Role of ILR for SCD

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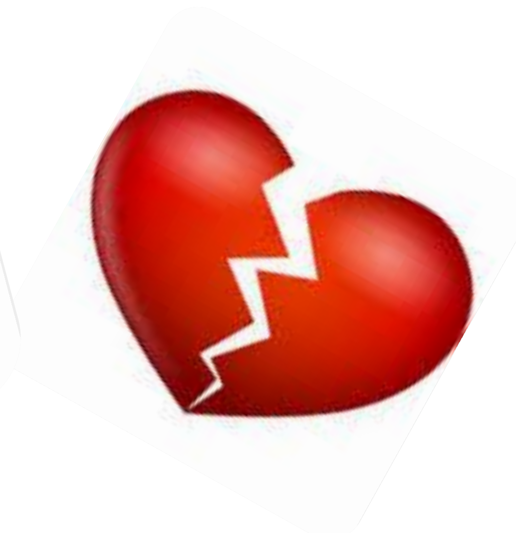
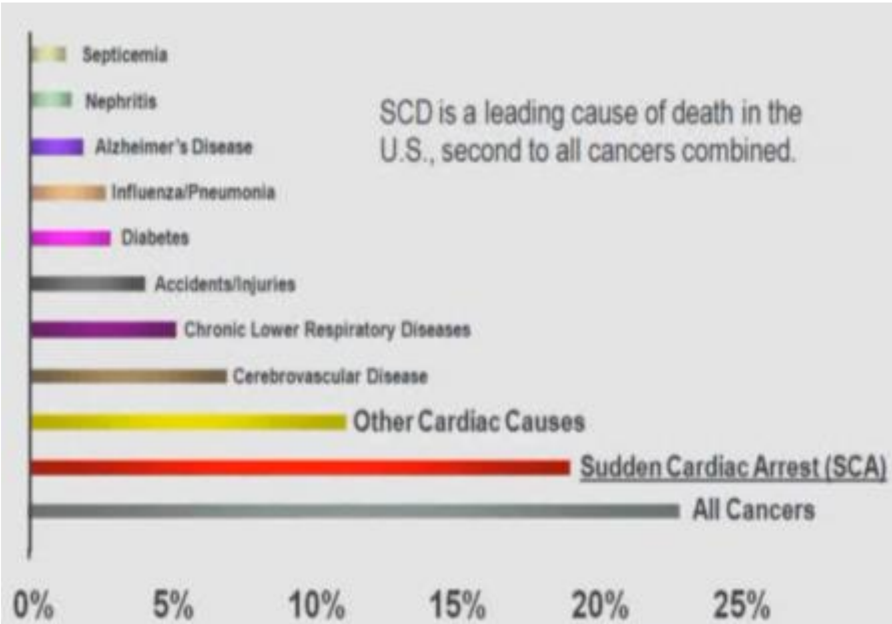
박승정
2014-춘계 심장학회

Sudden Cardiac Death



Leading Cause of Death



Annual incidence of SCD (per 100,000)	
USA	53 (41-89)
Netherland	90-100
Japan (Okinawa)	39
China	41
West Ireland	51
Canada	56
Korea	> 41 (~80)

Prospective Survey ~ Death Certificate Data

- **6~15%** of Annual mortality
- Estimated number of SCD in U.S. in 1999 ≈ **450,000**

National Vital Statistics Report. 2001;49:11

MMWR Morb Mortal Wkly Rep. 2002;51(6):123

Circulation.2001 Oct 30;104(18):2158-63

Journal of Korean Arrhythmia Society. 2010; 11 (2): 13-16

Heart 2006;92:1873-1878

Major Causes of Sudden Death

with Structural Heart Disease	80%

without Structural Heart Disease	10%

Non-Cardiac Sudden Death	10%

Major Causes of Sudden Death

with Structural Heart Disease	80%
Ischemic HD	60-70%
Coronary Artery Disease	
Coronary Artery Spasm	
Coronary Artery Embolism	
Congenital Coronary Artery Anomalies	
non-Ischemic HD	10%
Hypertrophic Cardiomyopathy	
Dilated Cardiomyopathy	
Adult Congenital Heart Disease	
Arrhythmogenic right ventricular dysplasia	
Pericardial tamponade	
Myocarditis	
Valvular Heart Disease	

without Structural Heart Disease	10%

Non-Cardiac Sudden Death	10%

Major Causes of Sudden Death

with Structural Heart Disease	80%
Ischemic HD	60-70%
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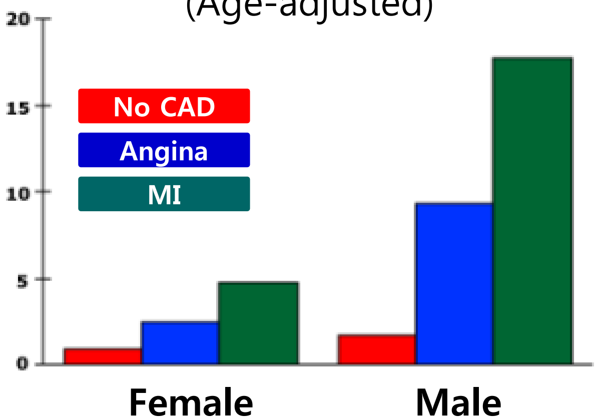
Dilated Cardiomyopathy	
Adult Congenital Heart Disease	
Arrhythmic right ventricular dysplasia	
Pericardial tamponade	
Myocarditis	
Valvular Heart Disease	

without Structural Heart Disease	10%
Idiopathic VF (primary channelopathy)	
Brugada syndrome	
Long QT syndrome	
Short QT syndrome	
Preexcitation syndrome (WPW + AF)	
CPVT (Familial Polymorphic VT)	
Complete Atrioventricular Block	
Chest wall trauma (Commotio Cordis)	
Emotional stress (Catecholamine Surge)	
Non-Cardiac Sudden Death	**10%**
Pulmonary Embolism	
Drug-induced	
SUDEP (Sudden unexpected death in epilepsy)	

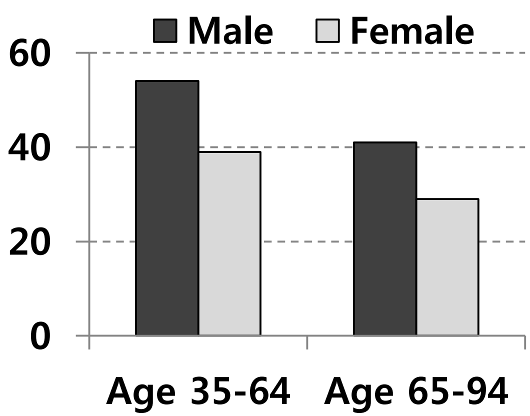
CAD & SCD risk

the Framingham Heart Study Cohort

Annual Death Rate/1000,
(Age-adjusted)

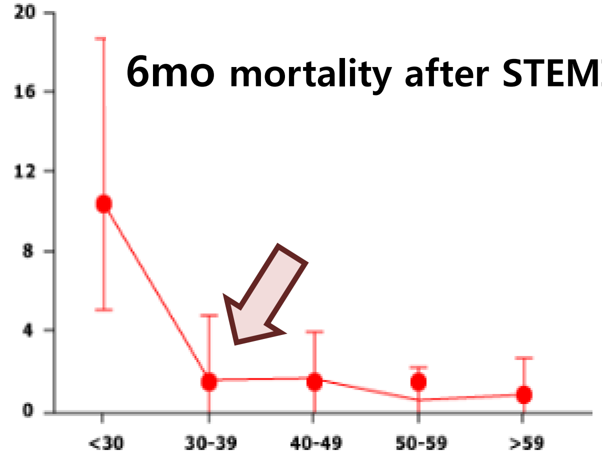


% of SCD in CAD patients

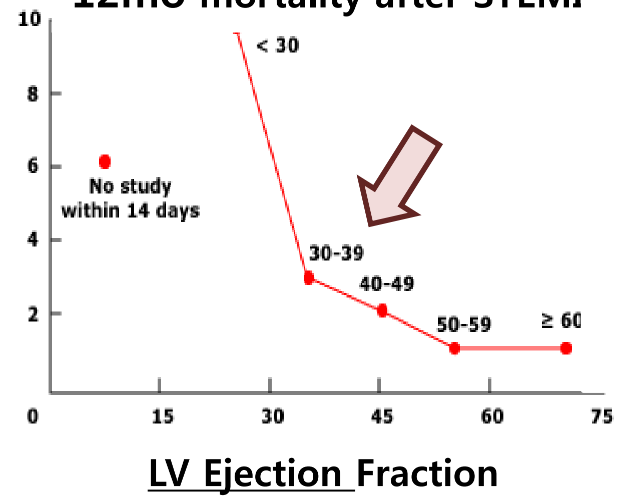


Am Heart J. 1998;136(2):205

Circulation. 1989;79(4):756.



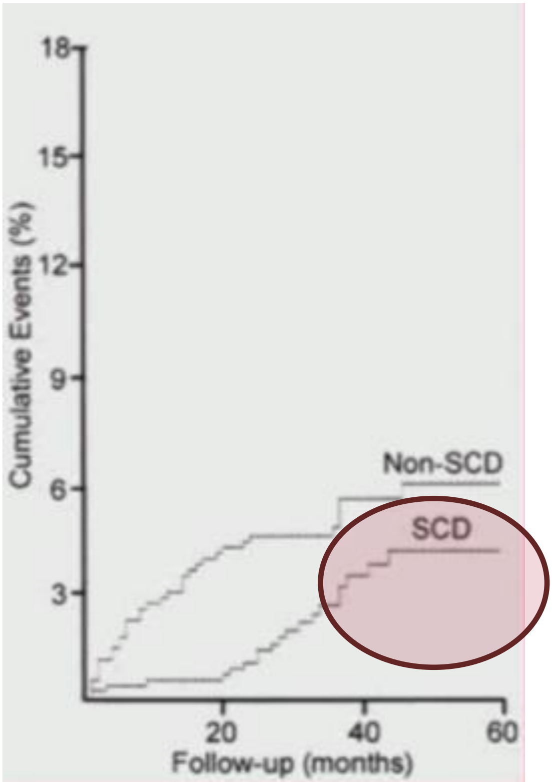
12mo mortality after STEMI



J Am Coll Cardiol 2002; 39:30.

J Am Coll Cardiol 1995; 26:73.

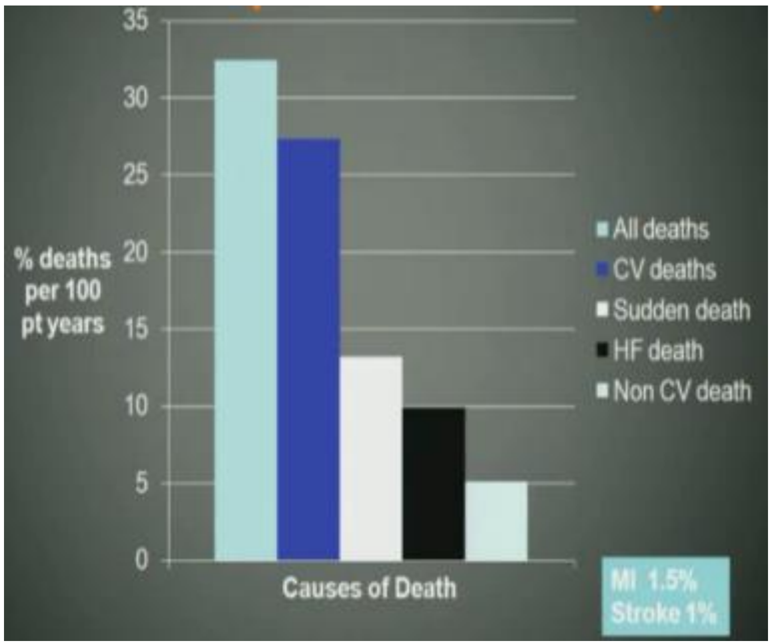
MRFAT trial



J Am Coll Cardiol 2003; 42:652.

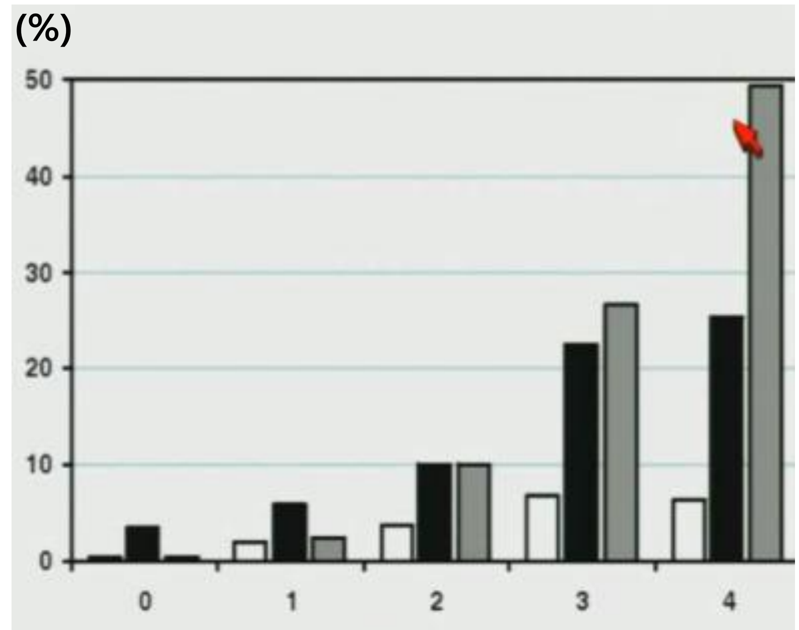
Heart Failure & SCD

NYHA Class II-III (CHARM Added)



SCD ≒ 50% of CV death

Absolute Risk of 1Yr Mortality



Seattle Heart Failure Score

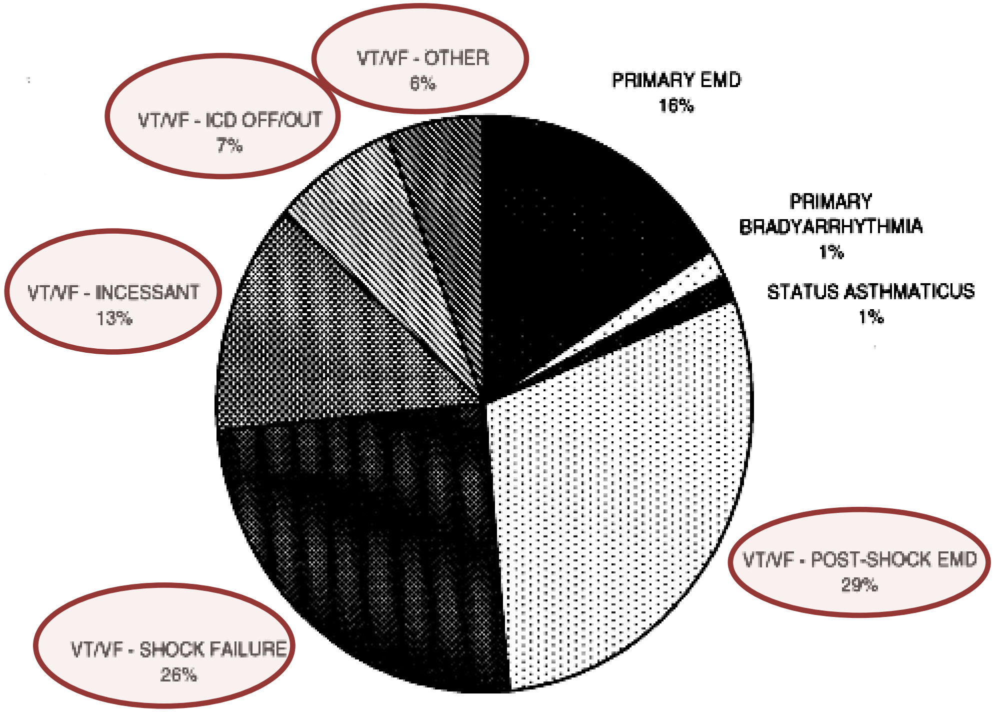
Other Death Sudden Death Pump Failure Death

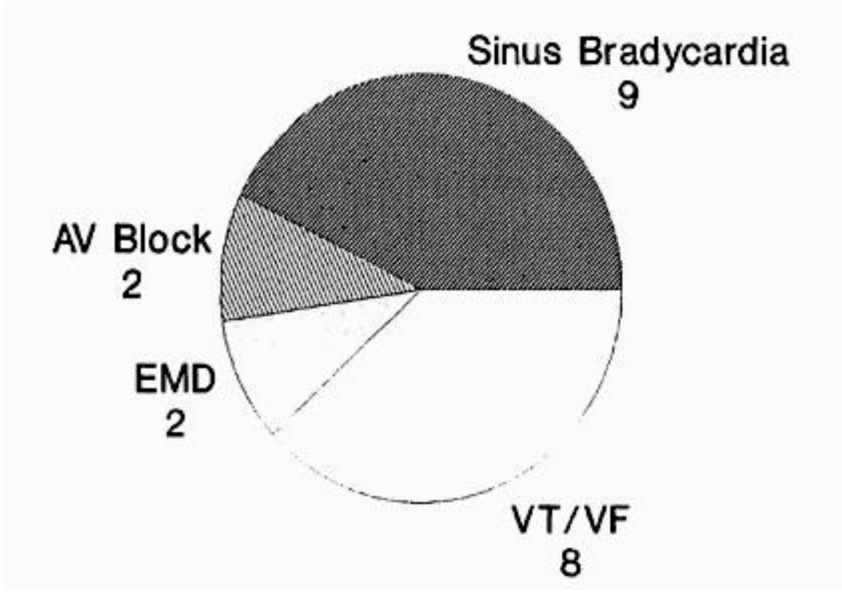
Circulation. 2004;110:2180-83.

Circulation. 2007;116:392-398.

Various Arrhythmic Causes

- **VT/VF**: most common: 30-70%
- **Bradycardia**: Sinus bradycardia, AV Block: 10-50%
- **PEA**: pulseless electrical activity





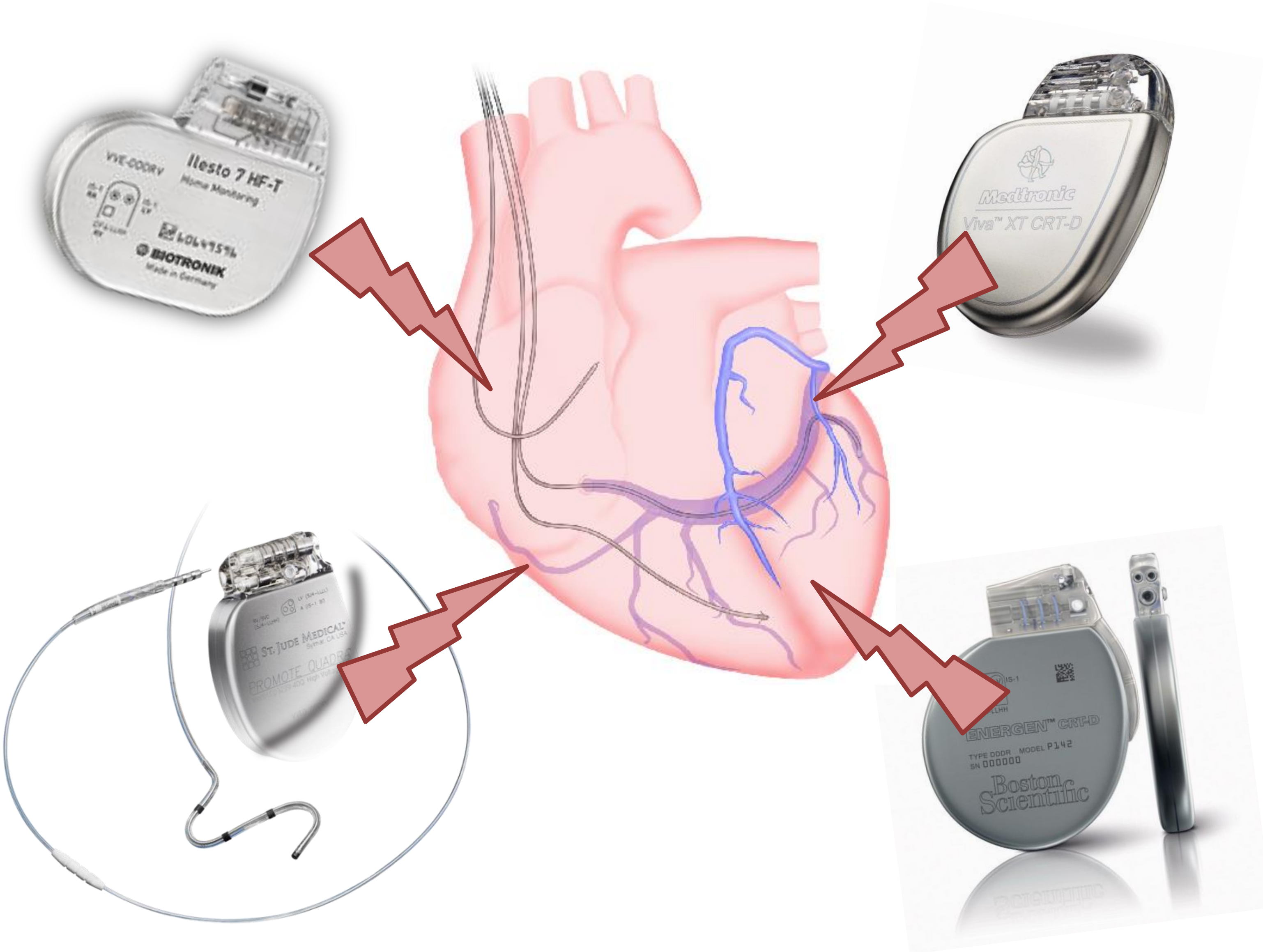
circulation. 1989 Dec;80(6):1675-80.

Am Heart J 1989; 117:151.

J Am Coll Cardiol. 2002 Apr 17;39(8):1323-8.

circulation. 2010; 121: 1258-64

ICD & CRT(D)



Ilesto 7 HF-T
Home Monitoring
BIOTRONIK
Made in Germany
Medtronic
Viva™ XT CRT-D
ST. JUDE MEDICAL
PROMOTE QUADRA
ENERGEN™ CRT-D
MODEL P142
SN 000000
Boston Scientific

ICD for Primary Prevention

Trial	F/U	Inclusion criteria	Time from MI	Mortality reduction
MADIT	2 yr	EF ≤ 35%, NSVT, inducible VT	≥ 3 wk	59%
MUSTT	5 yr	EF ≤ 40%, NSVT, inducible VT	Not defined	58%
MADIT II	2 yr	EF ≤ 30%	≥ 1mo	28%
SCD-HeFT	5 yr	EF ≤ 35%, NYHA (II, III), ischemic & nonischemic	Not defined	23%
DINAMIT	2.5 yr	EF ≤ 35%, recent MI	6-40 days	No

CRT for HF (III,IV)

Trial (Pt. Number)	NYHA	QRSd	Rhythm	ICD	Results
MIRACLE (453)	III, IV	≥130	Sinsu	-	+
MUSTIC SR (58)	III	>150	Sinsu	-	+
MUSTIC AF (43)	III	>200*	AF	-	+
PATH CHF (41)	III, IV	≥120	Sinsu	-	+
MIRACLE ICD (369)	III, IV	≥130	Sinsu	Yes	+
CONTAK CD (490)	II~IV	≥120	Sinsu	Yes	+
COMPANION (1520)	III, IV	≥120	Sinsu	-	+
PATH CHF II (89)	III, IV	≥120	Sinsu		+
MIRACLE ICD II (186)	II	≥130	Sinsu	Yes	+
CARE HF (814)	III, IV	≥120	Sinsu	-	++

LVEF ≤ 35% for all trials, * Paced QRS duration,

CRT for HF (I, II)

Trial (Pt. Number)	**NYHA**	**QRSd**	**EF**	**Rhythm**	**Results**
REVERSE (610) **REVERSE long-term** (262)	I, II	≥120	≤40%	Sinus	+
RAFT (1798)	II, III	>120	≤30%	Sinus/AF	+
MADIT-CRT(1820) **MADIT-CRT long-term** (1818)	I (post-MI), II	≥130	≤30%	Sinus	+

Role of ILR for SCD ?

- Ischemic/Non-ischemic Cardiomyopathy
- Aborted SCD with/without Structural HD

  → ICD/CRT-P(D)

- Structural HD with preserved EF
- No Structural HD with potential risk of SCD

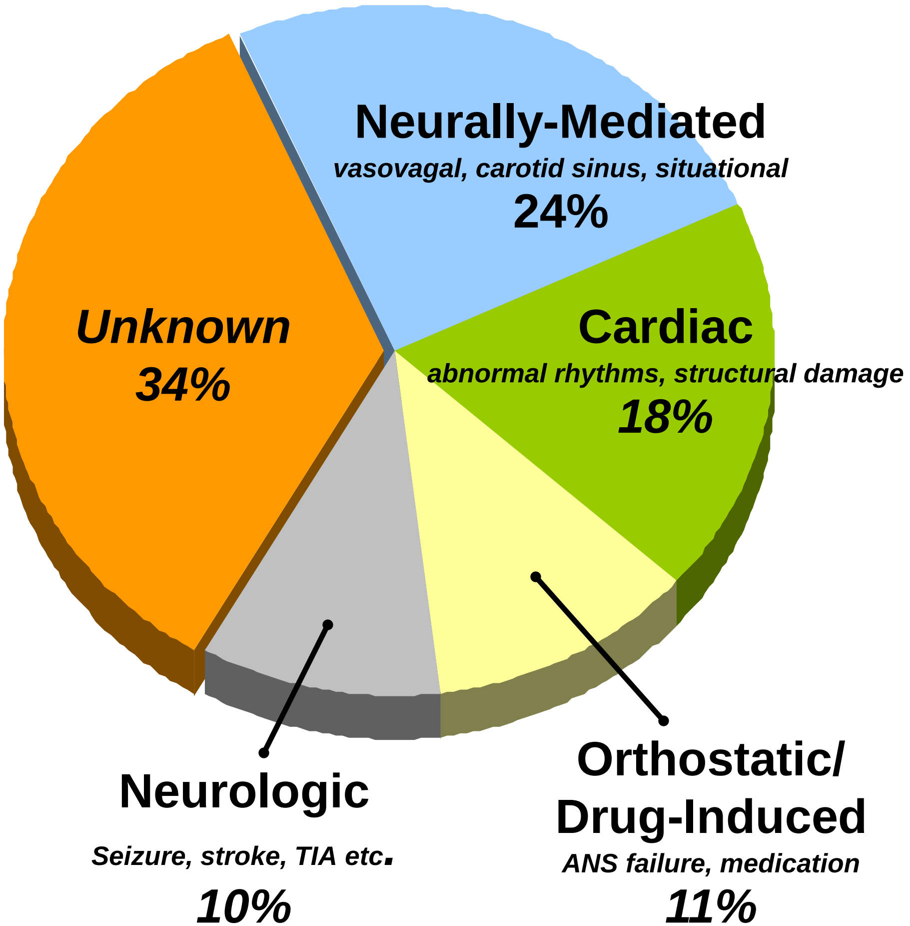
  (channelopathy, hereditary disease, …)

  → **Unexplained syncope**

ILR for unexplained syncope

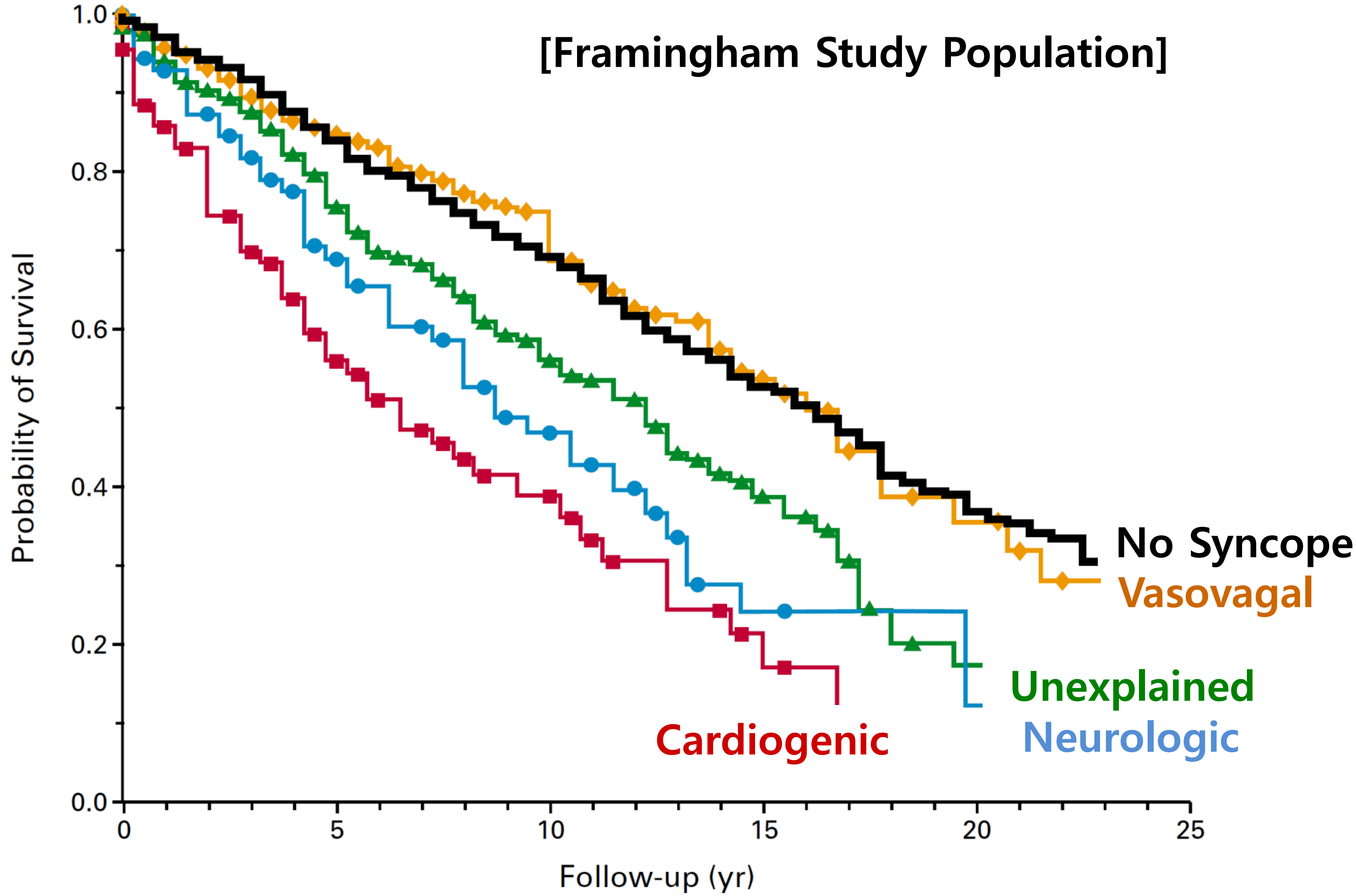
Unexplained Syncope

- Syncope remains **unexplained** in approximately **1/3** of cases



Linzer M, et al. Ann Intern Med. 1997;126:989-996.

Unexplained Syncope can be a harbinger of SCD

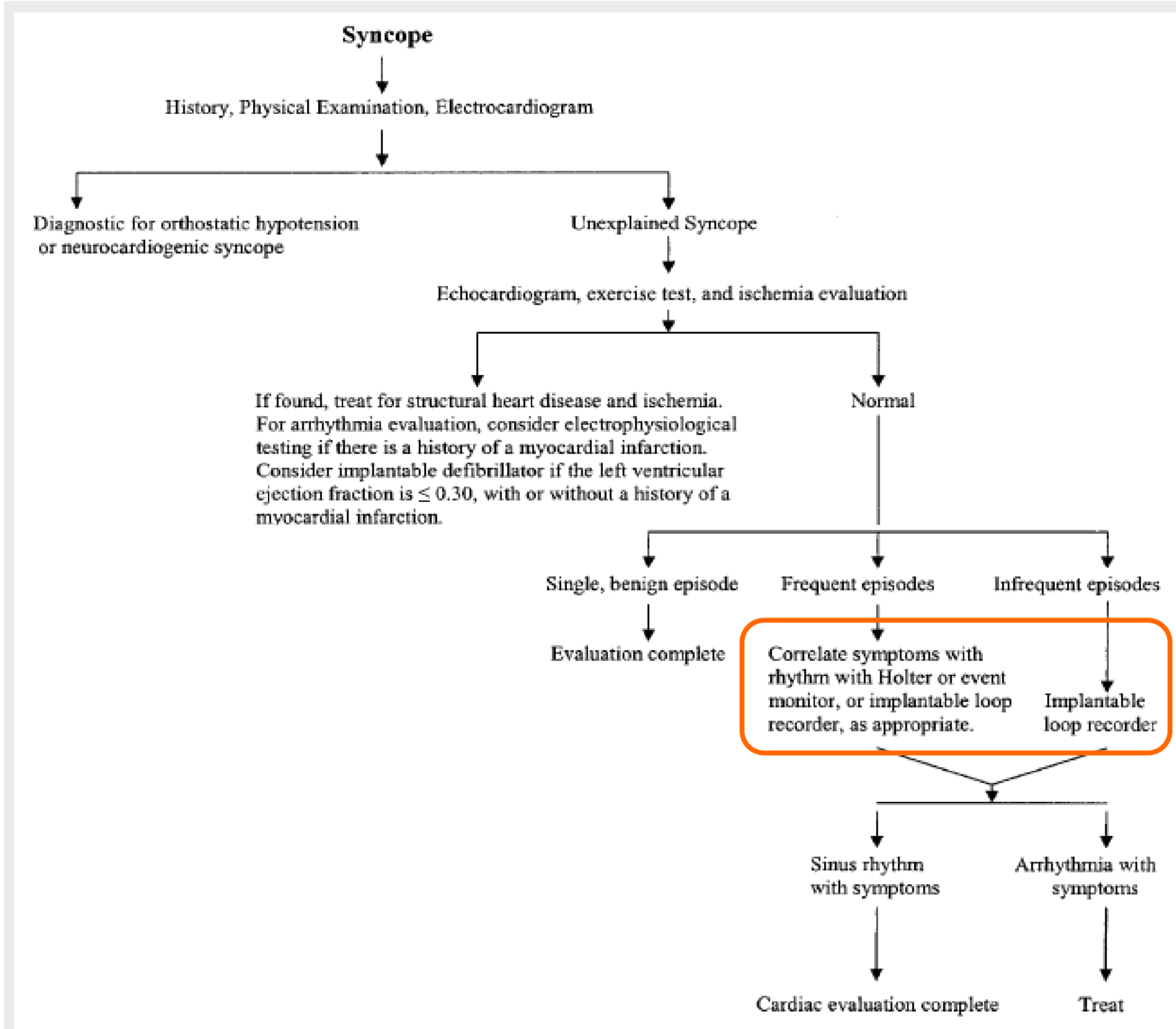


Soteriades ES, N Engl J Med. 2002;347(12):878-885.

Role of an ICM for Syncope

AHA/ACC Scientific Statement on the Evaluation of Syncope:

"This approach (ILRs) is more likely to identify the mechanism of syncope than is a conventional approach that uses Holter or event monitors and EP testing and is cost-effective."



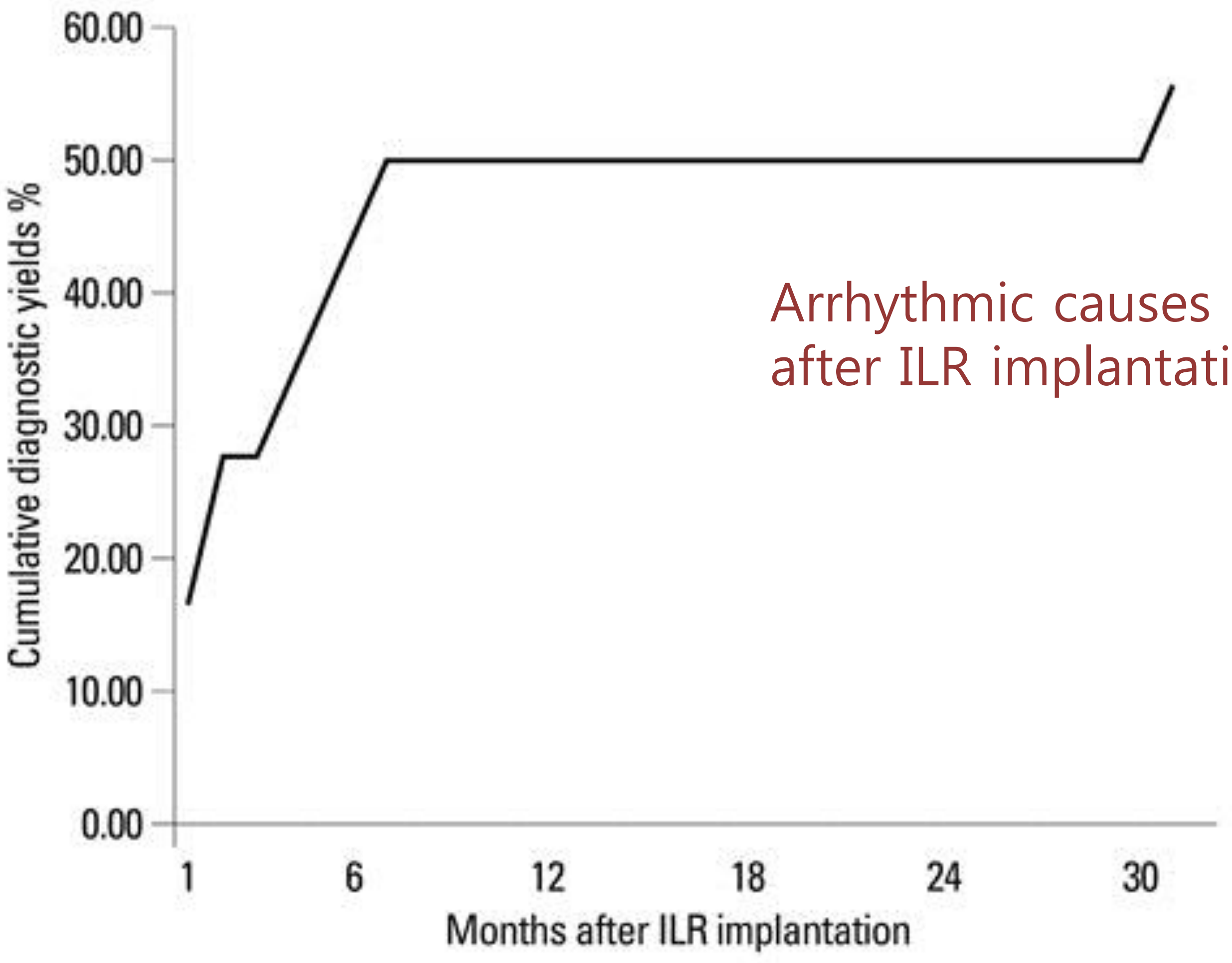
A. Strickberger et al. Circulation 2006; 113: 316-327

Test Options & Diagnostic Yields

Test/Procedure	Yield*
ECG	2-11%
Holter Monitoring	2%
External Loop Recorder	20%
Tilt Table	11-87%
EP Study without structural heart disease	11%
EP Study with structural heart disease	49%
Neurological (CT scan, carotid doppler)	0-4%
ILR	**30-50%**[1,2,3]

1.Europace 2005;7:19–24.
2.Europace 2004;6:70–76
3.Europace 2010;12:1475–1479.

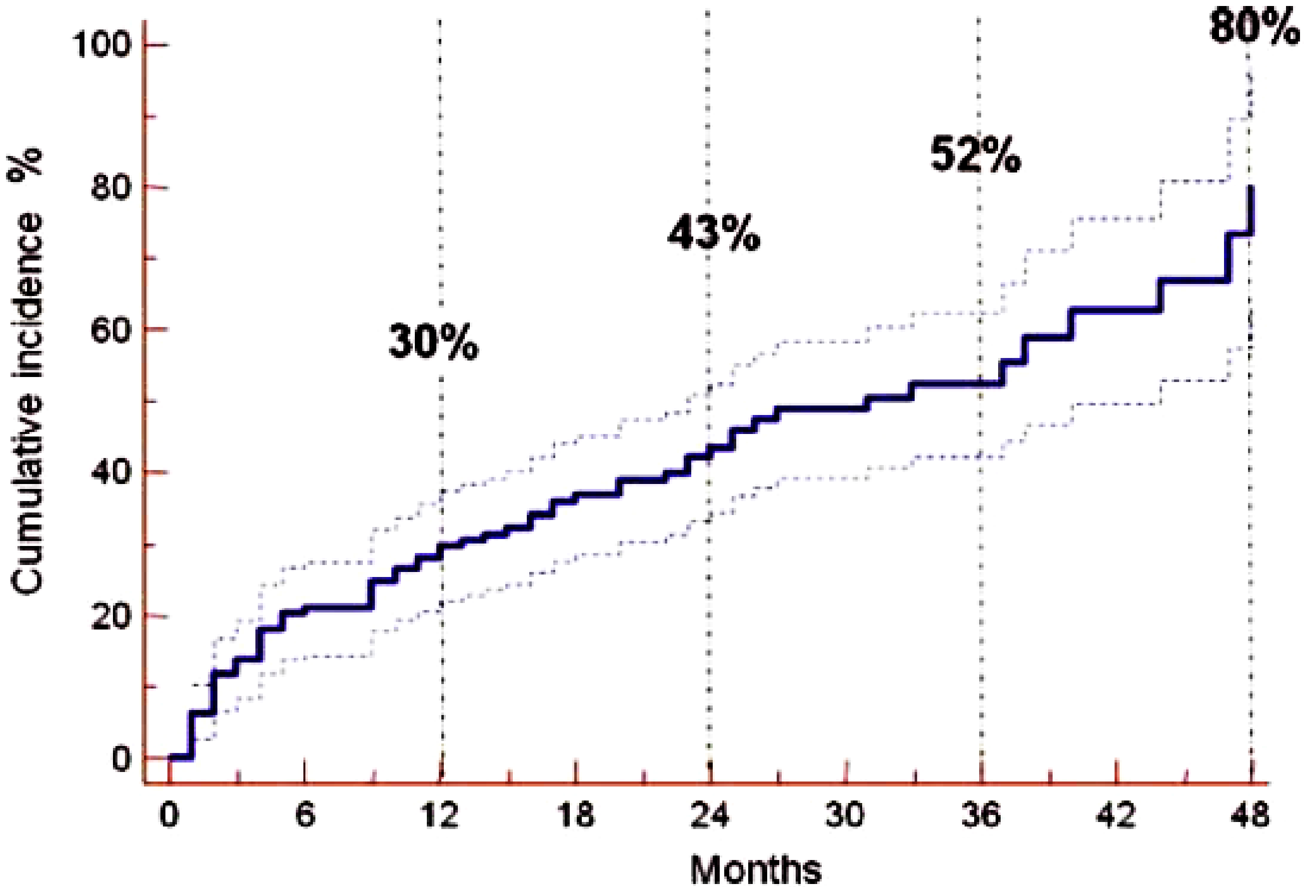
Cumulative diagnostic yields of ILR



Arrhythmic causes of syncope after ILR implantation

YMJ 2013 May;54(3):590-595.

Cumulative diagnostic yields of ILR



Furukawa et al. JCE 2012;23:67-71

ILR for Syncope:

Supporting Information and Clinical Data

Supporting Clinical Evidence

Randomized Assessment of Syncope Trial (RAST)

Methods:

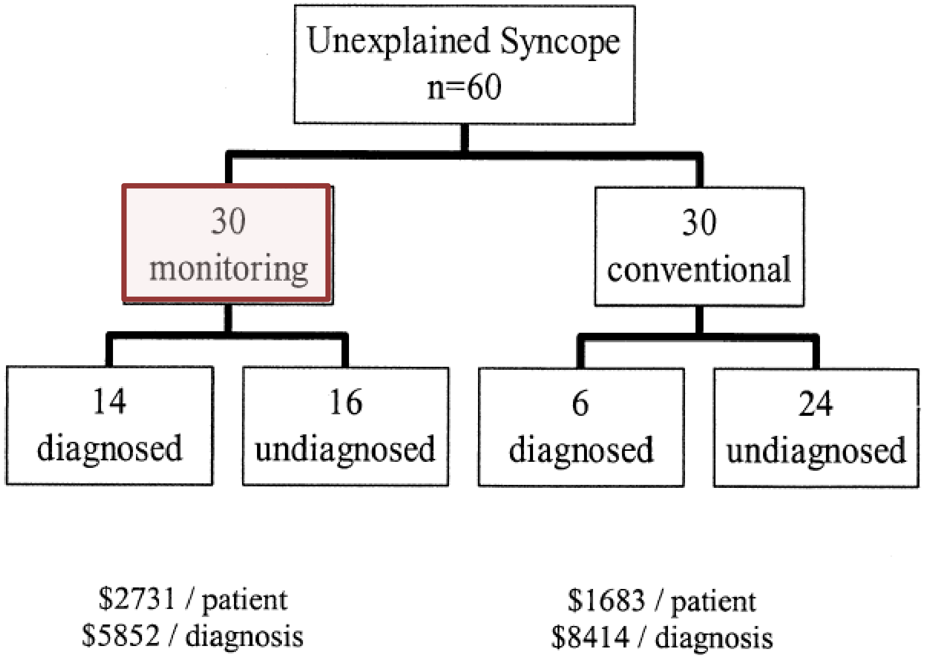
- 60 patients with **unexplained syncope** and **LV EF >35%** were randomized to conventional testing or a Reveal ILR
- If patients remained undiagnosed after their assigned strategy, they were offered a crossover to the alternate strategy

Results:

- Combining primary strategy with crossover, the diagnostic yield was 43% for ILR only versus 20% for conventional only
- Cost/diagnosis of ILR was 26% less than conventional testing

Krahn AD. Cost implications of testing strategy in patients with syncope. JACC. 2003;42(3):495-501.

Outcomes of Primary Diagnostic Strategy



"Although the cost of monitoring was greater than that of conventional testing, the cost/diagnosis was reduced because of the greater diagnostic yield ($p < 0.0001$)."

Supporting Clinical Evidence

Eastbourne Syncope Assessment Study (EaSyAS)

Methods:

- 201 patients presenting acutely with recurrent unexplained syncope were randomized to receive the **ILR** or **conventional** investigation/manage.
- Median follow-up 17 months

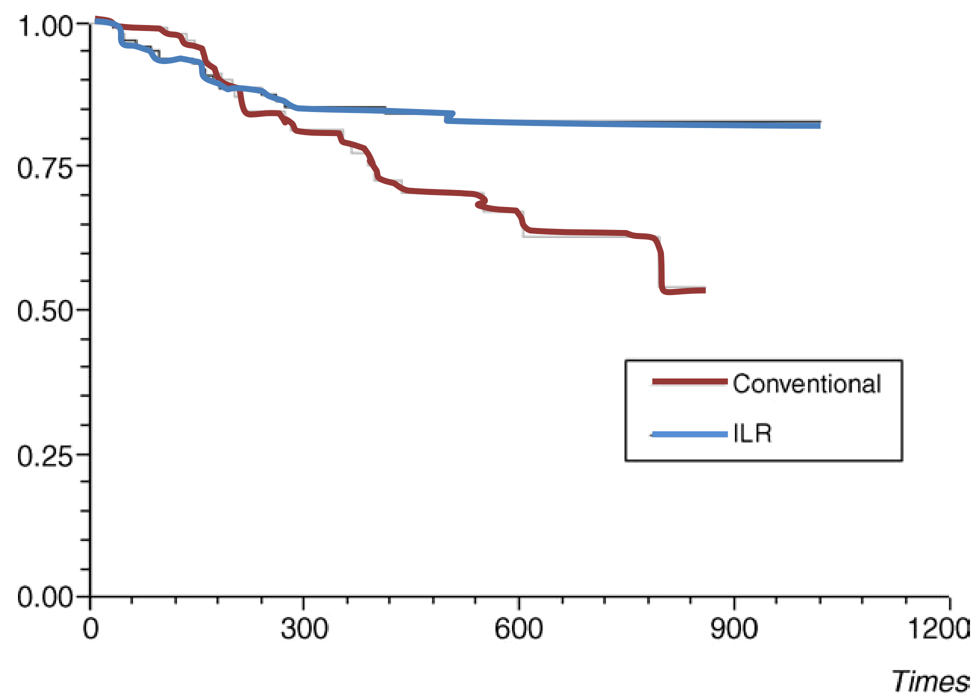
Results:

- 42 (43%) of ILR patients and 8 (6%) of conventional patients received an ECG diagnosis
- The ILR group also saw improved QOL

Farwell D, et al. *The clinical impact of implantable loop recorders in patients with syncope.* European Heart Journal (2006) 27, 351–356.

Time to Second Syncope Recurrence

*"ILR patients achieved a longer time to second syncope, suggesting **more appropriate treatment**."*



P = 0.04

Supporting Clinical Evidence

ISSUE 2

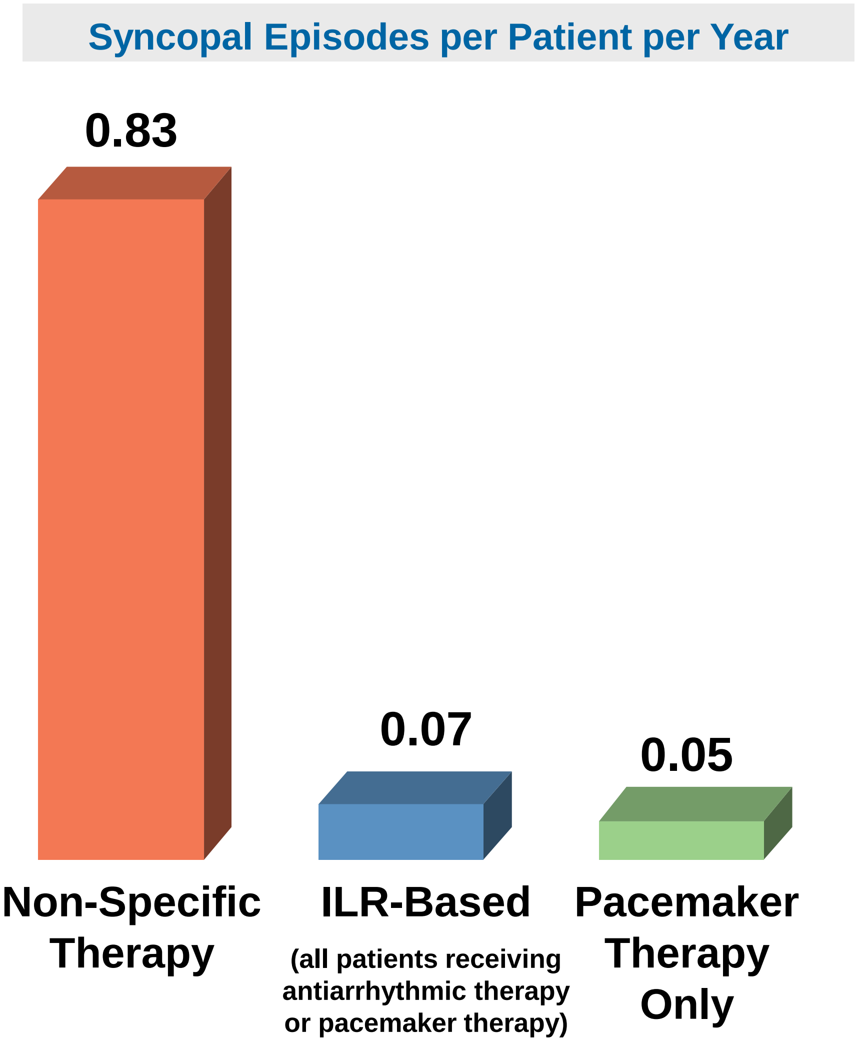
Methods:

- 392 patients with suspected neurally-mediated syncope were enrolled
- 103 pts. had an ECG documented syncope, leading to therapy and a follow-up observational period

Results:

- A 92% relative reduction in syncope burden and 80% relative reduction in one-year recurrence rate with pacing and antiarrhythmic therapies guided by ILR findings

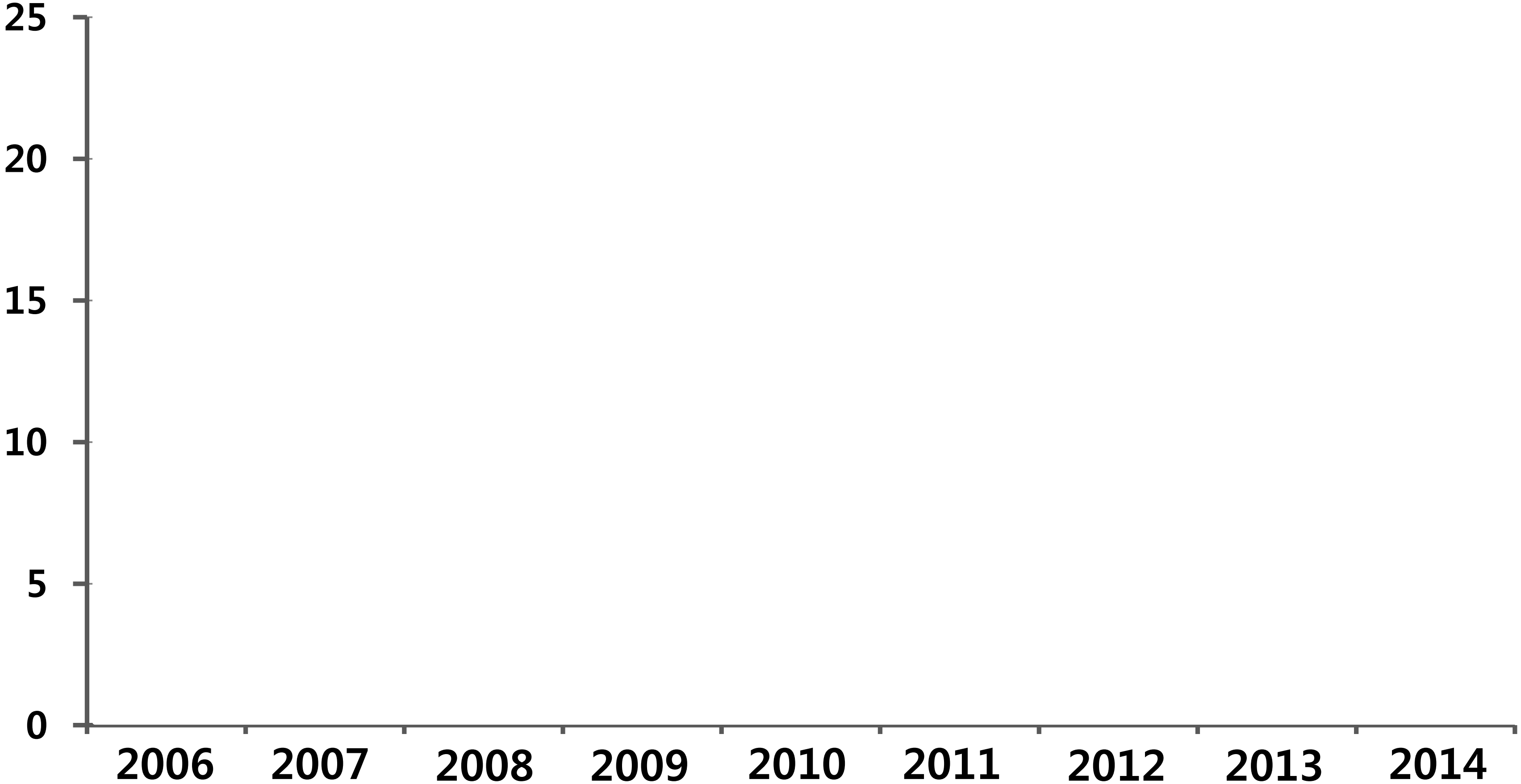
Brignole M. *Eur Heart J.* 2006;27:1085-1092 (ISSUE 2).



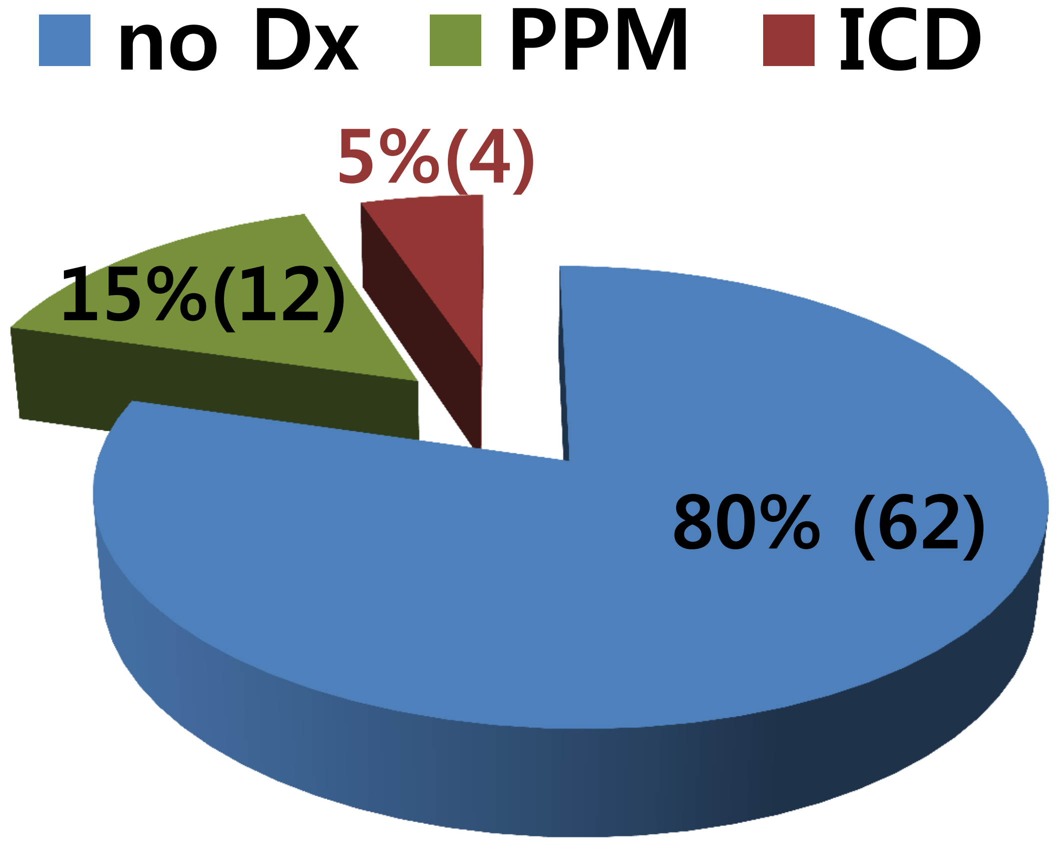
Diagnosis by ILR in SMC

2006~2013: ILRs in 31 patients

ILRs in Korea



VT/VF by ILR in Korea



(n=78)

VF cases

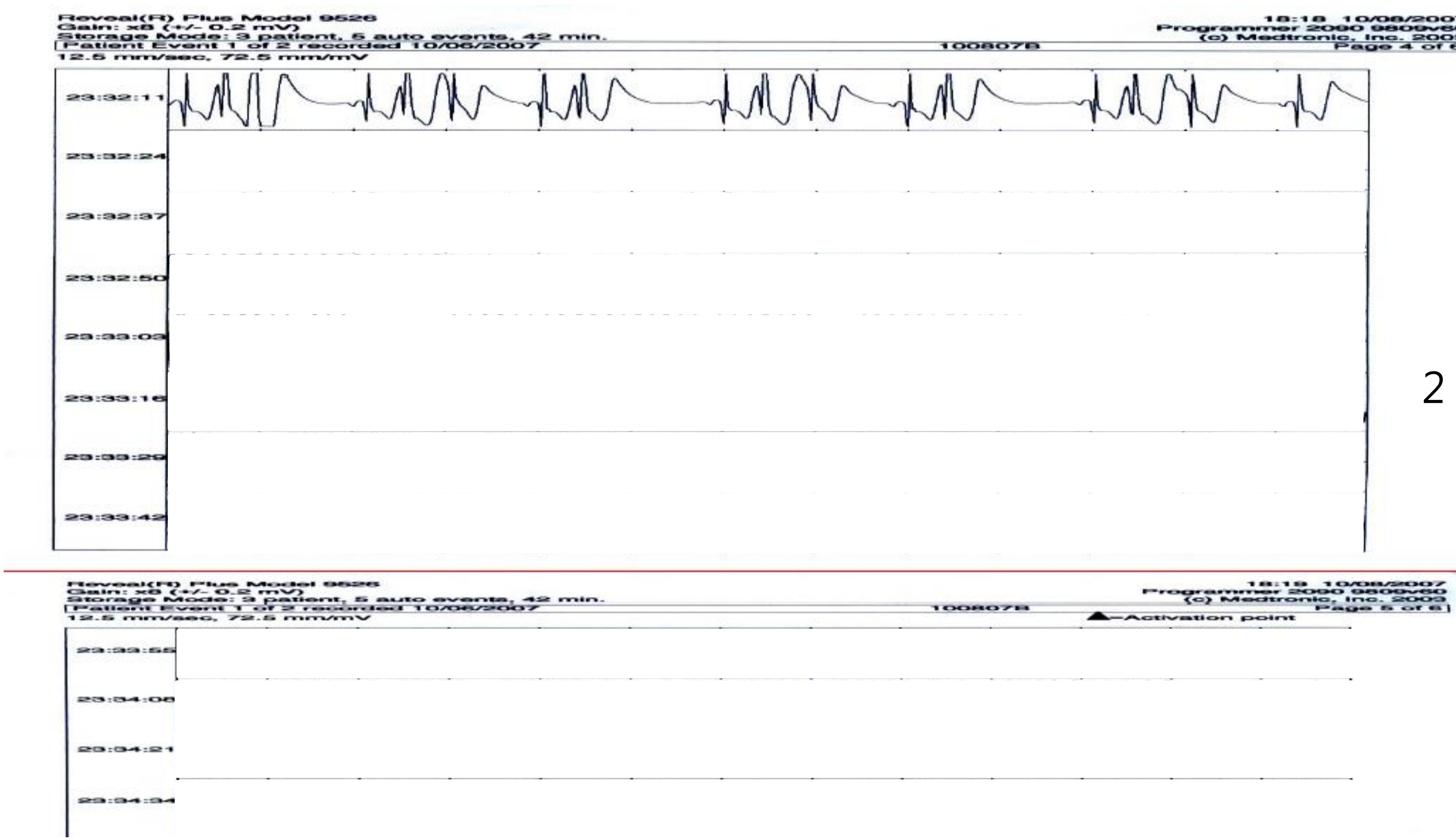
- 27 YO Male
- Recurrent episode of syncope (4 times)

- Family Hx of SCD (Patient's father)

- No prodromal symptoms
- Eye ball deviation
- Cyanotic change, free voiding

ILR recording during sleep

- Agonal respiration with gasping



2 min.

Shin et al. Korean Circ J 2008;38:205-11)

Indication of ILR:

2009 ESC Syncope Guidelines

Class I

- for early phase evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria which require prompt hospitalization or intensive evaluation, and a high likelihood of recurrence within the battery life of the device.

- for high-risk patients in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment.

Class IIa

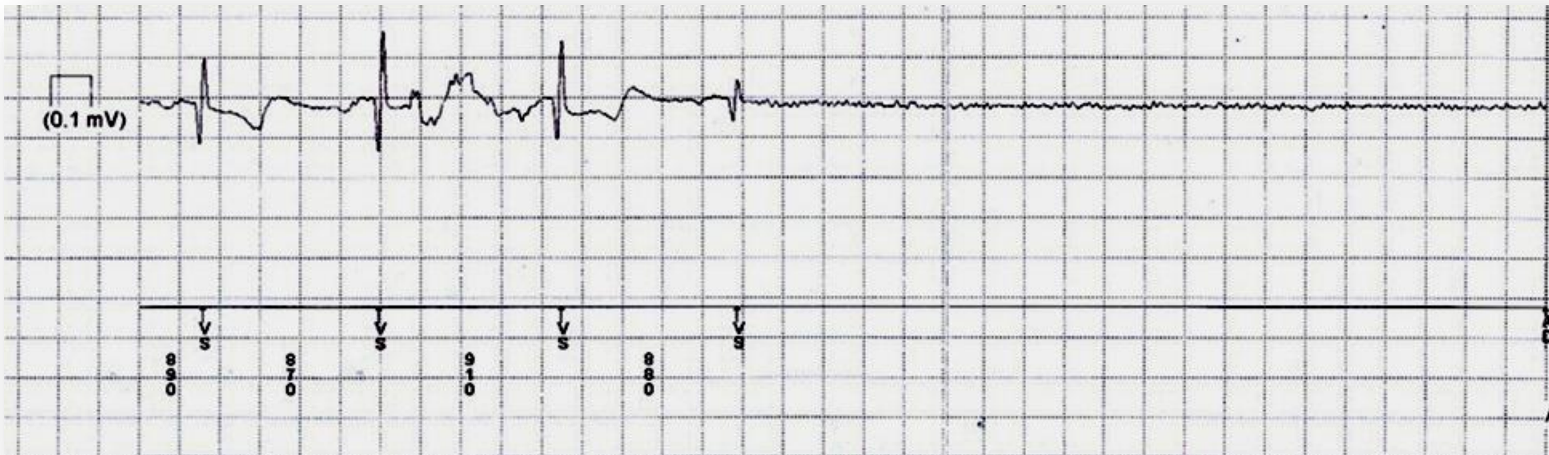
- to assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain reflex syncope with frequent or traumatic syncopal episodes.

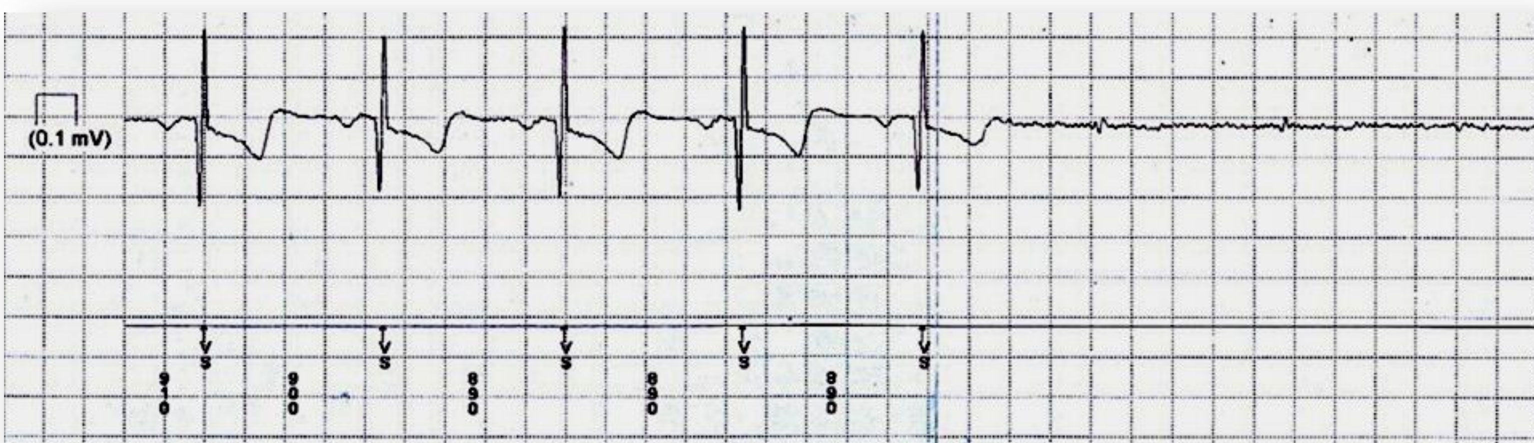
Limitations of ILR for SCD

- **Undersensing of signals**
- **Oversensing of signals**
- **Noise**
- **Limited storage capacity**

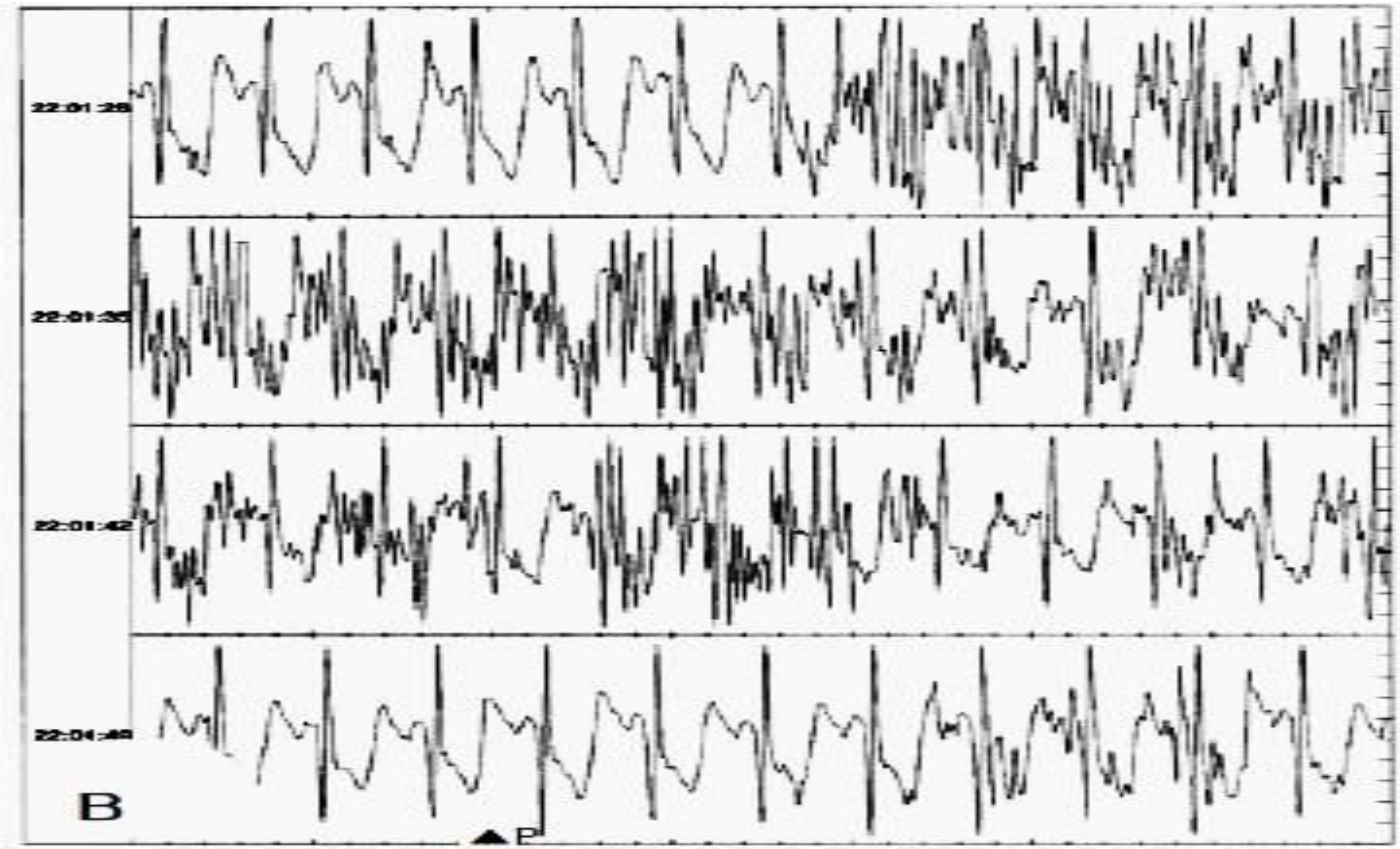
  Overwrite clinically significant arrhythmic events with ECG storage of events triggered by a sensing abnormality.

Undersensing of Signals



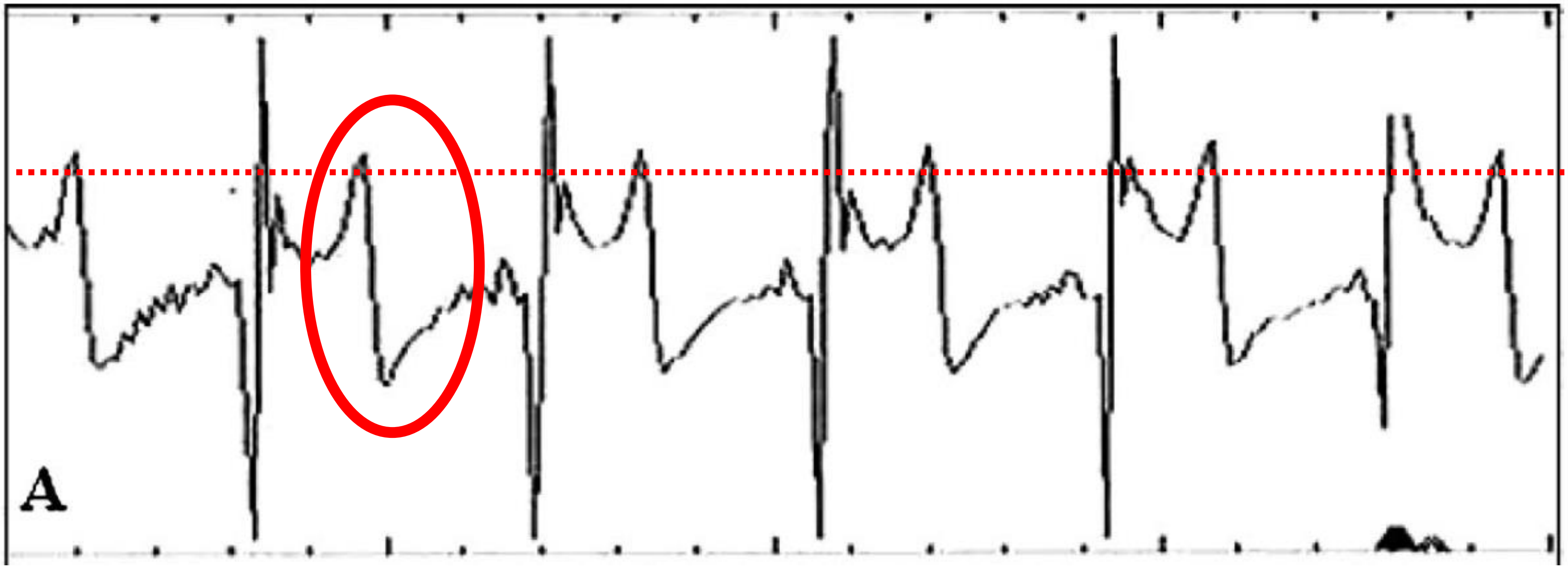


Oversensing of Noise



Shin et al. Korean Circ J 2008;38:205-211

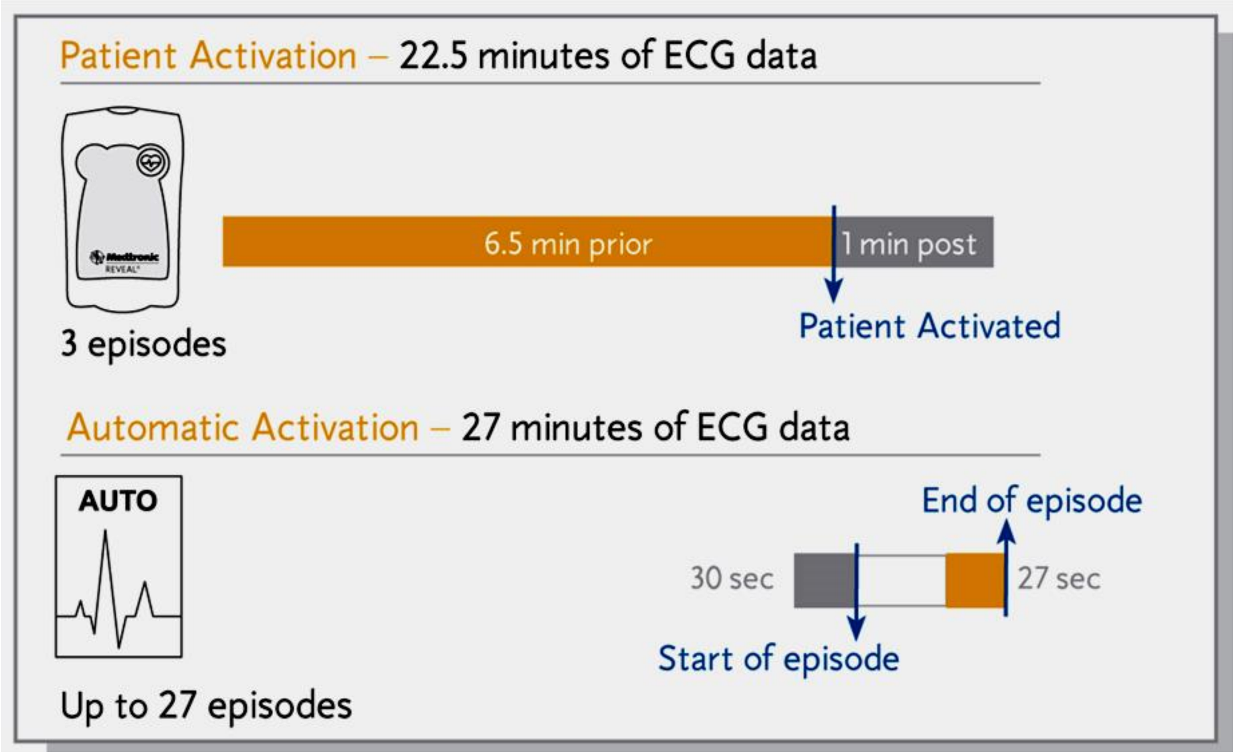
T-wave Oversensing



Improvement of ILR

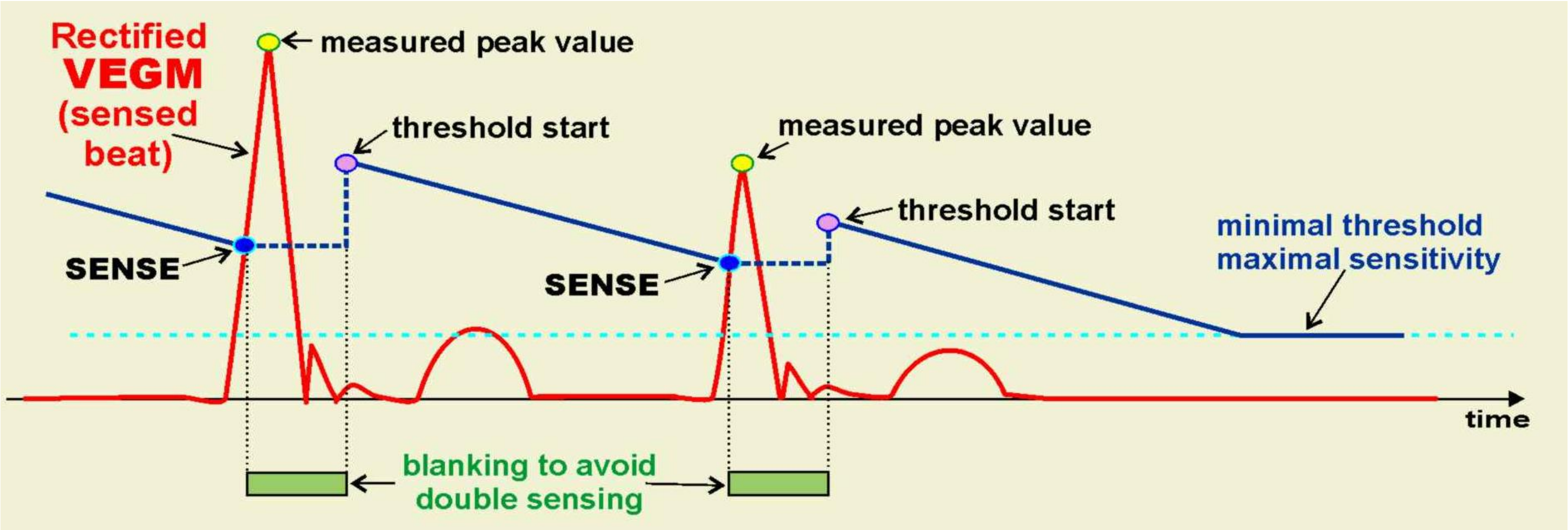
Automatic detection

- **49.5 minutes of ECG storage**
- **Episodes are captured automatically or via the Patient Assistant to establish a symptom-rhythm correlation**



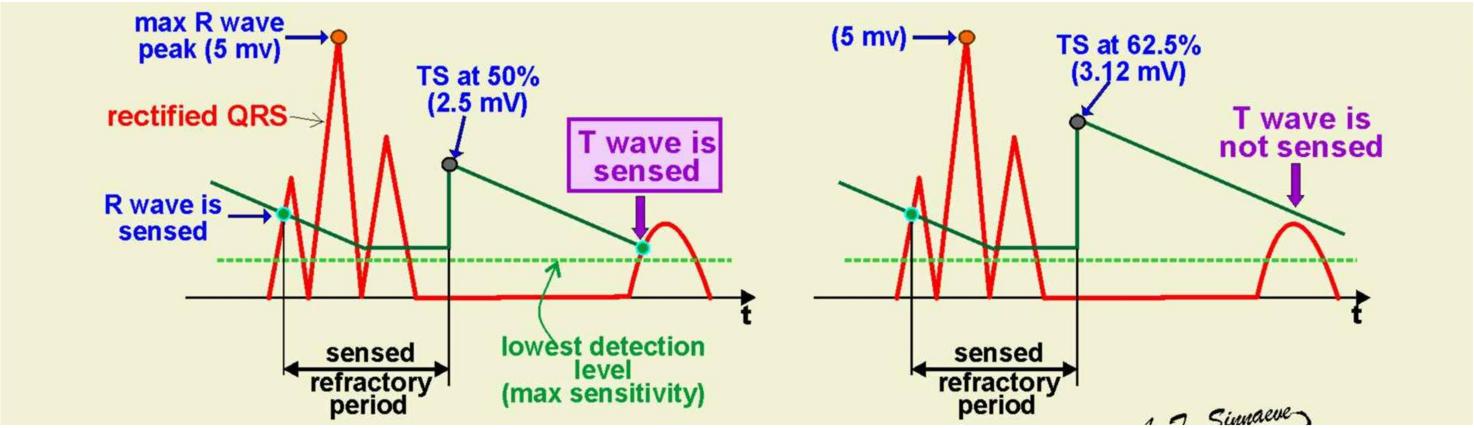
Improved sensing algorithm

- **Dynamic Sensitivity**: auto-adjusting sensing threshold

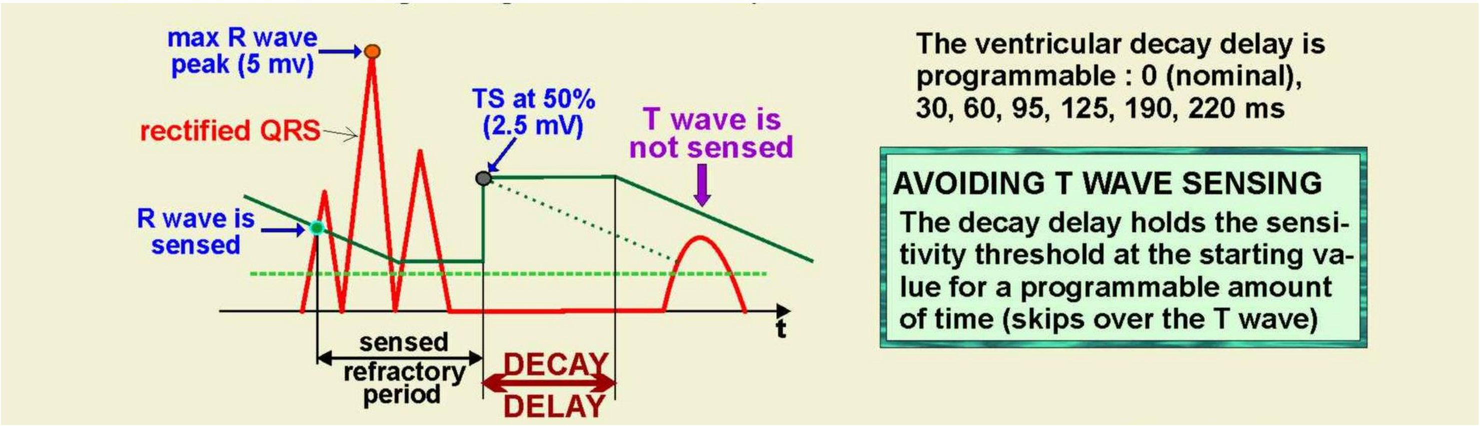


Improved sensing algorithm

- **Threshold Start**: pattern of HR increase

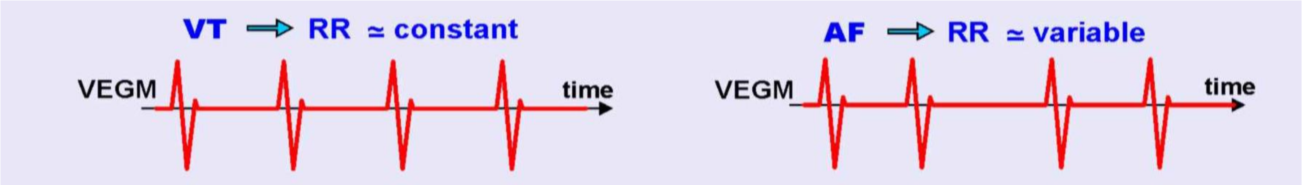


- **Decay Delay**: pattern of HR increase



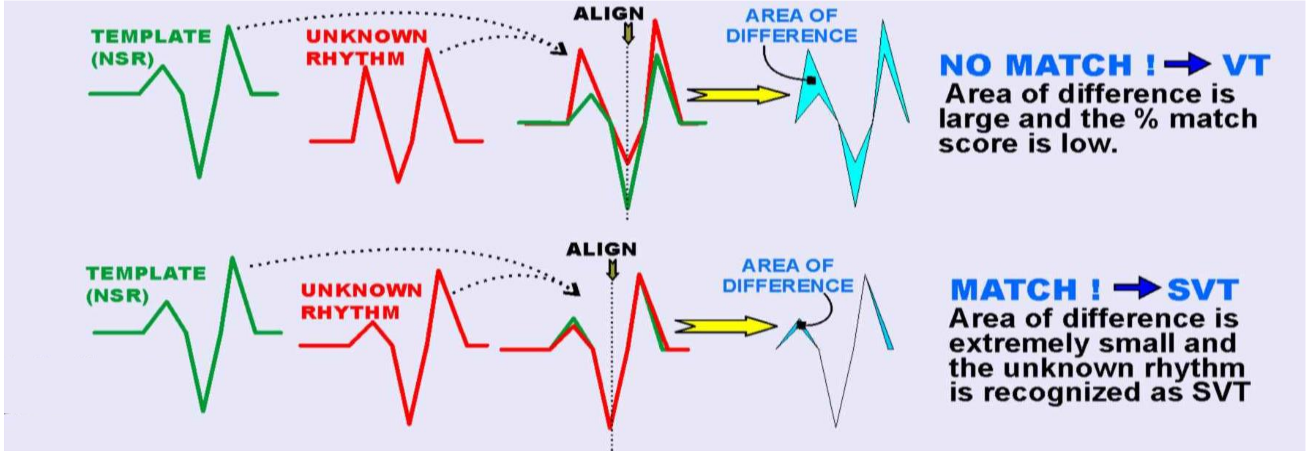
Enhanced Discrimination

- **Ventricular Stability**: regularity of RR interval (ex; 50ms)

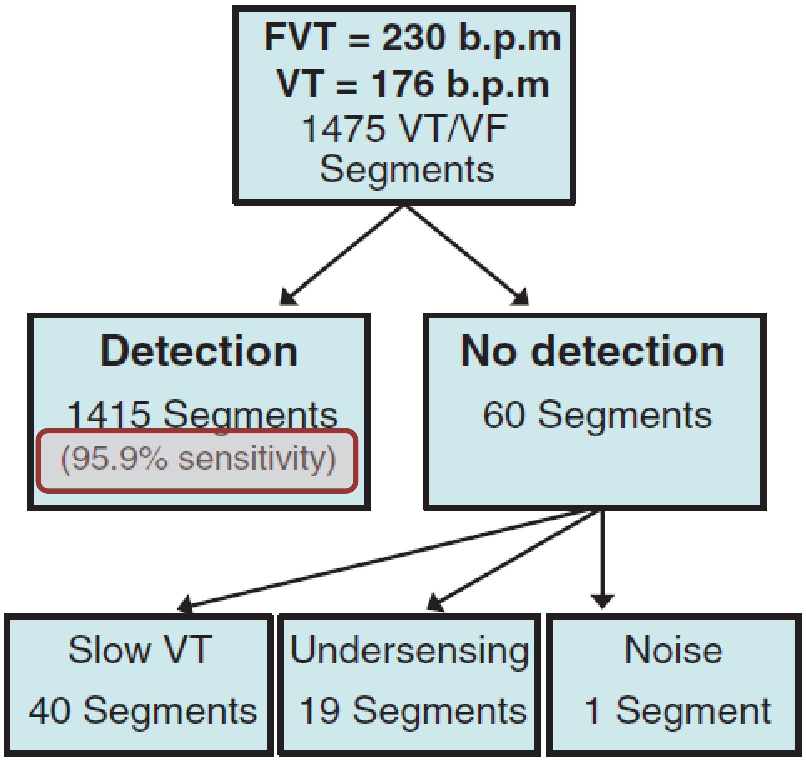


- **Sudden Onset**: pattern of HR increase

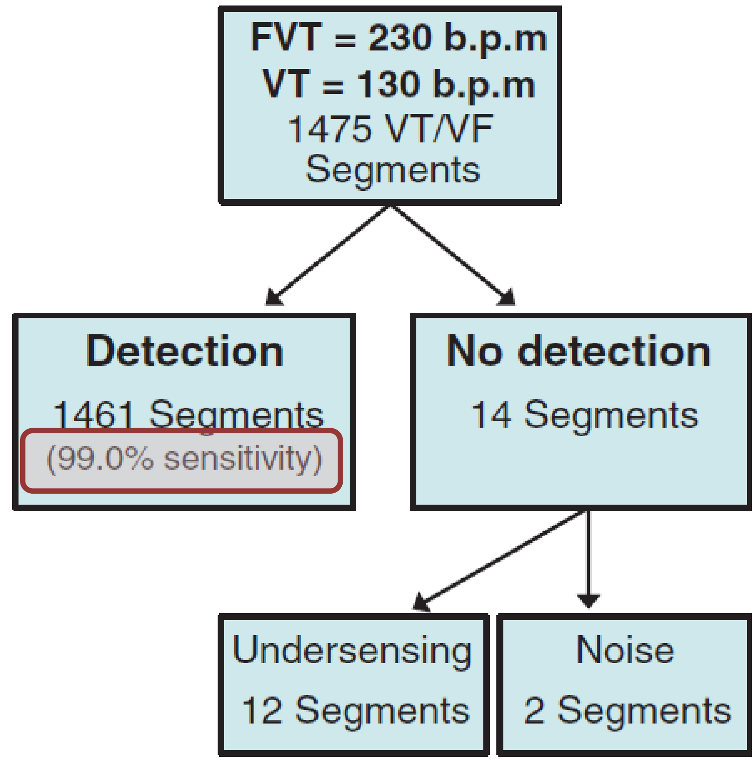
- **QRS morphology**: compare to SR (template)



High sensitivity to detect induced VT/VF



Nominal Setting



Rate threshold ≥ 130bpm
(VT detection)

Europace (2013) 15, 1215–1222

Better longevity

Reveal
1998

14 mo

Reveal Plus
2000

2 yrs

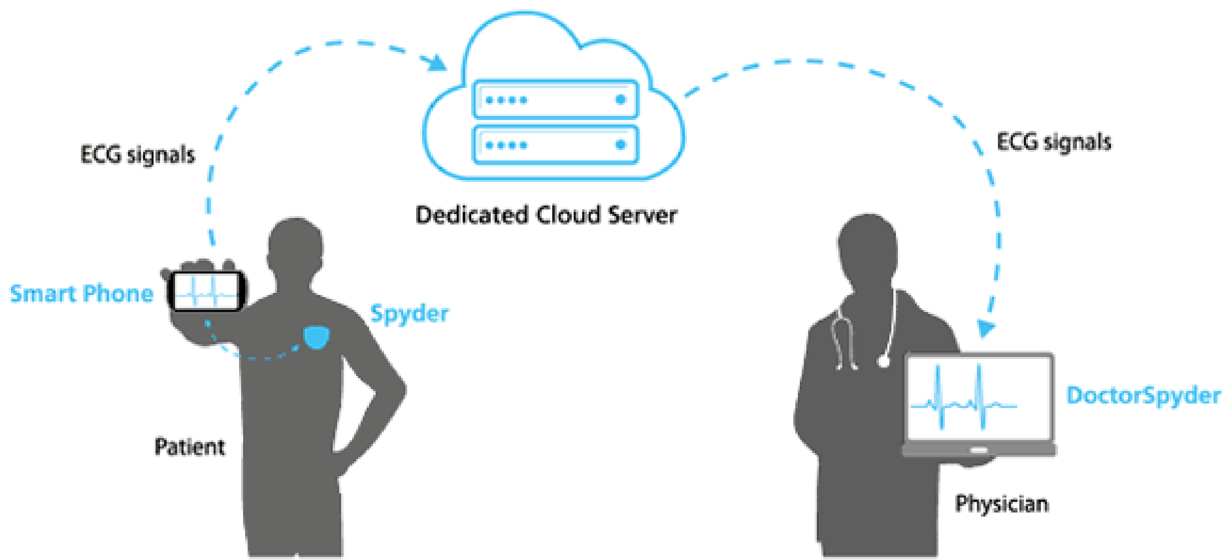
Reveal DX
2007

Confirm
2008

Up to 3yrs

Remote monitoring capabilities

- Remote real-time monitoring & automatic transmission of ECG data to central monitoring station



Reveal on CareLink

Transmission List

Medtronic CARELINK NETWORK

Help | Resources | View Profile: | Sign Out

HOME TRANSMISSIONS MANAGE MY PATIENTS MANAGE MY CLINIC

Clinic: **Bedrock Heart Institute**

Active Transmissions (182) | Reports List | Advanced Search

Transmissions: Search Results reveal (70)

Select a View: Search Results reveal (70)

Keyword Search: (patient name or ID; device model or serial number) reveal Search Advanced Search

Print Reports | Update Status | Customize Columns

« Previous **1** 2 3 4 5 ... 7 Next » 10 per page

Select:

All	Patient Name	Received	Event Summary	Status	Device ▲	Next Send	Total Sends	Battery	Alerts
☐	Smith, John RAB648208K	22-Aug-2008 2:01 PM	AF Episode	New	Reveal XT™ 30-Dec-2007	02-Mar-2009	4		
☐	Doe, Mary RAB012346H	20-Aug-2008 11:40 AM	No Events	New	Reveal XT™ 21-Dec-2007	Not Scheduled	12		
☐	Taylor, Chris RAB012347H	18-Aug-2008 12:09 AM	Asystole Episode	New	Reveal XT™ 1-May-2008	Not Scheduled	9		
☐	Hernandez, Joe RAB012348H	1-Aug-2008 12:08 AM	FVT/VT Episode	New	Reveal® DX 3-Apr-2008	17-Oct-2008	1		
☐	Johnson, Nancy RAB012349H	29-Jul-2008 2:56 AM	FVT/VT Episode	Viewed	Reveal® DX 2-Feb-2008	Not Scheduled	3		
☐	Fillmore, Zoe RAB012344H	25-Jul-2008 9:42 PM	Noise Detected, Asystole Episode	Viewed	Reveal® DX 13-Jul-2008	01-Oct-2008	1		
☐	Magnuson, Mike RAB012343H	14-Jul-2008 10:40 AM	FVT/VT Episode, Brady Episode	Viewed	Reveal® DX 28-Dec-2007	Not Scheduled	2		
☐	McGrath, Jeremy	11-Jul-2008	FVT/VT Episode	Viewed	Reveal®		2		

Several Cases

Case (1)

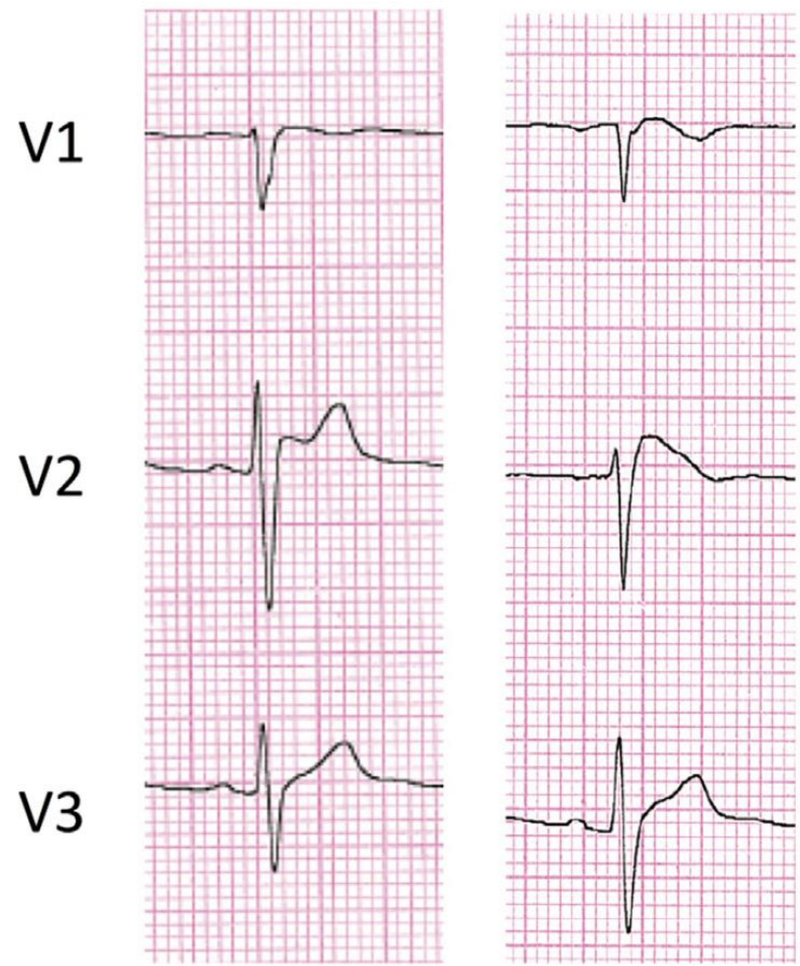
33-year-old male
with syncope

LOC for several minutes
& long postsyncopal
recovery period

Initial Type2 Brudaga pattern
→ Type I by challenge

EPS; negative
Vasovagal ?

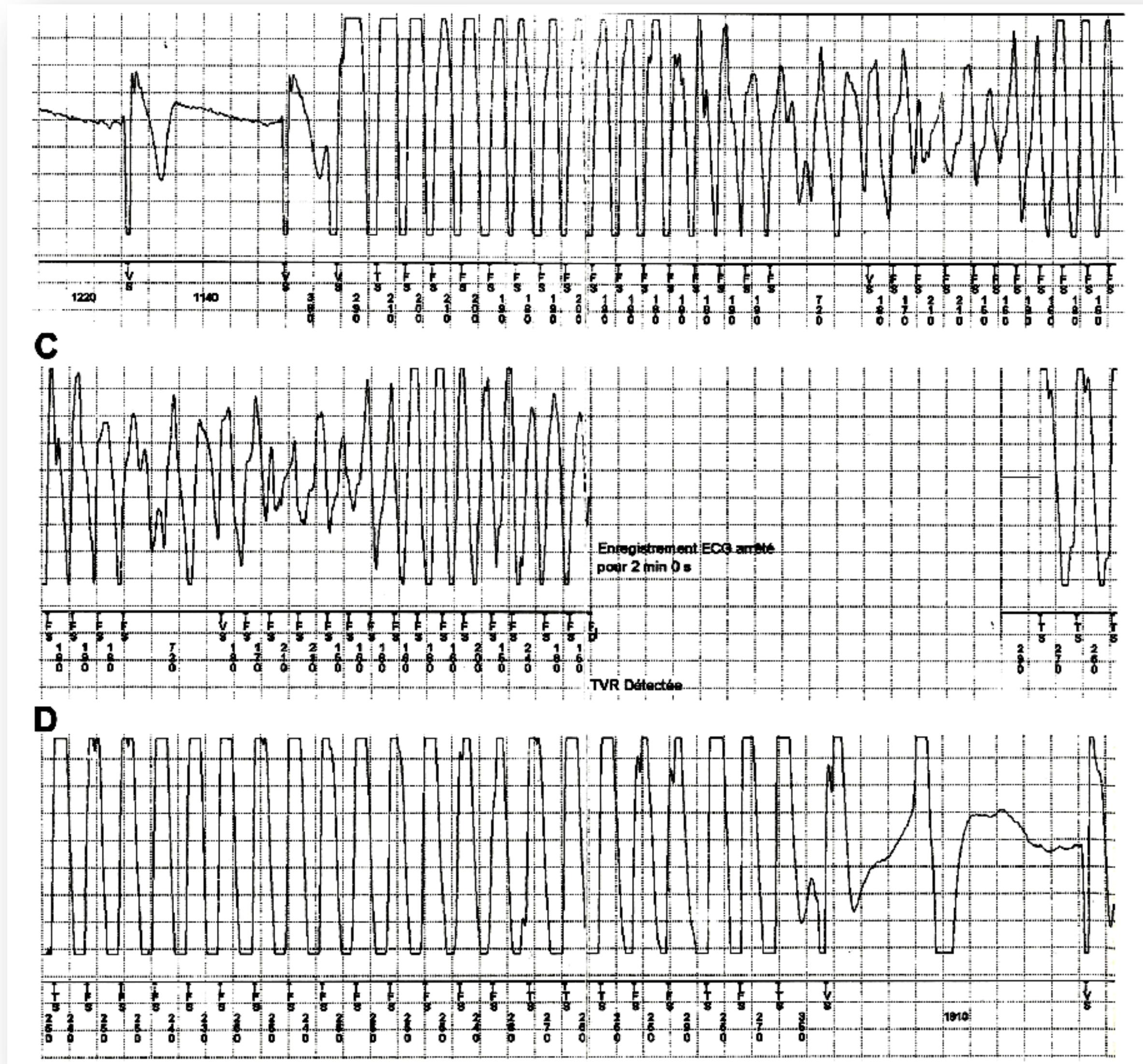
ILR → 11mo. later
Syncope



Prolonged Syncope in Brugada

Syncope recurred
→ECG: Type I

Interrogation:
2min. 41 sec.
VF → VT

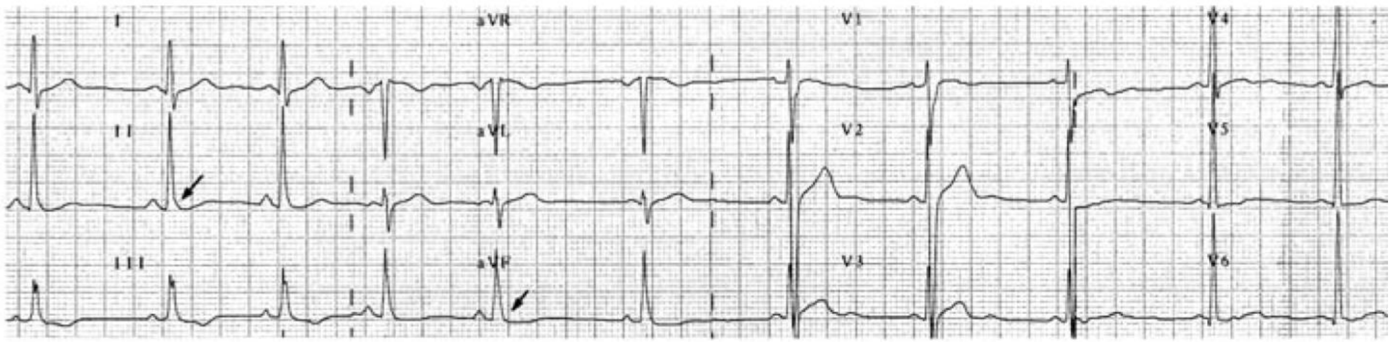


VF by ILR in Early Repolarization

14-year-old boy

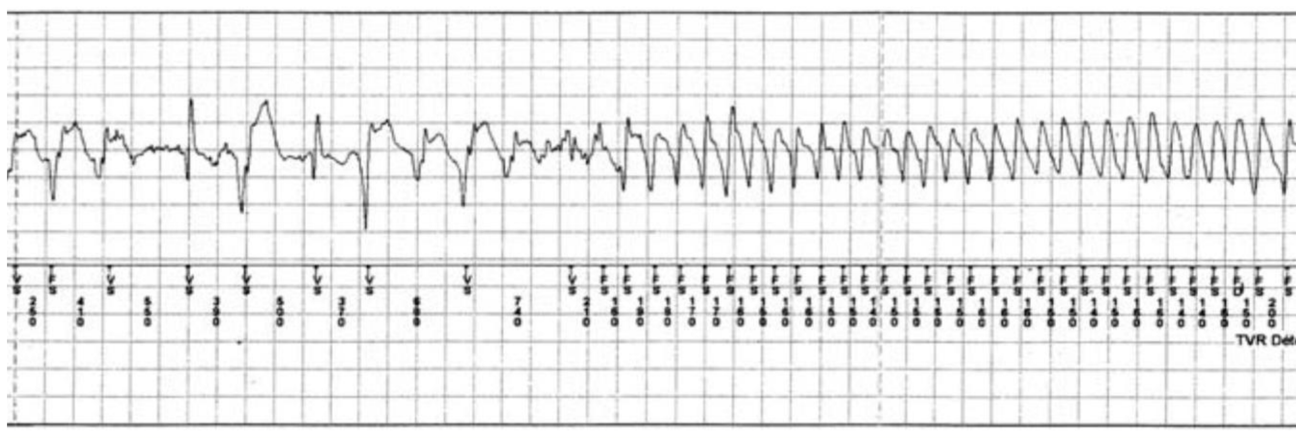
No FHx of SCD

Recurrent unexplain
Usually after exertio
Cyanosis, Seizure-lik



Diagnosed Epilepsy:
Tilt test positive
Abnormal EEG

VF during recreational
exertion



VF in Excersise-induced Syncope

9-year-old boy

Recurrent exercise-induced syncope

ILR

Colla

→ C

→ In

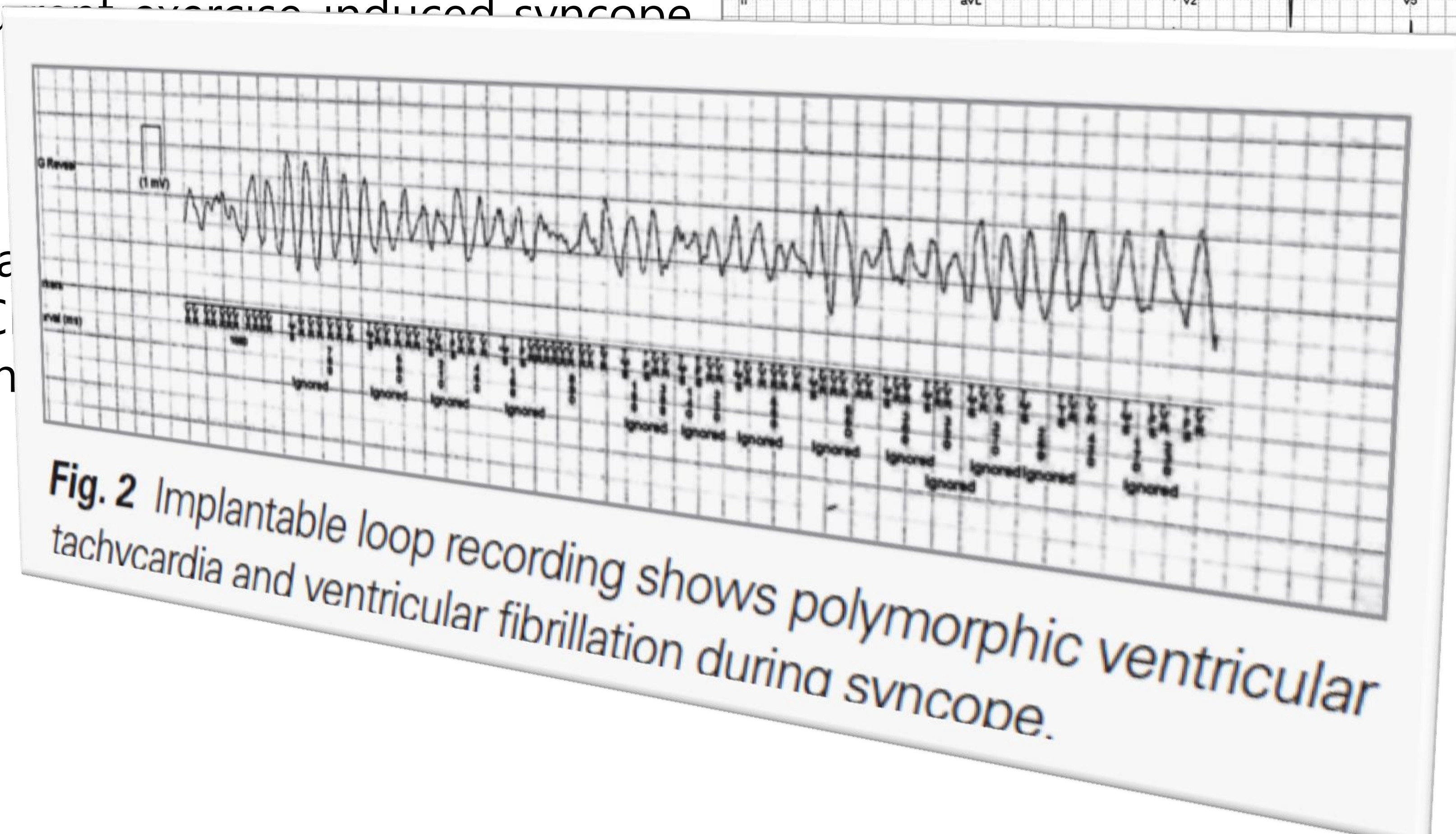


Fig. 2 Implantable loop recording shows polymorphic ventricular tachycardia and ventricular fibrillation during syncope.

Bidirectional VT by ILR

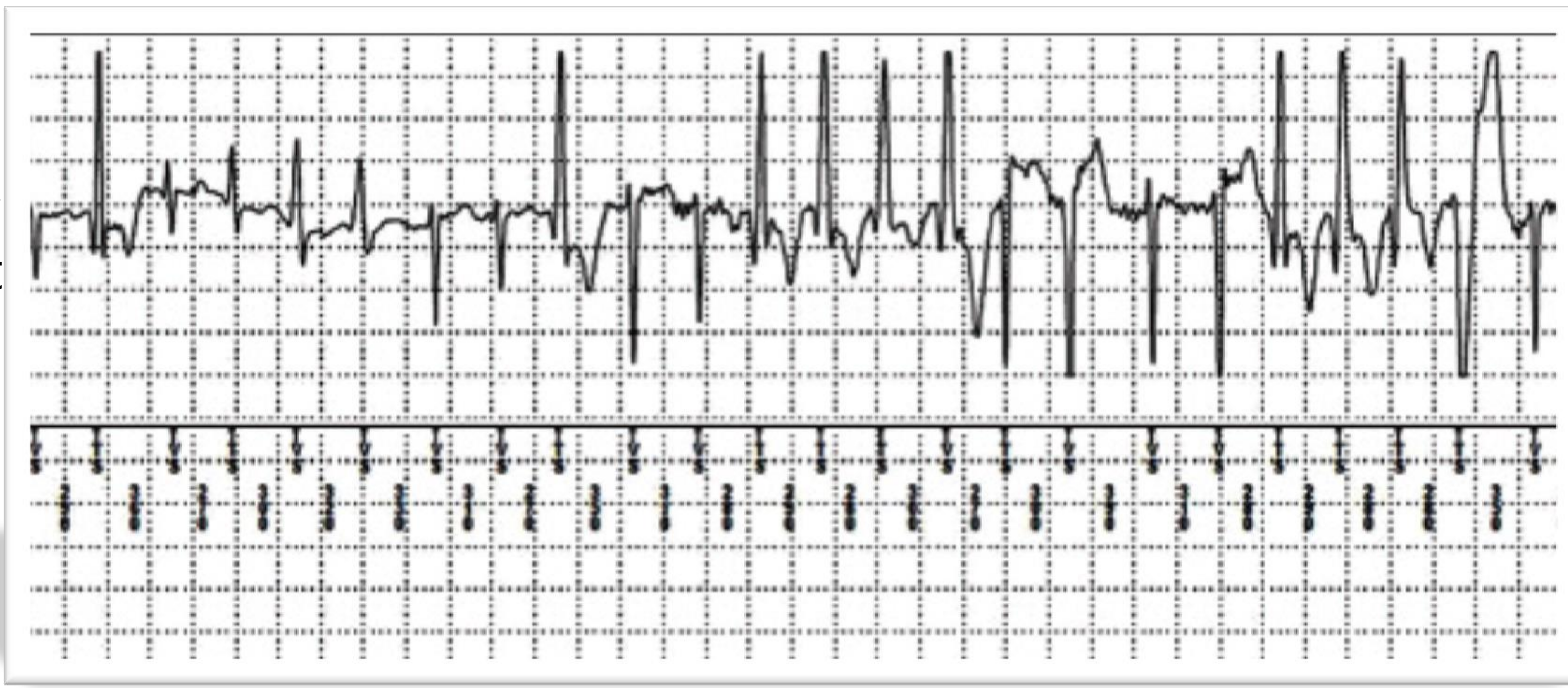
6-year-old boy

Recurrent exercise-induced syncope

ILR

Pre-sy

→ Act



Vasospastic angina by ILR

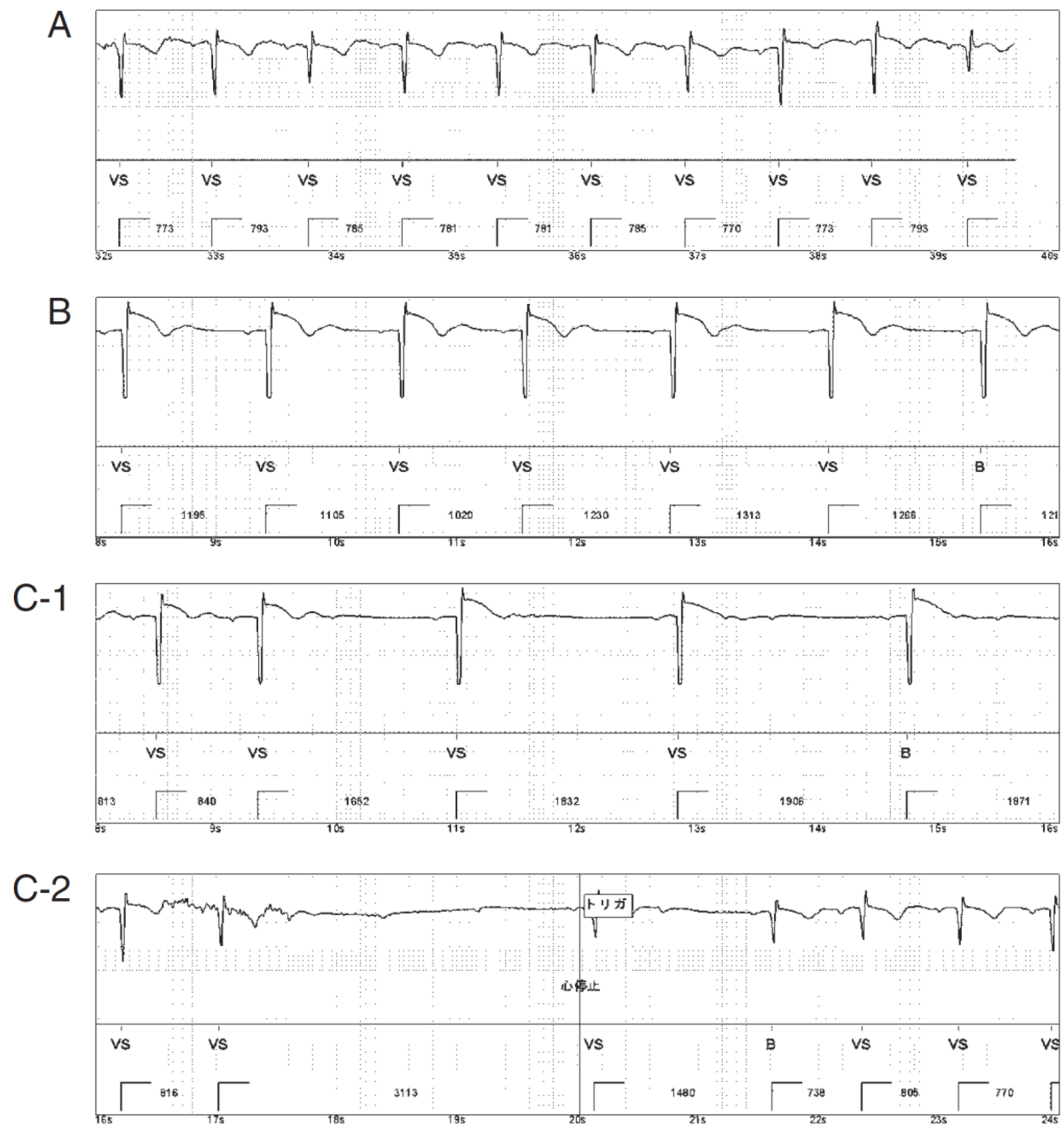
66-year-old woman

ILR for recurrent syncope

nighttime chest discomfort

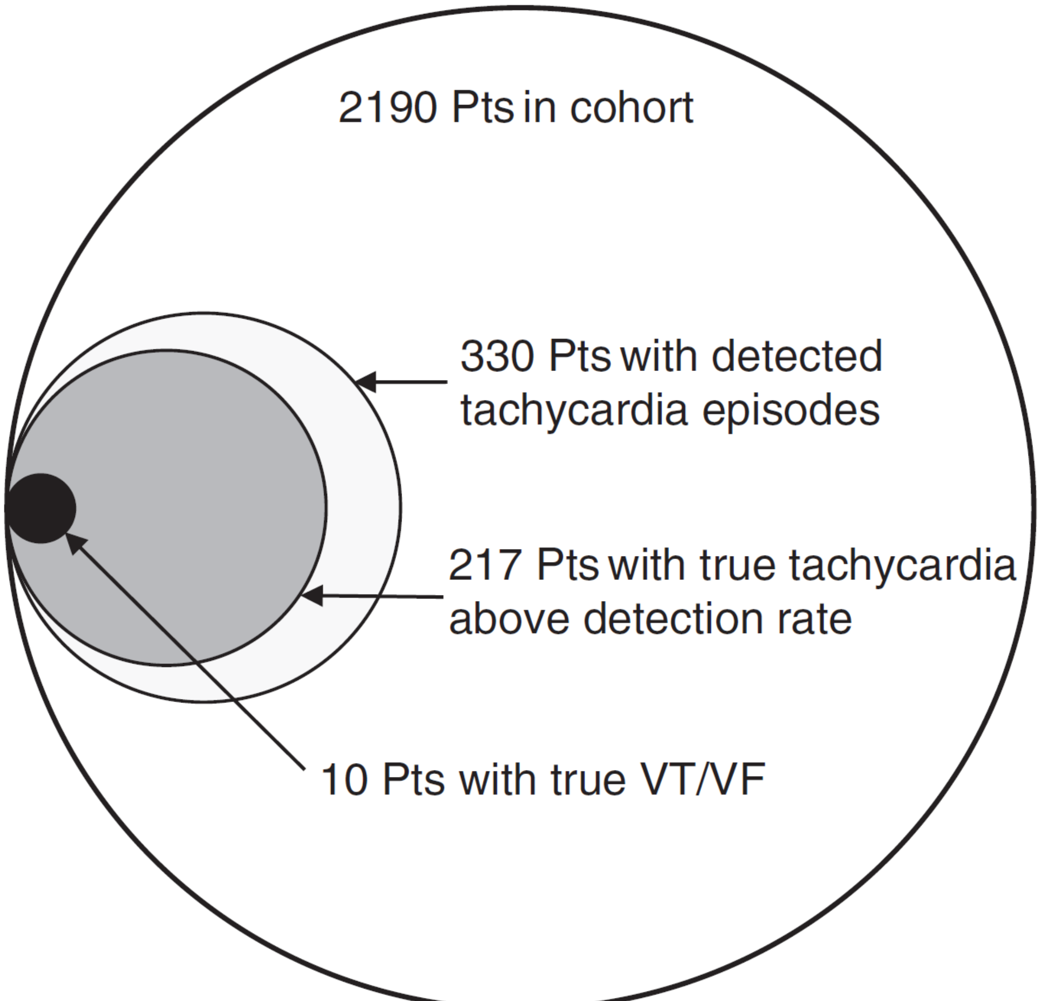
Provocation test:
Diffuse spasm
in 3 coronary artery

CCB & PPM



Tachycardia detection by ILR

Results from a large 'real-life' patient cohort



over a 4-month period

Europace (2013) 15, 1215–1222

Short-term High Risk Criteria

-Prompt hospitalization required-

Severe structural or coronary artery disease (heart failure, low LVEF, or previous myocardial infarction)

Clinical or ECG features suggesting arrhythmic syncope

- Syncope during exertion or supine
- Palpitations at the time of syncope
- Family history of SCD
- Non-sustained VT
- Bifascicular-block (LBBB or RBBB combined with left anterior or left posterior fascicular block) or other intraventricular conduction abnormalities with QRS duration $\geq$120 ms
- Inadequate sinus bradycardia ($<$50 bpm) or sinoatrial block in absence of negative chronotropic medications or physical training
- Pre-excited QRS complex
- Prolonged or short QT interval
- RBBB pattern with ST-elevation in leads V1–V3 (Brugada pattern)
- Negative T waves in right precordial leads, epsilon waves, and ventricular late potentials suggestive of ARVC

Important co-morbidities

- Severe anaemia
- Electrolyte disturbance

European Heart Journal (2009) 30, 2631–2671

Selection of High Risk Patients for Prolonged Monitoring

Table 2 – Prognostic significance of irregular ventricular activity detection in ambulatory ECG monitoring.

Clinical Condition	Prognostic Significance
Apparently healthy individuals	
PVCs and monomorphic NSVT	• No adverse prognostic significance (in the absence of occult pathology)
Multiform PVCs, polymorphic NSVT	• Probably increased risk of SCD
VA of right ventricular origin	• It is generally considered benign unless if ARVD is the underlying cause
Exercise induced VA	• Increased risk of life-threatening arrhythmias
Inherited cardiac channelopathies	• Symptomatic patients are at high risk for SCD
Trained athletes	• Benign condition when suppressed by exercise • "Athlete's heart syndrome"
ACS patients	
STEMI	
aMI < 24 h	• No adverse prognostic significance
aMI > 24 h (in-hospital)	• Increased risk of in-hospital cardiac arrest and death
Post-discharge	• Prognostic significance not established
NSTE-ACS	
Short episodes of NSVT beyond the first 48 h	• Increased risk of SCD

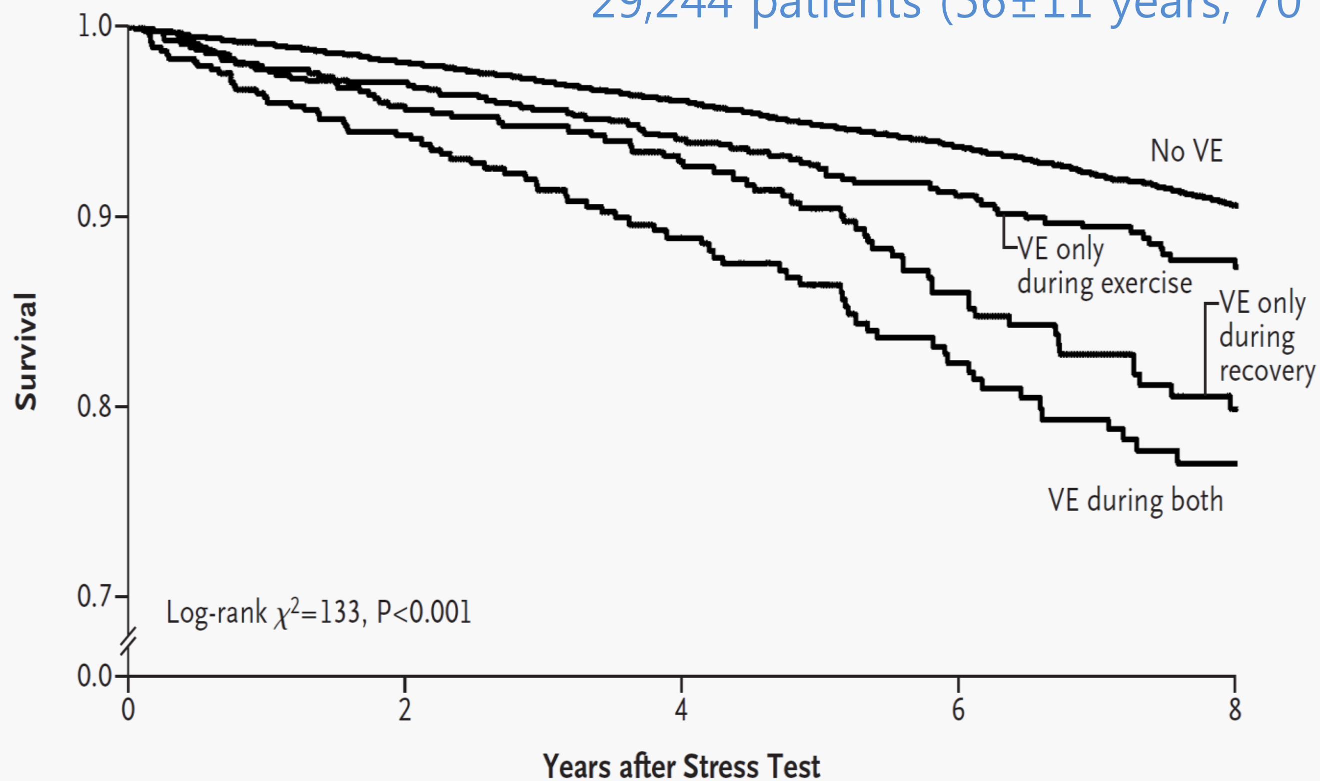
Table 2 – Prognostic significance of irregular ventricular activity detection in ambulatory ECG monitoring.

Clinical Condition	Prognostic Significance
Ischemic cardiomyopathy	• Prognostic significance not established
Dilated cardiomyopathy	• Prognostic significance not established
Hypertrophic cardiomyopathy	• Indicate increased risk of SCD in young adults
Other cardiomyopathies	
Amyloidosis, sarcoidosis, Chagas disease	• Adverse prognostic significance
Systematic arterial hypertension	• Prognostic significance not established
Valvular heart disease	• Prognostic significance not established
Congenital heart disease	• Prognostic significance not established
Syncope	• Adverse prognostic significance varies depending on the underlying cause

Ventricular Ectopy after Exercise

in apparently healthy people

29,244 patients (56±11 years; 70 % men)



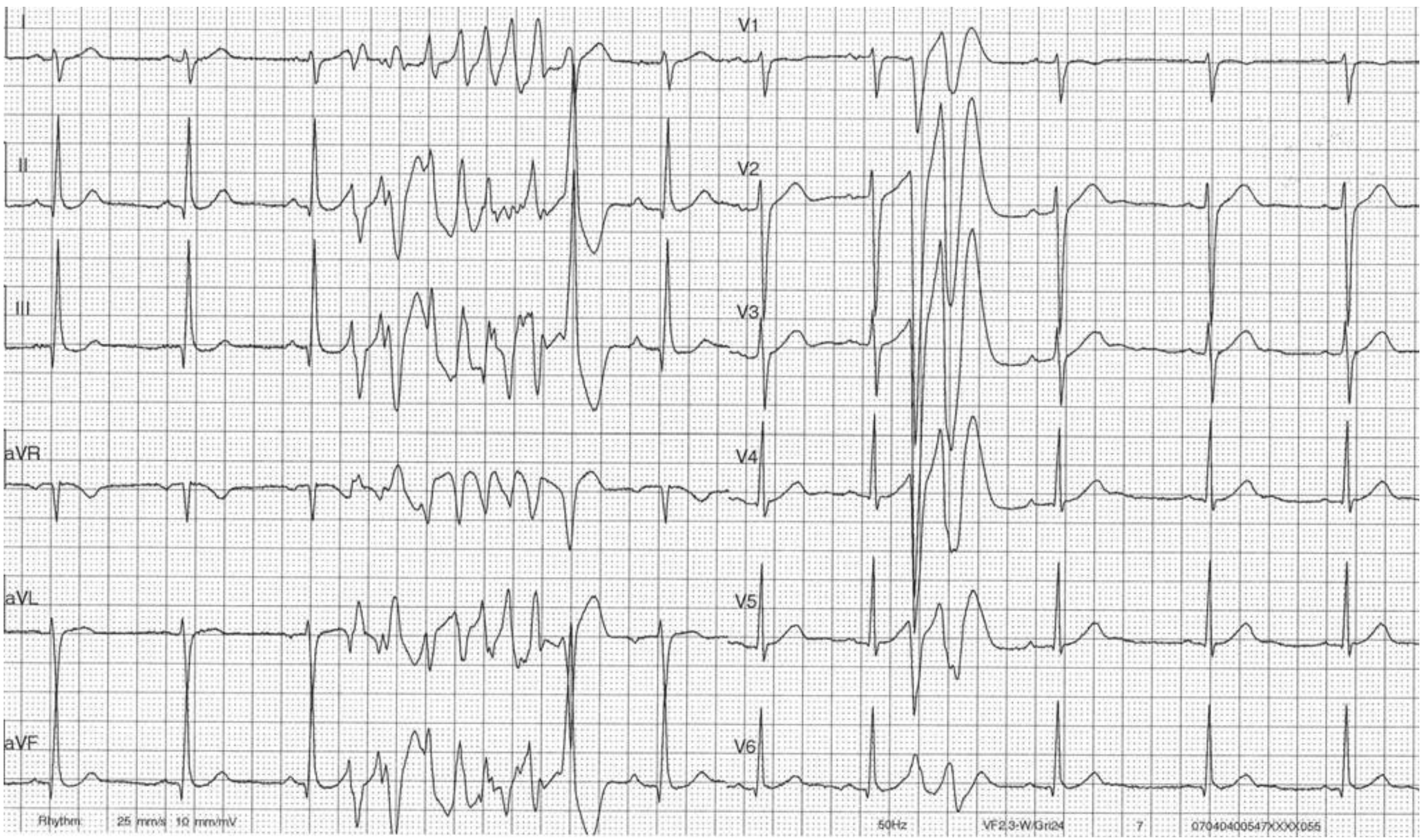
No. at Risk

No VE	27,219	26,295	22,900	19,576	16,708	13,971	11,283	9292	6480
VE only during exercise	945	900	840	687	598	504	418	352	255
VE only during recovery	589	564	474	425	331	276	226	162	121
VE during both	491	459	403	329	265	231	190	148	122

N Engl J Med 2003;348:781-90.

Short-coupled variant of torsade de pointes

Polymorphic VT which often results in VF



Circulation 1994;89:206-15.

Non-sustained VT & Cardiac death

-in patients with CAD-

STEMI

<24hr	**>24hr (in-hospital);** Increased **Risk**

Non–ST Elevation ACS

<48hr	**>48hr (in-hospital)**

CABG pt. with LV dysfunction

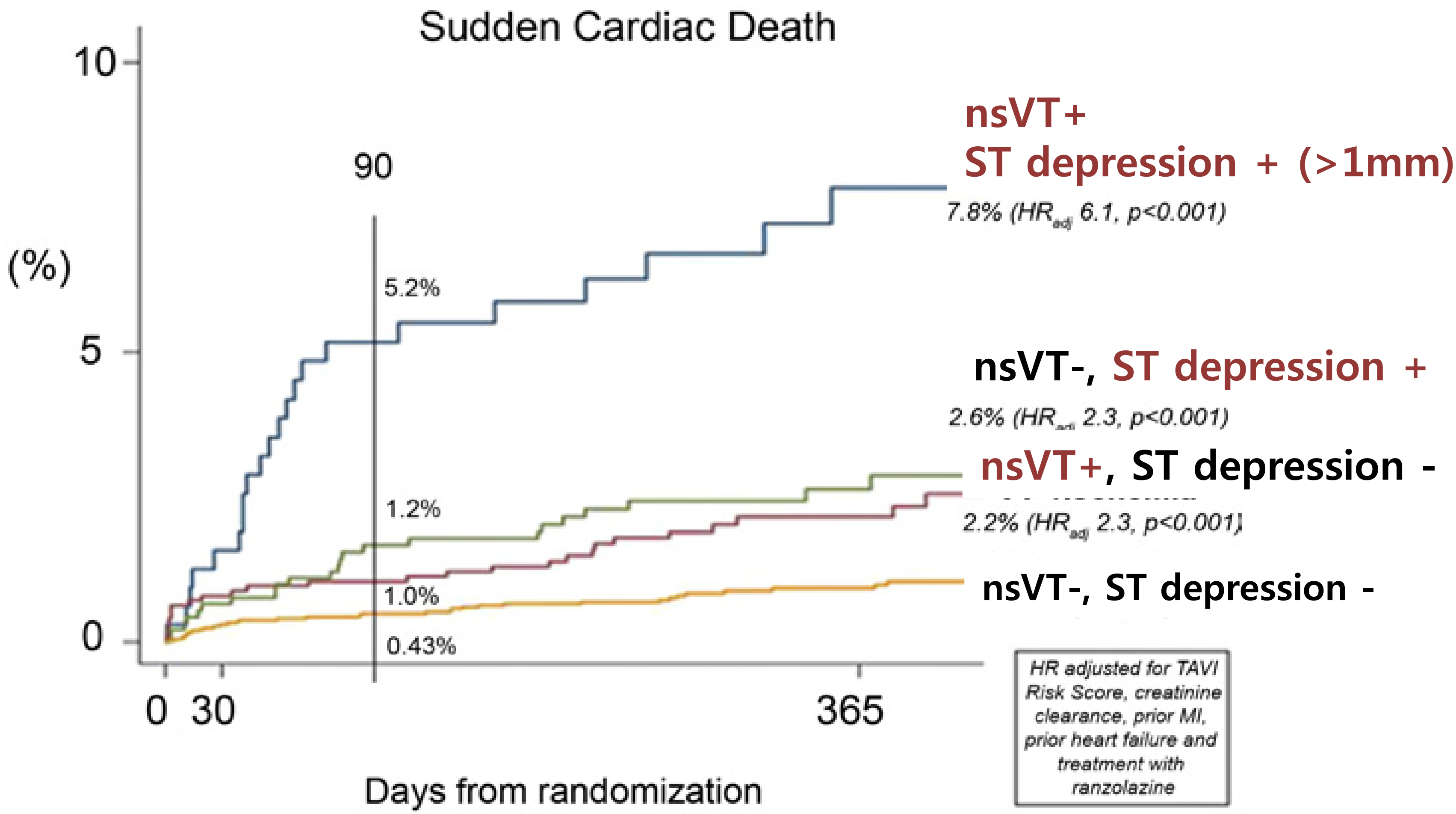
<10days	**>10days (post-CABG)**

J Am Coll Cardiol 2001;38:1156–62.

Circulation 2010;122:455–62.

J Cardiovasc Electrophysiol 2002;13:757–63.

nsVT & ST-depression
-in non-ST-elevation ACS-



Am J Cardiol 2011;108:1373–81.

Summary

- **Unexplained Syncope** can be **a harbinger of SCD**

Thank you for your attention!!

Guard Your Heart
above all else
For it determines the
course of your life .

--Proverbs 4: 23--