

DEVICE RECALLS: The Era of Regulation and Outcome Metrics: Optimizing Benefits and Managing Risks

Kenneth A. Ellenbogen, MD
Kontos Professor & Chairman
Virginia Commonwealth University
School of Medicine
Richmond, VA



Disclosures

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- Research Grants: Boston Scientific, Medtronic,
- Consultant/Advisor/DSMB: Medtronic, Boston Scientific, St. Jude Medical

Current climate for leads



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RIATA ICD LEAD SUMMIT

JANUARY 20, 2012

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COURSE DIRECTORS: ROBERT G. HAUSER, MD & DAVID L. HAYES, MD

Minneapolis Heart Institute Foundation
MAYO CLINIC

Riata and Fidelis: Shining a light on ICD risk

Posted Feb 22, 2012 at 08:45 AM, EDT by John Mandrola

There is an important debate going on in electrophysiology.

The issue of the moment involves the imperfect durability of human-made implantable cardiac devices. Yes, ICDs have again taken center stage.

Just off the heels of the recent **Sprint Fidelis** debacle comes the St Jude **Riata** defibrillator lead recall. Although fewer Riata leads (78 000 Riata vs 268 000 Fidelis) have been implanted, medical decision making concerning Riata may pose greater challenges than those of Fidelis. That's saying a lot, as dealing with Fidelis leads has been stressful.

Here's my quick summary of the Riata situation:

Riata (and **Riata ST**) defibrillator leads have a serious design problem. In a not-insignificant (and debatable) percentage of cases, these leads can exhibit a unique mechanism of failure involving internal wires wearing through their insulation. These abrasions can lead to the exposure of bare metal in the heart—called externalization. In addition to dramatic and



The NEW ENGLAND JOURNAL of MEDICINE

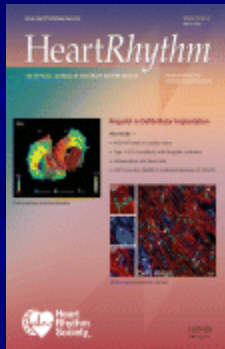
Perspective
MARCH 8, 2012

Here We Go Again — Another Failure of Postmarketing Device Surveillance

Robert G. Hauser, M.D.

The goal of postmarketing surveillance of medical devices is to enhance public health by gathering information about the incidence of adverse

system notorious for underreporting, no such data exist. Meanwhile, physicians and their patients are in a quandary. Will the



Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead

Robert G. Hauser, MD, Linda M. Kallinen, BS, Adrian K. Almquist, MD, Charles C. Gornick, MD, William T. Katsiyannis, MD

Few initial questions...

When and when not to implant?

- 80-year-old man with ischemic cardiomyopathy, estimated EF of 30%, CHF/NYHA class II, hypertension, and diet-controlled diabetes.
- Would you implant a primary prevention ICD in this patient?
- How about if the patient was 85 and also has ESRD on hemodialysis?

Risk prediction data & tools may also help guide management

- We know all patients do not have the same risk for developing lethal ventricular tachyarrhythmias
- How can clinical data be incorporated into individual's patient care: role of decision analysis?
- How do unique patient characteristics impact the decision?
 - Example of patients with renal failure, elderly, etc.
 - Some of these pt. subgroups have not been well studied in clinical trials

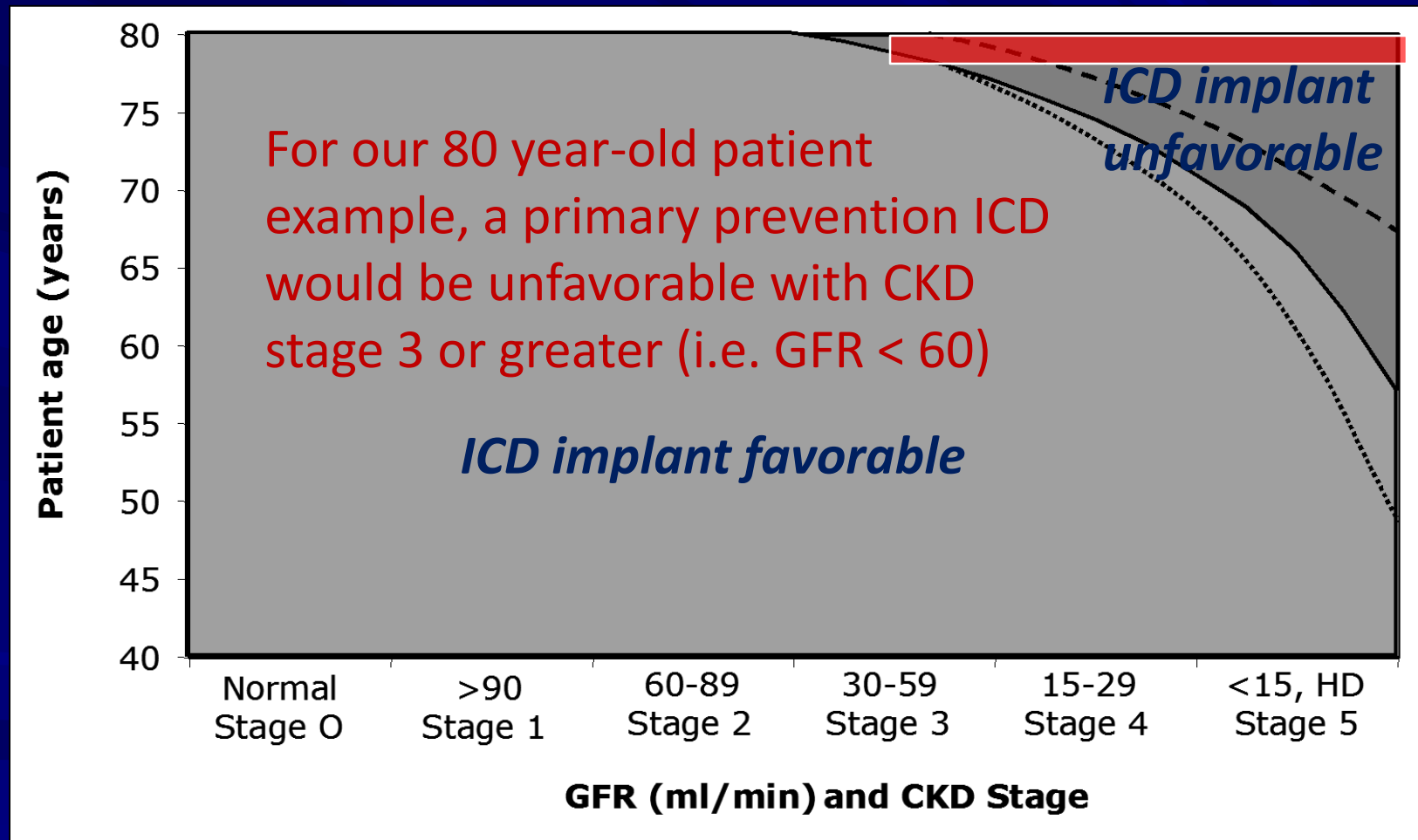
Back to our 1st question...

- 80-year-old man with ischemic cardiomyopathy, estimated EF of 30%, CHF/NYHA class II, hypertension, and diet-controlled diabetes.
- Would you implant a primary prevention ICD in this patient?
 - Mortality Score = 45 (event rate of ~ 20%)
 - Arrhythmic Death Score = 38 (event rate of ~ 5%)
 - **PROBABLY YES, without contraindications, both guidelines and major primary prevention trials support ICD implantation in this patient.**

Back to our 1st question...

- 80-year-old gentleman with ischemic cardiomyopathy, estimated EF of 30%, CHF/NYHA class II, hypertension, and diet-controlled diabetes.
- Would you implant an ICD if the patient also has ESRD?
 - **PROBABLY NOT, higher 2-year mortality and higher risk of device-related complications**

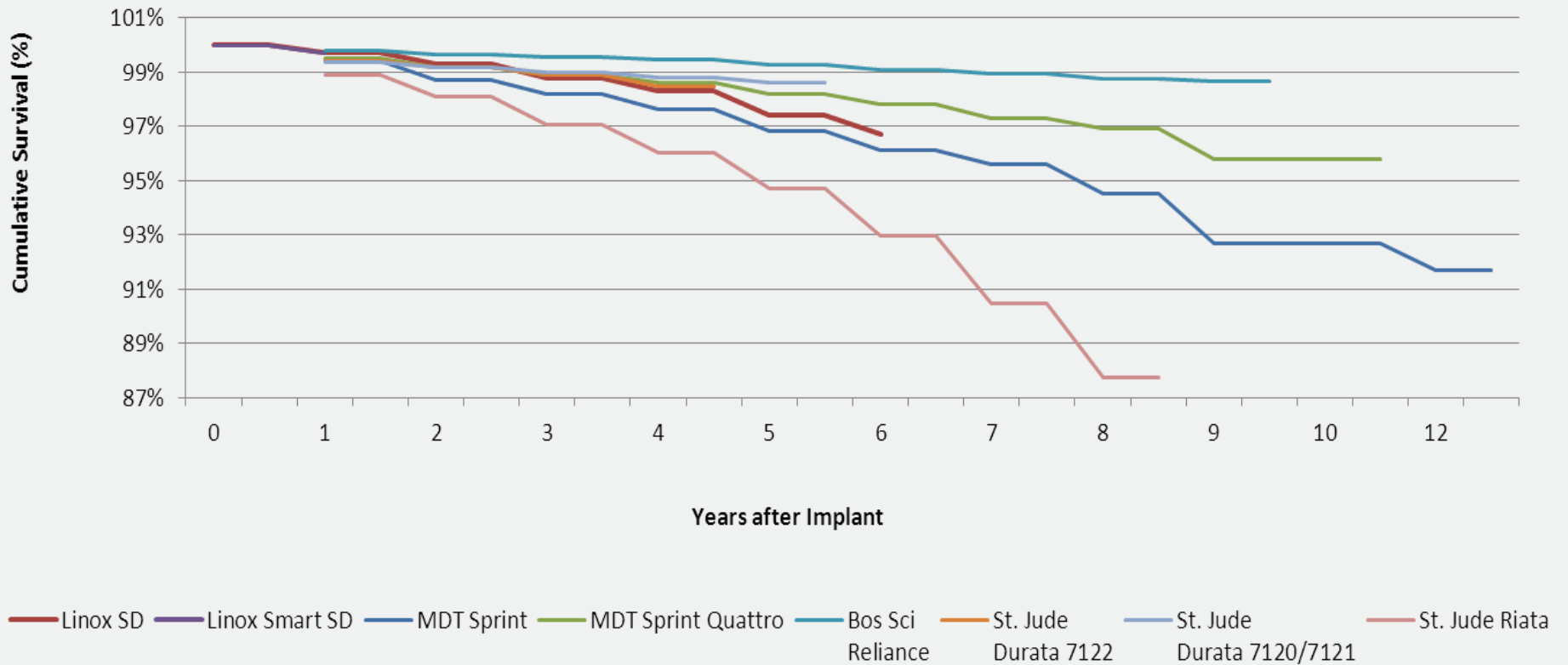
Elderly patients may not benefit from primary prevention ICDs with even moderate CKD



What is available to help us decide when to replace or how to manage a non functional lead?

How do ICD Leads Compare: PPR

Comparison of Active ICD Leads

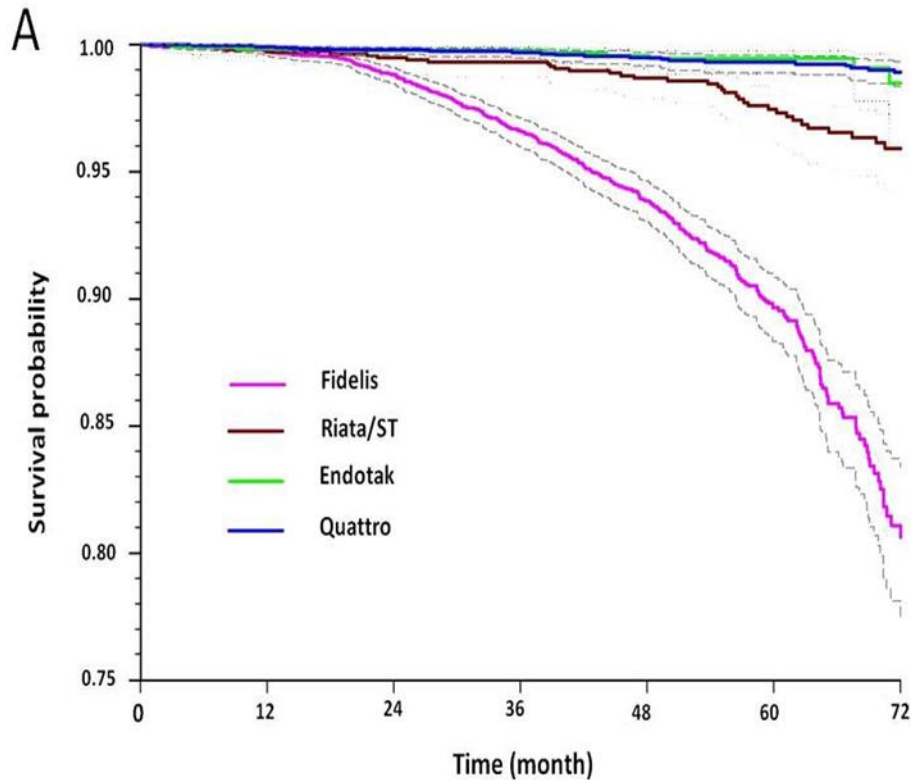


Data Reported from:

- BIOTRONIK Product Performance Report, July 2013
- St. Jude Medical Product Performance Report, 2013 1st Edition
- Medtronic Product Performance Report, 2013 1st Edition, Issue 68
- Boston Scientific CRM Product Performance Report, 2013 – Q2 Edition

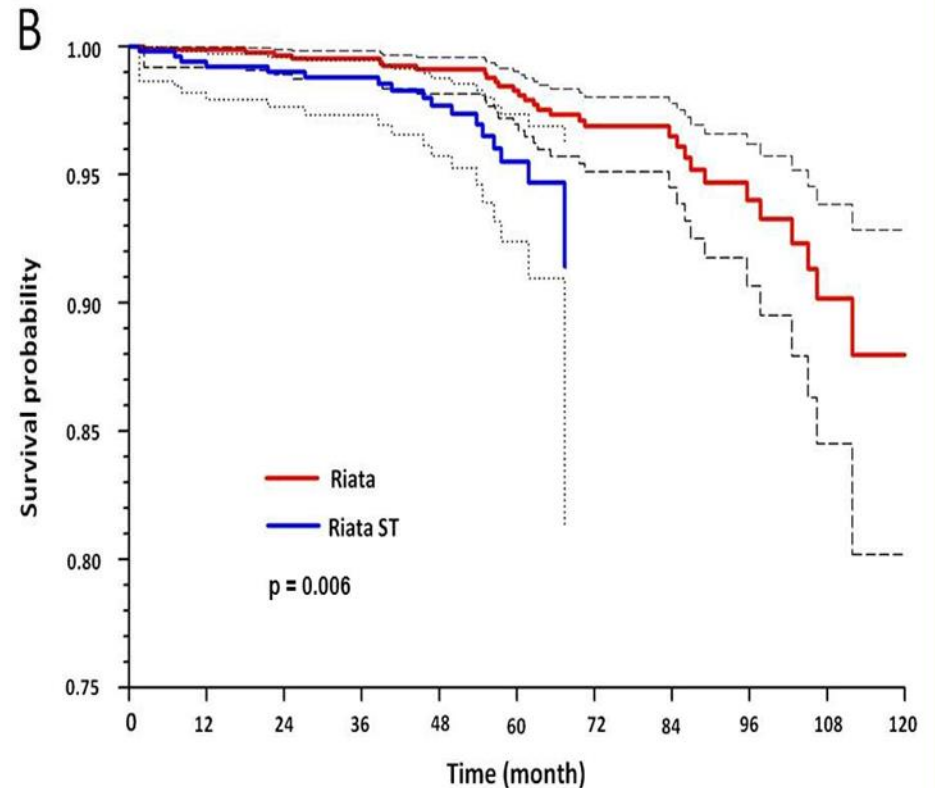
Long Term Survival of ICD Leads

Heart Rhythm. 2012;9:1954-61.



Units at Risk:

Fidelis	5073	4671	4135	3478	2265	965	179
Riata/ST	1403	1355	1285	1171	989	703	411
Endotak	2401	2100	1623	1222	798	501	143
Quattro	6091	4764	3479	2337	1760	1455	1156



Units at Risk:

Riata	877	852	822	765	667	554	409	247	135	70	3
Riata ST	526	503	463	406	322	149	2				

When and when not to replace?

- 65-year-old man with ICD implanted for secondary prevention, history of sudden cardiac death. The ICD (ICD lead) is now under advisory with a potential malfunction rate of 7%. Remaining battery life of 3 years.
- Would you replace the device (ICD lead) due to the advisory or continue monitoring the patient with current device?
- What if the estimated malfunction rate was less than 1.0%?

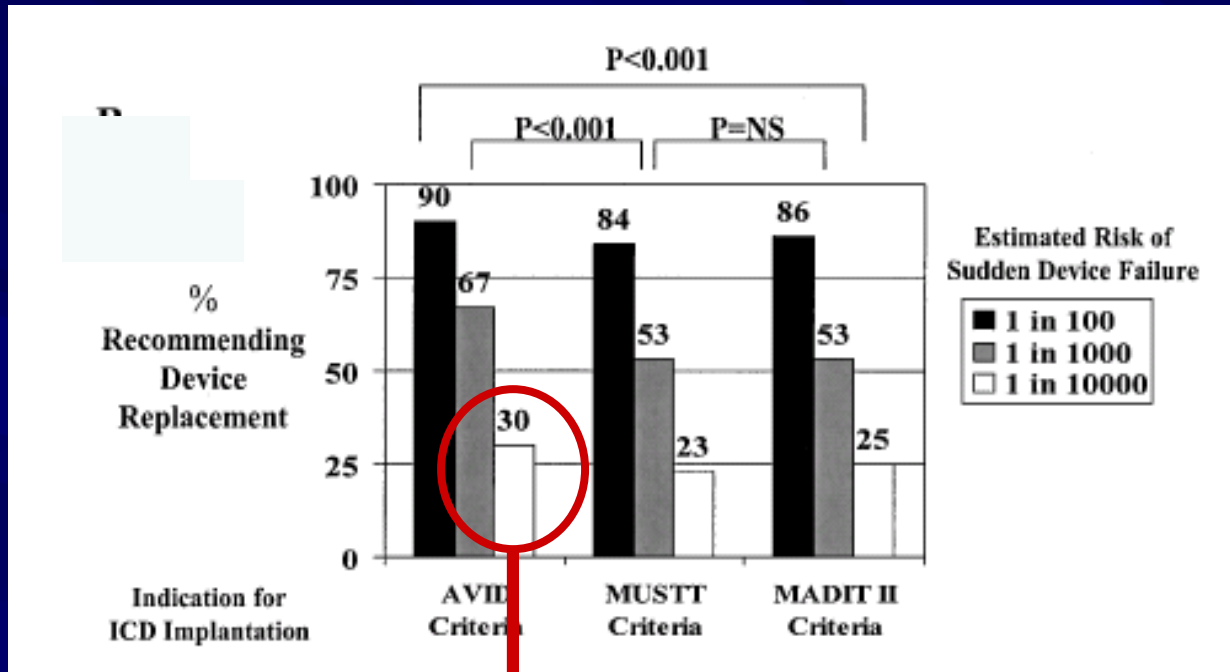
Expert Opinion on Device Alerts

Heart Rhythm Society Task Force

Carlson et al. Heart Rhythm 2006;3:1250-1273

- “Consider replacement” if malfunction:
 - Recurrent
 - Likely to result in serious harm
 - Risk replacement < risk from malfunction
 - Device near ERI
- “Consider replacement” if patient:
 - Pacemaker dependent
 - Has ICD for secondary prevention
 - Has received appropriate ICD therapy

Physicians Recommending Device Replacement



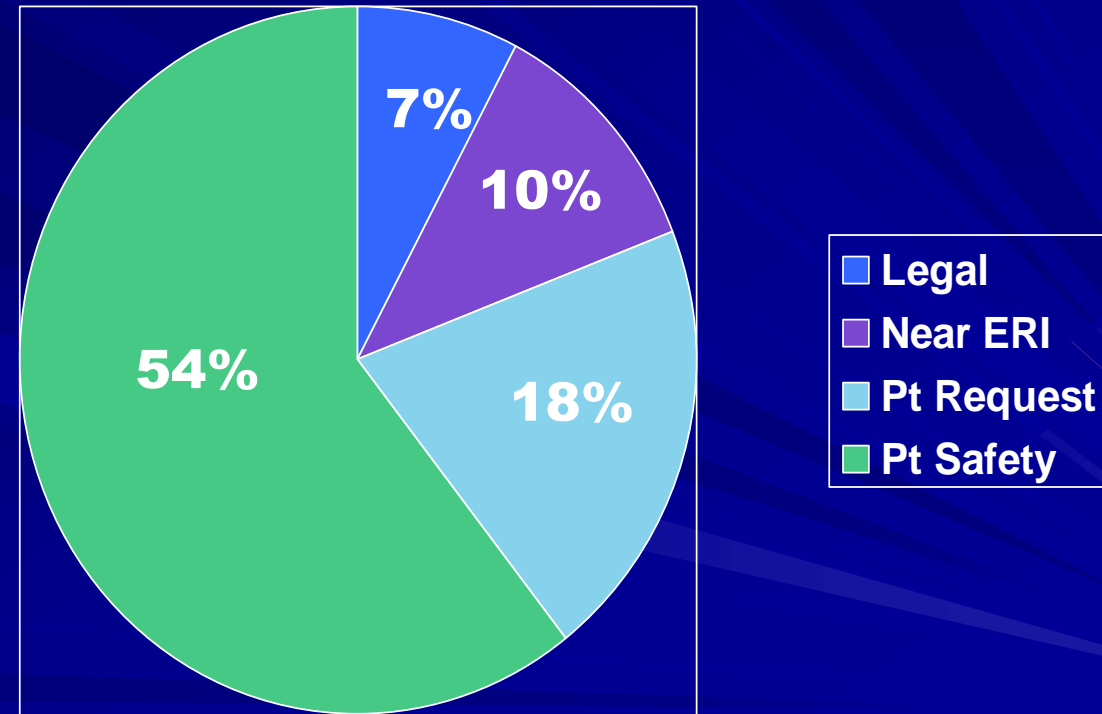
“A 1 in 10,000 failure rate exceeds the reliability of all known ICDs”

Maisel WH. PACE 2004; 27: 1-6.

Maisel WH. JAMA 2005; 294: 955-8

No consensus with management (courtesy of Eric Prystowsky, MD)

- On average 30.8% of recalled devices were replaced
- Some physicians replacing 0% and others replacing 100% of devices



We conducted a decision model analysis to study this clinical question

Amin M, Matcher D, Wood M, Ellenbogen KA. JAMA 2006;296:412-420

■ What is a decision model analysis?

- A mathematical model used to compare options
- Simple in concept, but can be tricky in reality - need to accurately mimic real-life situation
- Can do 1,000 or 10,000 simulations with a range of variables

■ Why did we use this method?

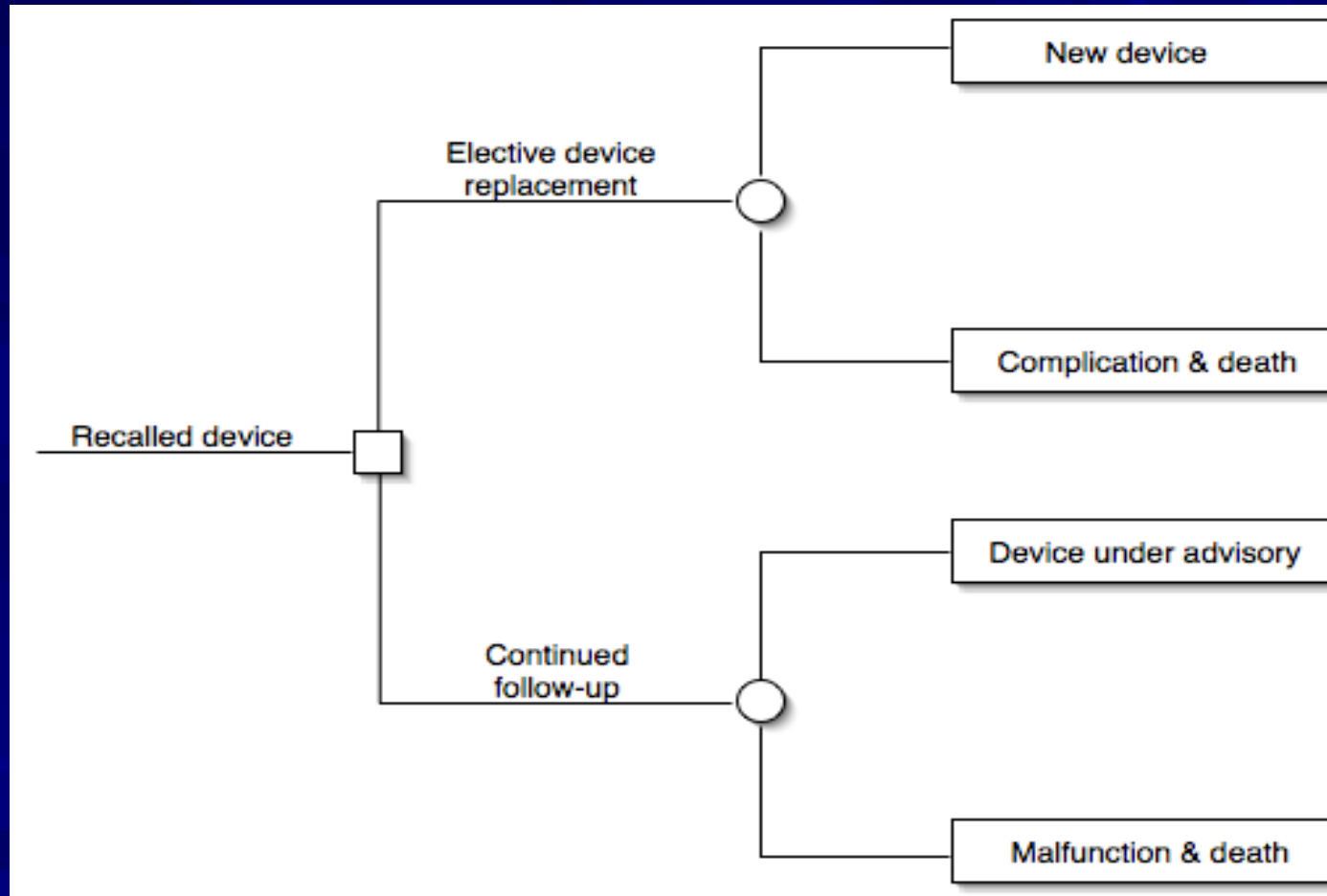
- Unable to study this problem in a traditional fashion (randomized prospective or retrospective study)
- Allows us to evaluate variations in risks (device failure rates, procedure complications) providing insight for different situations
- Lack real time data & we do not know future risk of ICD lead failure

Model examined 9 variables and their implications

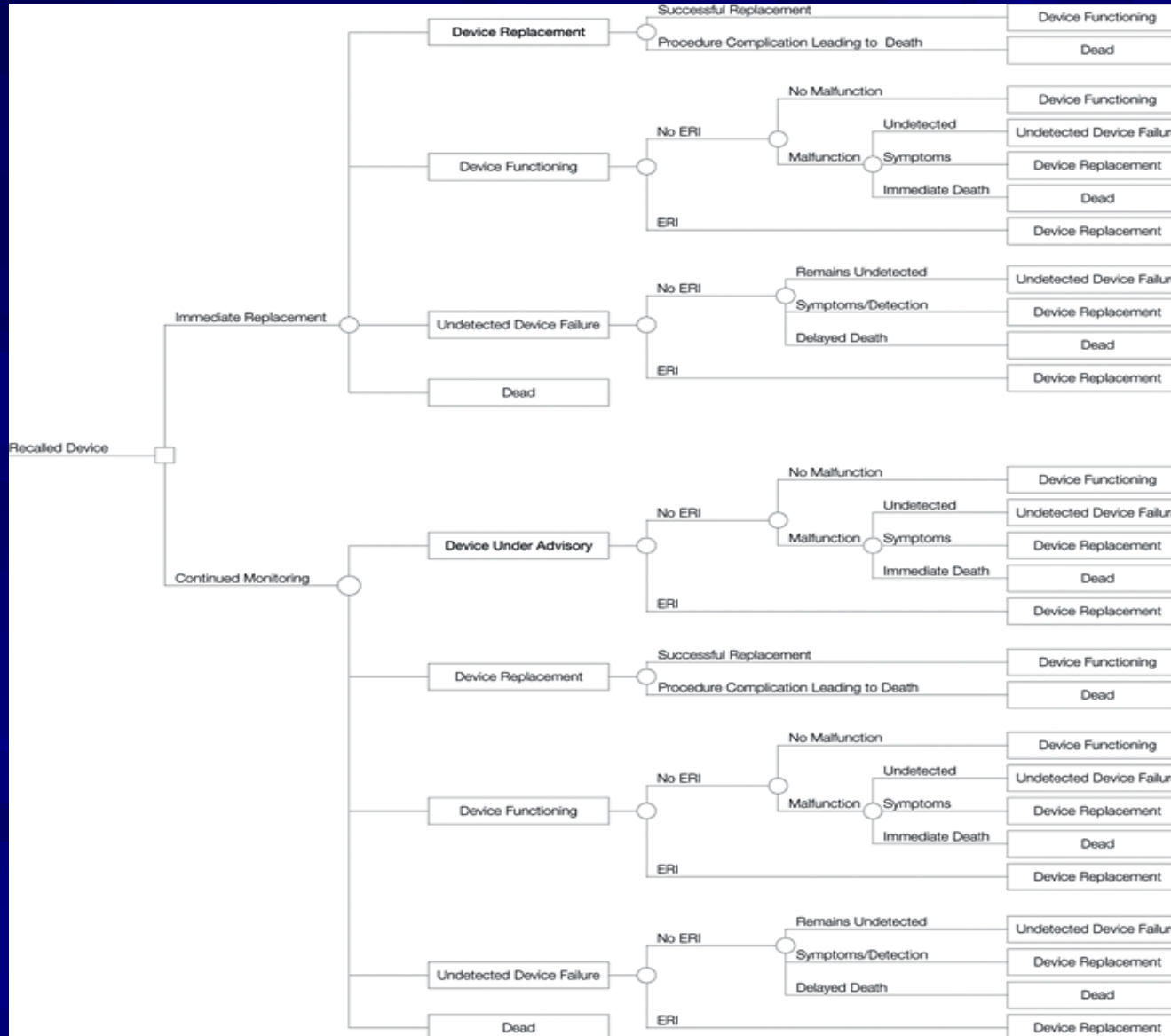
Amin M, Matcher D, Wood M, Ellenbogen KA. JAMA 2006;296:412-420

- *Patient age (40-80 years)*
- *Remaining generator life (0-100%)*
- *Procedure mortality rate (0.001-0.01%)*
- *Advisory failure rate (0.001-10.0%)*
- *Underlying random failure rate (0.01-4.0%)*
- *Immediate death with failure (0-0.60)*
- *Event-based death with failure (0.01-0.25)*
- *Symptoms with failure (0-0.50)*
- *Follow-up frequency (1-6 months)*

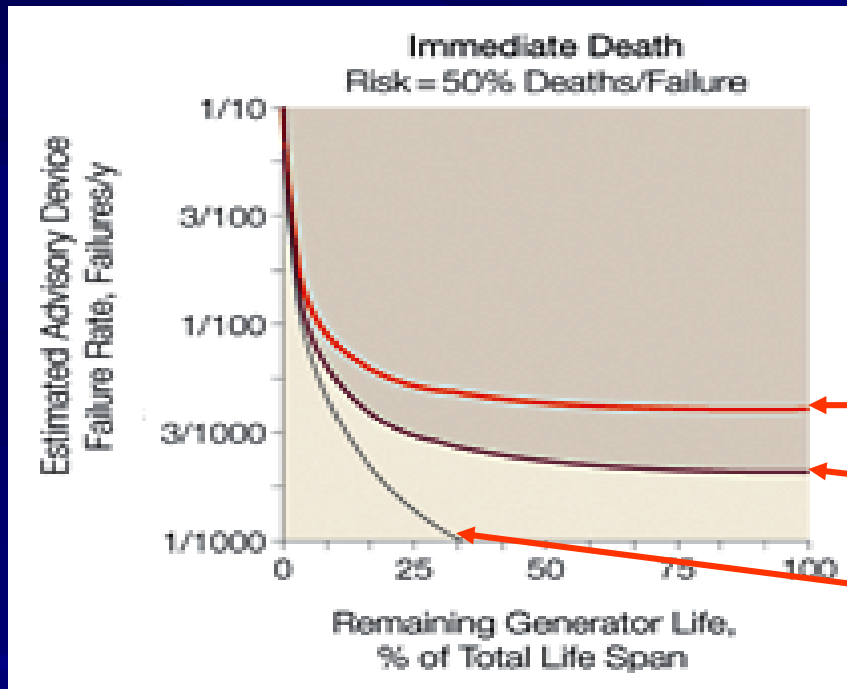
Markov model comparing 2 strategies...



... which expands into a complex model with multiple health states



Graphic Representation of Results



Procedural Mortality

1.0% Death/Procedure

0.5% Death/Procedure

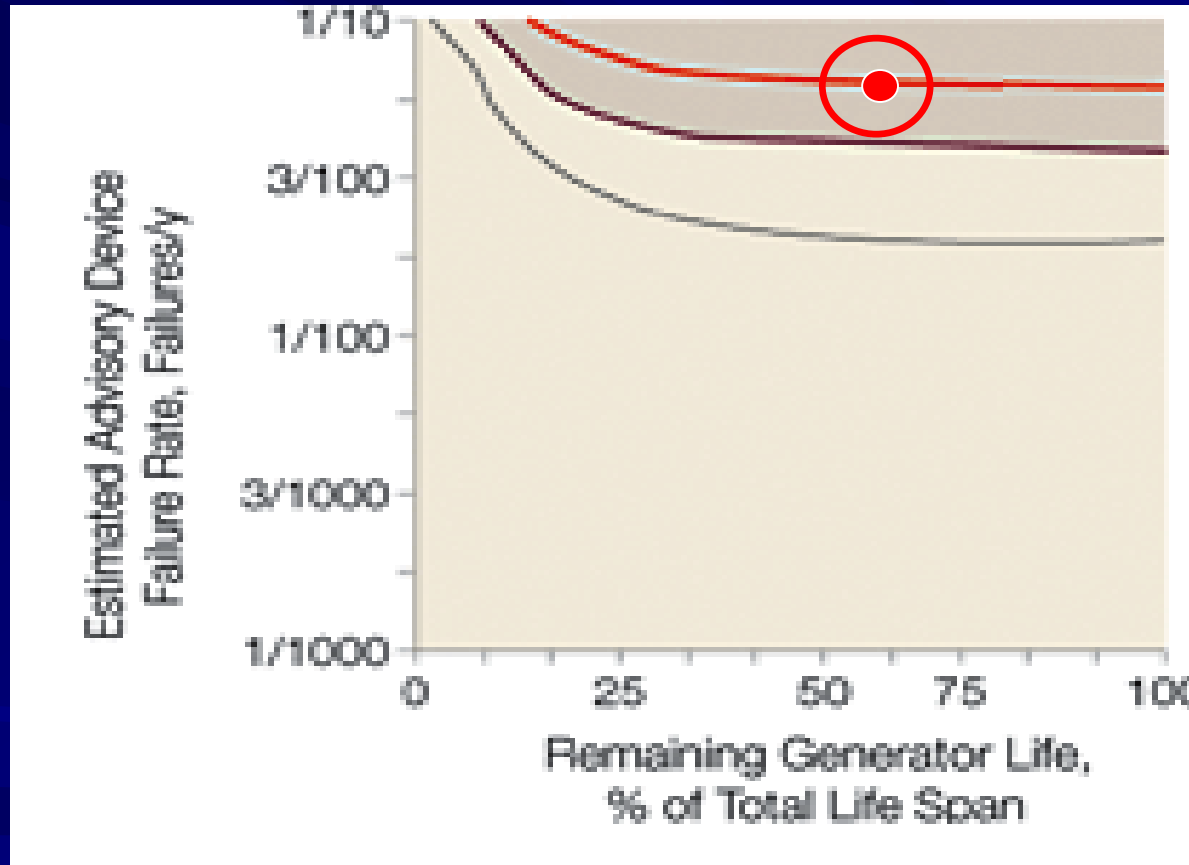
0.1% Death/Procedure

Replace

Do Not Replace

1st Model: Secondary SCD prevention

(Amin et al decision model)



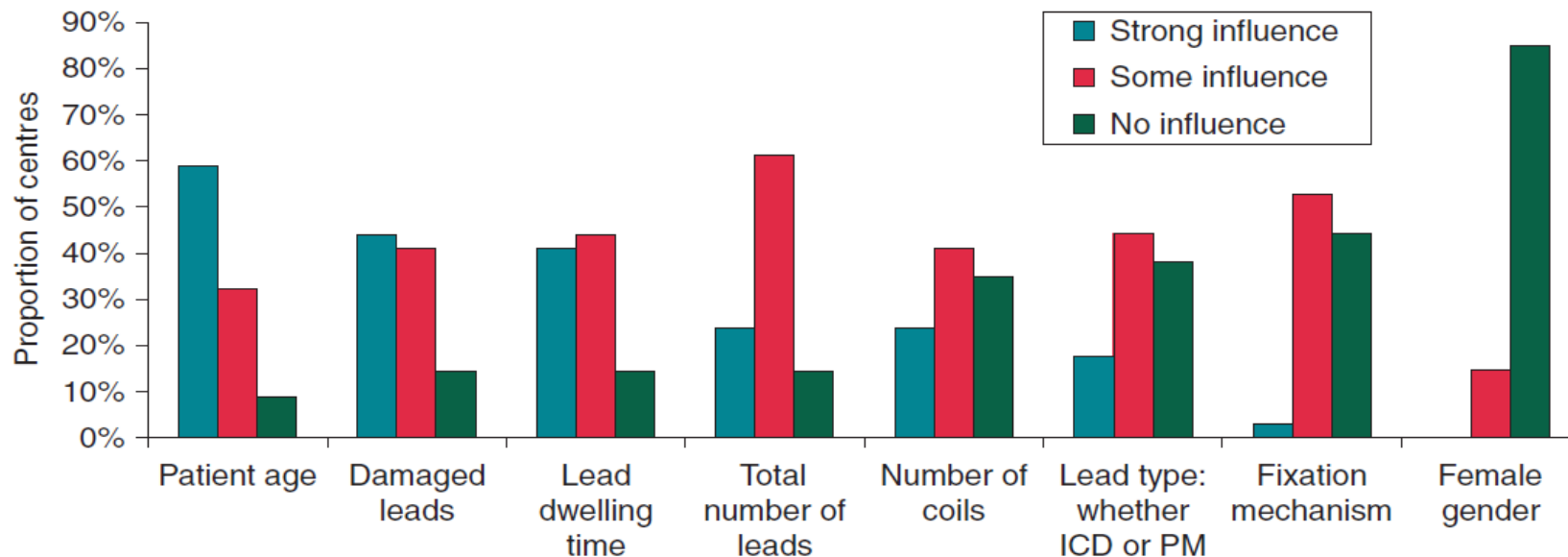
Advisory failure rate: 7%
Procedure mortality: 0.5%

Decision:
Replace device

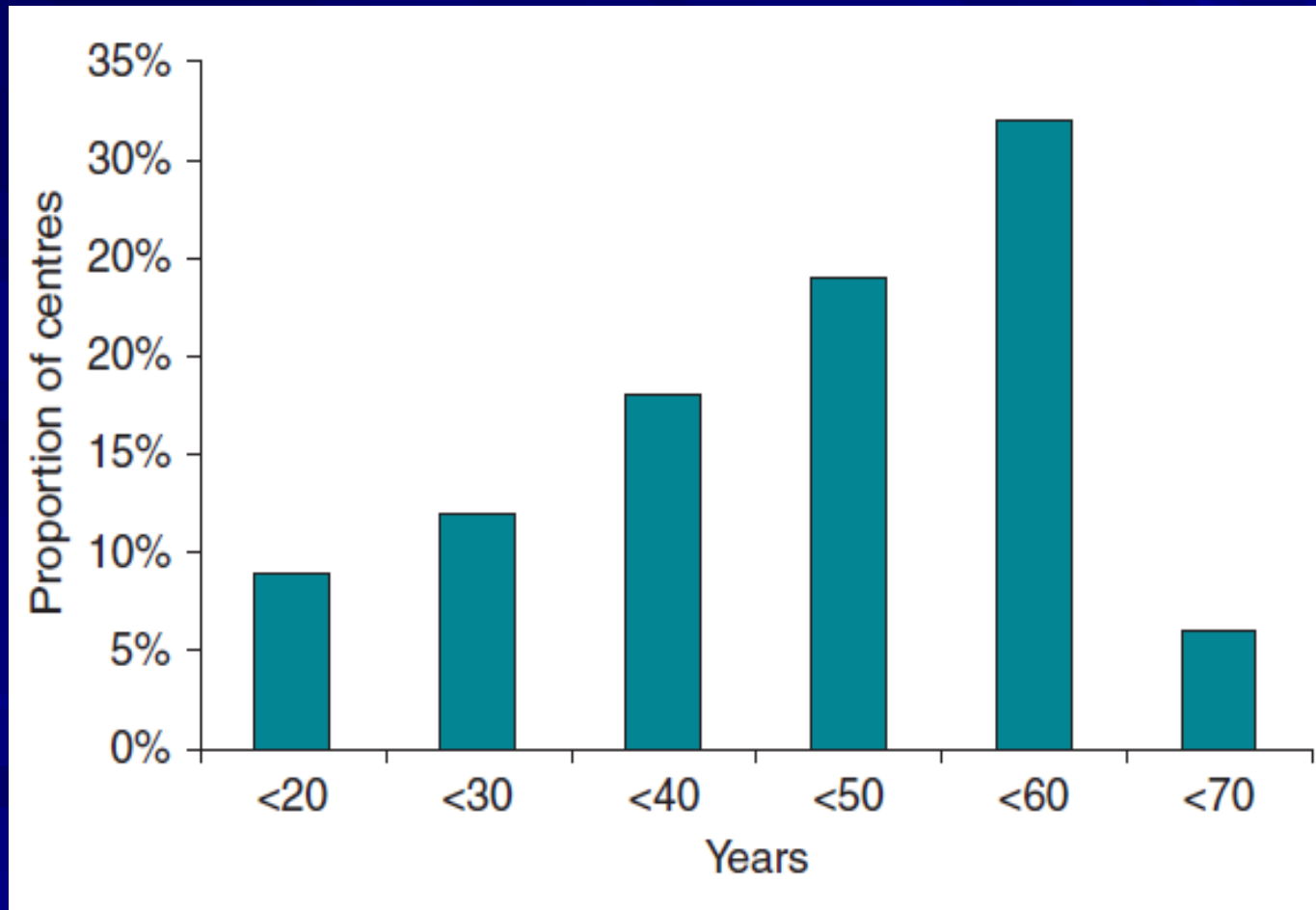
Probabilistic certainty:
Decision preferred in 99% of simulations

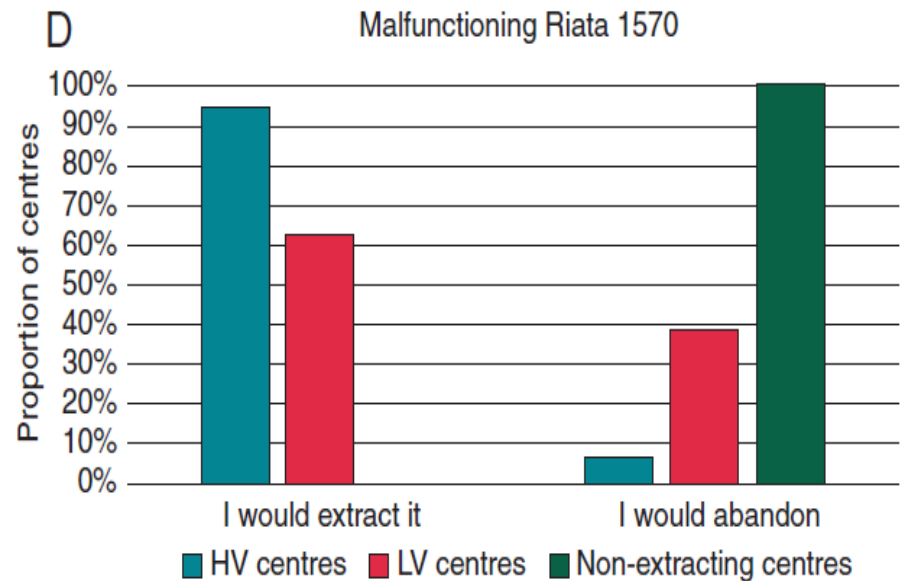
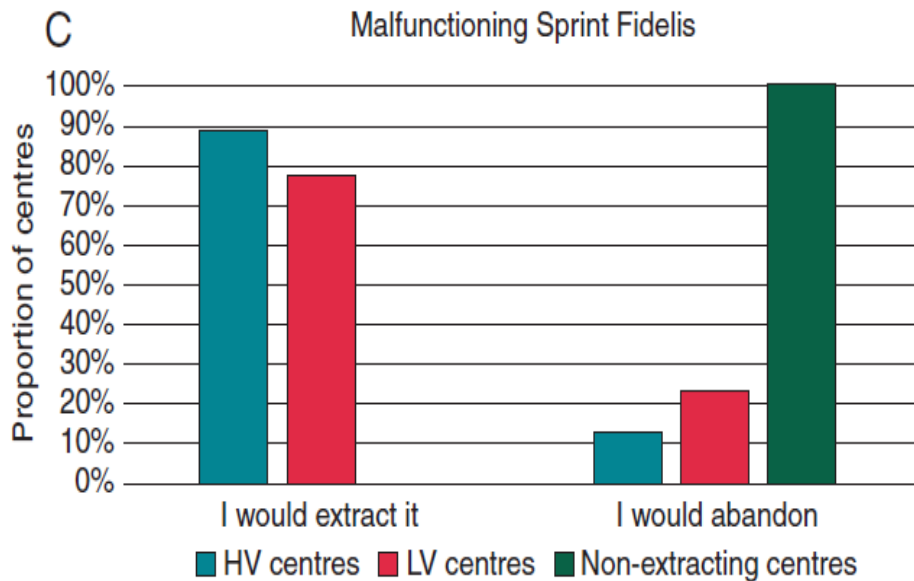
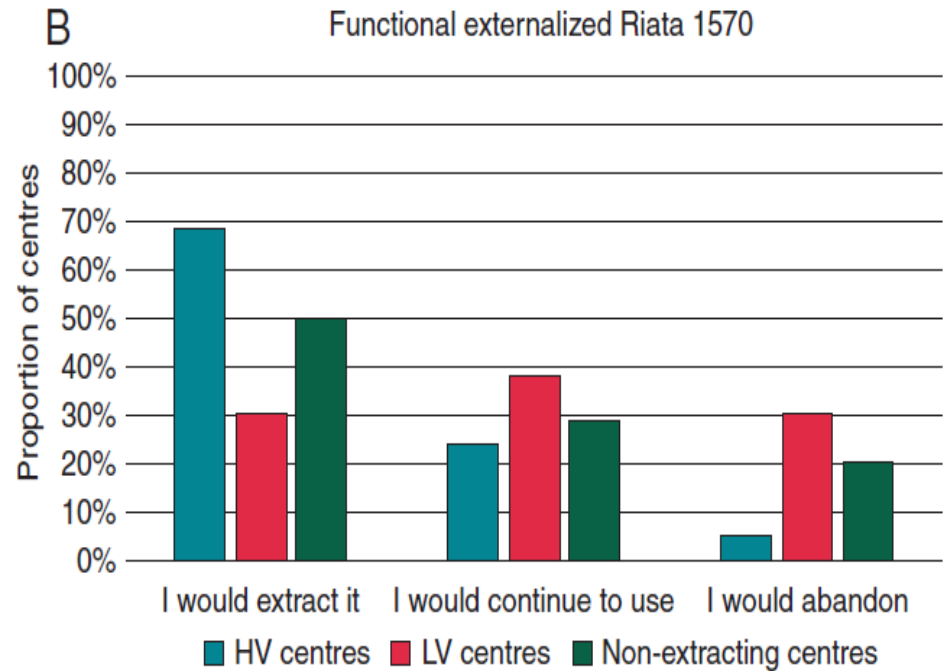
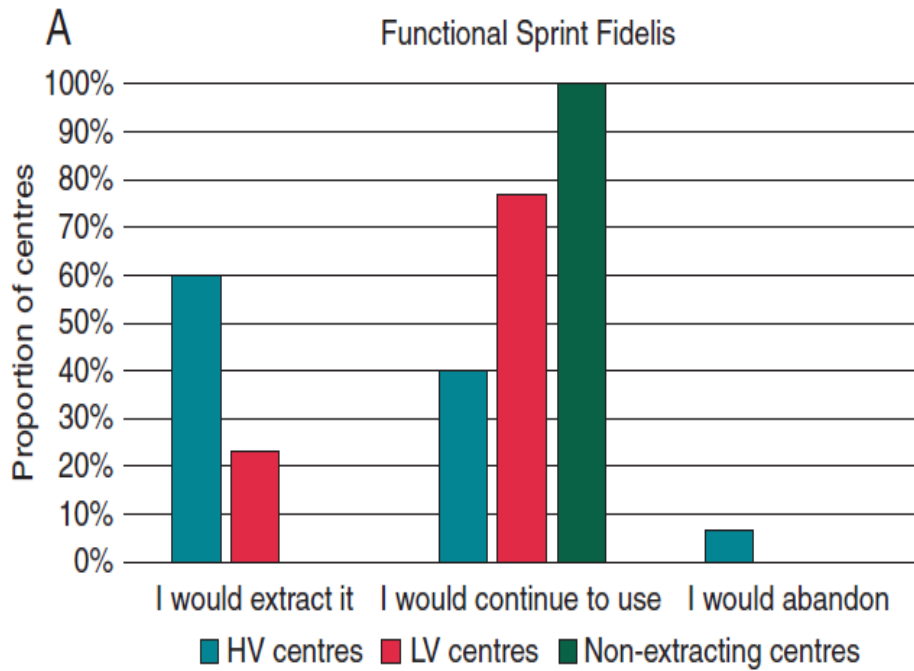
Management of malfunctioning and recalled pacemaker and defibrillator leads: results of the European Heart Rhythm Association survey

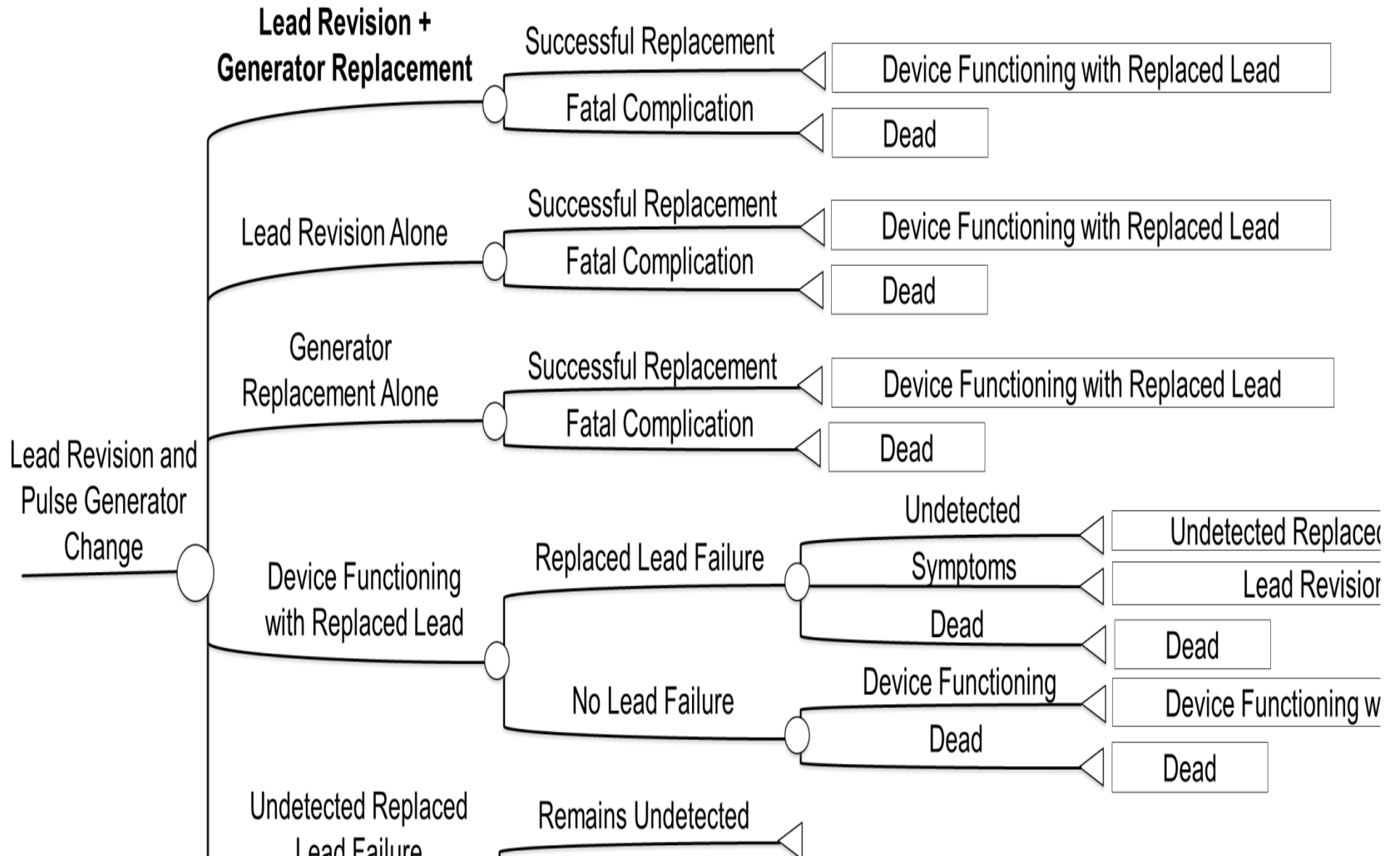
Maria Grazia Bongiorni^{1*}, Nikolaos Dagues², Heidi Estner³, Laurent Pison⁴, Derick Todd⁵, and Carina Blomstrom-Lundqvist⁶, conducted by the Scientific Initiative Committee, European Heart Rhythm Association *Europace* (2014) **16**, 1674–1678
doi:10.1093/europace/euu302



At what age is a patient considered “young” in lead management ?



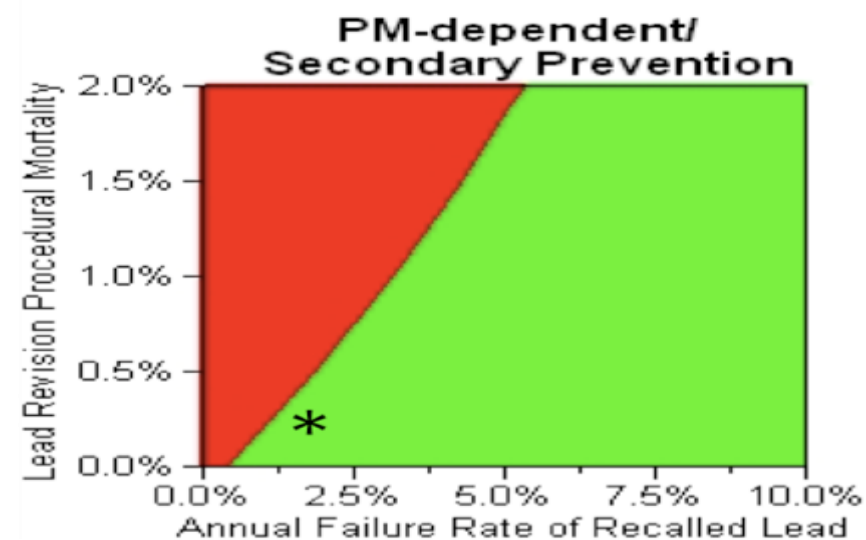
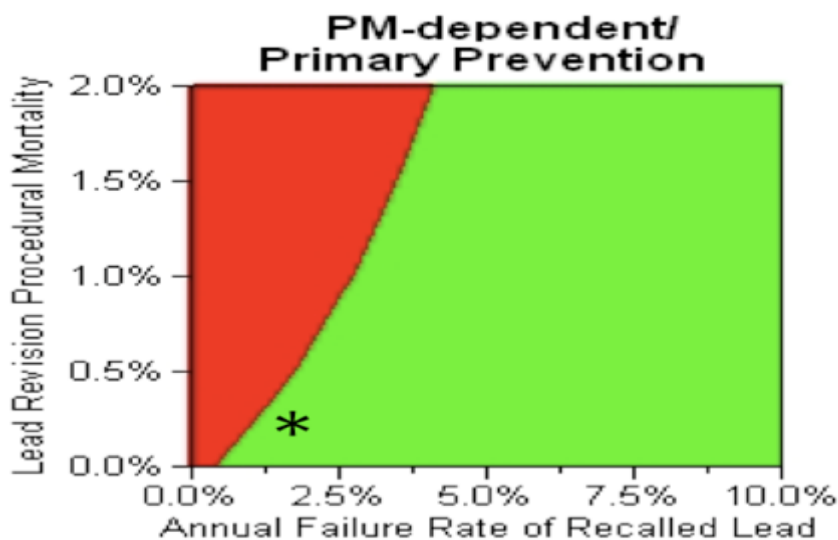
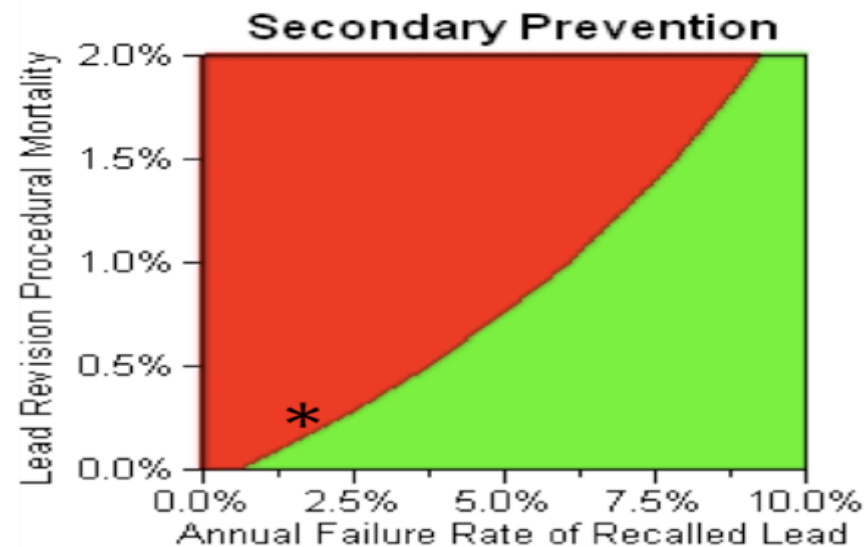
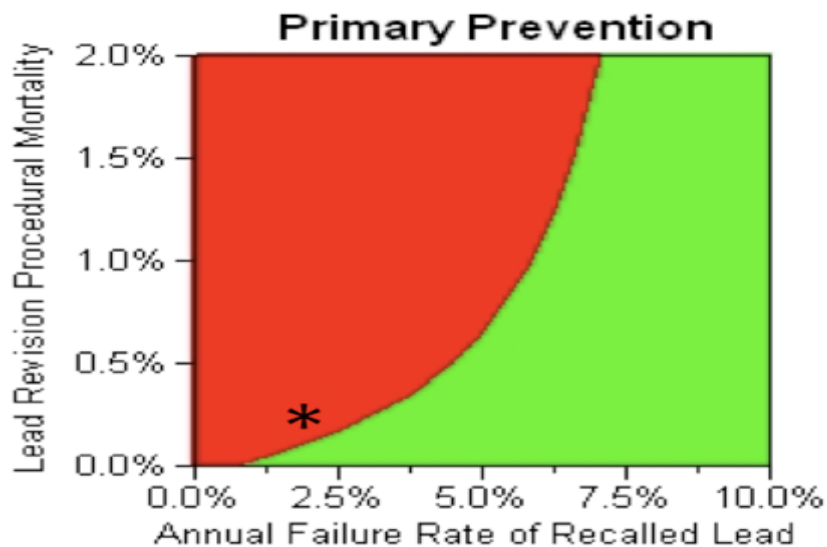




Courtesy of Dr. Marty Burke

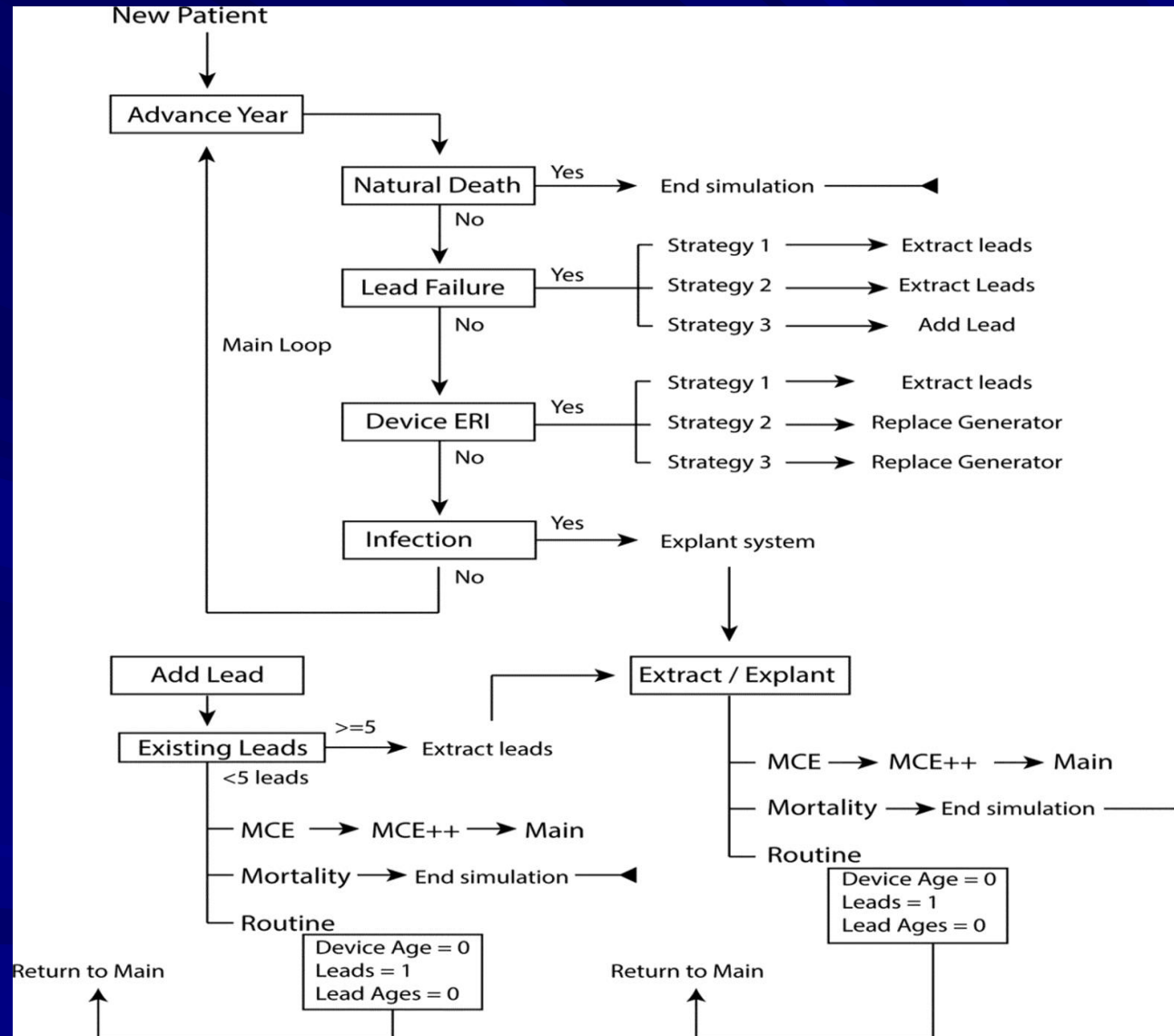
	Primary Prevention	Secondary Prevention	PM-dependent Primary Prevention	PM-dependent Secondary Prevention
Annual Rate of Failure in Recalled Lead (Sprint Fidelis) (%)	1.75			
Baseline Annual Rate of Failure in Lead (Sprint Quattro) (%)	0.10			
Lead Revision Procedural Mortality Rate (%)	0.28			
Pulse Generator Change Procedural Mortality Rate (%)	0.38			
Baseline Annual Mortality Rate (%)	5.8	10.7	5.8	10.7
Annual Patient Mortality Rate with Lead Failure (%)	7.7	17.7	17.7	32.7
Rate of Symptoms with Failure of Recalled Lead (%)	38.0	38.0	50.0	50.0
Rate of Symptoms with Failure of Non-recalled Lead (%)	5.0	5.0	12.0	12.0

		Threshold Value (%)	Effect on Life Expectancy with Sprint Fidelis Revision (months)	Plausible Variable Range (%) (low, high)	Range for Effect on Life Expectancy (months)
Primary Prevention	Annual Failure Rate of Recalled Lead	3.32	-0.3	0.1, 10.0	-0.6, +0.9
	Lead Revision Procedural Mortality	0.09		0.1, 2.0	-2.9, -0.1
Secondary Prevention	Annual Failure Rate of Recalled Lead	2.43	-0.1	0.1, 10.0	-0.4, +0.9
	Lead Revision Procedural Mortality	0.17		0.1, 2.0	-1.8, +0.1
PM-dependent Primary Prevention	Annual Failure Rate of Recalled Lead	1.14	+0.5	0.1, 10.0	-0.7, +4.2
	Lead Revision Procedural Mortality	0.54		0.1, 2.0	-2.3, +0.7
PM-dependent Secondary Prevention	Annual Failure Rate of Recalled Lead	1.20	+0.2	0.1, 10.0	-0.4, +2.3
	Lead Revision Procedural Mortality	0.47		0.1, 2.0	-1.5, +0.4



- **Favors Continued Monitoring of Recalled Lead at Time of Generator Change**
- **Favors Lead Revision at Time of Generator Change**

Simplified overview of simulation strategy



Questions

Would you withdraw use of a device associated with yearly mortality rate of 1 in 6500 (0.015%)

or

Recommend use of a device with 1% lifetime mortality risk?

- A. Yes
- B. No

How do we assess risk of sudden cardiac death and when should an ICD be implanted?

Doctors & Pts **do not** know how to think about risk



1 in 6500
chance/ year
fatality

1 in 84 lifetime
risk death

Summary

- No trials to tell us ICD lead failure (LF) rate over time
- No consensus on management because of lack of data
- Often no understanding of mechanism(s) of failure
- Limited understanding of clinical presentation of LF
- Must know **YOUR** local risk/benefit for lead extraction
- Must know risk factors for mortality/morbidity
- Decision analysis is helpful to put in perspective decisions about ICD lead replacement in individual patients; using mathematical models based on retrospective, registry and Medicare data may be of use