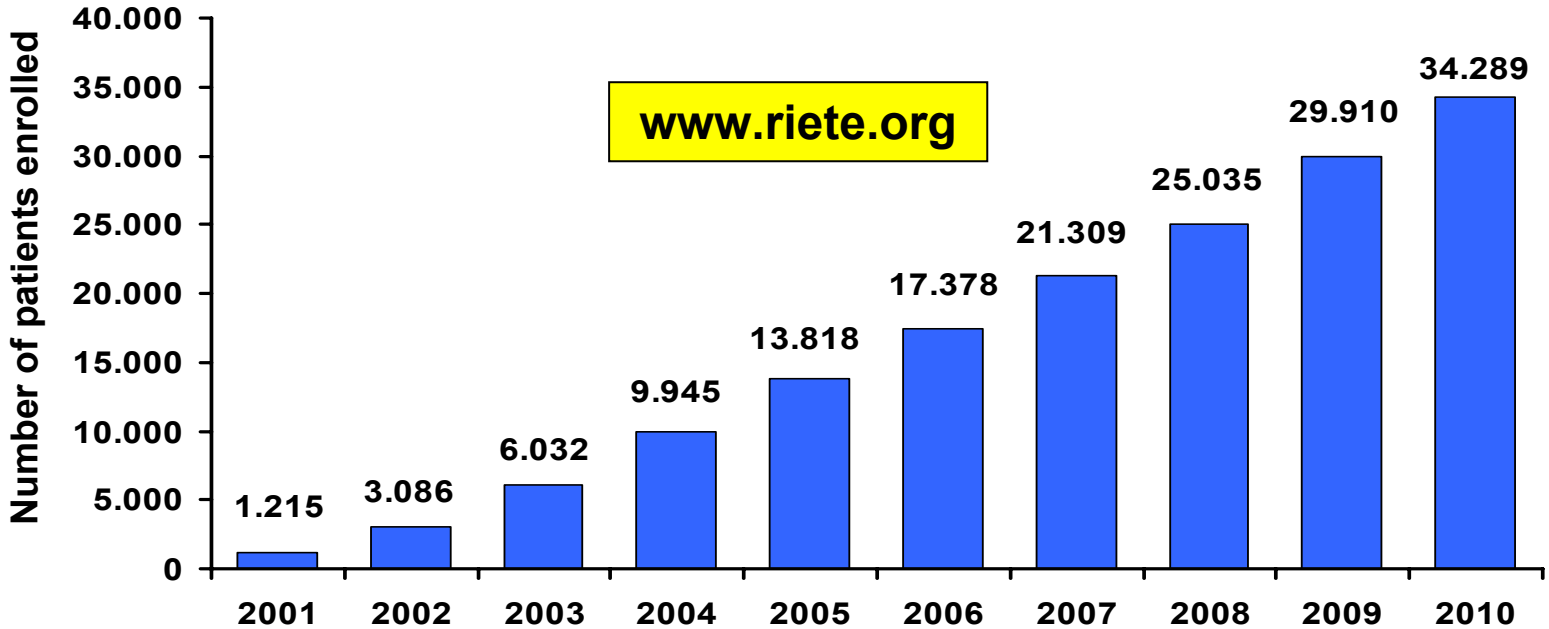
El futuro de RIETE

¿Para qué más pacientes?

Registro RIETE

36.476



31,397 patients

2,221 patients

1,681patients

611 patients

105 patients

74 patients

62 patients

39 patients

35 patients

10 patients

¿Para qué más pacientes?

- 1.- Profilaxis
- 2.- Estratificación de riesgo
- 3.- Tratamiento
- 4.- Nuevos estudios

Caso clínico 1

- **Varón, 68 años**
- **Hipertensión, diabetes**
- **Prótesis electiva rodilla**

¿Profilaxis?

1. **Si: HBPM, 4.000 UI día**
2. **No**
3. **Aspirina**

Caso clínico 2

- Varón, 68 años
- Carcinoma de pulmón
- Náuseas y vómitos tras quimioterapia
- En cama, en casa 4–6 días

¿Profilaxis?

1. Si: HBPM, 4.000 UI día
2. No
3. Aspirina

36,439 patients with acute VTE

	Elective knee or hip surgery	Cancer and recent immobility ≥4 days
Patients, N	630	1,582
Death, n (%)	82 (8.9)	821 (52)
Fatal PE, n (%)	4 (0.6)	76 (4.8)
Fatal bleeding, n (%)	3 (0.5)	50 (3.2)
VTE prophylaxis, n (%)	606 (96)	459 (29)

Cancer and immobility ≥4 days

N=1,582	All patients n (%)	Prophylaxis n (%)
Place of immobility,		
hospital	448 (28)	236 (59)
long-term facility	55 (3.5)	9 (21)
home	704 (45)	80 (13)
not reported	375 (24)	98 (26)
For those at home:		
Duration of immobility,		
<1 week	129 (22)	11 (8.5)
1–4 weeks	252 (40)	36 (14)
5–8 weeks	86 (14)	30 (35)
>8 weeks	160 (26)	19 (12)

Cancer and immobility ≥4 days

N=1,582	All patients n (%)	Fatal PE n (%)
Place of immobility,		
hospital	448 (28)	12 (2.7)
long-term facility	55 (3.5)	2 (3.6)
home	704 (45)	39 (5.5)
not reported	375 (24)	20 (5.3)
For those at home:		
Duration of immobility,		
<1 week	140 (20)	12 (8.6)
1–4 weeks	277 (39)	15 (5.4)
5–8 weeks	95 (14)	6 (6.3)
>8 weeks	192 (26)	6 (3.1)

Cancer and immobility at home

N=704	All patients n (%)	Prophylaxis n (%)
With metastases	336 (48)	36 (11)
Without metastases	291 (41)	41 (14)
Lung	88	5 (5.7)
Colorectal	82	2 (2.4)
Breast	83	10 (12)
Prostate	63	9 (14)
Hematologic	49	4 (8.2)
Bladder	52	3 (5.8)
Brain	58	13 (22)
Stomach	29	1 (3.4)
Pancreas	32	6 (19)

Cancer and immobility at home

N=704	All patients n (%)	Fatal PE n (%)
With metastases	336 (48)	30 (8.9)
Without metastases	291 (41)	8 (2.7)
Lung	88	9 (10)
Colorectal	83	2 (2.4)
Breast	83	4 (4.8)
Prostate	63	5 (7.9)
Hematologic	49	3 (6.1)
Bladder	52	4 (7.7)
Brain	58	2 (3.4)
Stomach	29	3 (10)
Pancreas	32	2 (6.3)

¿Para qué más pacientes?

- 1.- Profilaxis
- **2.- Estratificación de riesgo**
- 3.- Tratamiento
- 4.- Nuevos estudios

Caso clínico 3

Mujer de 24 años que toma anticonceptivos desde hace 3 meses. Sin antecedentes de interés

- **Acude a Urgencias por embolia pulmonar**
- **FC: 124 por minuto, FR: 26 por minuto, TA 102/50 mm Hg, Sat O_2 90%**

<u>Actitud:</u>

- **Ingreso en planta**
- **Hospital de día 24-48 horas**
- **Tratamiento a domicilio**

Table 1: The Pulmonary Embolism Severity Index.

Predictors	Points assigned
Age, per year	**Age, in years**
Male sex	+10
History of cancer	+30
History of heart failure	+10
History of chronic lung disease	+10
Pulse ≥110/minute	+20
Systolic blood pressure < 100 mm Hg	+30
Respiratory rate ≥30/minute*	+20
Temperature < 36°C	+20
Altered mental status†	+60
Arterial oxygen saturation < 90%*	+20

A total point score for a given patient is obtained by summing the patient's age in years and the points for each applicable predictor. Points assignments correspond with the following risk classes: ≤65 class I; 66–85 class II; 86–105 class III; 106–125 class IV; and > 125 class V. Patients in risk classes I and II are defined as low-risk. *Assessed with or without the administration of supplemental oxygen. †Defined as confusion, disorientation, or somnolence.

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Pulse ≥110/minute	+20
Systolic blood pressure < 100 mm Hg	+30
Respiratory rate ≥30/minute*	+20
Temperature < 36°C	+20
Altered mental status†	+60
Arterial oxygen saturation < 90%*	+20

A total point score for a given patient is obtained by summing the patient's age in years and the points for each applicable predictor. Points assignments correspond with the following risk classes: ≤65 class I; 66–85 class II; 86–105 class III; 106–125 class IV; and > 125 class V. Patients in risk classes I and II are defined as low-risk. *Assessed with or without the administration of supplemental oxygen. †Defined as confusion, disorientation, or somnolence.

Simplification of the Pulmonary Embolism Severity Index for Prognostication in Patients With Acute Symptomatic Pulmonary Embolism

David Jiménez, MD, PhD; Drahomir Aujesky, MD; Lisa Moores, MD; Vicente Gómez, MD; José Luis Lobo, MD, PhD; Fernando Uresandi, MD, PhD; Remedios Otero, MD, PhD; Manuel Monreal, MD, PhD; Alfonso Muriel, MSc; Roger D. Yusen, MD; for the RIETE Investigators

Table 1. Original and Simplified Pulmonary Embolism Severity Index (PESI)

Variable	Score: Original PESI[a]	Score: Simplified PESI[b]
Age >80 y	Age in years	1
Male sex	+10	
History of cancer	+30	1
History of heart failure	+10	1[c]
History of chronic lung disease	+10	
Pulse ≥110 beats/min	+20	1
Systolic blood pressure <100 mm Hg	+30	1
Respiratory rate ≥30 breaths/min	+20	
Temperature <36°C	+20	
Altered mental status	+60	
Arterial oxyhemoglobin saturation level <90%	+20	1

Arch Intern Med 2010;170:1383–1389

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Altered mental status	+60	
Arterial oxyhemoglobin saturation level <90%	+20	1

[a] A total point score for a given patient is obtained by summing the patient's age in years and the points for each predictor when present. The score corresponds with the following risk classes: 65 or less, class I; 66 to 85, class II; 86 to 105, class III; 106 to 125, class IV; and more than 125, class V. Patients in risk classes I and II are defined as being at low risk.

[b] A total point score for a given patient is obtained by summing the points. The score corresponds with the following risk classes: 0, low risk; 1 or more, high risk. Empty cells indicate that the variable was not included.

[c] The variables were combined into a single category of chronic cardiopulmonary disease.

Age	N	Dead	Low-risk	Dead	NPV
PESI					
All	*12019*	*778 (6.5%)*			
<20 y	44	1 (2.3%)			
20-29	311	2 (0.6%)			
30-39	542	6 (1.1%)			
40-49	725	17 (2.3%)			
50-59	1079	61 (5.7%)			
60-69	2061	84 (4.1%)			
70-79	3938	234 (5.9%)			
80-89	2884	294 (10%)			
>89 y	435	79 (18%)			

Age	N	Dead	Low-risk	Dead	NPV
PESI					
All	*12019*	*778 (6.5%)*	*4302 (36%)*		
<20 y	44	1 (2.3%)	43 (98%)		
20-29	311	2 (0.6%)	295 (95%)		
30-39	542	6 (1.1%)	486 (90%)		
40-49	725	17 (2.3%)	555 (77%)		
50-59	1079	61 (5.7%)	632 (59%)		
60-69	2061	84 (4.1%)	869 (42%)		
70-79	3938	234 (5.9%)	1094 (28%)		
80-89	2884	294 (10%)	328 (11%)		
>89 y	435	79 (18%)	0		

Age	N	Dead	Low-risk	Dead	NPV
PESI					
All	*12019*	*778 (6.5%)*	*4302 (36%)*	*49 (1.1%)*	*98.9 (98.5-99.1)*
<20 y	44	1 (2.3%)	43 (98%)	1 (2.3%)	97.7 (87.9-99.6)
20-29	311	2 (0.6%)	295 (95%)	2 (0.7%)	99.3 (97.6-99.8)
30-39	542	6 (1.1%)	486 (90%)	0	100 (99.2-100)
40-49	725	17 (2.3%)	555 (77%)	5 (0.9%)	99.1 (97.9-99.6)
50-59	1079	61 (5.7%)	632 (59%)	6 (0.9%)	99.1 (98.0-99.6)
60-69	2061	84 (4.1%)	869 (42%)	6 (0.7%)	99.3 (98.5-99.7)
70-79	3938	234 (5.9%)	1094 (28%)	16 (1.5%)	98.5 (97.6-99.1)
80-89	2884	294 (10%)	328 (11%)	13 (4.0%)	96.0 (93.3-97.7)
>89 y	435	79 (18%)	0	0	-

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Respiratory rate ≥30/minute*	+20
Temperature < 36°C	+20
Altered mental status†	+60
Arterial oxygen saturation < 90%*	+20

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Age	N	Dead	Low-risk	Dead	NPV
$_{s}$PESI					
All	*12019*	*778 (6.5%)*			
<20 y	44	1 (2.3%)			
20-29	311	2 (0.6%)			
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Age	N	Dead	Low-risk	Dead	NPV
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20-29	311	2 (0.6%)	176 (57%)		
30-39	542	6 (1.1%)	301 (56%)		
40-49	725	17 (2.3%)	345 (48%)		
50-59	1079	61 (5.7%)	444 (41%)		
60-69	2061	84 (4.1%)	738 (36%)		
70-79	3938	234 (5.9%)	1263 (32%)		
80-89	2884	294 (10%)	106 (3.7%)		
>89 y	435	79 (18%)	0		

Age	N	Dead	Low-risk	Dead	NPV
$_{s}$PESI					
All	*12019*	*778 (6.5%)*	*3399 (28%)*	*39 (1.1%)*	*98.9 (98.4-99.2)*
<20 y	44	1 (2.3%)	26 (59%)	0	100 (87.1-100)
20-29	311	2 (0.6%)	176 (57%)	0	100 (97.9-100)
30-39	542	6 (1.1%)	301 (56%)	0	100 (98.7-100)
40-49	725	17 (2.3%)	345 (48%)	2 (0.6%)	99.4 (97.9-99.8)
50-59	1079	61 (5.7%)	444 (41%)	4 (0.9%)	99.1 (97.7-99.7)
60-69	2061	84 (4.1%)	738 (36%)	3 (0.4%)	99.6 (98.8-99.9)
70-79	3938	234 (5.9%)	1263 (32%)	24 (1.9%)	98.1 (97.2-98.7)
80-89	2884	294 (10%)	106 (3.7%)	6 (5.7%)	94.3 (88.2-97.4)
>89 y	435	79 (18%)	0	0	

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Systolic blood pressure <100 mm Hg	+30	1
Respiratory rate ≥30 breaths/min	+20	
Temperature <36°C	+20	
Altered mental status	+60	
Arterial oxyhemoglobin saturation level <90%	+20	1

[a] A total point score for a given patient is obtained by summing the patient's age in years and the points for each predictor when present. The score corresponds with the following risk classes: 65 or less, class I; 66 to 85, class II; 86 to 105, class III; 106 to 125, class IV; and more than 125, class V. Patients in risk classes I and II are defined as being at low risk.

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Temperature <36°C	+20	
Altered mental status	+60	
Arterial oxyhemoglobin saturation level <90%	+20	1

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[c] The variables were combined into a single category of chronic cardiopulmonary disease.

1556 outpatients with cancer and PE

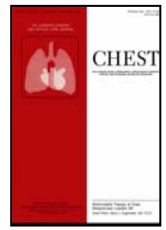
VARIABLES	Modelo reducido
metástasis	1
Inmovilización previa	1
Edad >=80 años	1
FC>=110	1
Neoplasias Agresivas	1

	Modelo reducido			
	MUESTRA DE DERIVACIÓN N=1048		MUESTRA DE VALIDACIÓN N=608	
	muerto a 30 días	vivo a 30d	muerto a 30 días	vivo a 30d
puntuación <1	3	155	2	65
puntuación >=1	222	668	121	320
Sensibilidad	98.7		98.4	
Especificidad	18.8		16.9	
VP+	24.9		24.4	
VP-	98.1		97.4	
LR+	1.22		1.18	
LR-	0.07		0.10	
AUC ROC	0.74 (0.71-0.77)		0.70 (0.65-0.75)	

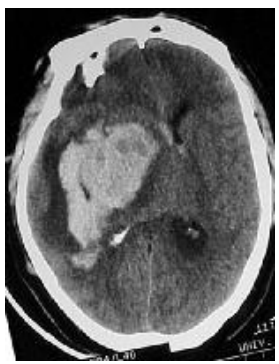
¿Para qué más pacientes?

- 1.- Profilaxis
- 2.- Estratificación de riesgo
- **3.- Tratamiento**
- 4.- Nuevos estudios

Caso clínico 4

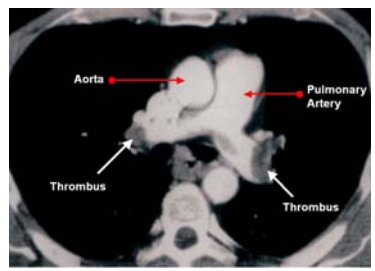


- Mujer 77 años, 76 kg
- Hipertensión, diabetes
- **Abril 1: Hemorragia cerebral**
- **Abril 21: Disnea + fibrilación auricular: Embolia pulmonar**



Tratamiento:

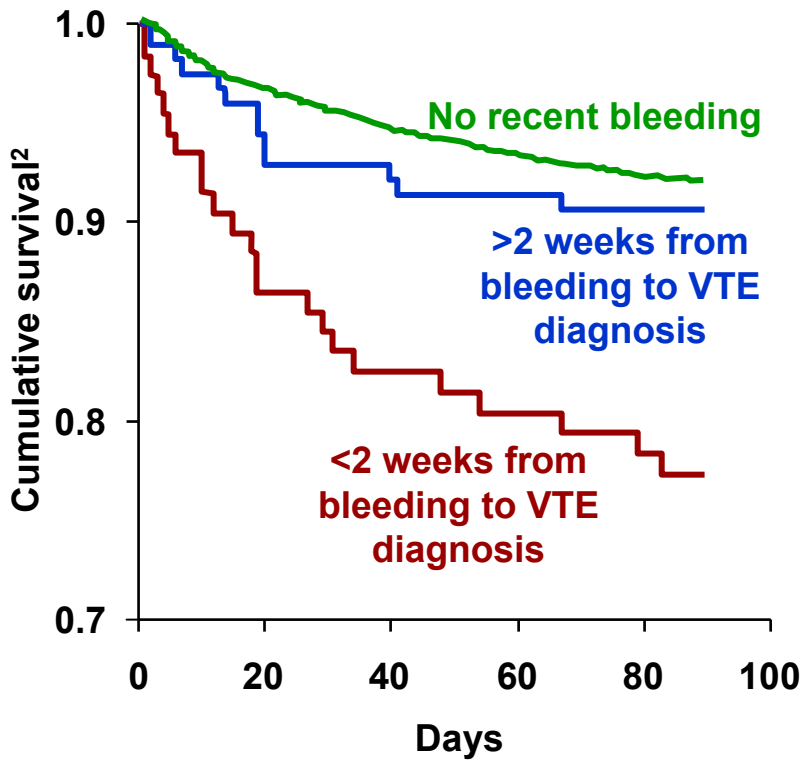
1. HBPM sc, 200 UI/kg/d
2. HBPM sc, 100 UI/kg/d
3. HNF iv.
4. Filtro vena cava + heparina
5. Filtro vena cava solo



Hemorragia grave reciente

Clinical outcomes of VTE patients with and without recent episode of major bleeding

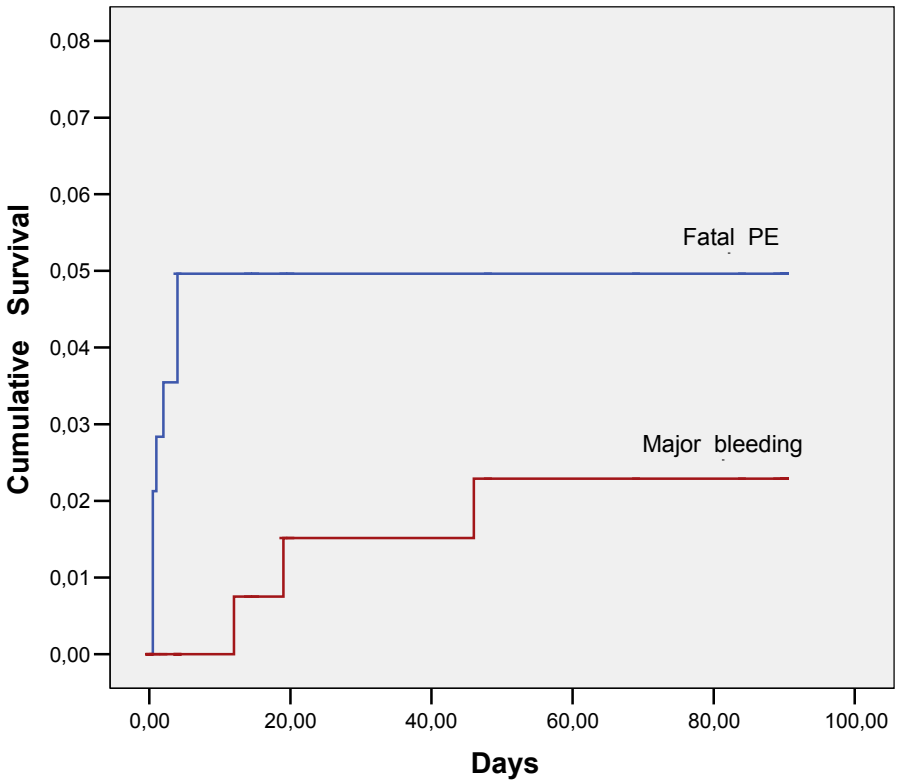
3-month outcome	Recent major bleeding (n=170) n (%)	No recent major bleeding (n=6,191) n (%)	Odds ratio (95% CI)	*p*-value
Fatal bleeding	7 (4.1)	41 (0.6)	**6.4** (2.6–15)	<0.001
Major bleeding	12 (7.1)	146 (2.3)	3.1 (1.6–5.9)	0.001
Minor bleeding	12 (7.1)	172 (2.8)	2.6 (14–5.0)	<0.005
Fatal initial PE	1 (0.6)	14 (0.2)	2.6 (0.2–19)	ns
Fatal recurrent PE	4 (2.4)	33 (0.5)	**4.5** (1.3–14)	<0.05
Recurrent VTE	8 (4.7)	184 (2.9)	1.6 (0.7–3.4)	ns
Overall mortality	25 (15)	479 (7.7)	2.1 (1.3–3.2)	<0.005



J Thromb Haemost 2005;3:703–709

J Thromb Haemost 2006;4:2367–2372

141 patients with recent intracranial bleeding



Type of VTE	Days	Event	Current therapy	Daily doses/kg	IVC filter
PE	1	Fatal PE	No	-	No
PE	1	Fatal PE	LMWH	81 IU	No
PE	2	Fatal PE	LMWH	198 IU	No
PE	5	Fatal PE	LMWH	67 IU	No
PE	12	Recurrent DVT	LMWH	81 IU	Yes
PE	12	Recurrent DVT	No	-	Yes
PE	18	Major bleeding	LMWH	100 IU	Yes
PE	38	Recurrent DVT	UFH	200 IU	Yes
PE	46	Major bleeding	LMWH	80 IU	Yes
DVT	1	Fatal PE	UFH	ND	No
DVT	2	Fatal PE	UFH	367 IU	No
DVT	4	Fatal PE	No	-	No
DVT	11	Recurrent DVT	LMWH	71 IU	No
DVT	12	Major bleeding	UFH	286 IU	No
DVT	18	Recurrent PE	LMWH	161 IU	No
DVT	63	Recurrent DVT	LMWH	39 IU	No

739 patients with recent major bleeding

	Recent bleeding, IVC filter	Recent bleeding, no IVC filter
Patients, N	*79*	*660*
Major bleeding	9 (11%)	49 (7.4%)
Fatal bleeding	4 (5.1%)*	11 (1.7%)
Recurrent DVT	4 (5.1%)*	9 (1.4%)
Recurrent PE	0	14 (2.1%)
Fatal PE	0	24 (3.6%)
Fatal, initial PE	0	16 (2.4%)
Fatal, recurrent PE	0	8 (1.2%)
Overall death	11 (14%)	114 (17%)

* $p < 0.05$

540 patients with IVC filter and no recent bleeding

	Bleeding during therapy	Recurrent VTE during therapy	Surgery required	Other	p value
Patients, N	*121*	*134*	*123*	*162*	
Major bleeding	20 (17%)	1 (0.7%)	3 (2.4%)	12 (7.4%)	<0.001
Fatal bleeding	0	1 (0.7%)	1 (0.8%)	4 (2.5%)	0.227
Recurrent DVT	5 (4.1%)	6 (4.5%)	6 (4.9%)	8 (4.9%)	0.988
Recurrent PE	3 (2.5%)	11 (8.2%)	1 (0.8%)	1 (0.6%)	<0.001
Fatal PE	1 (0.8%)	6 (4.5%)	1 (0.8%)	4 (2.5%)	0.145
Fatal, initial PE	0	0	1 (0.8%)	3 (1.9%)	0.010
Fatal, recurrent PE	1 (0.8%)	6 (4.5%)	0	1 (0.6%)	
Overall death	14 (12%)	18 (13%)	10 (8.1%)	23 (14%)	0.430

Caso clínico 5

- Mujer 77 años, 76 kg
- Hipertensión, diabetes
- **Abril 21: embolia pulmonar**
- **Abril 21: trombosis venosa poplítea**

<u>Tratamiento con AVK:</u>

1. **INR 2.0-3.0 a todos**
2. **INR distintos**

CHEST
Official publication of the American College of Chest Physicians
CHEST ONLINE

Antithrombotic Therapy for Venous Thromboembolic Disease

Clive Kearon, Susan R. Kahn, Giancarlo Agnelli, Samuel Goldhaber, Gary E. Raskob and Anthony J. Comerota

Summary of Recommendations

1.1 Initial Anticoagulation of Acute DVT of the Leg

1.1.1. For patients with objectively confirmed DVT, we recommend short-term treatment with SC LMWH (Grade 1A), **IV UFH** (Grade 1A), **monitored SC UFH** (Grade 1A), **fixed-dose SC UFH** (Grade 1A), **or SC fondaparinux** (Grade 1A) **rather than no such short-term treatment.**

1.1.2. For patients with a high clinical suspicion of DVT, we recommend treatment with anticoagulants while awaiting the outcome of diagnostic tests (Grade 1C).

1.1.3. In patients with acute DVT, we recommend initial treatment with LMWH, UFH, or fondaparinux for at least 5 days and until the INR is ≥ 2.0 for 24 h (Grade 1C).

1.1.4. In patients with acute DVT, we recommend initiation of VKA together with LMWH, UFH, or fondaparinux on the first treatment day rather than delayed initiation of VKA (Grade 1A).

4.0 Initial Treatment of Acute PE

Treatment regimens for DVT and PE are similar because the two conditions are manifestations of the same disease process. When patients with VTE are carefully studied, the majority of those with proximal DVT also have PE (symptomatic or asymptomatic) and vice versa.[185] Furthermore, clinical trials of anticoagulant therapy have yielded similar estimates for efficacy and safety in patients with DVT alone, in those with both DVT and PE, and in patients with only PE. The

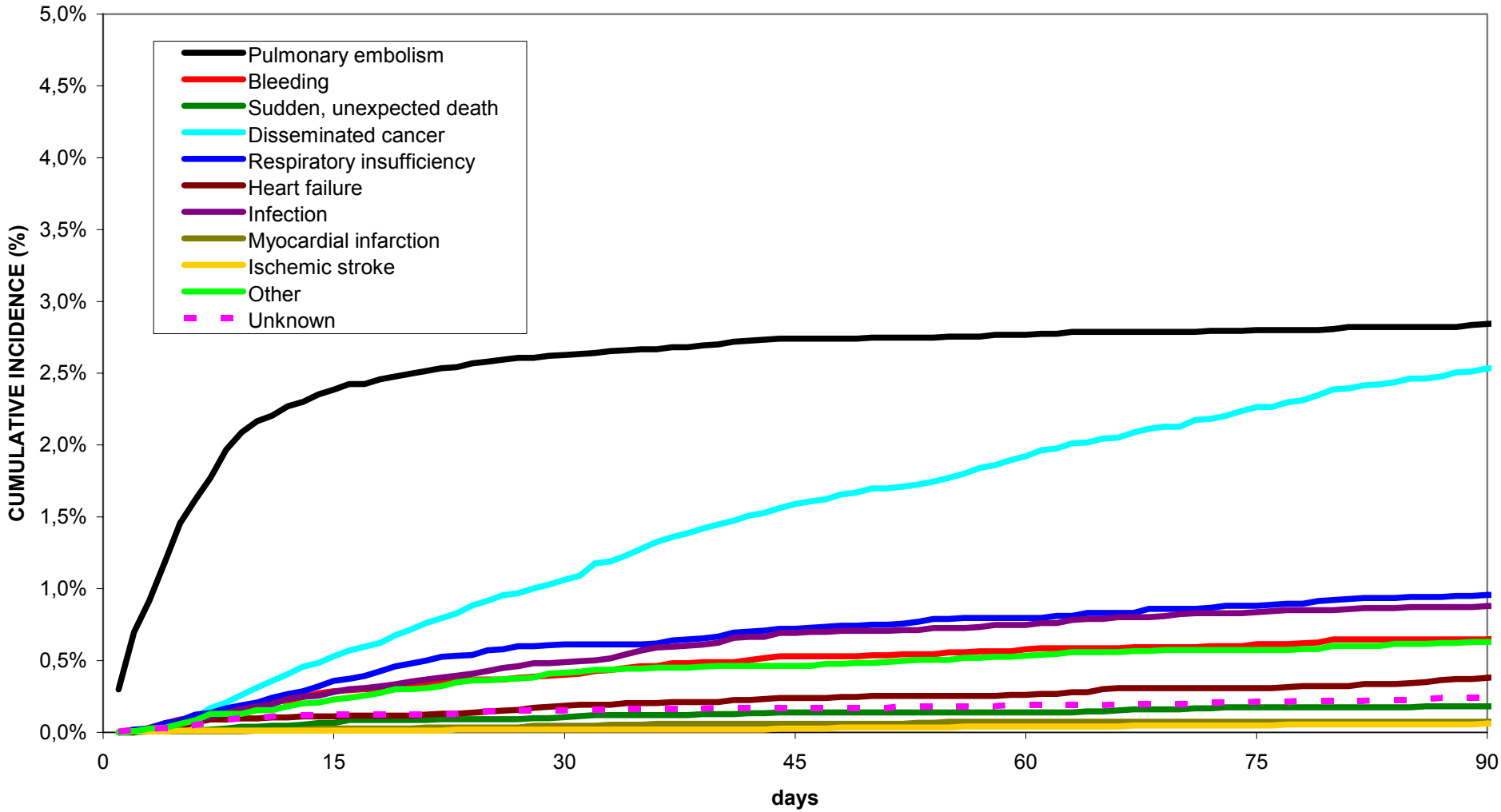
Mortality rate at different intervals

15,761 patients with PE	Day 7	Day 15	Day 30	Day 60	Day 90
Pulmonary embolism					
Disseminated cancer					
Dyspnea					
Infection					
Bleeding					
Heart failure					
Sudden, unexpected					
Myocardial infarction					
Ischemic stroke					
Other					
Unknown					
TOTAL	467 (3.0%)	710 (4.5%)	954 (6.1%)	1240 (7.9%)	1433 (9.1%)

Mortality rate at different intervals

15,761 patients with PE	Day 7	Day 15	Day 30	Day 60	Day 90
Pulmonary embolism	309 (2.0%)				
Disseminated cancer	32 (0.2%)				
Dyspnea	26 (0.2%)				
Infection	21 (0.1%)				
Bleeding	23 (0.1%)				
Heart failure	14 (0.1%)				
Sudden, unexpected	4 (0.0%)				
Myocardial infarction	1 (0.0%)				
Ischemic stroke	2 (0.0%)				
Other	20 (0.1%)				
Unknown	15 (0.1%)				
TOTAL	467 (3.0%)	710 (4.5%)	954 (6.1%)	1240 (7.9%)	1433 (9.1%)

Mortality rate in 15,761 patients with PE



Mortality rate at different intervals

15,761 patients with PE	Day 7	Day 15	Day 30	Day 60	Day 90
Pulmonary embolism	309	380 (2.4%)	412 (2.6%)	433 (2.8%)	444 (2.8%)
Disseminated cancer		87 (0.6%)	165 (1.1%)	294 (2.0%)	378 (2.5%)
Dyspnea		57 (0.4%)	93 (0.6%)	120 (0.8%)	143 (1.0%)
Infection		46 (0.3%)	75 (0.5%)	114 (0.8%)	131 (0.9%)
Bleeding	23	45 (0.3%)	62 (0.4%)	88 (0.6%)	99 (0.7%)
Heart failure		18 (0.1%)	29 (0.2%)	40 (0.3%)	57 (0.4%)
Sudden, unexpected		13 (0.1%)	17 (0.1%)	21 (0.1%)	27 (0.2%)
Myocardial infarction		4 (0.0%)	7 (0.0%)	11 (0.1%)	11 (0.1%)
Ischemic stroke		2 (0.0%)	3 (0.0%)	6 (0.0%)	9 (0.1%)
Other		37 (0.2%)	64 (0.4%)	81 (0.5%)	94 (0.6%)
Unknown		21 (0.1%)	27 (0.2%)	32 (0.2%)	40 (0.2%)
TOTAL	467	710 (4.5%)	954 (6.1%)	1240 (7.9%)	1433 (9.1%)

135

76

17,128 patients with DVT

	Day 7	Day 15	Day 30	Day 60	Day 90
Disseminated cancer	28 (0.2%)				
Infection	19 (0.1%)				
Bleeding	15 (0.1%)				
Dyspnea	13 (0.1%)				
Pulmonary embolism	15 (0.1%)				
Heart failure	3 (0.0%)				
Sudden, unexpected	3 (0.0%)				
Other	31 (0.2%)				
TOTAL	112 (0.7%)	287 (1.7%)	520 (3.0%)	834 (4.9%)	1056 (6.2%)

17,128 patients with DVT

	Day 7	Day 15	Day 30	Day 60	Day 90
Disseminated cancer		65 (0.4%)	136 (0.8%)	262 (1.6%)	347 (2.1%)
Infection		34 (0.2%)	60 (0.4%)	88 (0.5%)	108 (0.6%)
Bleeding	15	42 (0.2%)	66 (0.4%)	81 (0.5%)	91 (0.5%)
Dyspnea		22 (0.1%)	37 (0.2%)	49 (0.3%)	59 (0.4%)
Pulmonary embolism	15	21 (0.1%)	27 (0.2%)	32 (0.2%)	40 (0.2%)
Heart failure		6 (0.0%)	15 (0.1%)	20 (0.1%)	25 (0.2%)
Sudden, unexpected		7 (0.0%)	12 (0.1%)	18 (0.1%)	20 (0.1%)
Other		90 (0.5%)	167 (1.0%)	284 (1.6%)	366 (2.2%)
TOTAL		287 (1.7%)	520 (3.0%)	834 (4.9%)	1056 (6.2%)

76

35

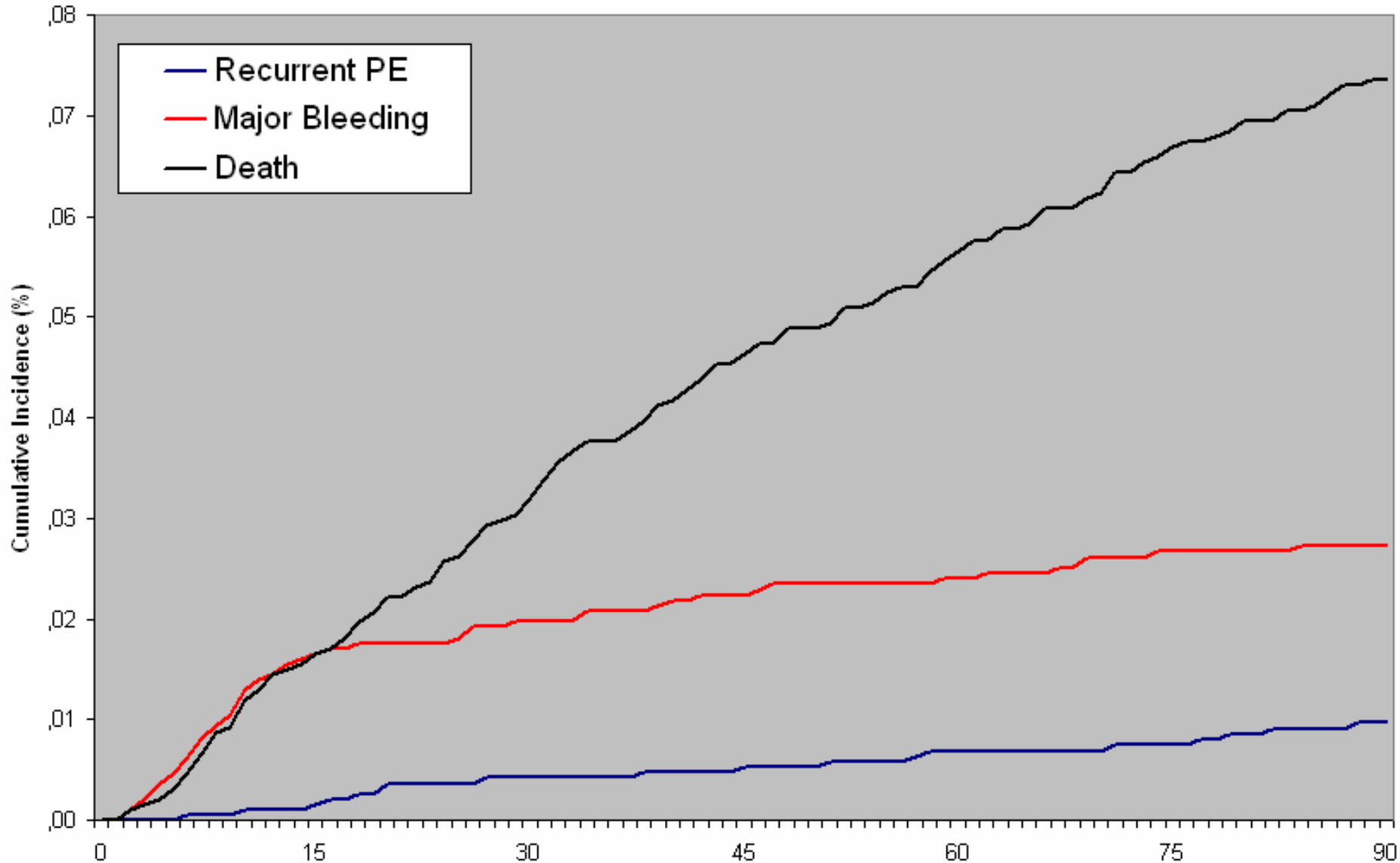
Caso clínico 6

Mujer de 72 años que llega a Urgencias con TVP femoropoplítea izquierda postquirúrgica

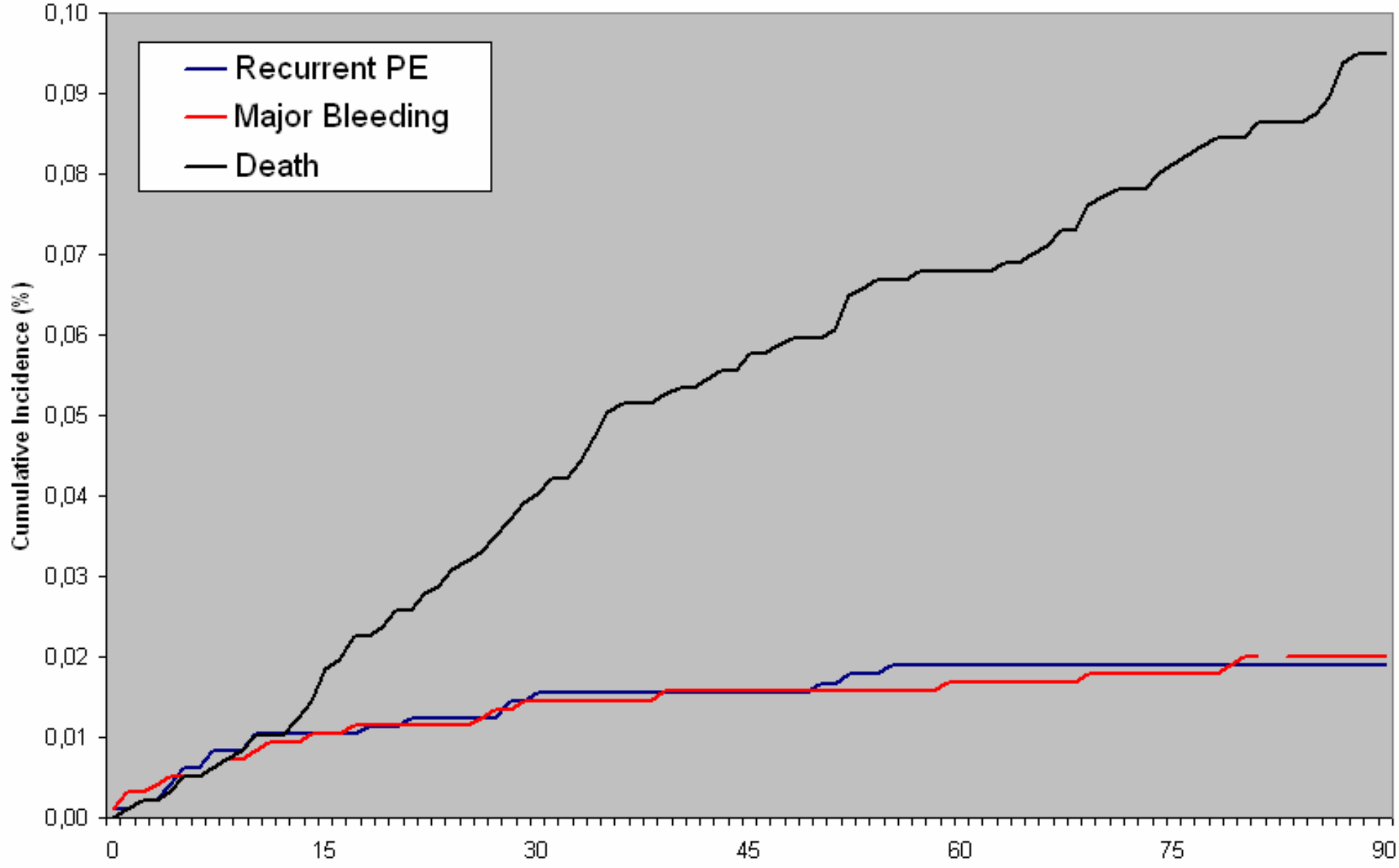
- **No disnea ni dolor torácico**
- **Sat O_2 95%**
- **Radiografía de tórax normal**

¿TC torácico? ¿Gammagrafía pulmonar?

1,933 DVT patients with normal V/Q or CT scans



962 DVT patients with silent PE



Caso clínico 7

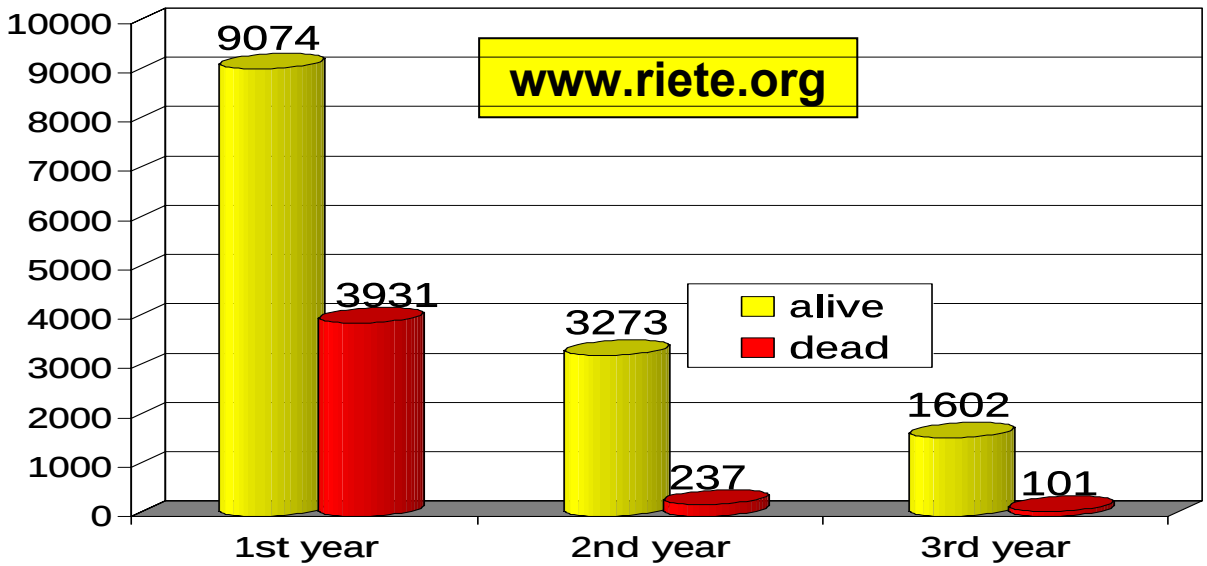
Mujer de 72 años con TVP femoropoplítea izquierda idiopática, ya 3 meses de tratamiento.

- **No D-dímero ni eco-doppler**

<u>Tratamiento anticoagulante:</u>

- **suspenderlo**
- **3 meses más**
- **9 meses más**
- **Indefinido**

Registro RIETE



31,397 patients

2,221 patients

1,681 patients

611 patients

105 patients

74 patients

62 patients

39 patients

35 patients

10 patients

	Day 1 to Day 30	Day 31 to Day 90	Day 91 to Day 180	After discontinuation of therapy[1]
Idiopathic VTE, N	*15,775*	*15,534*	*10,500*	*15,257 years*
Recurrent VTE,				
Patients, N	130 (0.82%)	97 (0.62%)	38 (0.36%)	2.93 (2.66-3.21) (438)[2]
Major bleeding,				
Patients, N	164 (1.0%)	58 (0.37%)	32 (0.30%)	0.16 (0.11-0.24) (25)[2]

[1] results expressed in events per 100 patient-years; [2] number of events

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Death at 10 days,	26 (0.16%)	3 (0.02%)	0	0.05 (0.002-0.01) (7)
CFR (95% CI)	20.0% (13.8-27.5)	3.09% (0.79-8.18-)	0% (0.0-7.58)	1.60% (0.70-3.13)
Major bleeding,				
Patients, N	164 (1.0%)	58 (0.37%)	32 (0.30%)	0.16 (0.11-0.24) (25)[2]

CFR, case-fatality rate

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Major bleeding,				
Patients, N	164 (1.0%)	58 (0.37%)	32 (0.30%)	0.16 (0.11-0.24) (25)[2]
Death at 10 days,	35 (0.22%)	11 (0.07%)	2 (0.02%)	0.04 (0.02-0.08) (6)
CFR (95% CI)	21.3% (15.6-28.1)	19.0% (10.4-30.6)	6.25% (1.06-19.1)	24.0% (10.3-43.4)

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CFR, case-fatality rate

[1] results expressed in events per 100 patient-years; [2] number of events

VTE treatment: clinical studies

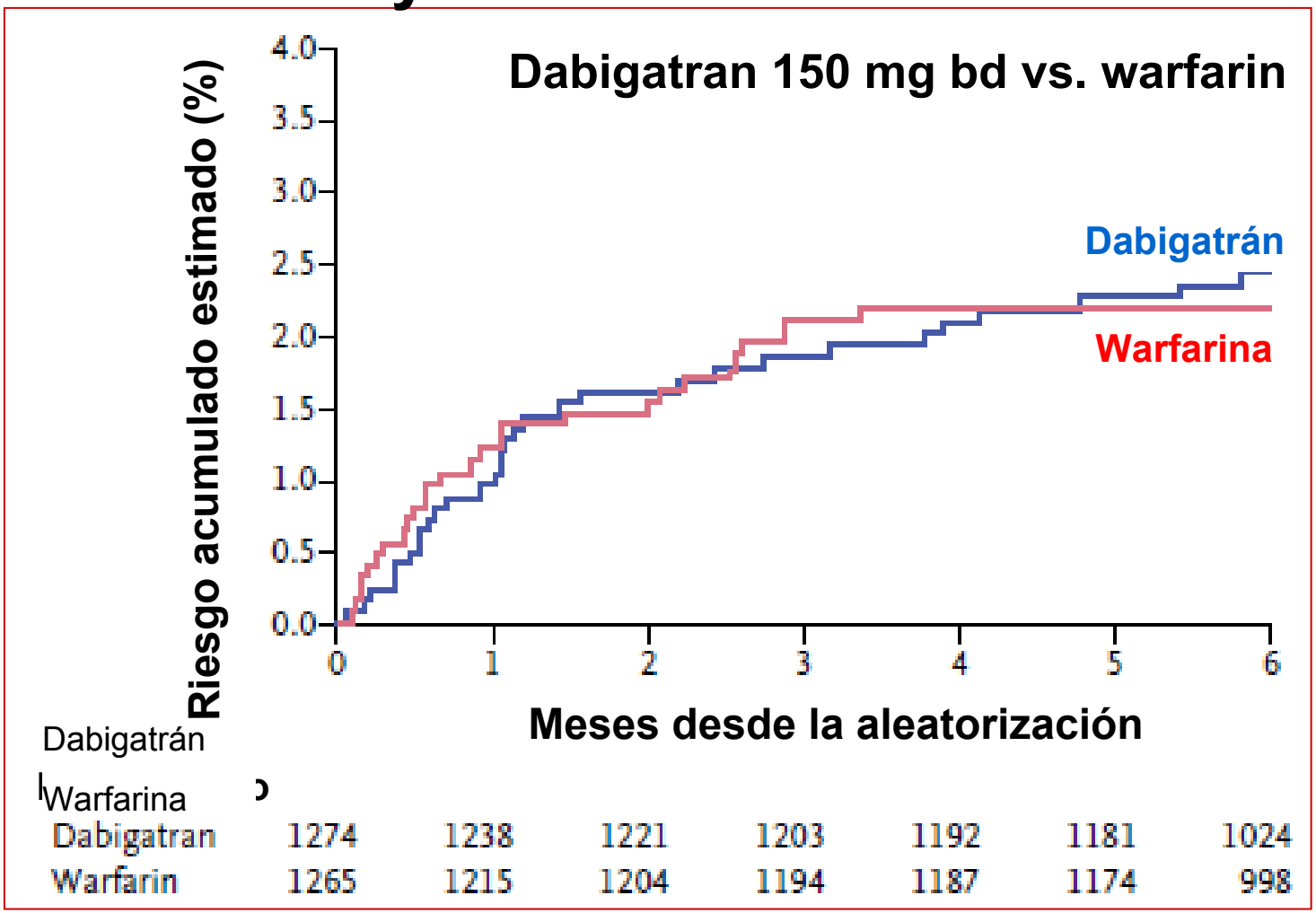
	Phase II	Phase III
Dabigatran Oral, direct thrombin inhibitor		**RE-COVER & RE-COVER II** 5–10 days pre-treatment with LMWH bridging to dabigatran or VKA for 6 months **RE-MEDY** 3–6 months' treatment with approved anticoagulant; switch to dabigatran or VKA **RE-SONATE** 6–18 months' VKA treatment followed by 6 months dabigatran or placebo
Rivaroxaban Oral, direct Factor Xa inhibitor	**EINSTEIN DVT** Rivaroxaban vs LMWH/UFH followed by VKA **ODIXa-DVT** Rivaroxaban vs enoxaparin followed by VKA	**EINSTEIN DVT/PE** Rivaroxaban for 3, 6 or 12 months vs enoxaparin for ≥5 days followed by VKA for 3, 6, or 12 months **EINSTEIN EXT** Pre-treatment with rivaroxaban or VKA for 6 or 12 months followed by rivaroxaban or placebo for 6 or 12 months
Apixaban Oral, direct Factor Xa inhibitor	**Botticelli-DVT** Apixaban vs LMWH or fondaparinux followed by VKA	**AMPLIFY** Apixaban 10 mg bid followed by 5 mg bid for 6 months vs enoxaparin followed by VKA **AMPLIFY-EXT** Apixaban 2.5 mg bid or 5 mg bid for extended 12 months period vs placebo

- Oral prodrug, converted to dabigatran, a potent reversible direct **thrombin** inhibitor (DTI)
- Rapid onset of action
- Half life of 12-17 h,
- ~ 80% renally excreted
- Predictable and consistent anticoagulant effects
- Low potential for drug-drug interactions, no drug-food interactions
- No requirement for routine coagulation monitoring

- Direct, specific, competitive **Factor Xa** inhibitor
- Rapid onset of action
- Half-life: 7–11 hours
- Dual mode of elimination:
  - 1/3 of drug excreted unchanged by the kidneys
  - 2/3 of drug metabolized by the liver: half excreted renally; half excreted by the fecal route
- No dietary restrictions

RECOVER™
Study of treatment of venous thromboembolism

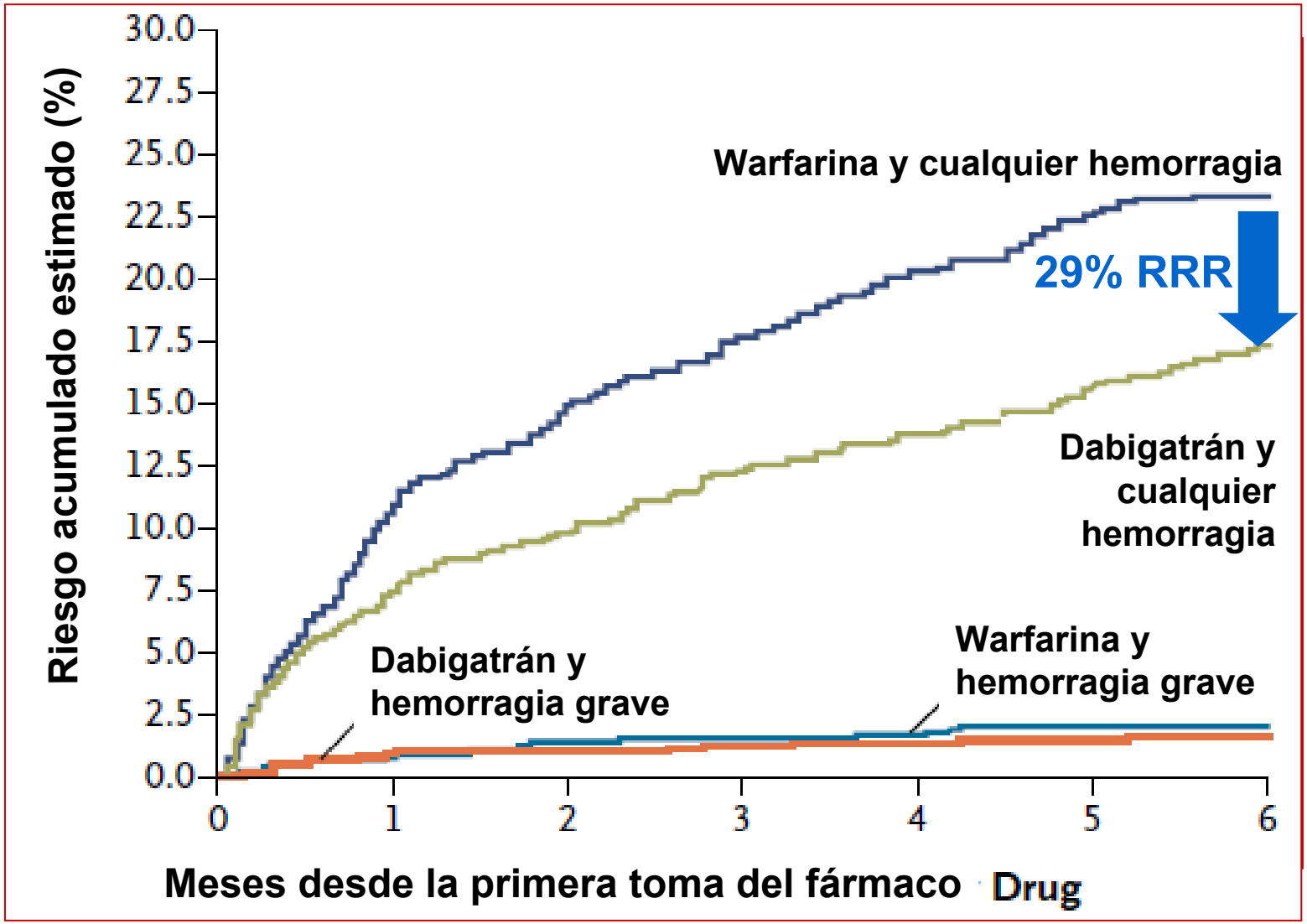
Riesgo acumulado de recurrencias y muerte relacionada



Schulman S, et al. N Engl J Med 2009;361:2342–2352

RECOVER™
Study of treatment of venous thromboembolism

Riesgo acumulado de hemorragia

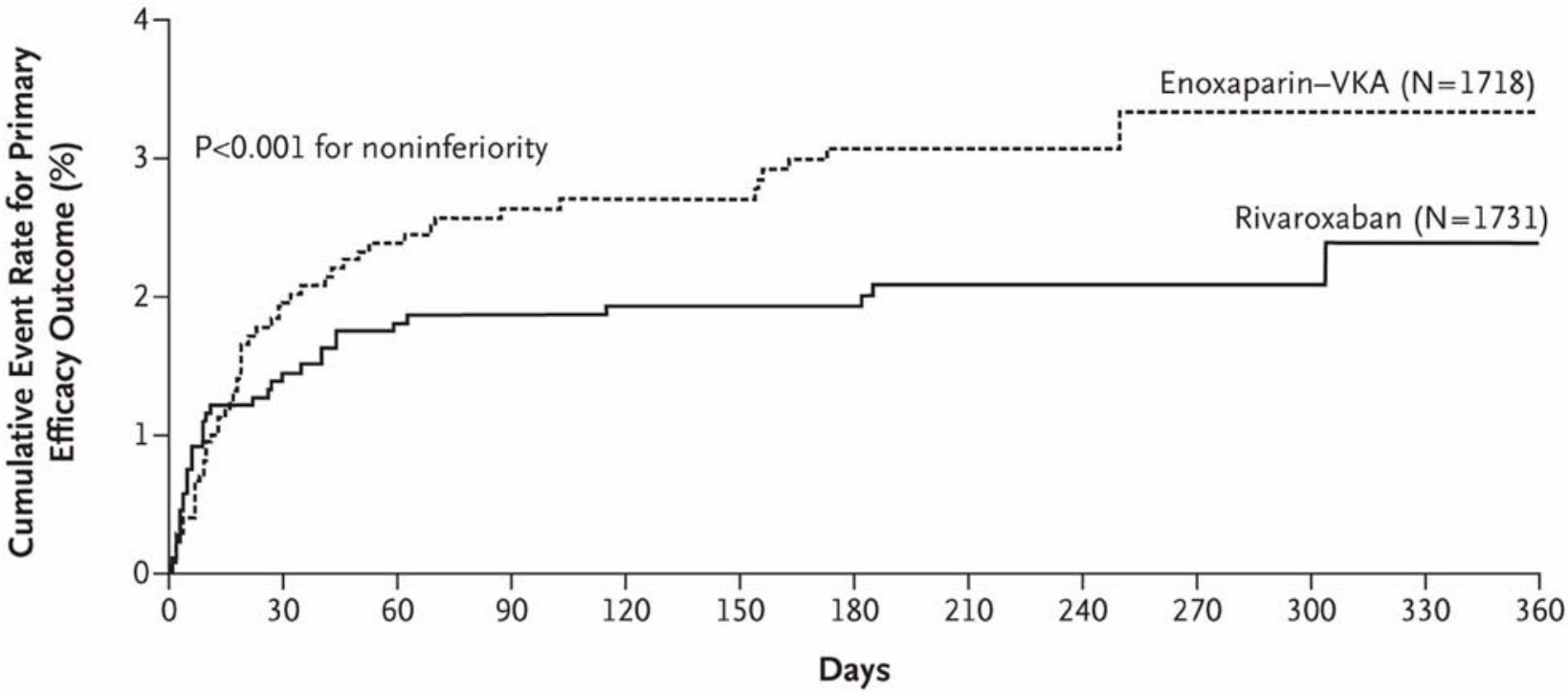


Schulman S, et al. N Engl J Med 2009;361:2342–2352

Oral Rivaroxaban for Symptomatic Venous Thromboembolism

The EINSTEIN Investigators*

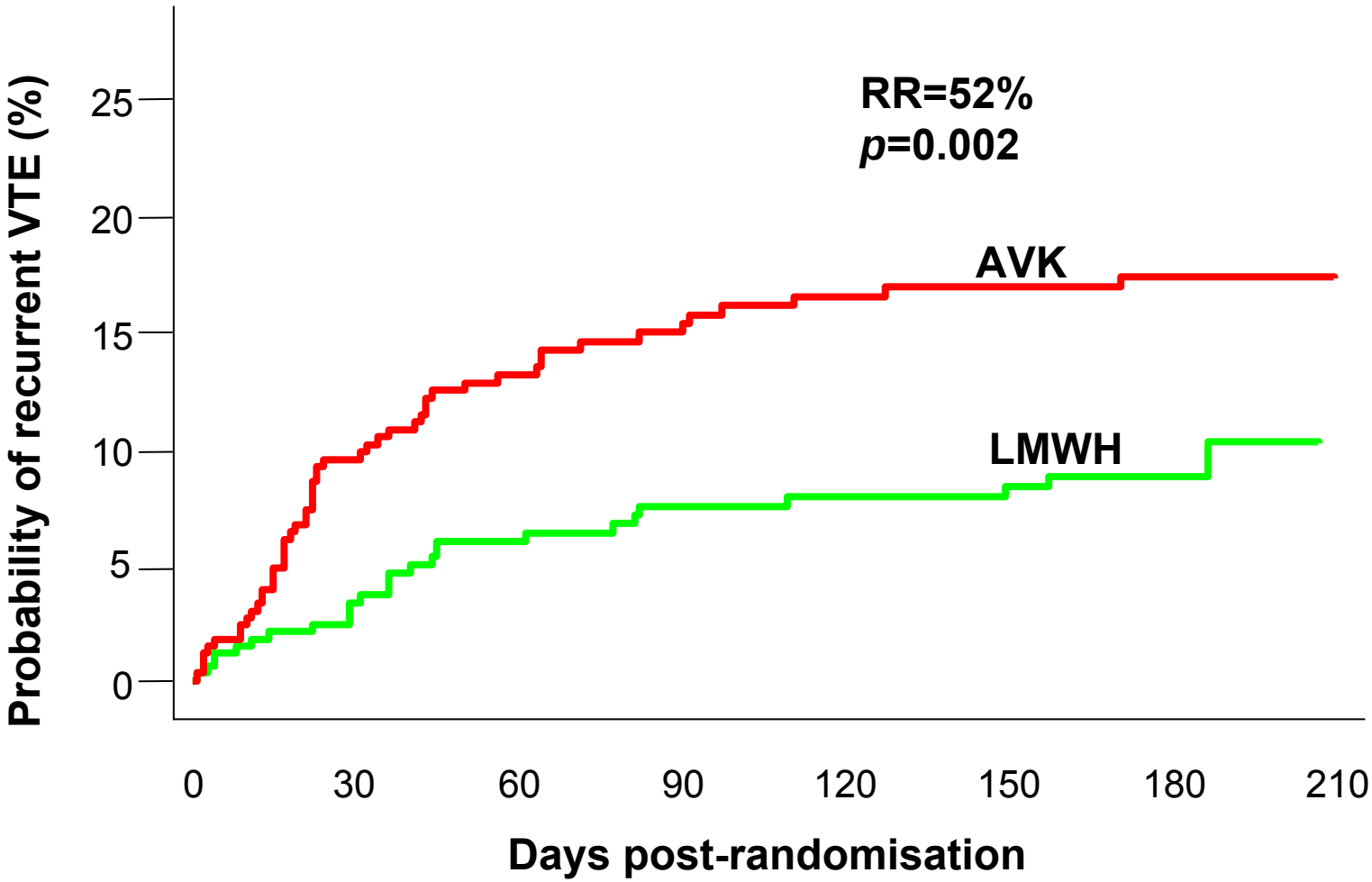
Acute DVT Study



No. at Risk

Rivaroxaban	1731	1668	1648	1621	1424	1412	1220	400	369	363	345	309	266
Enoxaparin–VKA	1718	1616	1581	1553	1368	1358	1186	380	362	337	325	297	264

CLOT: prevention of VTE recurrence



Lee AYY, et al. NEJM 2003

¿Para qué más pacientes?

- 1.- Profilaxis
- 2.- Estratificación de riesgo
- 3.- Tratamiento
- **4.- Nuevos estudios**

Enfermedad arterial

variables	si	no
IAM previo	871	9.890
AVC isquémico previo	767	9.998
Arteriopatía periférica	430	10.301
Fumador actual	1.574	8.889
Hipertensión arterial	4.790	6.013
Diabetes mellitus	1.567	9.163
Tratamiento con estatinas	1.931	8.696
Evento arterial	339	11.760
Muerte por IAM	54	
Muerte por AVC	61	

Seguimiento

Ecocardiograma a 12 meses	689
Ecocardiograma a 24 meses	180
Ecocardiograma a 36 meses	106
TC torácico a los 6 meses	323
TC torácico a los 12 meses	102
TC torácico a los 24 meses	28
Eco-doppler (primero)	2.006
Eco-doppler (segundo)	436

Síndrome postrombótico

A los 12 meses	1.635
A los 24 meses	725
A los 36 meses	412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NEAREST RECRUITING STATION


WE WANT YOU!


I WANT
YOU


I WANT YOU


I WANT YOU
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I WANT OUT


I WANT YOU TO
SPEAK ENGLISH


I WANT YOU
FOR U.S. ARMY
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I WANT YOU
TO PAY MY BILLS


I WANT YOU
TO SPEAK ENGLISH


I WANT YOU


I WANT YOU
FOR RUSSIAN FITNESS
REVOLUTION


I WANT YOU
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CONTAINERIST.COM
I WANT YOU
TO BUILD EMERGENCY SHELTERS
AND SAVE THE WORLD.
(BUT DON'T BLAME US IF WE NEVER USE THEM)

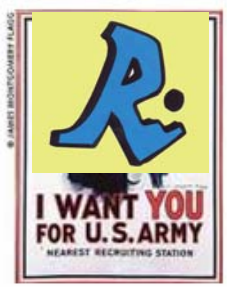

NAVY!
Uncle Sam is calling YOU
ENLIST in the Navy!
Recruiting Station.


I WANT YOU
FOR U.S. ARMY
NEAREST RECRUITING STATION


I WANT YOU
TO GO HOME AND PACK
IT IS TIME THAT WE FLEW
TO A LAND CALLED IRAQ


I WANT YOU


I WANT YOU


I WANT YOU
FOR U.S. ARMY
NEAREST RECRUITING STATION