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

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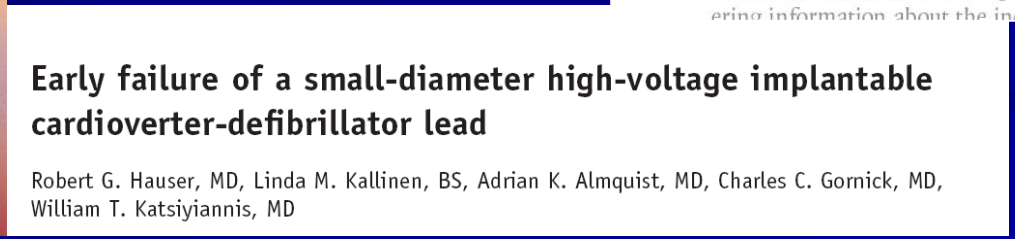
Disclosures

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

Current climate for leads



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.

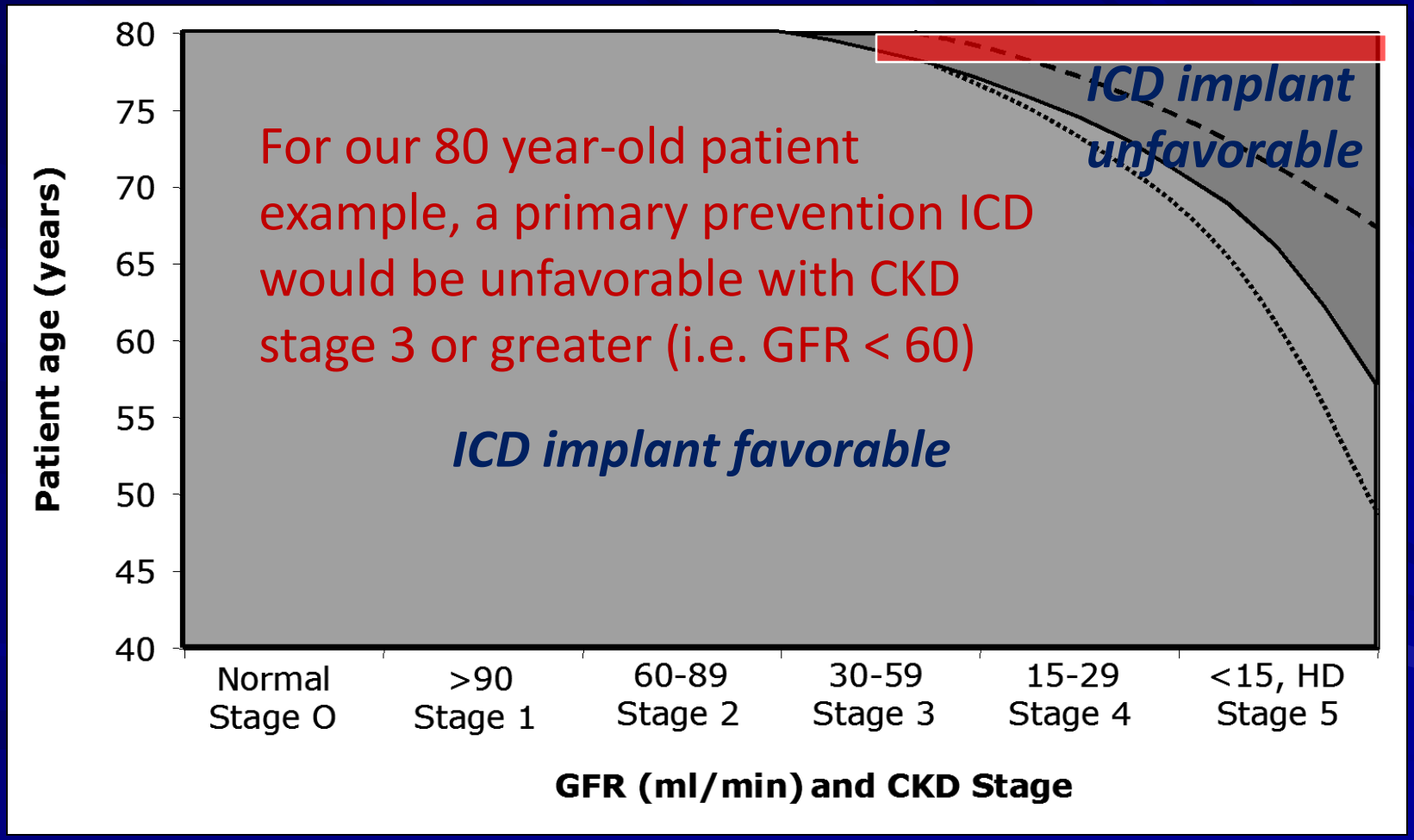
- Would you implant a primary prevention ICD in this patient?
  - Mortality Score = 45 (event rate of ~ 20%)
  - Arrhythmic Death Score = 38 (event rate of ~ 5%)
  - **PROBABLY YES, without contraindications, both guidelines and major primary prevention trials support ICD implantation in this patient.**

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**

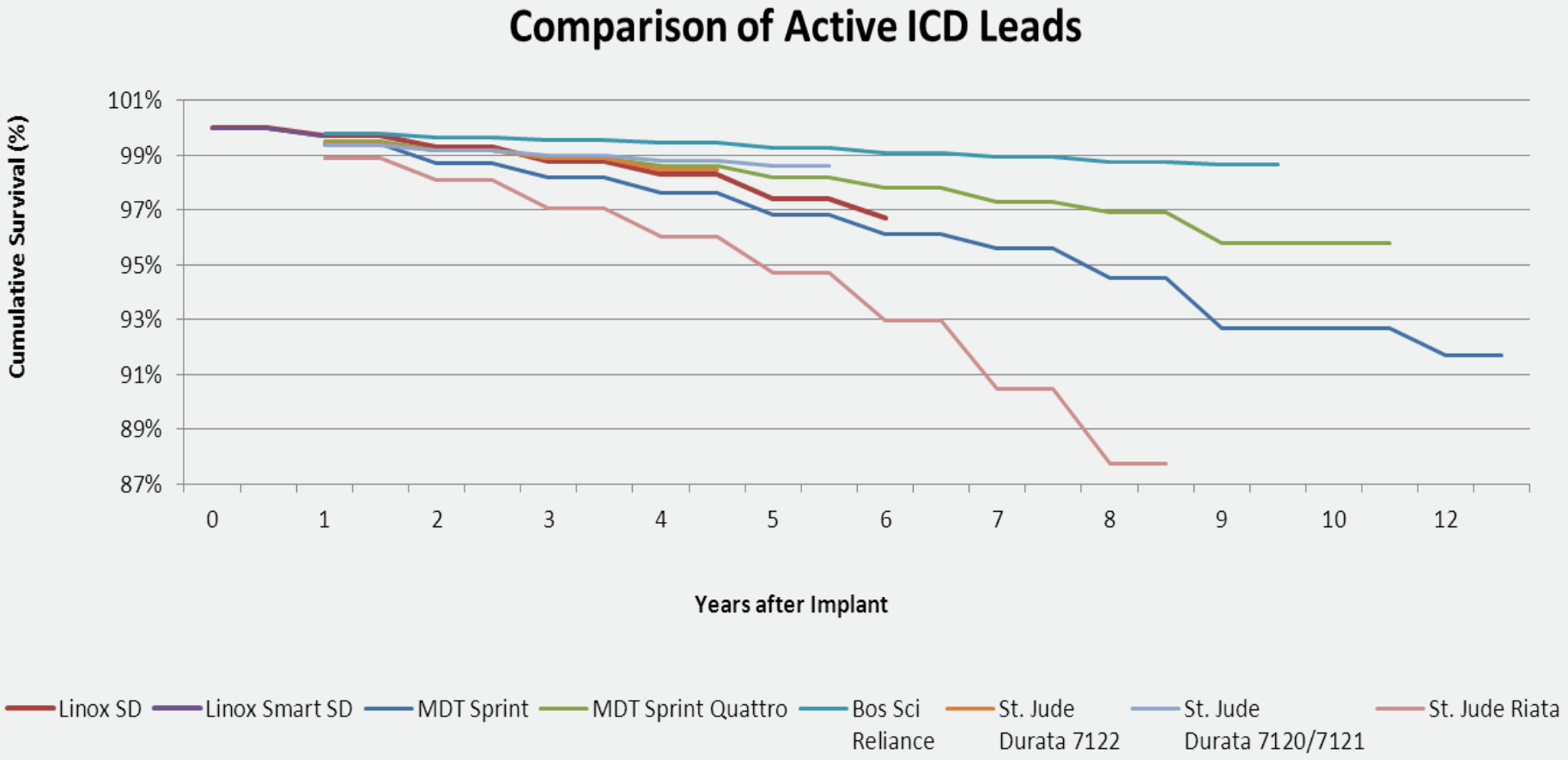
Elderly patients may not benefit from primary prevention ICDs with even moderate CKD



Amin MS et al. JCE 2008;19:1275-1280.

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

How do ICD Leads Compare: PPR

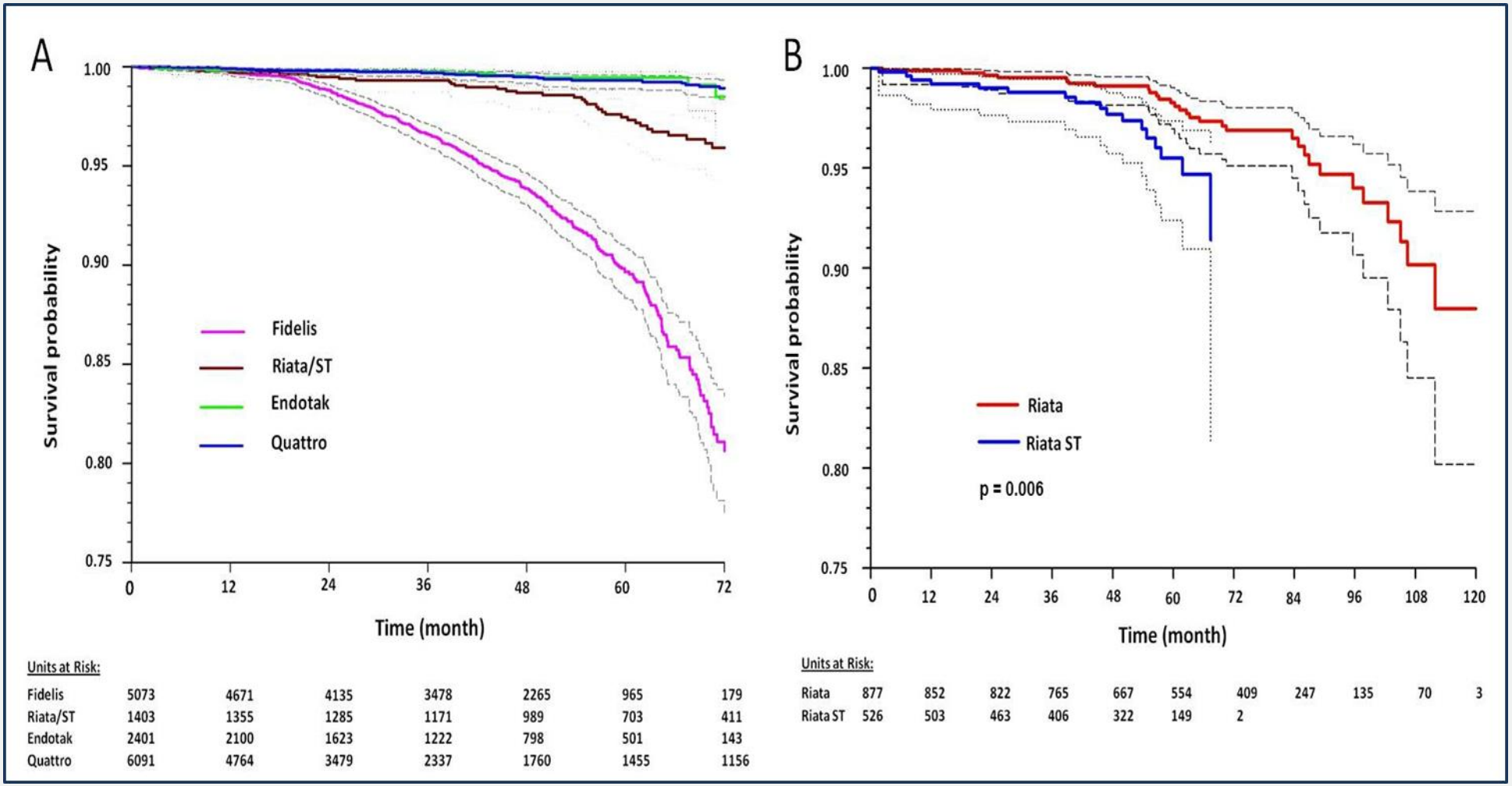


Data Reported from:

- 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.



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%?

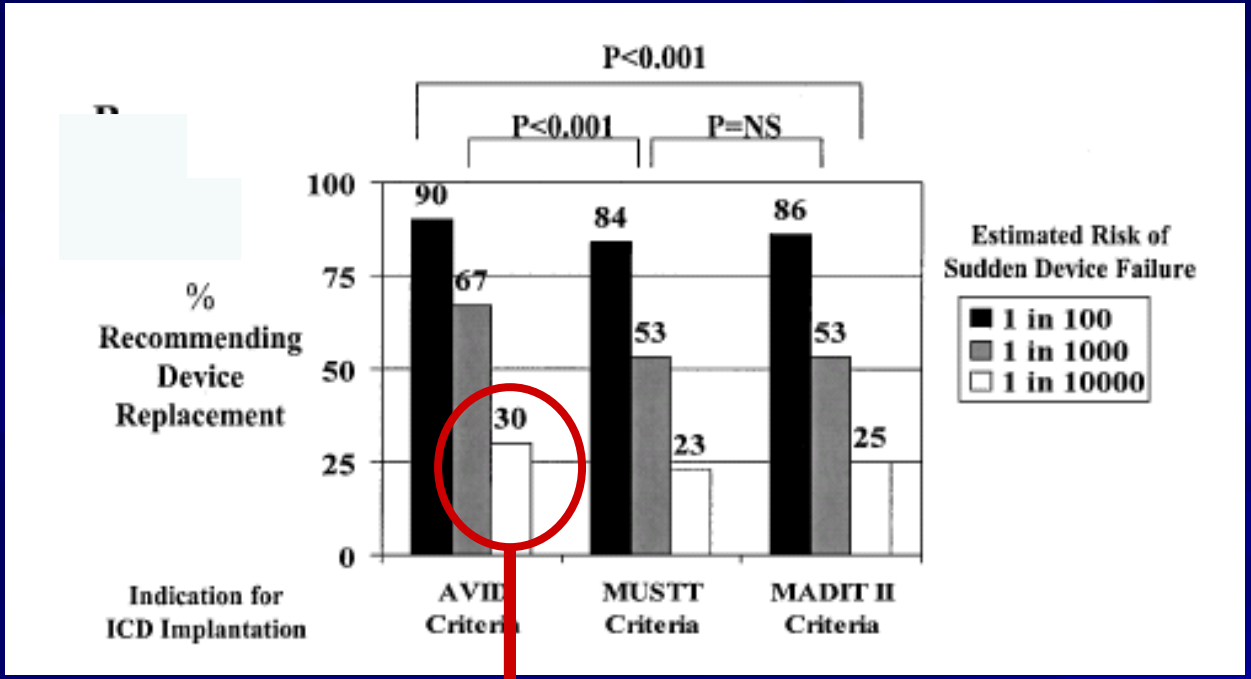
Expert Opinion on Device Alerts

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



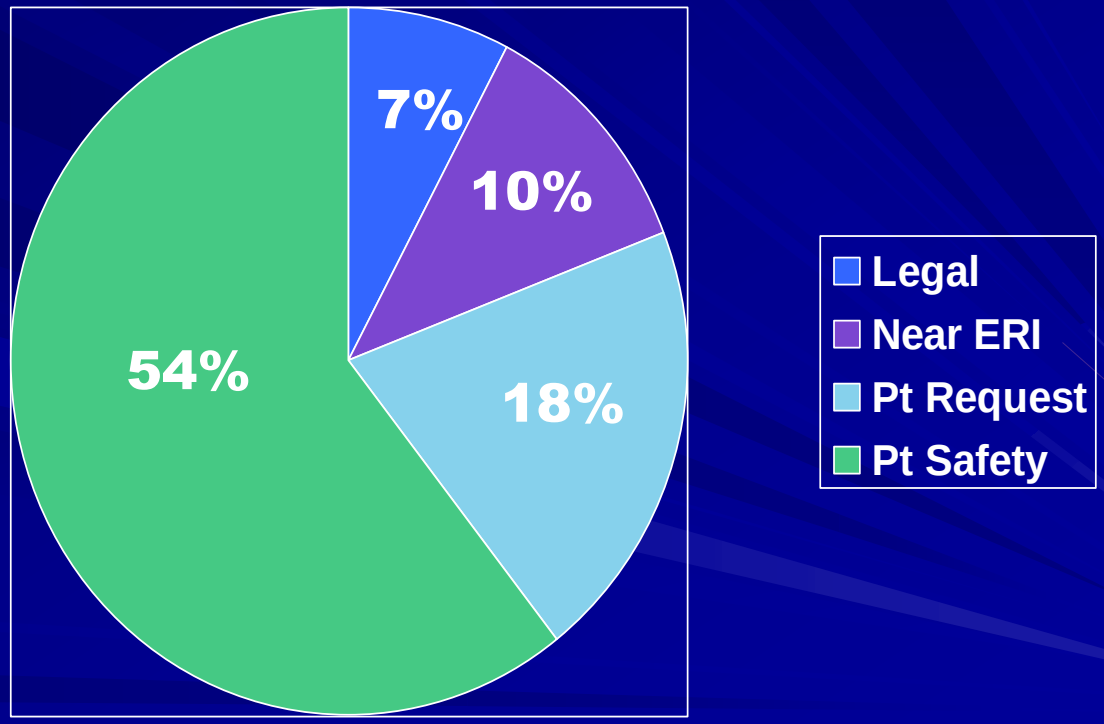
"A 1 in 10,000 failure rate exceeds the reliability of all known ICDs"

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

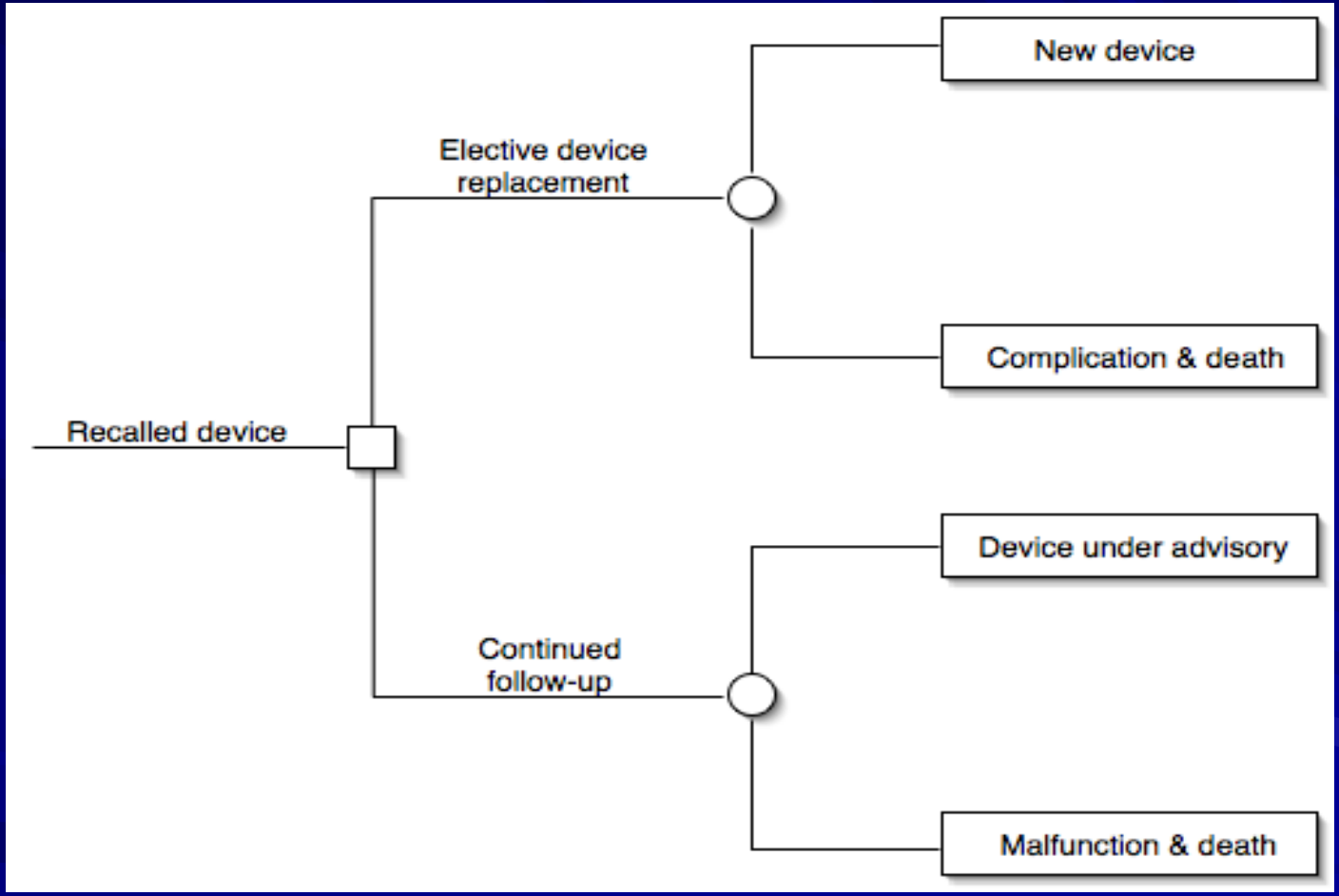
- What is a decision model analysis?
  - A mathematical model used to compare options
  - Simple in concept, but can be tricky in reality - need to accurately mimic real-life situation
  - Can do 1,000 or 10,000 simulations with a range of variables
- Why did we use this method?
  - Unable to study this 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

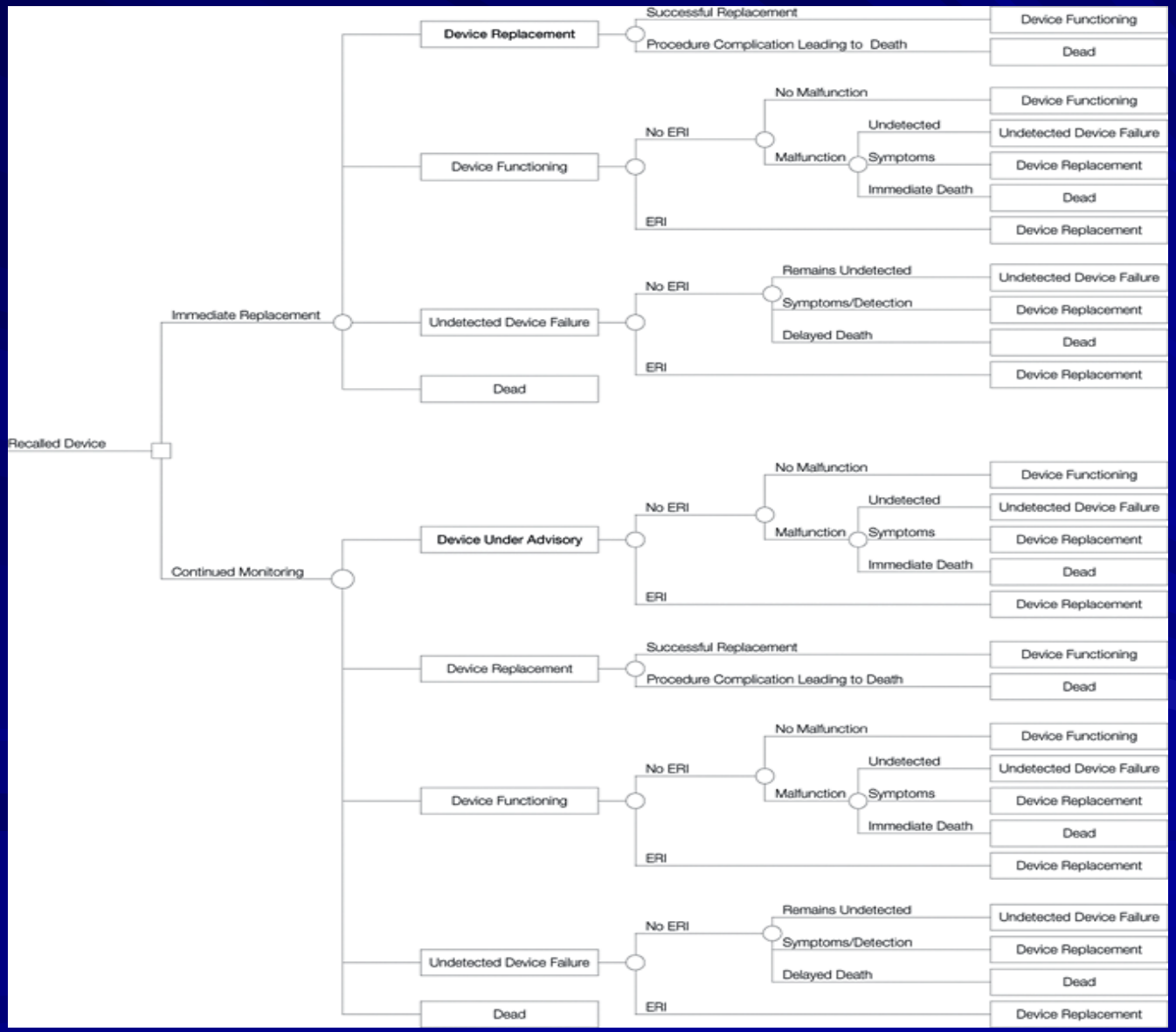
Amin M, Matcher D, Wood M, Ellenbogen KA. JAMA 2006;296:412-420

- ***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)***

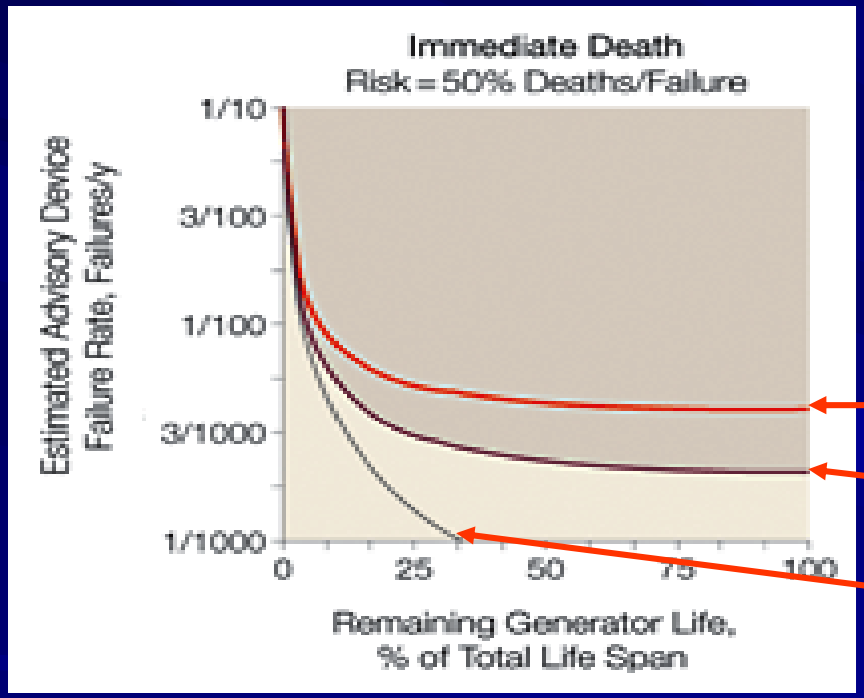
Markov model comparing 2 strategies…



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



Graphic Representation of Results



Procedural Mortality

1.0% Death/Procedure

0.5% Death/Procedure

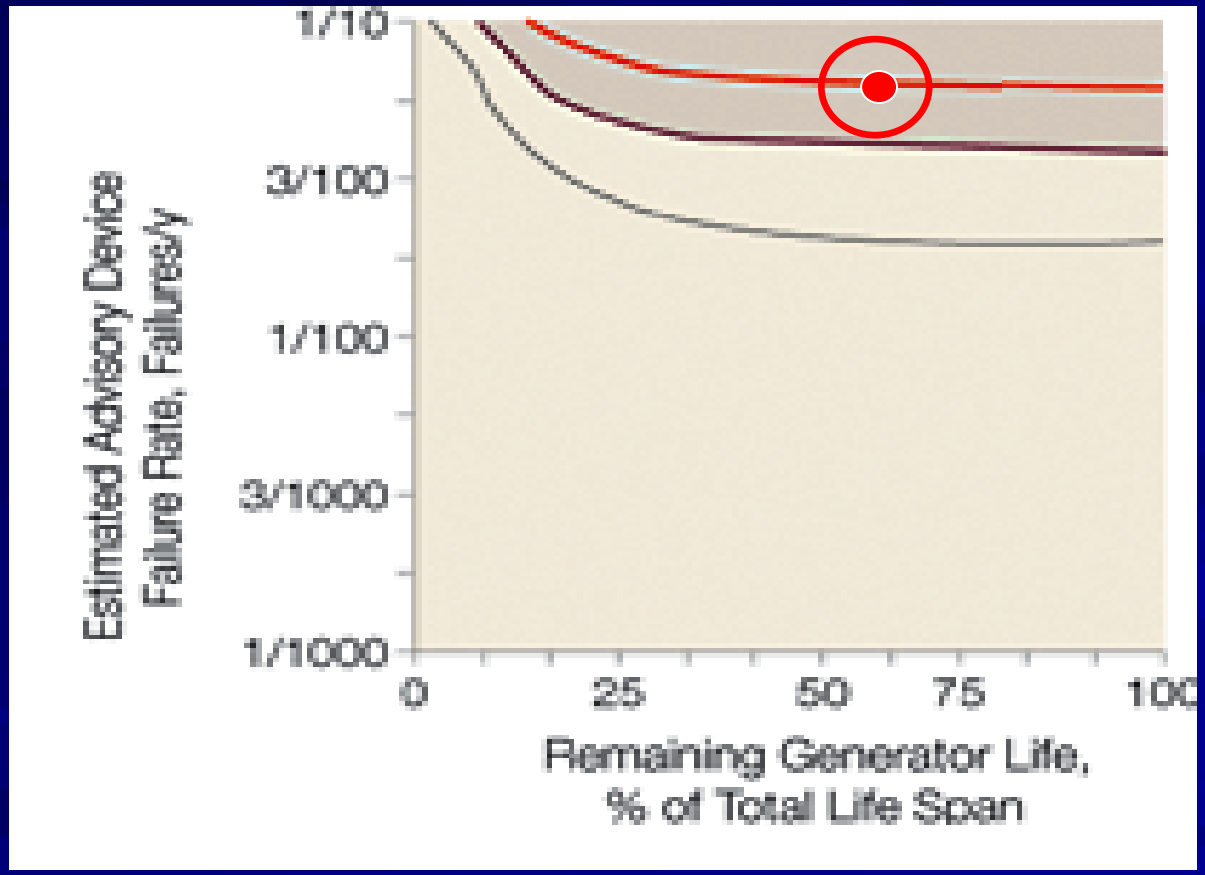
0.1% Death/Procedure

Replace

Do Not Replace

1st Model: Secondary SCD prevention

(Amin et al decision model)



Advisory failure rate: 7%
Procedure mortality: 0.5%

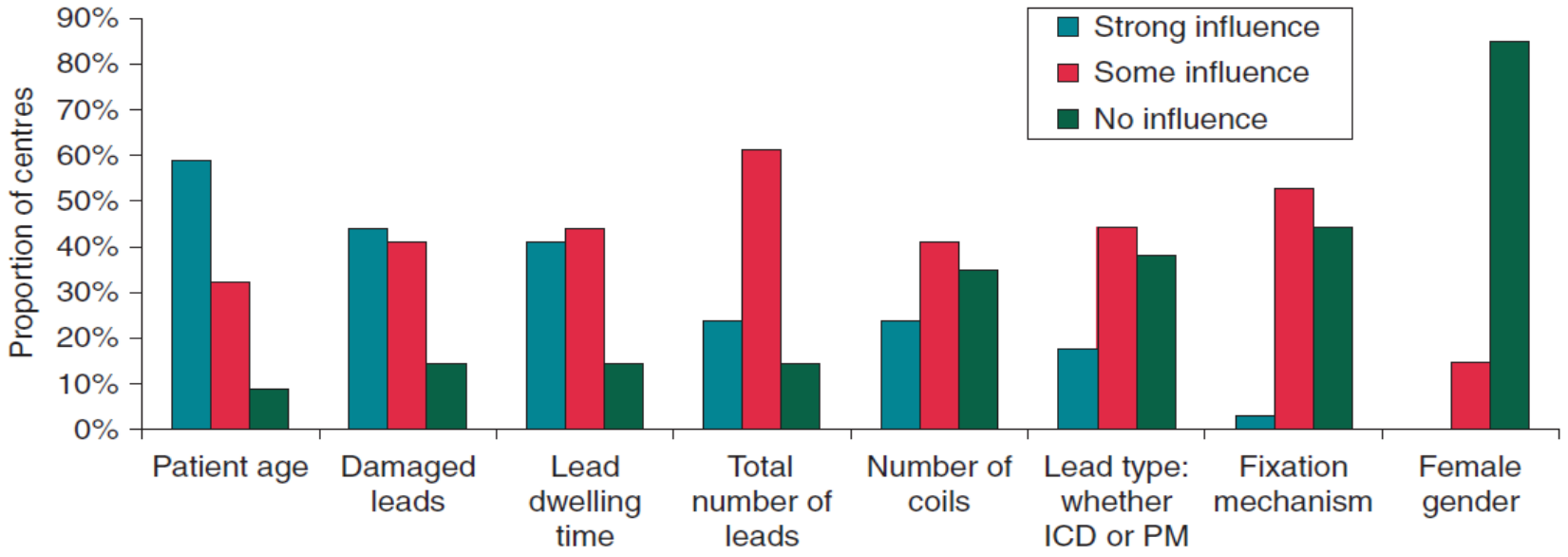
Decision:
Replace device

Probabilistic certainty:
Decision preferred in 99% of simulations

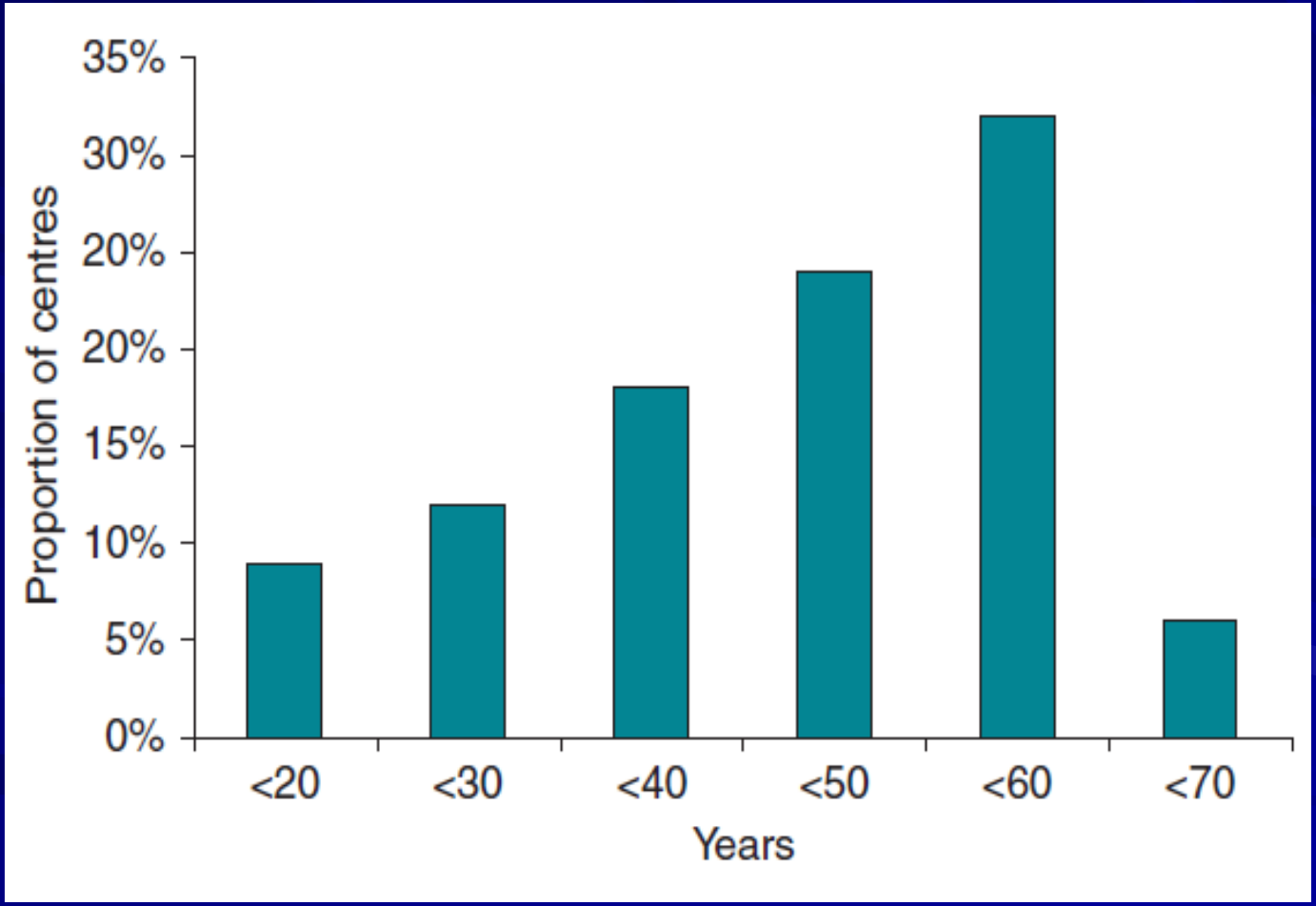
Management of malfunctioning and recalled pacemaker and defibrillator leads: results of the European Heart Rhythm Association survey

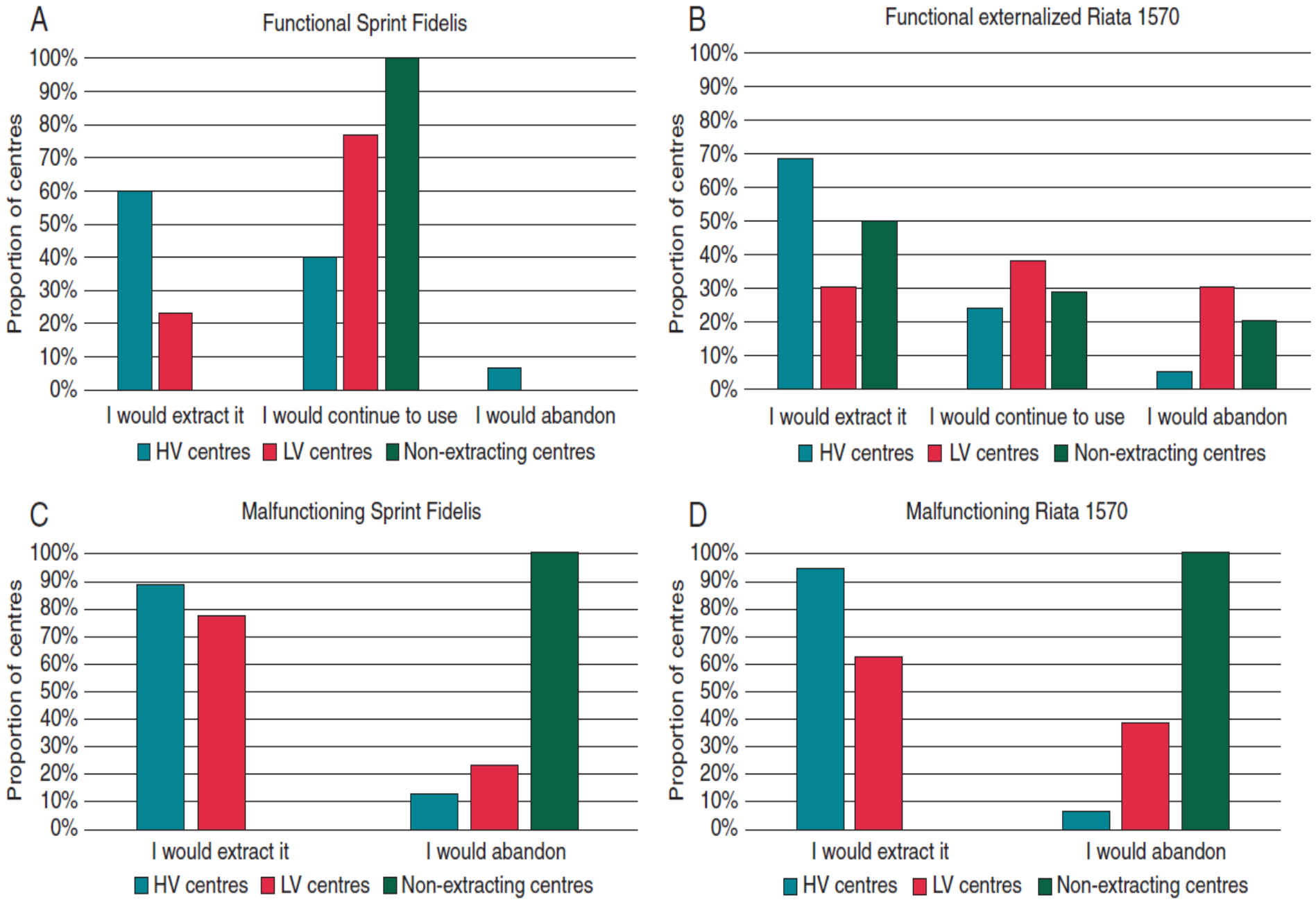
Maria Grazia Bongiorni[1]*, Nikolaos Dagres[2], Heidi Estner[3], Laurent Pison[4], Derick Todd[5], and Carina Blomstrom-Lundqvist[6], conducted by the Scientific Initiative Committee, European Heart Rhythm Association

Europace (2014) **16**, 1674–1678
doi:10.1093/europace/euu302



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




A
Functional Sprint Fidelis
Proportion of centres
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
I would extract it
I would continue to use
I would abandon
HV centres
LV centres
Non-extracting centres
B
Functional externalized Riata 1570
Proportion of centres
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
I would extract it
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HV centres
LV centres
Non-extracting centres
C
Malfunctioning Sprint Fidelis
Proportion of centres
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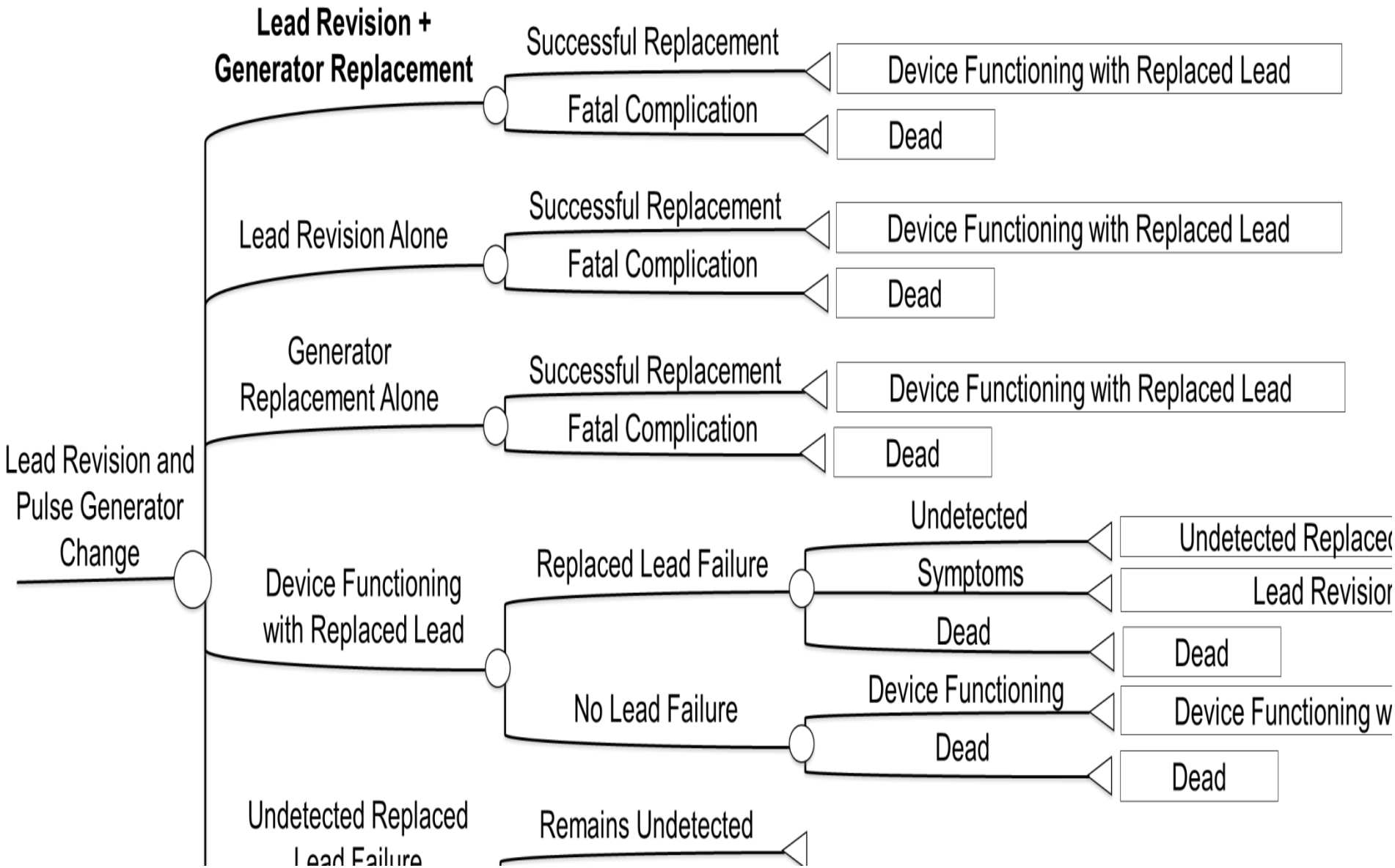
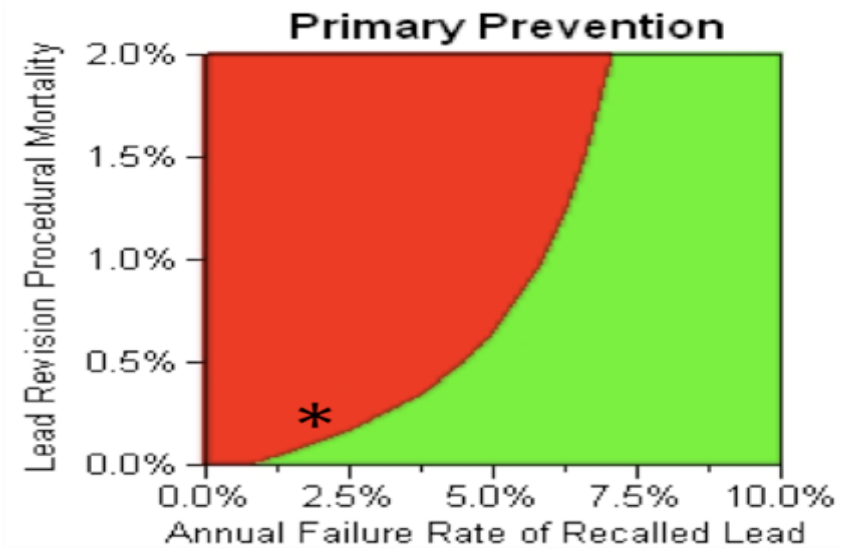
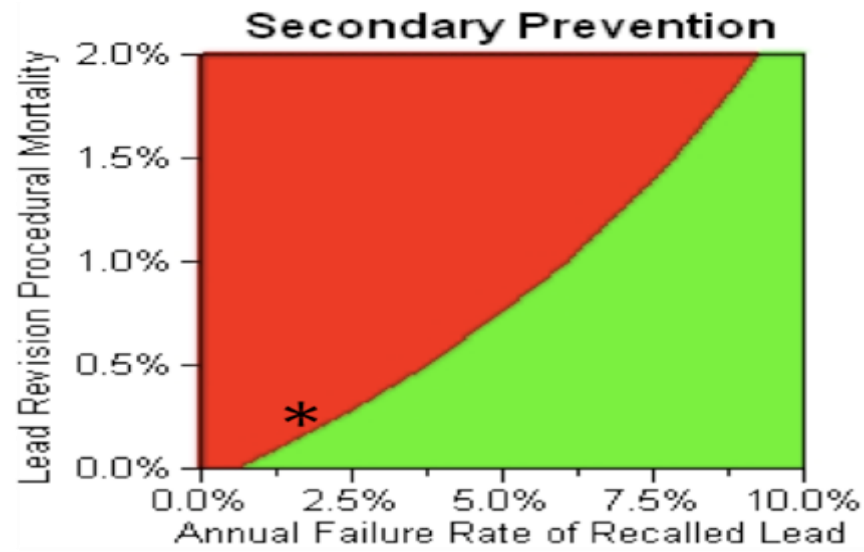


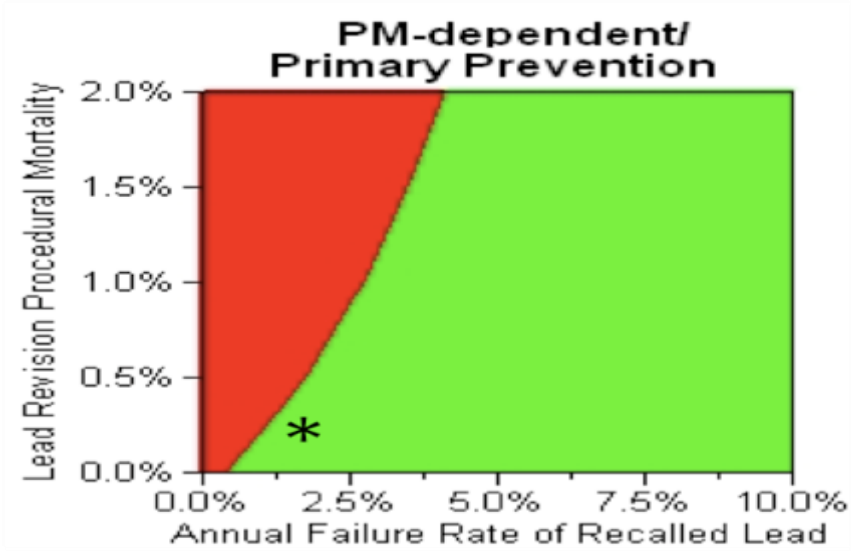
Courtesy of Dr. Marty Burke

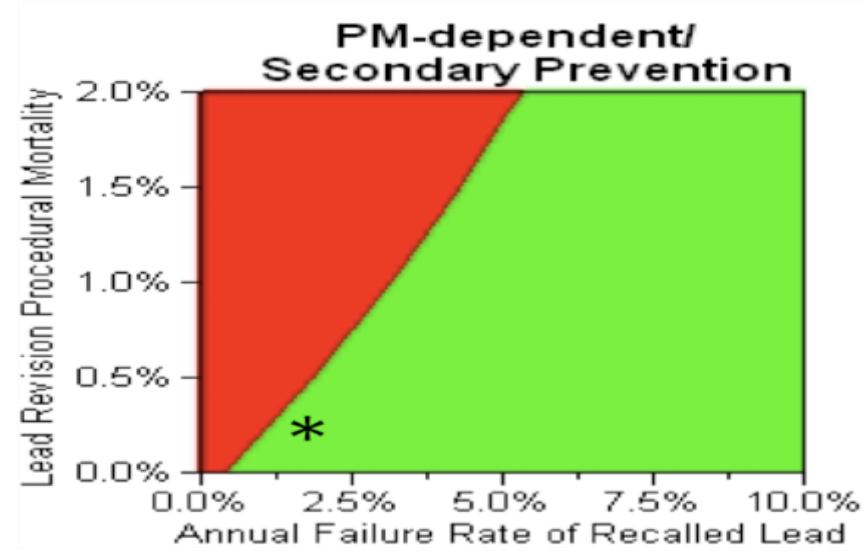
	Primary Prevention	Secondary Prevention	PM-dependent Primary Prevention	PM-dependent Secondary Prevention
Annual Rate of Failure in Recalled Lead (Sprint Fidelis) (%)	1.75			
Baseline Annual Rate of Failure in Lead (Sprint Quattro) (%)	0.10			
Lead Revision Procedural Mortality Rate (%)	0.28			
Pulse 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





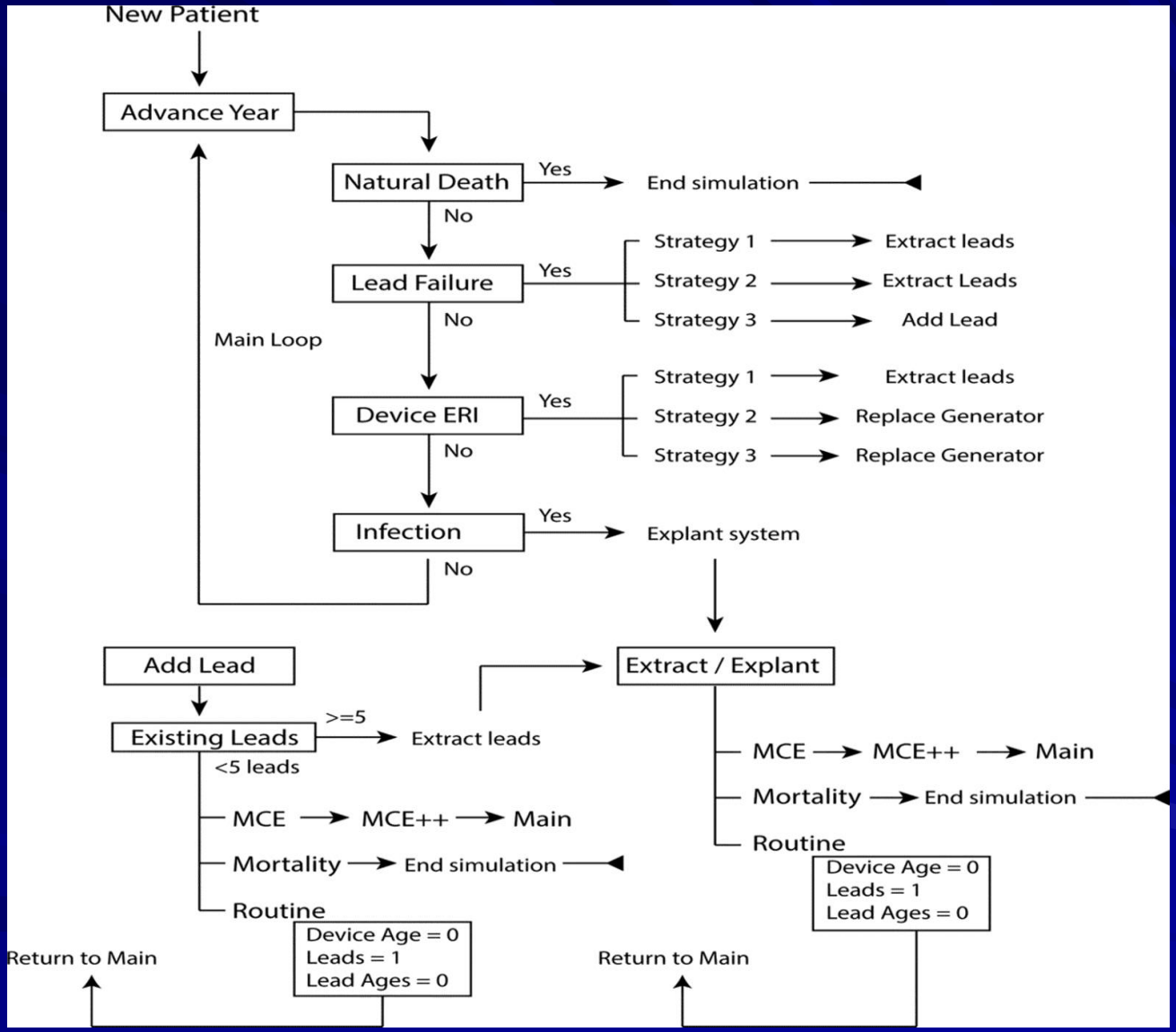




Favors Continued Monitoring of Recalled Lead at Time of Generator Change

Favors Lead Revision at Time of Generator Change

Simplified overview of simulation strategy



G. Stuart Mendenhall Circ Arrhythm Electrophysiol. 2014;7:330-336

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