Single vs. Dual Chamber ICDs

Mark Mason
Consultant Cardiologist
Harefield Hospital

Issues

- Implantation
- Detection/Discrimination
- Therapies

Implantation issues

- A lead complications
  - Subclavian issues
  - Displacement rates
  - Risk of crush
  - ? Risk of inappropriate therapies if lead fracture

Implantation issues

- Subclavian issues
  - Important pneumothorax in around 1%
  - Theoretical risk of vein/artery trauma
  - Perceived ↑risk of vessel thrombosis/occlusion with more leads[1]

1.Korkeila et al. Pacing Clin Electrophysiol. 2007 Feb;30(2):199-206.

Implantation issues

- Well recognised A leads displace more commonly than V
- *May* be mitigated by active vs. passive
- Mandates reintervention, thus increasing infection rates (up to 15-fold!)
- Lead fracture has been reported to result in inappropriate therapies!

Implantation issues-'CTOPP'

TABLE 1. INCIDENCE OF PERIOPERATIVE COMPLICATIONS.*

COMPLICATION	VENTRICULAR PACING (N=1471)	PHYSIOLOGIC PACING (N=1084)	P VALUE
	% of patients		
Any	3.8	9.0	<0.001
Pneumothorax	1.4	1.8	0.42
Hemorrhage	0.4	0.2	0.32
Inadequate pacing	0.3	1.3	0.002
Inadequate sensing	0.5	2.2	<0.001
Device malfunction	0.1	0.2	0.40
Lead dislodgment	1.4	4.2	<0.001

*Only patients who received a pacemaker are included. Some patients had more than one complication.

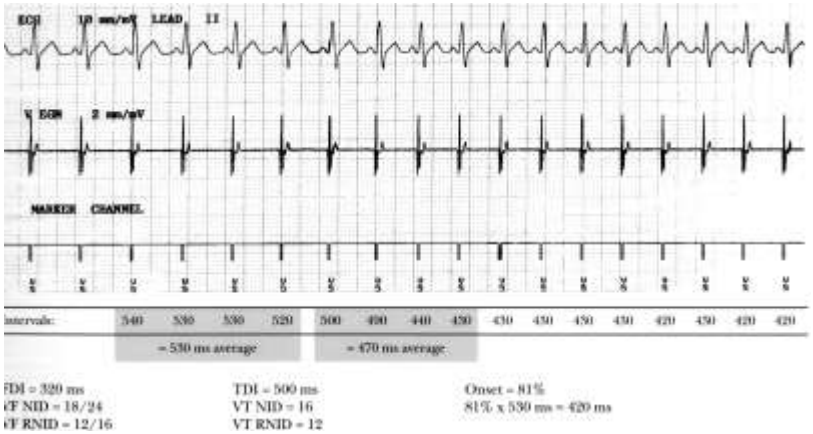
Connolly et al. N Engl J Med. 2000 May 11;342(19):1385-91

Detection/Discrimination issues

- Single chamber reliant upon:
  - Onset
  - Stability
  - Morphology

Onset

- Dependent upon comparison of R-R intervals prior to and during tachycardia
- Uses a sample of most recent complexes, and compares with similar sample of preceding complexes
- Determines whether the mean R-R differs by a programmed %age



- Example: From the strip above, when you compare the average rate of 4 V-V intervals (470ms) versus the average rate of previous 4 V-V intervals (530ms) multiplied by the programmable onset % threshold of 81%, will the device enable VT counting?
- What does the device need? It needs 470ms to be less than < (530ms X 81%)
- 530ms X 81%= 430ms
- 430ms is faster (< than) the 470ms average, so Sudden onset is not met and Onset WILL NOT enable VT counting

Stability

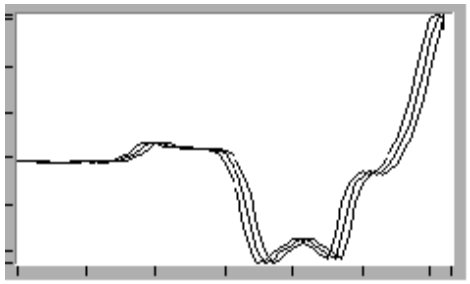
- Based upon perceived variation in R-R interval in AF/flutter
- Compares R-R intervals of a fixed number of complexes and determines whether they fall within a programmed ‘stability’ interval
- VT event counter then reset

Morphology

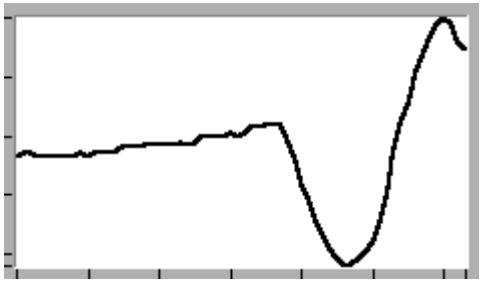
- Reliant upon the assumption that the QRS complex in a ventricular arrhythmia will differ from that within sinus/supra-ventricular tachycardia
- Uses comparison of a stored complex with those during the tachyarrhythmia

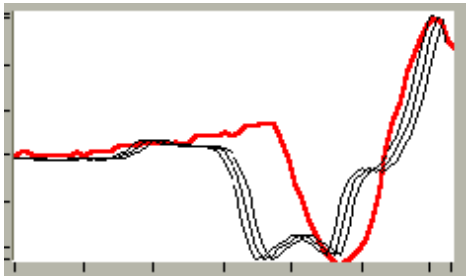
Does Unknown Beat Match known SVT morphology ?

Stored Template



Unknown Rhythm





No ⇩ VT

Yes ⇩ SVT

Detection/Discrimination issues

- Why dual chamber if no need for atrial pacing?
  - Have all above technologies
  - Additional discriminators better still
  - Opportunity to reduce impact of atrial arrhythmias

Detection/Discrimination issues

- Withhold therapies if evidence of AF/flutter
  - EGM counters
  - Lack of far-field R wave (FFRW)
  - Atrial rate as proportion of V rate
  - Irregularity of V rate

Detection/Discrimination issues

- Sinus tachy/SVT
  - Looks for 1:1 conduction
  - Looks for evidence of FFRW

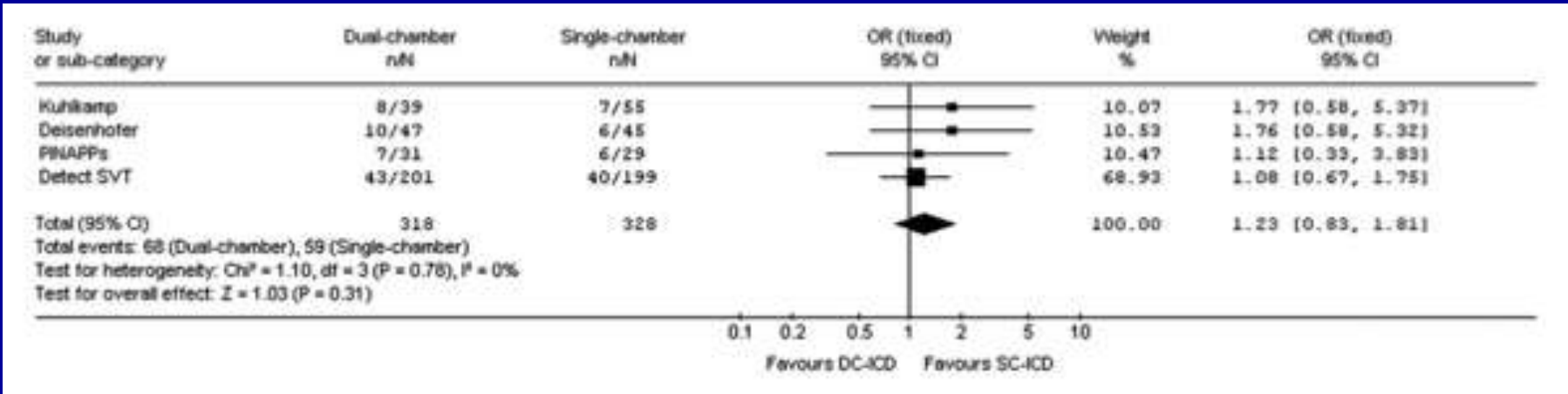
Detection/Discrimination issues

- Does it work?!
  - IJC meta-analysis
  - DATAS trial

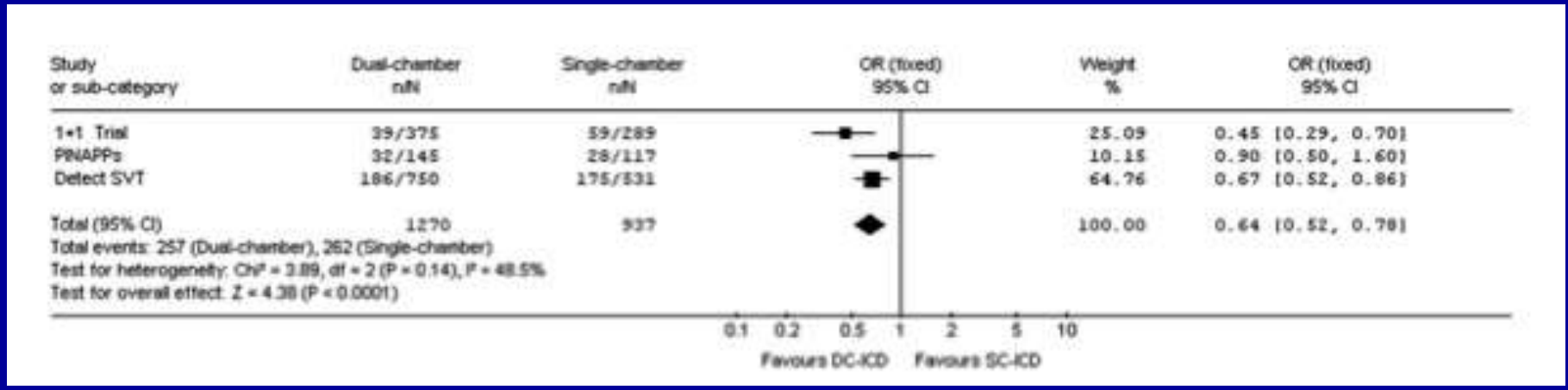
Does it work?

- IJC- Theuns et al. IJC 2008;125:252-357
  - Meta-analysis of 5 studies (published between 1999-2006)
  - Composite of 748 patients
  - Made the distinction between those receiving inappropriate ‘therapies’ (per patient basis) and ‘inappropriately treated atrial tachyarrhythmias’ (per episode basis)

‘Per patient’


Study or sub-category
Dual-chamber n/N
Single-chamber n/N
OR (fixed) 95% CI
Weight %
OR (fixed) 95% CI
Kuhlkamp 8/39 7/55 10.07 1.77 [0.58, 5.37]
Deisenhofer 10/47 6/45 10.53 1.76 [0.58, 5.32]
PINAPPs 7/31 6/29 10.47 1.12 [0.33, 3.83]
Defect SVT 43/201 40/199 68.93 1.08 [0.67, 1.75]
Total (95% CI) 318 328 100.00 1.23 [0.83, 1.81]
Total events: 68 (Dual-chamber), 59 (Single-chamber)
Test for heterogeneity: Chi² = 1.10, df = 3 (P = 0.78), I² = 0%
Test for overall effect: Z = 1.03 (P = 0.31)
0.1 0.2 0.5 1 2 5 10
Favours DC-ICD
Favours SC-ICD

‘Per episode’


Study or sub-category
Dual-chamber n/N
Single-chamber n/N
OR (fixed) 95% CI
Weight %
OR (fixed) 95% CI
1+1 Trial 39/375 59/289 25.09 0.45 [0.29, 0.70]
PINAPPs 32/145 28/117 10.15 0.90 [0.50, 1.60]
Detect SVT 186/750 175/531 64.76 0.67 [0.52, 0.86]
Total (95% CI) 1270 937 100.00 0.64 [0.52, 0.78]
Total events: 257 (Dual-chamber), 262 (Single-chamber)
Test for heterogeneity: Chi² = 3.89, df = 2 (P = 0.14), I² = 48.5%
Test for overall effect: Z = 4.38 (P < 0.0001)
0.1 0.2 0.5 1 2 5 10
Favours DC-ICD
Favours SC-ICD

What does this mean?

- It suggests that dual chamber devices do not reduce the number of patients who experienced inappropriate therapies, but that those who do have inappropriate therapies are likely to receive fewer if they have a dual chamber device

Does it work?

- DATAS trial
  - 334 patients enrolled between Nov 2000 and Dec 2003
  - Patients randomised to dual chamber (DC true), single chamber (SC true) and dual chamber programmed to single chamber (SC sim)
  - DC true and SC sim were crossed over after 8 months

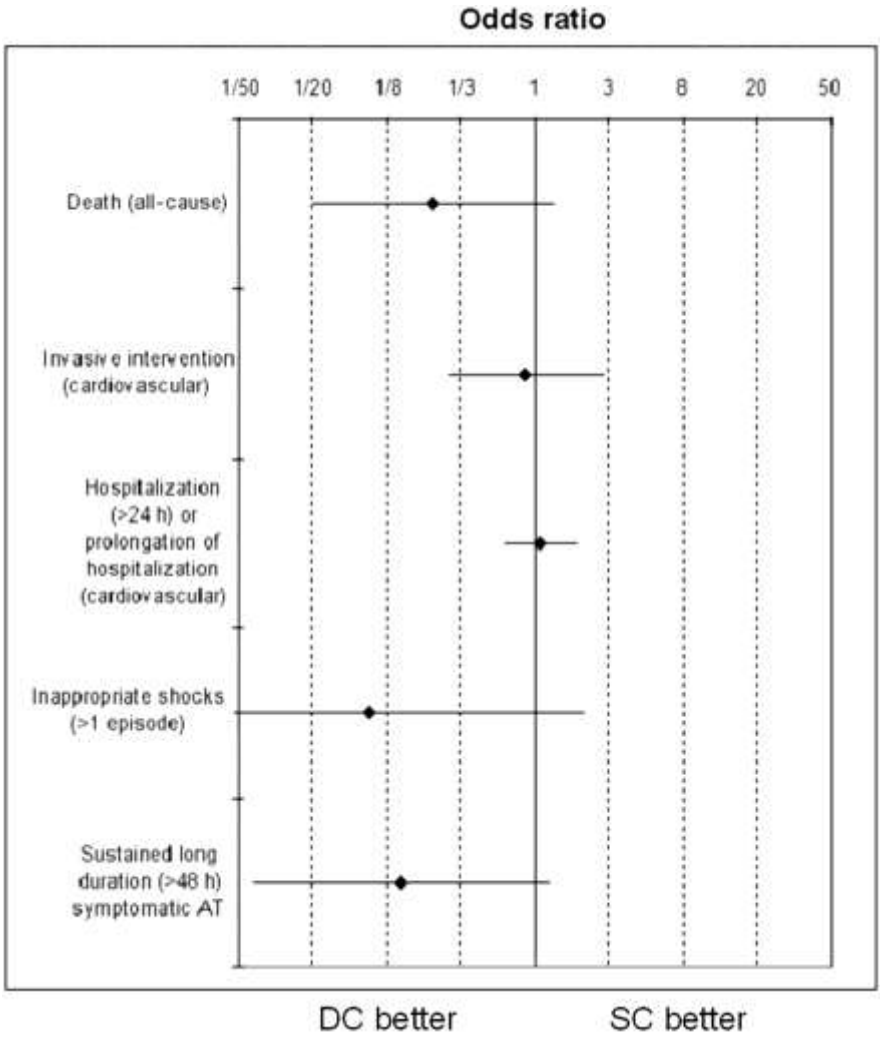
Does it work?

- Primary endpoint was a composite of:
  - All cause mortality
  - Invasive intervention
  - Hospitalisations
  - Inappropriate therapies
  - Sustained symptomatic atrial arrhythmias

Does it work?

- Results:
- Primary endpoint achieved
  - Significantly fewer events in ‘DC true’ arm
  - Trends towards reductions in inappropriate therapies and atrial arrhythmias

Odds ratio for each individual clinically significant adverse effect.



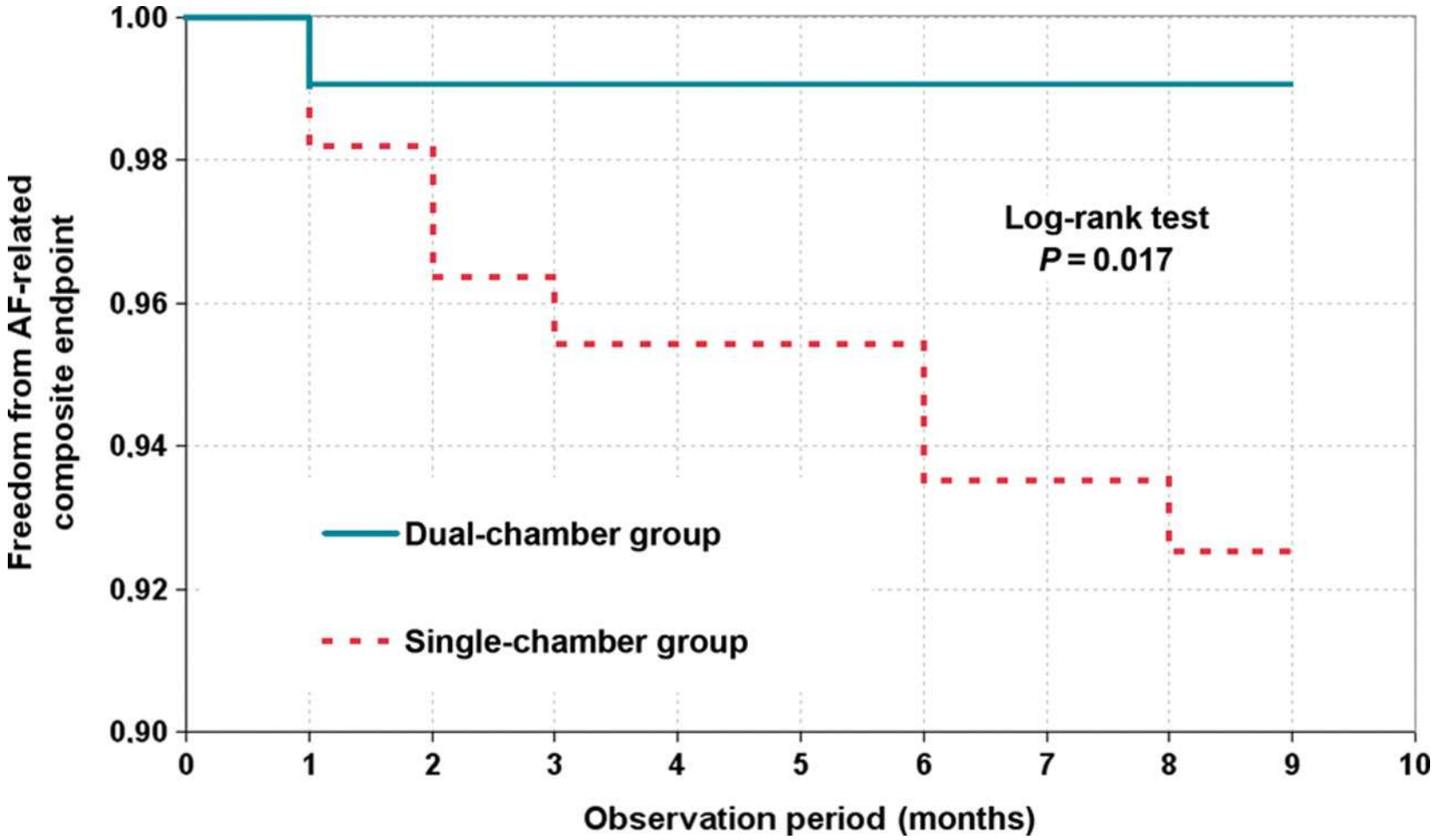
Almendral J et al. Europace 2008;10:528-535

Europace

Does it work?

- Subsequent post-hoc analysis suggests:
  - Reduction in a composite of permanent AF, AF-related hospitalisations, embolic events, inappropriate therapies believed due to AF.

Kaplan–Meier freedom from atrial fibrillation-related composite endpoint in single- vs. dual-chamber groups.



Ricci R P et al. Europace 2009;11:587-593

Europace

‘Therapies’

- Risk of clinical impact even when ‘functioning’ appropriately
  - Atrially-led, V pacing
  - How relevant?
  - Can this be overcome?

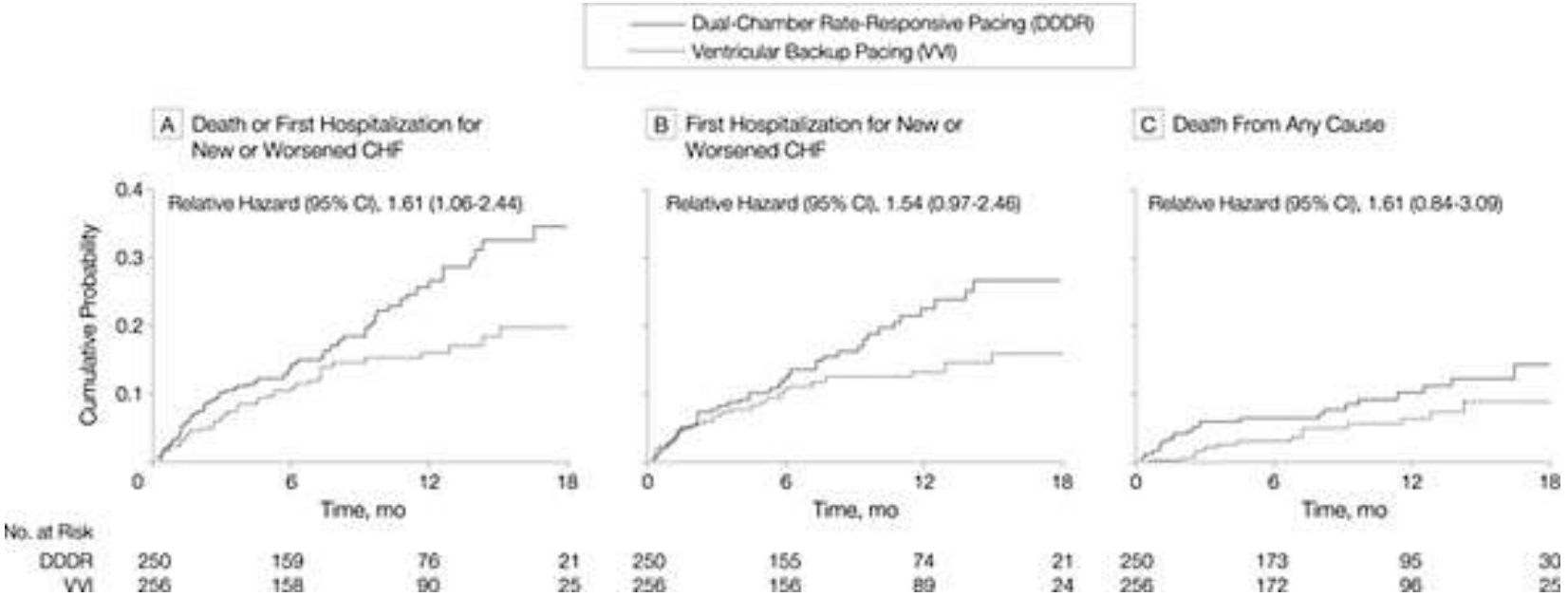
‘Therapies’

- How relevant?
  - DAVID
  - INTRINSIC RV

‘Therapies’

- DAVID
  - 506 patients enrolled and randomised to
    - VVI-40 (SVT discriminator be V rate only), or
    - DDDR-70 (SVT/VT by available discriminators)
    - All had DDDR devices
    - Median follow-up 8.4 months (0-23.6)

Figure 2. Survival to Main End Points in the Trial For all plots, time zero is the day of randomization.



JAMA 2002;288:3115-3123

Table 3. Follow-up ECG and ICD Results*.

Table 3. Follow-up ECG and ICD Results*

	VVI (n = 137)	DDDR (n = 140)	*P* Value
ECG (6 mo After Randomization)			
Sinus, No./total (%)	133/137 (97.1)	58/138 (42.0)	<.001
Paced, No. (%)	5 (3.6)	100 (71.4)	<.001
Atrial	2 (1.5)	83 (59.3)	<.001
Ventricular	4 (2.9)	78 (55.7)	<.001
Atrial fibrillation/flutter, No. (%)	0	3 (2.1)	.09
PR, mean (SD), ms	189 (43)	174 (34)	.004
QRS, mean (SD), ms	117 (29)	134 (39)	<.001
QTc, mean (SD), ms	434 (38)	452 (56)	.002
LBBB unpaced, No./total (%)	14/133 (10.5)	5/51 (9.8)	.89
RBBB unpaced, No./total (%)	11/133 (8.3)	4/51 (7.8)	.92
ICD Counters, % Beats Ventricular Paced, Mean (SD)			
3 mo	1.5 (8.0) (n = 193)	57.9 (35.8) (n = 188)	<.001
6 mo	0.6 (1.7) (n = 150)	59.6 (36.2) (n = 150)	<.001
12 mo	3.5 (14.9) (n = 78)	58.9 (36.0) (n = 77)	<.001

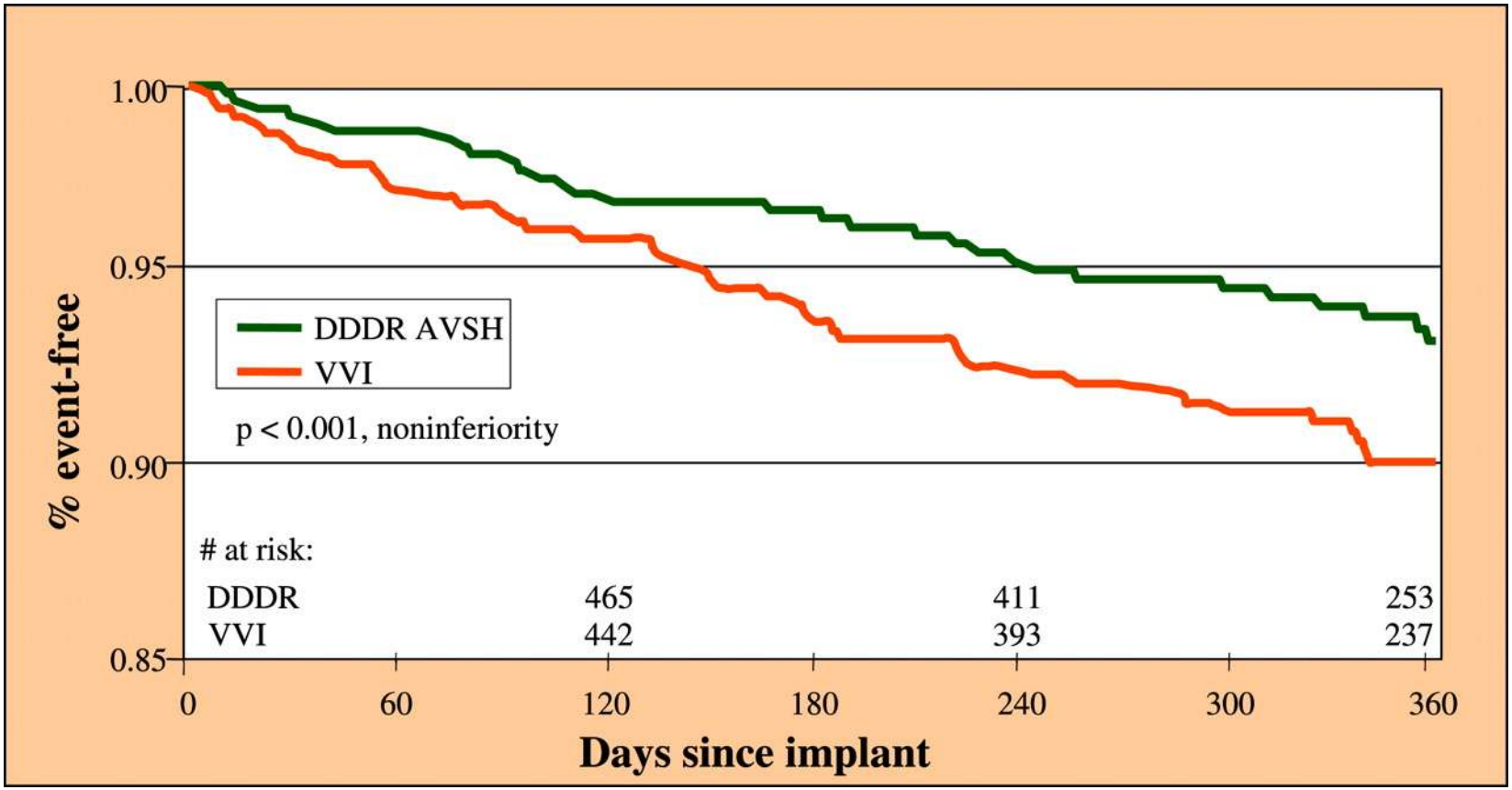
*ECG indicates electrocardiogram; ICD, implantable cardioverter defibrillator; LBBB, left bundle-branch block; and RBBB, right bundle-branch block.

JAMA 2002;288:3115-3123

‘Therapies’

- INTRINSIC RV
  - 988 patients randomised (on basis of <20% RV pacing at 1 week) to DDDR with AV search hysteresis vs. VVI-40
  - Composite endpoint of all-cause mortality and heart failure hospitalisation

Figure 2. Percent of patients free from the primary end point (% event-free [death or heart failure hospitalization]) by randomized group (DDDR AVSH vs VVI programming) over the 1-year follow-up.



Olshansky B et al. Circulation 2007;115:9-16

Conclusions

- Insertion of an atrial lead is not without complications
- Good, reliable algorithms are available on single chamber ICDs
- Inappropriate RV pacing can lead to significant clinical impact in this population

BUT

Conclusions

- When implanted correctly (and a little luck!)
- When programmed correctly
- Dual chamber ICDs can offer a reduced rate of inappropriate therapies, and perhaps modify the rate of important atrial arrhythmias