

Who should NOT get an ICD in 2013 ?

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Class I American Guidelines

Clinical situation	proof
Survivors of cardiac arrest by VF/VT after exclusion of any completely reversible cause	A
Spontaneous sustained VT in patients with structural heart disease, whatever its tolerance	B
Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT/VF induced at EPS	B
Pts with LVEF \leq 35% at least 40 days post-MI and in NYHA functional Class II or III	A
Pts with LVEF \leq 35% due to non-ischemic DCM and in NYHA functional Class II or III	B
Pts with LVEF \leq 30% at least 40 days post-MI and in NYHA functional Class I	A
NsVT after MI, LVEF \leq 40% and inducible VT/VF at EPS	B

2^{ary} prevention

1^{ary} prevention

Class IIa American Guidelines

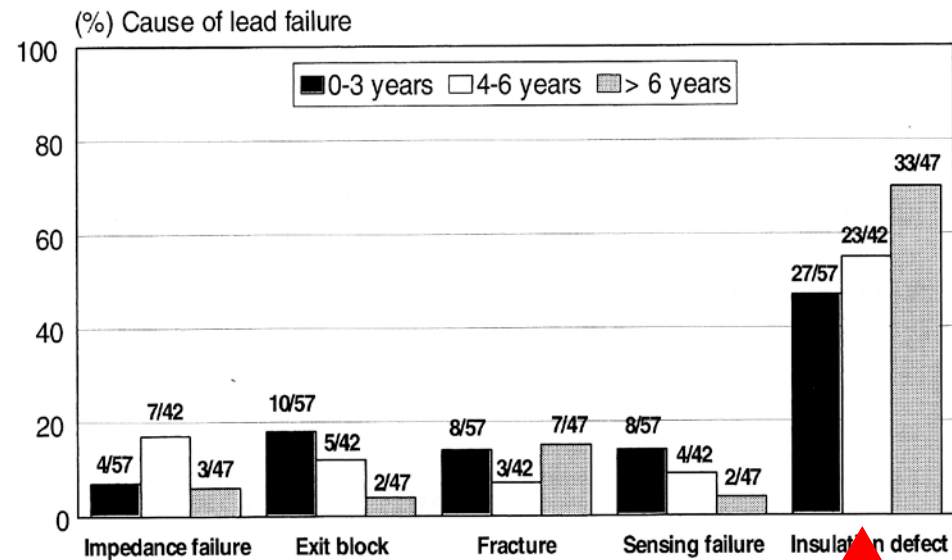
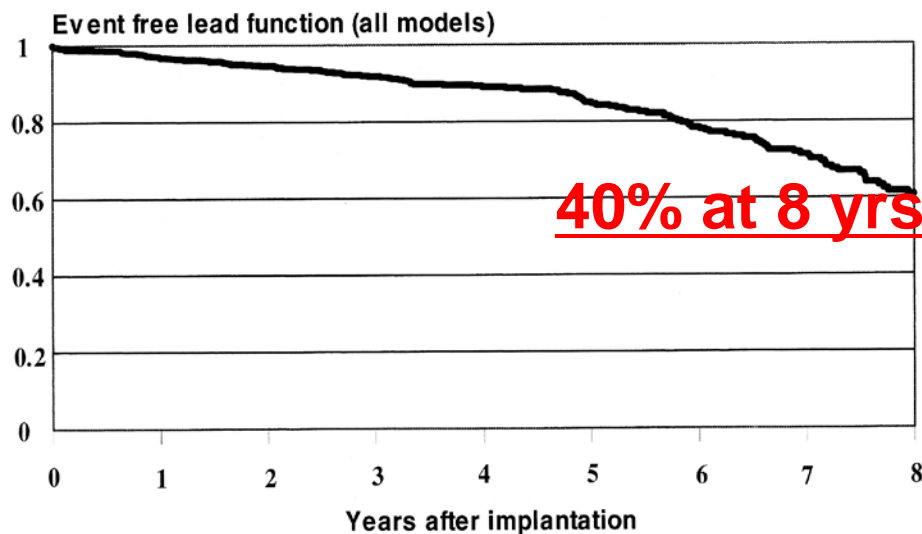
Clinical Situation	proof
Unexplained syncope, significant LV dysfunction, and nonischemic DCM	C
Sustained VT and normal or near-normal ventricular function.	C
HCM who have 1 or more major risk factors for SCD.	C
ARVD/C who have 1 or more risk factors for SCD	C
Long-QT syndrome with syncope and/or VT while taking beta blockers	B
Nonhospitalized patients awaiting transplantation.	C
Brugada syndrome who have had syncope	C
Brugada syndrome and documented VT without cardiac arrest	C
CPVT and syncope and/or documented sustained VT on beta blockers	C
Sarcoidosis, giant cell myocarditis, or Chagas disease.	C

Class III American Guidelines

Clinical Situation	proof
patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year , even if they meet ICD implantation criteria	C
incessant VT or VF	C
significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.	C
NYHA Class IV patients with drug-refractory congestive heart failure who are not candidates for cardiac transplantation or CRT-D.	C
syncope of undetermined cause in a patient without inducible ventricular tachyarrhythmia and without structural heart disease	C
VF or VT amenable to surgical or catheter ablation (eg, atrial arrhythmias associated with the Wolff-Parkinson- White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease)	C
ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease	C

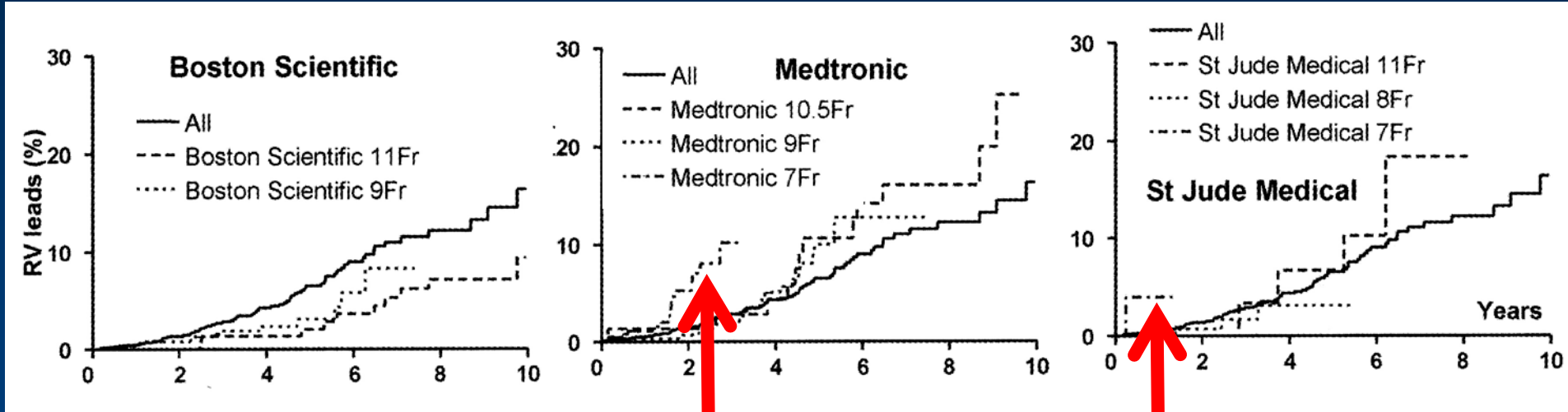
Dysfunctions of AICD leads

- High percentage of defibrillator lead dysfunction.
- It reaches an unacceptable level with time.
- Some lead dysfunctions are tolerable for pacing leads, but not for defibrillation leads



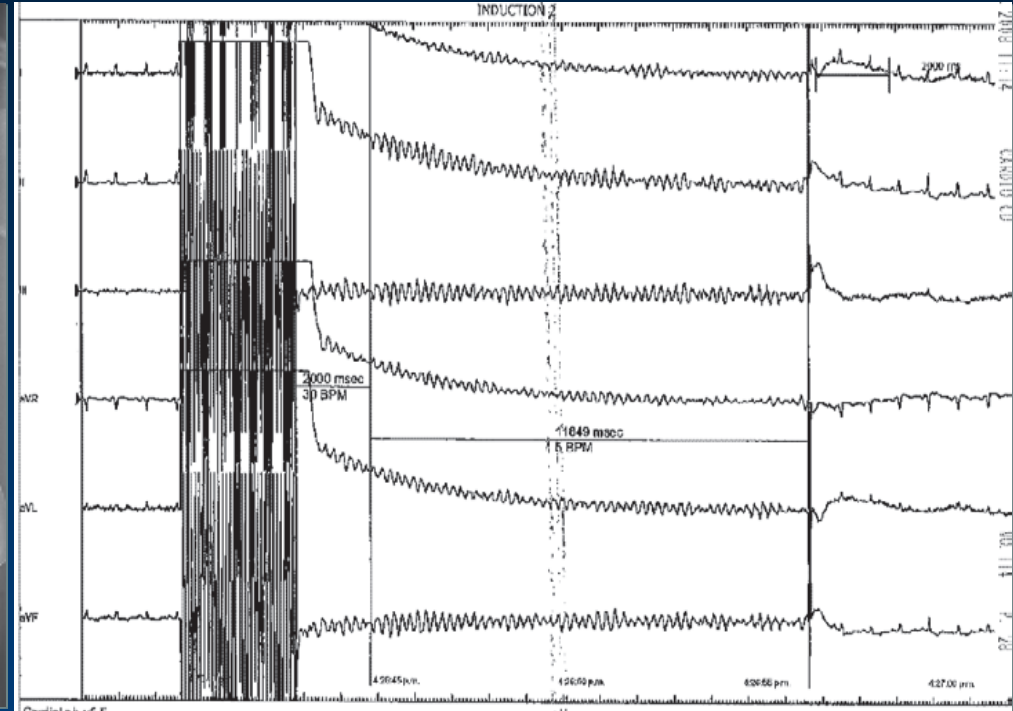
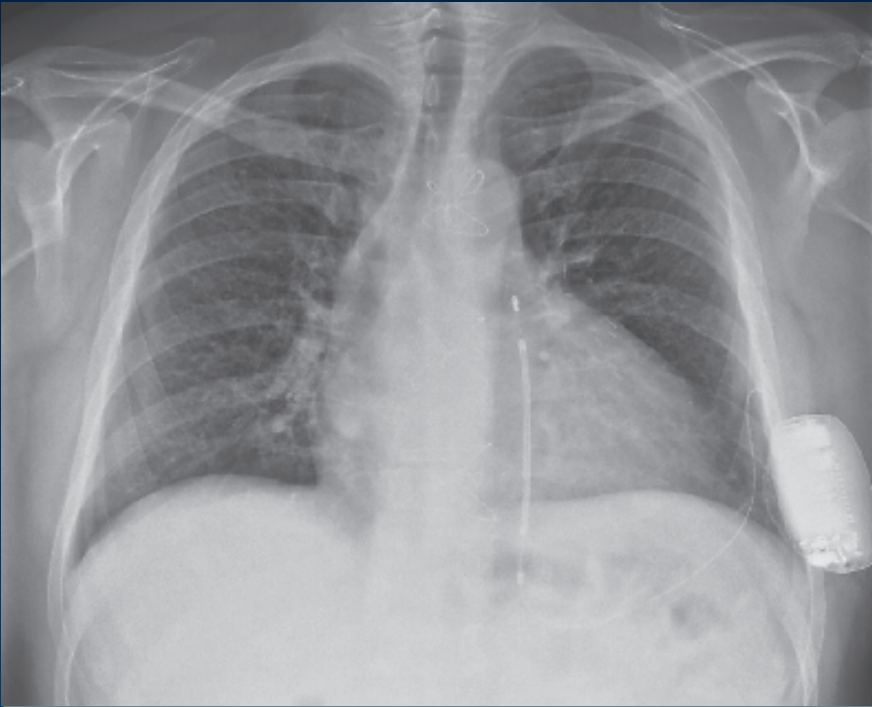
Lead problems with AICD

- Logically, big leads have less dysfunction than smaller ones.



Small is not always beautiful...

AID with subcutaneous lead



Certainly useful for young patients, especially pediatric.
Only for primary prevention (no ATP). Bridge to « true » implant ?
Quality of detection ? of memory ?

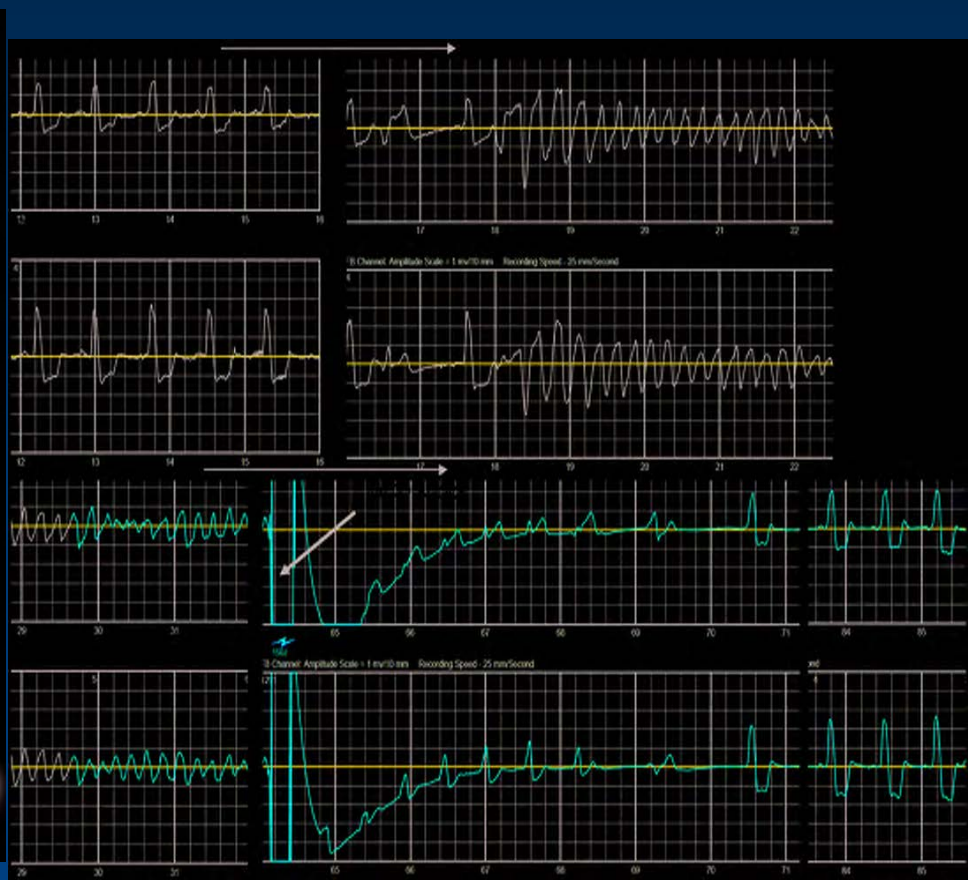
Bardy & al. N Engl J Med 2010;363:36

AID with subcutaneous lead

- 118 pts implanted in Nederland (mean age 50 yrs). After 18 months of F-U, 6.8% received appropriate and 13% inappropriate shocks (mainly T wave oversensing) **Olde Norkamp LR et al. J Am Coll Cardiol 2012;60:1933-9**
- 111 pts implanted in G-B (mean age 33 yrs). After 12 months, 12% received appropriate and 15% inappropriate shocks. Re-operation needed in 17%. **Jarman JW & Todd DM Europace 28/2/2013**
- Total of 321 pts (including NL & GB): 12% of inappropriate shocks. *HRS late-breaking trial 2012.*

Pts awaiting transplantation

- Classical indication of Class IIa
- Alternative treatment: the wearable defib



Indications of wearable defibrillator

- WEARIT-II study. Preliminary results on 882 pts presented at Heart Rhythm 2013: Life vest wearing **81+/-52 days**. Compliance: **21+/-3 hours per day**. 70 VT/VF episodes in 21 pts. Rate of inappropriate therapy: 0.3%.
- Finally, 40% of pts were not implanted because there was an improvement in LVEF.
- Indications: early after MI or coronary revascularisation, new-onset CMD, inherited arrhythmias or congenital disease.

Comment on class-I indications

Acute VF

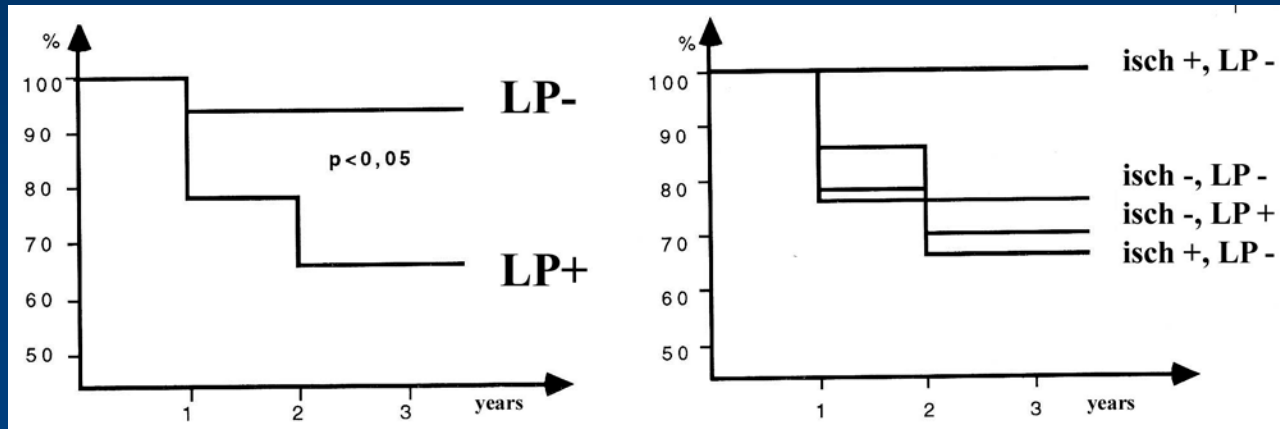
- Class I A indication in «*Survivors of cardiac arrest by VF/VT after exclusion of any completely reversible cause*» i.e. - myocardial ischemia - proarrhythmic effect
- Question: what means **COMPLETELY REVERSIBLE** ?
- Easy to answer in some cases such drug-induced *Torsade de pointes*, often less easy in pts with underlying heart disease.

Class III American Guidelines

Clinical Situation	proof
patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year, even if they meet ICD implantation criteria	C
VF or VT amenable to surgical or catheter ablation (eg, atrial arrhythmias associated with the Wolff-Parkinson- White syndrome, RV or LV outflow tract VT, idiopathic VT, or fascicular VT in the absence of structural heart disease)	C
ventricular tachyarrhythmias due to a completely reversible disorder in the absence of structural heart disease	C

Acute VF and ischaemia

- 38 pts with CHD and resuscitated VF, F-U: 46+/-30 months.
- 22 out of 38 occurred during proved ischemia (13 primary VF during MI, 9 during angina with ECG changes).



3-year recurrence rate: 25-33%

Only pts with «ischemic VF» but no VT substrate have a good prognosis

ESC Guidelines 2006

Coronary revascularization is indicated in patients with VF when direct, clear evidence of acute myocardial ischemia is documented to immediately precede the onset of VF I B

Patients with sustained monomorphic VT in the presence of antiarrhythmic drugs or electrolyte abnormalities should be evaluated and treated in a manner similar to that of pts with VT without electrolyte abnormalities or AAD therapy I B

Iatrogenic VT: AICD indication?

- Inferior MI 1982 (44 yrs). Tritroncular lesions. No angor. LVEF: 46%.
- **Single** sustained monomorphic VT 1987 during exercise test on Flecainide 300 mg/day for frequent PVCs, well tolerated, stopping spontaneously.
- Fast inducible VT (280 bpm) off therapy. No longer inducible on Nadolol.

« *Spontaneous sustained VT in patients with structural heart disease, whatever its tolerance* »: IB

« *NsVT after MI, LVEF \leq 40% and inducible VT/VF at EPS* »: IB

Iatrogenic VT: AICD indication?

- No event on Nadolol
- Very active man throughout the world
- Sudden death 2001, 19 years after MI and 14 years after this single VT...

So, there was an indication of AICD...

The true question is: when ?

New-onset Heart Failure

- Guidelines recommended AICD implant in pts still in heart failure or LVEF **despite maximal medical therapy**
- What's about pts with 1st episode of HF?
- 224 pts with HF of <6 months and LVEF<30%: 1-year mortality rate= 4.5%.
22 normalizations of LVEF. Out of 87 pts tolerating large dosage of β -blocker: 1.1%.

Pts with severe extra-cardiac diseases

- *“patients who do not have a reasonable expectation of survival with an acceptable functional status for at least **1 year**, even if they meet ICD implantation criteria” : III C*
- **Retrospective study of 283 pts implanted for CAD or CMD. Predictors of 1-year mortality:**
 - Liver dysfunction (INR >1.5 or X3 upper limit ALAT)
 - Recent mechanical ventilation
 - Renal clearance <30 ml/mn
- **1-year mortality: 1.9% for 0 criterion, 14.3% for 1 criterion, 38% for 2 or more.**

Pts with severe extra-cardiac diseases

- Retrospective analysis of 1-year mortality after AICD implant in 861 pts, then validation on 706 primary prevention pts
- Risk score based on 4 criteria: **age > 75 yrs, LVEF < 20%, history of AF, renal clearance < 30 ml/mn**
- Mortality rate: 2.5% if 0 or 1 risk factor, 13.3% if 2 risk factors, 46.3% if 3 or 4 risk factors.

AICD in most severe patients ?

- 8-year survival benefit in MADIT-II (no CRT)
- 5 risk factors: NYHA III or IV, age >70 yrs, urea >26 mg/dl, QRS >0.12, atrial fibrillation.
- Clear benefit of implant in pts with 2 or less risk factors (HR 0.52 if 0, 0.66 if 1 or 2 risk factors, all $p < 0.001$) **but not in high-risk patients with 3 or + risk factors** (HR 0.85, $p = 0.25$) who represent 17% of the population.

CRT-P or CRT-D in severe HF?

- 752 pts implanted with CRT-D in MADIT-CRT trial. Analysis of 1-year LVEF change.
- Super-responders (top quartile) had a LVEF increase of $17.5 \pm 2.7\%$ and a low 2-year probability of death or HF: 4%
- Six baseline predictors of super-response:
 - Female sex
 - No prior MI
 - LBBB
 - QRS > 150ms
 - BMI < 30 kg/m²
 - small LA volume

CRT-P or CRT-D in severe HF?

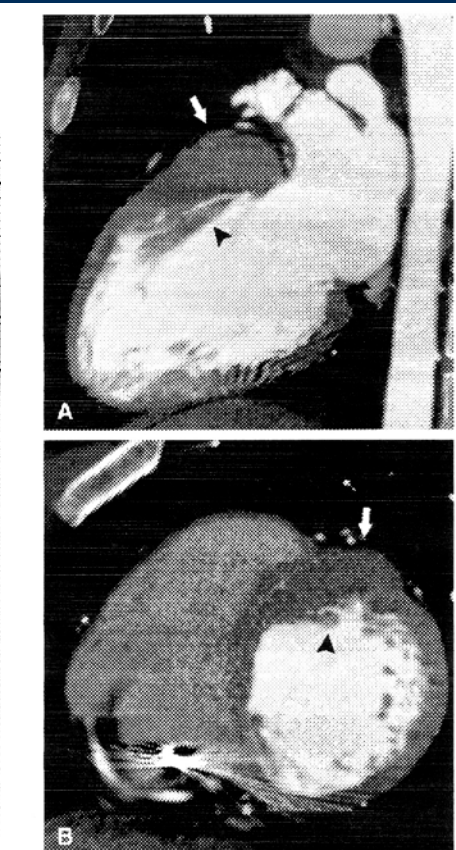
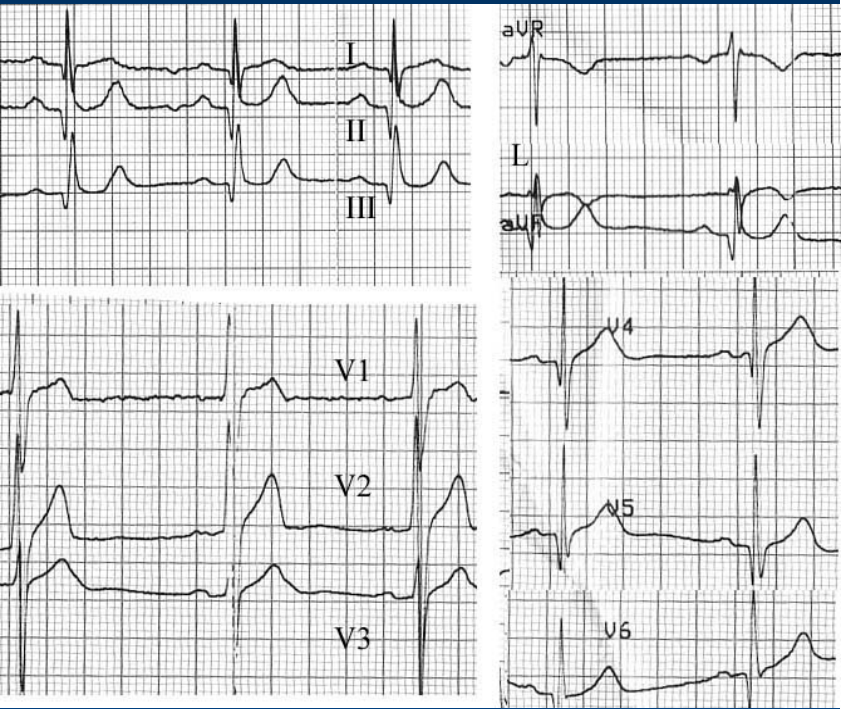
- CRT-P preferred if :
 - Advanced HF
 - Severe renal insufficiency (dialysis)
 - Other major co-morbidity of cachexia
- CRT-D preferred if
 - Life expectancy > 1 year
 - Stable HF, NYHA II
 - Ischaemic heart disease

Hypertrophic Cardiomyopathy

- 1,606 pts evaluated according to the 5 risk factors defined in 2003:
 - NsVT
 - Severe hypertrophy
 - Family history of SD
 - Unexplained syncope
 - Abnormal BP response to exercise
- Mean F-U: 6.6 years. Annual rate of SD or appropriate discharge = 0.45% if 0, **0.65% if 1**, 1.3% if 2, 1.9% if 3, and 5% if more than 3 risk factors are present.

Hypertrophic Cardiomyopathy

- Personal case report: 23 years old, no sportive activity. Rescue from VF occurring during strong exercise and stress.
- Apical HCM



AICD implanted by british colleagues

F-U: no event after 10 years, on a small dosage of β -blocker

Should I perform the replacement now ?

AICD in asymptomatic patients with Brugada syndrome

- 378 pts (mean age 46 yrs, F-U 6.5 yrs). 31 with aborted SD, 181 with syncope, 166 asymptomatic.
- Appropriate shocks: 12%; Inappropriate shocks: 24%.
- 10-year expected rate of
 - inappropriate shock: 37%
 - lead failure: 29%
 - appropriate shocks in asymptomatic patients: 12%

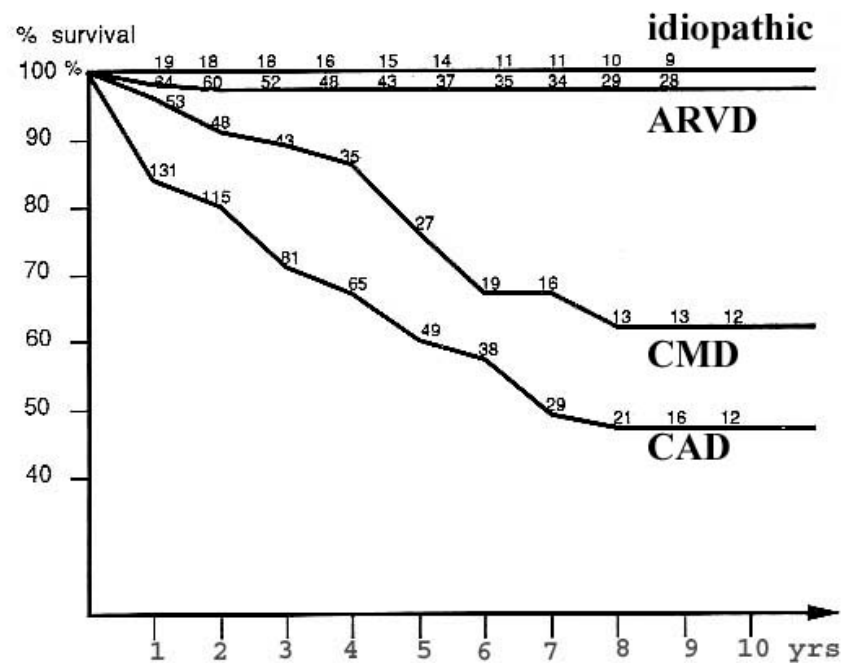
AICD in asymptomatic patient with Brugada syndrome

- Personal case: male, 30 years old, nocturnal SD of father with documented Brugada Σ , nocturnal SD of grandfather and SD of great-grandfather.
- Permanent class-I Brugada Σ , easily induced VF, late potentials, prolonged HV interval, SCN5A mutation, asking for AICD..
- F-U after implant: 14 years.. No VT, no shock. Should I make the 2nd replacement ?

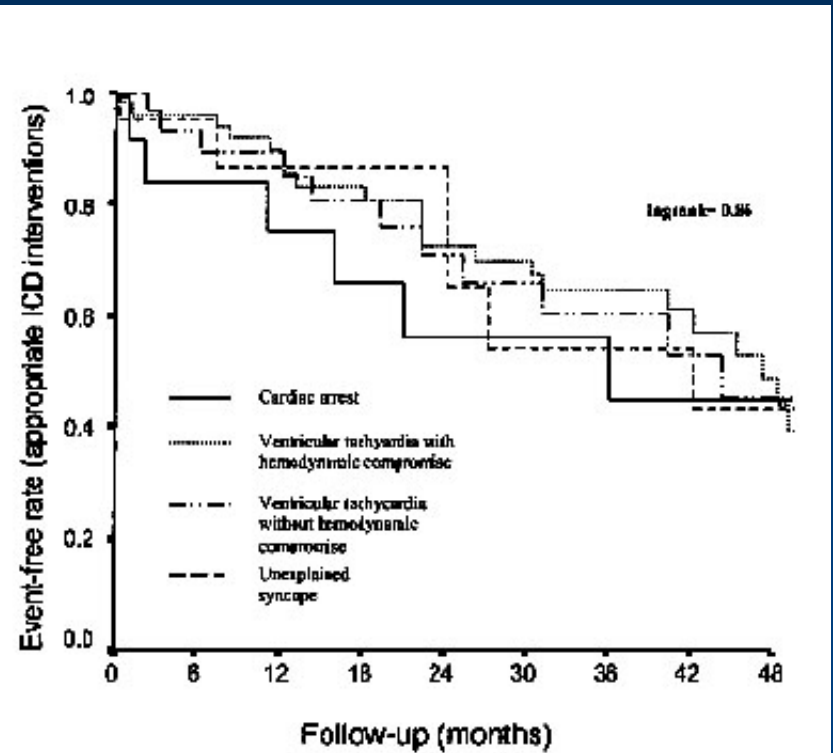
ARVD

- Pts with ARVD and sustained monomorphic VT: good prognosis

Intervention rate of AICD does not depend on clinical presentation



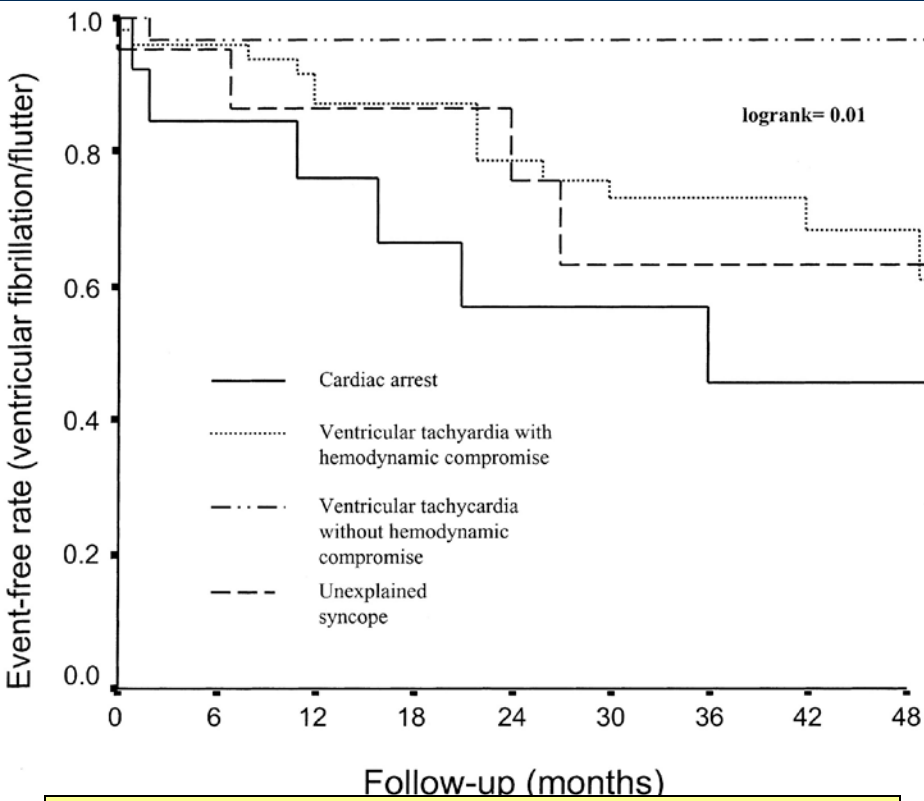
Leclercq & al Am Heart J 1991;121:1685



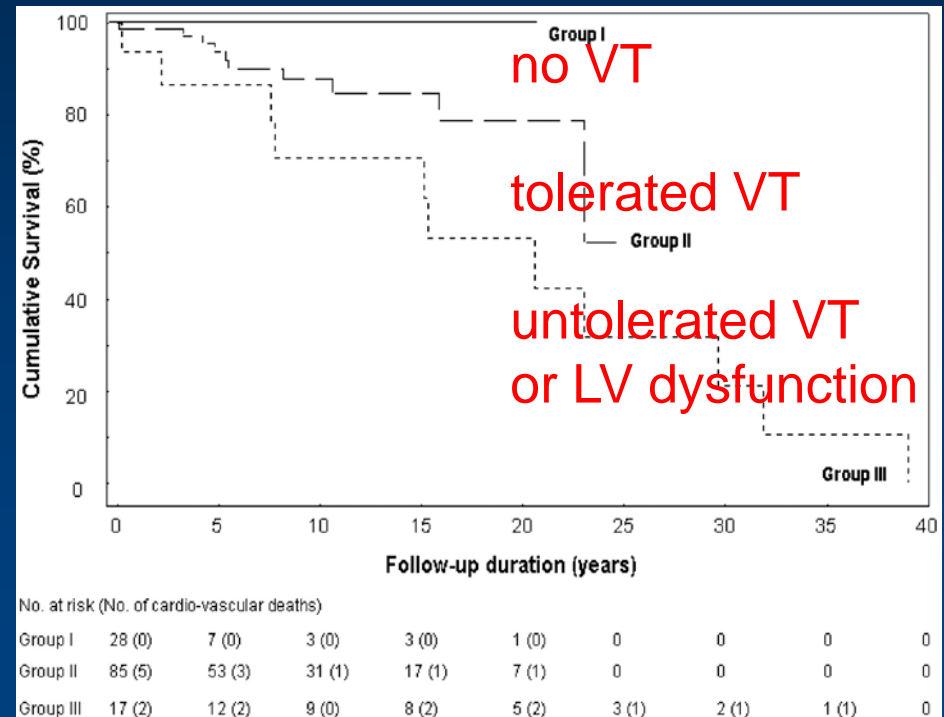
Corrado & al Circulation 2003;108:3084

ARVD

- Risk of VF is higher when first event is VF, or if VT is not well tolerated, or if LV is involved



Corrado & al Circulation 2003;108:3084



Hulot & al Circulation 2004;110:1879

Japanese Guidelines

- Class I indication in VT in structural disease if:
 - Syncope
 - Hypotension or cerebral ischemia
 - Polymorphic VT
 - Stable but inefficacy of medical Trt and ablation

Class IIa if medical treatment or ablation are effective

Conclusion

Who should not receive an ICD?

- Pts without VT nor heart disease
- Pts without expected medical or social benefit
- Pts with VF due to completely reversible cause
- Primary prevention in HF beneficial only in less severe patients. CRT-P rather than-D in others
- Indication in rare diseases is difficult because of
 - lack of controlled studies
 - uncertainty about long-term behavior of the material

*Le plus irréparable des vices
est de faire le mal par bêtise*

The most irreparable vice is to hurt by stupidity

Il piu irreparabile vizio e di fare male per stupidità

Charles Baudelaire

Le spleen de Paris