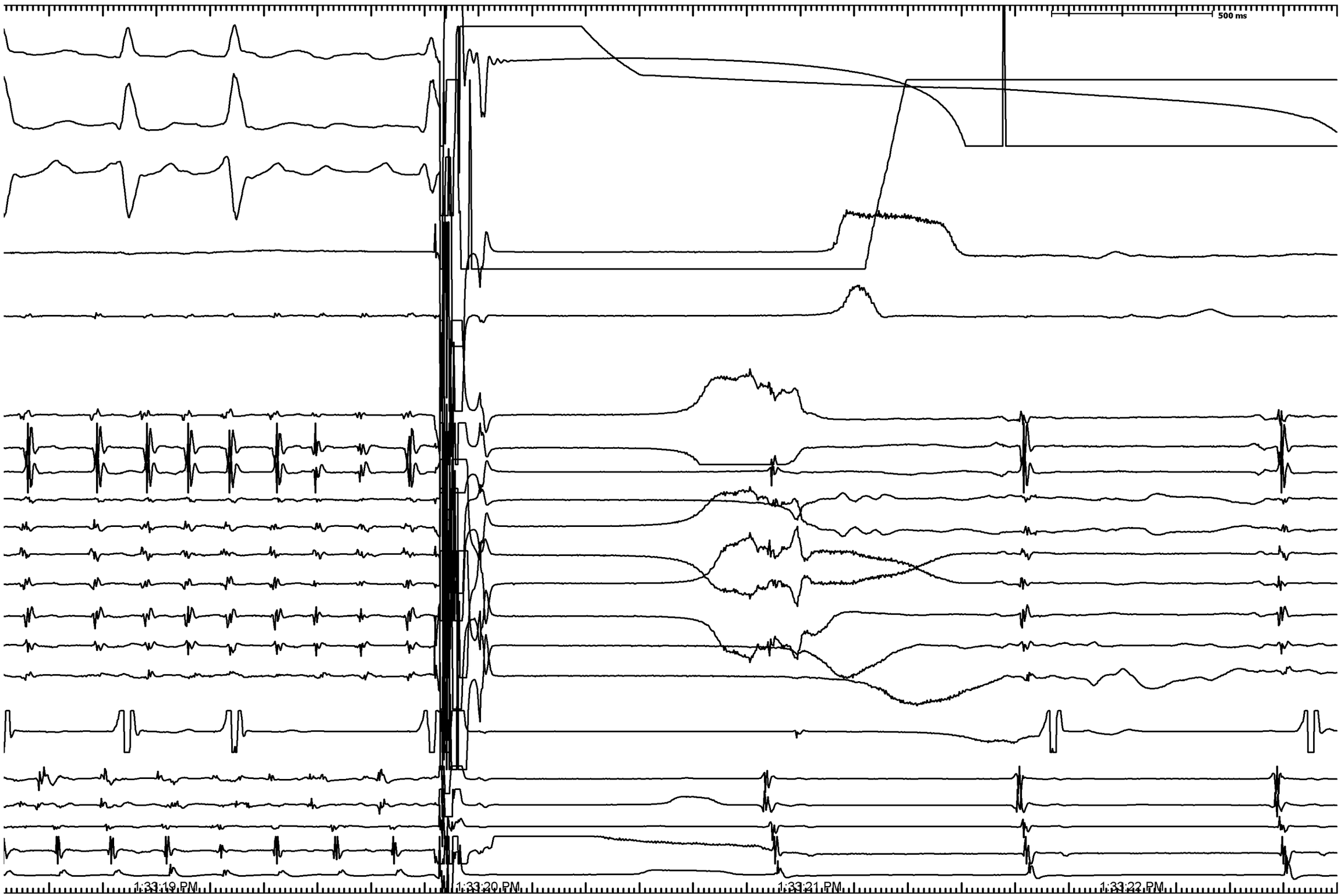
Nuevos ACO
Situaciones “especiales”

Pericardioversion

Implantes Marcapasos

Dr Xavier Viñolas
Director Unidad de Arritmias
Hospital de Sant Pau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Predictors of success and effect of biphasic energy on electrical cardioversion in patients with persistent atrial fibrillation

Josep M. Alegret[1*], Xavier Viñolas[2], Jaume Sagristá[3], Antonio Hernandez-Madrid[4], Luisa Pérez[5],

1515 pctes

CV farmacológica no intentada
n=763

CV farmacológica intentada
n=752

No efectiva
n=592 (79%)

Efectiva
n=160 (21%)

CV eléctrica
n=1355

no efectiva
n=114
8%

efectiva
n=1241
92%

recidiva precoz
n=66
5,5%

efectiva
n=1175
87%

RS
1335 (88%)

Volumen de CVE ***electivas***

		centros	meses	# pctes
REVERCAT 2003	**Catalunya**	**32**	**9**	**436**
REVERSE 2005	**España**	**96**	**4**	**1500**
REVERCAT 2010	**Catalunya**	**30**	**9**	**397**
CARDIOVERSE 2012	**España**	**100**	**4**	**--**

REVERSE seguimiento 800 pctes

RS a los 12m

51%

ausencia de FA persistente

37%

Riesgo de embolismo en la CVE sin anticoagulación

Periodo pericardioversion es de alto riesgo!

4% anual ⟹ 0,3% teorico mes pericardioversión

- Duración de la FA (>48h)
- Riesgo embólico paciente
  - protesis, valv reumatica, AVC previo
  - $CHADS_2$

- *Datos ecocardiográficos (**trombo**, "humo" auricular, bajos flujos orejuela, etc...)*

Historia CV y anticoagulación

- 1967 Lown describe 456 CV sin anticoagulación con una incidencia de embolias del **1,2%**

- 1969 Berkelund describe 467 CV con ACO o sin (no randomizado) con **5,3% vs 0,8%**

- 1990 Mancini presenta la revisión de 10 a de CV en la universidad de Michigan con **0% vs 7%**

Role of Prophylactic Anticoagulation for Direct Current Cardioversion In Patients With Atrial Fibrillation or Atrial Flutter

ANITA ZEILER ARNOLD, DO, MATTHEW J. MICK, MD, ROBERT P. MAZUREK, MD, FLOYD D. LOOP, MD, FACC, RICHARD G. TROHMAN, MD, FACC

Cleveland, Ohio

The need for prophylactic anticoagulation to prevent embolism before direct current cardioversion is performed for atrial fibrillation or atrial flutter is controversial. To examine this issue further, a retrospective review was undertaken to assess the incidence of embolic complications after cardioversion. The review involved 454 elective direct current cardioversions performed for atrial fibrillation or atrial flutter over a 7 year period.

The incidence rate of embolic complications was 1.32% (six patients); the complications ranged from minor visual disturbances to a fatal cerebrovascular event. All six patients had atrial fibrillation, and none had been on anticoagulant therapy ($p = 0.026$). The duration of atrial fibrillation was <1 week in five of the six patients who had embolic complications.

Baseline characteristics of patients with a postcardioversion embolic event are compared with those of patients who did not have an embolic event. There was no difference in the prevalence of hypertension, diabetes mellitus or prior stroke between the two groups, and there was no difference in the number of patients who were postoperative or had poor left ventricular function. Left atrial size was similar between the two groups. No patient in the embolic group had valvular disease.

No patient with atrial flutter had an embolic event regardless of anticoagulant status; therefore, anticoagulation is not recommended for patients with atrial flutter undergoing cardioversion. Prophylactic anticoagulation is pivotal in patients undergoing elective direct current cardioversion for atrial fibrillation, even those with atrial fibrillation of <1 week's duration.

(J Am Coll Cardiol 1992;19:851–5)

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7 años
457 cardioversiones

6 embolismos
1,32%

179 sin ACO

153 con ACO

3% embolismos

0% embolismos

JACC1992

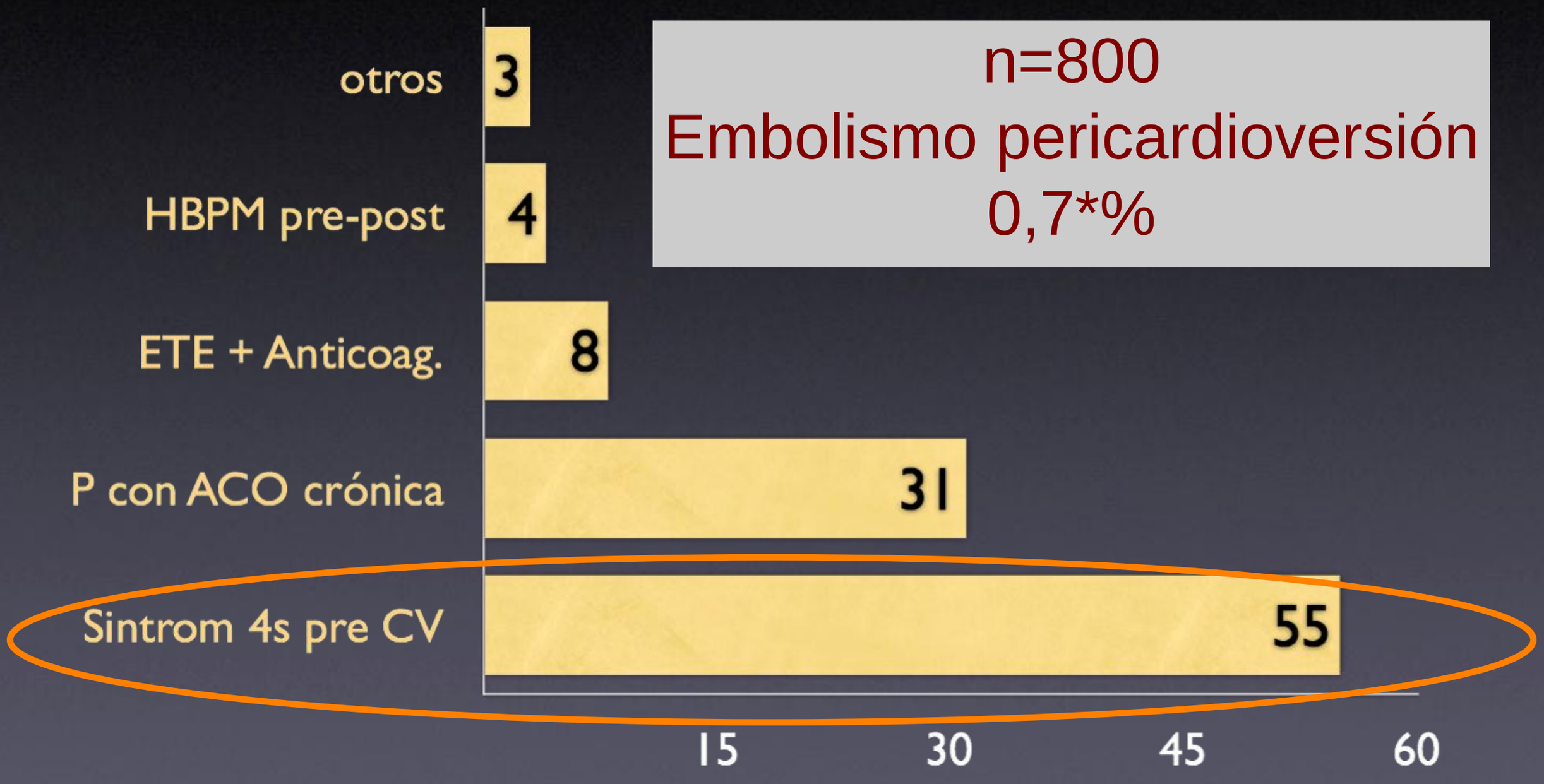
Guidelines for the management of atrial fibrillation

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

Increased risk of thrombo-embolism following cardioversion is well recognized. Therefore, anticoagulation is considered mandatory before elective cardioversion for AF of >48 h or AF of unknown duration. Based on observational cohort studies, VKA treatment (INR 2.0–3.0) should be given for at least 3 weeks before cardioversion. Thromboprophylaxis is recommended for electrical and pharmacological cardioversion of AF >48 h. VKA should be continued for a minimum of 4 weeks after cardioversion because of risk of thrombo-embolism due to post-cardioversion left atrial/LAA dysfunction (so-called 'atrial stunning'). In patients with risk factors for stroke or AF recurrence, VKA treatment should be continued lifelong irrespective of apparent maintenance of sinus rhythm following cardioversion.

REgistro cardioVERSión España

Anticoagul. Pericardioversión



n=800
Embolismo pericardioversión
0,7*%

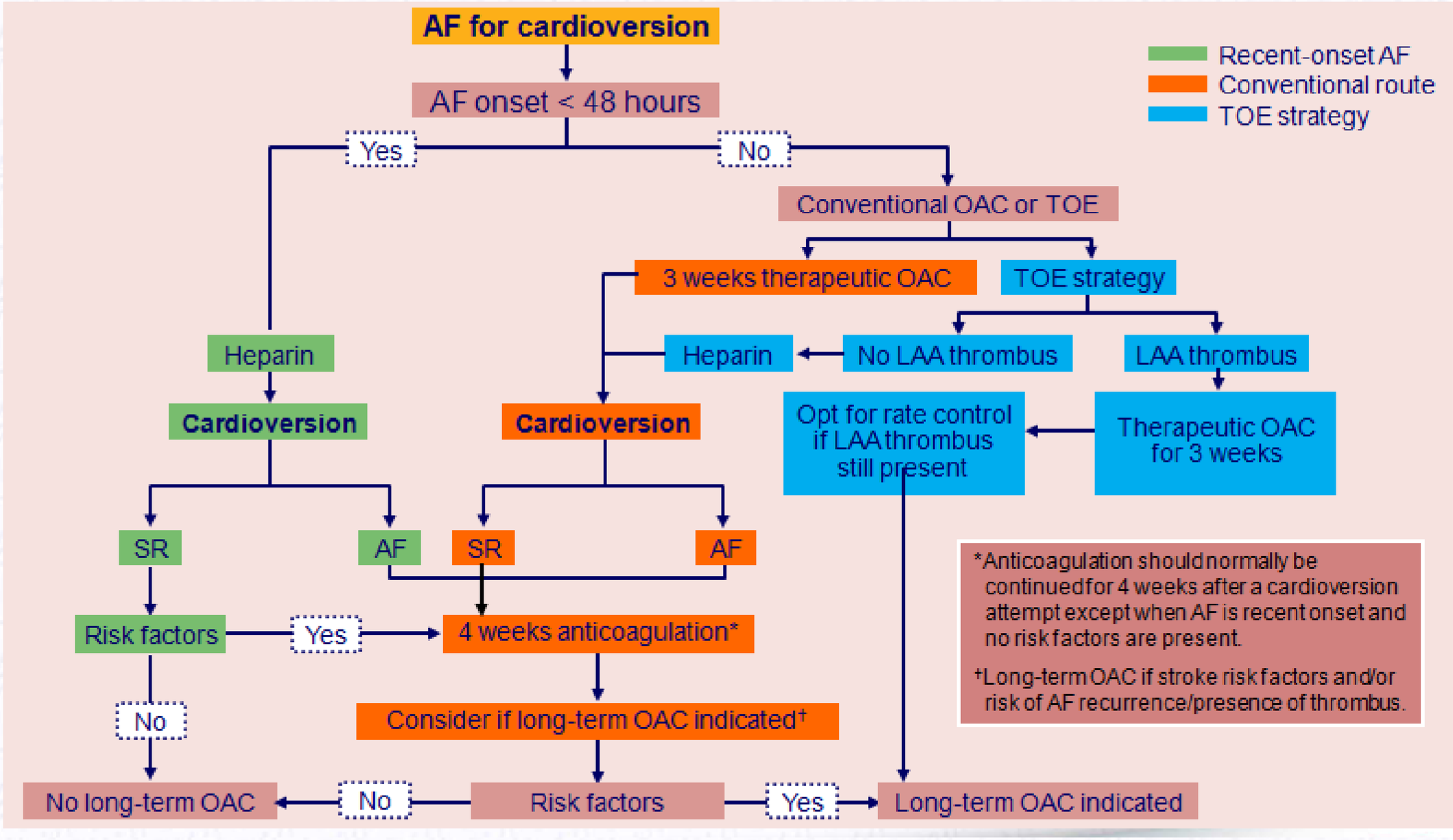
* Alegret, Viñolas Med Clin 2011

ESTUDIOREVERSE

Riesgo embolia pericardioversion en los diferentes ensayos con anticoagulación y CVE

ACUTE I	n=1222	0,5%-0,8%
Yigiz et al . Jpn Heart J 2003	n=172	0%
Seildz et al. JACC 2002	n=1076	0,8%
ACE trial		
Alegret, Viñolas et al REVERSE (2010)	**n=1500**	**0,7%**

Cardioversion, TOE and anticoagulation



AF = atrial fibrillation; DCC = direct current cardioversion; LA = left atrium; LAA = left atrial appendage; OAC = oral anticoagulant; SR= sinus rhythm; TOE= transoesophageal echocardiography.

www.escardio.org/guidelines

European Heart Journal (2010) 31, 2369-2429

EUROPEAN SOCIETY OF CARDIOLOGY®

Mitos a erradicar

- La CV farmacológica es menos embolígena
- la CV “espontánea” no tienen riesgo
- “como ya lo veo en RS” ha pasado el riesgo
- al mes de la CVE ya “ha pasado el riesgo

Medicina basada en la evidencia

- Ensayos clínicos
- Ensayos clínicos son posibles??
  - qué volumen pctes necesitamos?
- Podemos asumir que cualquier ACO es igual?

Nuevos anticoagulantes y CVE

Comparación Re-Ly / Rocket AF

	Re-Ly	Rocket AF	Aristotle
Age	71 y	73 y	70y
Permanent AF	**35%**	**--**	**52%**
# cardioversiones	**7%**	**1,4%***	

** datos no publicados*

Name	Trial	design	published ?
Idraparinux	Borealis Amadeus	AF & stroke risk Idrap vs Warfarine	2008
Ximelagatran	Sportif III Sportif IV	Ictus/embolias 1,3% - 2,3% Sangrados mayores 1,3 - 1,8% **Hepatotoxicidad**	
Apixaban	Averroes	Apixaban vs AAS *pts unable to warfarine*	2010
	Aristotle	Apixaban vs Warfarine *AF + CHADS ≥1*	2011-12?
Dabigatran	Re-Ly	Dabigatran vs Warfarine *AF + CHADS ≥1*	2009
Rivaroxaban	Rocket AF	Rivaroxaban vs Warfarine AF + CHADS ≥2	2011?

CVE en el Sportif

- Suspensión temporal de la medicacion del ensayo. Se pasaba a Sintrom para la Cardioversión eléctrica.
- No disponemos por tanto de datos.....
- Clinicamente es “una locura”

CVE en el Rocket AF

- la CVE programada era un criterio de exclusión
  - No hay datos en el Rocket AF sobre CV
  - un 1,4% de los pacientes fueron cardiovertidos*

** datos no publicados*

Nuevos ACO

- DBG Aumento de los infartos miocardio?.
- Qué dosis usar? 110? 150 mg?.
- **Dabigatran y Cardioversión eléctrica.**
- Sólo es útil si INR mal controlado?.
- Prevención 2ª (ictus previo).
- Anticoagularemos gente menos riesgo? CHADS1?

Dabigatran Versus Warfarin in Patients With Atrial Fibrillation

An Analysis of Patients Undergoing Cardioversion

Rangadham Nagarakanti, MD; Michael D. Ezekowitz, MBChB, DPhil, FRCP, FACC; Jonas Oldgren, MD, PhD; Sean Yang, MSc; Michael Chernick, PhD; Timothy H. Aikens, BA; Greg Flaker, MD; Josep Brugada, MD; Gabriel Kamenský, MD, PhD, FESC; Amit Parekh, MD; Paul A. Reilly, PhD; Salim Yusuf, FRCPC, DPhil; Stuart J. Connolly, MD

Background—The Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY) trial compared dabigatran 110 mg BID (D110) and 150 mg BID (D150) with warfarin for stroke prevention in 18 113 patients with nonvalvular atrial fibrillation.

Methods and Results—Cardioversion on randomized treatment was permitted. Precardioversion transesophageal echocardiography was encouraged, particularly in dabigatran-assigned patients. Data from before, during, and 30 days after cardioversion were analyzed. A total of 1983 cardioversions were performed in 1270 patients: 647, 672, and 664 in the D110, D150, and warfarin groups, respectively. For D110, D150, and warfarin, transesophageal echocardiography was performed before 25.5%, 24.1%, and 13.3% of cardioversions, of which 1.8%, 1.2%, and 1.1% were positive for left atrial thrombi. Continuous treatment with study drug for ≥3 weeks before cardioversion was lower in D110 (76.4%) and D150 (79.2%) compared with warfarin (85.5%; $P<0.01$ for both). Stroke and systemic embolism rates at 30 days were 0.8%, 0.3%, and 0.6% (D110 versus warfarin, $P=0.71$; D150 versus warfarin, $P=0.40$) and similar in patients with and without transesophageal echocardiography. Major bleeding rates were 1.7%, 0.6%, and 0.6% (D110 versus warfarin, $P=0.06$; D150 versus warfarin, $P=0.99$).

Conclusions—This study is the largest cardioversion experience to date and the first to evaluate a novel anticoagulant in this setting. The frequencies of stroke and major bleeding within 30 days of cardioversion on the 2 doses of dabigatran were low and comparable to those on warfarin with or without transesophageal echocardiography guidance. Dabigatran is a reasonable alternative to warfarin in patients requiring cardioversion.

Clinical Trial Registration—URL: http://www.ClinicalTrials.gov. Unique identifier: NCT00262600.

(***Circulation***. **2011;123:131-136.**)

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AF & 1 "Risk factors"*
chronic warfarine & naïf
n=**18113** / 951 hospitals / 44 countries

** risk factors= Stroke, FE<40%, NYHA II, edad>75, edad 65-75 +diabetes, HTA, C isquemica*

Warfarine INR 2-3
"open"
n=6022

Dabigatran 110 mg/12h
"Blinded"
n=6015

Dabigatran 150 mg/12h
"Blinded"
n=6076

Follow-up of 12 to 48 m
median 20 m

Non inferiority trial at reducing the combined outcome of STROKE (ischemic &hemorragic) and systemic embolism

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n=6076

Recomendaciones
- se aconsejaba mantener el Trat
- se aconsejaba ETE si <60d trat
- se aconsejaba trat al menos 3 s!

- tratamiento ACO periCV
- otros trat antitrombóticos
- CV farmacológica o eléctrica
- ETE si/ no
- Presencia trombo AI
- **Embolismos 1 m post**
- **Sangrados**

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Dabigatran 150 mg/12h
"Blinded"
n=6076

1983 CV en 1270 pctes -85% son CVE-

	D110		D150		Warfarin		D110 vs Warfarin		D150 vs Warfarin		D150 vs D110	
	n	%	n	%	n	%	Relative Risk (95% CI)	P	Relative Risk (95% CI)	P	Relative Risk (95% CI)	P
Total randomized	6015		6076		6022							
Cardioversions performed	647*		672		664							
Electric	554	85.63	550	81.85	553	83.28	1.03 (0.98–1.08)	0.2420	0.98 (0.94–1.03)	0.4886	0.96 (0.91–1.00)	0.0631
Pharmacological	91	14.06	122	18.15	111	16.72	0.84 (0.65–1.08)	0.1836	1.09 (0.86–1.37)	0.4886	1.29 (1.01–1.66)	0.0436
TEE	165	25.50	162	24.11	88	13.25	1.92 (1.52–2.43)	<0.0001	1.82 (1.44–2.30)	<0.0001	0.95 (0.78–1.14)	0.5575
Normal sinus rhythm at discharge	566	87.48	596	88.69	595	89.61	0.98 (0.94–1.02)	0.2263	0.99 (0.95–1.03)	0.5897	1.01 (0.97–1.05)	0.4976
Stroke and systemic embolism	5	0.77	2	0.30	4	0.60	1.28 (0.35–4.76)	0.7087	0.49 (0.09–2.69)	0.4048	0.39 (0.07–1.98)	0.2351
<30 d after cardioversion												
Major bleeding	11	1.70	4	0.60	4	0.60	2.82 (0.90–8.82)	0.0617	0.99 (0.25–3.93)	0.9865	0.35 (0.11–1.09)	0.0585
<30 d after cardioversion												

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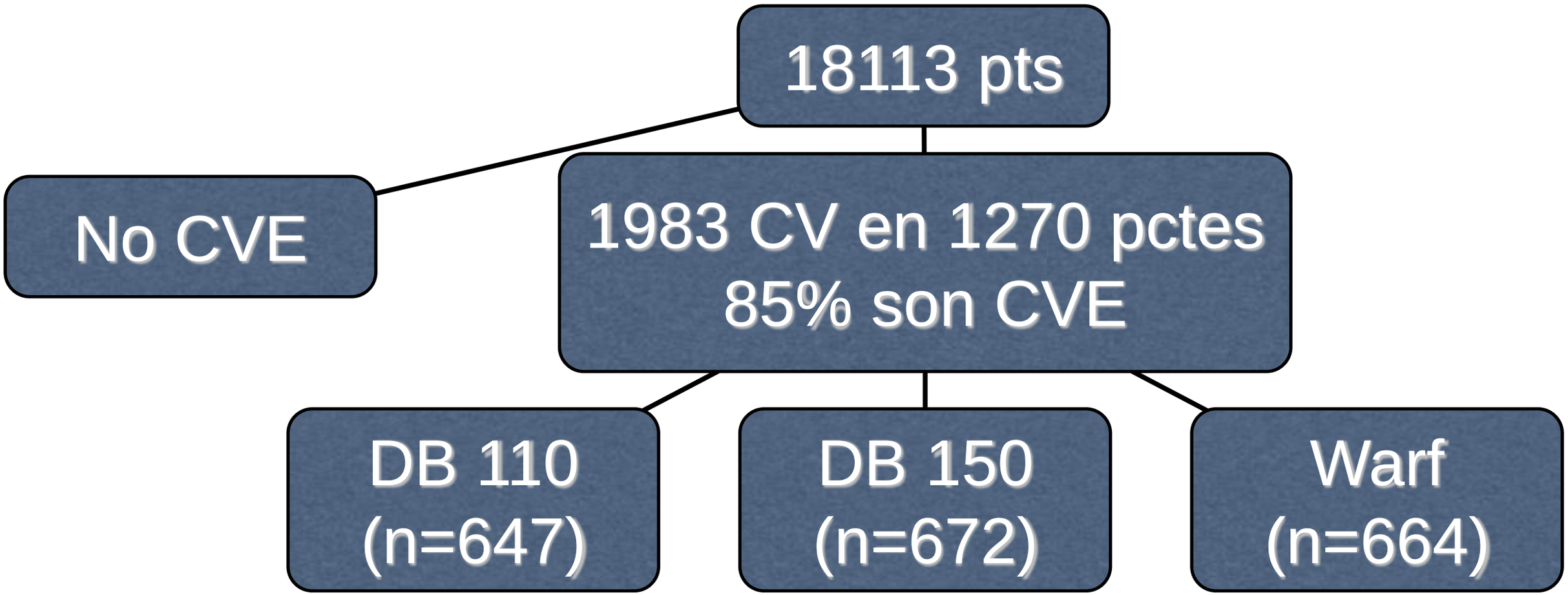

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n=6076

1983 CV en 1270 pctes
85% son CVE

	Warfarine n=664	D110 n=647	D150 n=672
Tratamiento asignado	94%	**85%**	**88%**
ACO que no está en el estudio	13,8%	**19,8%**	16,8%
AAS+clopi	1,81%	**3,7%**	2,2%
Heparina IV	3,6%	**5%**	2%

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n=6076

1983 CV en 1270 pctes
85% son CVE

	Warfarine n=664	D110 n=647	D150 n=672
>3w treatment before CV	85%	76%	70%
switch to a non-study drug	5,4%	9,7%	8,6%
study drug after CV	94%	85%	88%
ETE pre CV	13%	**24%**	**25%**

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1983 CV en 1270 pctes
85% son CVE

	Warfarine n=664	D110 n=647	D150 n=672
ETE pre CV	13%	**24%**	**25%**
Thrombus in TEE			

Preguntas en el aire con CV y nuevos anticoagulantes

- la ventana de 3 semanas sigue siendo valida?
- se podrá acortar?
- en la pauta de ETE + dabigatran como o haremos?

¿Tenemos evidencias?

- No! no hay ensayo randomizado
- Necesidad de algún ensayo especifico de CVE y nuevos anticoagulantes
- Necesidad de registros amplios de CVE: CARDIOVERSE

Nuevos anticoagulantes en Implantes MCP/DAI

- Riesgo de Sangrado
- Hematomas

Riesgo embolia sin tratamiento

- Risk of clinically significant bleeding should be weighed against the risk of stroke and thrombo-embolism in an individual patient before the administration of bridging anticoagulant therapy.

- If the VKA used is warfarin (half-life 36–42 h), treatment should be interrupted 5 days before surgery (five half-lives). If the VKA is phenprocoumon, treatment should be interrupted 10 days before surgery (half-life 96–140 h)

- In patients with NO mechanical prosthetic heart valves or NOT at high risk for thrombo-embolism, iInterruption of OAC (with subtherapeutic anticoagulation for up to 48 h) should be considered, without substituting heparin as 'bridging' anticoagulation therapy (Iia C)

-In patients WITH mechanical prosthetic heart valve or HIGH risk AF for thrombo-embolism, 'bridging' anticoagulation with therapeutic doses of either LMWH or unfractionated heparin during the temporary interruption of OAC therapy should be considered (Iia C)

- VKA should be resumed at the 'usual' maintenance dose (without a loading dose) on the evening of (or the morning after) surgery, assuming there is adequate haemostasis.

- If there is a need for surgery or a procedure where the INR is still elevated (>1.5), the administration of low-dose oral vitamin K (1–2 mg) to normalize the INR may be considered.

European Heart Journal (2010) 31, 2369-2429

Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010: Prevention of Stroke and Systemic Thromboembolism in Atrial Fibrillation and Flutter

John A. Cairns, MD, FRCPC,[a] Stuart Connolly, MD, FRCPC,[b]
Sean McMurtry, MD, PhD, FRCPC,[c] Michael Stephenson, MD, FCFP,[b]
Mario Talajic, MD, FRCPC,[d] and the CCS Atrial Fibrillation Guidelines Committee[e]

Procedimientos invasivos

Riesgo Embólico

Bajo riego $CHADS_2 \leq 2$

Stop antitrombóticos

- AAS o clopi 7 dias
- Sintrom 5 d
- Dabigatran 2 d
- Rivaroxaban 1 d*

reinicio 24-48h

alto riesgo Prótesis, AVC reciente $CHADS_2 \geq 3$

Suspensión ACO y terapia puente con heparina

reinicio tan pronto como sea posible

Riesgos de la Terapia Puente en implantes DAI/MCP

- 10-20%

hematomas!

Continuation of warfarin during pacemaker or implantable cardioverter-defibrillator implantation: a randomized clinical trial. Nazarian et al. Heart Rythm 2011
Cardiac resynchronization therapy device implantation in patients with therapeutic international normalized ratios. PACE 2010

Rivaroxaban

Terapia puente para cirugía programada:

- En un futuro, en los pacientes que puedan estar tratados con rivaroxaban de forma crónica por patología médica (por ejemplo, para las posibles futuras indicaciones de prevención del ictus por fibrilación auricular o como tratamiento de una trombosis previa) y precisen ser intervenidos quirúrgicamente de manera urgente, si se considera imprescindible, se podrá administrar la dosis equivalente de una HBPM a las 24 horas de la administración de la última dosis de rivaroxaban. Si no se considera necesario realizar esta "terapia puente", la cirugía se podrá iniciar a las 24 horas de la última administración del fármaco.

- De la misma manera, se puede realizar el paso de una HBPM a rivaroxaban en caso de considerarse necesario, iniciando el tratamiento con rivaroxaban a las 24h de la última

¿Hay que suspender Sintrom?

123 pctes implante DAI-CRT

49 alto riesgo embólico

79 bajo riesgo

HBPM o hep IV

warfarina

Stop warfarina

20%

5%

4,1%

Preparation for pacemaker or implantable cardiac defibrillator implants in patients with high risk of thrombo-embolic events: oral anticoagulation or bridging with intravenous heparin? A prospective randomized trial

Jose M. Tolosana[1], Paola Berne[1], Lluis Mont[1]*, Magda Heras[1], Antonio Berruezo[1], Joan Monteagudo[2], David Tamborero[1], Begoña Benito[1], and Josep Brugada[1]

	Heparin group ($n = 51$)	OAC group ($n = 50$)	P-value
Pocket haematoma	4/51 (7.8%)	4/50 (8%)	1.00
Drainage haematoma	1/51 (1.9%)	1/50 (2%)	1.00
Thrombo-embolic events	0/51 (0%)	0/50 (0%)	1.00
Active endocarditis	1/51 (1.9%)	1/50 (2%)	1.00
Pneumothorax	1/51 (1.9%)	0/50 (0%)	0.49
Lead displacement	0/51 (0%)	1/50 (2%)	0.50

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Table 1 Baseline characteristics of the patients included in the study

	Heparin group ($n = 51$)	OAC group ($n = 50$)	*P*-value
Age (years)	66 ± 11	68 ± 10	0.28
Male sex	33 (65%)	30 (60%)	0.45
BMI (kg/m^2)	25 ± 5	27 ± 5	0.62
New implant	41 (80%)	38 (76%)	0.36
ICD	15 (29.4%)	16 (32%)	0.88
Mechanical prosthetic valve	26 (51%)	28 (56%)	0.77
Mitral mechanical prosthetic valve	20 (39%)	19 (38%)	0.77
Mitro-aortic prosthetic valve	6 (12%)	9 (18%)	0.42
AF and prosthetic valve	17 (37%)	19 (38%)	0.73
Prosthetic valve + ictus	10 (19%)	5 (10%)	0.15
AF and previous stroke	11 (21%)	14 (28%)	0.52
AF and ≥3 moderate risk factors	7 (14%)	5 (10%)	0.55
AF + non-mechanical prosthetic valve	4 (8%)	2 (4%)	0.43
Protruding intracavitary thrombi	1 (2%)	1 (2%)	1.00
DVT or PTE	2 (4%)	0 (0%)	0.24
LVEF (%)	42.2 ± 17	39.9 ± 17	0.55

OAC, oral anticoagulants; LVEF, left ventricular ejection fraction; ICD, internal cardioverter defibrillator; CRT, resynchronization device; AF, permanent, persistent or paroxysmal atrial fibrillation; HTA, hypertension; DVT, deep venous thrombosis; PTE, pulmonary thrombo-embolism; moderate risk factors: age ≥75, LVEF ≤35%, HTA, diabetes.

¿Hay que suspender Sintrom?

123 pctes implante DAI-CRT

49 alto riesgo embólico

79 bajo riesgo

HBPM o hep IV

warfarina

Stop warfarina

20%

5%

4,1%

¿y con nuevos ACO qué?

- NO suspenderlos?
- Suspender una sola dosis? dos?
- Reiniciar de inmediato?
- **Ha acabado la era de la “terapia puente”?**

Necesitamos ensayos y registros!!