Gestione del tromboembolismo venoso in Europa: il contributo dello studio RIETE

Adriana Visonà
Direttore UOC Angiologia, Castelfranco Veneto (TV)
Presidente Nazionale SIAPAV
Presidente ESVM

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Simposio SISET/ATBV/SIAPAV

"Esperienza dal mondo reale nella gestione della patologie tromboemboliche e delle terapie anticoagulanti"

Moderatori: M. Camera, C. Fresco, A. Visonà

Gestione del tromboembolismo venoso in Europa: il contributo dello studio RIETE
A. Visonà

Gestione dei pazienti con fibrillazione atriale con i farmaci anticoagulanti orali diretti
M. Lettino

Gestione dei pazienti con tromboembolismo venoso con i farmaci anticoagulanti orali diretti
B. Cosmi

XXIV Congresso XXIV SISET

Abano Terme (PD) 9-12 Novembre 2016

Il sottoscritto dott. Adriana Visonà

dichiara che negli ultimi due anni NON ha avuto i seguenti rapporti anche di finanziamento con soggetti portatori di interessi commerciali in campo sanitario:

- Alfa Wasserman
- Bayer
- Italfarmaco
- Pfizer

Il sottoscritto dichiara altresì che detti rapporti non sono tali da poter influenzare l'attività di docenza espletata nell'ambito di codesto evento pregiudicando la finalità esclusiva di educazione/formazione di professionisti.

Il dott. Adriana Visonà non si trova pertanto in una situazione di conflitto di interessi rispetto all'evento ai sensi e per gli effetti dell'Accordo Stato-Regioni del 5 /01/2009

Registro Informatizado de Enfermedad Trombo Embólica (RIETE)

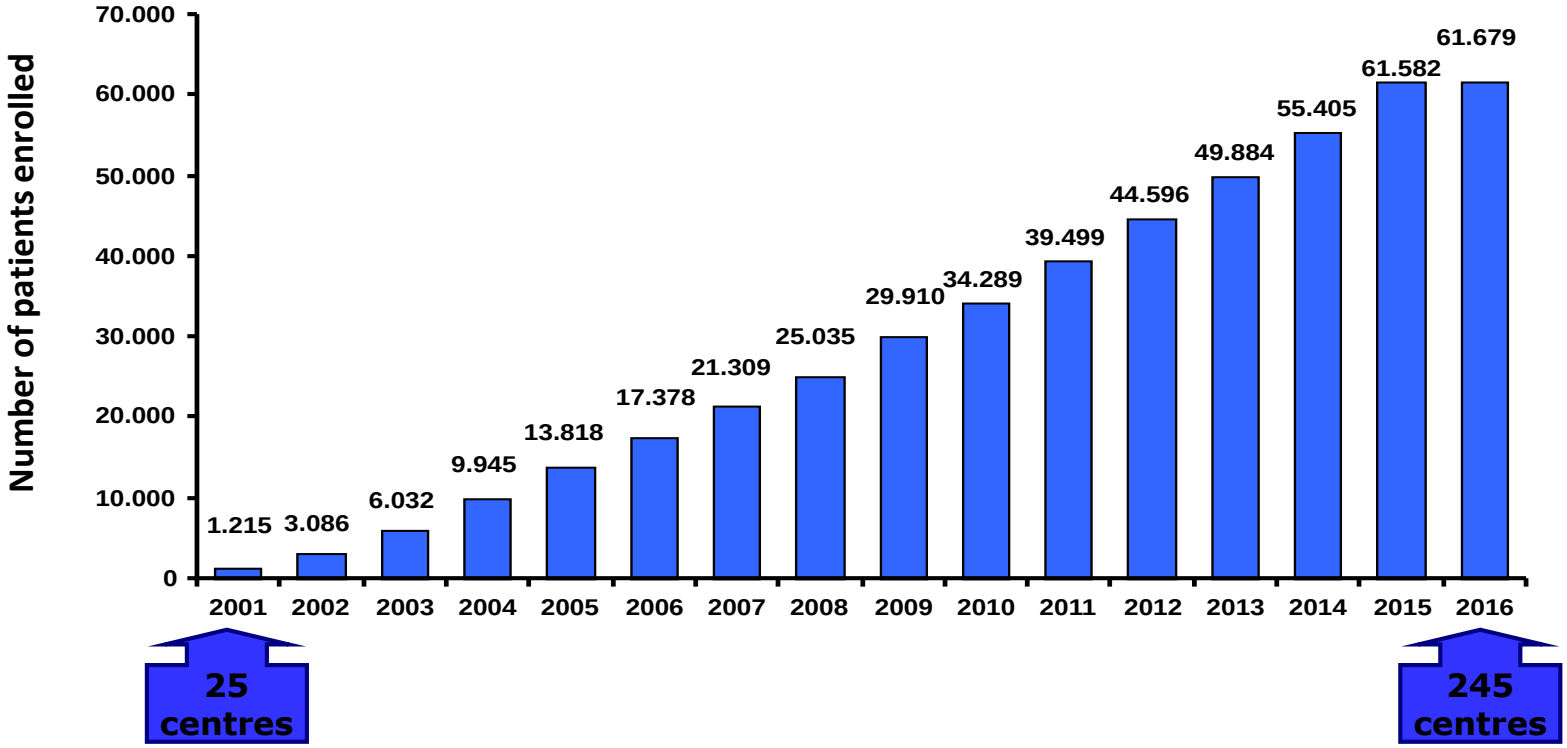
- consecutive DVT/PE
- confirmed diagnosis
- follow-up: 3 months

Aim:

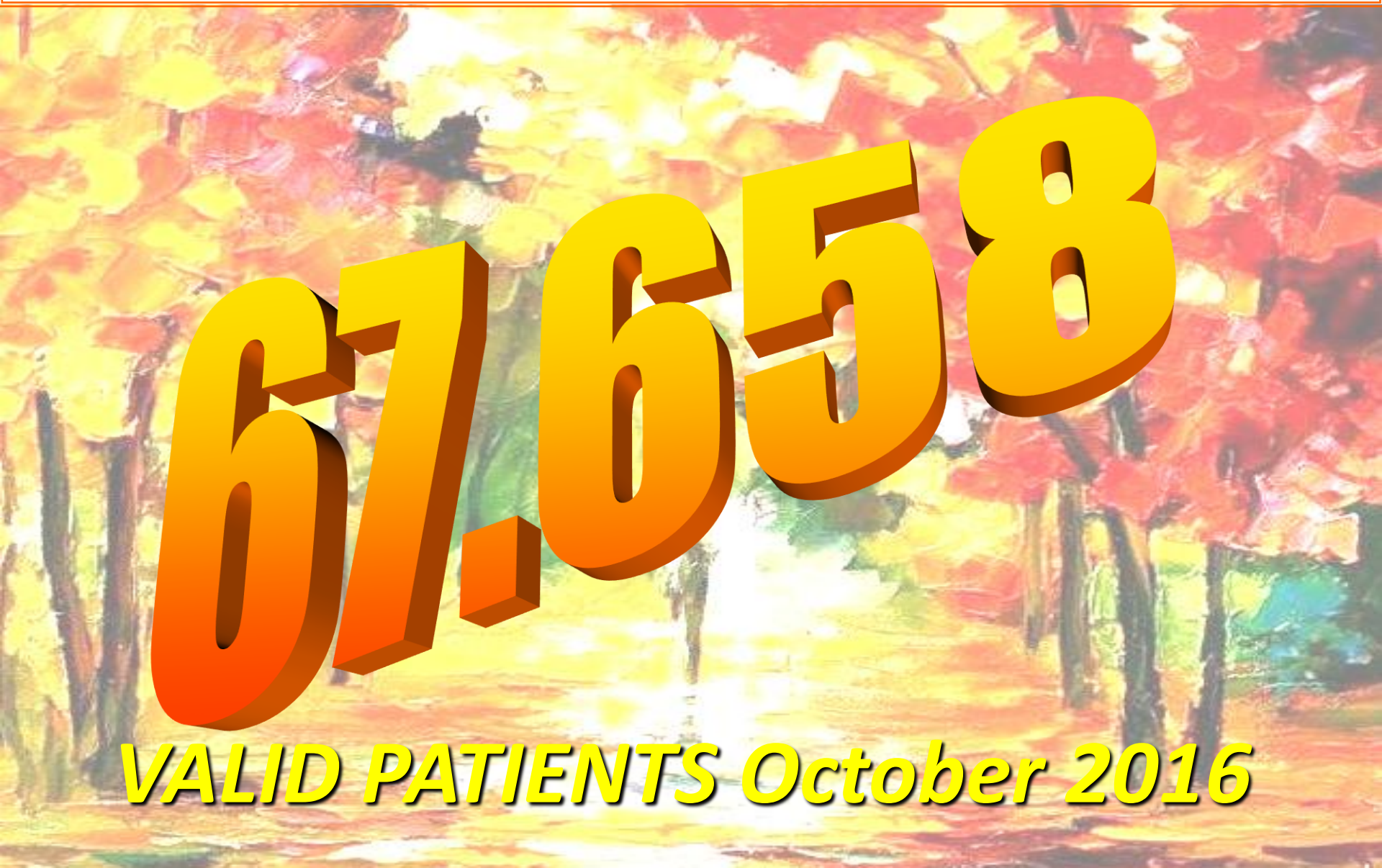
- To provide information on what happens in real-life for patients with VTE in special conditions

www.riete.org

67 658



The number of valid patients included up-to-date is …



Computerized Registry of Patients with Venous Thromboembolism (RIETE)

Information about the Registry | Advisory Board | Participating centers | eStiMaTe calculator | Links | Home

Advisory Board of the Computerized Registry of Patients with Venous Thromboembolism (R.I.E.T.E.)

- **Dr. Manuel Monreal Bosch**
  (Coordinator of the Registry)
  Department of Internal Medicine, Hospital Germans Trias i Pujol, Badalona, Barcelona.

Coordinating Center: S&H Medical Science Service

Software development by Inetsys

RIETE REGISTRY

Coordinator of the RIETE Registry: Monreal M (Spain)
RIETE Steering Committee Members: Decousus H (France), Prandoni P (Italy), Brenner B (Israel).
RIETE National Coordinators: Barba R (Spain), Di Micco P (Italy), Bertoletti L (France), Tzoran I (Israel), Reis A (Portugal), Bosevski M (R. Macedonia), Bounameaux H (Switzerland), Malý R (Czech Republic), Wells P (Canada), Verhamme P (Belgium).
RIETE Registry Coordinating Center: S & H Medical Science Service

Computerized Registry of Patients with Venous Thromboembolism (RIETE)

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Information about the Registry

The Computerized Registry of Patients with Venous Thromboembolism (RIETE) is a multidisciplinary Project initiated in march 2001 and consisting in obtaining an extensive data registry of consecutive patients with venous thromboembolism

Objectives

1. The main objective is to provide information on the Internet to help physicians to improve their knowledge on the natural history of thromboembolic disease, particularly in those subgroups of patients who are usually not recruited in randomized clinical trials (pregnant women, elderly patients, disseminated cancer, severe renal insufficiency, patients with contraindications to anticoagulation therapy, extreme body weight, etc), with the purpose of decreasing mortality, frequency of thromboembolic recurrences as well as bleeding complications and arterial events.
2. As an additional objective RIETE is also aimed to create predictive scores that help physicians to better identify patients with high risk of presenting some of these complications.

eStiMaTe calculator

estiMaTe calculator

estiMaTe | Instructions | Publications | Copyright

This calculator is not suitable for hemodynamically unstable patients with PE

sPESI (Simplified Pulmonary Embolism Severity Index)	No	Yes
Age > 80 years	●	○
History of cancer	●	○
History of chronic cardiopulmonary disease	●	○
Heart rate ≥ 110 beats/min	●	○
Systolic blood pressure < 100 mmHg	●	○
Arterial oxyhemoglobin saturation < 90 %	●	○

sPESI value: 0

	Unknown	No	Yes
Cardiac troponin > 0.05 ng/mL	●	○	○
Brain natriuretic peptide > 100 pg/mL	●	○	○
Deep vein thrombosis by CCUS	●	○	○

Risk of 30-day mortality: 0.3 %

Risk of 30-day complicated course: 1.6 %

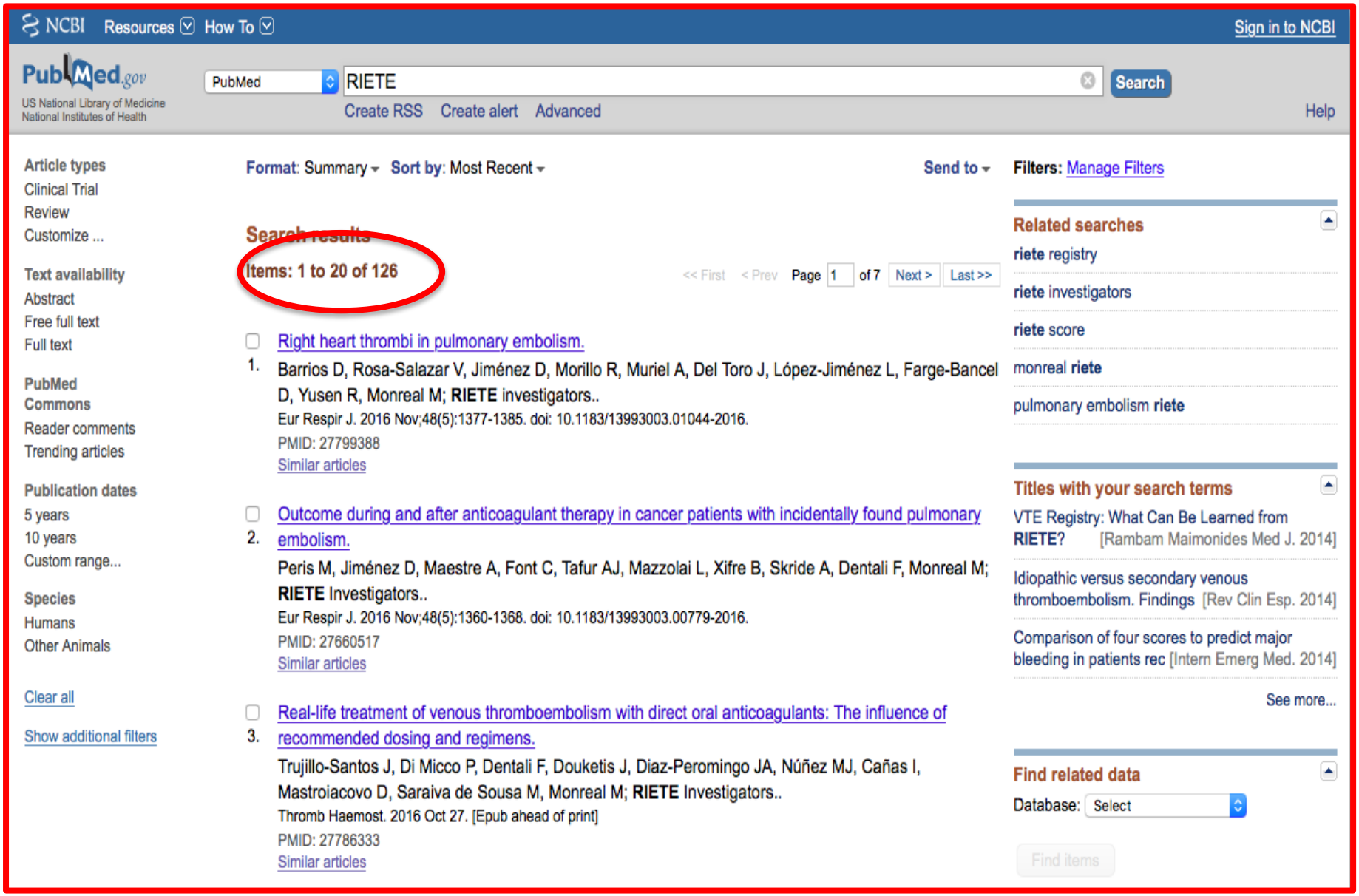
FUENTE
Fundación para el Estudio de la Enfermedad Tromboembólica en España

Supported by an educational grant from RIETE

PII SEPAR de TEP
Área de Circulación SEPAR

SaludMadrid Hospital Universitario Ramón y Cajal
Comunidad de Madrid

RIETE PUB MED



NCBI Resources How To Sign in to NCBI

PubMed.gov
US National Library of Medicine
National Institutes of Health

PubMed | RIETE | Search

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Article types
Clinical Trial
Review
Customize ...

Text availability
Abstract
Free full text
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Publication dates
5 years
10 years
Custom range...

Species
Humans
Other Animals

Clear all

Show additional filters

Format: Summary **Sort by:** Most Recent **Send to**

Filters: Manage Filters

Search results

Items: 1 to 20 of 126

<< First < Prev Page 1 of 7 Next > Last >>

1. Right heart thrombi in pulmonary embolism.
Barrios D, Rosa-Salazar V, Jiménez D, Morillo R, Muriel A, Del Toro J, López-Jiménez L, Farge-Bancel D, Yusen R, Monreal M; **RIETE** investigators..
Eur Respir J. 2016 Nov;48(5):1377-1385. doi: 10.1183/13993003.01044-2016.
PMID: 27799388
Similar articles

2. Outcome during and after anticoagulant therapy in cancer patients with incidentally found pulmonary embolism.
Peris M, Jiménez D, Maestre A, Font C, Tafur AJ, Mazzolai L, Xifre B, Skride A, Dentali F, Monreal M; **RIETE** Investigators..
Eur Respir J. 2016 Nov;48(5):1360-1368. doi: 10.1183/13993003.00779-2016.
PMID: 27660517
Similar articles

3. Real-life treatment of venous thromboembolism with direct oral anticoagulants: The influence of recommended dosing and regimens.
Trujillo-Santos J, Di Micco P, Dentali F, Douketis J, Diaz-Peromingo JA, Núñez MJ, Cañas I, Mastroiacovo D, Saraiva de Sousa M, Monreal M; **RIETE** Investigators..
Thromb Haemost. 2016 Oct 27. [Epub ahead of print]
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Related searches
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Titles with your search terms
VTE Registry: What Can Be Learned from **RIETE**? [Rambam Maimonides Med J. 2014]
Idiopathic versus secondary venous thromboembolism. Findings [Rev Clin Esp. 2014]
Comparison of four scores to predict major bleeding in patients rec [Intern Emerg Med. 2014]

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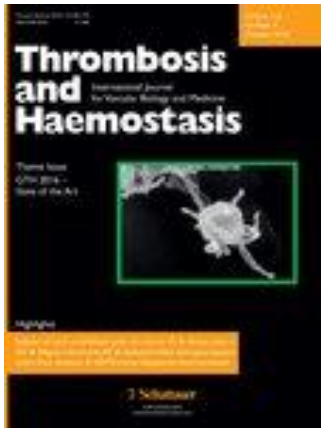
GOOD NEWS - NEW RIETE ARTICLE in Thrombosis and Haemostasis

As we recently informed you via Email, the RIETE article entitled: *"Real-life treatment of venous thromboembolism with direct oral anticoagulants. The influence of recommended dosing and regimens"*, prepared by Dr. Javier Trujillo *(Department of Internal Medicine, Hospital General Universitario Santa Lucía. Murcia, Spain)*, has been PUBLISHED in *Thrombosis and Haemostasis.*



"Real-life treatment of venous thromboembolism with direct oral anticoagulants. The influence of recommended dosing and regimens"

Trujillo J, Di Micco P, Dentali F, Douketis J, Díaz-Peromingo JA, Núñez MJ, Cañas I, Mastroiacovo D, de Sousa MS, Monreal M, and the RIETE investigators.

Please, do not forget to press over the icon to see the final version of the article!!!

¡¡Congratulations RIETE Group!!

Dr. Trujillo Article

GOOD NEWS - NEW RIETE ARTICLE in CHEST

As you all know, the RIETE article entitled:

"Development of a risk prediction score for occult cancer in patients with venous thromboembolism"*, prepared by Dr. Luis Jara Palomares *(Department of Pneumonology, Hospital Virgen del Rocío, Sevilla, Spain)*, has been ACCEPTED FOR PUBLICATION in *CHEST.

We now have available the proofs of the article!

"Development of a risk prediction score for occult cancer in patients with venous thromboembolism"

Jara-Palomares L, Otero R, Jiménez D, Carrier M, Tzoran I, Brenner B, Margeli M, Praena-Fernández JM, Grandone E, Monreal M, and the RIETE investigators

Please, do not forget to press over the icon to see the proofs of the article!!!

¡¡Congratulations RIETE Group!!

WE CONTINUE WITH GOOD NEWS - NEW RIETE ARTICLE in CHEST

We would like to inform you all that the RIETE article entitled: *"Clinical prognosis of non-massive central and non-central pulmonary embolism: a registry-based cohort study"*, prepared by Dr. Bobby Gouin *(Division of Angiology and Hemostasis, Geneva University Hospital and Faculty of Medicine, Geneva, Switzerland)*, has been ACCEPTED FOR PUBLICATION in *CHEST.*

"Clinical prognosis of non-massive central and non-central pulmonary embolism: a registry-based cohort study"

Gouin B, Blondon M, Jiménez D, Fernández-Capitán C, Bounameaux H, Soler S, Duce R, Sahuquillo JC, Ruiz-Giménez N, Monreal M, and the RIETE investigators

Do not forget to press over to see the final version of the article!

¡¡Congratulations RIETE Group!!

Dr. Gouin Article

GOOD NEWS - NEW RIETE ARTICLE in European Respiratory Journal

Furthermore, as we informed you all, the RIETE article entitled: *"Right Heart Thrombi in Pulmonary Embolism"*, prepared by Dr. David Jiménez *(Respiratory Department, Ramón y Cajal Hospital and Instituto Ramón y Cajal de Investigación Sanitaria IRYCIS, Madrid, Spain)*, has been ACCEPTED FOR PUBLICATION in *European Respiratory Journal.*

We now have available the proofs of the article!

"Right Heart Thrombi in Pulmonary Embolism"

Barrios D, Rosa-Salazar V, Jiménez D, Morillo R, Muriel A, del Toro J, López-Jiménez L, Farge-Bancel D, Yusen R, Monreal M and the RIETE investigators.

Please, do not forget to press over the icon to see the final version of the article!!!

¡¡Congratulations RIETE Group!!

Dr. Jiménez Article

Quality Control in RIETE

The number of publications based on the RIETE Registry data every day is greater, and for this reason we are constantly carrying out revisions of the data and requesting for your collaboration to solve queries, inconsistencies and missing data.

We need to ensure data quality of the RIETE database.

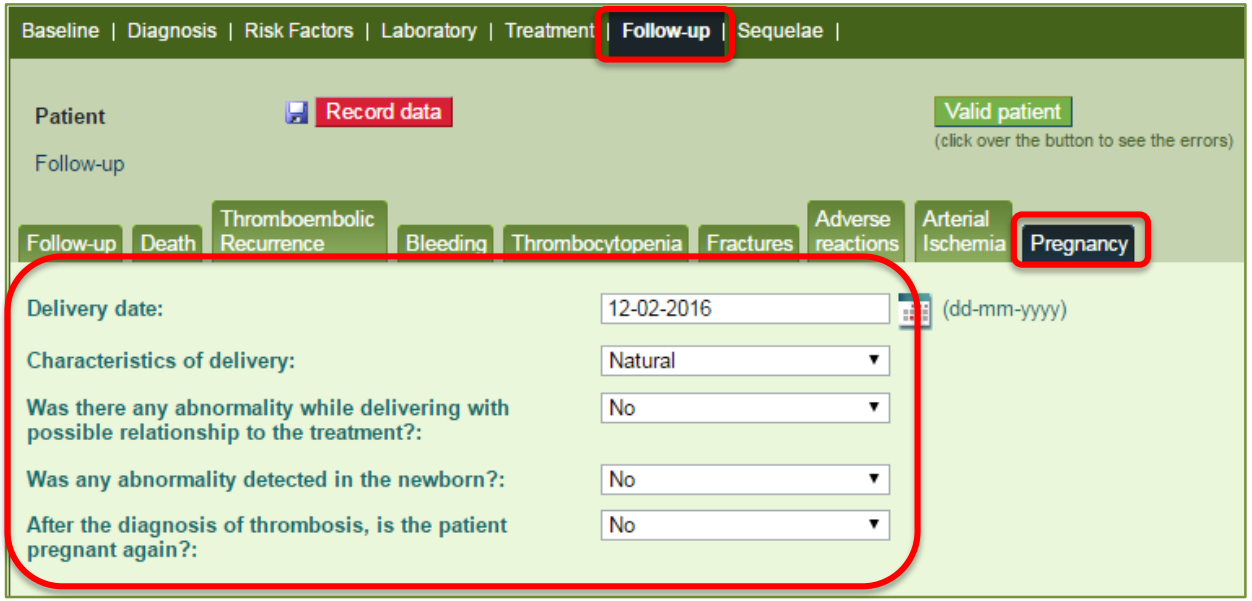
This is fundamental for the success of the Registry.

You all know that for this purpose you can count with the support of S&H Medical Science Service.

Thank you for your collaboration!!

Quality Control in RIETE

Currently we are requesting revisions for those patients in which you have filled out "Yes" for "Pregnancy?" within the Section "Risk Factors", but you have not completed the subvariables regarding pregnancy within the Follow-up Section-Pregnancy Menu-tab:



Please bear in mind that it is very important to update your data regarding pregnancy in follow-up section.

Important issues in the RIETE Database

As you all know, the RIETE Registry is a Prospective Study. Therefore, please take note that all patients included in the RIETE database:

- Must be patients with *date of diagnosis as from your registration in the RIETE Registry as an Active Member.*
- Must be *consecutive patients.*
- Although the **RIETE Registry** do not allow retrospective patients, please note that *you have to include some retrospective data (medical history of the patient).* This information is necessary for the different research projects that we carry out.

1st International RIETE Meeting

7th Update Meeting on DOACs

Last 6th – 7th October 2016 the 1st International RIETE Meeting was held in Seville.

After 15 years of work, the RIETE Group had the opportunity to bring together worldwide experts to share their experience and knowledge on VTE.

This meeting has achieved an important goal. Investigators from different specialities have established communication and networks at worldwide level.

World Thrombosis Day: 13th October

WORLD THROMBOSIS DAY
13 OCTOBER

Last 13th October the World Thrombosis Day took place.

The celebration of this day aims to raise awareness about this disease, being one of the leading causes of death and disability worldwide.

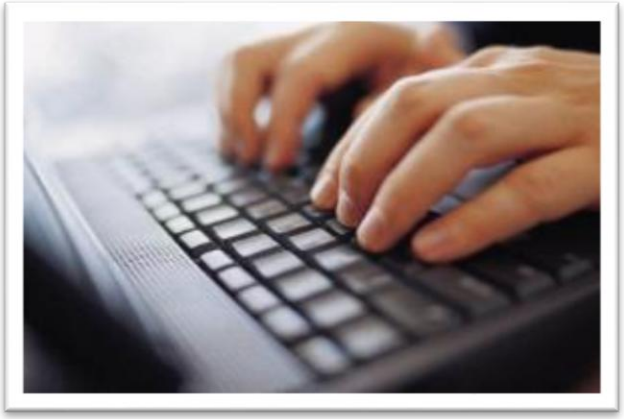
We would like to highlight the presentation made by Dr. Manuel Monreal of the *White Paper on cancer and thrombosis* at the European Parliament. The objective of this document is to raise awareness of the incidence and severity of the combination of both diseases.

You may consult the white paper on cancer and thrombosis by clicking on the following link:

White paper on Cancer and Thrombosis

Definitely, the RIETE Registry has achieved international recognition at a scientific level and this is very important for the RIETE Group.

Congratulations to all the RIETE Members for making this possible!!!



WE ALL MUST FEEL VERY PROUD BELONGING TO THIS GREAT PROJECT!!!

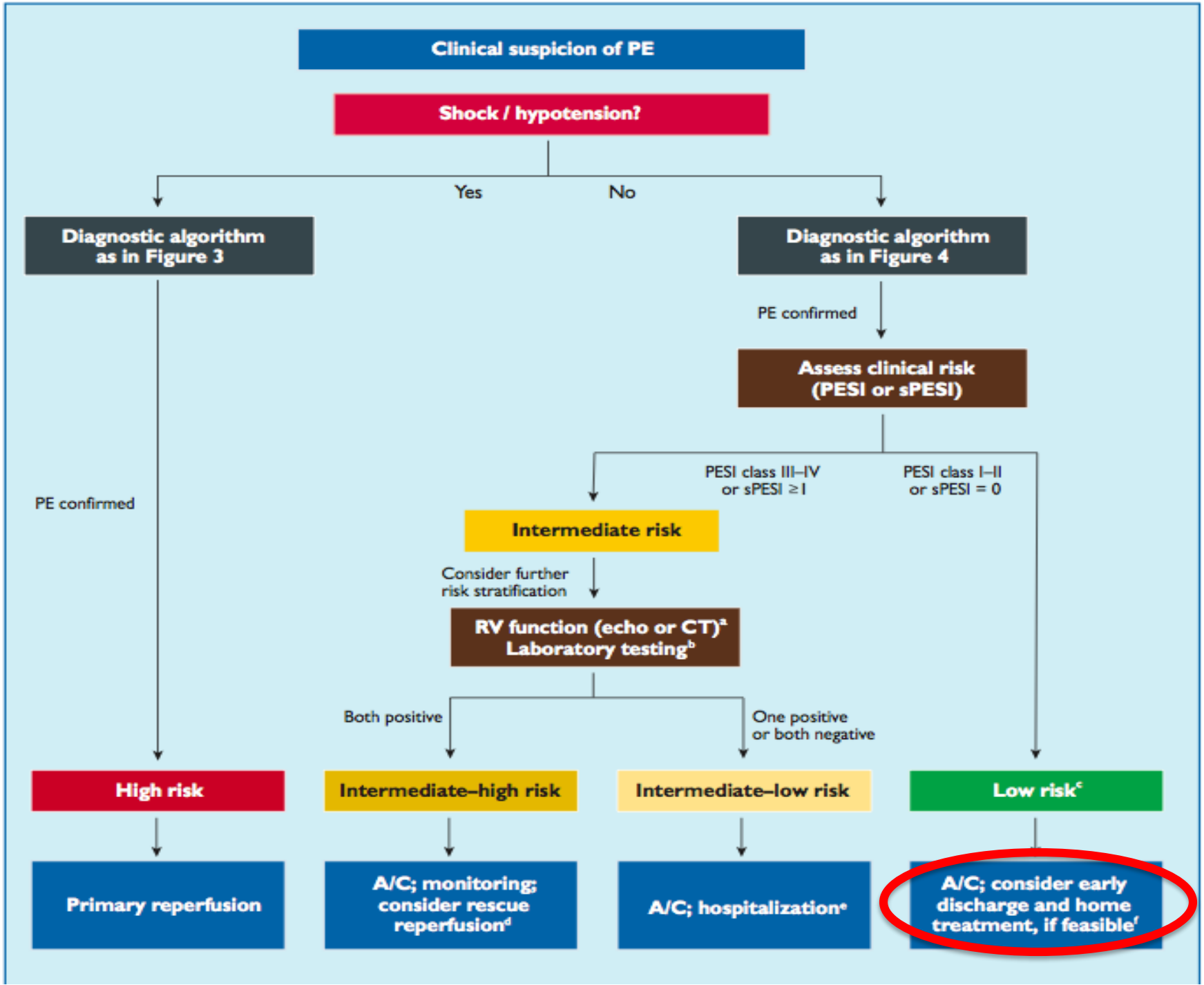
Kind regards,

RIETE Advisory Board

VTE in the world

Off GL

Balance


Clinical suspicion of PE
Shock / hypotension?
Yes
No
Diagnostic algorithm as in Figure 3
Diagnostic algorithm as in Figure 4
PE confirmed
Assess clinical risk (PESI or sPESI)
PE confirmed
PESI class III–IV or sPESI ≥ I
PESI class I–II or sPESI = 0
Intermediate risk
Consider further risk stratification
RV function (echo or CT)[a] Laboratory testing[b]
Both positive
One positive or both negative
High risk
Intermediate–high risk
Intermediate–low risk
Low risk[c]
Primary reperfusion
A/C; monitoring; consider rescue reperfusion[d]
A/C; hospitalization[e]
A/C; consider early discharge and home treatment, if feasible[f]

TRATTAMENTO DOMICILIARE E DIMISSIONE PRECOCE

- Studi randomizzati hanno dimostrato che questi pazienti possono essere trattati al domicilio o possono essere dimessi dopo breve osservazione

Outpatient versus inpatient treatment for patients with acute pulmonary embolism: an international, open-label, randomised, non-inferiority trial

Drahomir Aujesky, Pierre-Marie Roy, Franck Verschuren, Marc Righini, Joseph Osterwalder, Michael Egloff, Bertrand Renaud, Peter Verhamme, Roslyn A Stone, Catherine Legall, Olivier Sanchez, Nathan A Pugh, Alfred N'gako, Jacques Cornuz, Olivier Hugli, Hans-Jürg Beer, Arnaud Perrier, Michael J Fine, Donald M Yealy

Lancet 2011; 378: 41–48

Home treatment in pulmonary embolism

Remedios Otero [a,*], Fernando Uresandi [b], David Jiménez [c], Miguel Ángel Cabezudo [d], Mikel Oribe [e], Dolores Nauffal [f], Francisco Conget [g], Consolación Rodríguez [h], Aurelio Cayuela [i]

Thrombosis Research 126 (2010) e1–e5

In Italia?

RIETE AND DURATION OF HOSPITALIZATION

Ann Med. 2015;47(7):546-54. doi: 10.3109/07853890.2015.1085127. Epub 2015 Sep 30.

Rate and duration of hospitalization for deep vein thrombosis and pulmonary embolism in real-world clinical practice.

Dentali F[1], Di Micco G[2], Giorgi Pierfranceschi M[3], Gussoni G[4], Barillari G[5], Amitrano M[6], Fontanella A[7], Lodigiani C[8], Guida A[9], Visonà A[10], Monreal M[11], Di Micco P[7].

⊕ Author information

Abstract

BACKGROUND: Current guidelines recommend initial treatment with anticoagulants at home in patients with acute deep vein thrombosis (DVT) and in patients with low-risk pulmonary embolism (PE) with adequate home circumstances. However, most of the patients with acute venous thromboembolism (VTE) are currently hospitalized regardless of their risk of short-term complications.

AIM OF THE STUDY: To assess the proportion of outpatients with acute VTE initially treated in hospitals, to assess the mean duration of hospitalization, and to identify predictors for in-hospital or home treatment.

METHODS: Data of Italian patients enrolled in the RIETE registry from January 2006 to December 2013 were included.

RESULTS: Altogether 766 PE and 1,452 isolated DVT were included. Among PE patients, mean PESI score was 84 points (SD 35), and 56% of patients had a low-risk PESI score (<85). In all, 53.7% of DVT and 17.0% of PE were entirely treated at home, and 38.2% of DVT patients and 19.9% of PE patients were hospitalized for ≤5 days. On multivariate analysis, low PESI score was not independently associated with the hospitalization of PE patients.

CONCLUSIONS: One in every two patients with DVT and five in every six with PE are still hospitalized.

KEYWORDS: Hospitalization; treatment; venous thromboembolism

SCOPO DELLO STUDIO

I. Fornire informazioni sul trattamento in Italia del TEV acuto in termini di ***tasso e durata dell'ospedalizzazione*** utilizzando i dati forniti dai centri Italiani dello studio RIETE (Registro Informatizado de Enfermedad TromboEmbólica)

II. Valutare potenziali fattori predittivi di un ***completo trattamento domiciliare o di una precoce dimissione***

Caratteristiche di base (i)

	Popolazione globale	EP	TVP
Caratteristiche cliniche	**2,218**	**766**	**1,452**
Età	61±18	63±19	60±18
Sesso (maschile)	1,088 (49.1%)	335 (43.7%)	753 (51.9%)
Peso corporeo	75±16	75±16	75±16
Presentazione iniziale			
FC > 110 bpm (N=1,522)	107 (7.0%)	84 (16.5%)	23 (2.27%)
PA < 100 mmHg (N=1,913)	43 (2.25%)	32 (4.18%)	11 (0.96%)
FR > 30 min (N=438)	35 (7.99%)	17 (8.90%)	18 (7.29%)
Temperatura < 36 ° C, (N=786)	7 (0.89%)	3 (0.96%)	4 (0.84%)
Alterazioni di coscienza, (N=779)	29 (3.72%)	21 (6.73%)	8 (1.71%)
Saturazione arteriosa di O2 <90%, (N=319)	82 (25.7%)	75 (26.5%)	7 (19.4%)

Caratteristiche di base (ii)

	Popolazione globale	EP	TVP
Fattori di rischio			
Cancro	481 (21.7%)	172 (22.5%)	309 (21.3%)
Chemioterapia in atto (N=446)	225 (50.4%)	76 (47.5%)	149 (52.1%)
Chirurgia	159 (7.2%)	78 (10.2%)	81 (5.58%)
Immobilità ≥4 giorni	251 (11.3%)	90 (11.7%)	161 (11.1%)
Terapia estrogenica	185 (8.3%)	84 (11.0%)	101 (6.96%)
Gravidanza e puerperio	51 (2.30%)	16 (2.09%)	35 (2.41%)
Lunghi viaggi	43 (1.94%)	13 (1.70%)	30 (2.07%)
Idiopatica	1,098 (49.5%)	334 (43.6%)	764 (52.6%)
Condizioni sottostanti			
Insufficienza cardiaca cronica	129 (5.82%)	67 (8.75%)	62 (4.27%)
Malattia polmonare cronica	131 (5.91%)	73 (9.53%)	58 (3.99%)
Sanguinamenti maggiori	19 (0.86%)	7 (0.91%)	12 (0.83%)
CrCl <60 mL/min	578 (26.1%)	238 (31.1%)	340 (23.4%)
Anemia	682 (30.7%)	252 (32.9%)	430 (29.6%)
Pregresso TEV	389 (17.5%)	118 (15.4%)	271 (18.7%)
TVP concomitante (solo per pazienti con EP)	358 (16.1%)	358 (46.7%)	-

EP vs TVP (i)

		Popolazione globale	EP	TVP	OR (95% IC)
	N. di pazienti	**2,218**	**766**	**1,452**	
Trattamento iniziale	ENF	179 (8.1%)	150 (19.6%)	29 (2.00%)	12.0 (7.94-18.0)
	EBPM	1,818 (82.0%)	566 (73.9%)	1,252 (86.2%)	0.45 (0.36-0.56)
	Fondaparinux	176 (7.94%)	29 (3.79%)	147 (10.1%)	0.35 (0.23-0.53)
	DOACs	3 (0.14%)	1 (0.13%)	2 (0.14%)	0.95 (0.09-10.5)
	Trombolitici	9 (0.41%)	9 (1.17%)	0	-
Terapia a lungo termine	Antagonisti della vitamina K	1,558 (70.2%)	599 (78.2%)	959 (66.0%)	1.84 (1.51-2.26)
	EBPM	486 (21.9%)	134 (17.5%)	352 (24.2%)	0.66 (0.53-0.83)
	Fondaparinux	119 (5.37%)	18 (2.35%)	101 (6.96%)	0.32 (0.19-0.54)
	DOACs	28 (1.26%)	8 (1.04%)	20 (1.38%)	0.76 (0.33-1.72)
Score PESI (pazienti con EP)	Basso rischio score PESI (<= 85)		430 (56.1%)		
	PESI (>85)º		336 (43.9%)		
	Score PESI medio		84±35		
	Score PESI mediano		82 (60-105)		

EP vs TVP (ii)

TIPO DI GESTIONE	Popolazione globale	EP	TVP	p
Trattamento ambulatoriale completo (N= 2,127)	875 (41.1%)	124 (17.0%)	751 (53.7%)	< 0.001
Numero di pazienti dimesso in 5 giorni	230 (28.8%)	82 (19.9%)	148 (38.2%)	< 0.001
Durata ospedalizzazione (media ± DS)	10 ± 11	12 ± 13	9 ± 8	< 0.01
Durata ospedalizzazione (mediana - IQR)	8 (5-12)	9 (6-13)	7 (4-10)	< 0.001

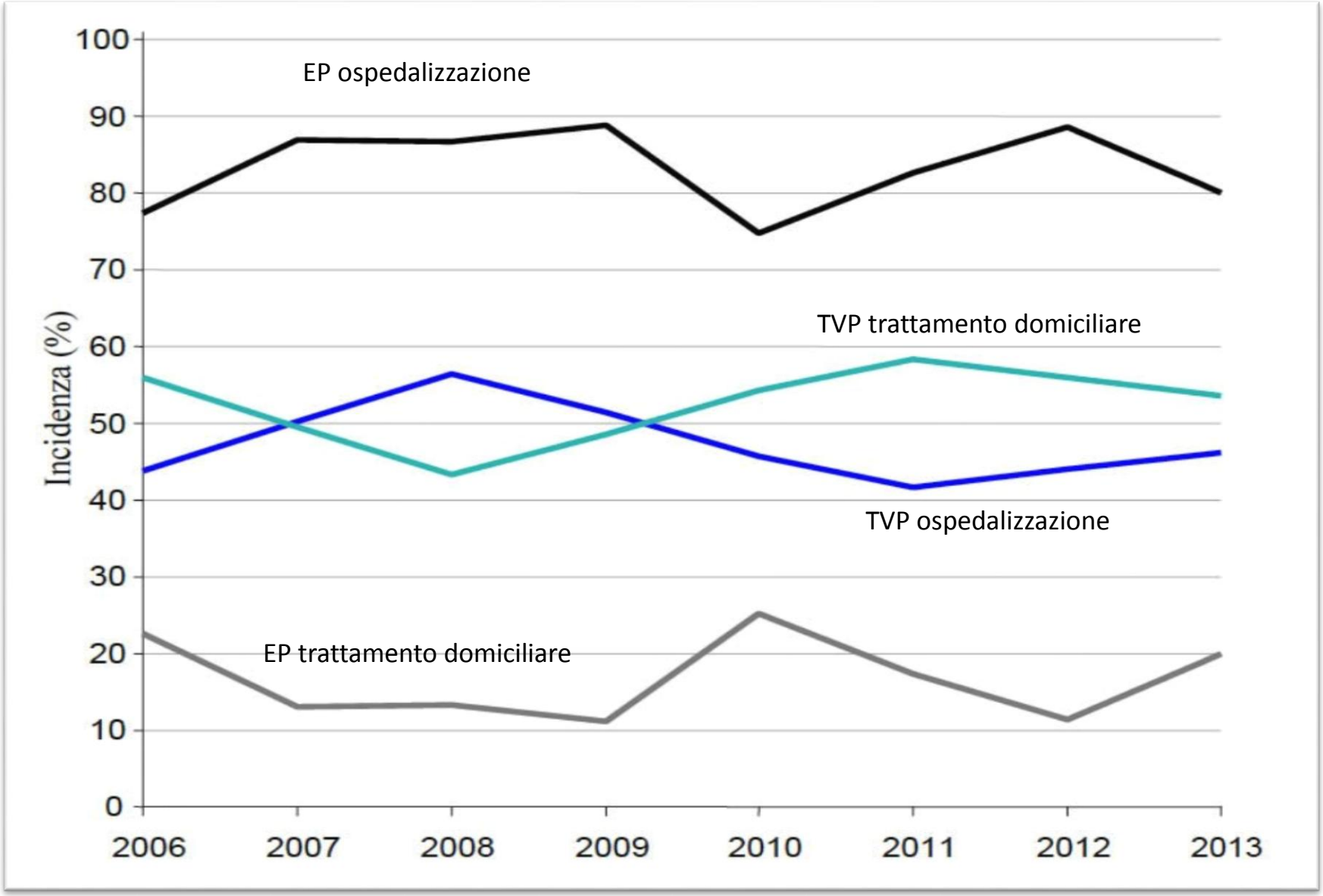
Analisi Univariata

	***Trattamento Domiciliare* vs trattamento ospedaliero**		**Ospedalizzazione > 5 giorni vs *ospedalizzazione < 5 giorni***	
	EP	**TVP**	**EP**	**TVP**
	P-value	P-value	P-value	P-value
Età	<0.001	<0.001	< 0.01	< 0.001
FC > 110 bpm	0.005	0.004	< 0.01	< 0.005
Terapia estrogenica	0.012	<0.001	< 0.05	< 0.001
CrCl <60 mL/min	<0.001	<0.001	< 0.05	< 0.001
Anemia	0.046	<0.001	< 0.05	< 0.001
Cancro	N.S	N.S	< 0.01	N.S
Gravidanza e puerperio	0.02	N.S	0.02	N.S
PESI < 85	< 0.058		N.S	

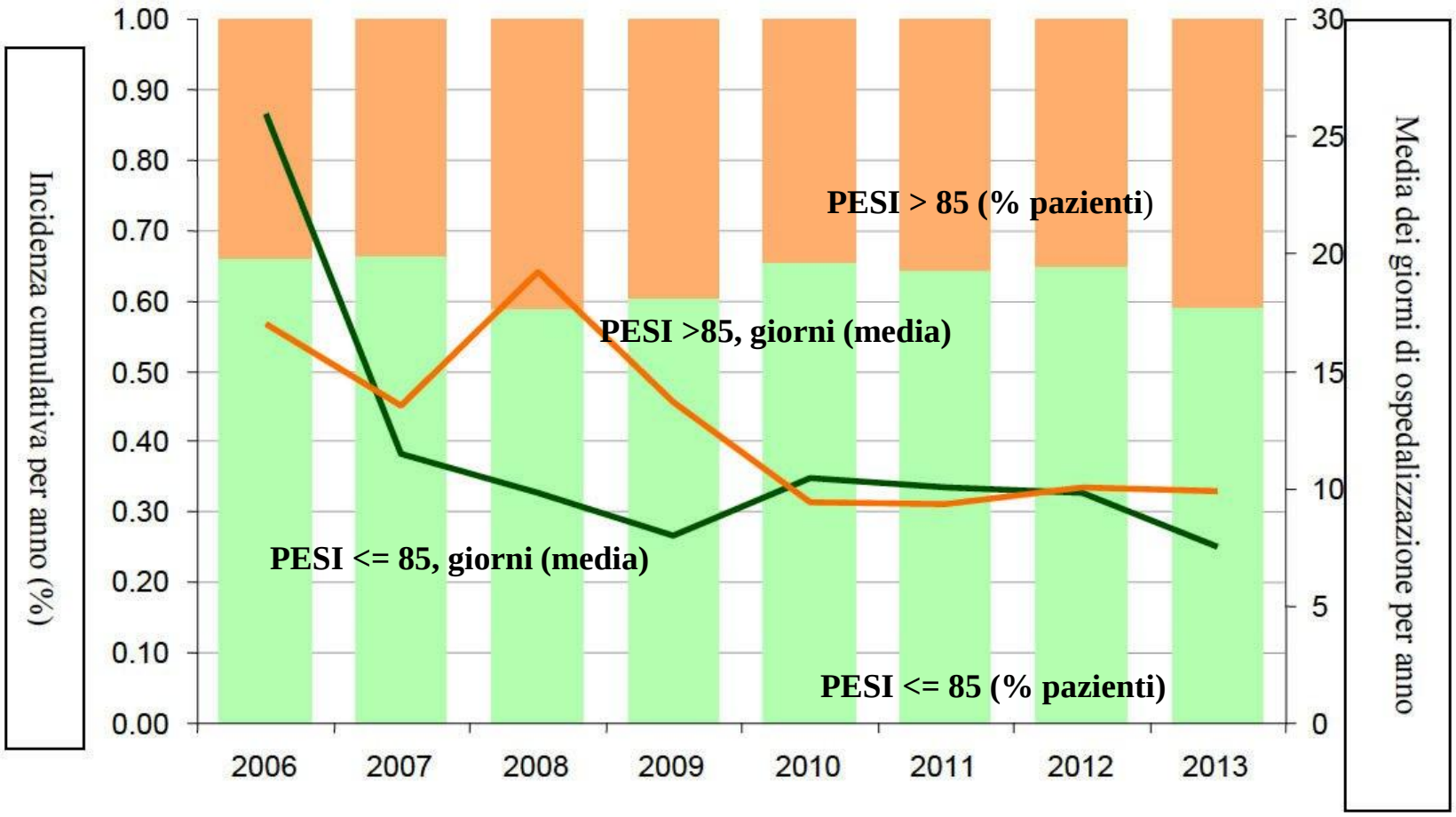
Analisi Multivariata

	Trattamento ambulatoriale		Dimissione precoce < 5 giorni e trattamento domiciliare vs dimissione > 5 giorni	
Caratteristiche cliniche	**EP**	**TVP**	**EP**	**TVP**
Età > 65 anni	-	0.53 (0.39-0.71)	-	0.58 (0.41-0.81)
Presentazione iniziale				
FC > 110 bpm	0.12 (0.02-0.86)	0.17 (0.05-0.59)	0.27 (0.10-0.73)	-
Fattori di rischio				
Cancro	-	-	1.91 (1.06-3.46)	-
Gravidanza o puerperio	4.58 (1.10-19.05)	-	-	-
Condizioni sottostanti				
Insufficienza cardiaca cronica	-	-	-	0.51 (0.27-0.96)
CrCl <60 mL/min	-	0.60 (0.42-0.85)	-	0.50 (0.35-0.71)
Anemia	-	0.56 (0.42-0.76)	-	0.70 (0.51-0.97)

Tasso ospedalizzazione per TEV



Durata media di ospedalizzazione dei pazienti con EP in relazione al PESI durante il periodo di studio



Il resto del mondo?

METODI (i)

- Solo Embolie Polmonari ambulatoriali al momento della diagnosi
- 4 Principali Nazioni Arruolatrici vs resto del mondo:
  - Spagna
  - Italia
  - Francia
  - Israele

METODI (ii)

- Profilo di Rischio (PESI)
- Tasso di ospedalizzazione
- Degenza media
- Potenziali predittori

Risultati (preliminari)

	Spain	Italy	France	Israel	Rest of the world
Patients, N	***5,601***	***417***	***477***	***203***	***987***
Age	68±17	61±18‡	65±19‡	62±19‡	62±18‡
Gender (male)	2,580 (46%)	184 (44%)	239 (50%)	96 (47%)	480 (49%)
Initial presentation					
Pulse > 110 bpm	1,143 (21%)	37 (13%)‡	51 (11%)‡	36 (18%)	178 (18%)
Systolic BP levels < 100 mmHg	494 (8.8%)	14 (3.4%)‡	12 (2.5%)‡	10 (4.9%)	50 (5.1%)‡
Respiratory rate > 30 min	261 (9.3%)	16 (9.1%)	12 (8.7%)	4 (7.7%)	53 (6.8%)*
Temperature < 36° C	591 (11%)	3 (1.2%)‡	5 (1.1%)‡	17 (8.9%)	8 (0.84%)‡
Altered mental status,	382 (7.0%)	12 (4.8%)	31 (6.5%)	8 (4.2%)	33 (3.5%)‡
Arterial oxygen saturation <90%,	996 (28%)	24 (21%)	33 (17%)‡	3 (8.8%)*	93 (17%)‡
Risk factors,					
Cancer	1,228 (22%)	86 (21%)	96 (20%)	86 (42%)‡	187 (19%)*
Active chemotherapy	405 (36%)	36 (46%)	33 (48%)	46 (55%)‡	51 (31%)
Surgery	368 (6.6%)	41 (9.8%)*	29 (6.1%)	18 (8.9%)	94 (9.5%)†
Immobility ≥4 days	877 (16%)	56 (13%)	41 (8.6%)‡	22 (11%)	98 (9.9%)‡
None of the above (unprovoked)	2,799 (50%)	189 (45%)	259 (54%)	67 (33%)‡	478 (48%)
Underlying conditions,					
Chronic heart failure	460 (8.2%)	19 (4.6%)†	37 (7.8%)	13 (6.4%)	89 (9.0%)
Chronic lung disease	802 (14%)	41 (9.8%)*	36 (7.5%)‡	28 (14%)	129 (13%)
Recent major bleeding	80 (1.4%)	6 (1.4%)	11 (2.3%)	7 (3.4%)*	24 (2.4%)*
CrCl levels <60 mL/min	2,159 (39%)	106 (25%)‡	133 (28%)‡	64 (32%)*	251 (25%)‡
Anemia	1,660 (30%)	149 (36%)*	126 (26%)	105 (52%)‡	273 (28%)
Prior VTE	731 (13%)	67 (16%)	125 (26%)‡	33 (16%)	194 (20%)‡
Hospitalization,					
Complete outpatient treatment	122 (2.2%)	67 (17%)‡	6 (1.3%)	3 (1.5%)	204 (21%)‡
N. patients discharged within 5 days	1,283 (25%)	63 (19%)*	129 (28%)	77 (40%)‡	226 (31%)‡
Duration of hospital stay (mean days±SD)	10±16	11±9	9±19	7±5*	9±8
Duration of hospital stay (median days, IQR)	8 (5-11)	9 (6-13)‡	7 (5-10)†	6 (4-10)†	8 (5-12)

LIMITI DELLO STUDIO

- Dati derivati da Registro osservazionale
- Generalizzabilità risultati?
- Numero limitato pazienti con specifiche condizioni cliniche

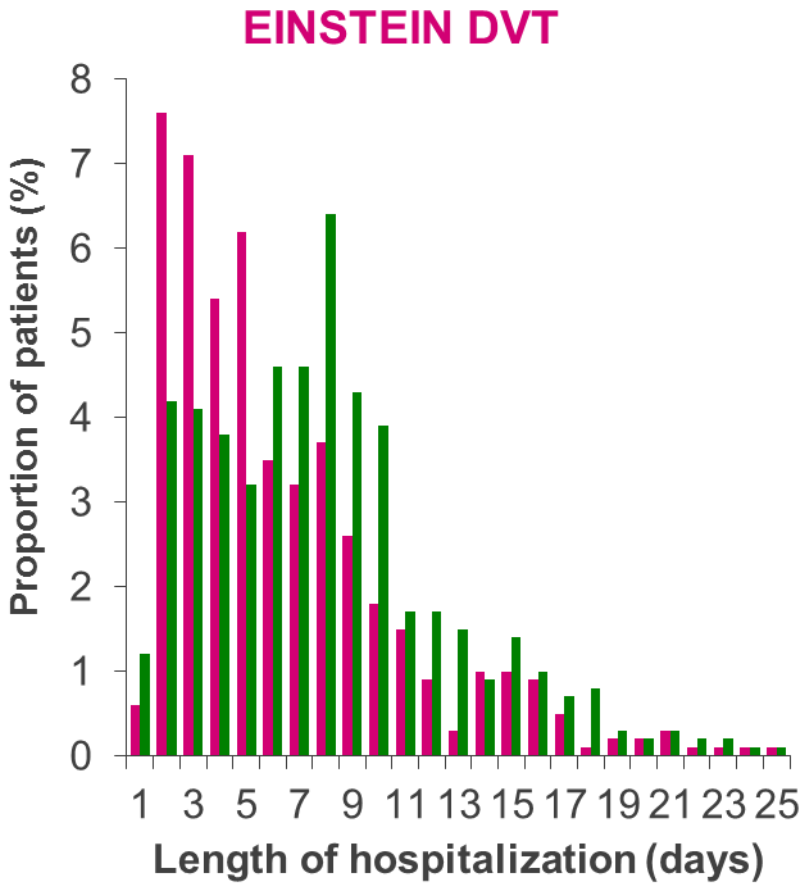
CONCLUSIONI

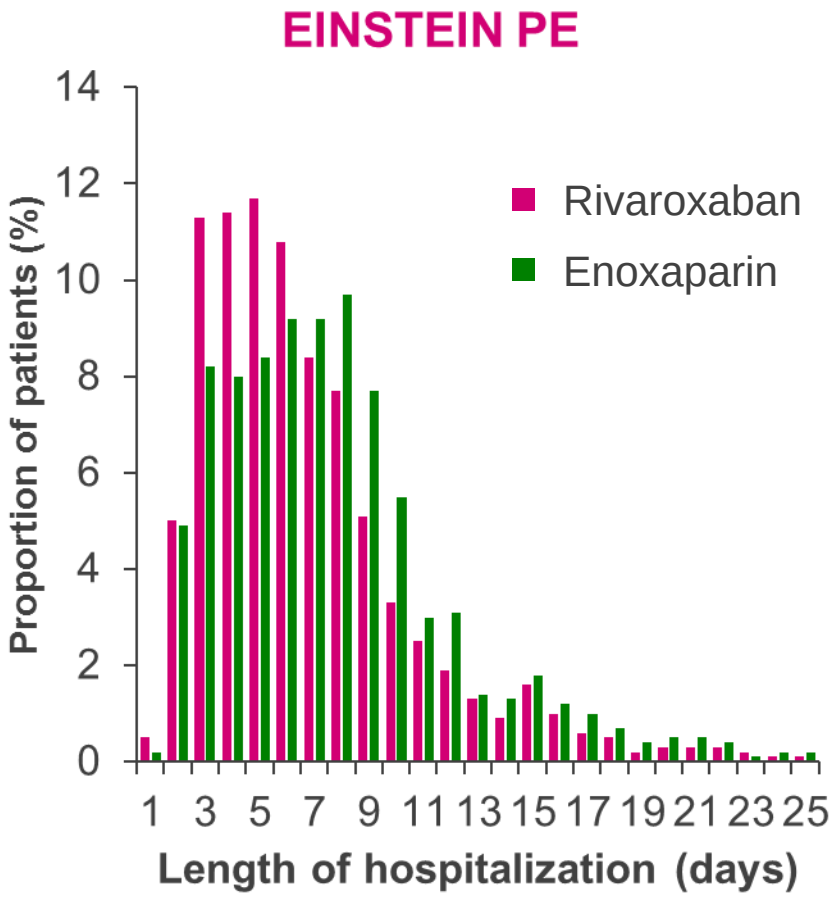
- Un ***significativo numero di pazienti con EP e con TVP viene ancora ospedalizzato*** per il trattamento della fase acuta

- Lo ***score PESI non sembra influenzare significativamente*** il tasso e la durata dell'ospedalizzazione nei pazienti con EP acuta

- Altri ***studi sono necessari*** per la valutazione di strategie che semplifichino il trattamento domiciliare del TEV acuto in Italia

Rivaroxaban reduces the length of hospital stay after PE: potential cost savings





van Bellen *et al,* 2012

RIETE REAL LIFE DOAC

Thromb Haemost. 2016 Oct 27. [Epub ahead of print]

Real-life treatment of venous thromboembolism with direct oral anticoagulants: The influence of recommended dosing and regimens.

Trujillo-Santos J, Di Micco P, Dentali F, Douketis J, Diaz-Peromingo JA, Núñez MJ, Cañas I, Mastroiacovo D, Saraiva de Sousa M, Monreal M[1]; RIETE Investigators.

Author information

Abstract

In patients with venous thromboembolism (VTE), the influence on outcome of using direct oral anticoagulants (DOACs) at non-recommended doses or regimens (once vs twice daily) has not been investigated yet. We used the RIETE (Registro Informatizado Enfermedad TromboEmbólica) registry to compare the outcomes in patients with VTE receiving DOACs according to the recommendations of the product label versus in those receiving non-recommended doses and/or regimens. The major outcomes were the rate of VTE recurrences, major bleeding and death during the course of therapy. As of March 2016, 1635 VTE patients had received DOACs for initial therapy and 1725 for long-term therapy. For initial therapy, 287 of 1591 patients (18 %) on rivaroxaban and 22 of 44 (50 %) on apixaban did not receive the recommended therapy. For long-term therapy, 217 of 1611 patients (14 %) on rivaroxaban, 29 of 81 (36 %) on apixaban and 15 of 33 (46 %) on dabigatran did not receive the recommended therapy. During the course of therapy with DOACs, eight patients developed VTE recurrences, 14 had major bleeding and 13 died. Patients receiving DOACs at non-recommended doses and/or regimens experienced a higher rate of VTE recurrences (adjusted HR: 10.5; 95 %CI: 1.28-85.9) and a similar rate of major bleeding (adjusted HR: 1.04; 95 %CI: 0.36-3.03) or death (adjusted HR: 1.41; 95 %CI: 0.46-4.29) than those receiving the recommended doses and regimens. In our cohort, a non-negligible proportion of VTE patients received non-recommended doses and/or regimens of DOACs. This use may be associated with worse outcomes.

Methods and Statistical Analysis

- Consecutive patients with the first, objectively confirmed, symptomatic VTE (DVT and/or PE) treated with a DOAC were prospectively followed for up to 3 months.
- Chi-square test and Student's t-test were used for comparison of baseline characteristics between pts treated with and without recommended DOAC dosage and/or regimen
- We calculated the cumulative incidence of death, recurrent VTE, major bleeding and death after 3 months
- Hazard ratios (HR) and their 95% CIs for the effect of not recommended DOAC dosage and/or regimen on the development of death, recurrent VTE and major bleeding were calculated using the proportional hazard Cox's regression model adjusted for several covariates

The treatment of VTE with DOAC: data from the RIETE Registry

Initial therapy

	Rivaroxaban	Apixaban
Patients, N	***1,591***	***44***
Daily doses		
Recommended	**1,315 (83%)**	**22 (50%)**
Lower	276 (17%)	22 (50%)
Regimen		
Twice daily	**1,234 (78%)**	**40 (91%)**
Once daily	158 (9.9%)	2 (4.5%)
Not provided	199 (13%)	2 (4.5%)

Recommendations of the product label:
- Rivaroxaban: 15 mg bd.
- Apixaban: 10 mg bd.

The treatment of VTE with DOAC: data from the RIETE Registry

Initial therapy

	Low doses	Recommended doses	Once daily	Twice daily
		Rivaroxaban		
Patients, N=1,591	***275***	***1,315***	***158***	***1,234***
Active cancer	34 (12%)‡	77 (5.9%)	19 (12%)†	77 (6.2%)
CrCl levels <30 mL/min	7 (5.5%)†	8 (1.3%)	4 (5.7%)*	8 (1.4%)
		Apixaban		
Patients, N=44	***22***	***22***	***2***	***40***
Age >70 years	8 (36%)†	12 (55%)	0	19 (48%)

*p <0.05 ; †p <0.01; ‡p <0.001

The treatment of VTE with DOAC: data from the RIETE Registry

Long-term therapy

	Rivaroxaban	Apixaban	Dabigatran
Patients, N	***1,611***	***81***	***33***
Daily doses			
Recommended	**1,432 (89%)**	**53 (65%)**	**18 (55%)**
Lower	66 (4.1%)	22 (27%)	15 (45%)
Higher	113 (7.0%)	6 (7.4%)	0
Regimen			
Twice daily	125 (7.8%)	**72 (89%)**	**24 (73%)**
Once daily	**1,136 (71%)**	4 (4.9%)	1 (3.0%)
No data	350 (22%)	5 (6.2%)	8 (24%)

Recommendations of the product label:
- Rivaroxaban: 20 mg od.
- Apixaban: 5 mg bd.
- Dabigatran: 150 mg bd.

The treatment of VTE with DOAC: data from the RIETE Registry

Long-term therapy

	Low doses	Recommended doses	High doses	Once daily	Twice daily
		Rivaroxaban			
Patients, N=1,611	***66***	***1,432***	***113***	***1,136***	***125***
Age >70 years	45 (68%)‡	370 (26%)			
Body weight <60kg	10 (15%)*	100 (7.0%)			
Active cancer	16 (24%)‡	92 (6.4%)	2 (1.8%)*	2 (1.6%)	86 (7.6%)*
CrCl levels <30 mL/min	6 (9.1%)‡	13 (0.9%)			
		Apixaban			
Patients, N=81	***22***	***53***	***6***	***4***	***72***
Active cancer	4 (18%)*	2 (3.8%)			
CrCl levels <30 mL/min	1 (4.5%)†	0			
		Dabigatran			
Patients, N=33	***15***	***18***	***0***	***1***	***24***
Age >70 years	10 (67%)†	3 (17%)	-		

*p <0.05 ; †p <0.01; ‡p <0.001

The treatment of VTE with DOAC: data from the RIETE Registry

Outcomes during the course of therapy
Any DOACs

	N	Rate (95%CI)	N	Rate (95%CI)	Adj. HR (95%CI)
	Non-recommended doses or regimen		Recommended doses and regimen		
Patients, N	*528*		*983*		
Follow-up (years)	255.3		417.2		
DVT recurrences	4	1.57 (0.42-4.01)	1	0.24 (0.003-1.33)	6.35 (0.71-57.0)
PE recurrences	3	1.18 (0.24-3.43)	0	-	-
VTE recurrences	7	2.74 (1.10-5.65)	1	0.24 (0.003-1.33)	10.5 (1.28-85.9)*
Major bleeding	6	2.35 (0.86-5.12)	8	1.92 (0.83-3.78)	1.04 (0.36-3.03)
Death	7	2.74 (1.10-5.65)	6	1.44 (0.53-3.13)	1.41 (0.46-4.29)

*p <0.05

The treatment of VTE with DOAC: data from the RIETE Registry

Outcome during the course of therapy
Rivaroxaban

	N	Rate (95%CI)	N	Rate (95%CI)	Adj. HR (95%CI)
	Non-recommended doses or regimen		Recommended doses and regimen		
Patients, N	*454*		*950*		
Follow-up (years)	225.9		402.0		
DVT recurrences	4	1.77 (0.48-4.53)	1	0.25 (0.003-1.38)	7.20 (0.80-64.8)
PE recurrences	2	0.89 (0.10-3.20)	0	-	-
VTE recurrences	6	2.66 (0.97-5.78)	1	0.25 (0.003-1.38)	10.7 (1.29-89.0)*
Major bleeding	5	2.21 (0.71-5.17)	8	1.99 (0.86-3.92)	1.05 (0.34-3.23)
Death	6	2.66 (0.97-5.78)	6	1.49 (0.97-5.78)	1.44 (0.45-4.59)

*p <0.05

Conclusions

- A non-negligible proportion of VTE patients were prescribed DOACS at ***daily doses and/or regimens different from those recommended*** in the product label.

- These patients had a ***higher rate of VTE recurrences*** with no difference in bleeding.

- Clinicians should prescribed the ***recommended doses***, that are different from those of NVAF.

Thank you for your kind attention !

Bologna, vista delle Torri

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