대한심장학회
The Korean Society of Cardiology

2012년 춘계학술대회

Device Update
Implantable Cardioverter Defibrillator (ICD)

박상원

Arrhythmia Center, KUMC

www.korea-heartrhythm.com

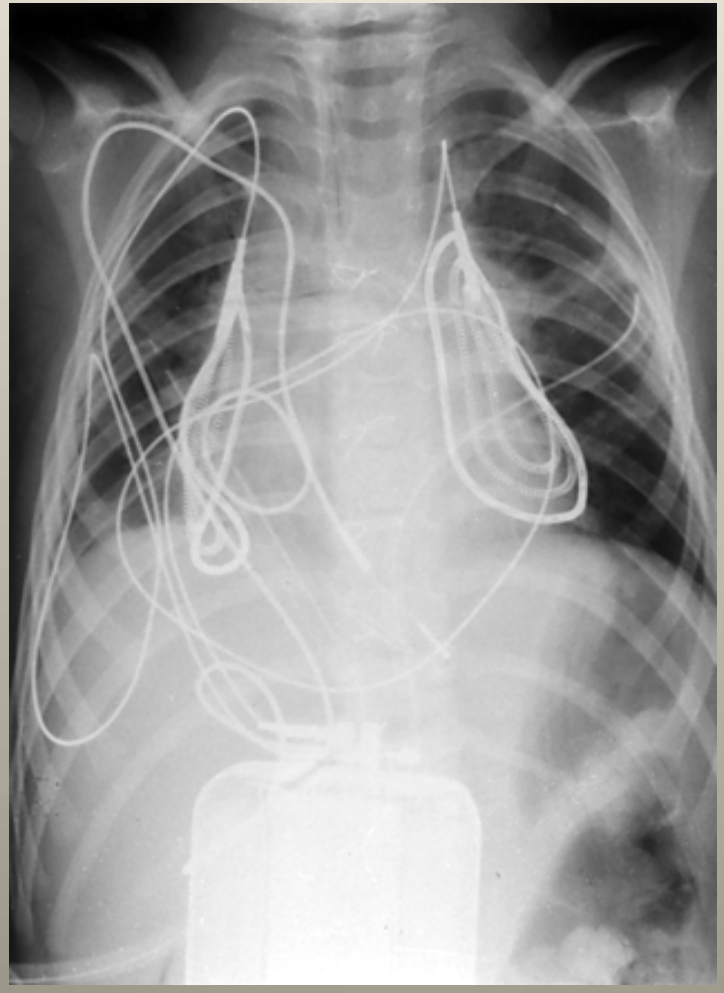
Korea University Medical Center

Seoul, Korea

The Development of ICD

- by a team including Michel Mirowski, Morton Mower, and William Staewen at Sinai Hospital in Baltimore
- In 1980, the first patient received an ICD at Johns Hopkins Hospital.
- 1985: FDA approves the ICD, specifying that patients had to have survived 2 cardiac arrests to qualify for ICD implantation

ICD implantation require thoracotomy



Dr. Bernard Lown

the inventor of the external defibrillator

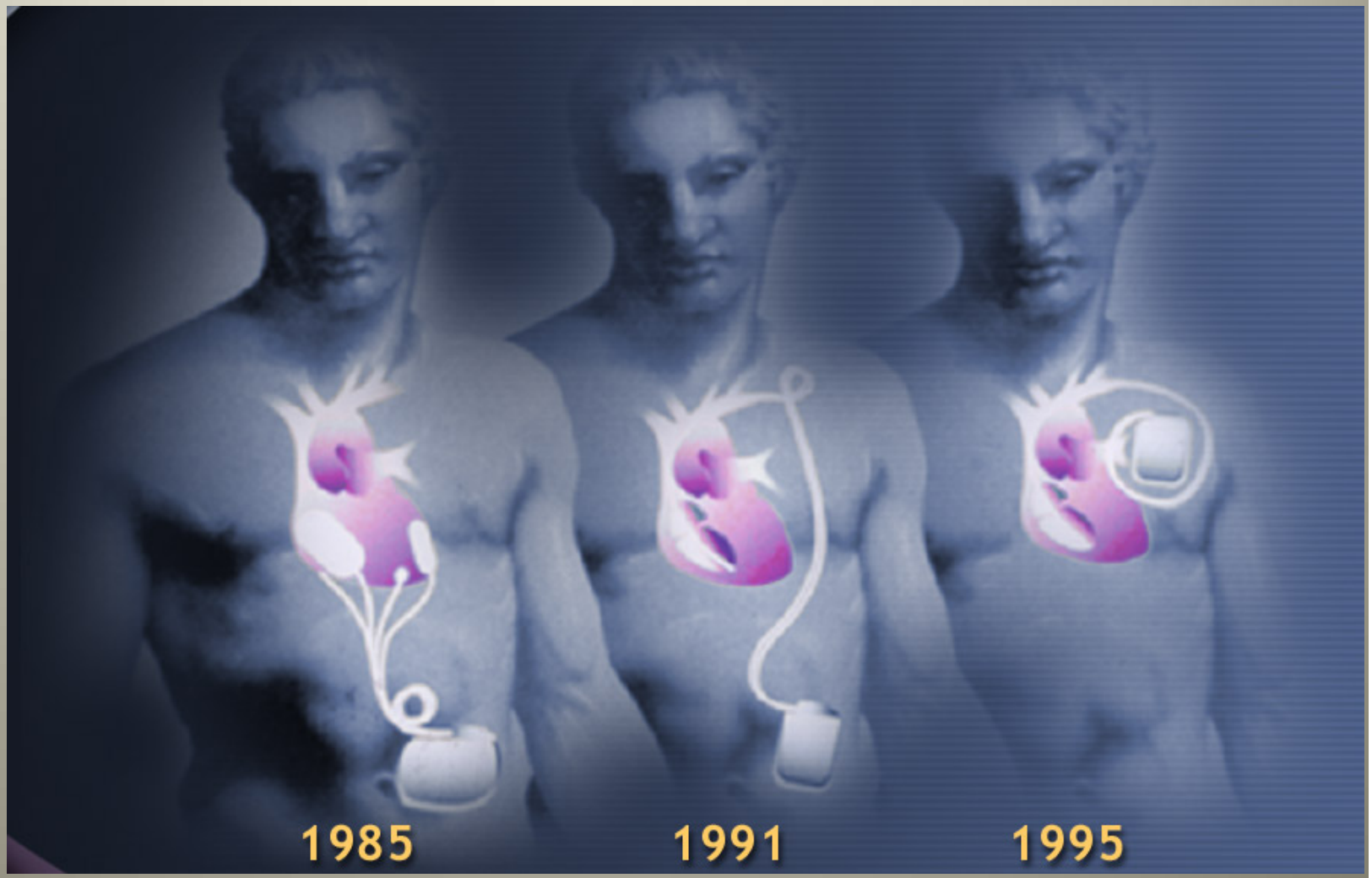
- “In fact, the implanted defibrillator system represents an imperfect solution in search of a plausible and practical application".

Medtronic Implantable Defibrillators (1989-2000)

209 cc | 113 cc | 80 cc | 80 cc | 72 cc | 54 cc

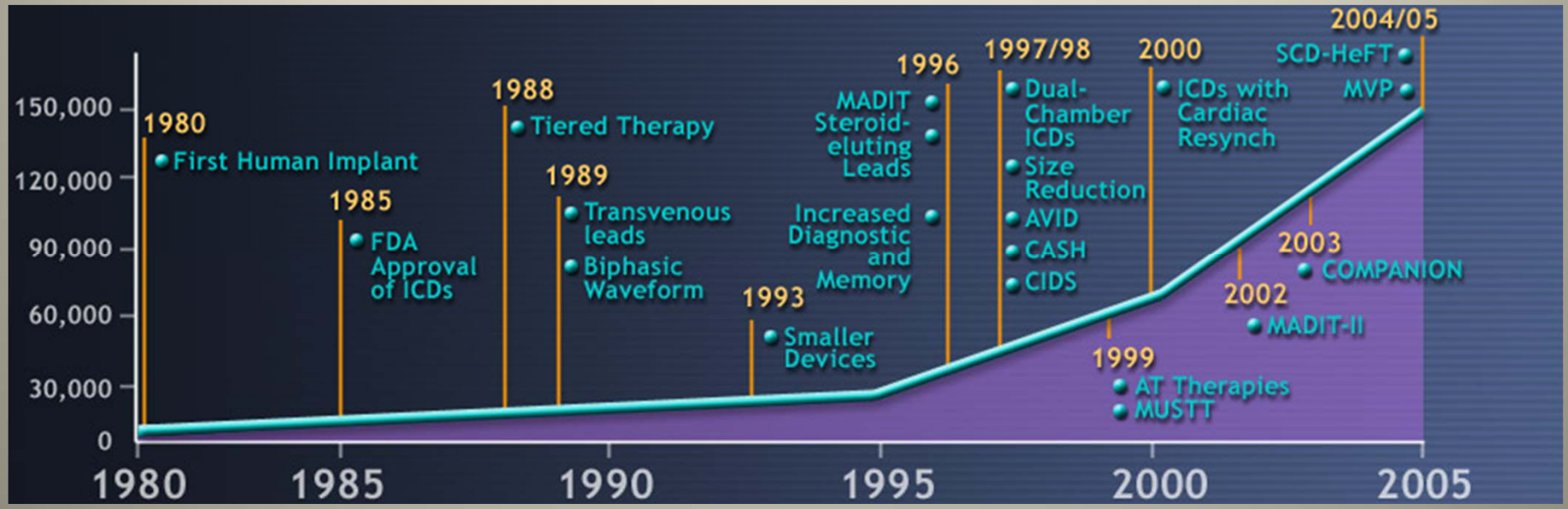
62 cc | 49 cc | 39.5 cc | 39 cc | 39.5 cc | 39 cc

ICD Evolution



Evolution of ICD Technology

Evolution of ICD therapy



Number of Worldwide ICD Implants Per Year
(Ref: Corporate Market Share Database)

Early Indication of ICD

- ICD's first treatment group to be studied were those had already suffered a VT or VF event.
- Important trial
  - **AVID**
- Preceding AVID (smaller trials)
  - **CASH -** Cardiac Arrest Survival in Hamburg (349 subjects)
  - **CIDS –** Canadian Implantable Defibrillator Study (659 subjects)
  - The above two showed trends, but not significant trends towards less mortality with ICD's (underpowered)

AVID Trial

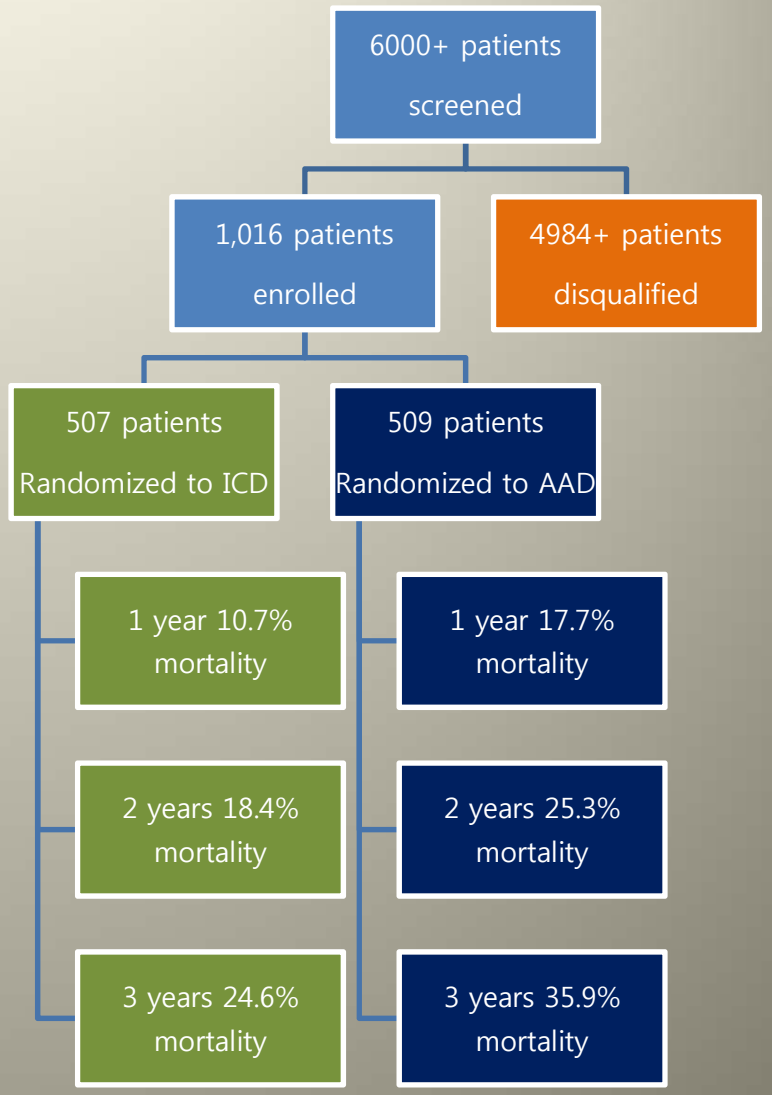
- Anti-arrhythmics Versus Implantable Defibrillators (AVID)
- Multicenter Randomized Controlled Study. 1993 - 1997
- To determine the impact of ICDs and AADs on all cause mortality
- Secondary prevention trial

AVID trial

Inclusion Criteria

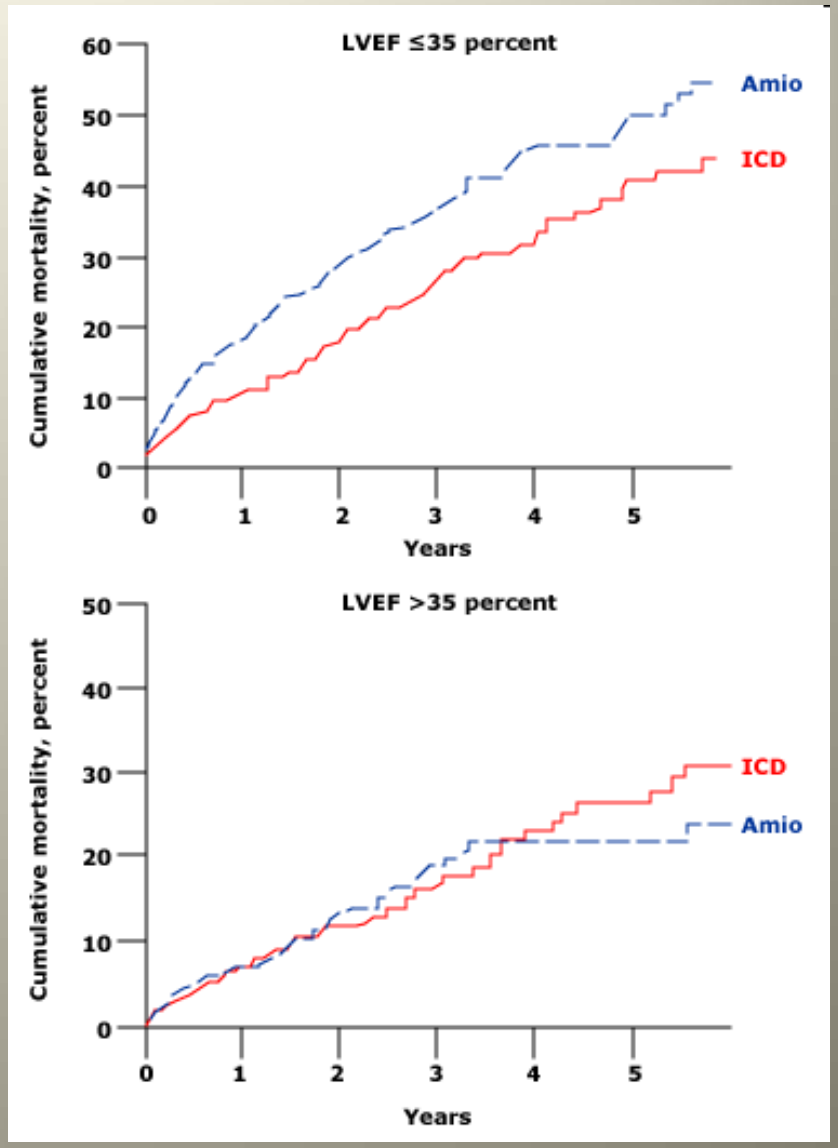
►VF survivors
►VT with syncope
►Sustained VT without syncope
►LVEF <40% with one of the following
  ►Systolic BP<80mmHg, chest pain, near syncope, acute CHF

Study terminated early due to greatly improved outcome in ICD group.



Important Observation

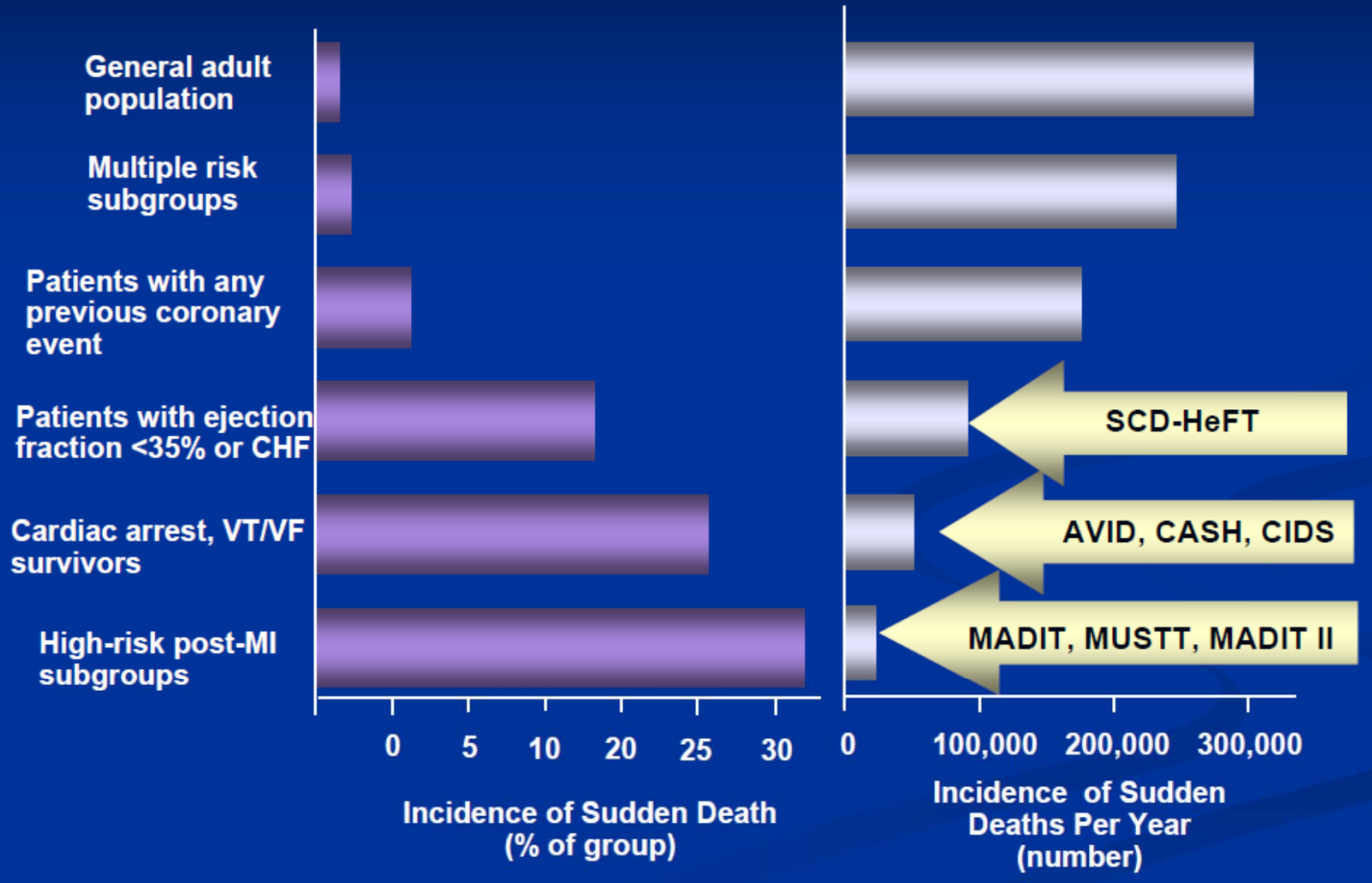
- From the AVID and other secondary prevention trials, those with a low EF actually did much better with ICD's than patients with preserved EF's.



ICD Indication Expansion for Primary Prevention

- Ischemic CMP
  - MADIT
  - MADIT II
  - CABG Patch
  - MUSTT
  - SCD-HeFT
  - DINAMIT
  - IRIS
- Non-ischemic CMP
  - CAT and AMIOVIRT
  - SCD-HeFT
  - DEFINITE

Incidence of SCD in Specific Populations and Annual SCD Numbers



Adapted from: Myerburg RJ. Sudden Cardiac Death: Exploring the Limits of Our Knowledge. *J Cardiovasc Electrophysiol* Vol. 12, pp. 369-381, March 2001.

우리나라의 ICD
보험급여 인정기준

- 일시적이거나 가역적인 원인에 의한 것이 아닌 심실세동이나 심실 빈맥에 의한 심정지
- 기질적 심질환이 있는 자발성 지속성 심실빈맥 환자
- 기질적 심질환이 없는 자발성 지속성 심실빈맥 환자에서 다른 치료 방법으로 조절되지 않는 경우
- 실신에 대한 충분한 평가로도 원인을 알 수 없는 실신에서 임상적으로 연관되고 혈역동학적으로 의미있는 심실빈맥이나 심실세동이 임상전기생리학적검사에 의해 유발되고 약물치료는 효과가 없거나 복용을 못하는 경우

- 이전의 심근경색 환자, 관상동맥질환자 또는 좌심기능 부전환자 중에서 아래의 세가지 모두에 해당되는 경우
  ① 30%이하의 낮은 좌심실 구혈률
  ② 비지속성 심실빈맥
  ③ 임상 전기생리학적 검사상 심실세동이나 지속성 심실빈맥이 유발되는 경우

① 실신의 증상
② 급사의 가족력
③ 좌심실중격의 과도한 비후(〉 30 mm)
④ 24시간 활동 중 심전도에서 나타난 비지속성 심실빈맥
⑤ 운동부하 검사 상 이상 혈압증가 반응이 없는 경우(충분한 운동부하에도 혈압상승이 < 20 mmHg 인 경우)

- Long QT syndrome 환자로 실신에 대한 충분한 평가로도 원인을 알 수 없는 실신의 경력이 있고 베타차단제 치료에도 재발하거나 약물치료를 지속할 수 없는 경우

Device Update
-ICD-

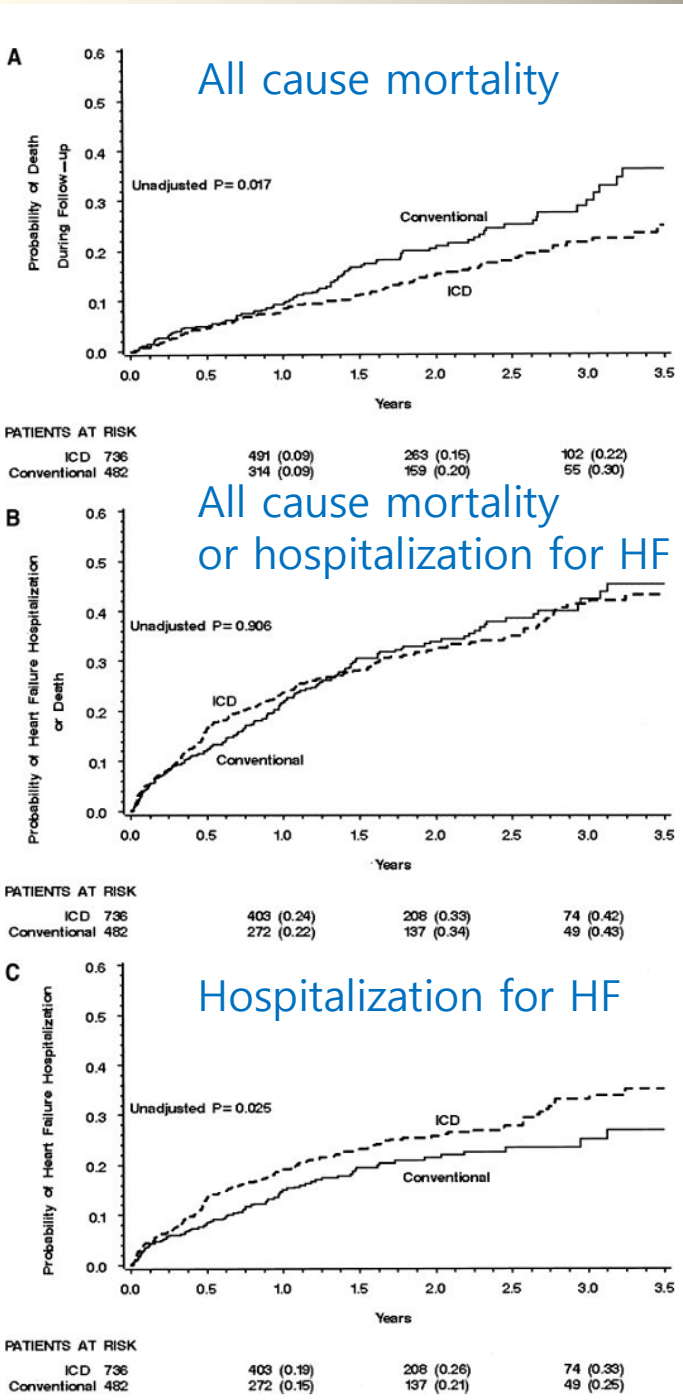
- **ISSUE OF ICD SHOCK**
- **ISSUE OF ICD REPLACEMENT**

Issue of ICD shock

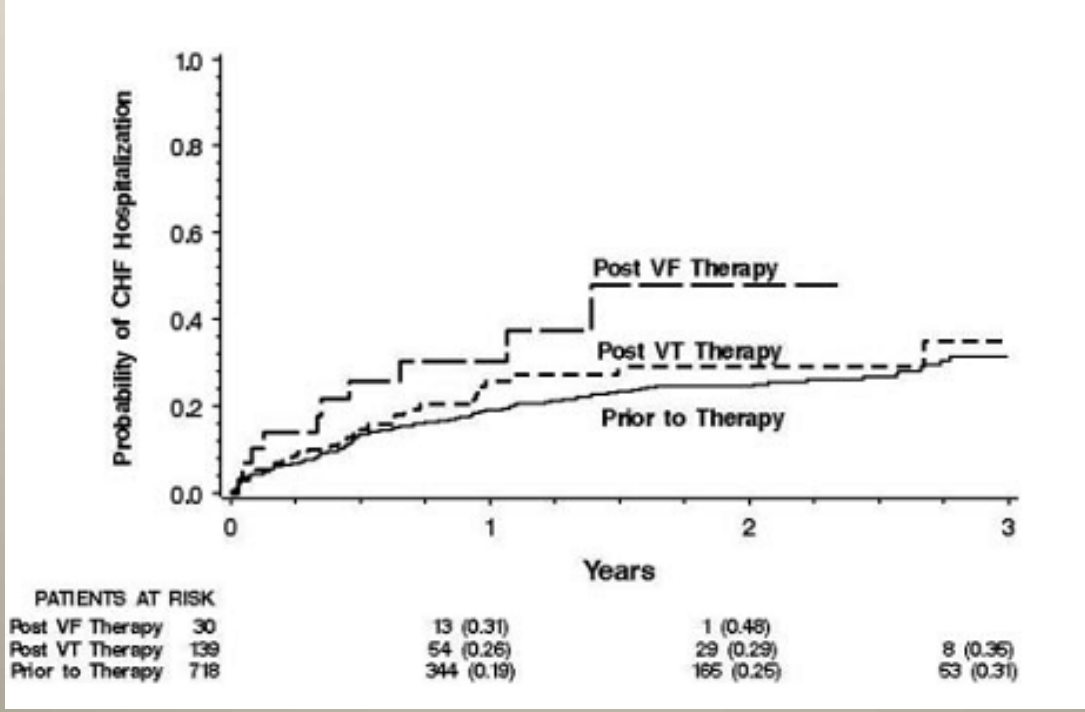
From MADIT II Trial

- Chronic ischemic heart disease who are treated with ICD have improved survival.
- But ICD arm have more increased risk of heart failure (HF).

Circulation . 2006;113:2810-2817



From MADIT II Trial

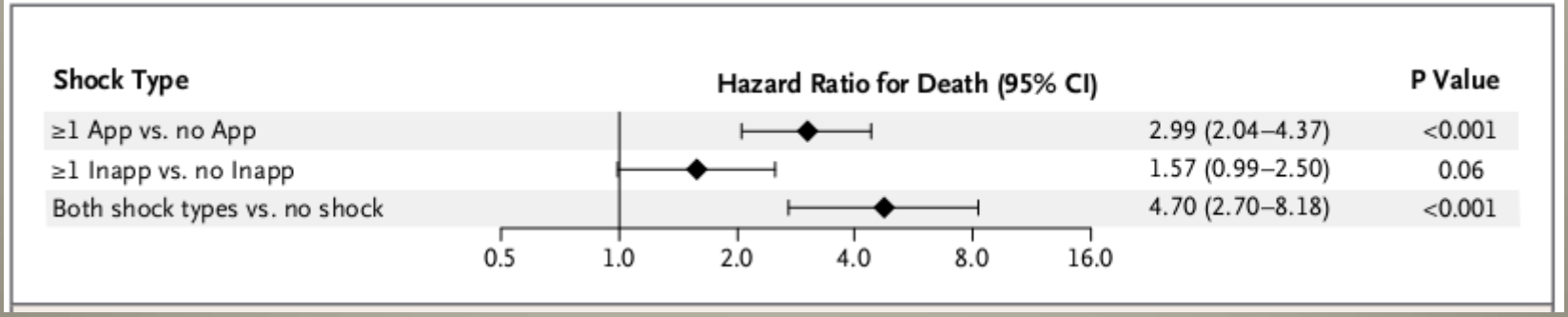


Patients who experienced appropriate shock therapy had more increased risk of CHF hospitalization

Circulation . 2004;110:3760-3765

From SCD-HeFT study

- Appropriate shock : 3 X increased risk of death
- Inappropriate shock : 1.5 X increased risk of death

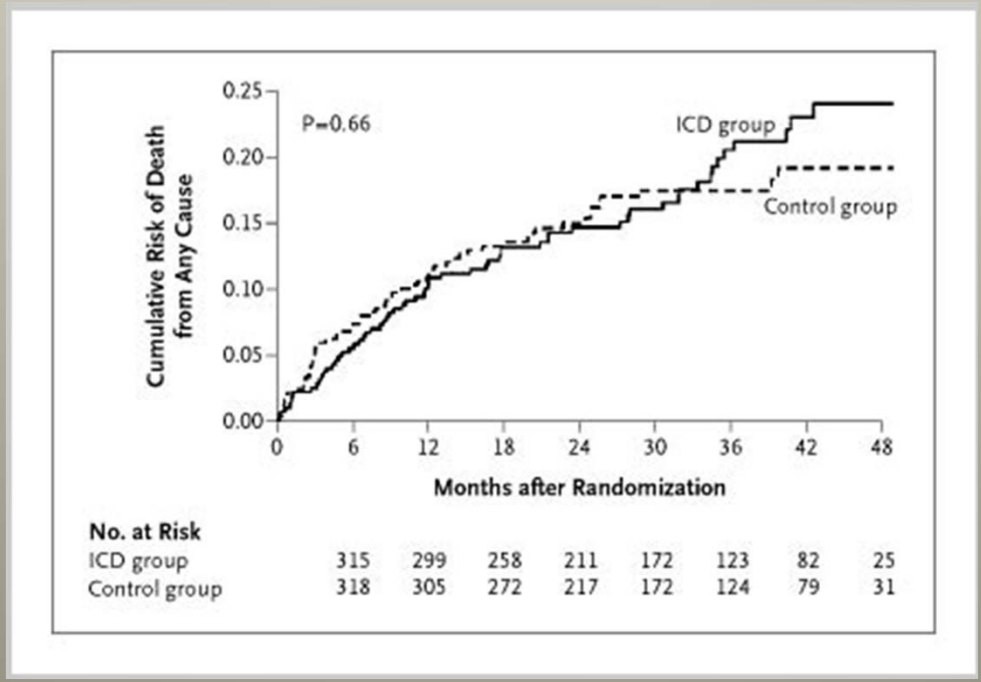


Hazard Ratios for the Risk of Death among patients who survived at least 24 hours after a First ICD Shock

N Engl J Med. 2008 September 4; 359(10): 1009–101

Defibrillation in Acute Myocardial Infarction Trial (DINAMIT).

- randomized 653 patients with EF <35%, recent MI (6 to 40 days), and low heart rate variability or high resting heart rate to primary prevention ICD (311) or medical therapy (342).



N Engl J Med 2004;351:2481-8.

From DINAMIT study

- In patients randomized to an implantable cardioverter-defibrillator (ICD), sudden deaths were reduced but nonarrhythmic mortality was increased, which was confined to the ICD minority subgroup that recorded electric therapies (mostly shocks) for VTA

Circulation . 2010;122:2645-2652

Risk for Death by Rhythm and Therapy Types in Primary Prevention Trials

Electrical Therapy Type	Hazard of Death			
	MADIT-II	SCD-HeFT	DINAMIT	COMPANION
Appropriate shock only Ischemic HF Nonischemic HF	3.4 (2.0-5.6)	5.7 (4.0-8.1) 8.7 (5.7-13.4) 2.61 (1.4, 4.8)	4.9 (2.4-10.2)	1.7-2.4
Inappropriate shock only	2.3 (1.2-4.7)	2.0 (1.3-3.1)	Not reported	Not reported
Appropriate ATP only	0.4(0.2-1.2)	NA (all shocks)	Not reported	Not reported
Inappropriate ATP only	0.7 (0.2-2.5)	NA (all shocks)	Not reported	Not reported

1.Conditioning rhythm type influences shocked episode risk
   1. Shocked VTA mortality risk > shocked SVT mortality risk
   2. Shocked VF mortality > shocked VT mortality risk
2.Risk is greater in ischemic HF
3.ATP does not increase VTA or SVT episode risk

Paradox of shock therapy

Sudden Cardiac Death Prevention

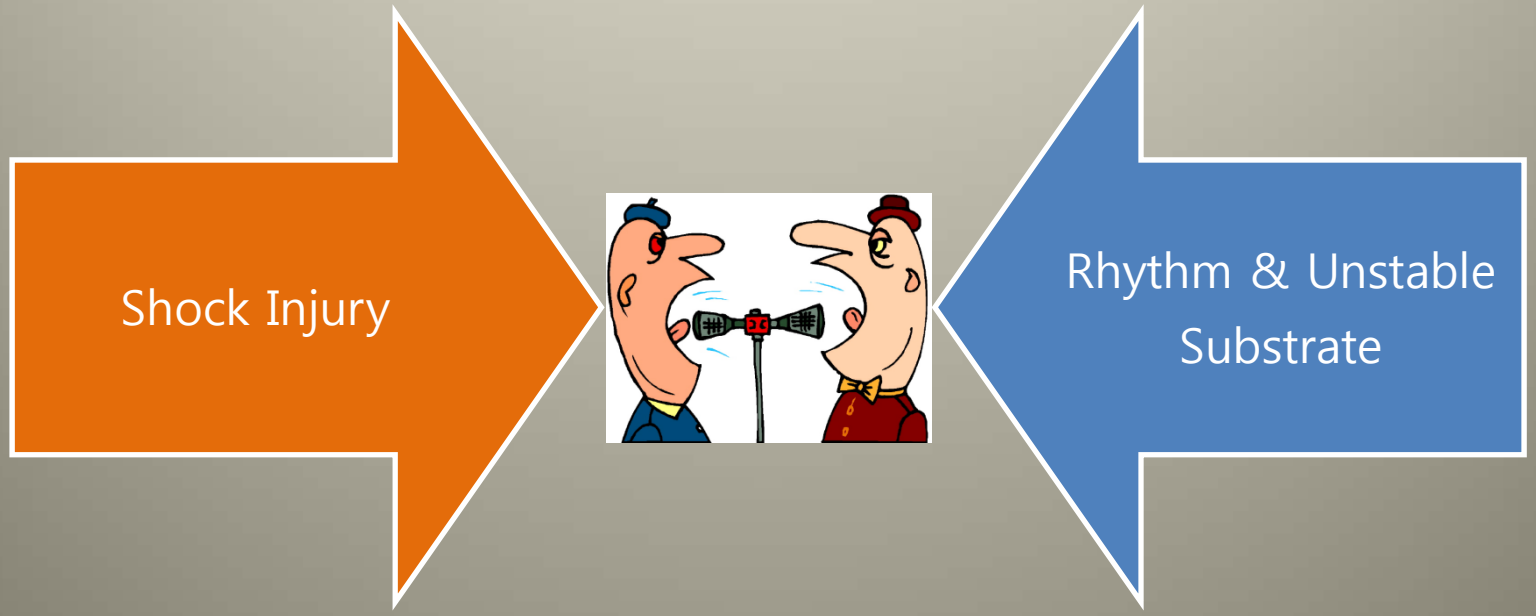
V.S.

Heart failure death acceleration

Cause of higher mortality in shocked patient ?

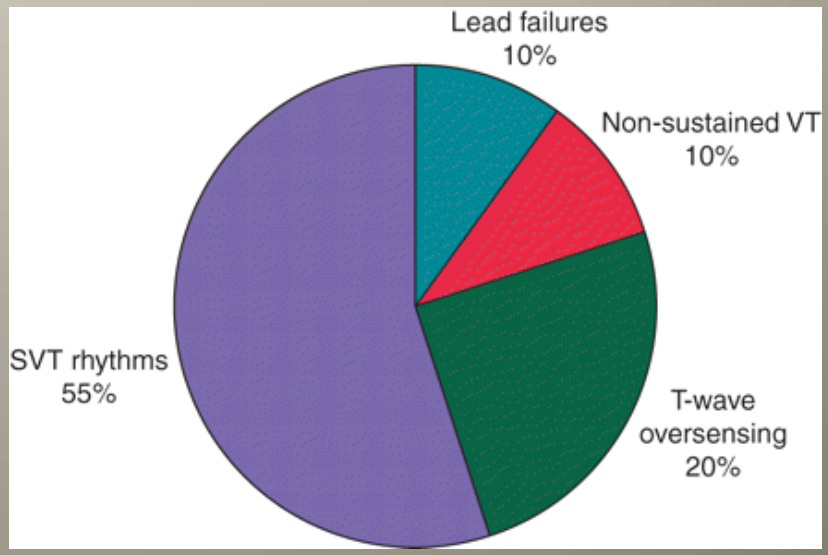
- Direct myocardial injury by high voltage shock.

- patients with **VTA** and **shocks** are at higher risk for death, and the former is a marker for, but mechanistically unrelated to, the latter.



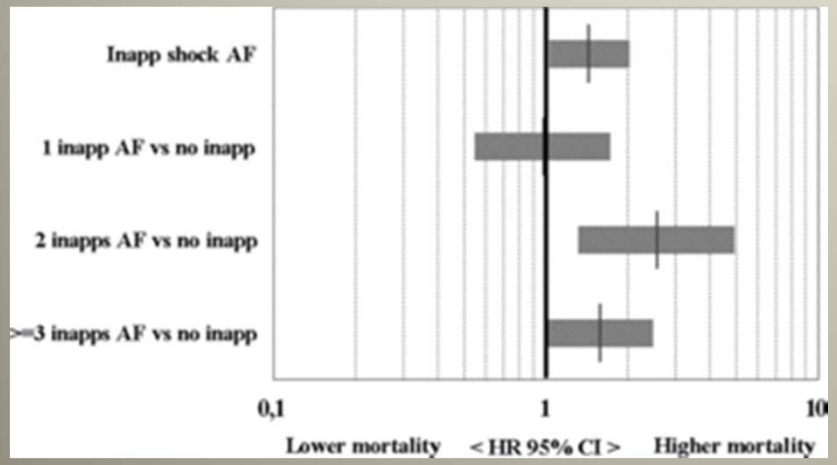
Inappropriate shock

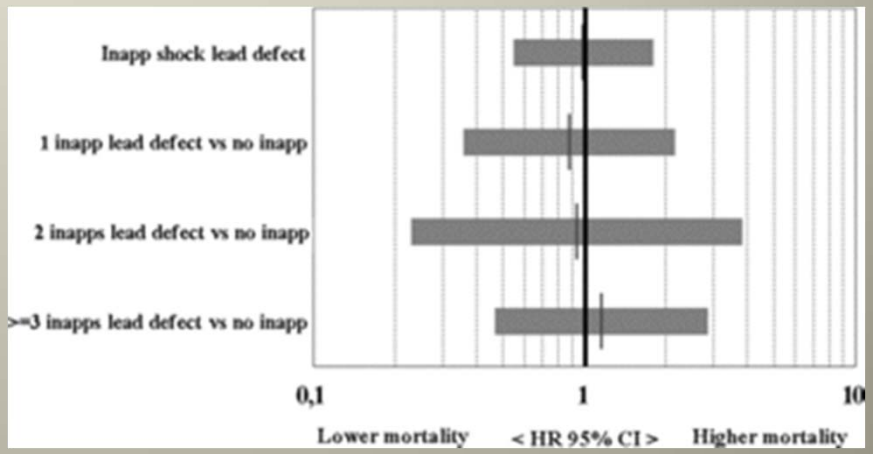
- patients receiving an inappropriate shock had a 2-fold increase in risk of death
- Inappropriate shock usually from
  - Atrial fibrillation, supraventricular tachycardia
  - Oversensing (QRS and T wave double count)
  - Lead problem (lead fracture, insulation break, and lead dislodgement)
  - Others



Matter of Rhythm

- Analysis of inappropriate shock
  - Increased mortality by Af development, but no effect on mortality by lead failure.



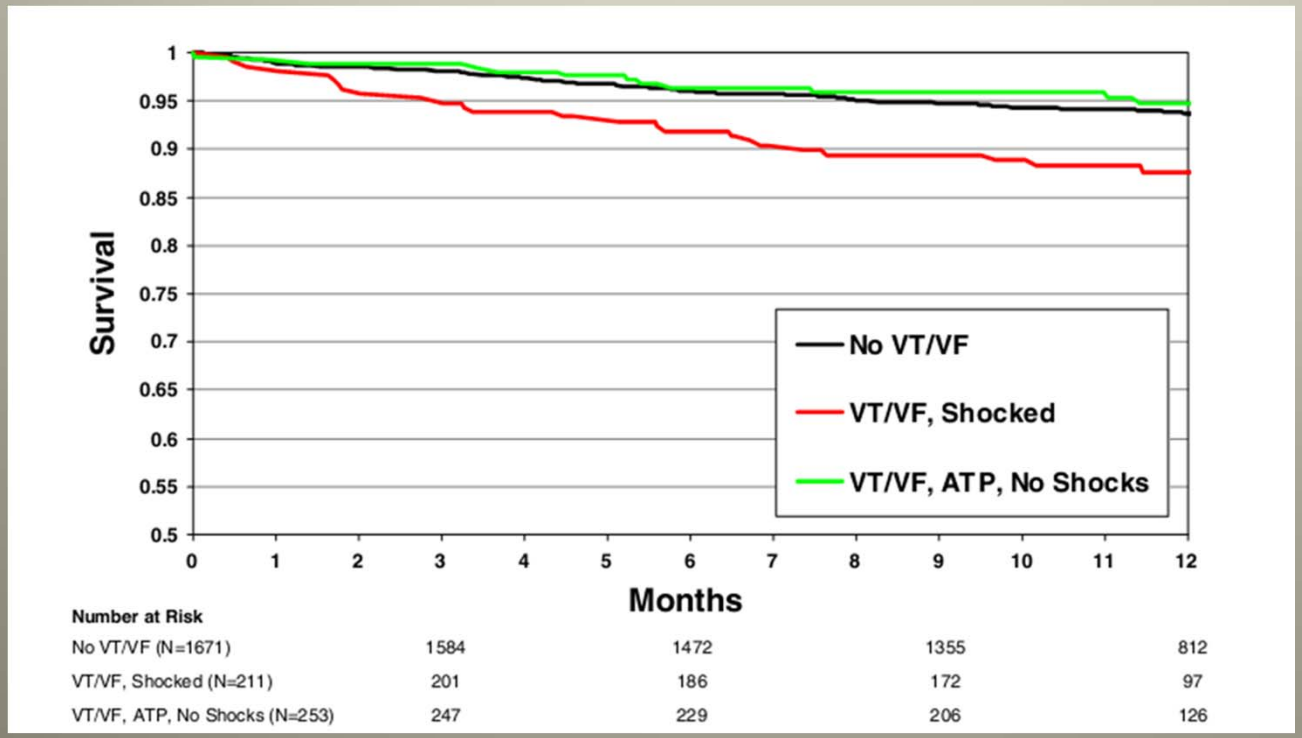


  - the risk associated with ICD shock therapy is related to the underlying rhythm and not to the shock itself

J Cardiovasc Electrophysiol, 2012 FEb pp. 1-6

Matter of Shock

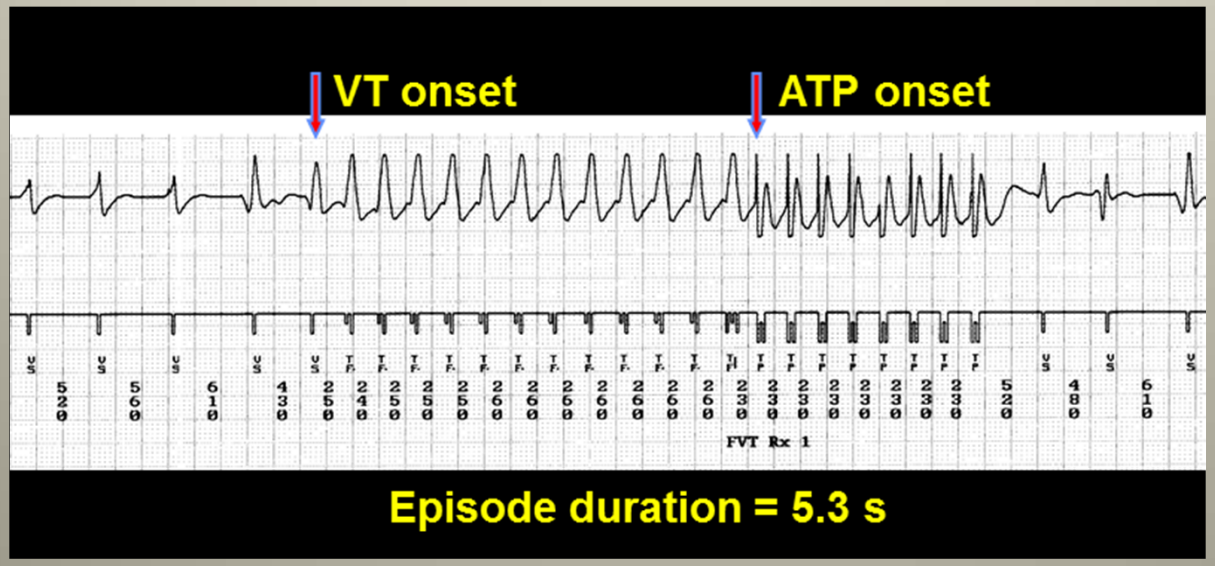
- Cellular change by high voltage shock in animal
- Patient with VTA treated by Anti Tachycardia Pacing (ATP) showed better survival by retrospective analysis of PAINFREE I & II, EMPIRIC, and PREPARE study.



Heart Rhythm 2010;7:353–360

Anti Tachycardia Pacing (ATP)

- Overdrive pacing with shorter cycle length of tachycardia could terminate the tachycardia

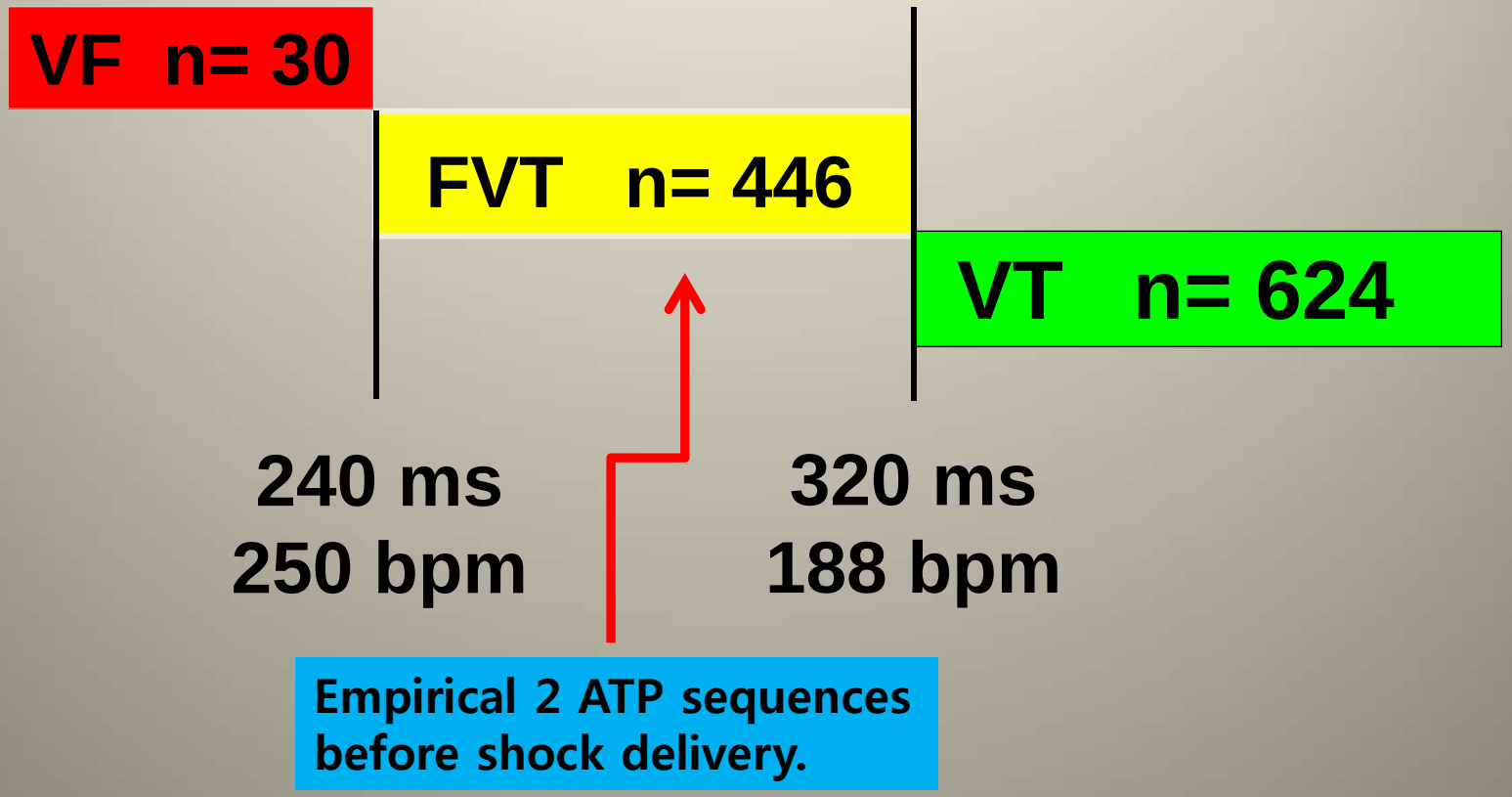


- The Failure of ATP termination may lead to acceleration of VT to VF.
- Early recognition of this relationship resulted in a historical hesitancy to apply ATP for FVT (rates > 190-250 beats/min).

PainFREE R_x

220 pts with ischemic CMP

VTA Detected (n= 1100)

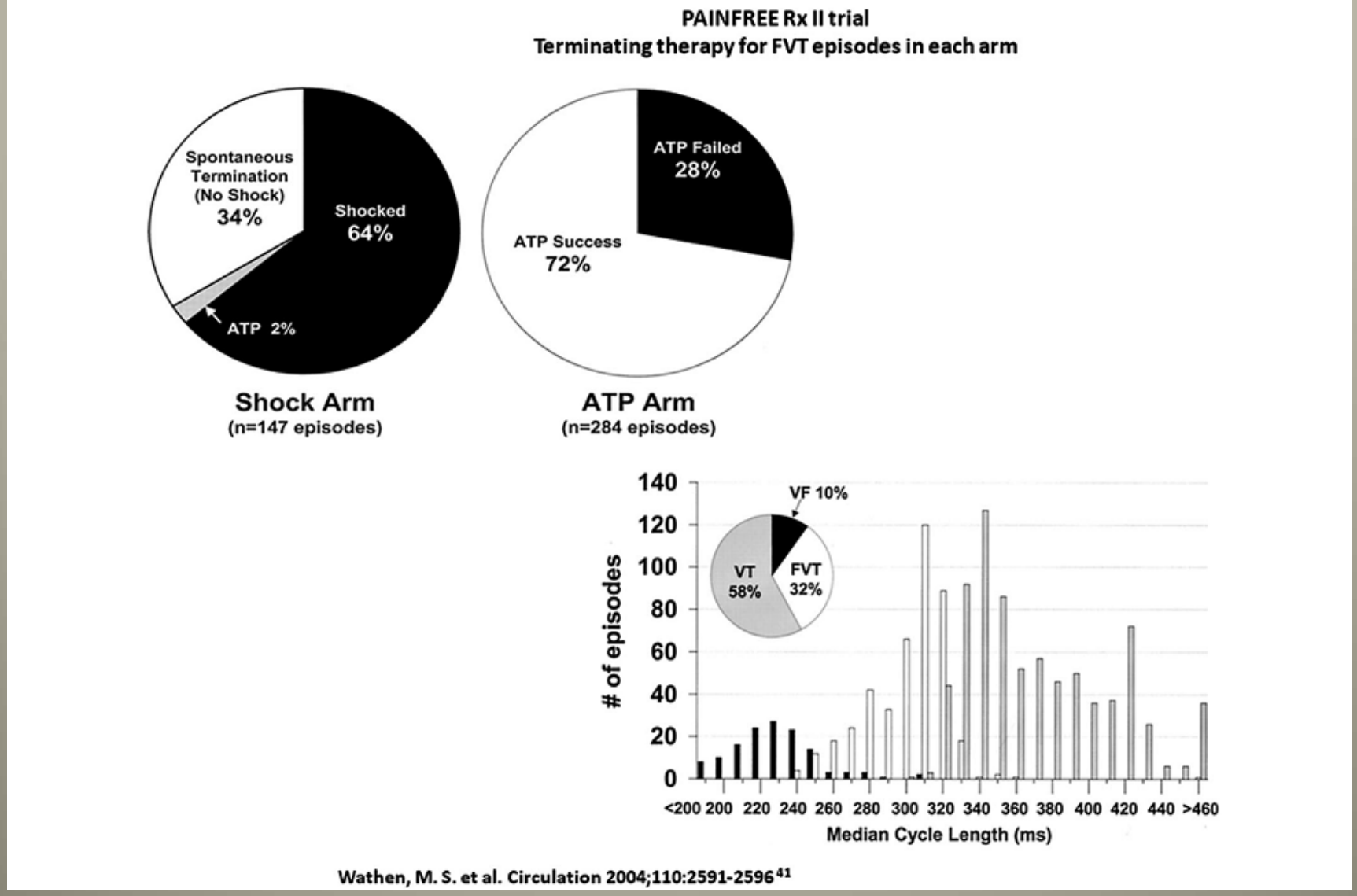


. *Circulation*. 2001; 104: 796-801.

PainFREE R_x Conclusions

- **FVT is common - 40% of all episodes**
  - **93% of episodes detected in traditional VF zone were detected as FVT**
- **ATP is highly effective**
  - **Raw ATP success rate: 85%**
  - **ATP success rate adjusted for multiple episodes: 77%**
- **Low risk for acceleration**
  - **Acceleration rate of 4-7%**
- **Low risk for syncope**
  - **Syncope rate of 2%**

Circulation. 2001; 104: 796-801.



However, because ATP requires no delay for capacitor charging after detection of VT/VF, it treats even more self-terminating VT/VF than shocks

Morbidity of shock

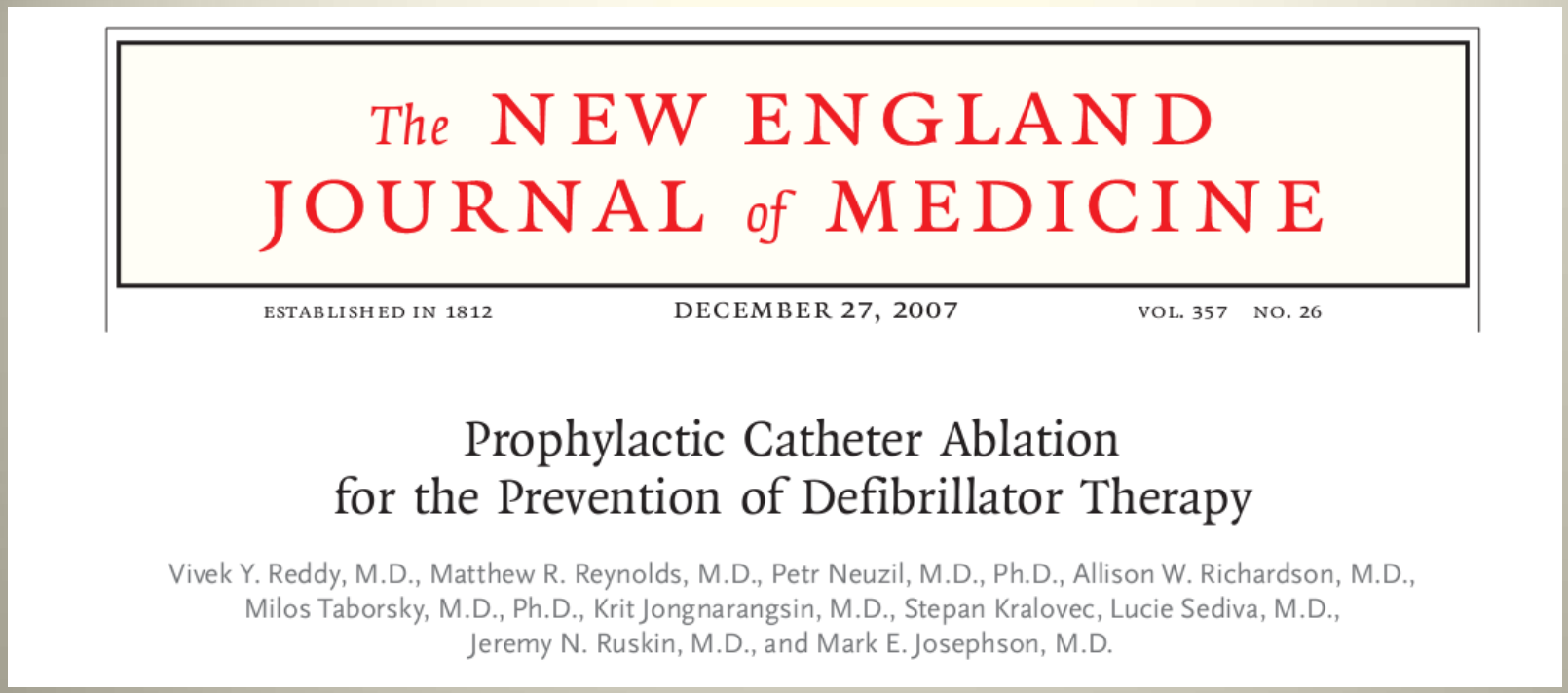
- Psychological problem
- Reduce quality of life
- Heart failure acceleration
- Proarrythmia (rare)

Modern ICD means the device which could terminate the tachycardia by overdrive pacing with the back up support of shock therapy.

ICD update to minimize inappropriate and unnecessary shocks

- ICD Programming
  - rate and duration for initial detection
  - SVT-VT discrimination (algorithm, SC vs DC)
  - ATP and shock strength
  - Sensing enhancements (T wave oversensing)
- Lead Fracture surveillance
- Remote Monitoring

Circ Arrhythm Electrophysiol 2011;4;778-790



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 27, 2007 VOL. 357 NO. 26

Prophylactic Catheter Ablation for the Prevention of Defibrillator Therapy

Vivek Y. Reddy, M.D., Matthew R. Reynolds, M.D., Petr Neuzil, M.D., Ph.D., Allison W. Richardson, M.D., Milos Taborsky, M.D., Ph.D., Krit Jongnarangsin, M.D., Stepan Kralovec, Lucie Sediva, M.D., Jeremy N. Ruskin, M.D., and Mark E. Josephson, M.D.

- Eligible patients with a history of a MI with ICD for spontaneous VT or VF.
- Control vs adjunctive catheter ablation (64 patients in each group)
- The primary end point: survival free from any appropriate ICD therapy

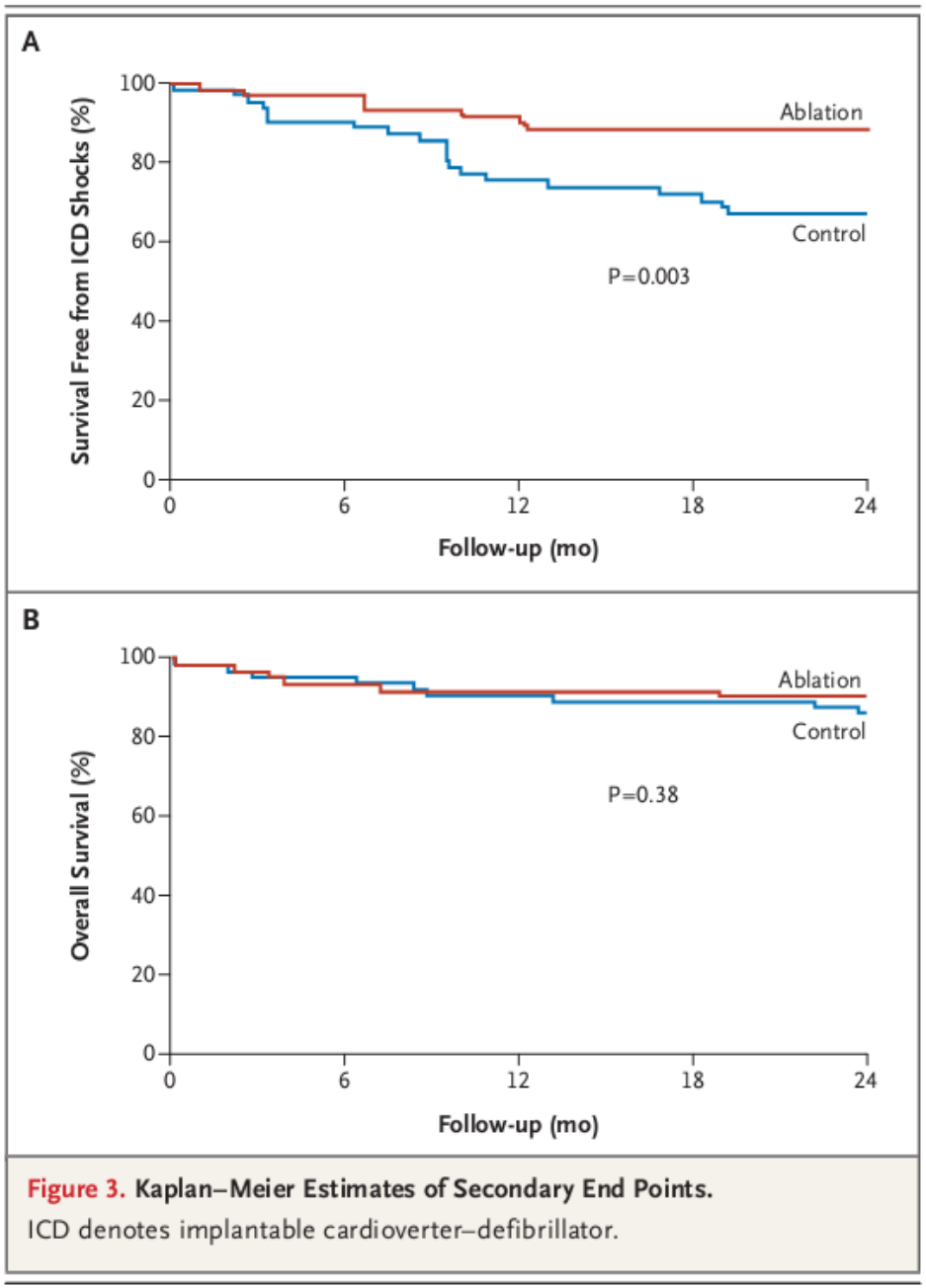


Figure 3. Kaplan–Meier Estimates of Secondary End Points.
ICD denotes implantable cardioverter–defibrillator.

a 65% reduction in the risk of receiving ICD therapy

a trend toward decreased mortality in the ablation group (9% vs. 17%, P = 0.29)

Issue of shock therapy

- Minimizing ICD shocks requires a comprehensive approach,
  - patient selection
  - general medical care (eg, preventing electrolyte abnormalities)
  - general cardiac care (preventing ischemia and treating heart failure).
  - use of antiarrhythmic drugs and catheter ablation both to prevent VT or SVT and to control the ventricular rate in Af
  - appropriate choice of hardware and device programming

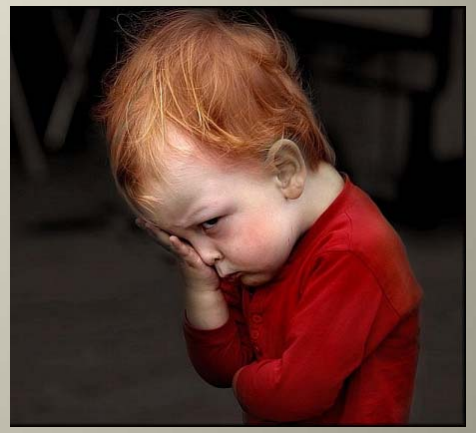
Issue of Replacement

Issue of Replacement

- More than 100,000 ICDs are implanted in the US annually.
- Of these procedures, at least 25% are generator replacements required as a result of depleted battery life

What is your Opinion ?

- Case I
  - 85 year old man with ICMP who had ICD for primary prevention
  - Comorbidity with progressive dementia
  - ICD has never fired appropriately
  - He referred for replacement of ICD for battery depletion.
- Case II
  - 55 year old woman with DCMP who had CRT-D for primary prevention.
  - Now her LV function was nearly normalized
  - ICD has never fired appropriately
  - She referred for replacement of CRT-D
  - CRT-P vs CRT-D



What is your opinion?

- Case III
  - 43 year old man with typical Brugada ECG
  - Inducible VF by EPS
  - ICD implantation for primary prevention
  - ICD has never fired appropriately
  - He referred for replacement of ICD for battery depletion

Time dependence of ICD therapy in Ischemic CMP

- 525 patients with prior MI and LVEF ≤ 35%, who received an ICD
- 115 (22%) had appropriate ICD therapy.
- Incidence of first appropriate ICD therapy was highest in the first year post-implant (20%), decreased to 12% in year 2, and remained at 6–11% yearly thereafter.

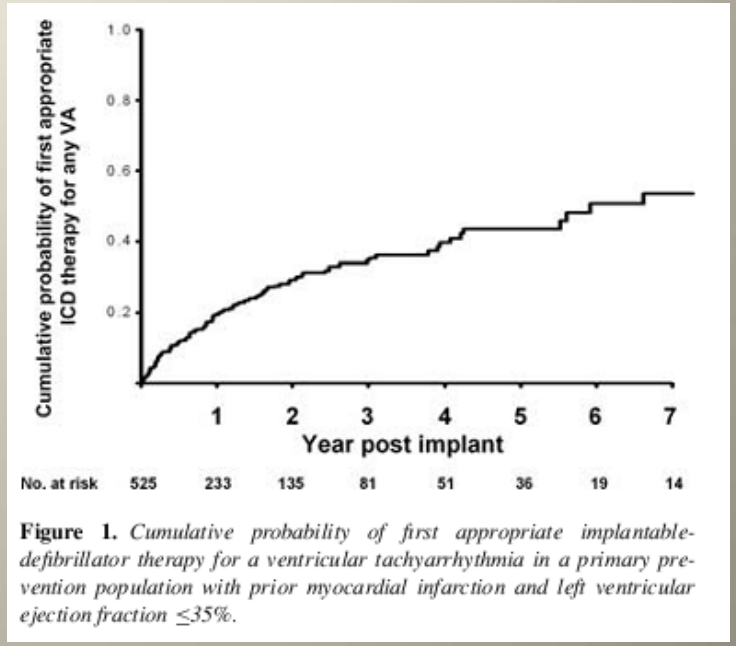


Figure 1. *Cumulative probability of first appropriate implantable-defibrillator therapy for a ventricular tachyarrhythmia in a primary prevention population with prior myocardial infarction and left ventricular ejection fraction ≤35%.*

J Cardiovasc Electrophysiol, 2008, pp. 784-789

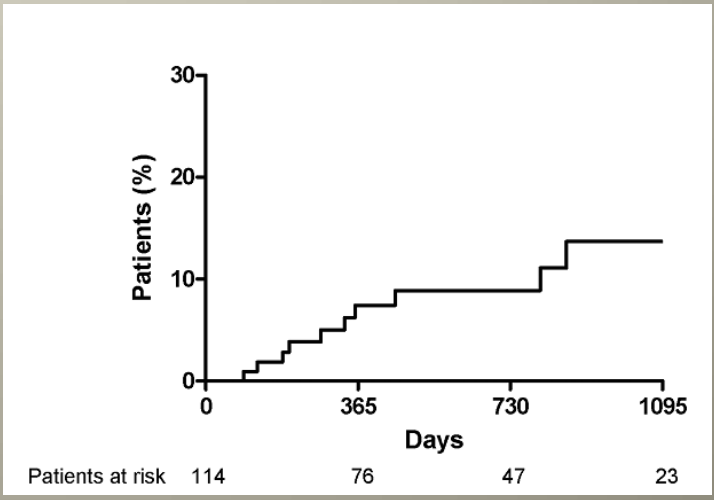
Primary Prevention Implantable Cardioverter Defibrillator Recipients: The Need for Defibrillator Back-Up After an Event-Free First Battery Service-Life

GUIDO H. VAN WELSENES, M.S.,* JOHANNES B. VAN REES, M.D.,* JOEP THIJSSEN, M.D., SERGE A. TRINES, M.D., PH.D., LIESELOT VAN ERVEN, M.D., PH.D., MARTIN J. SCHALIJ, M.D., PH.D., and C.J.W. BORLEFFS, M.D., PH.D.

From the Department of Cardiology, Leiden University Medical Center, Leiden, the Netherlands

Of 154 primary prevention ICD patients needing replacement because of battery depletion, 114 (74%) patients (mean age 61± 11 years, 80% male) had not received appropriate ICD therapy for VA.

Following replacement, 3-year cumulative incidence of appropriate therapy in response to VA was 14% (95% CI 5–22%)



J Cardiovasc Electrophysiol, 2011 pp. 1346-1350

Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures

Results From the REPLACE Registry

Jeanne E. Poole, MD; Marye J. Gleva, MD; Theofanie Mela, MD; Mina K. Chung, MD; Daniel Z. Uslan, MD; Richard Borge, MD; Venkateshwar Gottipaty, MD, PhD; Timothy Shinn, MD; Dan Dan, MD; Leon A. Feldman, MD; Hanscy Seide, MD; Stuart A. Winston, DO; John J. Gallagher, MD; Jonathan J. Langberg, MD; Kevin Mitchell, RN, BS; Richard Holcomb, PhD; for the REPLACE Registry Investigators

prospectively assessed procedure-related complication rates associated with elective pacemaker or ICD generator replacements over 6 months of follow-up.

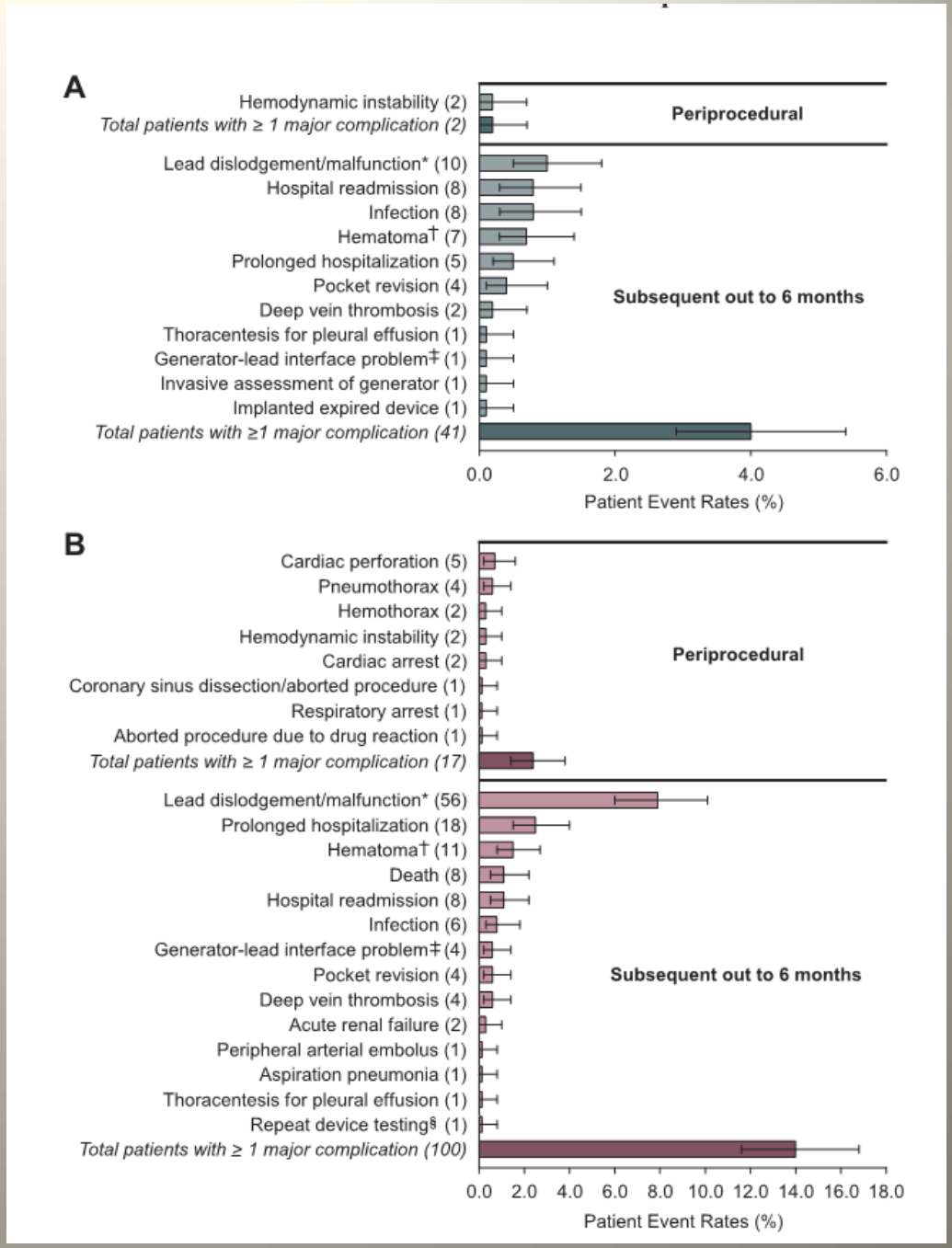
Two groups were studied: those without (cohort 1) and those with (cohort 2) a planned transvenous lead addition for replacement or upgrade

Circulation . 2010;122:1553-1561

From REPLACE registry

Major complication rate for simple generator replacement group is 4%,

and for generator replacement with additional lead insertion group was 15.3%

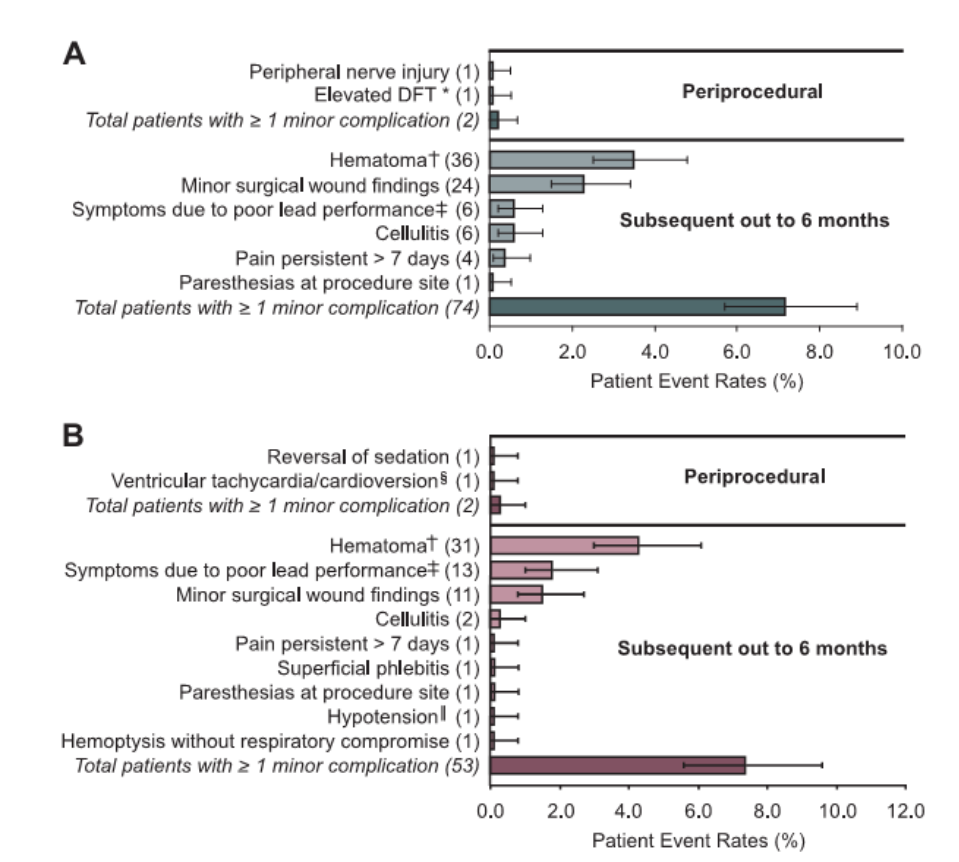


Circulation . 2010;122:1553-1561

From REPLACE registry

Minor complication rate for simple generator replacement group is 7.4%,

and for generator replacement with additional lead insertion group was 7.6%



Circulation . 2010;122:1553-1561

From Ontario ICD Database

In 1081 patients undergoing ICD replacement,
47 patients (4.3%) had a complication within 45 days.

Major complications in 28 patients (2.6%)

- infection (n=23), lead revision (n=35), electrical storm (n=14), and pulmonary edema (n=13).

Minor complications occurred in 20 patients (2.3%)

- incisional infection (n=10) and pocket hematoma (n=10).

Major complications may be associated with increased risk of subsequent mortality.

Circ Arrhythm Electrophysiol. 2011;4:136-142

Long-Term Follow-Up in Patients with Presumptive Brugada Syndrome Treated with Implanted Defibrillators

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33 patient with Brugada type I and type II ECG
- prior cardiac arrest (n=3)
- history of syncope (n=23)
- ventricular arrhythmias by the EPS (n=18)

During 7.9± 3.6 years of follow-up, 2 patients with prior arrest received appropriate ICD shocks. None of the 30 patients without prior arrest had a sustained arrhythmia detected.

ICD-related adverse effects occurred in 11 (33%) patients,

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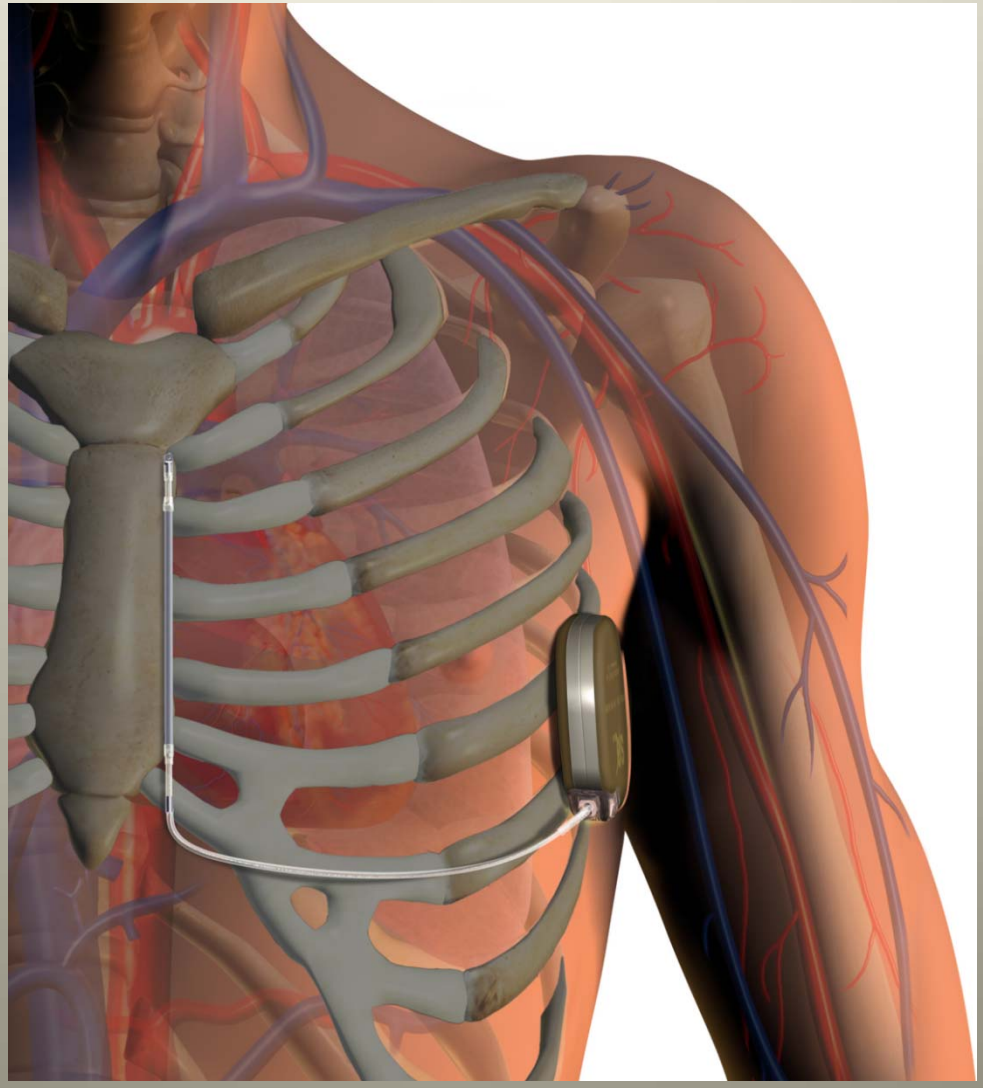
Brugada syndrome with ICD in Our Hospital

- Inclusion (1998-2010)
  - Brugada type I and II ECG
  - Inducible VF by EPS
- N=12 (male=12, age 44±11 yo)
  - 4 cardiac arrest survivor with documented VF
  - 2 family Hx of SCD
  - 3 syncope
  - 3 only inducible VF by EPS
- Follow Up duration: 71±41 months
- All of the 4 cardiac arrest survivor had received appropriate ICD therapy, but none of the 9 patients without documented VF had received appropriate ICD therapy
- Complication (n=8, 66%)
  - Pneumothorax (2), pocket erosion (1), early replace due to ICD generator recall (2), inappropriate shock (3)

Issue of Replacement

- Somewhat complex for decision making and not conclusive.
- We need thorough evaluation for patient who need for replacement, including current status, benefit of device therapy, and risk of replacement procedure.
- Future development of ICD directed at extending battery longevity and minimizing lead-related complications, and development of simple and less invasive device.

ICD with subcutaneous lead



Consideration while waiting for an ICD in patients at Risk for SCA

Wearable Cardioverter-Defibrillator

Conclusion

- Current development of ICD is focusing on minimizing shock therapy, extending battery longevity, better lead performance, small size and simple and less invasive device. Additionally, we hope cheaper in price.
- To improve the efficacy of ICD therapy, we need…
  - improved risk stratification
  - improved ICD programming
  - improved ICD technology
  - improved therapy for heart failure

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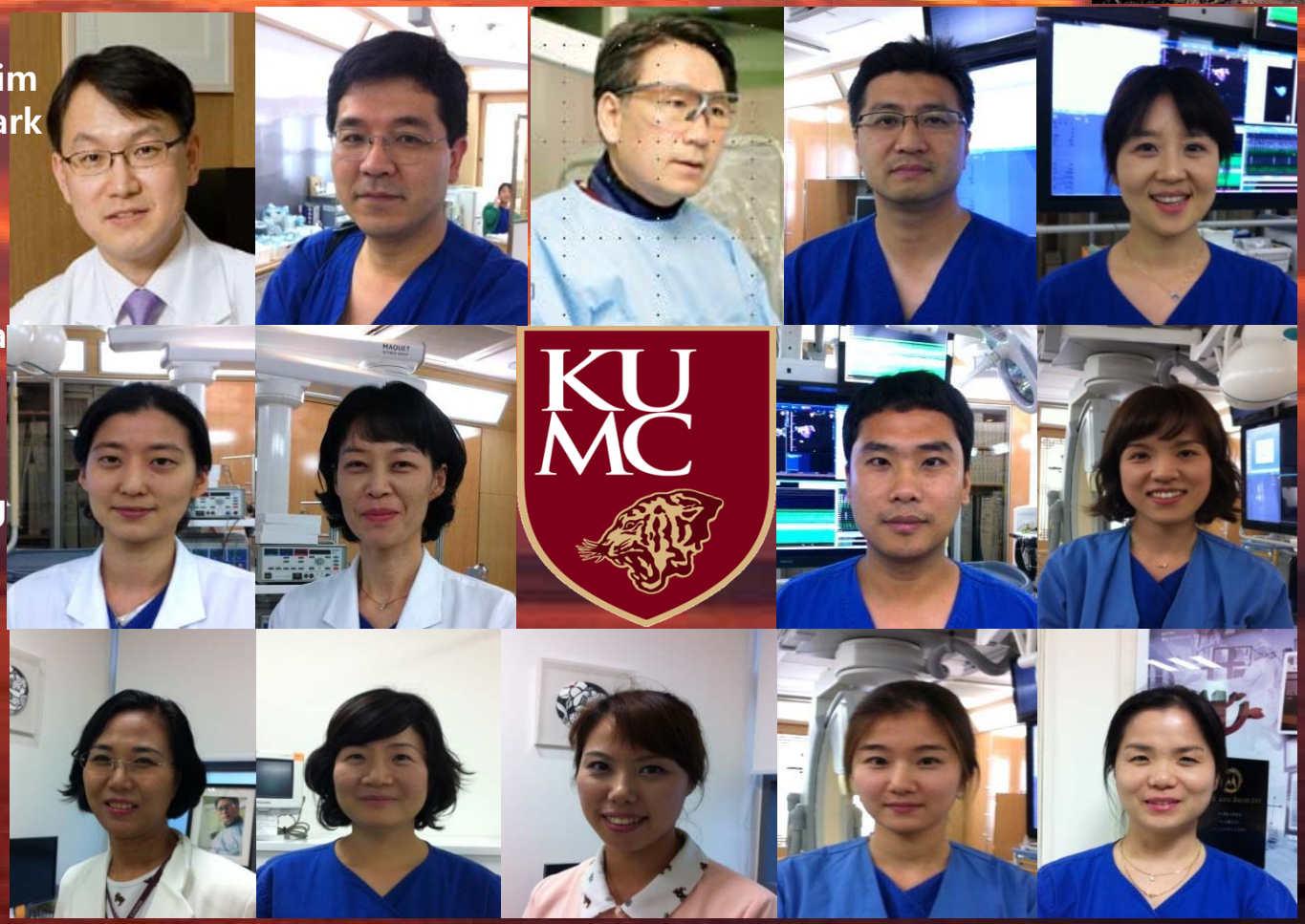

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