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Advances in the Remote Monitoring of the Cardiology Patient; Can we keep up?

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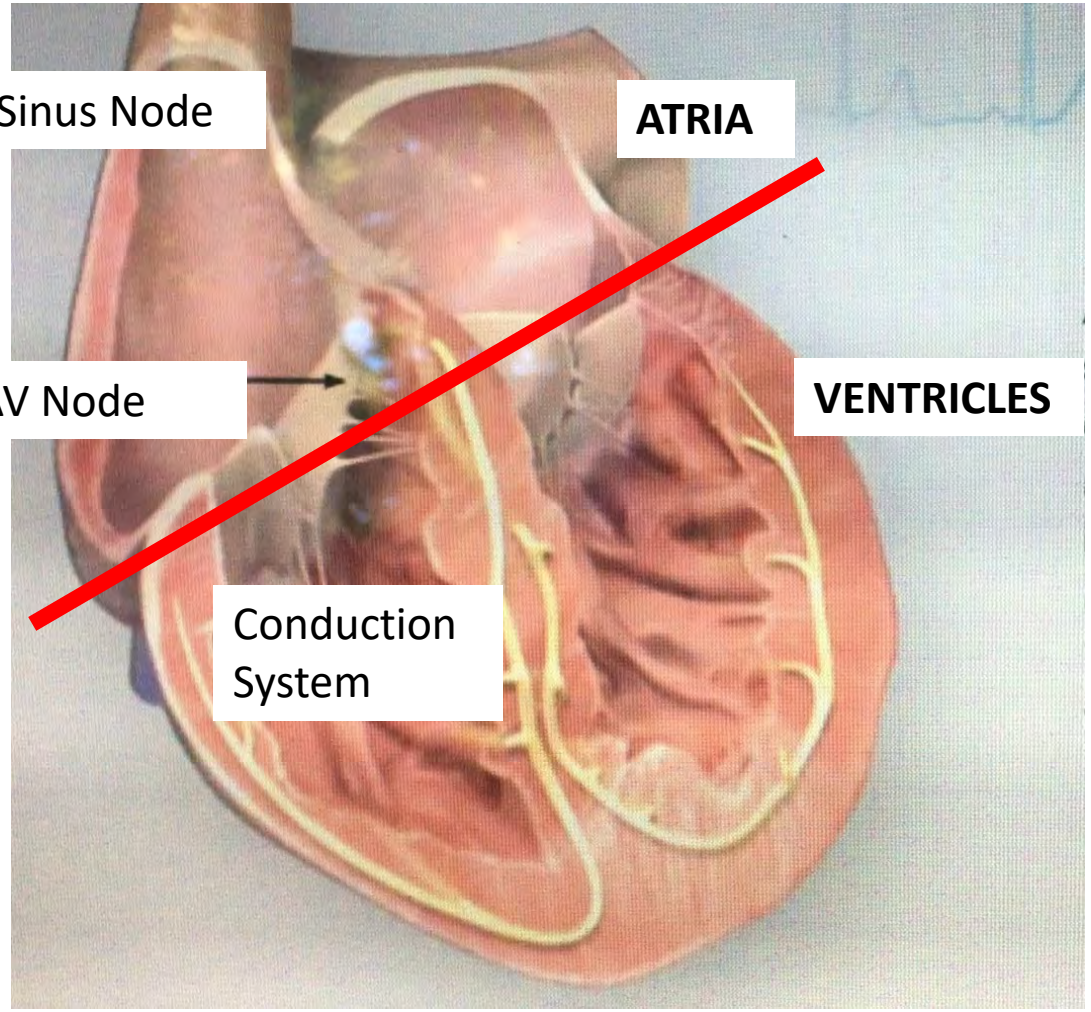
New York, NY, USA

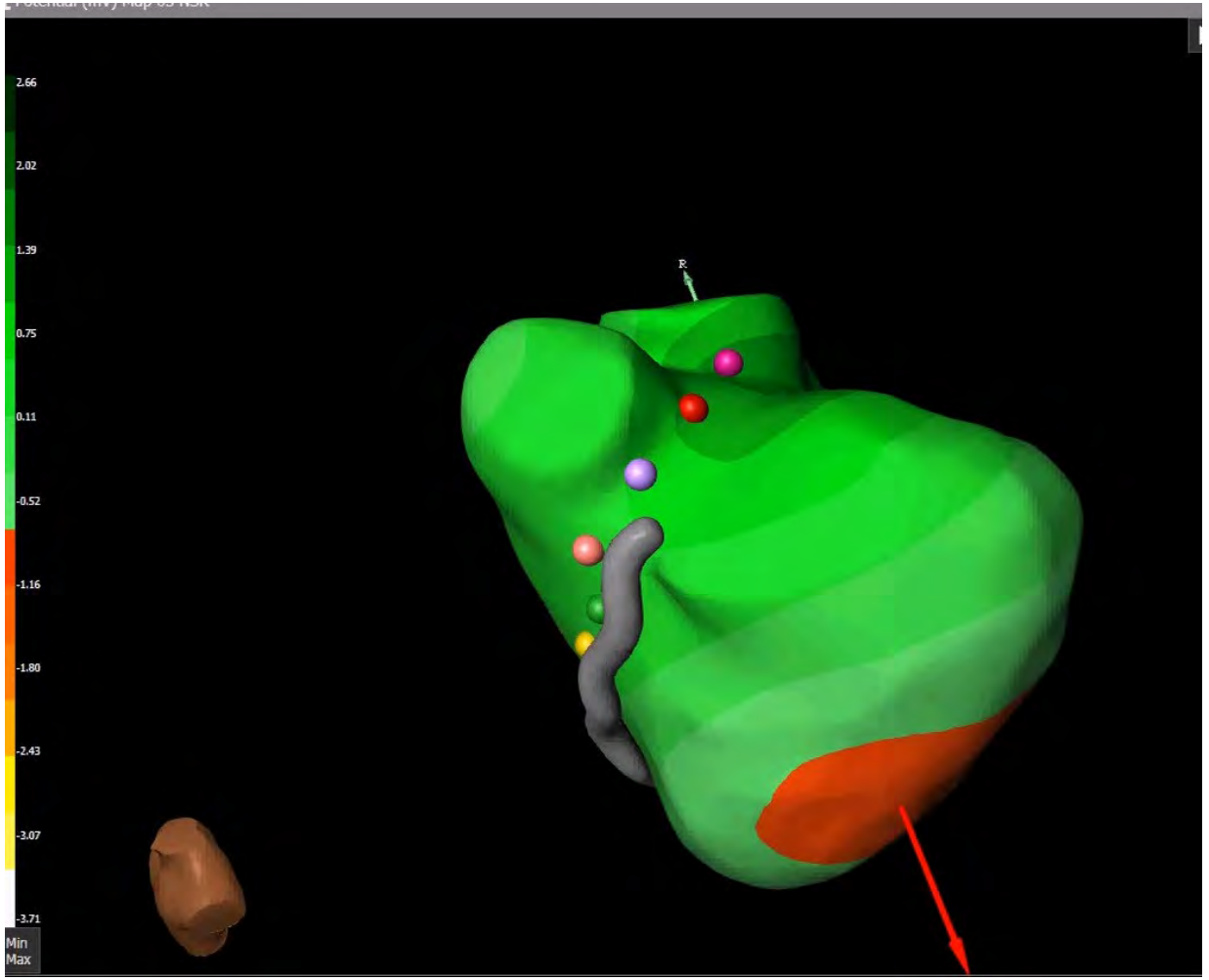
Outline

- What is cardiac electrophysiology?
- Why do we need to monitor remotely patients for heart rhythm abnormalities (arrhythmias)?
- How do we monitor patients for arrhythmias?
- What is happening in clinical practice?

What is Cardiac Electrophysiology?

- Branch of cardiology that specializes in heart rhythm disorders





What is Cardiac Electrophysiology?

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Branch of Cardiology that specializes in heart rhythm disorders

- Slow Rhythm – Bradycardia (heart rate <50)
  - Older patients
  - Might Require pacemaker
- Fast Rhythm – Tachycardia (heart rate >100)
  - Benign tachycardias in patients with normal hearts
  - Very serious tachycardias in patients with abnormal hearts
    - These patients might require a defibrillator
- Irregular Rhythm
  - Atrial fibrillation
  - Can cause a stroke

Symptoms related to Heart Rhythm Problems

- Fatigue
- Dizziness
- Decrease Exercise Tolerance
- Palpitations
- No Symptoms (silent)!
- Paroxysmal or episodic (come and go)

- **Fainting spells (syncope)**

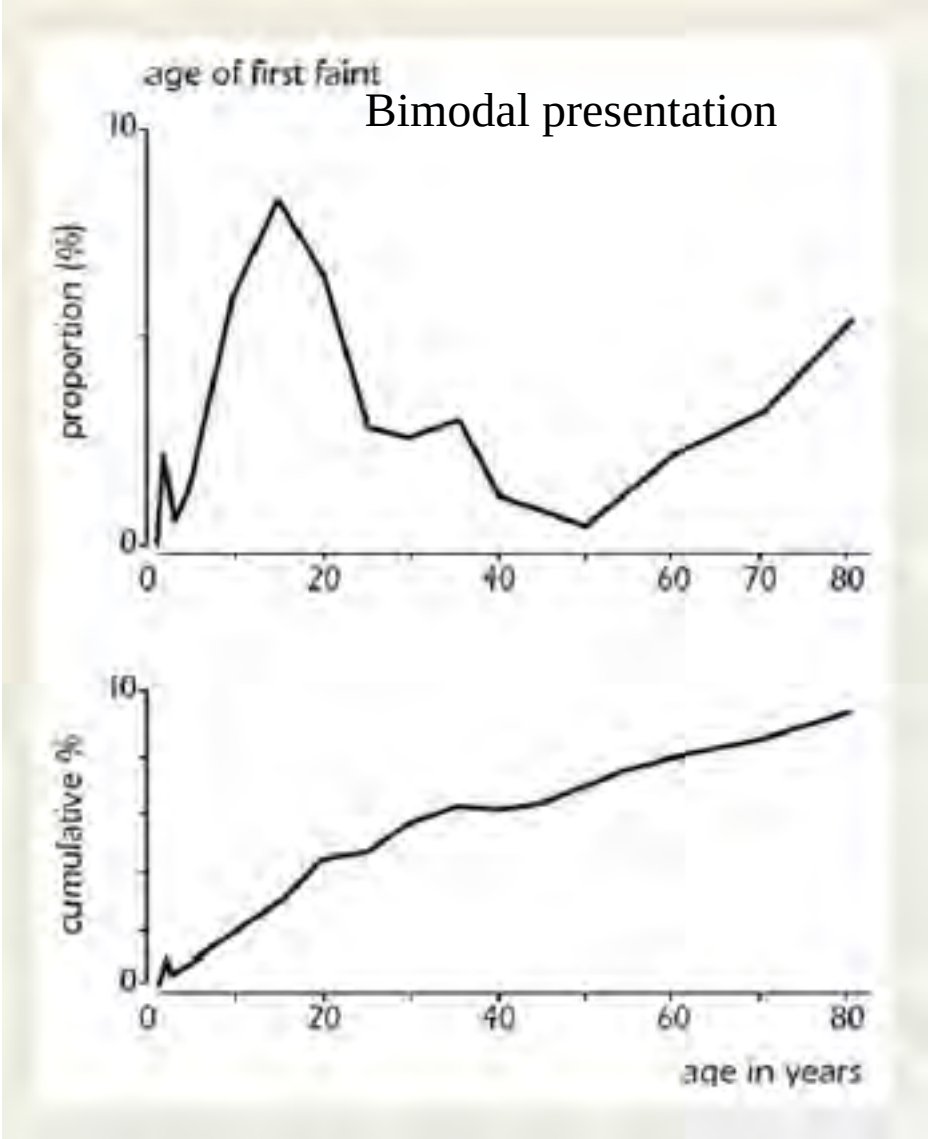
- **Stroke**

- **Sudden Death**

Who faints and when?

First Faint

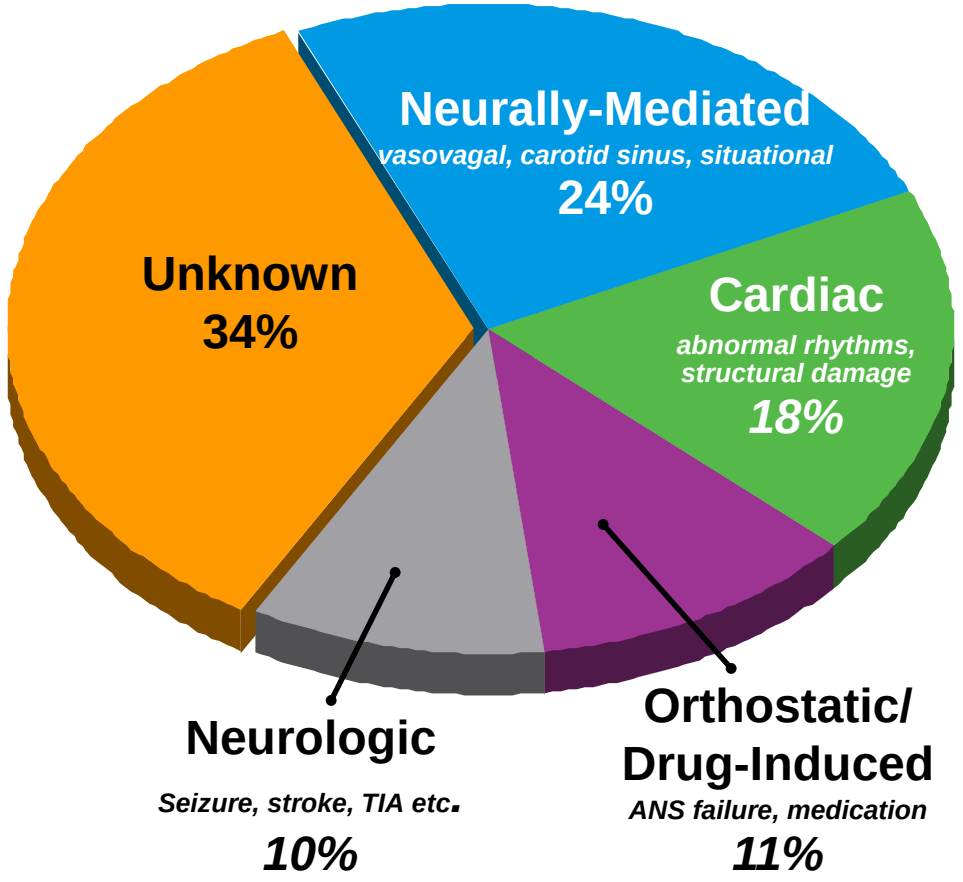
- **40% of the population will have at least one syncopal event**[1]
- **High prevalence of first faints in patients between 10 and 30 years of age with a peak of 47% in females and 31% in males.**
- **Syncope before 30 typically benign, after age of 50 carries worse prognosis**



ESC Task Force Guidelines for Diagnosis and Management of Syncope. Eur Heart Journal (2009) 30, 2631 – 2671.

Why do we faint?

- **Syncope remains unexplained in approximately 1/3 of cases**
- **Approximately half of patients admitted for syncope leave the hospital without a diagnosis[3]**
- **Unexplained Syncope + Cardiac Syncope = Over 50% of Patients**



Heart rhythm problems are the most common cause of cardiac syncope

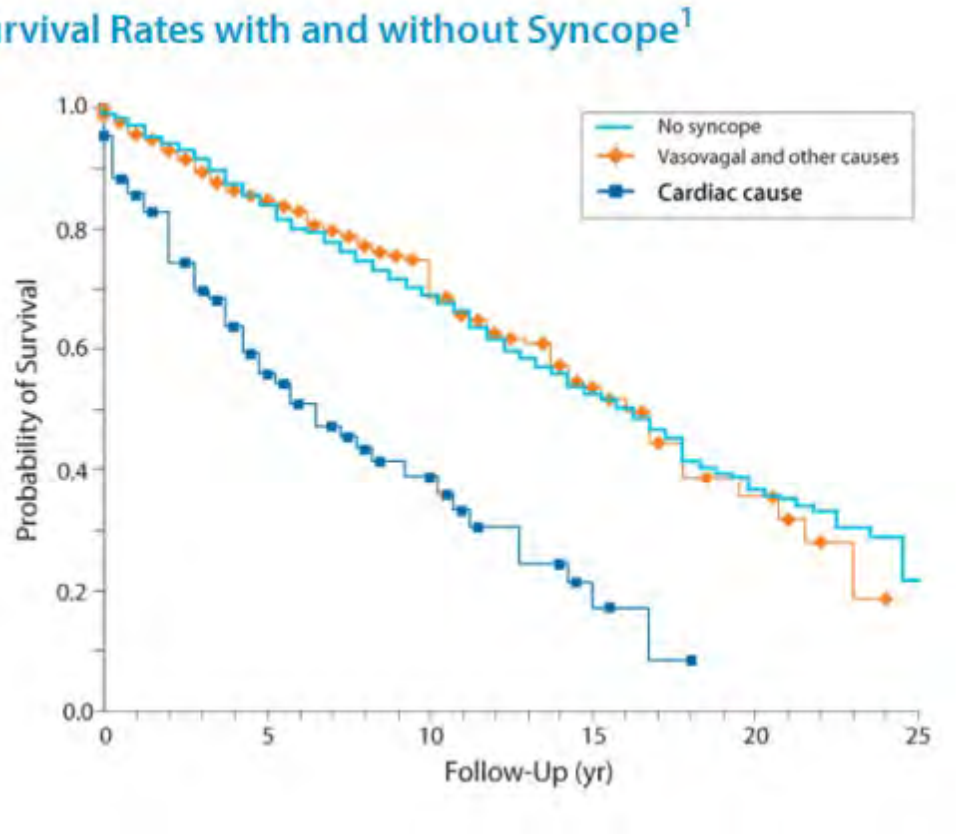
Linzer M, et al. Clinical Guideline: Diagnosing Syncope: Part 2: Unexplained Syncope. *Ann Intern Med*. 1997;126:989-996.

Is it Important why we faint?

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10% of patients who present to the ER with syncope will die within 1 year.

Messi L et al, Canadian Journal of Cardiology 2011



Survival Rates with and without Syncope

Higher mortality rates for patients with a cardiac cause for syncope

1. Soteriades ES, Evans JC, Larson MG, et al. Incidence and prognosis of syncope. *N Engl J Med.* September 19, 2002; 347(12):878-885.

How much evaluation of syncope cost?

- Estimated hospital costs exceeded $10 billion US[1]
- Estimated physician office expenses exceeded $470 million[2]
- Over $7 billion is spent annually in the US to treat falls in older adults[3]

[1]Kenny RA, Kapoor WN. In: Benditt D, et al. eds. *The Evaluation and Treatment of Syncope*. Futura;2003:23-27.
[2]OutPatientView v. 6.0. Solucient LLC, Evanston IL.
[3]Olshansky B. In: Grubb B and Olshansky B. eds. *Syncope: Mechanisms and Management*. Futura. 1998:15-71.

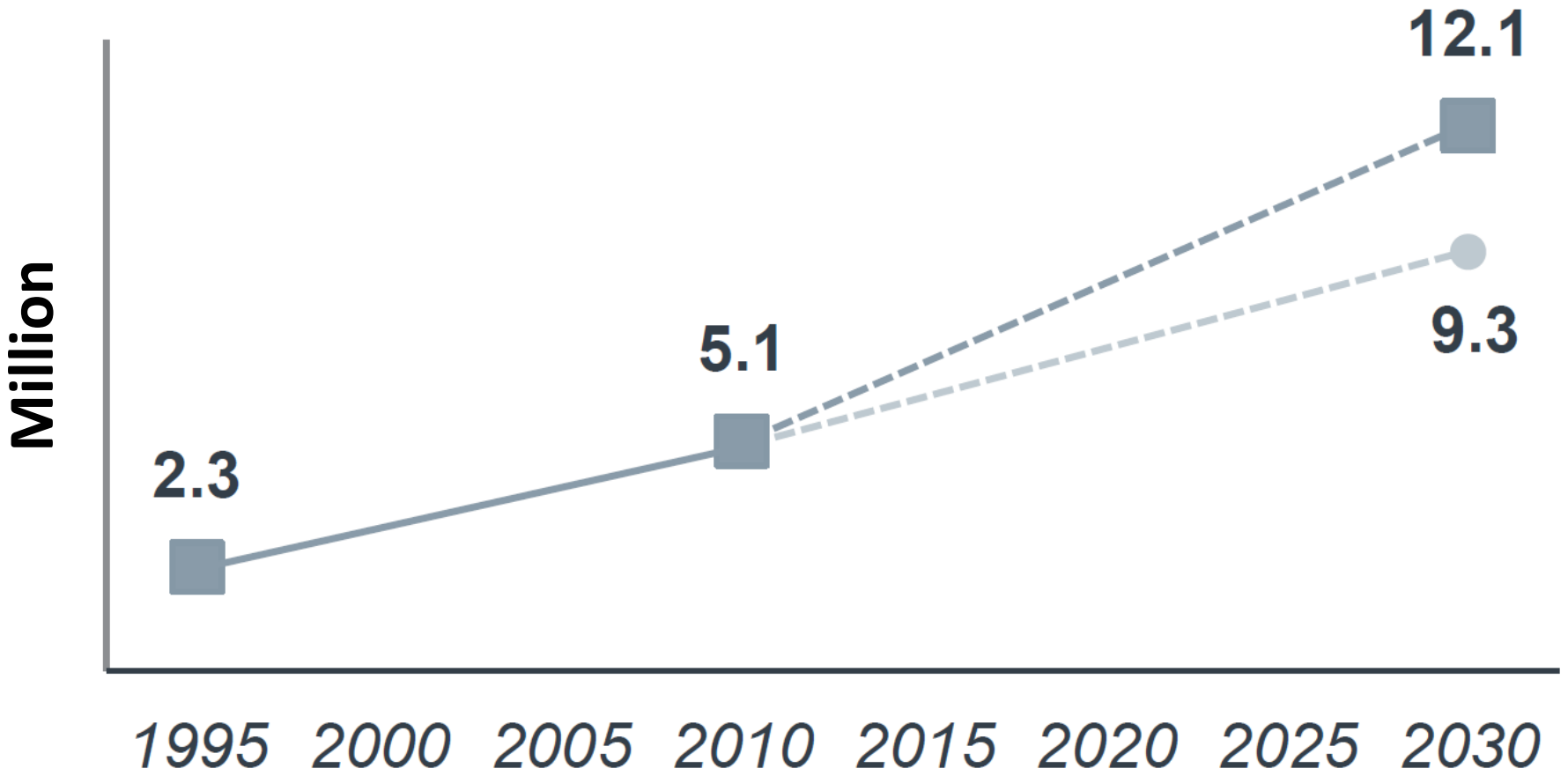
Atrial Fibrillation – A modern Epidemic

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- Irregular and fast rhythm from the upper cardiac chambers
- Most frequently diagnosed arrhythmia
- Incidence increases with age
- ¼ chance to have atrial fibrillation if >80y/o
- Cost of the treatment of atrial fibrillation > $10 billion per year

Atrial Fibrillation – A modern Epidemic

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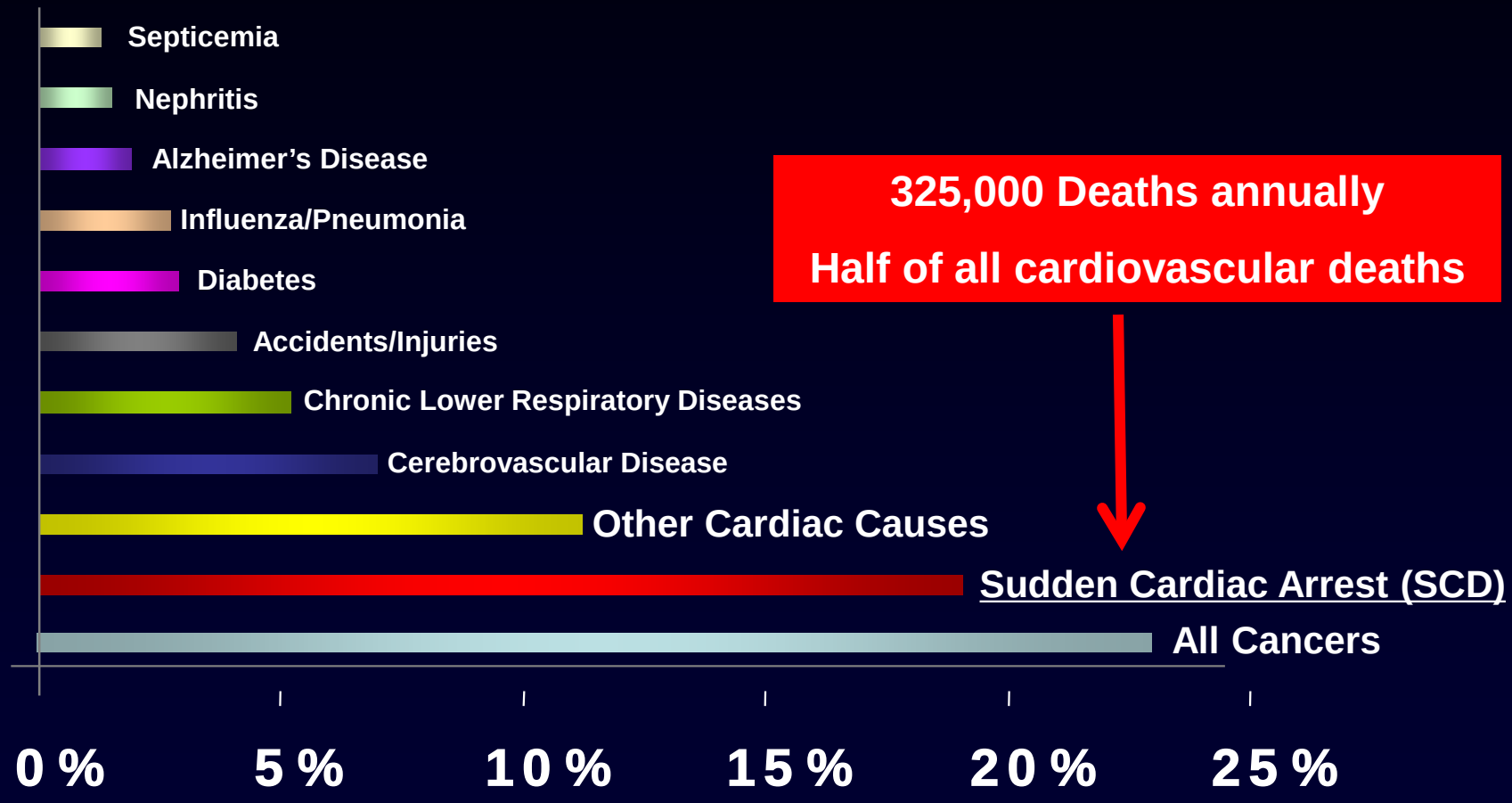


Atrial Fibrillation Morbidity and Mortality

- **Approximately five-fold risk of stroke[2]**
- **25% of acute strokes in the ER are related to atrial fibrillation**
- **Independent risk factor for heart failure**
- **Independent risk factor for all-cause mortality**

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Leading Causes of Death in the US



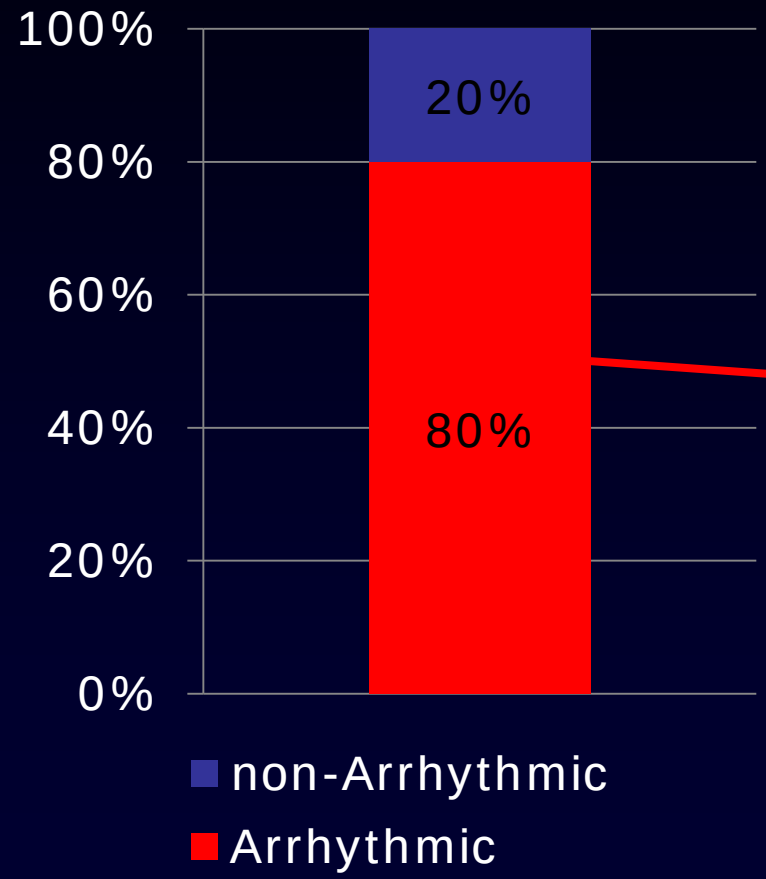
325,000 Deaths annually

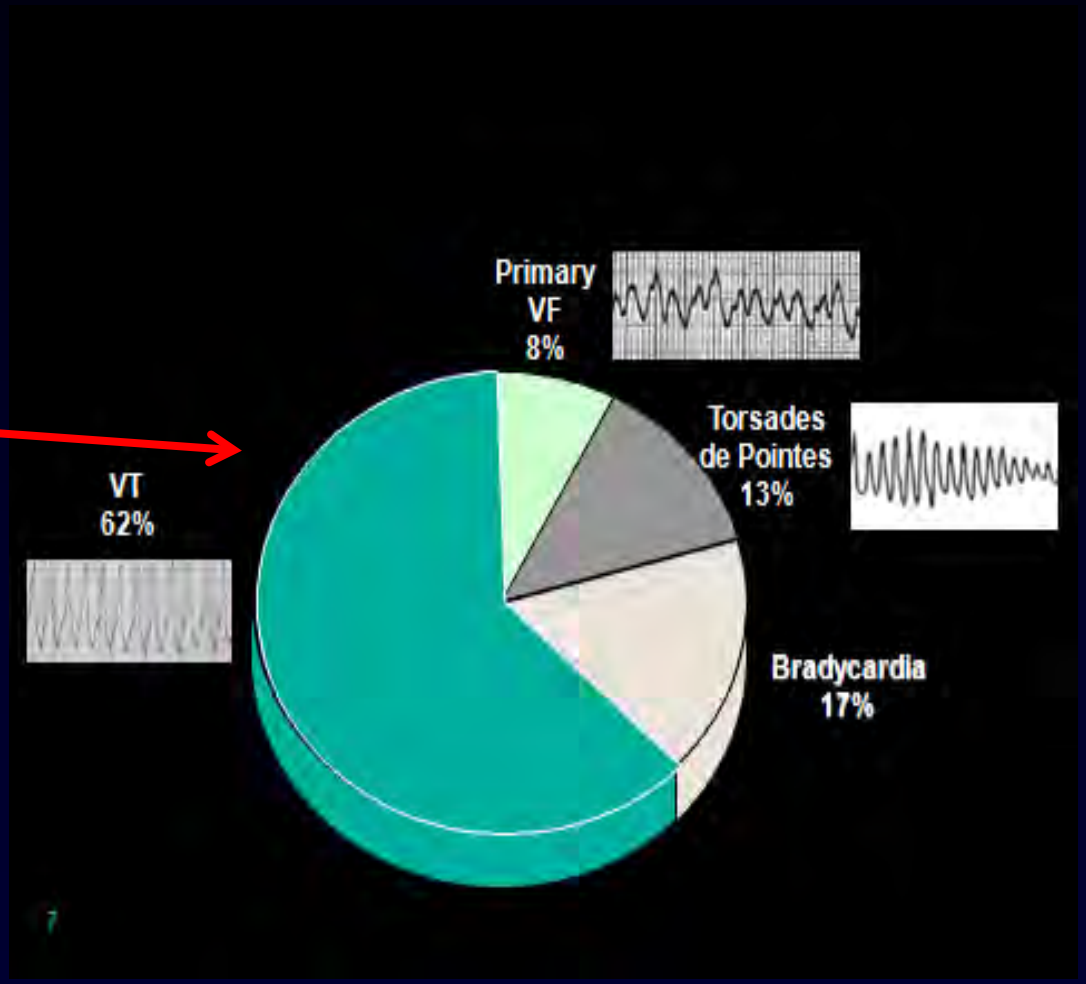
Half of all cardiovascular deaths

National Vital Statistics Report. 2001;49;11.
MMWR. 2002;51:123-126.

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Etiology of Sudden Cardiac Death





Why do we need to screen and monitor for heart rhythm problems?

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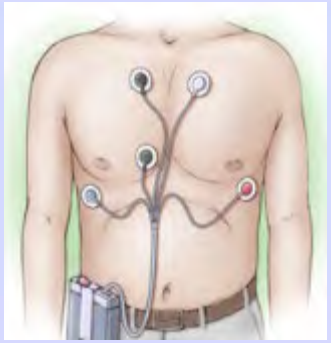
- Heart rhythm problems are very common
- Heart rhythm problems may occur only under certain circumstances
  - Outpatient heart rhythm monitoring is required for effective diagnosis
- Heart rhythm problems can be paroxysmal/episodic
  - Doctor visits typically are not enough to diagnose the problem
  - The longer the monitoring the higher the chance of diagnosis
- Some heart rhythm problems can lead to serious conditions including fainting, stroke and death
  - Immediate notification of the treating physician is often necessary

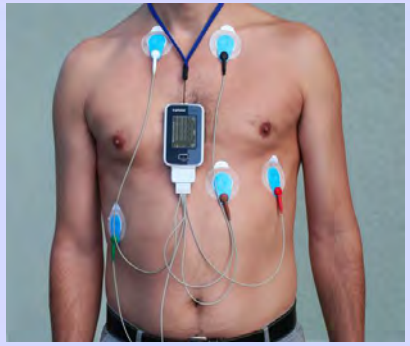
Methods to diagnose a Heart Rhythm Problem

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ECG | Holter | Short term (Event) | Implantable Monitors | Watches











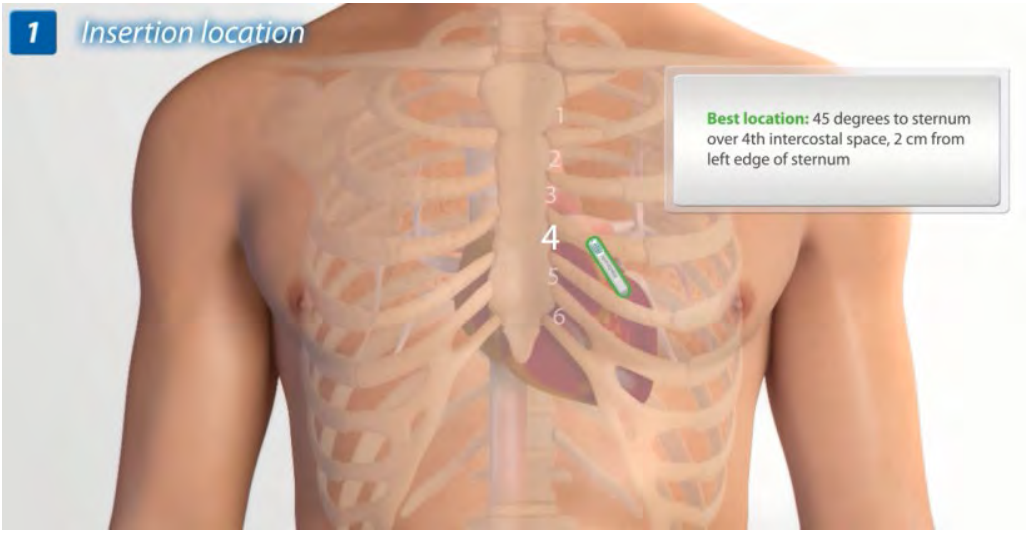
10 secs | *24-72 hrs* | *2-4 weeks* | *> 3 years* | *Indefinitely...*

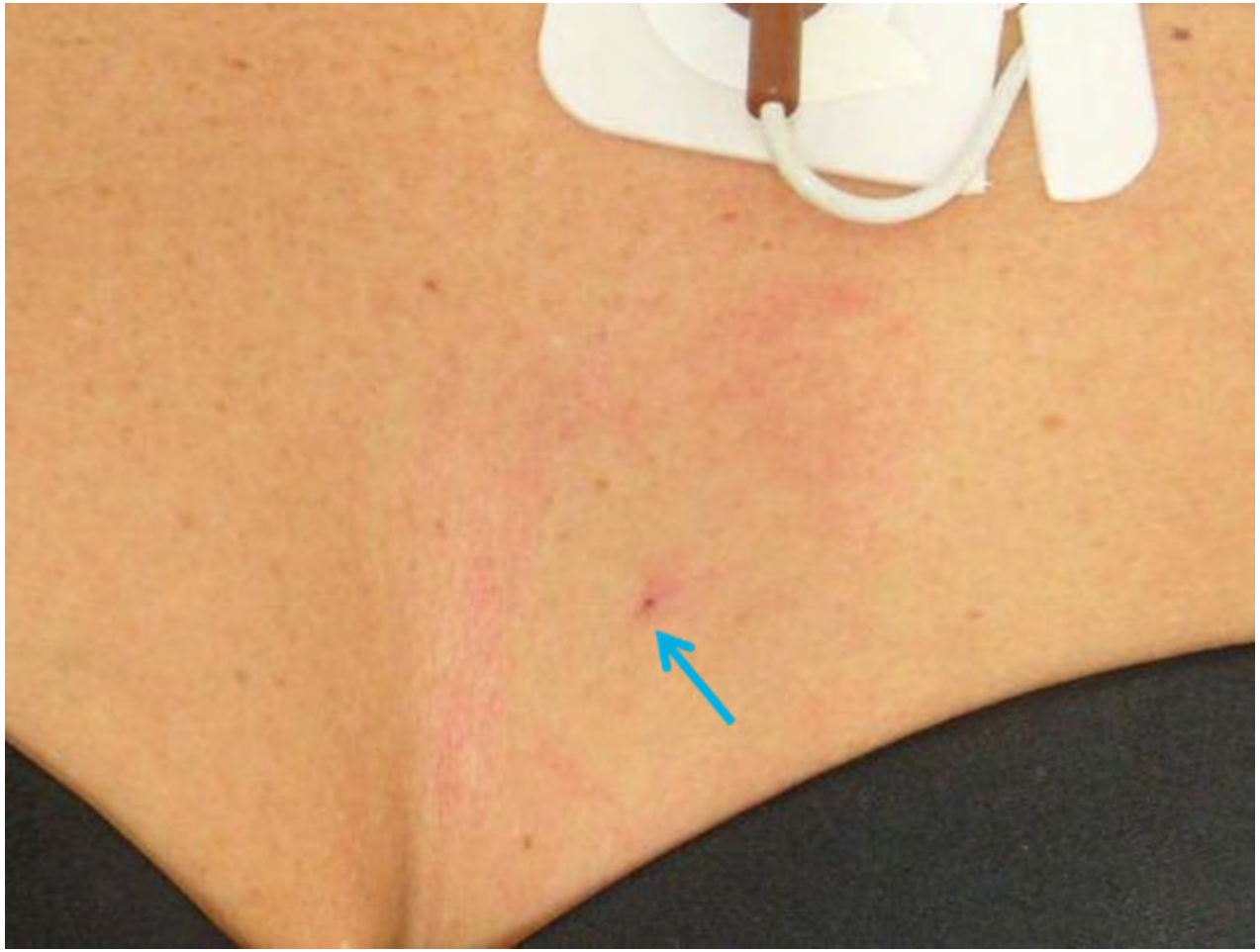
Patient Symptoms

Implantable Loop Recorders

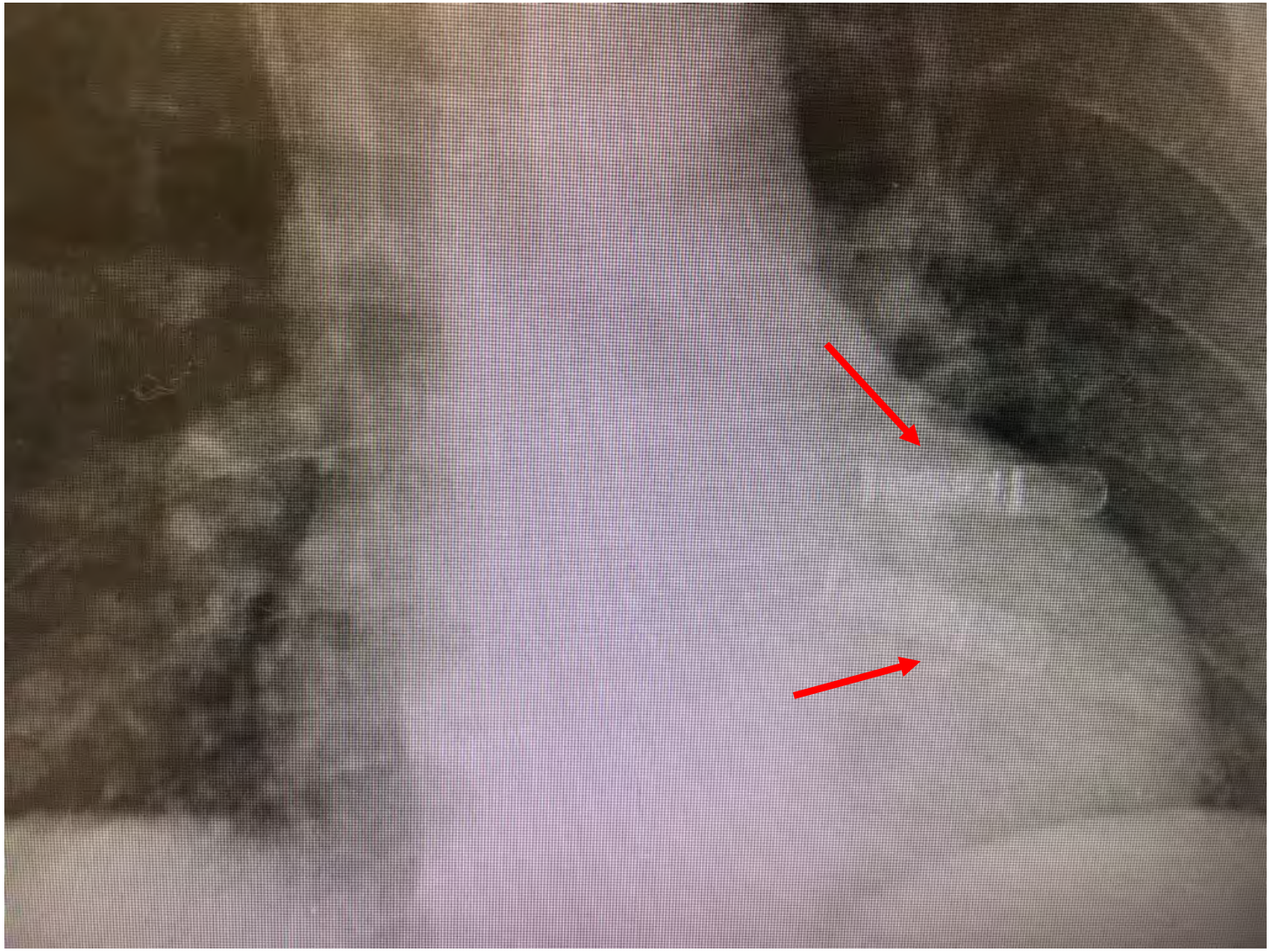
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Easy to implant, hard to detect…



“Diagnosing” Unexplained Syncope with Implantable Loop Recorder

PICTURE: Registry on 570patient found that syncope patients…

- Moved from specialist to specialist without answers and saw an average of 3 specialists
- Had a median of 13 inconclusive tests before a implantable monitor was implanted
- 70% were hospitalized at least once for syncope and of those, one third experienced significant trauma
- Implantable Recorder Guides Diagnosis in 78% of Patients with a Recurrent Syncopal Event **(f/u 10 ± 6 months)**
- 75% of diagnosis required cardiac intervention

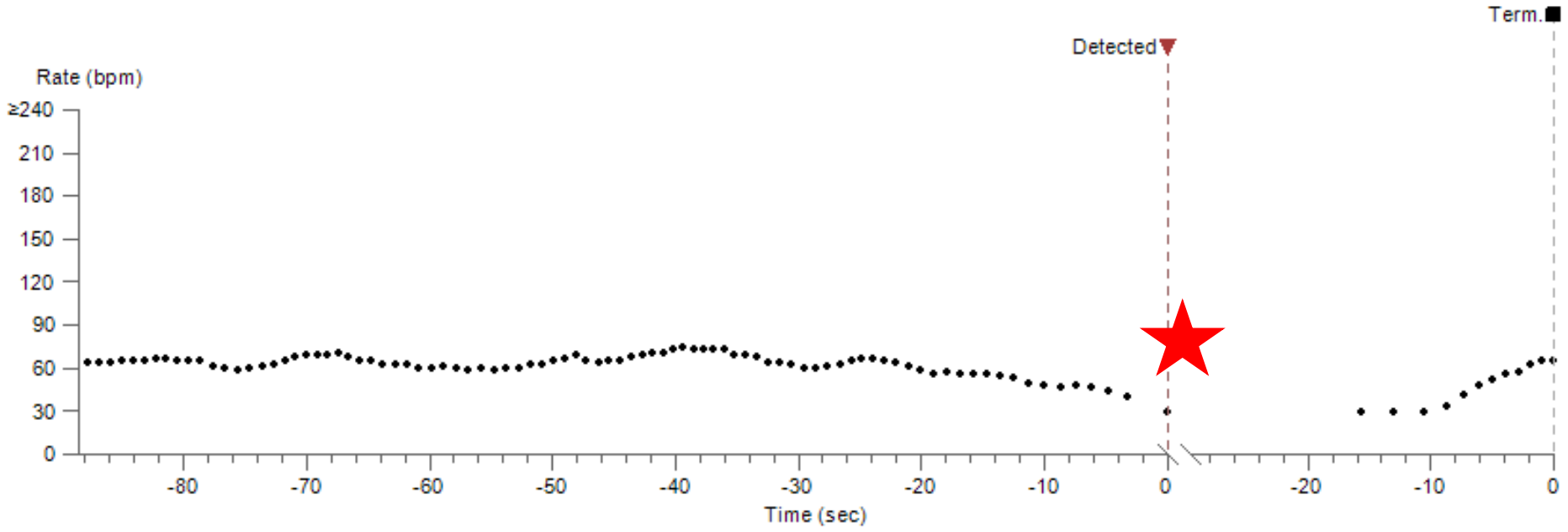
Edvardsson N, Frykman V, van Mechelin R, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: Results from the PICTURE registry. *Europace*. February 2011;13(2):262-269.

74y/o with recurrent unexplained traumatic syncope and negative cardiac and neurological work up



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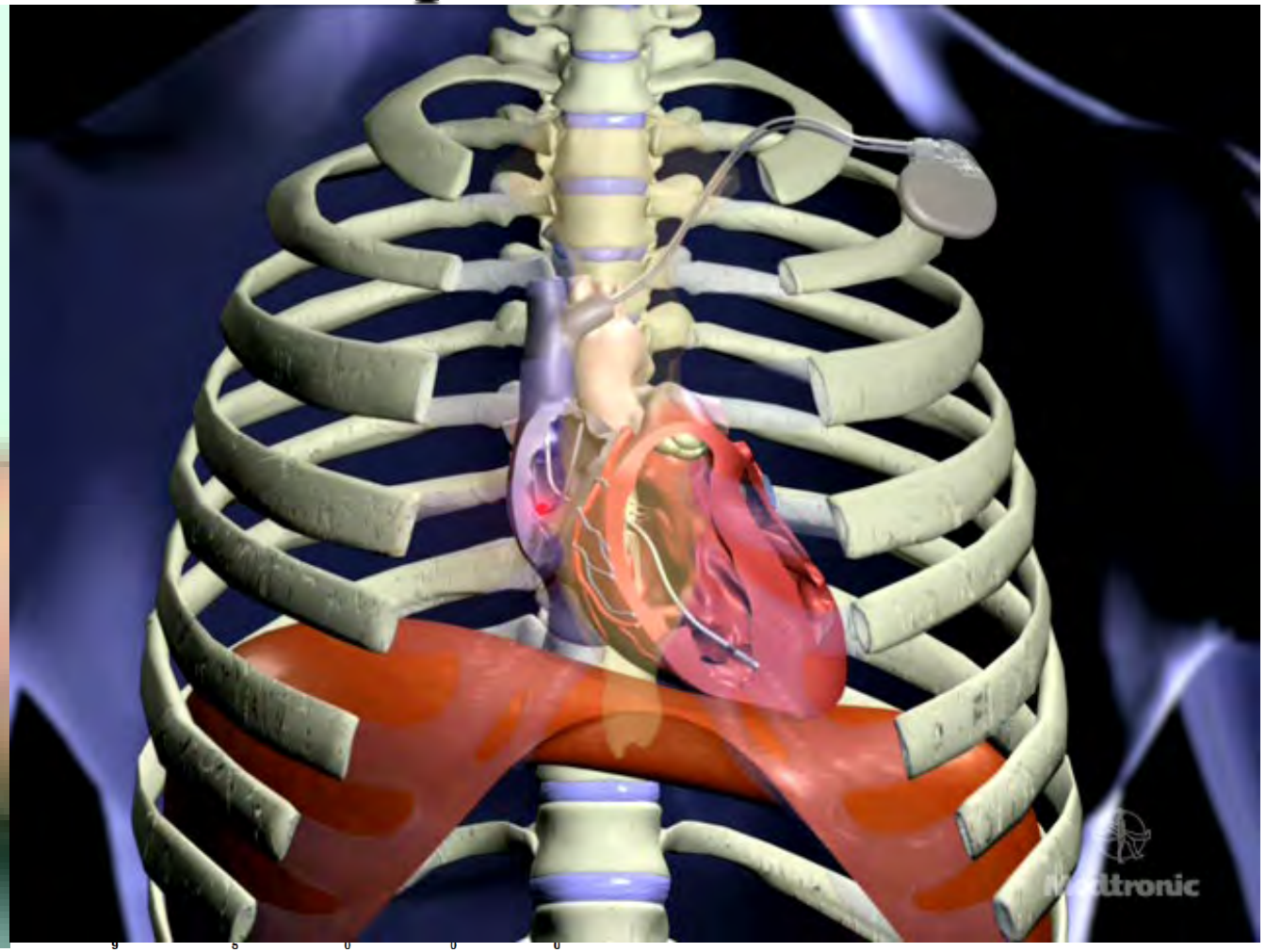
74y/o with recurrent unexplained traumatic syncope and negative cardiac and neurological work up



74y/o with recurrent unexplained syncope and negative cardiac and neurological work up

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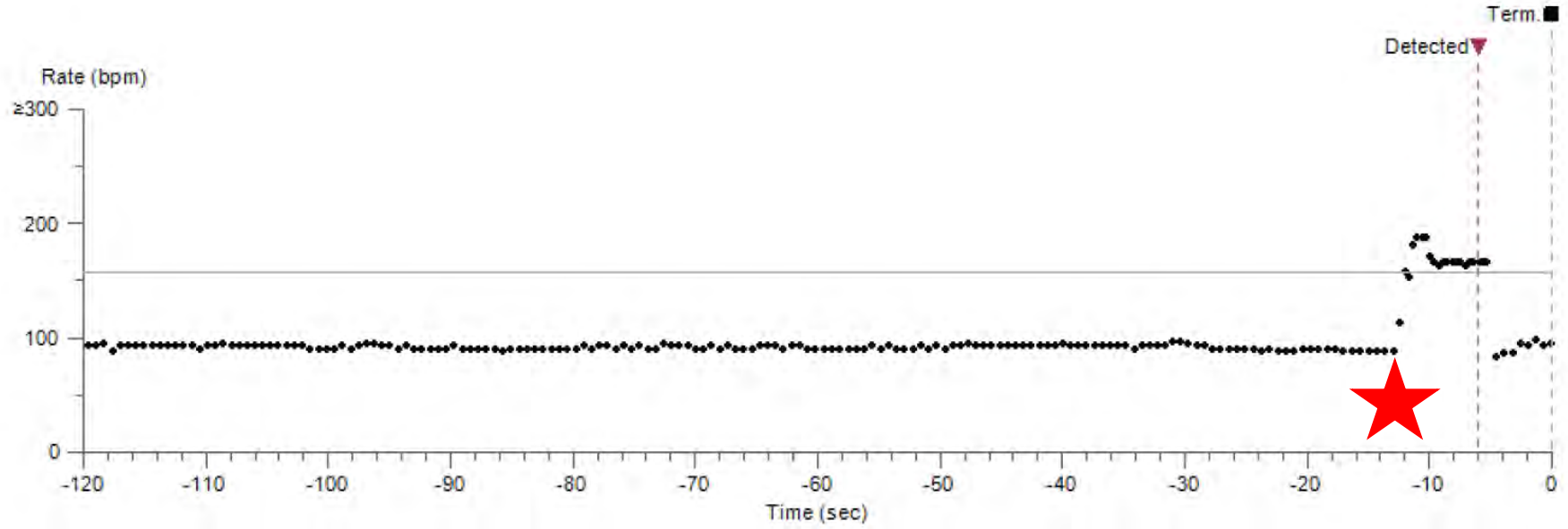


69y/o female with history of myocardial infarction and recurrent palpitations and syncope



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69y/o female with history of myocardial infarction and recurrent palpitations and syncope



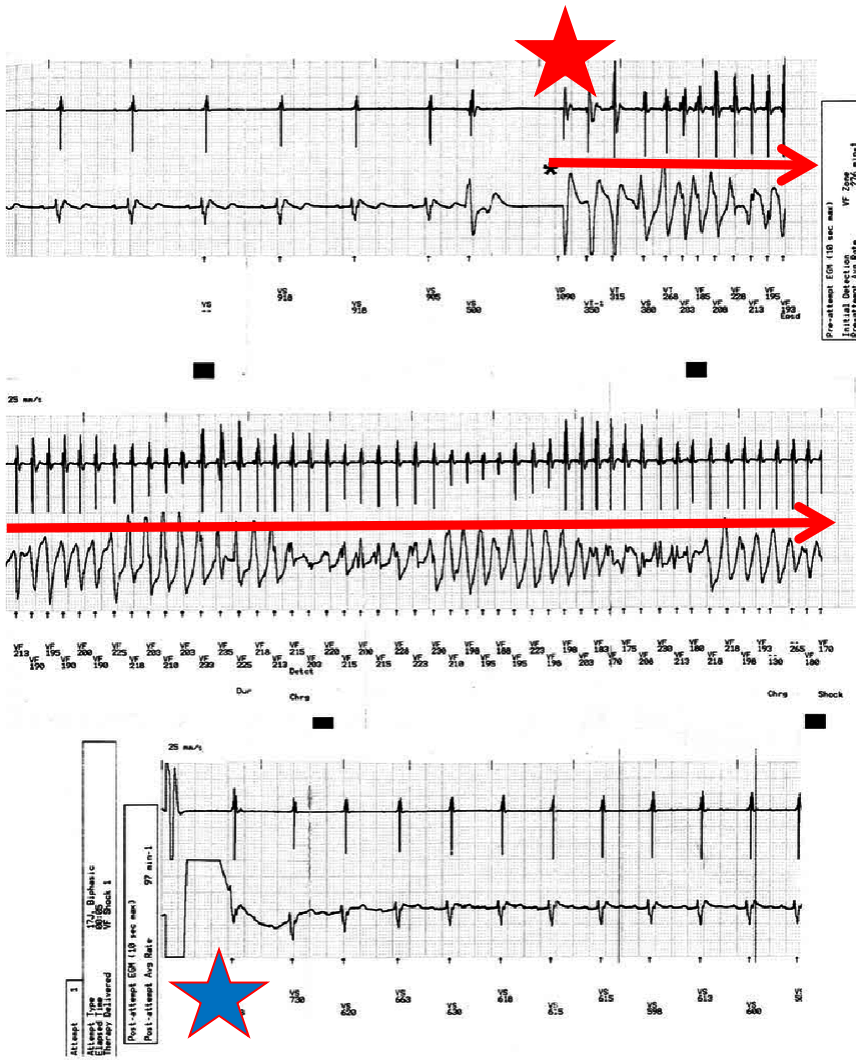
ID#	Type	Date	Detected hh:mm	Duration hh:mm:ss	Max V. Rate	Median V. Rate
7	Tachy	16-Jun-2014	18:42	00:00:06	167 bpm	167 bpm

69y/o female with history of myocardial infarction and recurrent palpitations and syncope

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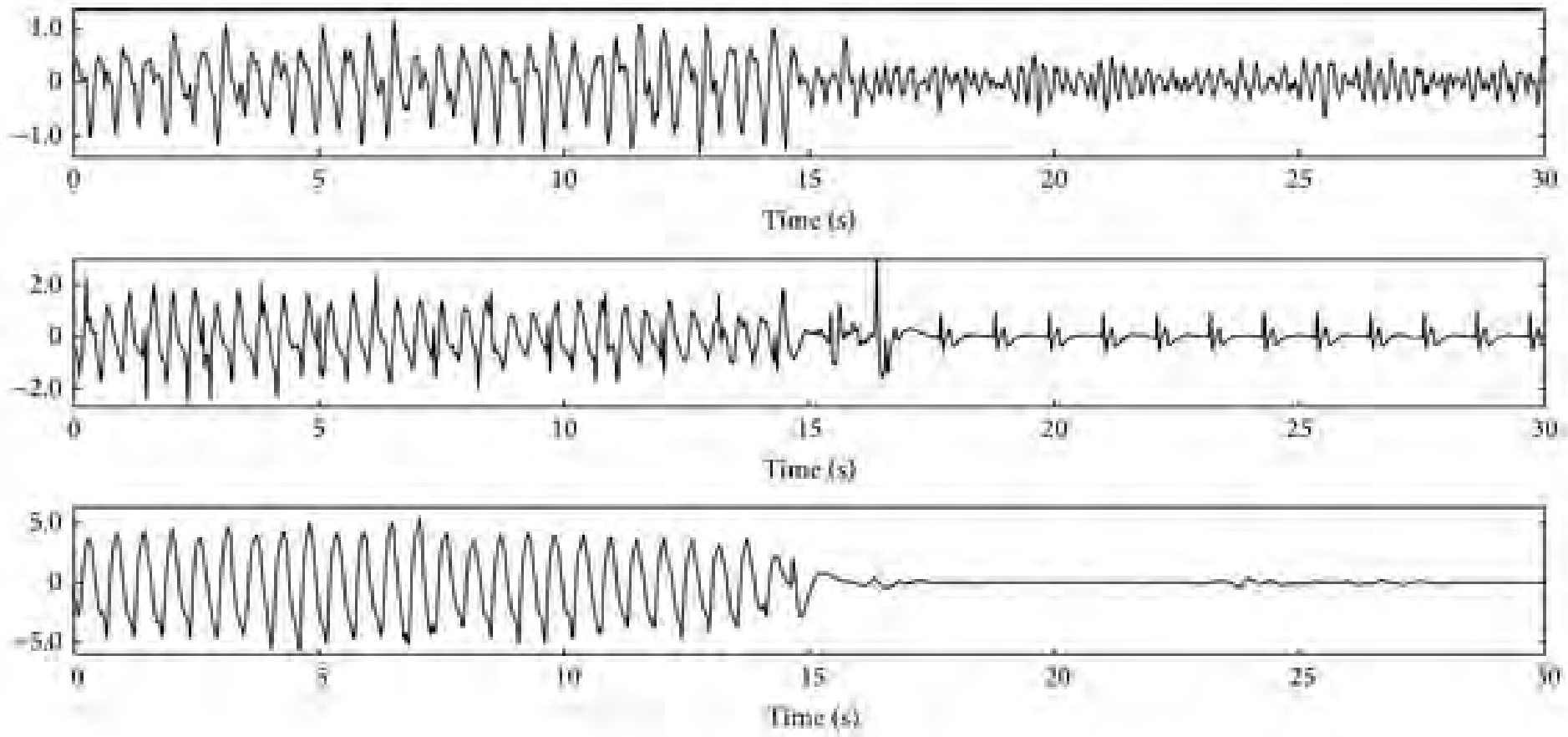


How does “sudden death” looks like to a defibrillation (ICD)?



What happens to ventricular fibrillation if untreated…

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Sudden Cardiac Death from a patient's perspective



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Warning Symptoms of Sudden Death



How do we follow devices during an office visit?

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How do we follow devices remotely?

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My weekly homework…

Medtronic **Quick Look II**

Remaining Longevity 8.7 years (13-Mar-2019)

RRT > 5 years

(based on initial interrogation)

	Atrial(4076)	RV(6935M)
Pacing Impedance	456 ohms	456 ohms
Defibrillation Impedance		RV=63 ohms
Capture Threshold	0.625 V @ 0.40 ms	0.375 V @ 0.40 ms
Measured On	13-Mar-2019	13-Mar-2019
Programmed Amplitude/Pulse Width	1.50 V / 0.40 ms	2.00 V / 0.40 ms
Measured P/ R Wave	3.0 mV	6.9 mV
Programmed Sensitivity	0.30 mV	0.30 mV

Parameter Summary

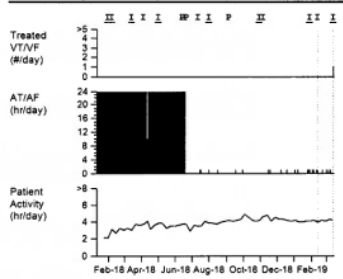
Mode	AAI<=>DDD	Lower Rate	70 bpm	Paced AV	340 ms
Mode Switch	171 bpm	Upper Track	120 bpm	Sensed AV	350 ms
		Upper Sensor	120 bpm		

Detection		Rates	Therapies
AT/AF	Monitor	>171 bpm	All Rx Off
VF	On	>188 bpm	ATP During Charging, 35J x 6
FVT	via VF	188-222 bpm	Burst(3), 35J x 5
VT	OFF		All Rx Off

Enhancements On: AF/Afl, Sinus Tach, Wavelet, TWave, Noise

Clinical Status	Since 13-Feb-2019
Treated	
VF	1
FVT	0
VT (Off)	
AT/AF(Monitor)	
Monitored	
VT (Off)	
VT-NS (>4 beats, >188 bpm)	0
High Rate-NS	1
SVT: VT/VF Rx Withheld	0
V. Oversensing-TWave Rx Withheld	0
V. Oversensing-Noise Rx Withheld	0
AT/AF	0
Time in AT/AF	<0.1 hr/day (<0.1%)
Functional	**Last Week**
Patient Activity	4.2 hr/day

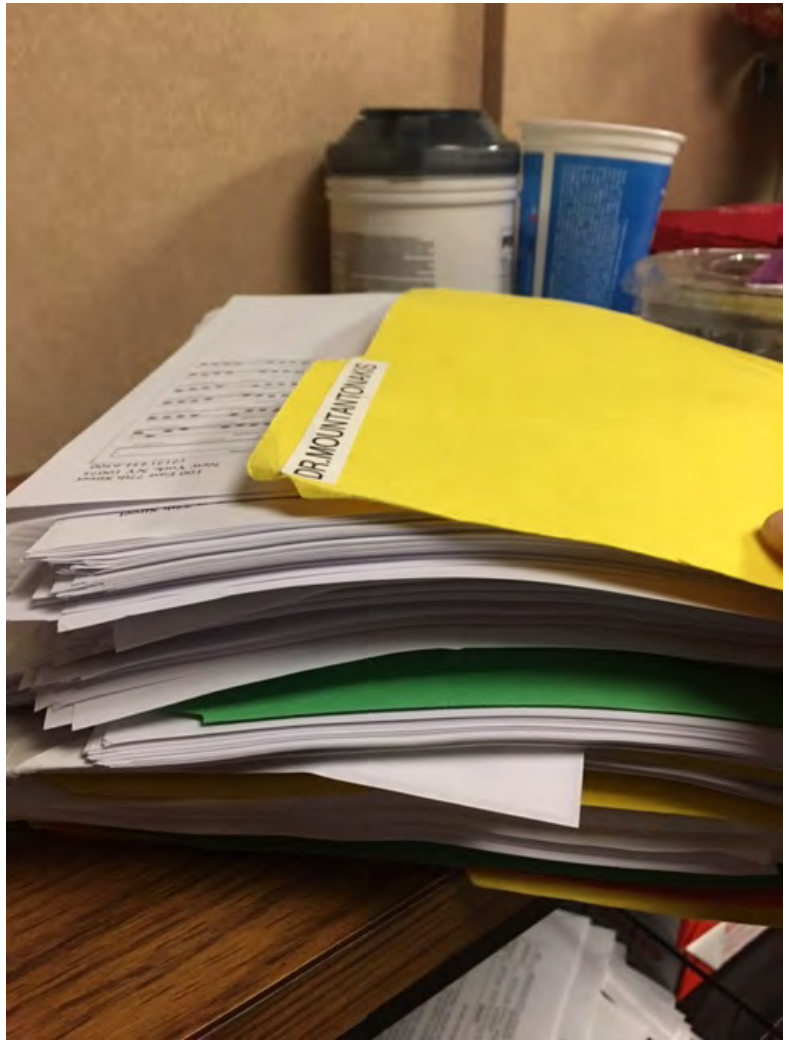
Cardiac Compass Trends (Jan-2018 to Mar-2019)



Therapy Summary	VT/VF	AT/AF	Pacing	(% of Time Since 13-Feb-2019)
Pace-Terminated Episodes	0	0	Total VP	6.0% (MVP On)
Shock-Terminated Episodes	1 of 1	0	AS-VS	68.9%
Total Shocks	1	0	AS-VP	5.4%
Aborted Charges	0	0	AP-VS	25.2%
			AP-VP	0.5%

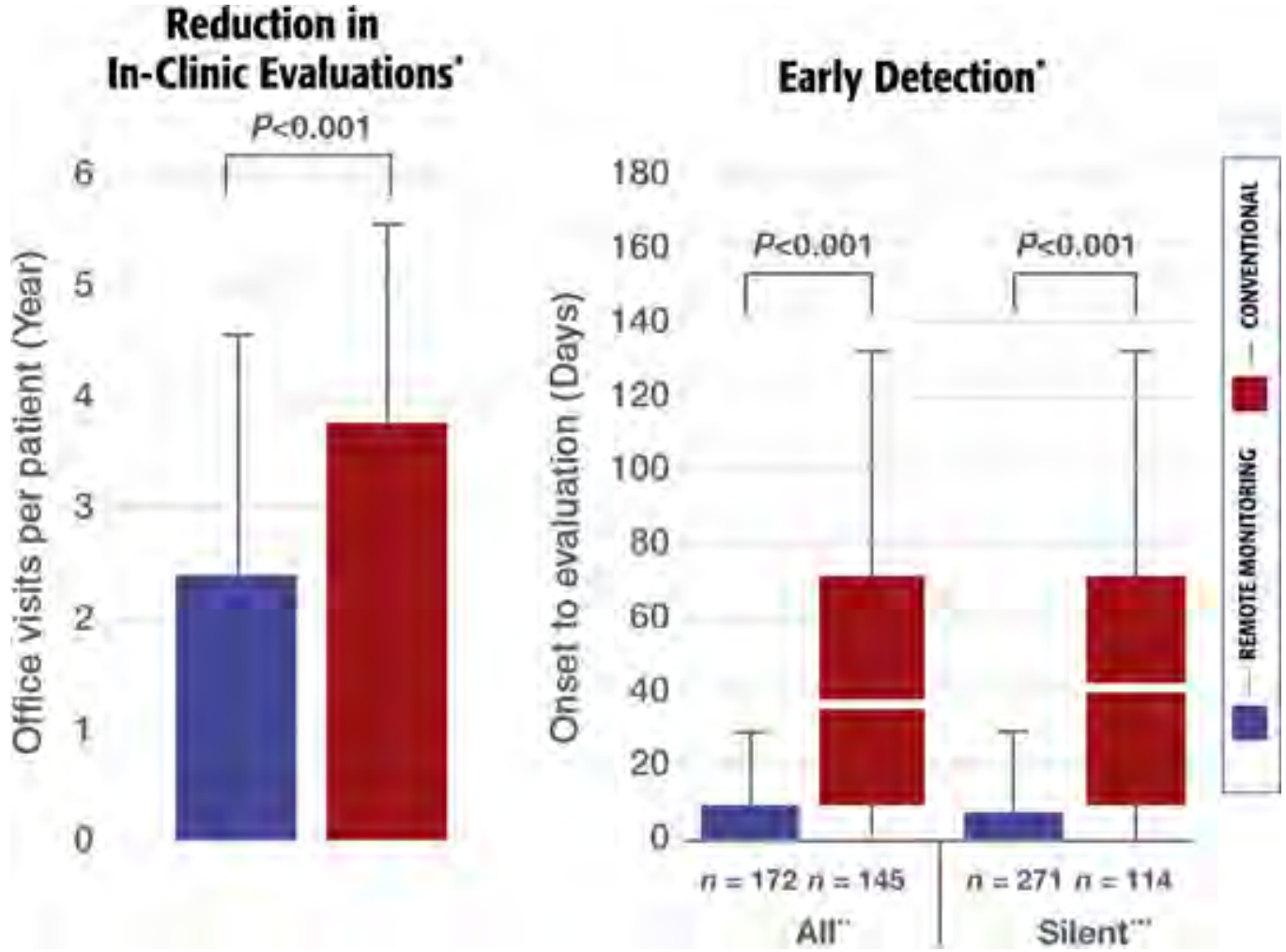
Medtronic CareLink Network Confidential Patient Information 13-Mar-2019 21:17:34

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Remote monitoring decreases number of office/hospital visits and improves outcomes

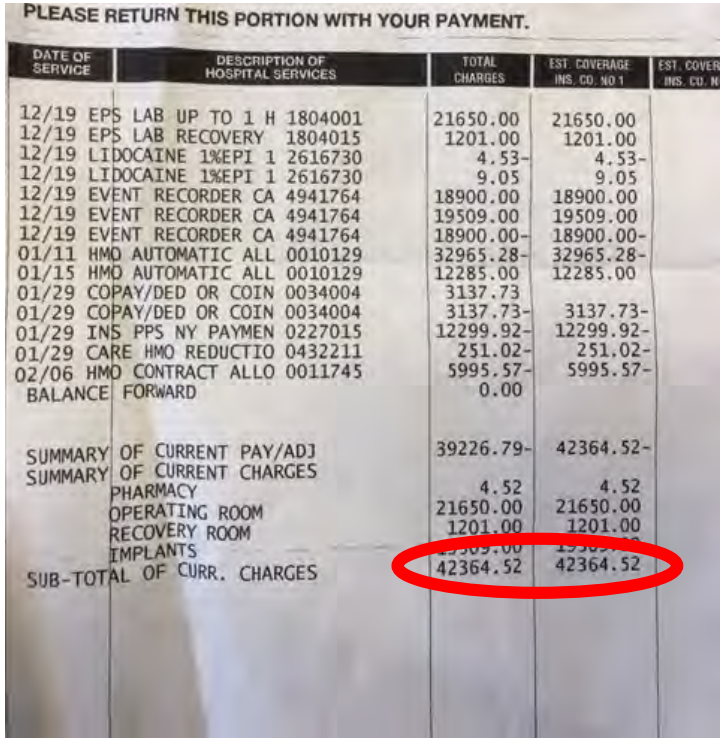
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How is reimbursement for remote monitoring?

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Implantation of Monitor



PLEASE RETURN THIS PORTION WITH YOUR PAYMENT.

DATE OF SERVICE	DESCRIPTION OF HOSPITAL SERVICES	TOTAL CHARGES	EST. COVERAGE INS. CO. NO 1	EST. COVER INS. CO. N
12/19	EPS LAB UP TO 1 H 1804001	21650.00	21650.00	
12/19	EPS LAB RECOVERY 1804015	1201.00	1201.00	
12/19	LIDOCAINE 1%EPI 1 2616730	4.53-	4.53-	
12/19	LIDOCAINE 1%EPI 1 2616730	9.05	9.05	
12/19	EVENT RECORDER CA 4941764	18900.00	18900.00	
12/19	EVENT RECORDER CA 4941764	19509.00	19509.00	
12/19	EVENT RECORDER CA 4941764	18900.00-	18900.00-	
01/11	HMO AUTOMATIC ALL 0010129	32965.28-	32965.28-	
01/15	HMO AUTOMATIC ALL 0010129	12285.00	12285.00	
01/29	COPAY/DED OR COIN 0034004	3137.73		
01/29	COPAY/DED OR COIN 0034004	3137.73-	3137.73-	
01/29	INS PPS NY PAYMEN 0227015	12299.92-	12299.92-	
01/29	CARE HMO REDUCTIO 0432211	251.02-	251.02-	
02/06	HMO CONTRACT ALLO 0011745	5995.57-	5995.57-	
BALANCE	FORWARD	0.00		
SUMMARY	OF CURRENT PAY/ADJ	39226.79-	42364.52-	
SUMMARY	OF CURRENT CHARGES			
	PHARMACY	4.52	4.52	
	OPERATING ROOM	21650.00	21650.00	
	RECOVERY ROOM	1201.00	1201.00	
	IMPLANTS	[illegible]	[illegible]	
SUB-TOTAL	OF CURR. CHARGES	42364.52	42364.52	

Follow Up of an Implantable Loop Recorder

- Hospital fee :$1,000
- Physician Interpretation: $100
- Approved Medicare Frequency: Monthly

What percentage of implantable monitors are followed remotely currently?

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Number of	Nationwide Numbers
Monitors implanted per year	100,000
Monitors currently implanted and active	300,000
Implantable monitors are followed remotely	50,000
Percentage of implantable monitors followed remotely	17%

Companies in the space of remote monitoring

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- Carelink - Medtronic
- Merlin - St Jude
- Boston Scientific - LATITUDE
- Biotronik
- ZioPatch
- Biotel
- Lifewatch
- Ambucor
- Geneeva
- TACTIO
- QardioMD
- Telehealth
- Vivify
- And many more….

Where does liability start?

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Where does liability start?

- Not setting up remote monitoring at all?
- Not confirming appropriate function of the transmitter?
  - Wrong place
  - Loss of power
  - Malfunctioning of the transmitting device
- Not identifying correctly “urgent alerts”
- Not checking the website often enough to review events?
  - How often is good enough?
- Not reviewing the printed transmissions sitting on my desk soon enough?
- Not informing the patient promptly?

Cases we have seen so far…

- Device was implanted but remote monitoring was not
  - Patient presents in the ER with stroke and interrogation of implantable monitor has recorded atrial fibrillation for days prior to the stroke
  - Patient presents to the ER after traumatic falls and interrogation shows multiple episodes or bradycardia
  - Patient dies and interrogation shows episodes of device malfunction or serious arrhythmias that could have been treated
- Remote monitoring was set up but was inactive
- Remote monitoring was set up but alert came to the office too late
- Remote monitoring was set up but the doctor was too busy to review transmissions on time

Guidelines for Remote monitoring (RM) of ICDs

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- A strategy of remote monitoring and interrogation, combined with at least annual in-person examination, is recommended over a calendar-based schedule of in-person CIED evaluation alone (**when technically feasible**).
- All patients with CIEDs **should be offered** RM as part of the standard follow-up management strategy.
- Before implementing RM, it is recommended that **each patient be educated** about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.
- It is recommended that RM programs **develop and document appropriate policies** and procedures to govern program operations, the roles and responsibilities of those involved in the program, and the expected timelines for providing service.

Slotwiner, Heart Rhythm 2015

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Do patients feel safer with remote monitoring?



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Thoughts after surviving death…



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Thank you!