

- Un significativo numero di pazienti con FA a rischio di stroke non riceve la TAO

International Journal of Cardiology xxx (2012) xxx–xxx

Contents lists available at SciVerse ScienceDirect

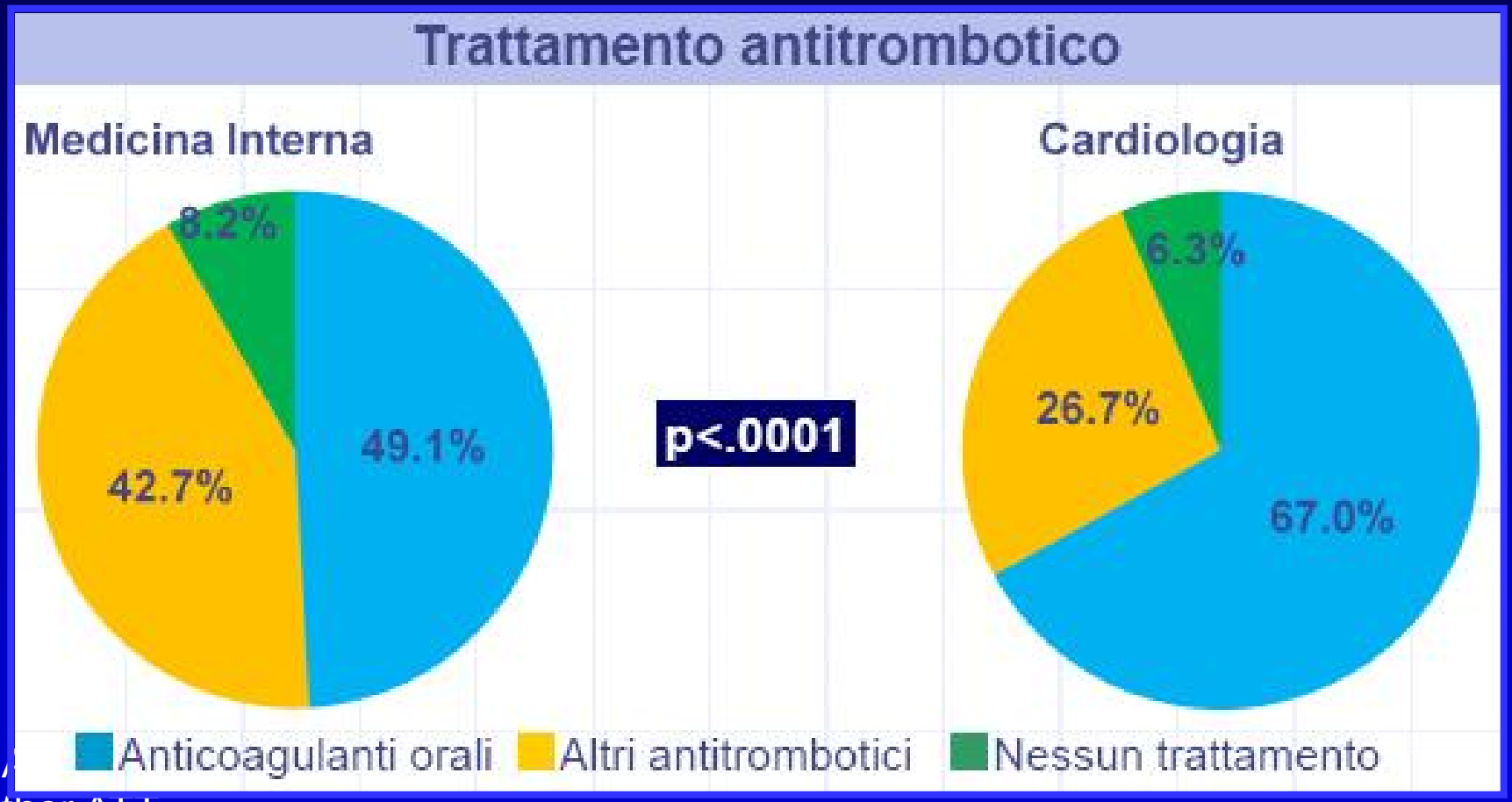
International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Current presentation and management of 7148 patients with atrial fibrillation in cardiology and internal medicine hospital centers: The ATA AF study ☆

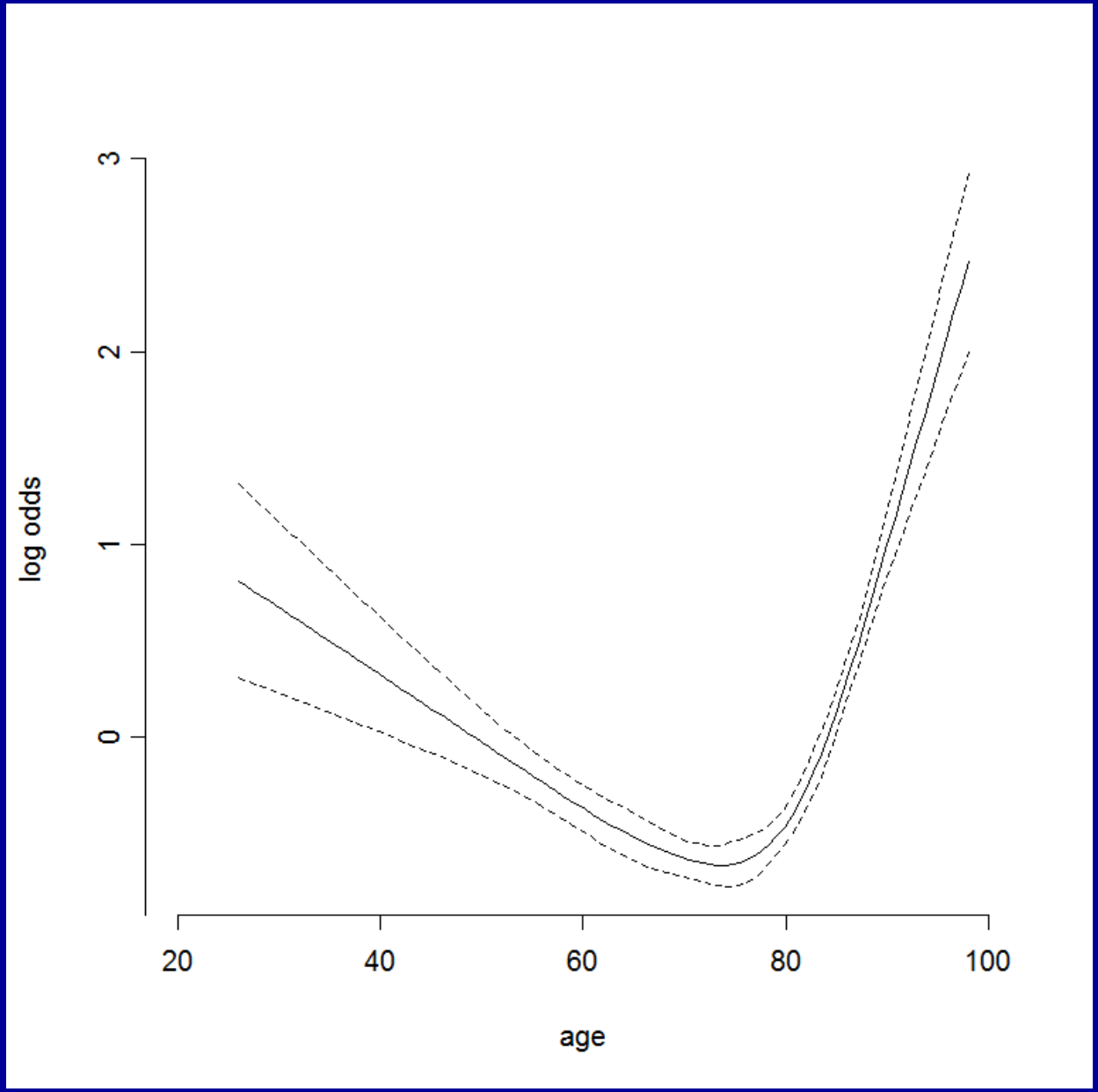
Giuseppe Di Pasquale [a], Giovanni Mathieu [b], Aldo Pietro Maggioni [c,*], Gianna Fabbri [c], Donata Lucci [c], Giorgio Vescovo [d], Salvatore Pirelli [e], Francesco Chiarella [f], Marino Scherillo [g], Michele Massimo Gulizia [h], Gualberto Gussoni [i], Fabrizio Colombo [j], Domenico Panuccio [k], Carlo Nozzoli [l], Massimo Zoni Berisso [m] on behalf of ATA-AF Investigators [1]

Antithrombotic Treatments in non valvular AF (4.845 pts)



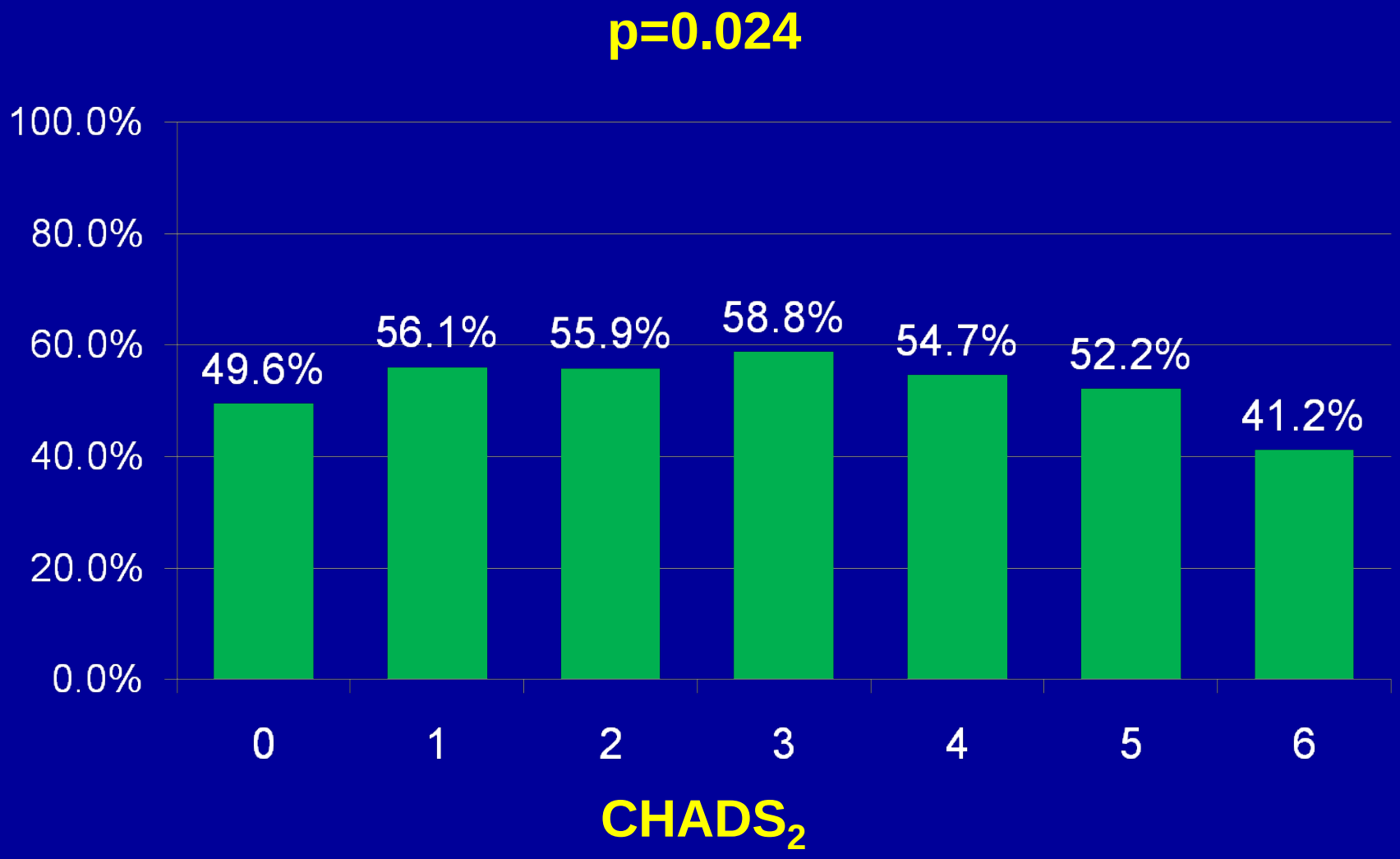
- O/
- Other ATT
- None

Risk of non prescription of OAC by age



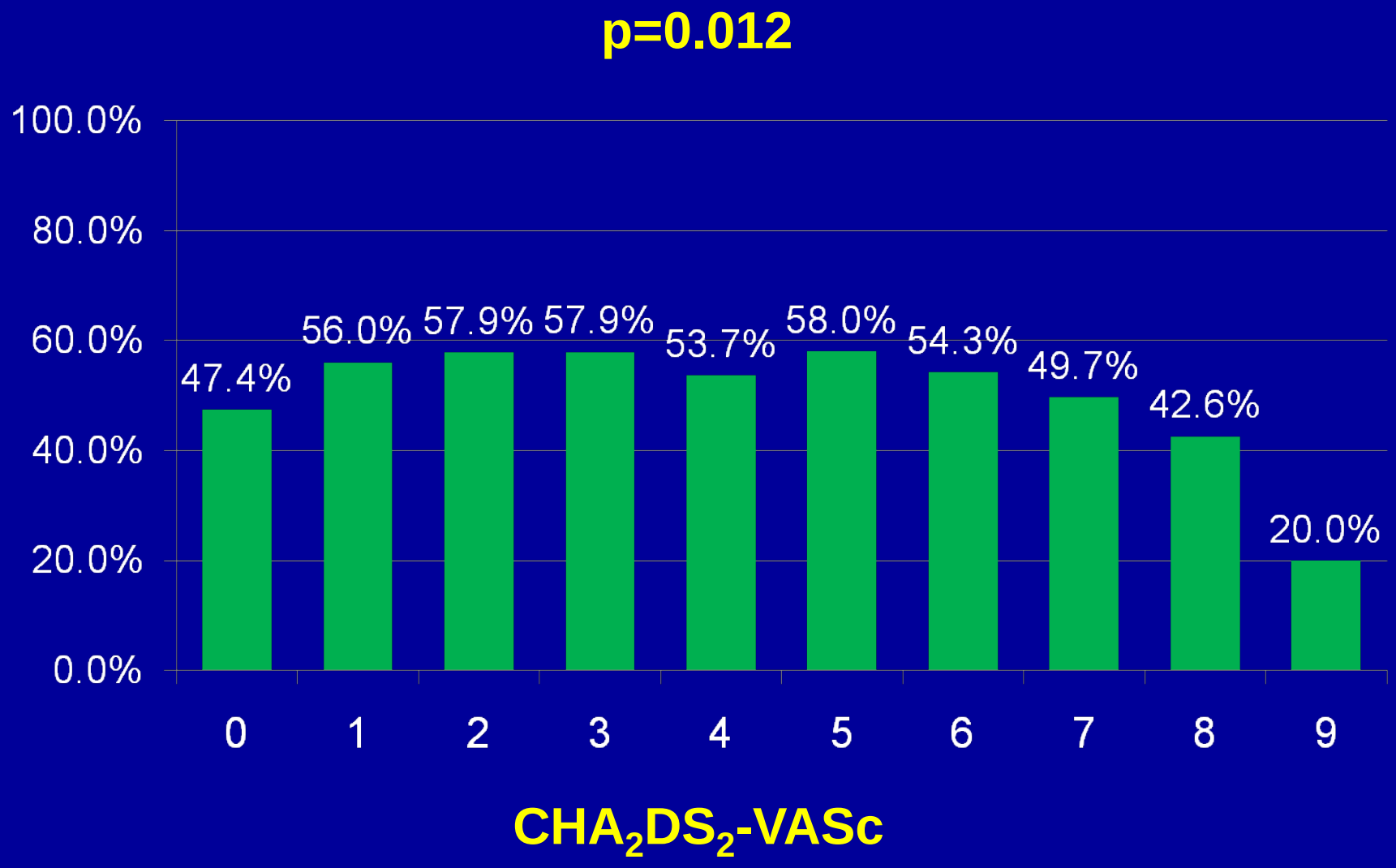
Prescription of OAC by $CHADS_2$

(non valvular AF, 4845 pts)



Prescription of OAC by CHA_2DS_2-VASc

(non valvular AF, 4845 pts)



Limiti della Terapia Anticoagulante Orale

Conseguenze nella FA

- Un significativo numero di pazienti con FA a rischio di stroke non riceve la TAO
- L'intensità della scoagulazione è spesso al di fuori del range terapeutico (INR 2.0 – 3.0)

Adherence to treatment and anticoagulation control in vitamin K antagonists-treated patients: an administrative databases analysis in a large Italian population

RICERCA ORIGINALE

Luca Degli Esposti [1], Diego Sangiorgi [1], Giuseppe Di Pasquale [2], Gian Franco Gensini [3,4], Ido Iori [5], Stefano Buda [1], Ezio Degli Esposti [1] on the behalf of the Study Group

Farmeconomia e percorsi terapeutici 2011; 12(2): 69-75

Anticoagulation Control in Real Life in Italy

% of INR Determinations by Range in VKA Treated Patients

Range INR	*VKA Experienced*	*mean*	*median*	*(p25 - p75)*
% INR < 2	No	33.4%	28.8%	(15.4% - 47.9%)
% INR < 2	Yes	25.3%	20.0%	(7.7% - 36.4%)
% INR 2.0-3.0	No	47.9%	50.0%	(33.3% - 66.7%)
% INR 2.0-3.0	Yes	56.3%	58.3%	(42.5% - 73.1%)
% INR > 3	No	16.9%	13.3%	(0.0% - 25.0%)
% INR > 3	Yes	17.9%	14.3%	(4.0% - 26.7%)

Correlation Between INR Quality Control and Outcome

	TTR < 60%	TTR 60 – 75%	TTR > 75%
MORTALITY (%)	4.20	1.84	1.69
MAJOR BLEEDING (%)	3.85	1.96	1.58
STROKE / SYSTEMIC EMBOLISM (%)	2.10	1.07	0.02

White HD et al. Arch Inten Med 2007; 167: 239-45

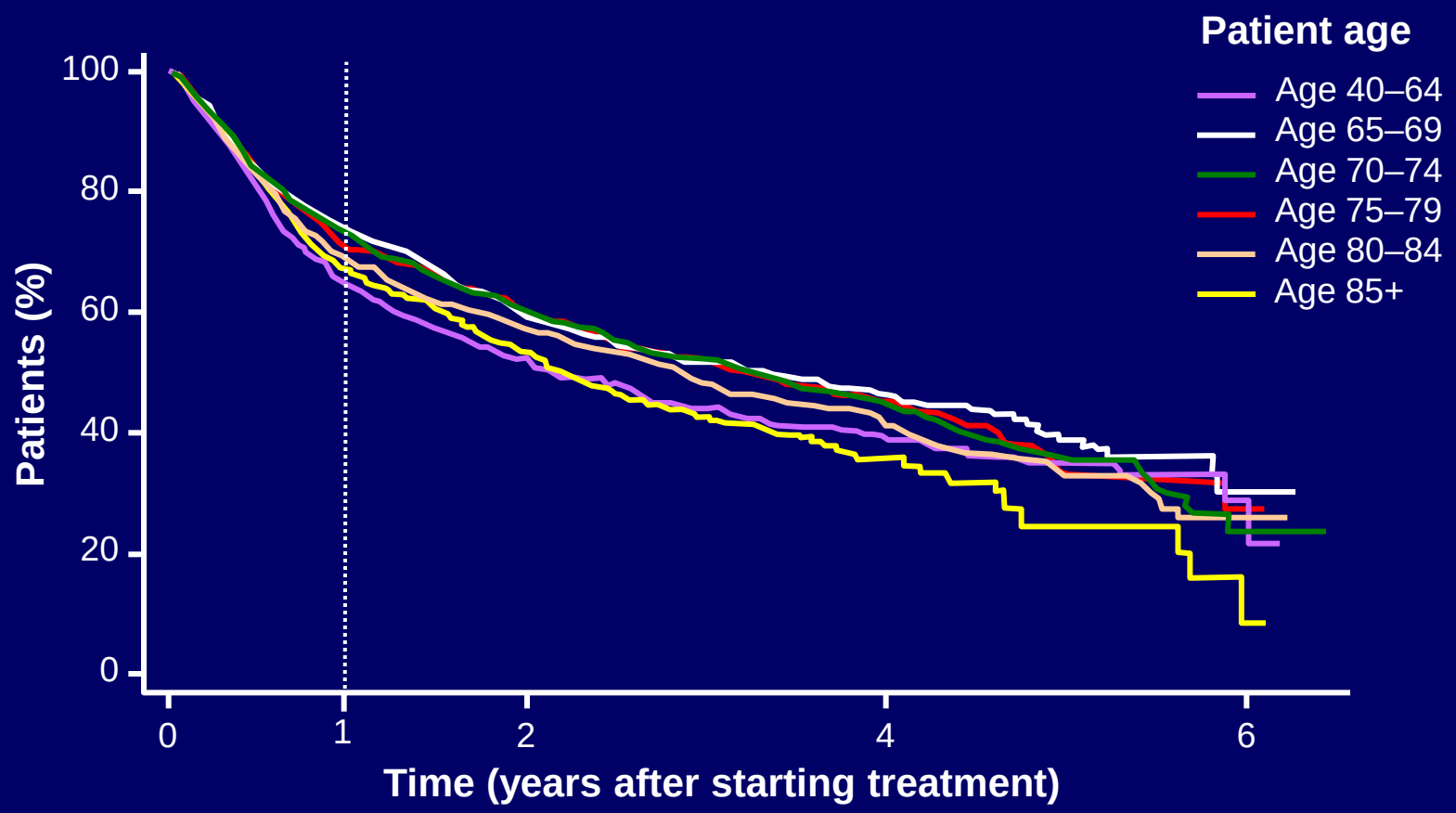
Limiti della Terapia Anticoagulante Orale

Conseguenze nella FA

- Un significativo numero di pazienti con FA a rischio di stroke non riceve la TAO
- L'intensità della scoagulazione è spesso al di fuori del range terapeutico (INR 2.0 – 3.0)
- Un significativo numero di pazienti sospende la TAO entro un anno dall'inizio

Patients Stop Taking Warfarin Over Time

- Approximately 30% of patients with AF treated with warfarin discontinue within 1 year



Gallagher AM et al. J Thromb Haemost 2008;6:1500–1506

BO.N.TAO
Bologna.Network.Terapia Anticoagulante Orale

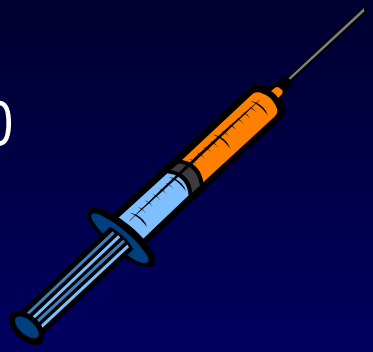


Rete di punti di prelievo e di centri prescrittori:

- Punti di prelievo (54)
- Centri ospedalieri (11)
- Specialisti territoriali
- MMG

Prelievo venoso in Laboratorio Analisi

Ore 7.30



Preparazione scheda terapeutica (Centro TAO)

Ore 12.00

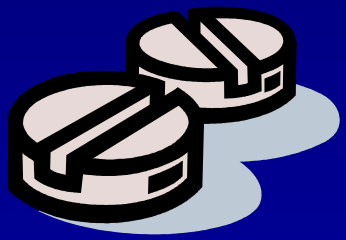


Ritiro della scheda terapeutica

Ore 14.00



Assunzione della TAO



Ore 16.00

BO.N.TAO Anno 2012

	Pazienti per Centro	Pazienti Domiciliari
Angiologia S. Orsola Malpighi	3321	762
CS Cardiologia Maggiore	2494	735
Cardiologia S. Orsola Malpighi	2402	-
CS Bentivoglio	2152	563
CS Ospedale Bellaria	1885	680
CS S. Giovanni in Persiceto	1184	249
CS Porretta Terme	960	296
CS Bazzano	712	
CS Loiano	536	
CS Zola Predosa	434	
CS Budrio	305	
P.P. Laboratorio Maggiore	275	
CS Vergato	265	
CS Borgoreno	246	
Totale	17587	3585 (20%)

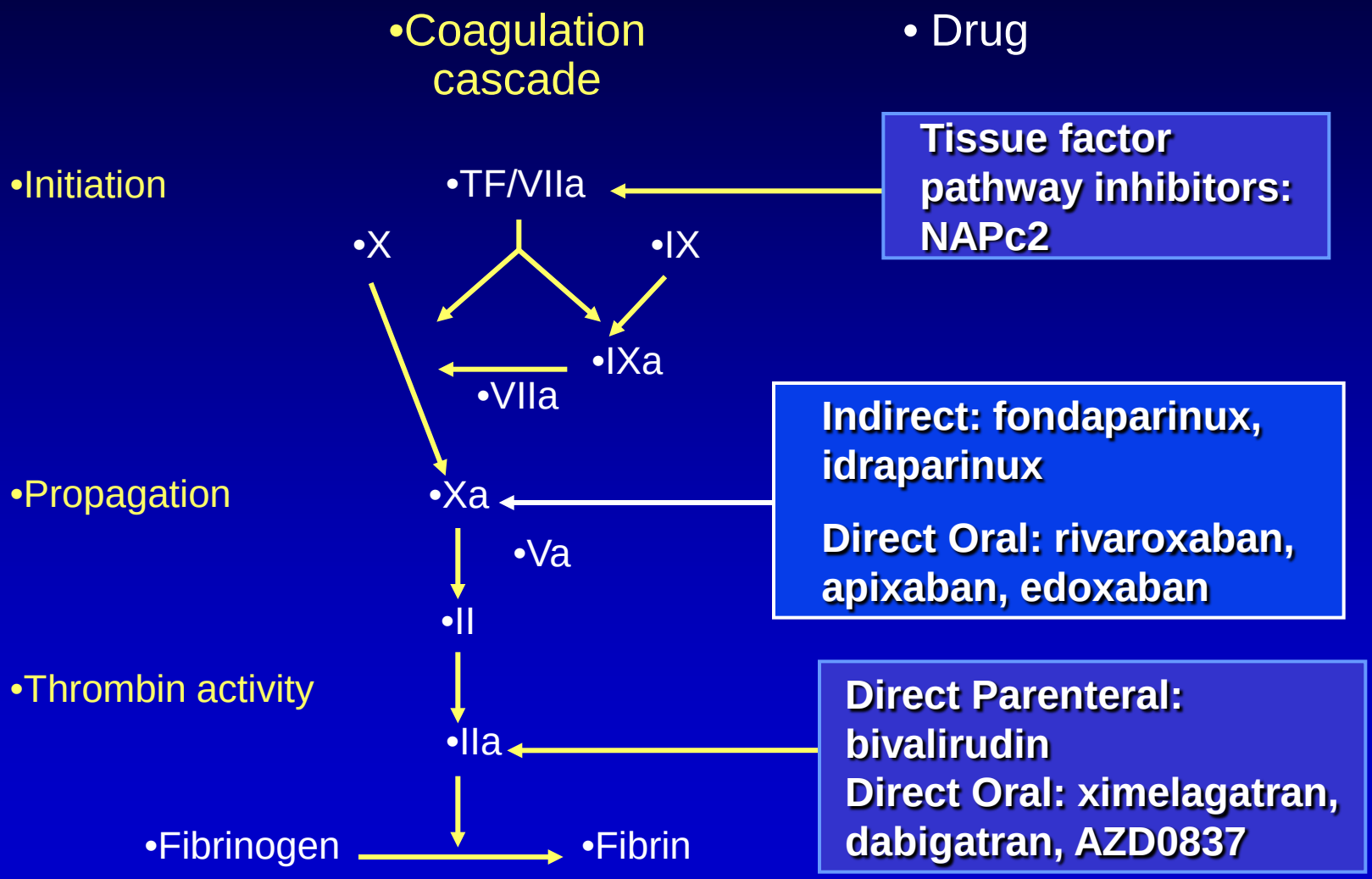
Assistenza Domiciliare TAO Bologna Anno 2012

1° Semestre 2012

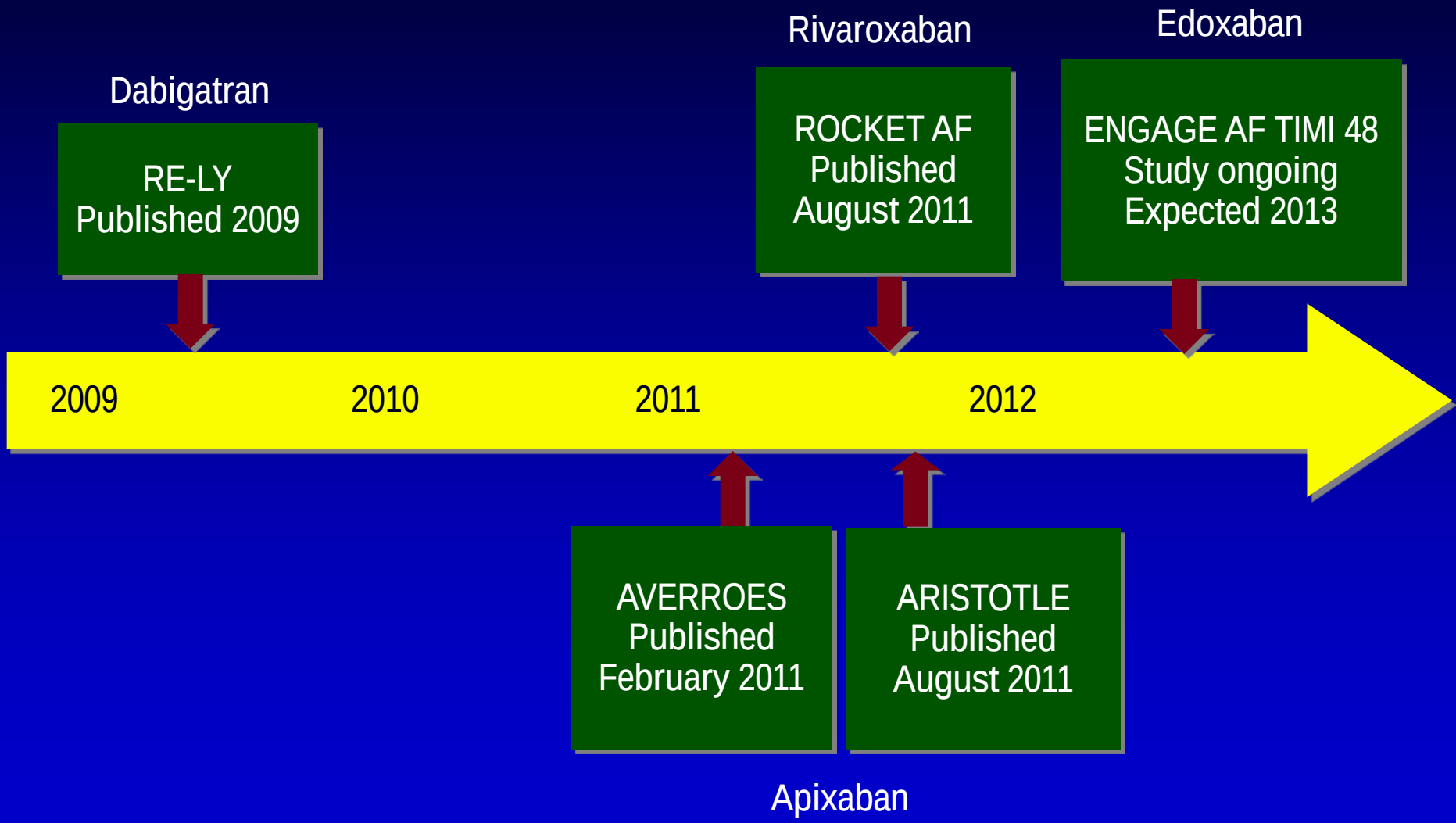
- Prelievi per monitoraggio TAO 45.100
- TAO sui prelievi totali 67.2%

The Promise of New Anticoagulants

New Anticoagulants



Atrial Fibrillation
NOAs Phase 3 Study Timelines



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 17, 2009 VOL. 361 NO. 12

Dabigatran versus Warfarin in Patients with Atrial Fibrillation

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 8, 2011 VOL. 365 NO. 10

Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 15, 2011 VOL. 365 NO. 11

Apixaban versus Warfarin in Patients with Atrial Fibrillation

Current Publications on New Agents vs Warfarin in AF

	RELY 2009	ROCKET 2011	ARISTOTLE 2011
Number with original information	17	4	5
Design publication	+	+	+
Main publication	+	+	+
Previous stroke	+	+	+
$CHADS_2$-score	+		+
Renal dysfunction		+	+
Warfarin naïve and experienced	+		
Different TTR levels	+		
Risk factors for bleeding	+		
Intracranial bleeding	+		
Peri-procedural bleeding	+		
Different types of AF	+		
Previous CAD	+		
Cardioversion	+		
Asian population	+		
Pharmacokinetics	+		
Health economy	+		

AF, atrial fibrillation; CAD, coronary artery disease; TTR, time in therapeutic range.

1. Connolly SJ, et al. *N Engl J Med.* 2009;361:1139-1151; 2. Patel M, et al. *N Engl J Med.* 2011;365:883-91; 3. Granger C, et al. *N Engl J Med.* 2011;365(11):981-992.

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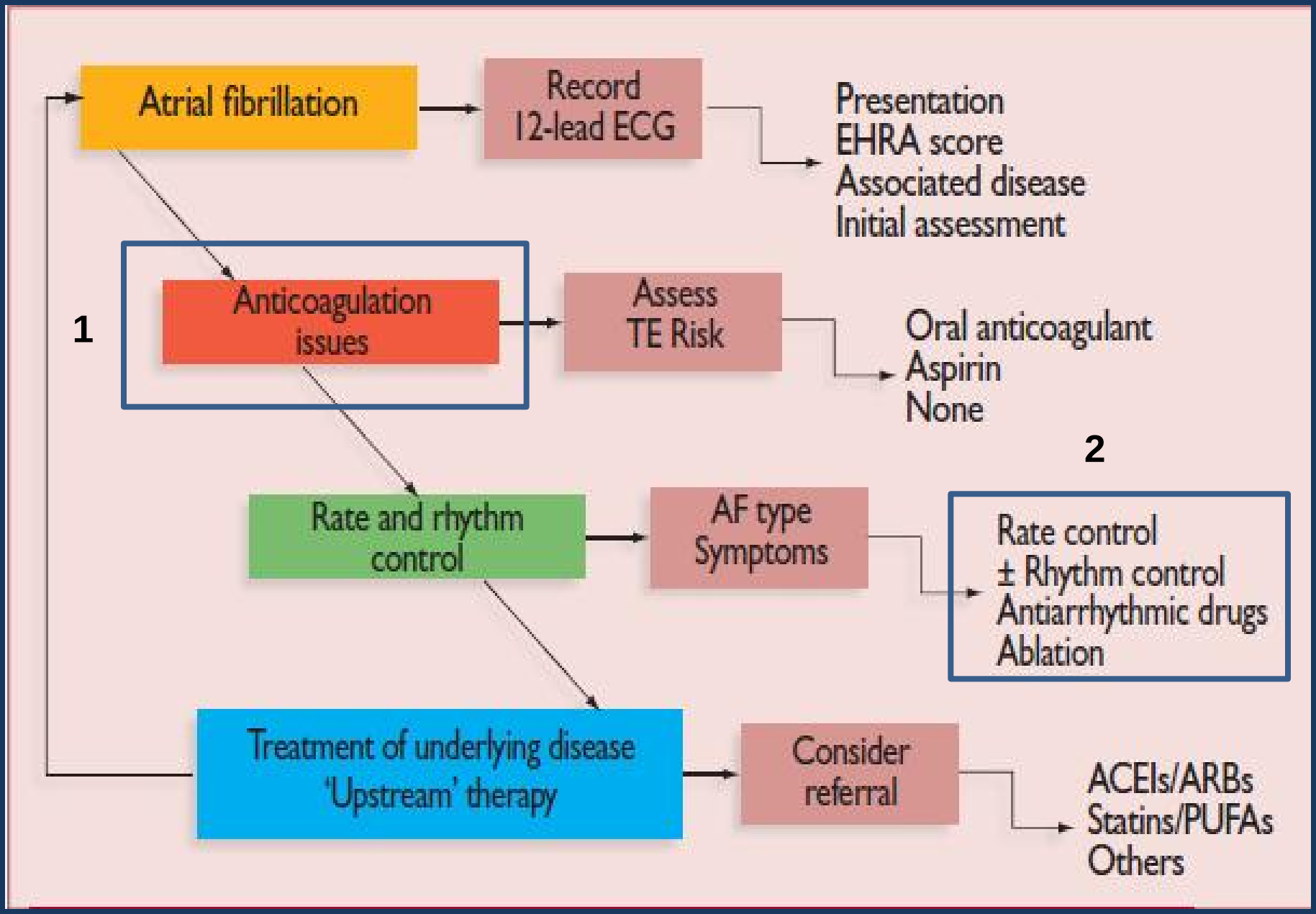
EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2013) **15**, 625–651
doi:10.1093/europace/eut083

EHRA PRACTICAL GUIDE

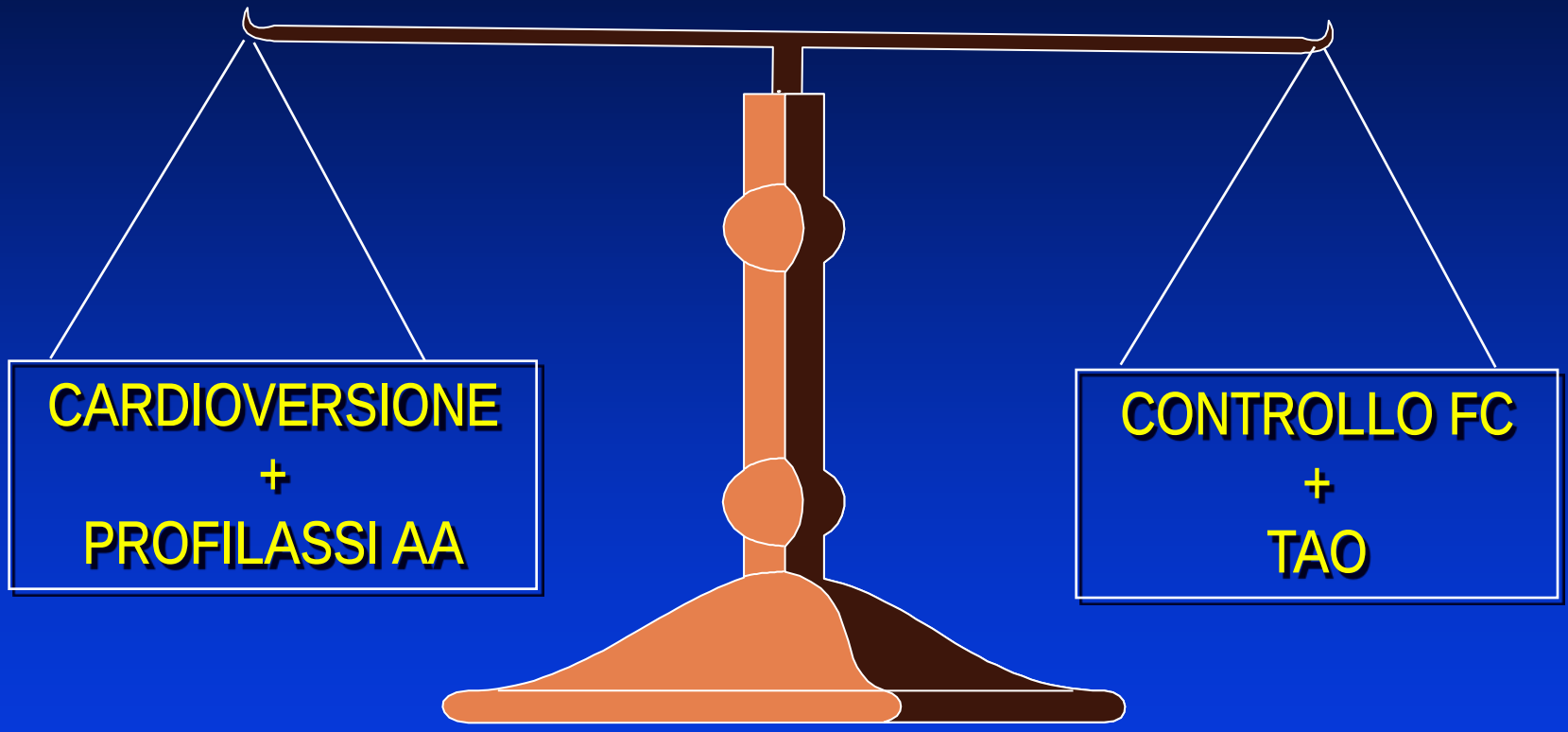
European Heart Rhythm Association Practical Guide on the use of new oral anticoagulants in patients with non-valvular atrial fibrillation

Hein Heidbuchel[1]*, Peter Verhamme[1], Marco Alings[2], Matthias Antz[3], Werner Hacke[4], Jonas Oldgren[5], Peter Sinnaeve[1], A. John Camm[6], and Paulus Kirchhof[7,8]



ESC Guidelines 2010

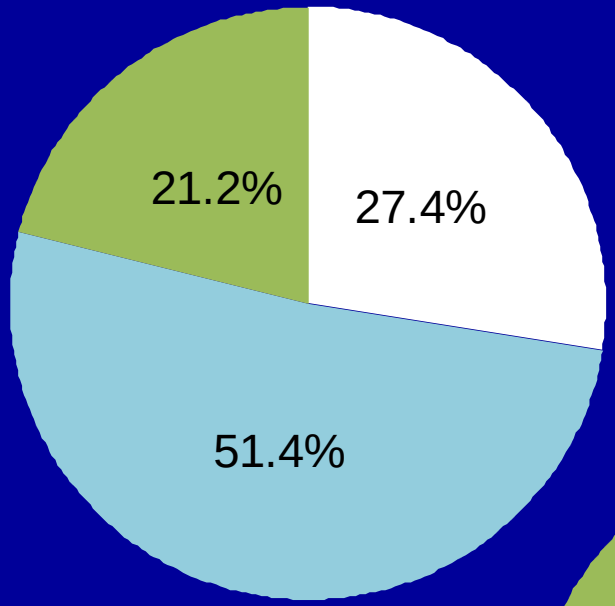
SCELTA DI STRATEGIE NELLA FA



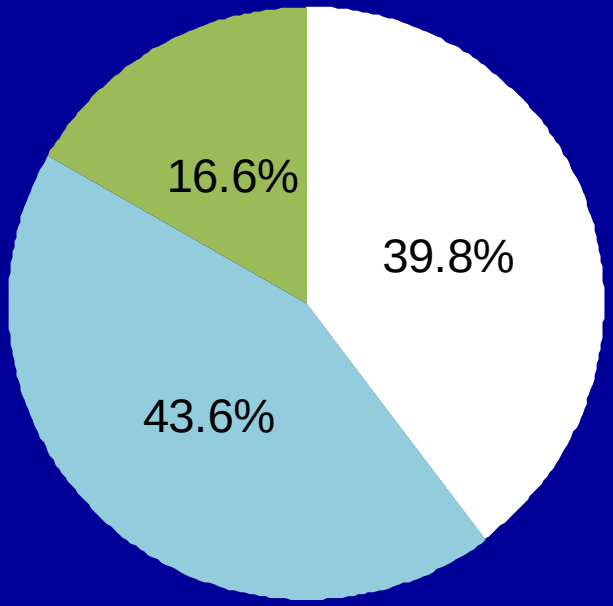
Efficacia ?
Sicurezza ?
Qualità di vita ?
Preferenze del paziente ?

Therapeutic Strategies

Total (7148 pts)



Cardiology (3862 pts)



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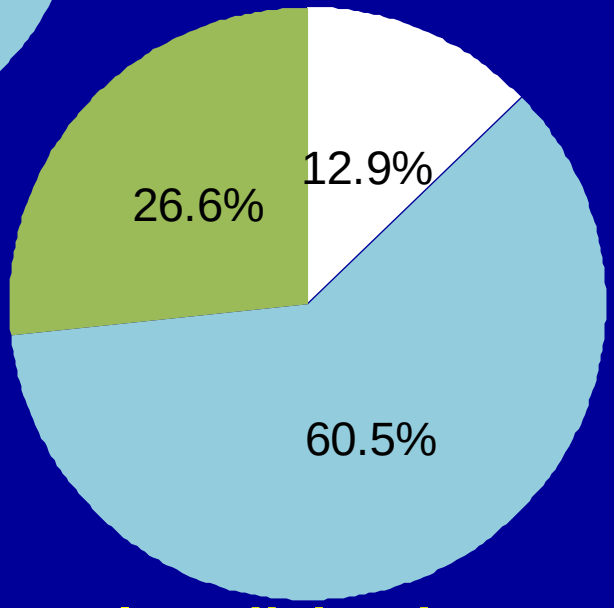
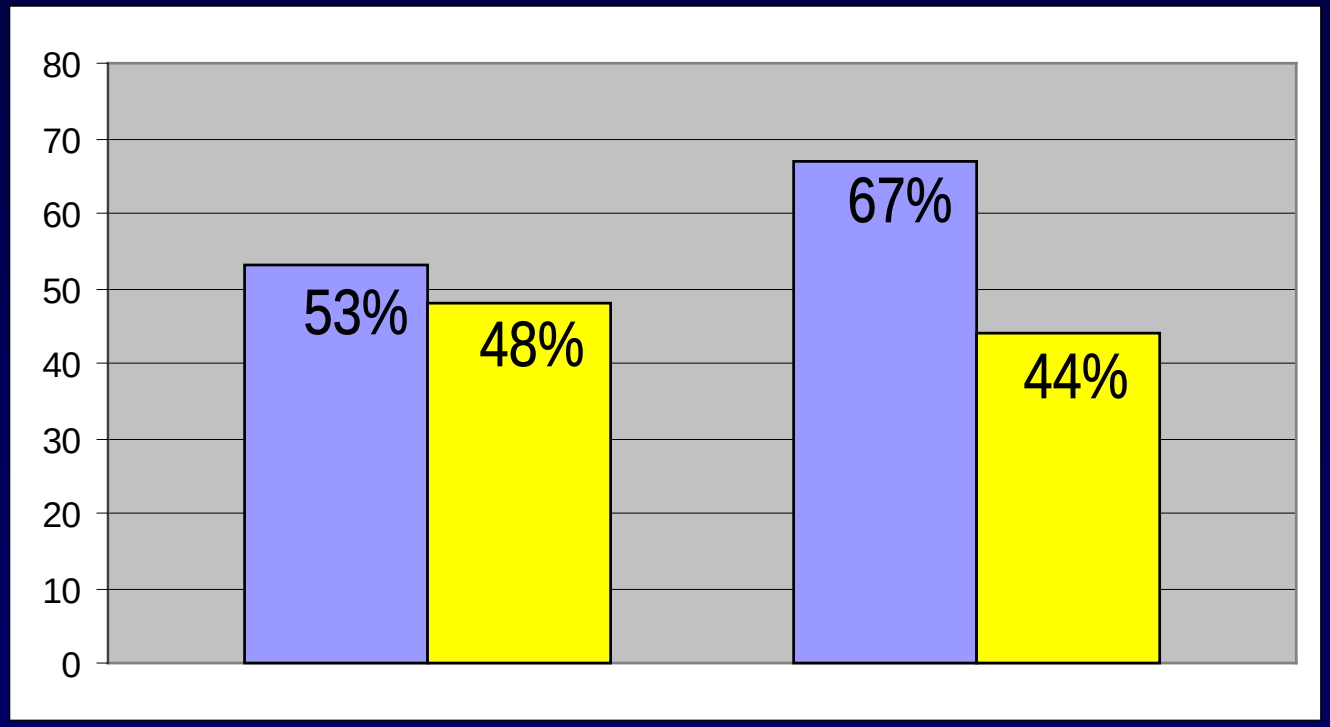


Internal Medicine (3286 pts)

- Rhythm control
- Rate control
- Unknown

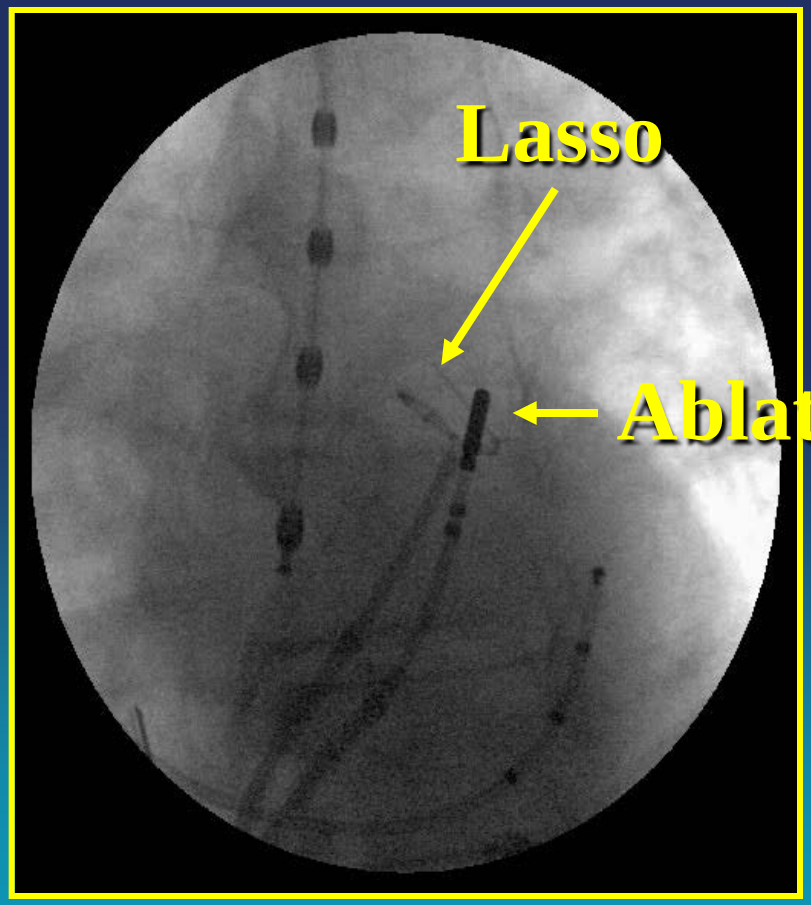
Decision on Rate and Rhythm Control in Patients With Persistent AF

Rhythm control strategy

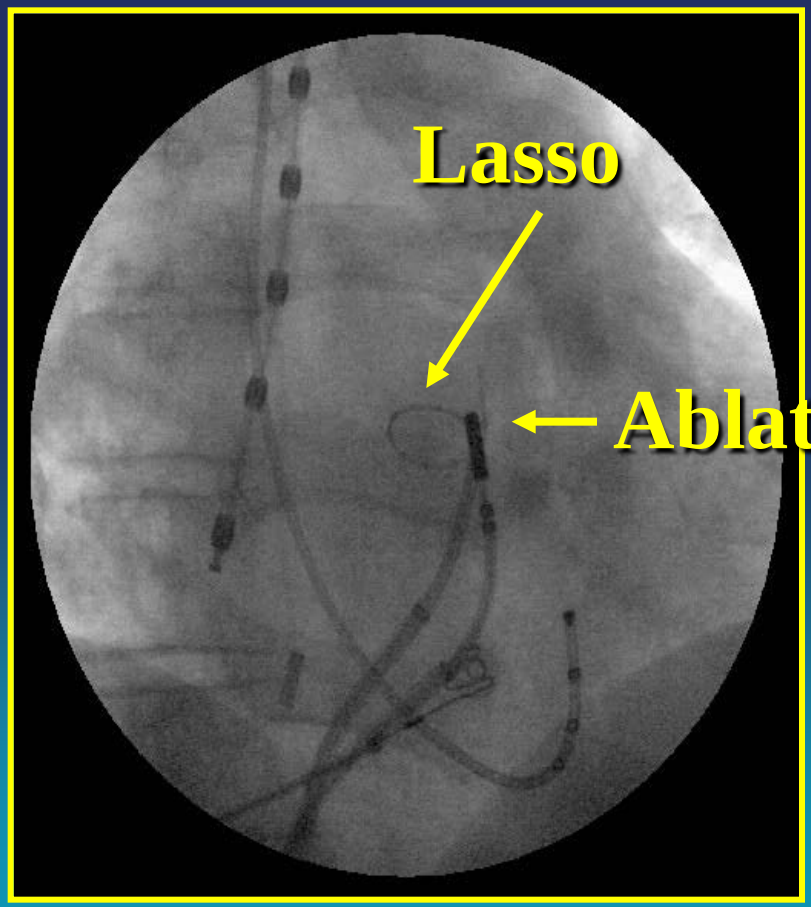


Rhythm control
Left atrial catheter ablation

Catheter Ablation for AFib



LAO



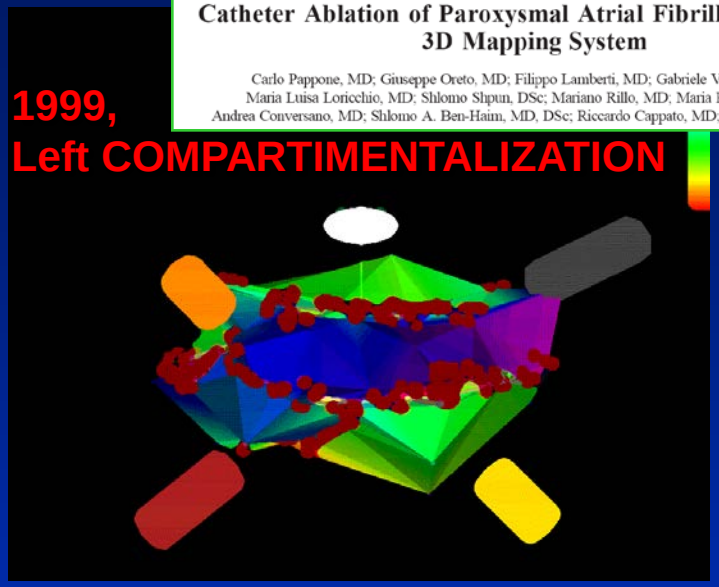
RAO

Catheter Ablation for AF

Catheter Ablation of Paroxysmal Atrial Fibrillation Using a 3D Mapping System

Carlo Pappone, MD; Giuseppe Oreto, MD; Filippo Lamberti, MD; Gabriele Vicedomini, MD; Maria Luisa Loricchio, MD; Shlomo Shpun, DSc; Mariano Rillo, MD; Maria Pia Calabrò, MD; Andrea Conversano, MD; Shlomo A. Ben-Haim, MD, DSc; Riccardo Cappato, MD; Sergio Chierchia, MD

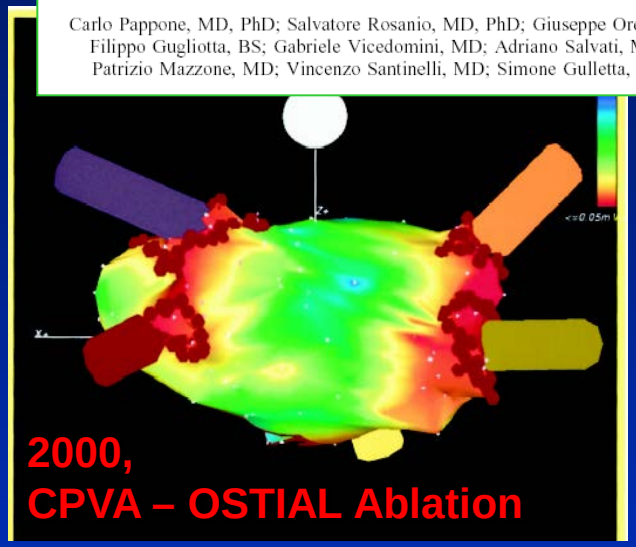
1999,
Left COMPARTIMENTALIZATION



Circumferential Radiofrequency Ablation of Pulmonary Vein Ostia

A New Anatomic Approach for Curing Atrial Fibrillation

Carlo Pappone, MD, PhD; Salvatore Rosanio, MD, PhD; Giuseppe Oreto, MD; Monica Tocchi, MD; Filippo Gugliotta, BS; Gabriele Vicedomini, MD; Adriano Salvati, MD; Cosimo Dicandia, MD; Patrizio Mazzone, MD; Vincenzo Santinelli, MD; Simone Gulletta, MD; Sergio Chierchia, MD

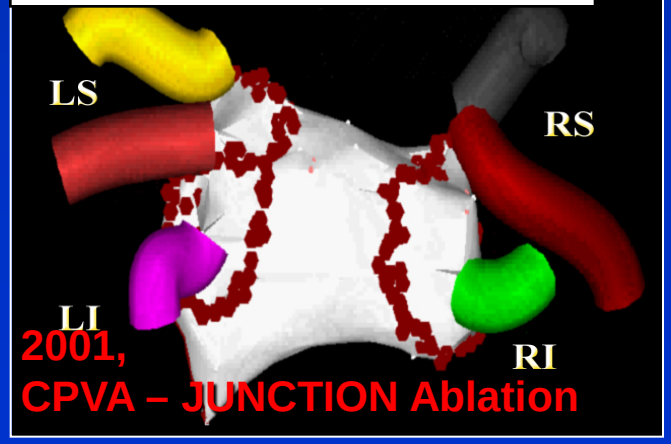


2000,
CPVA – OSTIAL Ablation

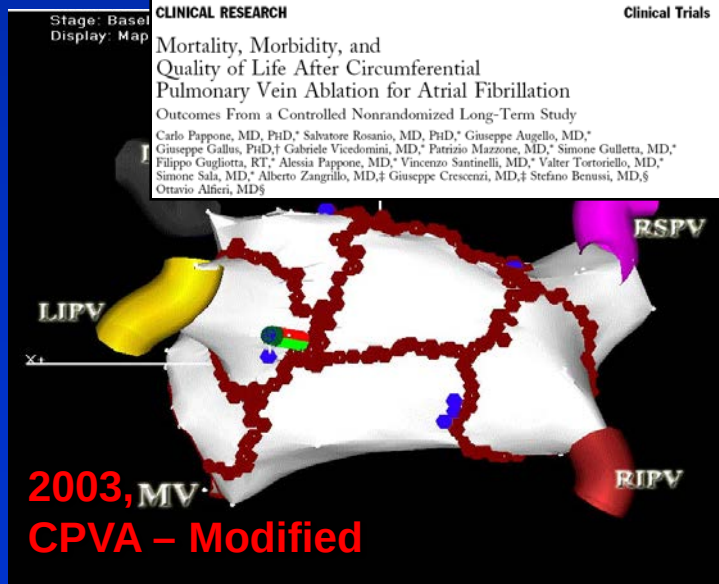
Atrial Electroanatomic Remodeling After Circumferential Radiofrequency Pulmonary Vein Ablation

Efficacy of an Anatomic Approach in a Large Cohort of Patients With Atrial Fibrillation

Carlo Pappone, MD, PhD; Giuseppe Oreto, MD; Salvatore Rosanio, MD, PhD; Gabriele Vicedomini, MD; Monica Tocchi, MD, PhD; Filippo Gugliotta, BS; Adriano Salvati, MD; Cosimo Dicandia, MD; Maria Pia Calabrò, MD; Patrizio Mazzone, MD; Eleonora Ficarra, MD; Claudio Di Gioia, MD; Simone Gulletta, MD; Stefano Nardi, MD; Vincenzo Santinelli, MD; Stefano Benussi, MD; Ottavio Alfieri, MD



2001,
CPVA – JUNCTION Ablation



2003,
CPVA – Modified

Underuse of Non-Pharmacological Treatment

EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2010) **12**, 1070–1077
doi:10.1093/europace/euq158

CLINICAL RESEARCH
Atrial Fibrillation – Clinical Issues

Adherence to guidelines for atrial fibrillation management of patients referred to cardiology departments: Studio Italiano multicentrico sul Trattamento della Fibrillazione Atriale (SITAF)

Nicola Bottoni[1]*, Massimo Tritto[2], Renato Ricci[3], Michele Accogli[4], Matteo Di Biase[5], Saverio Iacopino[6], Matteo Iori[1], Sakis Themistoclakis[7], Nadir Sitta[8], Gianmario Spadacini[2], Roberto De Ponti[9], and Michele Brignole[10] on behalf of the SITAF investigators

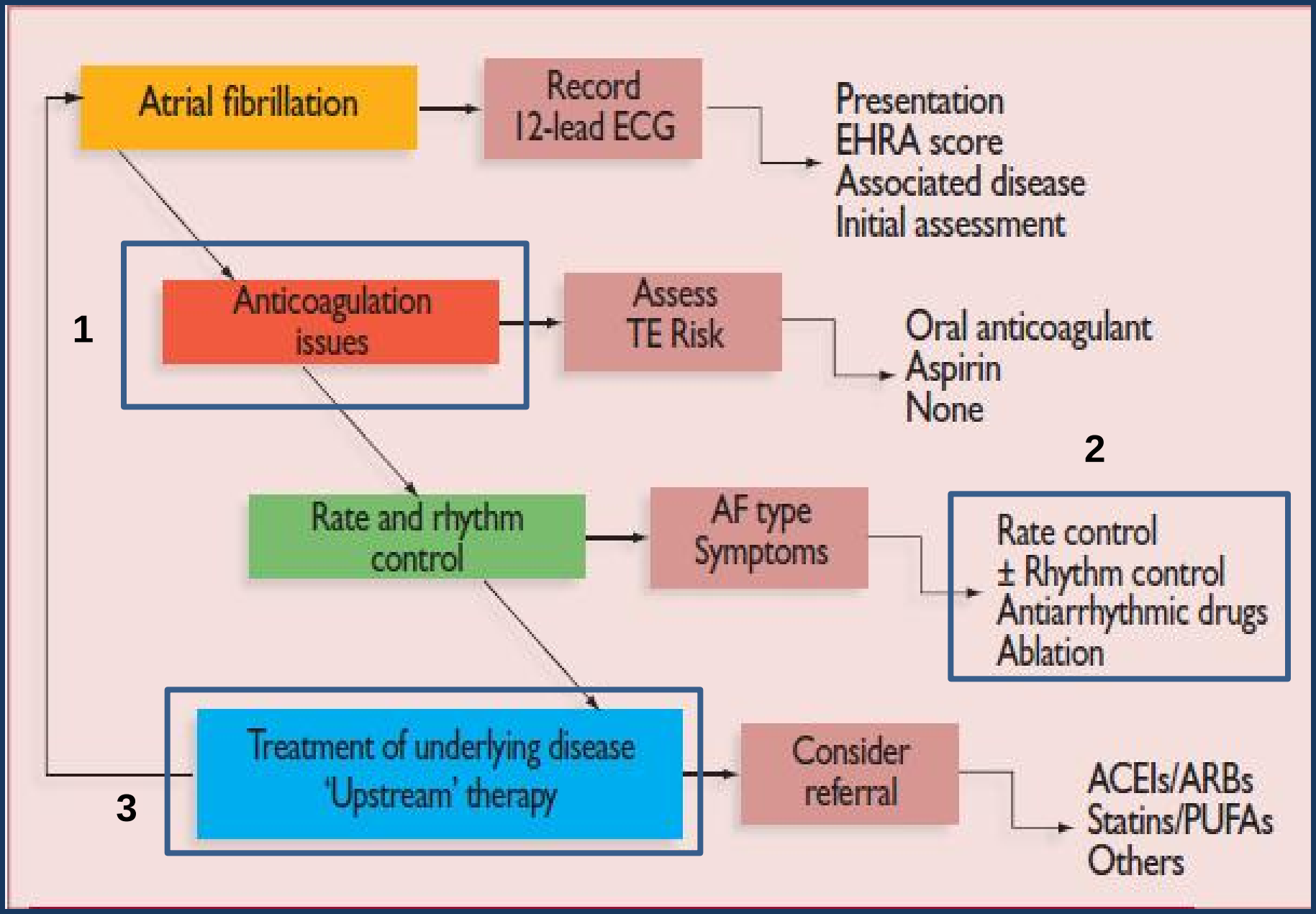
Adherence to Guidelines for AF Management
The SITAF Study

Table 4 Substrate catheter ablation: correlation between the treatment that was actually indicated by the centres and that based on the guidelines

All Centres		Guideline indications		
		No	Yes	Total
Centre indications	No	991	78	1069
	Yes	82	105	187
	Total	1073	183	1256

K statistics for agreement for indications = 0.47.

Bottoni N et al. Europace 2010;12:1070-77

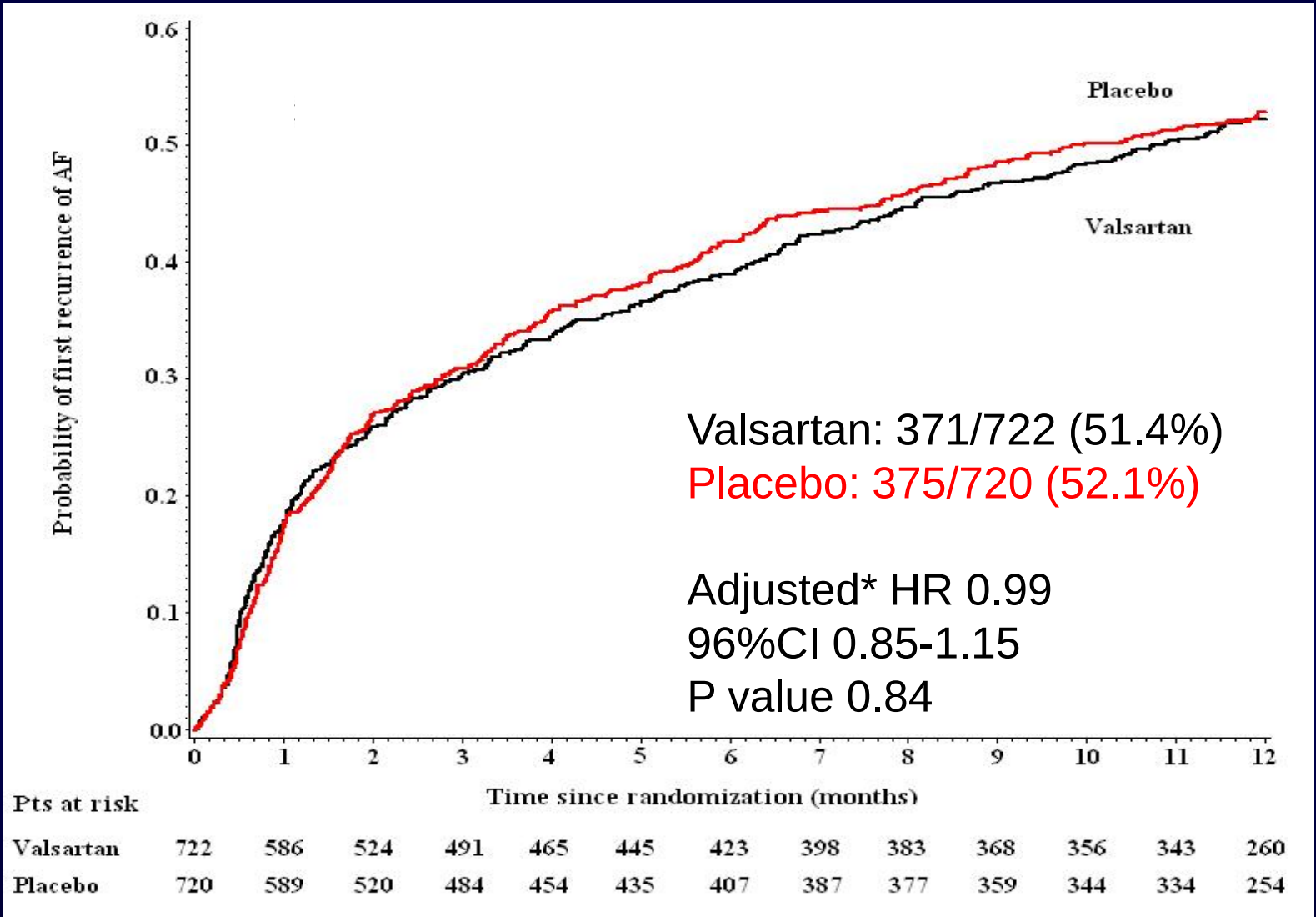


ESC Guidelines 2010

GISSI AF

To evaluate whether in patients with previous AF episodes treated with the best recommended therapies the addition of valsartan can prevent AF recurrence

Time to first recurrence of AF (n. 1442)



Valsartan: 371/722 (51.4%)
Placebo: 375/720 (52.1%)

Adjusted* HR 0.99
96%CI 0.85-1.15
P value 0.84

** The 96%CI was calculated by Cox proportional hazards model adjusted for ACE-I, amiodarone use, cardioversion, PAD, CAD*

Profilassi cardioembolica 2011: siamo vicini al tramonto del warfarin?

Giuseppe Di Pasquale, Letizia Riva

U.O. di Cardiologia, Ospedale Maggiore, Bologna

Warfarin has been the effective treatment in the prophylaxis of cardioembolism, in particular in patients with atrial fibrillation, for more than 50 years. Nevertheless, many patients with atrial fibrillation are not currently treated because of the numerous limits of oral anticoagulation and in those treated the quality of anticoagulation is often poor.

Novel oral anticoagulant drugs, the direct thrombin antagonist dabigatran and factor Xa inhibitors such as rivaroxaban, apixaban, edoxaban, and betrixaban are more predictable and convenient anticoagulants in comparison with warfarin, mainly because of the non-requirement of regular laboratory monitoring and dose adjustments. Current data from phase III clinical trials are available for dabigatran and rivaroxaban, which show to be at least noninferior in efficacy to warfarin for the prevention of stroke in patients with atrial fibrillation.

This review focuses on the potential of novel anticoagulants to replace warfarin in patients with atrial fibrillation. Also the place in therapy and the potential limitations of the new agents in clinical practice represent important issues to be considered. The promise of new oral anticoagulants gives us the hope that warfarin will finally be replaced in a near future, but more importantly that anticoagulant undertreatment of atrial fibrillation will be partially overcome.

Key words. Atrial fibrillation; Oral anticoagulant therapy; Thromboembolic prophylaxis.

G Ital Cardiol 2011; 12(9): 556-65

National Trends in Oral Anticoagulant Use in the United States, 2007 to 2011

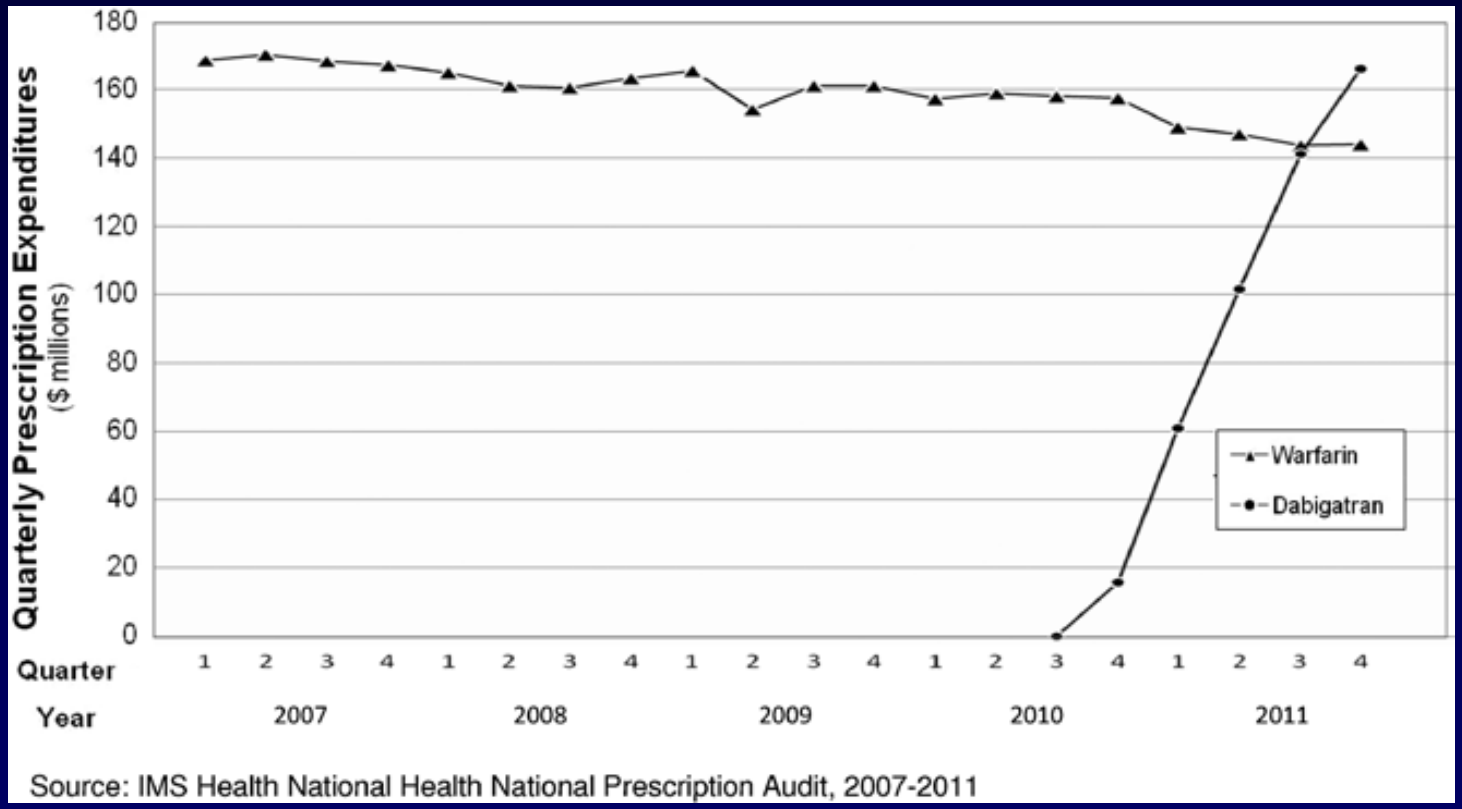
Kate Kirley, MD; Dima M. Qato, PharmD, MPH, PhD; Rachel Kornfield MA; Randall S. Stafford, MD, PhD; G. Caleb Alexander, MD, MS

Background—Little is known regarding the adoption of direct thrombin inhibitors in clinical practice. We examine trends in oral anticoagulation for the prevention of thromboembolism in the United States.

Methods and Results—We used the IMS Health National Disease and Therapeutic Index, a nationally representative audit of office-based providers, to quantify patterns of oral anticoagulant use among all subjects and stratified by clinical indication. We quantified oral anticoagulant expenditures using the IMS Health National Prescription Audit. Between 2007 and 2011, warfarin treatment visits declined from ≈2.1 million (M) quarterly visits to ≈1.6M visits. Dabigatran use increased from 0.062M quarterly visits (2010Q4) to 0.363M visits (2011Q4), reflecting its increasing share of oral anticoagulant visits from 3.1% to 18.9%. In contrast to warfarin, the majority of dabigatran visits have been for atrial fibrillation, though this proportion decreased from 92% (2010Q4) to 63% (2011Q4), with concomitant increases in dabigatran's off-label use. Among atrial fibrillation visits, warfarin use decreased from 55.8% visits (2010Q4) to 44.4% (2011Q4), whereas dabigatran use increased from 4.0% to 16.9%. Of atrial fibrillation visits, the fraction not treated with any oral anticoagulants has remained unchanged at ≈40%. Expenditures related to dabigatran increased rapidly from $16M in 2010Q4 to $166M in 2011Q4, exceeding expenditures on warfarin ($144M) in 2011Q4.

Conclusions—Dabigatran has been rapidly adopted into ambulatory practice in the United States, primarily for treatment of atrial fibrillation, but increasingly for off-label indications. We did not find evidence that it has increased overall atrial fibrillation treatment rates. **(*Circ Cardiovasc Qual Outcomes*. 2012;5:615-621.)**

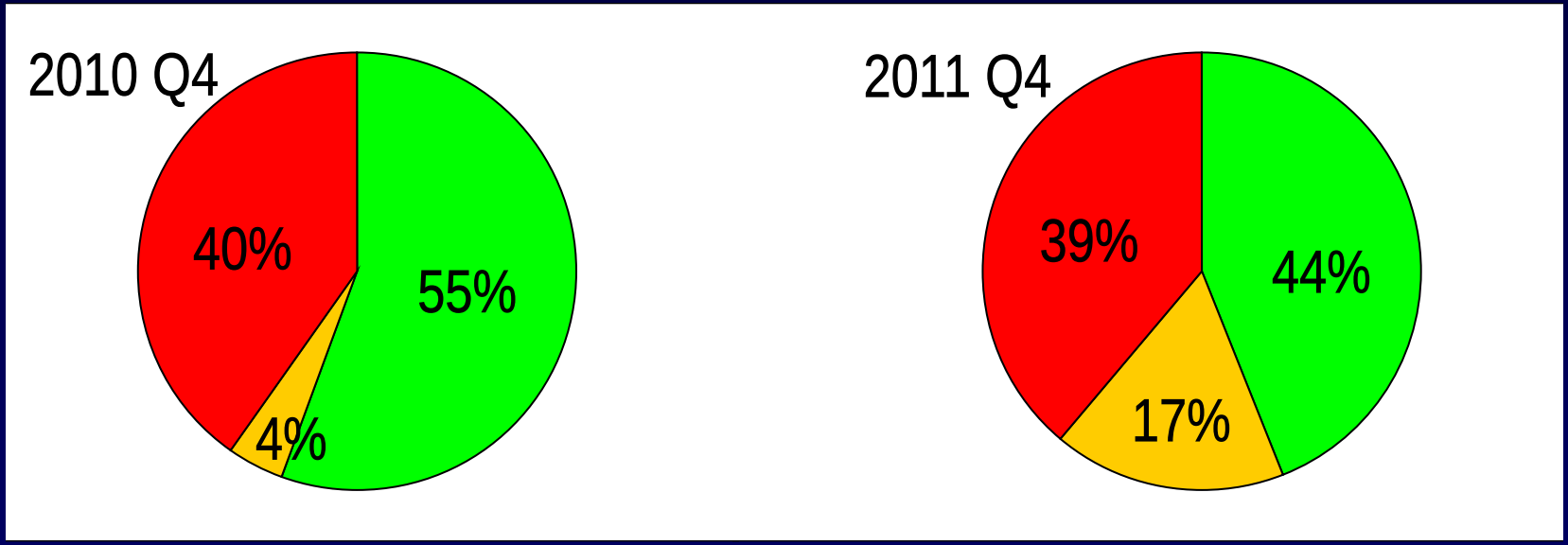
Quarterly Prescription Expenditures for Warfarin and Dabigatran (retail value), 2007 to 2011



(Circ Cardiovasc Qual Outcomes 2012;5:615-21

National Trends in Oral Anticoagulant Use in the United States, 2007 to 2011

Dabigatran FDA Approval October 2010



Kirley K et al.Circ Cardiovasc Qual Outcomes 2012;5:615-21

Farmeconomia. Health economics and therapeutic pathways 2012; 13(3): 105-115

Budget impact analysis resulting from the use of dabigatran etexilate in preventing stroke in patients with non-valvular atrial fibrillation in Italy

ORIGINAL RESEARCH

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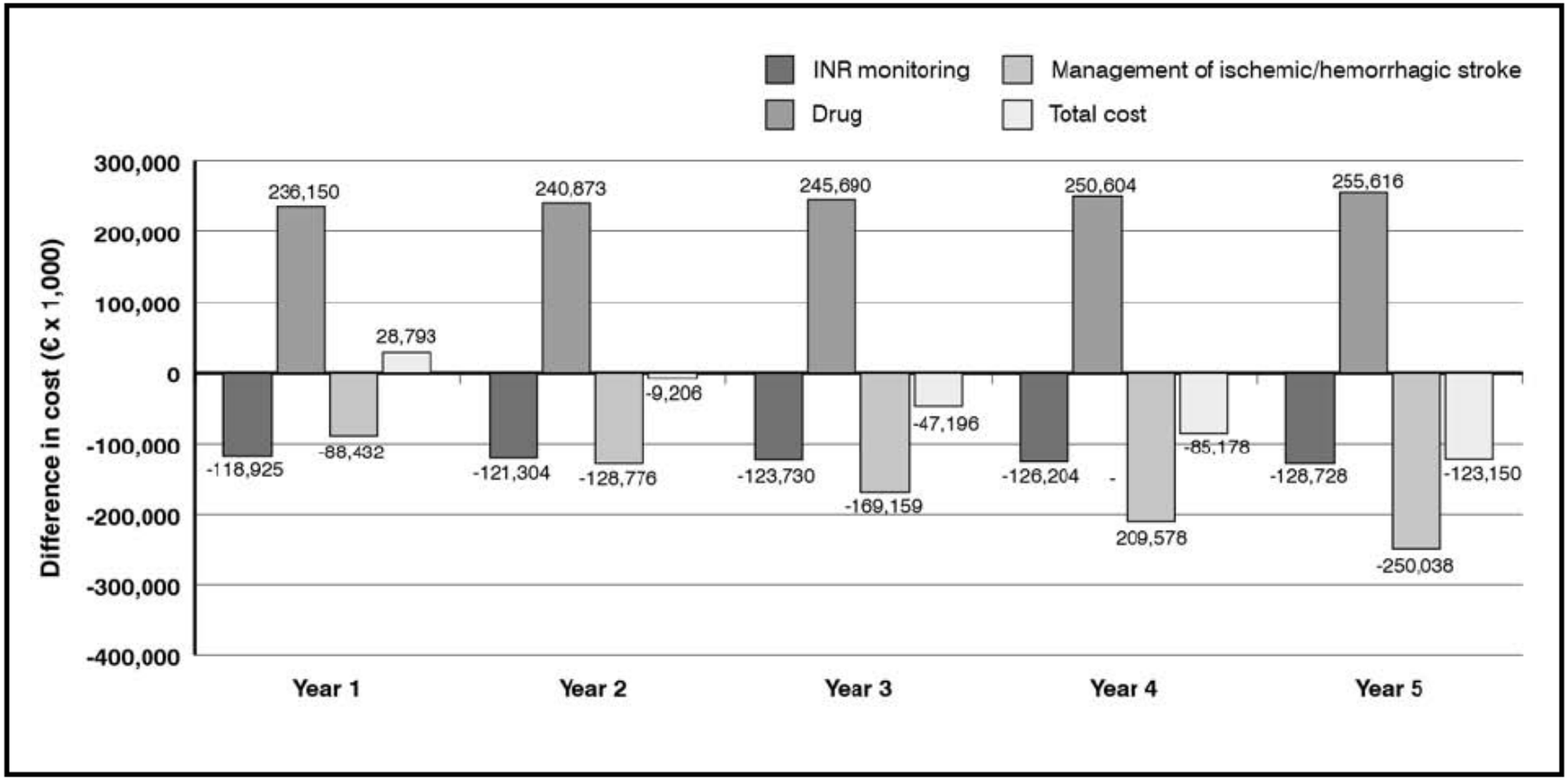

Figure 3. *Differences in cost of dabigatran etexilate vs. treatment with VKA*

Farmeconomia. Health economics and therapeutic pathways 2012;13(3): 105-15



Con il Patrocinio di:

ICTUS E FIBRILLAZIONE ATRIALE: ASPETTI CLINICI, ECONOMICI, SOCIALI E STRATEGIE DI INTERVENTO

27 Settembre 2011, Ore 11.00
Sala Caduti di Nassirya
Senato della Repubblica
Piazza Madama, 11 Roma