WEARABLE DEFIBRILLATOR FOR PATIENTS WITH HIGH RISK FOR CARDIAC ARREST

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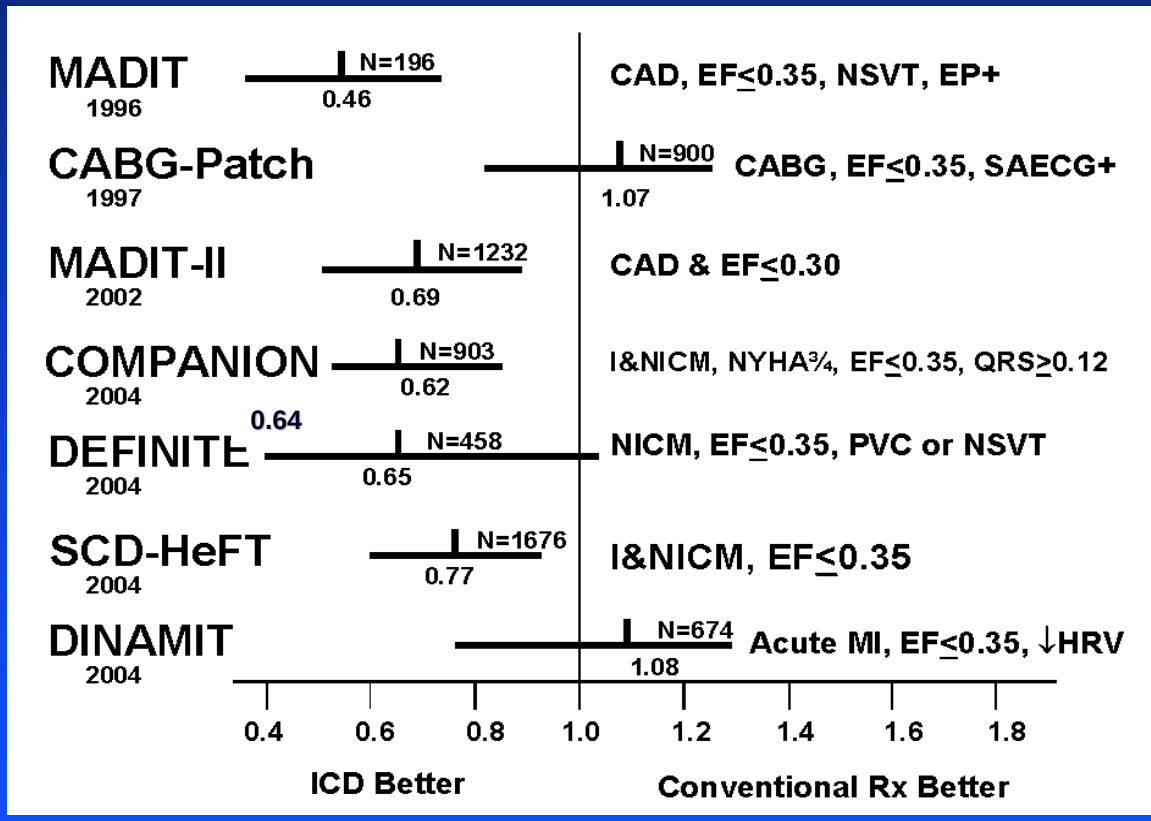
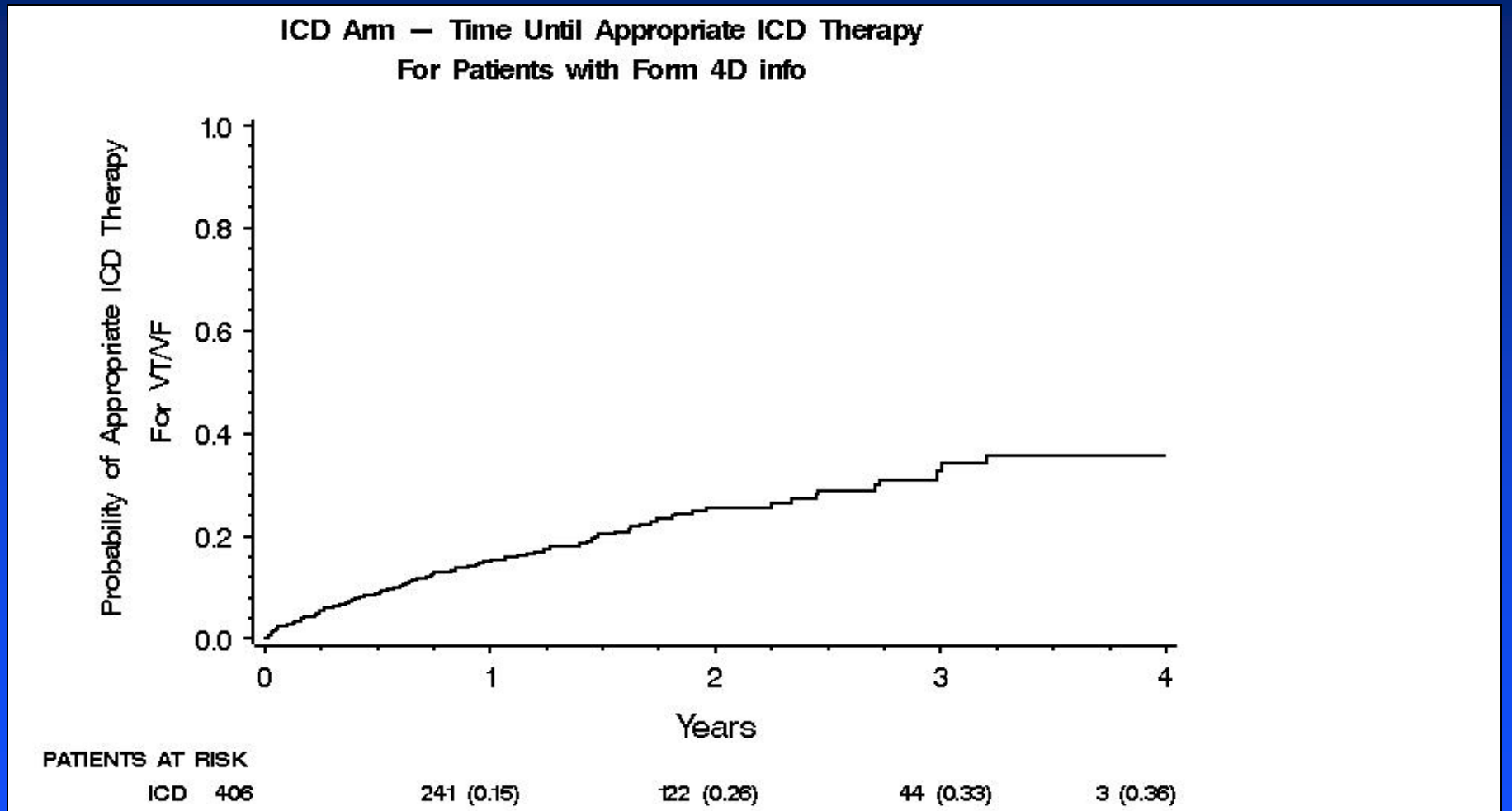
BACKGROUND: CURRENT GUIDELINES FOR PRIMARY ICD THERAPY

- EF ≤ 35%
- High-risk inherited arrhythmias

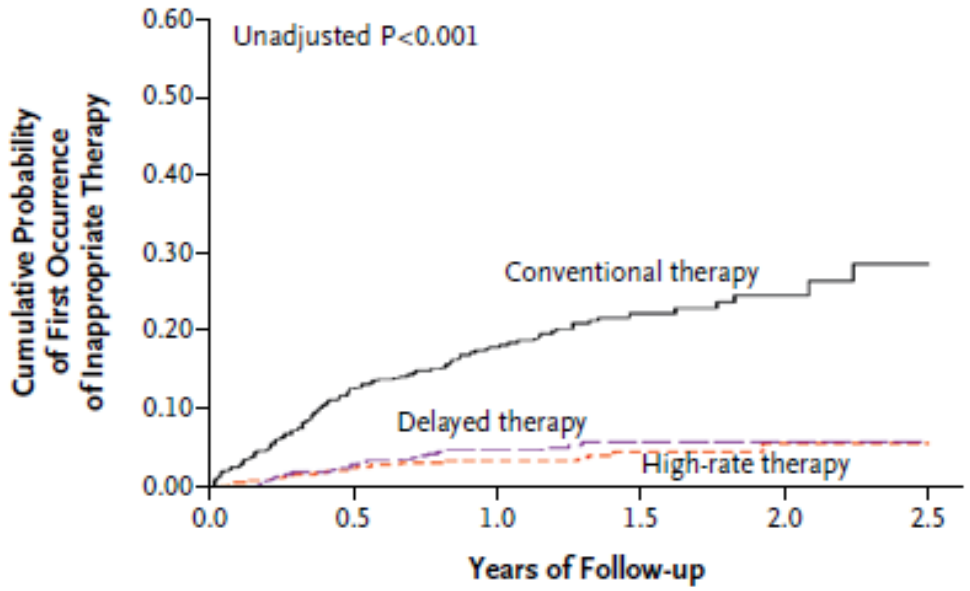
AHA/ACC/HRS 2012 Guidelines

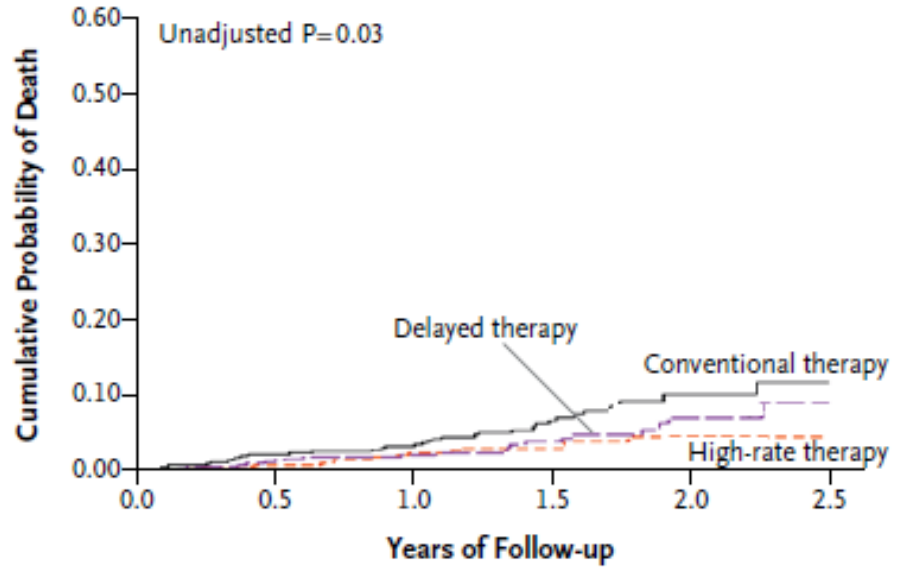


APPROPRIATE THERAPY FOR VT/VF IN MADIT-II



MADIT-RIT: OUTCOMES





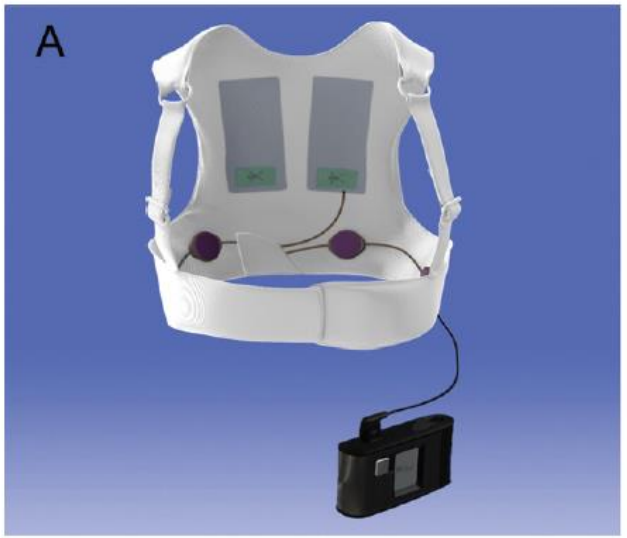
Variable	Conventional Therapy (N=514)	High-Rate Therapy (N=500)	Delayed Therapy (N=486)
First occurrence of therapy — no. of patients (%)			
Appropriate therapy	114 (22)	45 (9)	27 (6)
Shock	20 (4)	22 (4)	17 (3)
Antitachycardia pacing	94 (18)	23 (5)	10 (2)

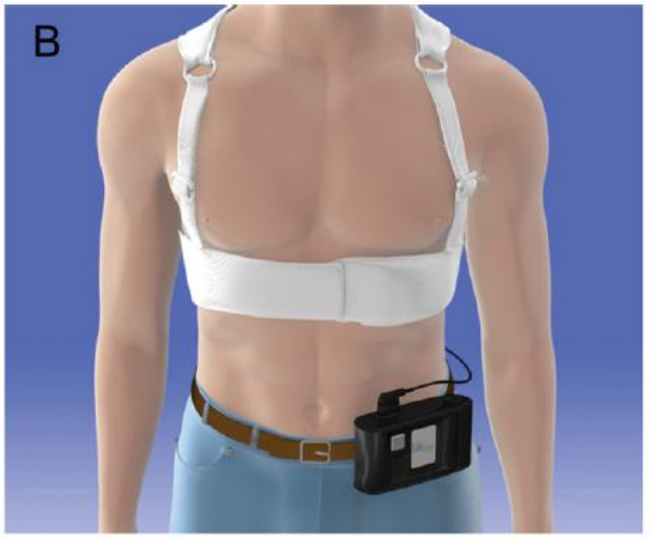
LIFEVEST WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD)

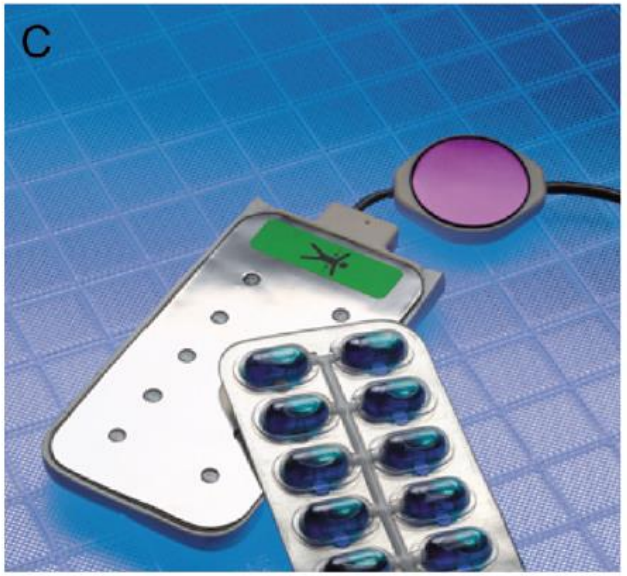
- Can be used to bridge a decision for appropriate ICD therapy in:
  - Post-MI pts
  - Following coronary revascularization
  - New onet dilated (nonischemic) CMP
  - High risk patients until stabilization
  - Inherited arrhythmic or congenital disorders
- Availability of response button can be used to reduce inappropriate Rx

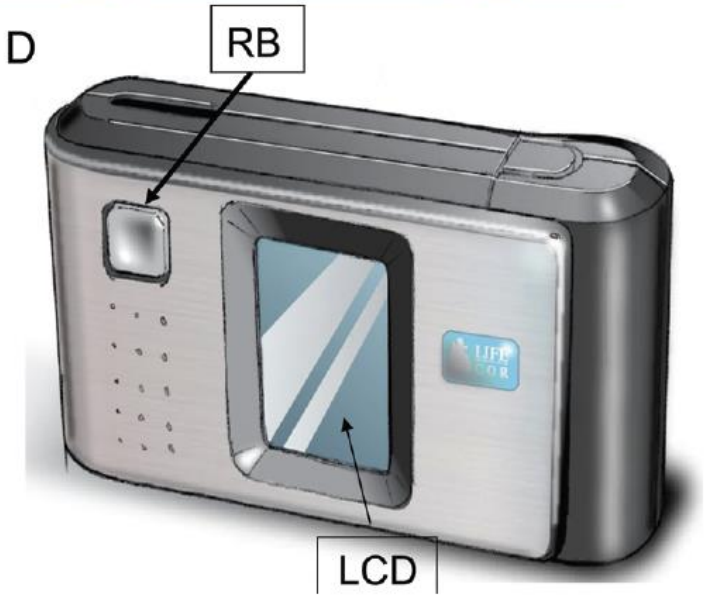
WEARABLE CARDIOVERTER DEFIBRILLATOR: COMPONENTS

A. Garment, elastic belt, monitor + defibrillator unit, back defibrillation electrodes, non-adhesive ECG recording electrodes
B. LifeVest put on with the monitor unit in a hip holster
C. Gel capsules inserted in each of the defibrillation patch electrodes.
D. Monitor and defibrillator unit: with response button and the LCD display

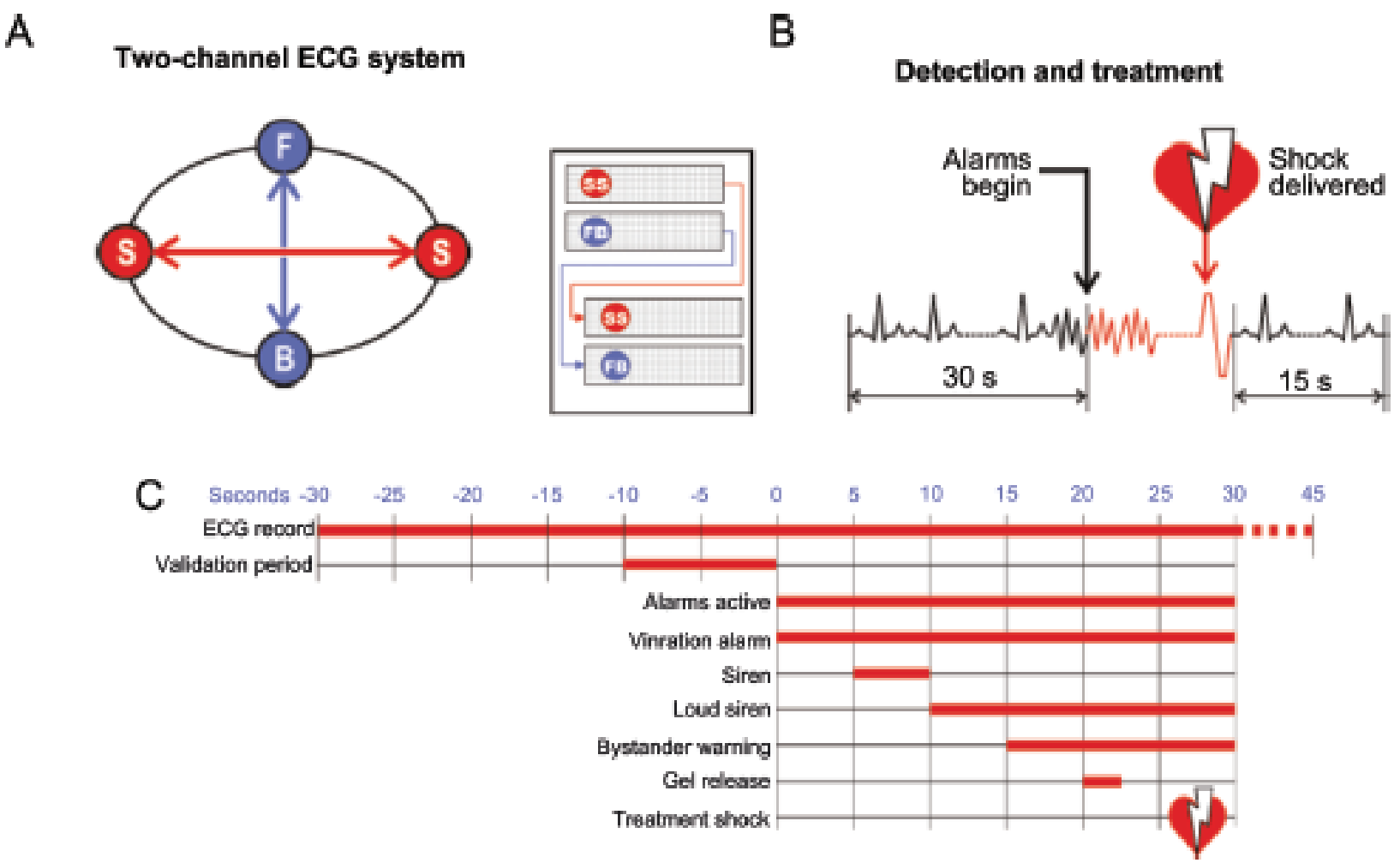




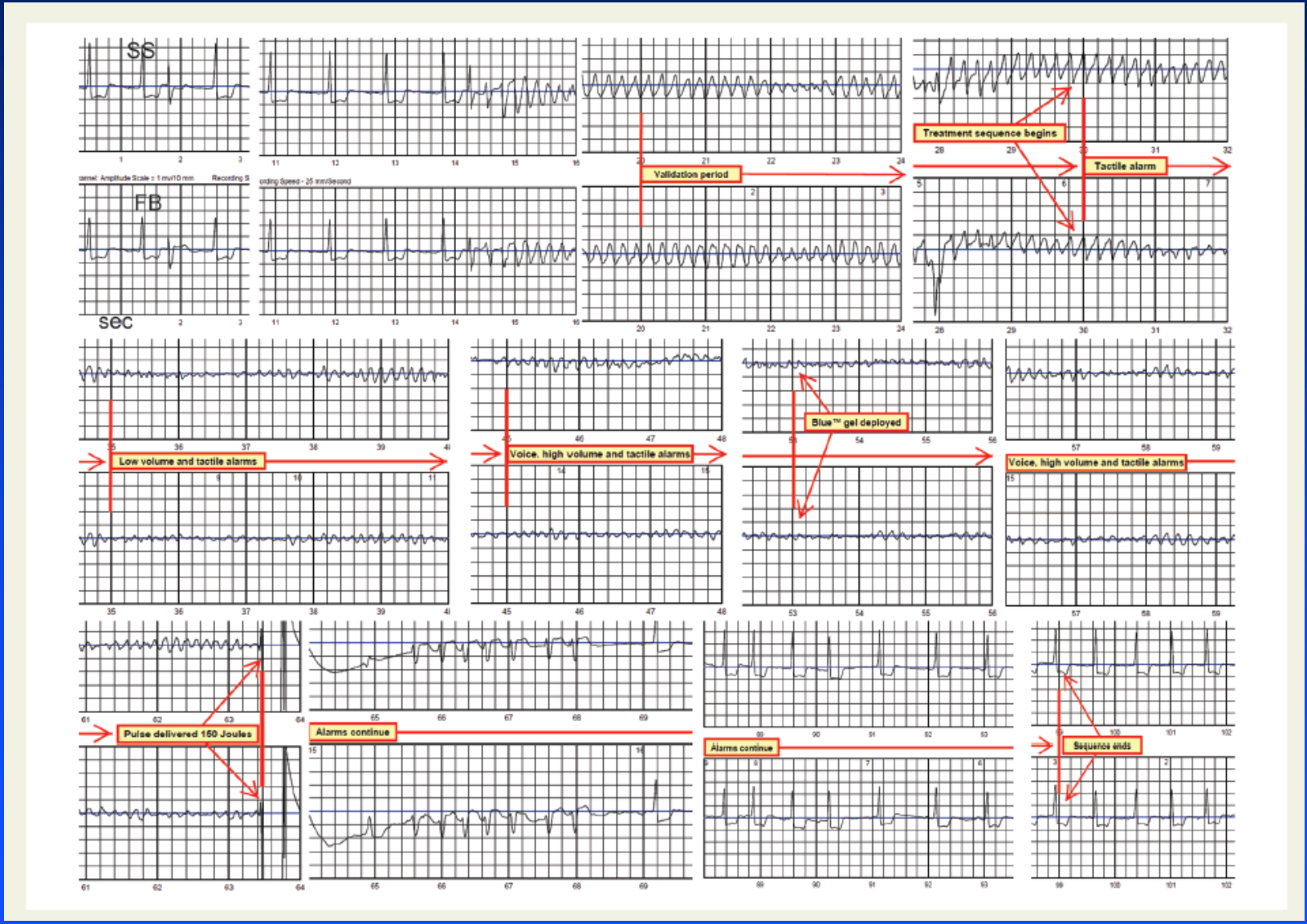




WEARABLE CARDIOVERTER DEFIBRILLATOR: THERAPY



WEARABLE CARDIOVERTER DEFIBRILLATOR: THERAPY



LIFEVEST WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD): PROGRAMMING

Programming Parameters of the WCD

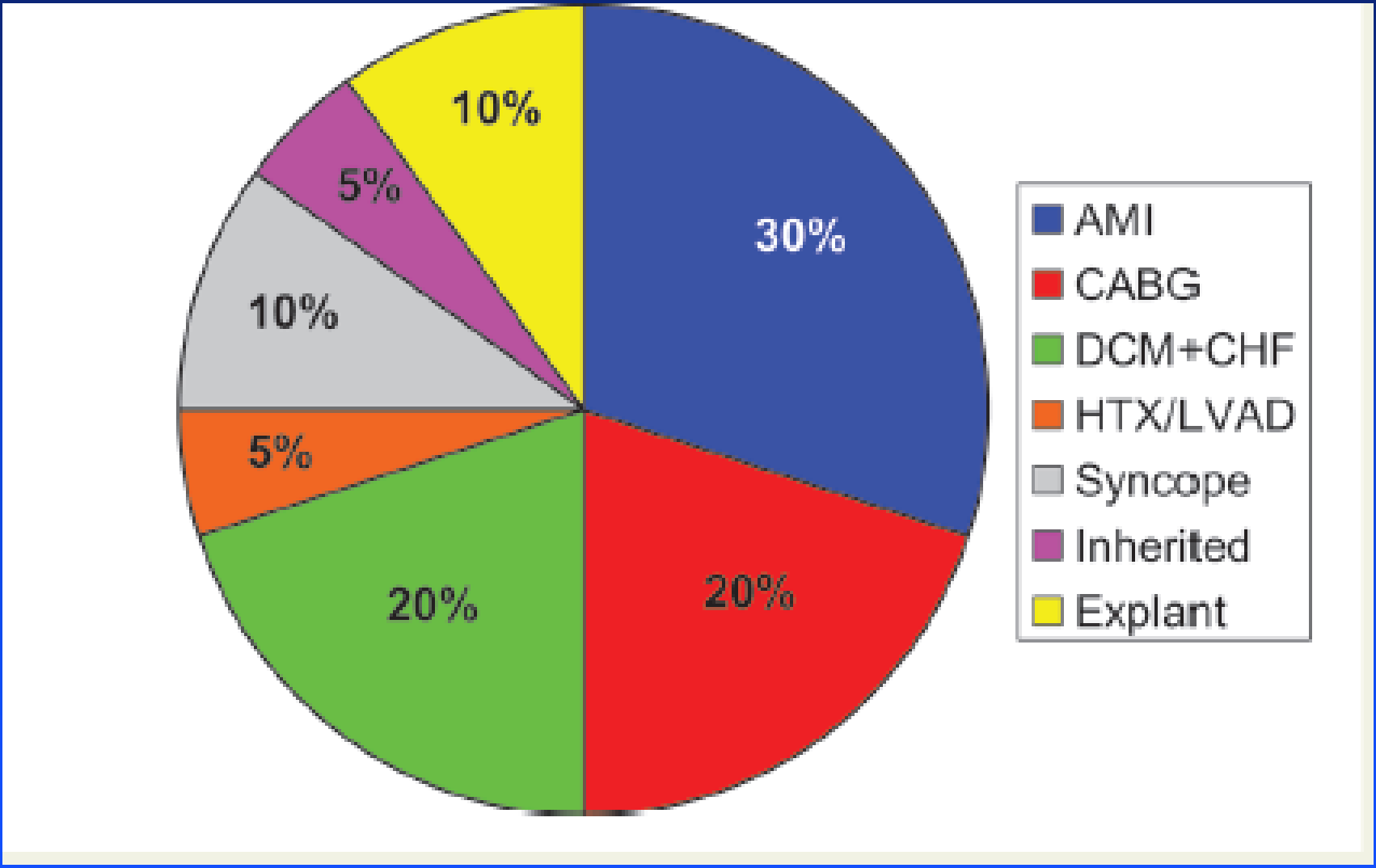
Programming Ventricular Tachycardia (VT)	Programming Ventricular fibrillation (VF)
Programmable: 120 - VF cut-off (default 150 b.p.m.)	Programmable: 120–250 b.p.m. (default 200 bpm)
Recommendation: 170–220 b.p.m.	*Recommendation:* >220 b.p.m.
Shock delay	**Shock delay**
Programmable 60–180 s (default 60s) - at night 0–30 s	Programmable 25–55 s (default 25 s)
Recommendation: 60 s; - at night 90 s	*Recommendation:* 30 s; - no shock delay at night
Shock energy	**Shock energy**
Programmable: 75–150 J	Programmable: 75-150 J
Recommendation: 150 J	*Recommendation: 150 J*

LIFEVEST WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD): INDICATIONS

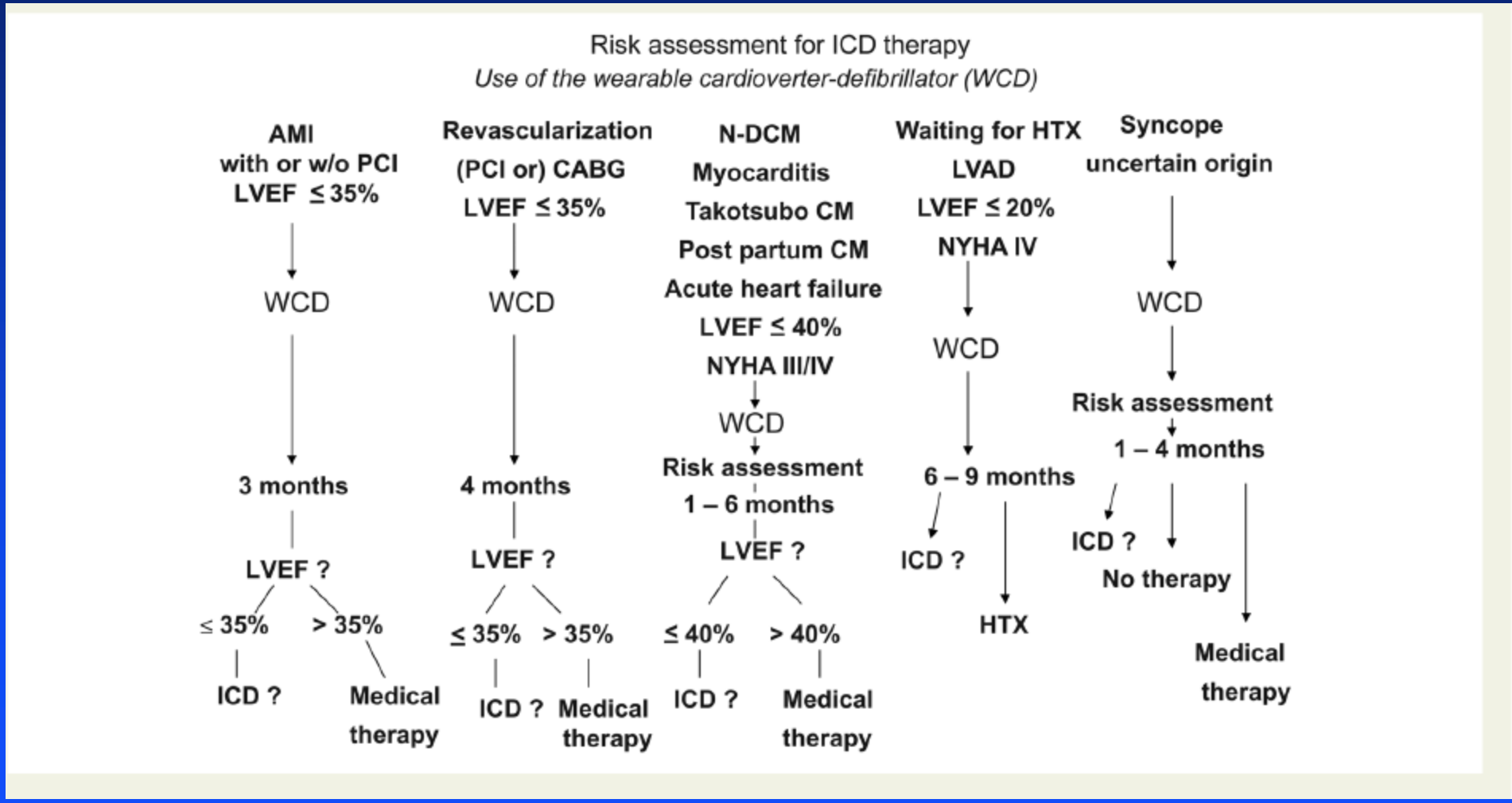
Indication for the wearable cardioverter-defibrillator (WCD)

Risk stratification	Bridging period for ICD or Heart transplantation	Future indication for WCD (?)
After AMI; LVEF ≤ 35% with or without PCI	ICD explantation for infection or lead problems	Haemodialysis patients
Revascularization with CABG or PCI with LVEF ≤35%	Delayed ICD implantation due to co-morbidities	Peri-partum cardiomyopathy
Non-ischaemic cardiomyopathy with acute heart failure; suspected myocarditis; LVEF ≤40%	Waiting list for Heart transplantation	Chemotherpy-induced cardiomyopathy
Syncope of unknown cause with structural heart disease	Patients on LV-assist devices	Drug-induced QT-prolongation
Suspected inherited arrhythmia syndrome (LQT-S; Brugada-S; Short QT-S; CPVT; idiopathic VT; HCM; ARVC)		After VT-catheter ablation

LWEARABLE CARDIOVERTER DEFIBRILLATOR: CURRENT EXPERIENCE IN EUROPE



RISK ASSESSMENT FOR ICD THERAPY WITH THE WCD



Eighteen Month Results From the Prospective Registry And Follow-up Of Patients Using the Lifevest Wearable Defibrillator (WEARIT-II Registry)

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STUDY PURPOSE

- ***To provide prospective data on the safety and efficacy of a bridging strategy with the WCD in a real world setting***

WEARIT-II: REGISTRY DESIGN

WCD (LifeVest) prescription in the US/Europe/Israel

↓

Informed consent

↓

Acquisition of baseline clinical data

↓

Wearing time: 2-6 months

↓

Clinical and Arrhythmic event acquisition

↓

WCD return: end of use evaluation

↓

12 month FU

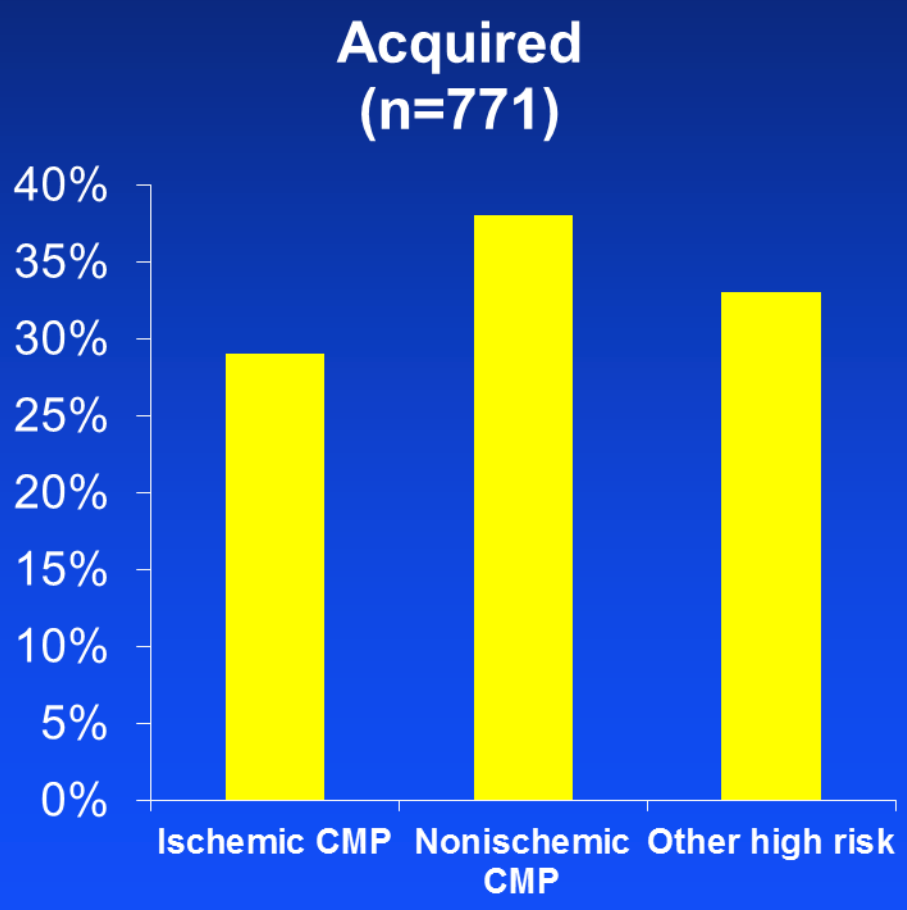
PLANNED ENROLLMENT

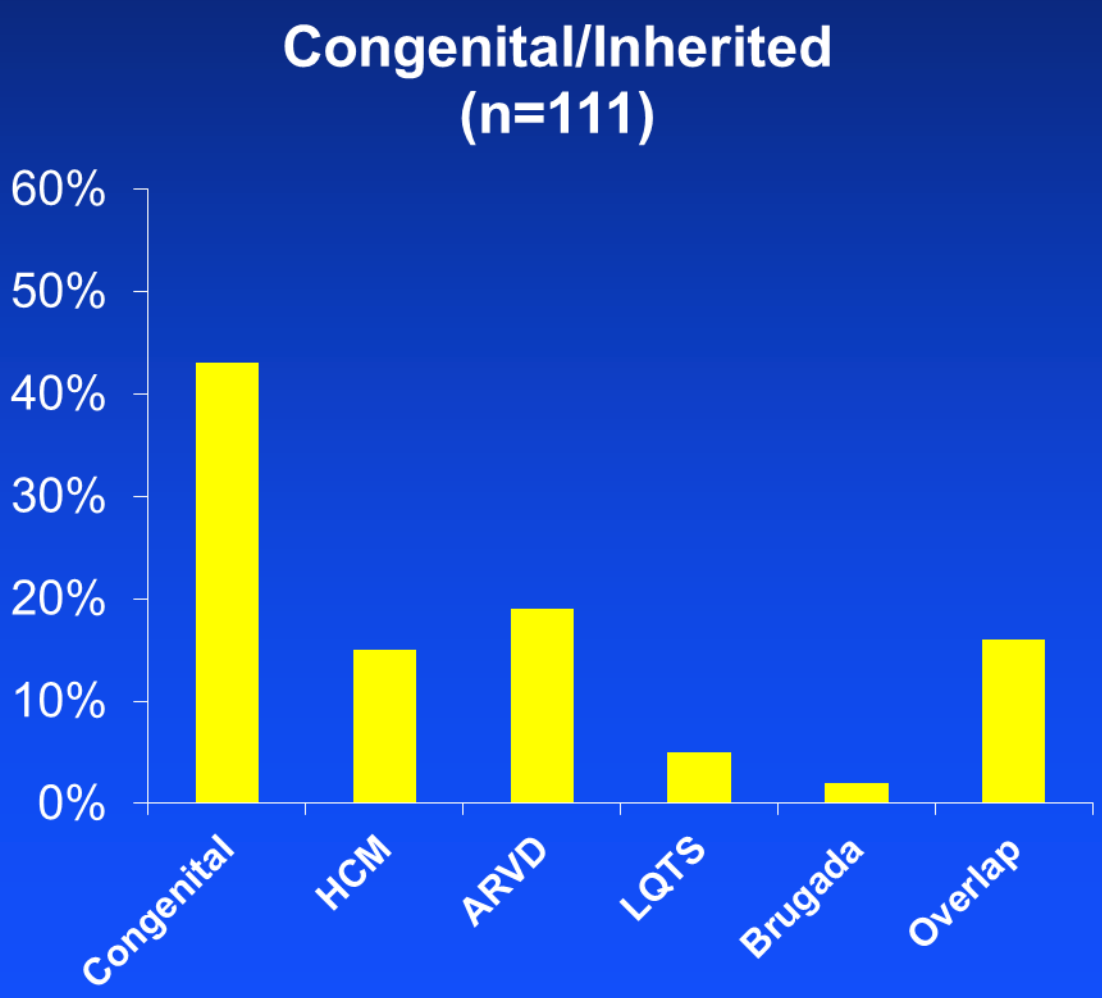
- US: 2000 pts
- Europe and Israel: 1000 pts
- Data management: University of Rochester
- Current report:
  - First 882 pts enrolled in the US from August 2011 through April 2013

CLINICAL CHARACTERISTICS

	All patients N=882
Age, yrs	61 ± 12
Female	31%
LVEF, %	25 ± 11
Renal disease	8%
Diabetes	29%
Afib	28%
Prior cardiac arrest	22%
Beta-blockers	85%
ACE-I/ARBs	74%
Amiodarone	13%

DISEASE ETIOLOGY





CHARACTERISTICS OF PTS WITH ACQUIRED HEART DISEASE

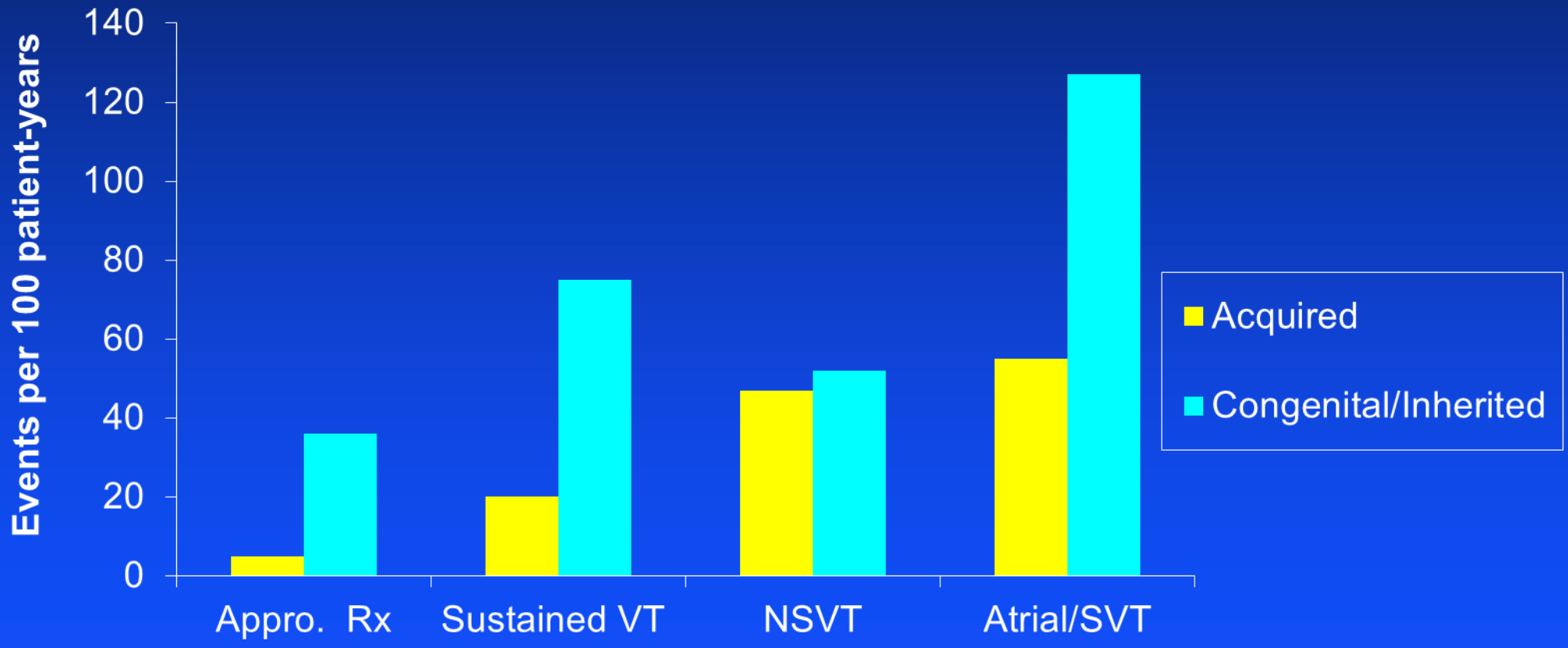
	Ischemic CMP N=220	Nonischemic CMP N=294	Other High-Risk N=257
Age, yrs	64 ± 11	56 ± 13*	63 ± 12
Female	30%	40%*	21%
LVEF, %	28 ± 12	22 ± 8*	38 ± 12
Renal disease	14%	6%	5%
Diabetes	35%*	22%	26%
Afib	34%*	22%	25%
Prior ACA	21%	12%	28%
Syncope	25%*	11%	20%
Beta-blockers	87%	86%	81%
ACE-I/ARBs	73%	80%*	71%
Amiodarone	16%	11%	13%

*p<0.05 ; ACA= aborted cardiac arrest

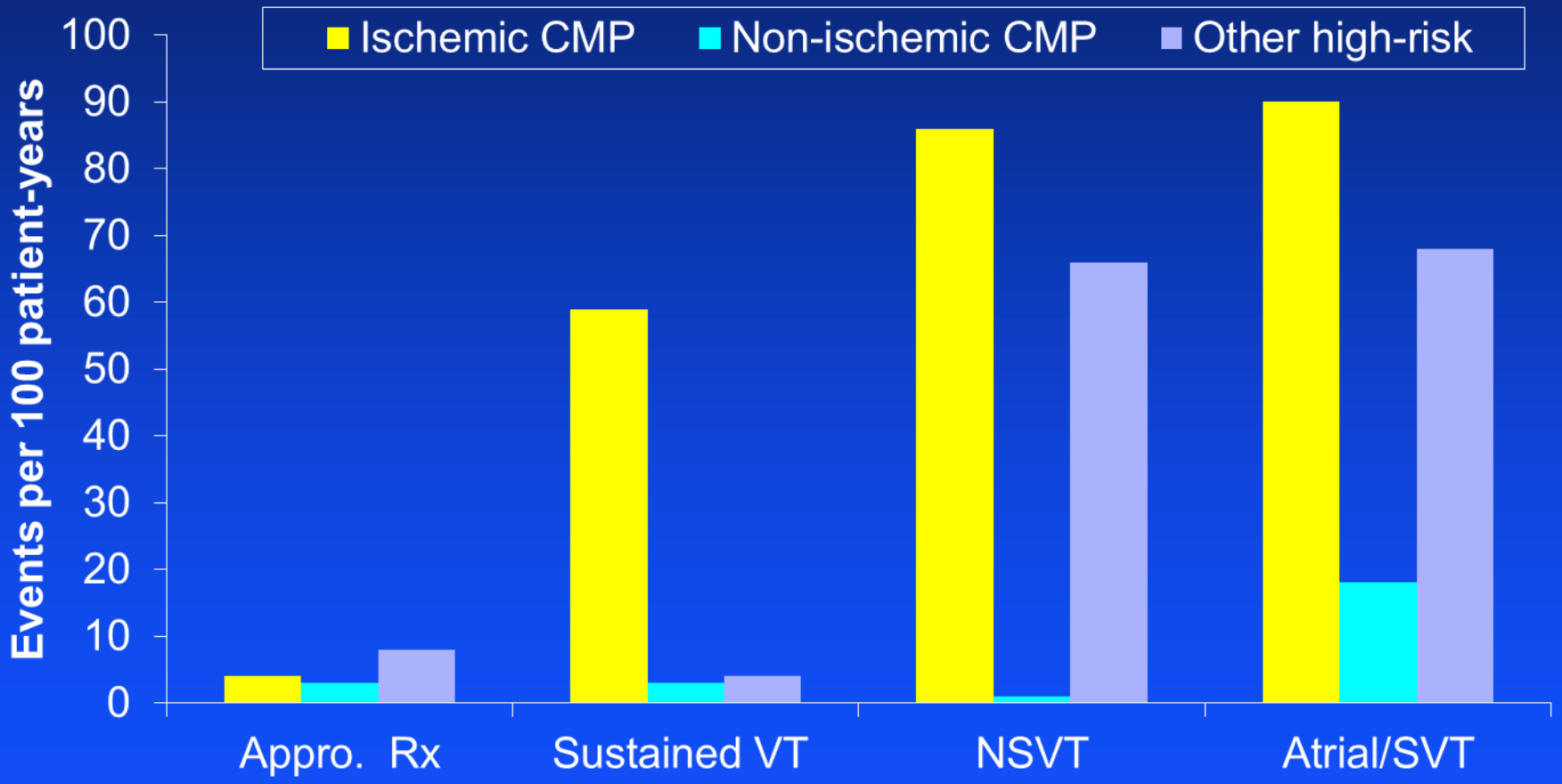
ARRHYTHMIC EVENTS: TOTAL POPULATION (AVERAGE WEARING DAYS: 81 ± 52)

	Patients	Events	Event Rate (per 100 pt/yrs)
WCD Therapy for VT/VF	10	17	9
Sustained VT (untreated)	11	53	27
NSVT	9	93	47
Atrial arrhythmias/SVT	21	126	64
Asystole	2	5	3

ARRHYTHMIC EVENTS BY ETIOLOGY

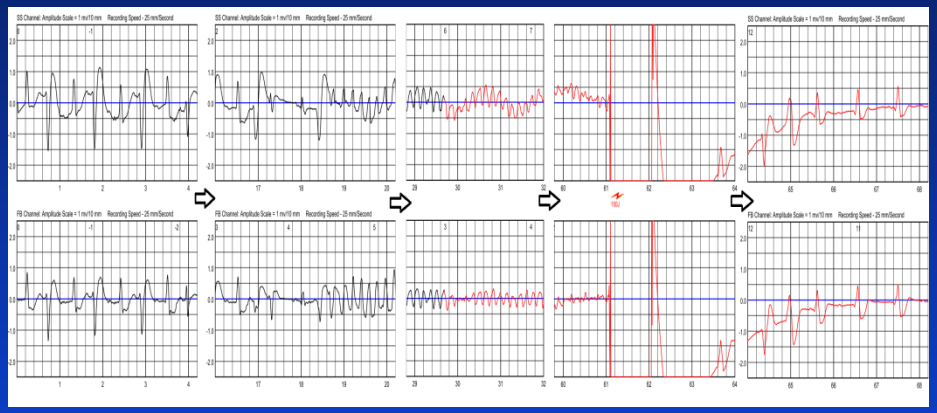


ACQUIRED: ARRHYTHMIC EVENTS

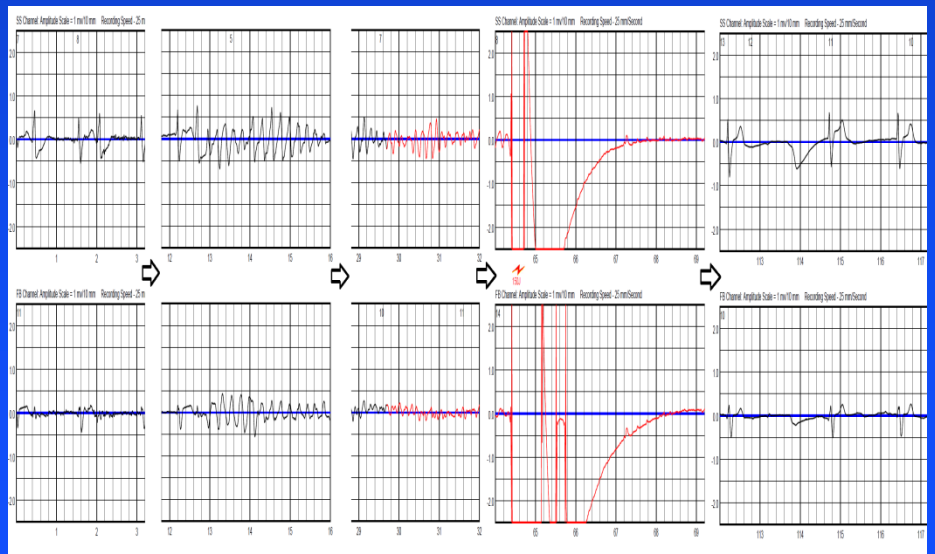


Treated episodes

Patient A: Congenital heart disease

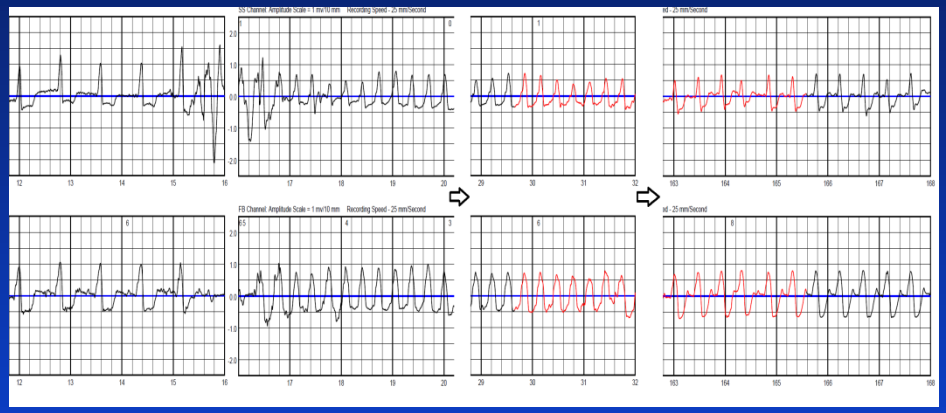


Patient B: NICM

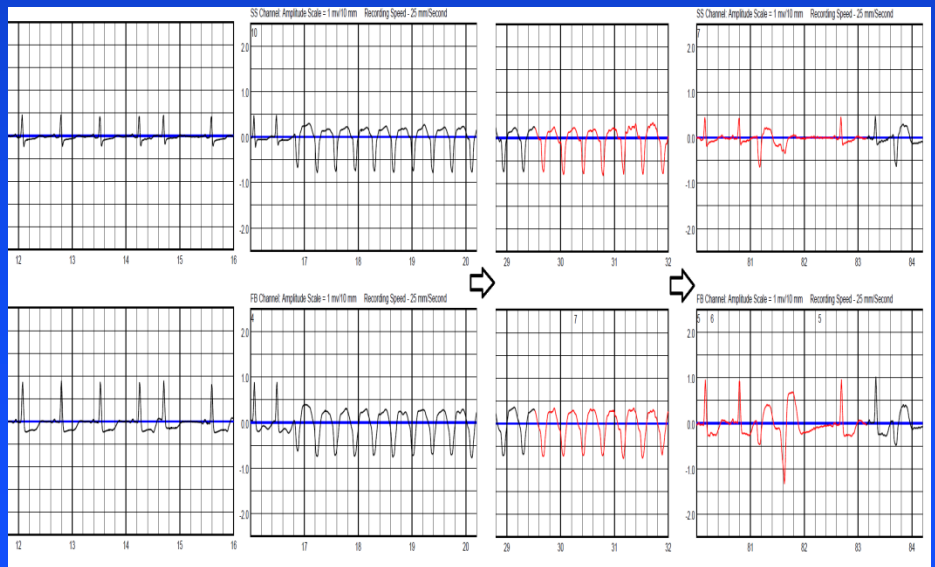


Use of response button

Patient C: ARVD



Patient D: ICM



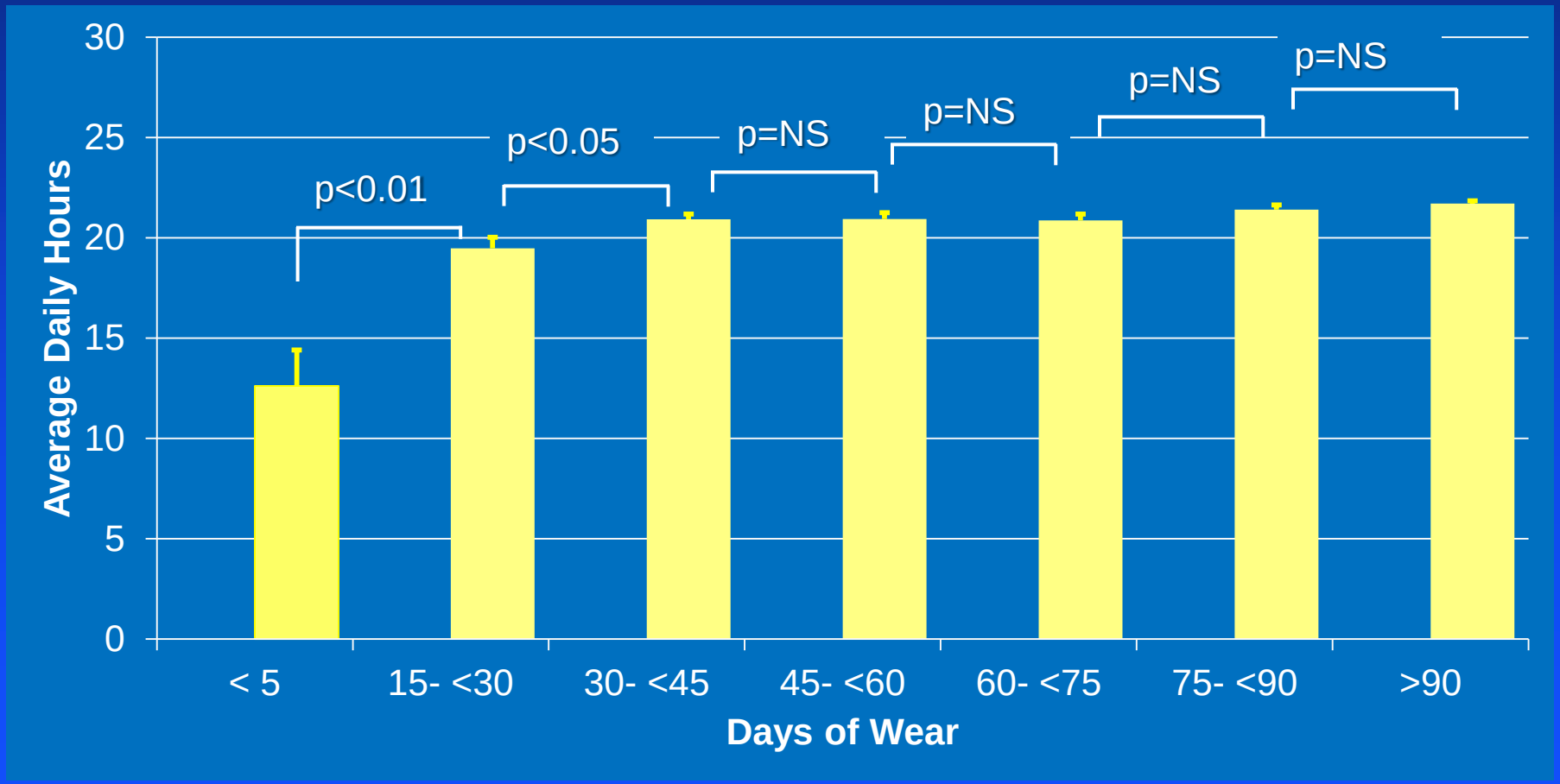
ADVERSE EVENTS

TYPE	TOTAL POPULATION N=882	ACQUIRED N=771	CONG./ INHERITED N=111
Inappropriate Rx, n (%)	3 (0.3%)	2 (0.3%)	1 (0.9%)
Death,* n (%)	4 (0.5%)	2 (0.3%)	2 (1.8%)

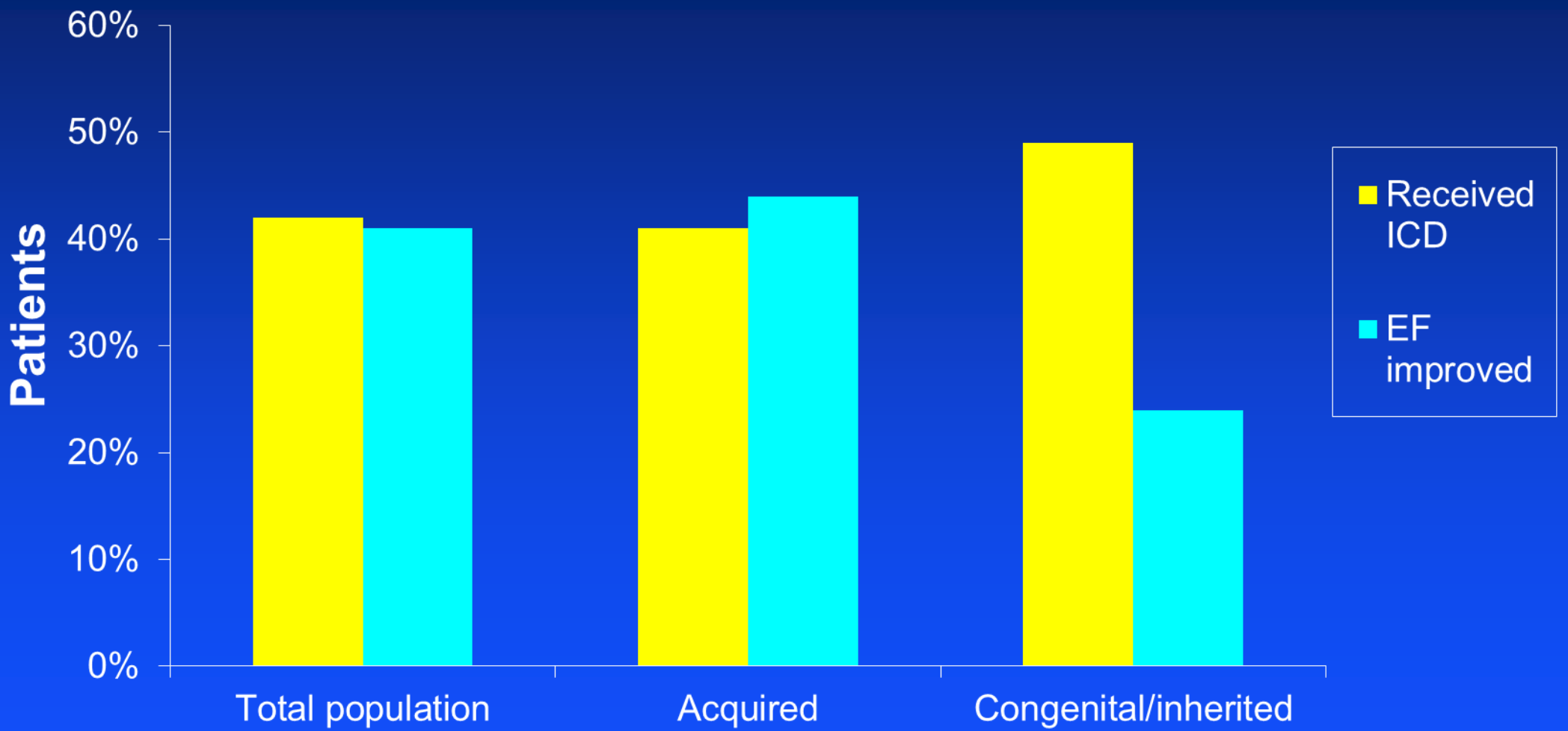
*3 deaths without WCD; 1 with WCD (asystole)

COMPLIANCE: DAILY HOURS

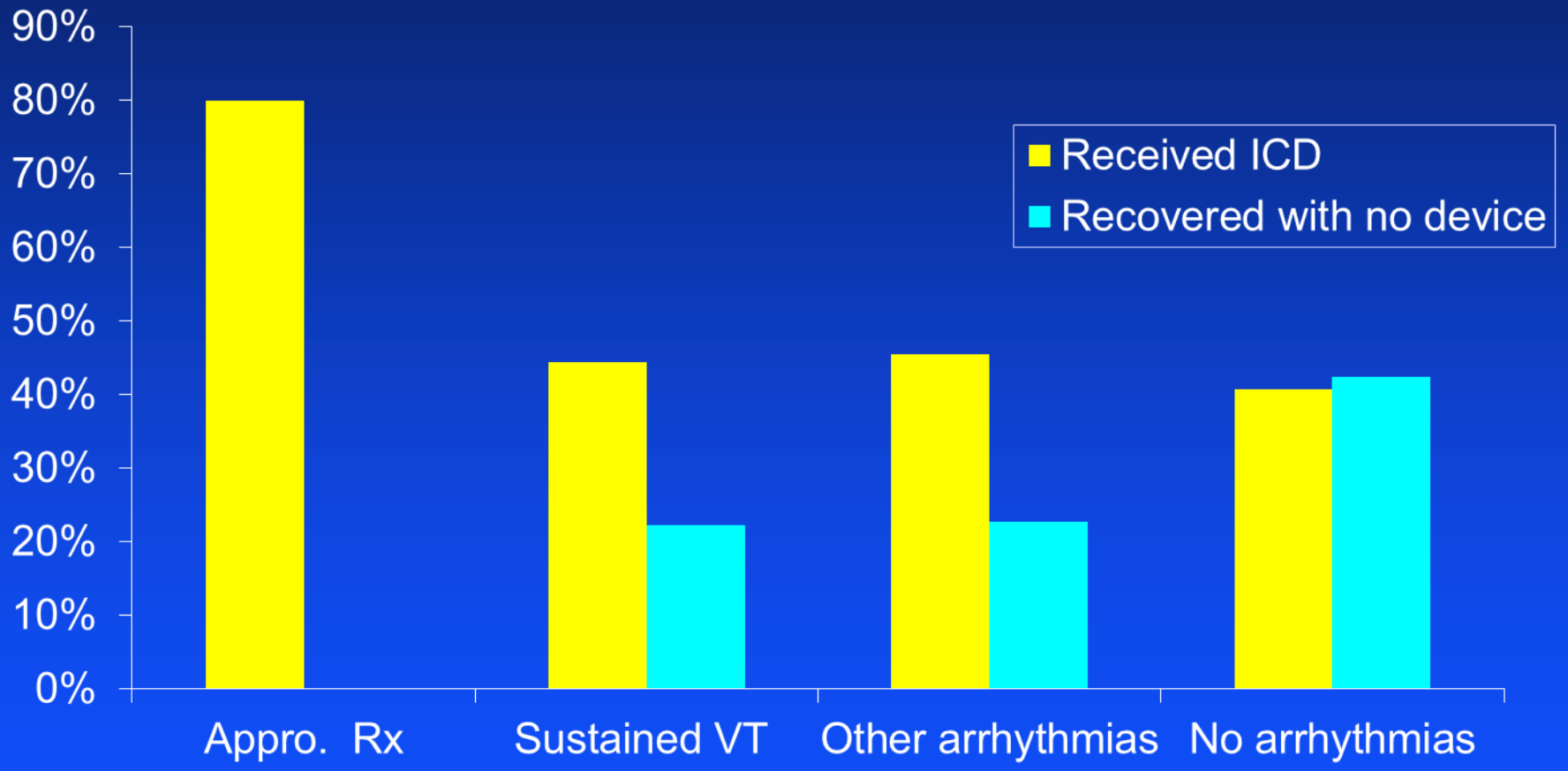
- **Mean:**
  - **21 ± 3 hours**
- **Median:**
  - **22 (IQ range 22-23)**



END OF USE


60%
50%
40%
30%
20%
10%
0%
Patients
Total population
Acquired
Congenital/inherited
Received ICD
EF improved

DETECTED WCD ARRHYTHMIAS AND END OF USE DECISION



CONCLUSIONS

- In a real world setting a management strategy that incorporates the WCD can be safely used to bridge a decision for appropriate ICD therapy in patients with acquired, inherited, and congenital, heart disease:
  - Safe termination of life-threatening arrhythmic events
  - Avoidance of unnecessary therapies for non-life-threatening arrhythmias
  - Low rate of inappropriate therapies

Thank You