Leadless CRM technology

•Wireless systems are intuitively desirable

- Leadless pacemaker: future
- “Leadless” ICD: present

Leadless CRM technology:
Physician's point of view

Shared philosophy

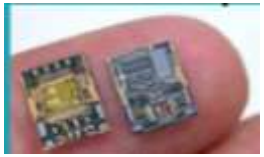
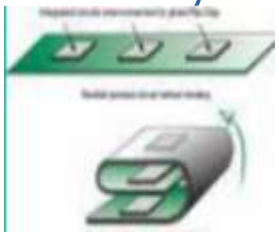
- To avoid venous system
- To eliminate leads
- To avoid (or cut short) fluoroscopy

Leadless CRM technology:
Technology point of view

Different philosophy

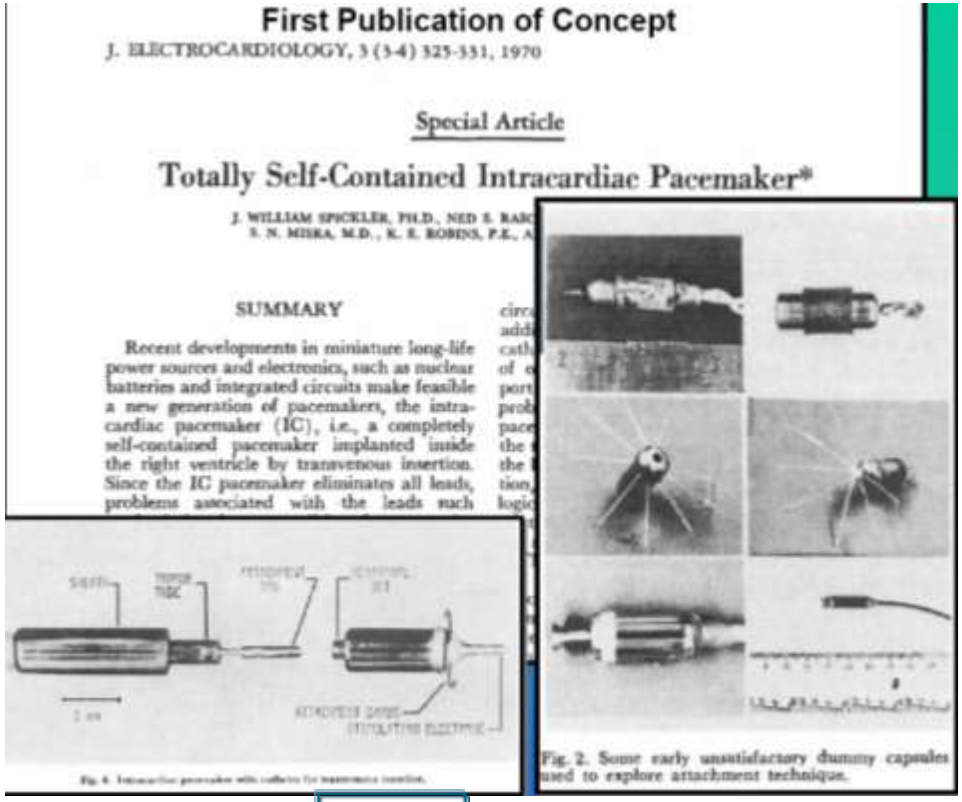
- *Leadless PM*: miniaturization, more cosmetic, no surgery



- *"Leadless" ICD*: more widespread implantation capability, easy to implant and to extract

Leadless PM: Idea from past – reality in future


First Publication of Concept

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 1970

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASK
S. N. MISRA, M.D., K. E. ROBINS, P.E., A

SUMMARY

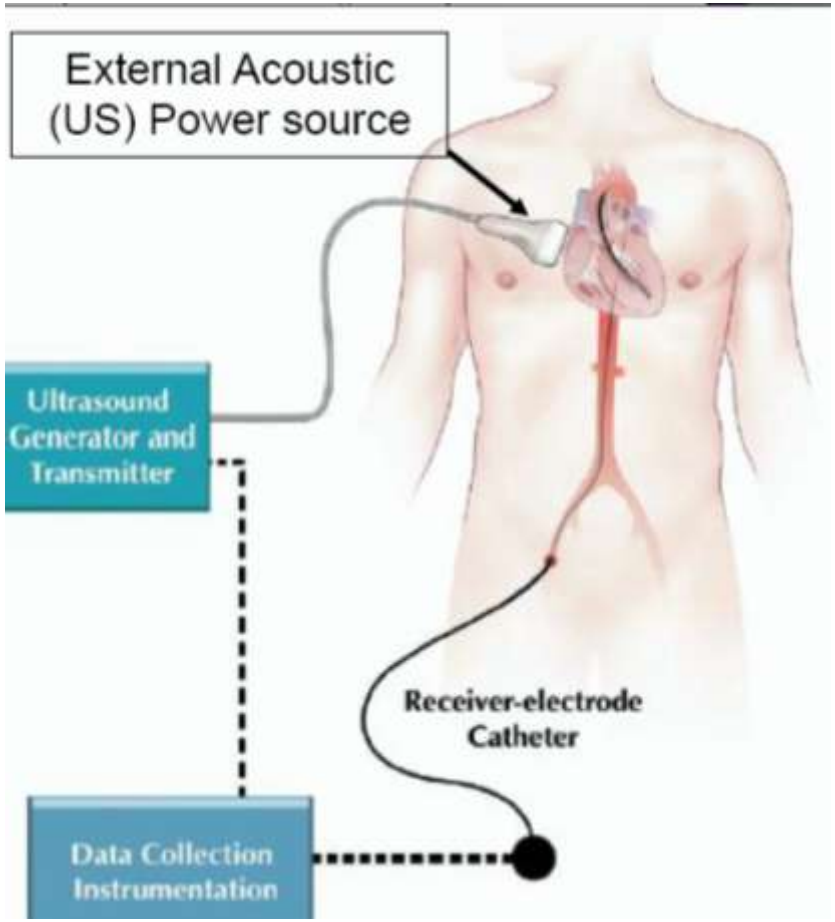
Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion. Since the IC pacemaker eliminates all leads, problems associated with the leads such

Fig. 2. Some early unsatisfactory dummy capsules used to explore attachment technique.

1970

- Ultrasound
- Inductive
- Micro-battery
- Biological

Ultrasound: LV Endocardial Implant



Lee et al, JACC 2009

Electrical Induction: transmitter + receiver

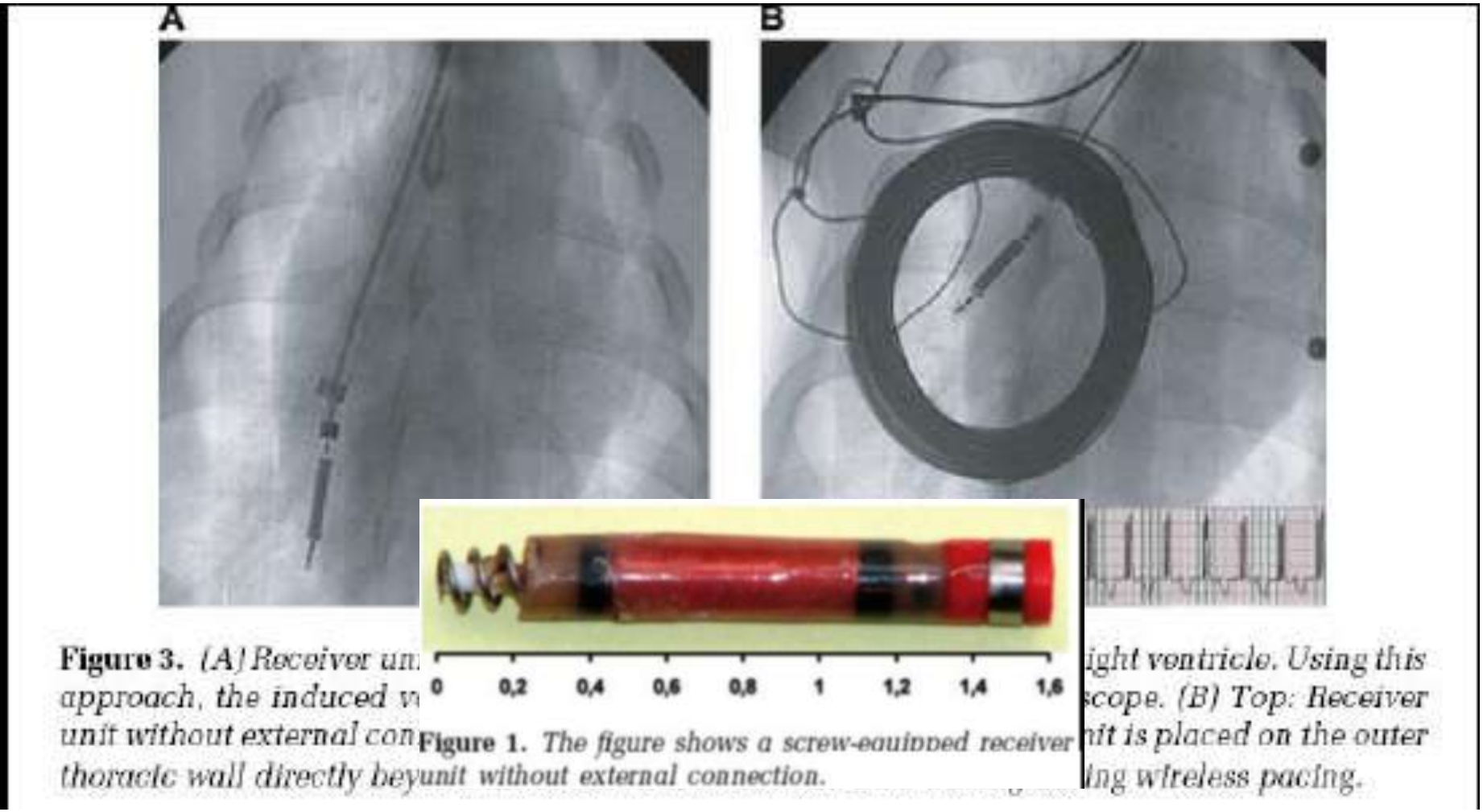
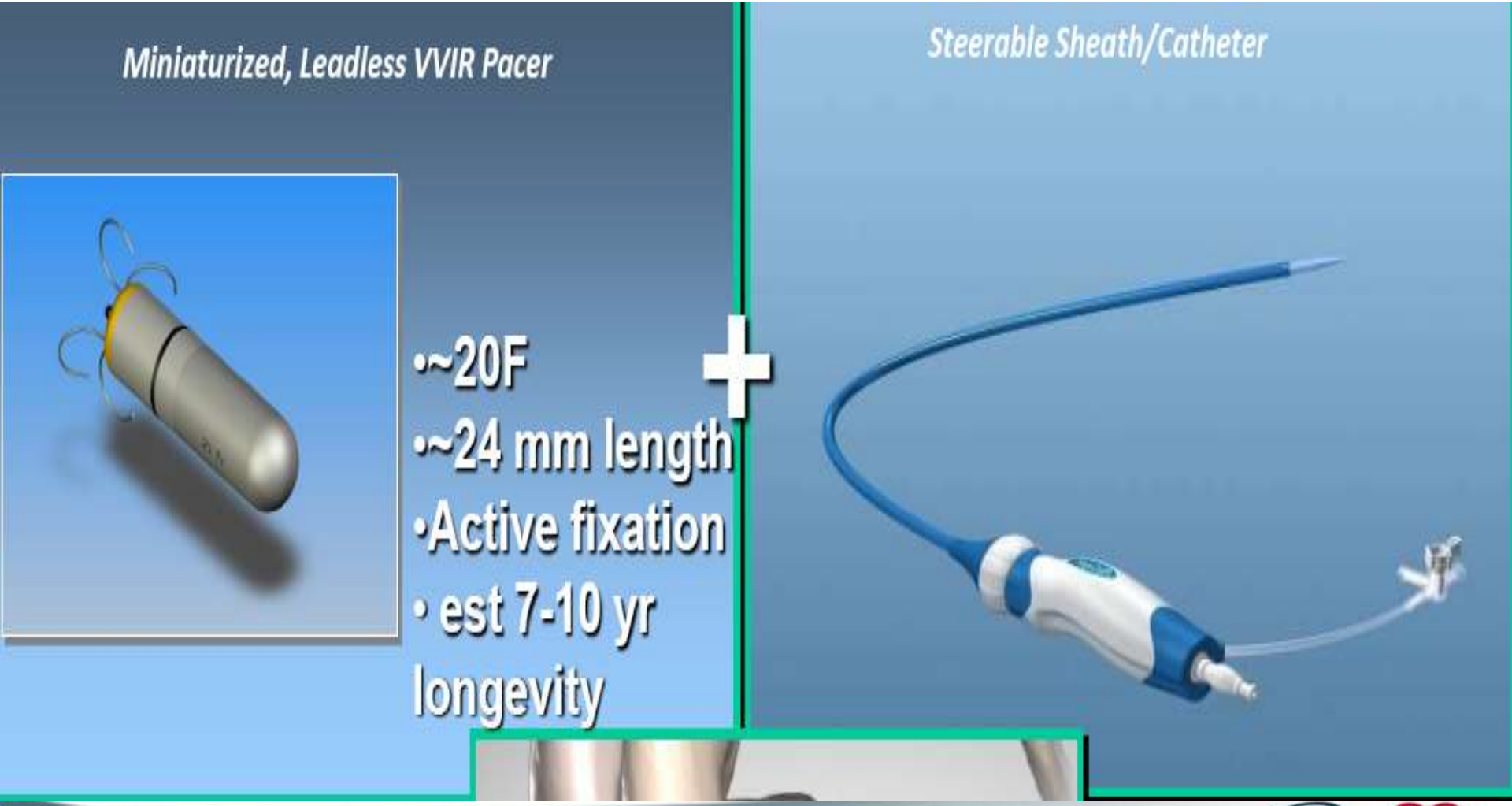


Figure 3. *(A) Receiver un* ... *ight ventricle. Using this approach, the induced v* ... *scope. (B) Top: Receiver unit without external con* ... *nit is placed on the outer thoracic wall directly beyunit without external connection.* ... *ing wireless pacing.*

Figure 1. *The figure shows a screw-equipped receiver*

Micro-battery



Smartphone!

Biological (gene) pacing

Med Bio Eng Comput (2007) 45:133–144
DOI 10.1007/s11517-007-0165-2

SPECIAL ISSUE

Creation of a biological pacemaker by gene- or cell-based approaches

Eduardo Marbán · Hee Cheol Cho

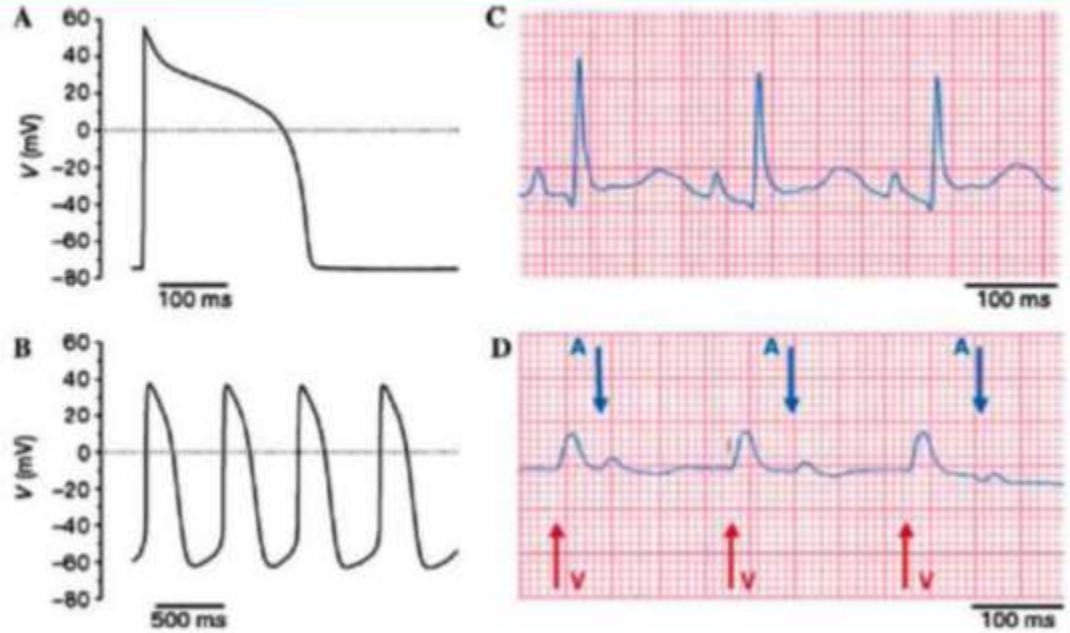
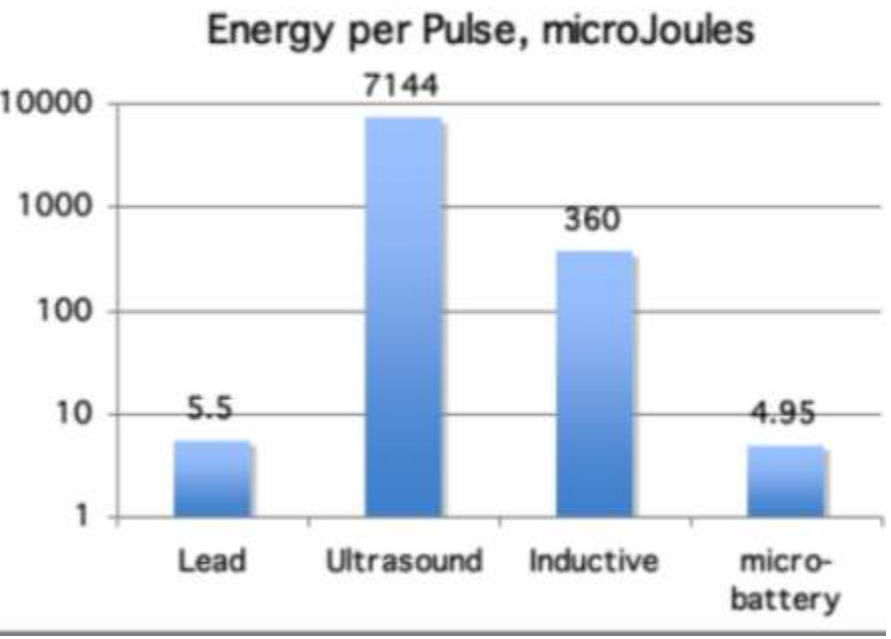
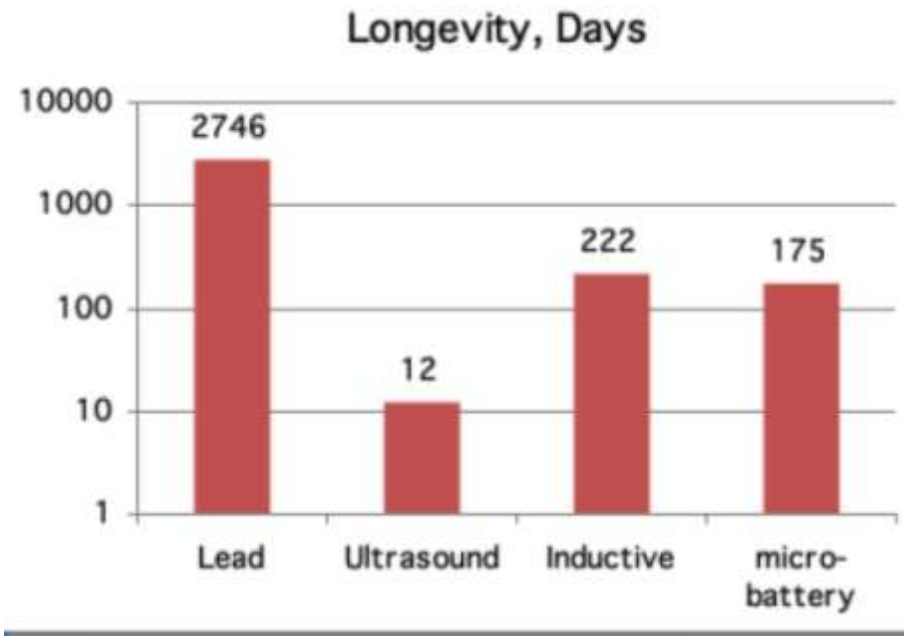


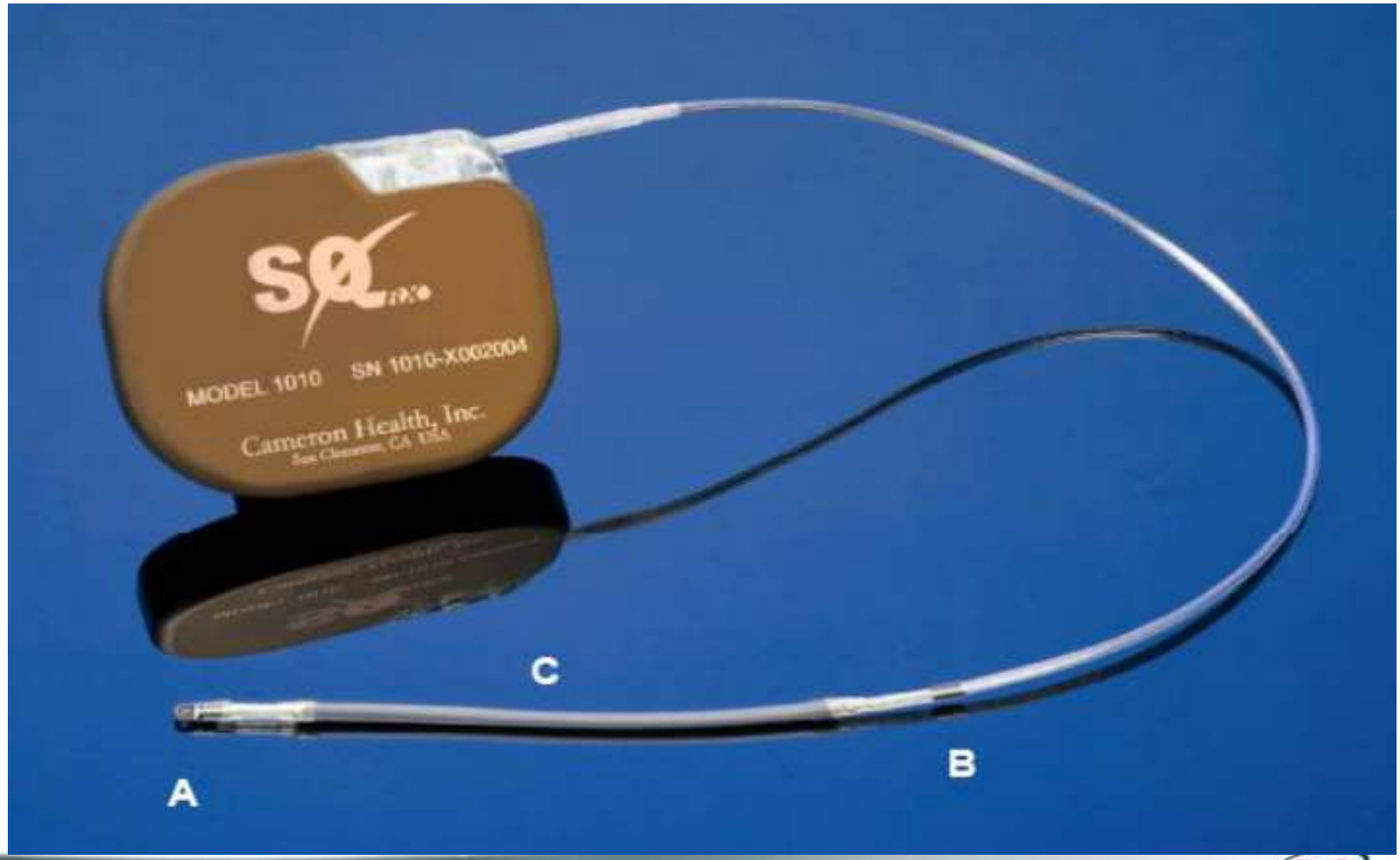
Fig. 1 Suppression of Kir2.1 channels unmasks latent pacemaker activity in ventricular cells. **a** Action potentials evoked by depolarizing external stimuli in control ventricular myocytes. **b** Spontaneous action potentials in Kir2.1AAA-transduced myocytes with depressed I_{K1}. **c** Baseline electrocardiograms in normal sinus rhythm. **d** Ventricular rhythms 72 h after gene transfer of Kir2.1AAA. P waves (*A* and *arrow*) and wide QRS complexes (*V* and *arrow*) march through to their own rhythm

Energy and Longevity

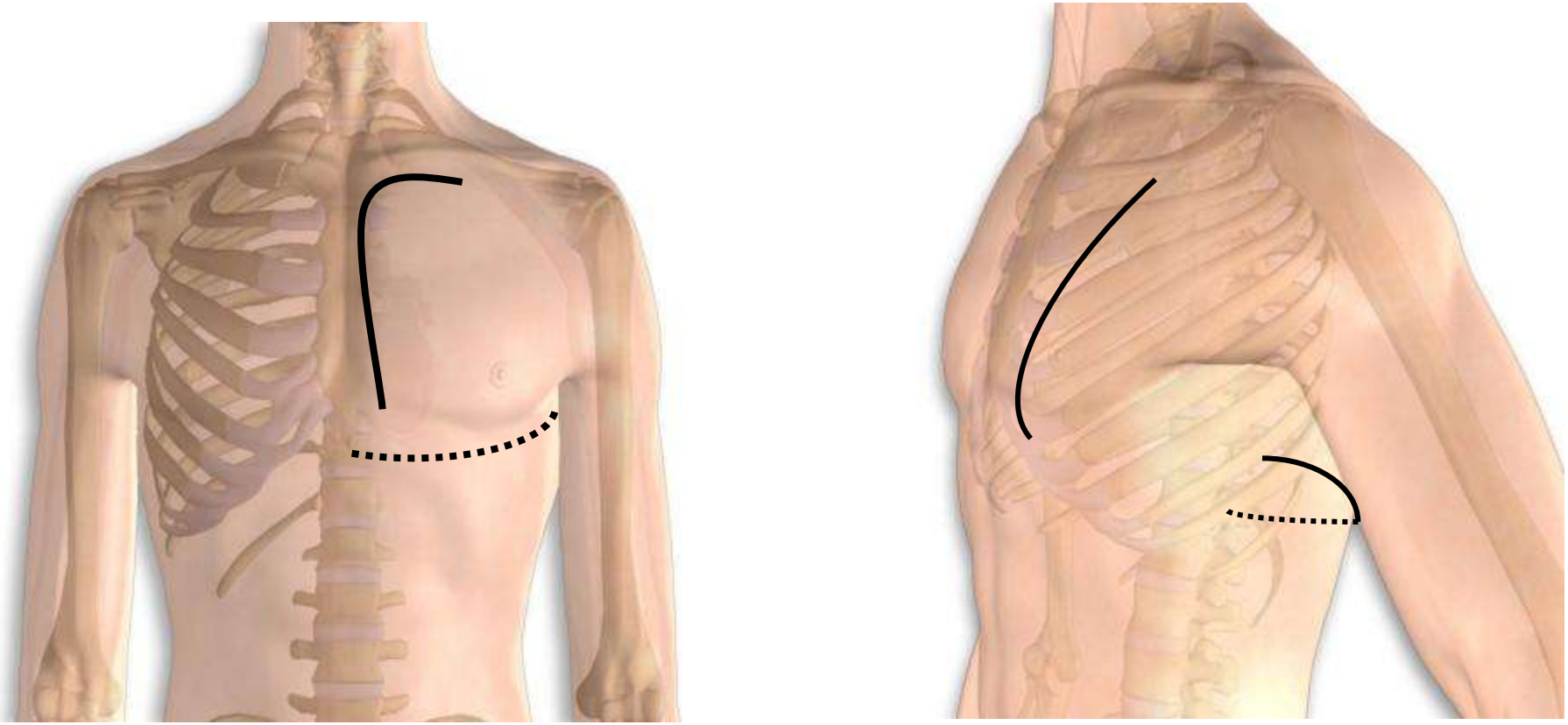




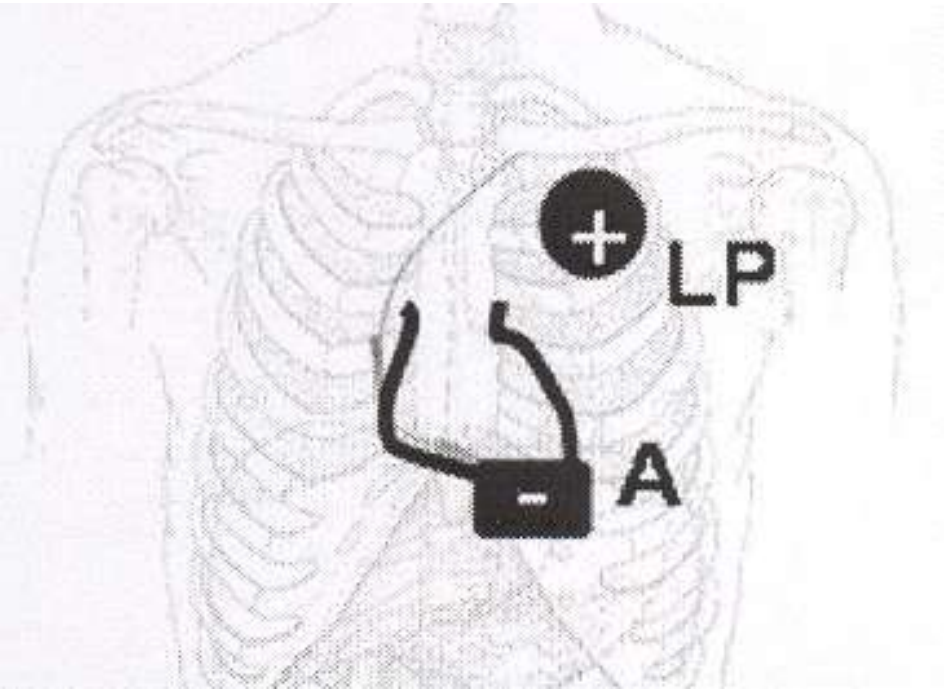
“Leadless” ICD



Subcutaneous leads:
Electrical sandwich of the Heart



Guidant-sponsored Research on Defibrillation Energy Requirements Using Left Anterior Chest to SQ Shocking Vector



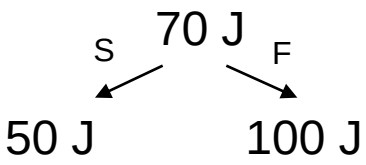
Purpose: to estimate DER in pts using investigational system with external defibrillator and left chest cutaneous (C) electrode to SQ shock vector

Burke. Heart Rhythm 2005;2:1332-8

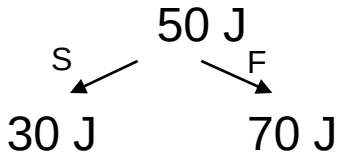
LP = left pectoral active can
A = apical patch (cutaneous)

Guidant-sponsored Research on Defibrillation Energy Requirements Using Left Anterior Chest to SQ Shocking Vector

Stage 1



Stage 2



- 50-J shock successful in 10/11 (91%) patients.
- 30-J shock successful in 7/9 (78%)

Totally Extravascular System
May Offer:

- Safer for extraction: resolution of lead or device complications is easier without having hardware in the transvenous space
- Potentially simpler implant
- Shorter procedure time
- Easier and safer for low volume implanters
- Fluoroless implant

Potential Patient

Has transvenous Obstruction or Low Arrhythmia Burden

1. In whom transvenous systems are not desirable or possible

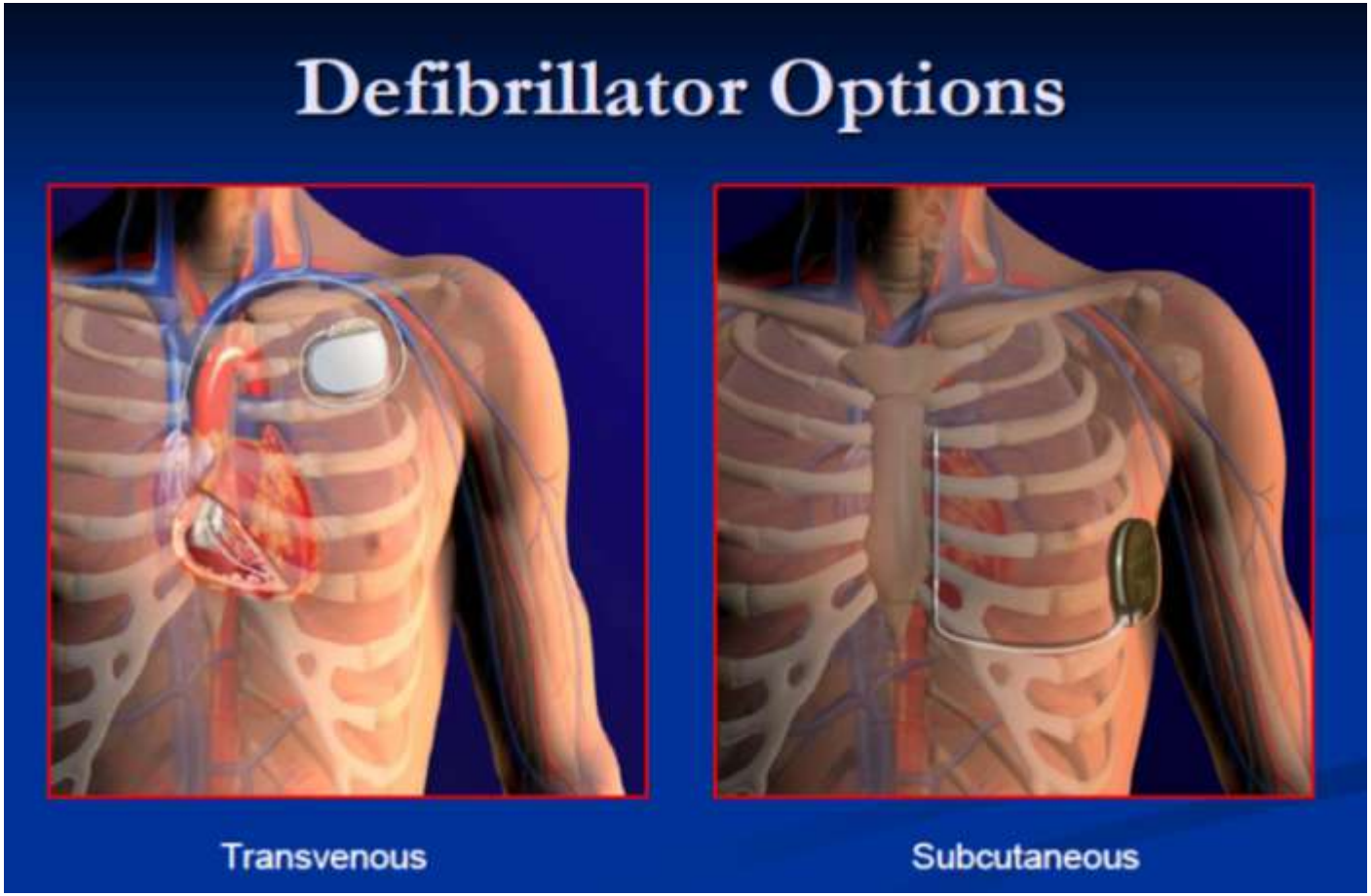
2. At lower risk of arrhythmia management:

   MADIT II, SCD-HeFT, Brugada, HCM, ARVD

Not ideal for patients:

- who could benefit from pacing therapies, e.g., bradycardia pacing
- with high burden of monomorphic, pace-terminable VT
- who are candidates for CRT-D

Do we really need it?



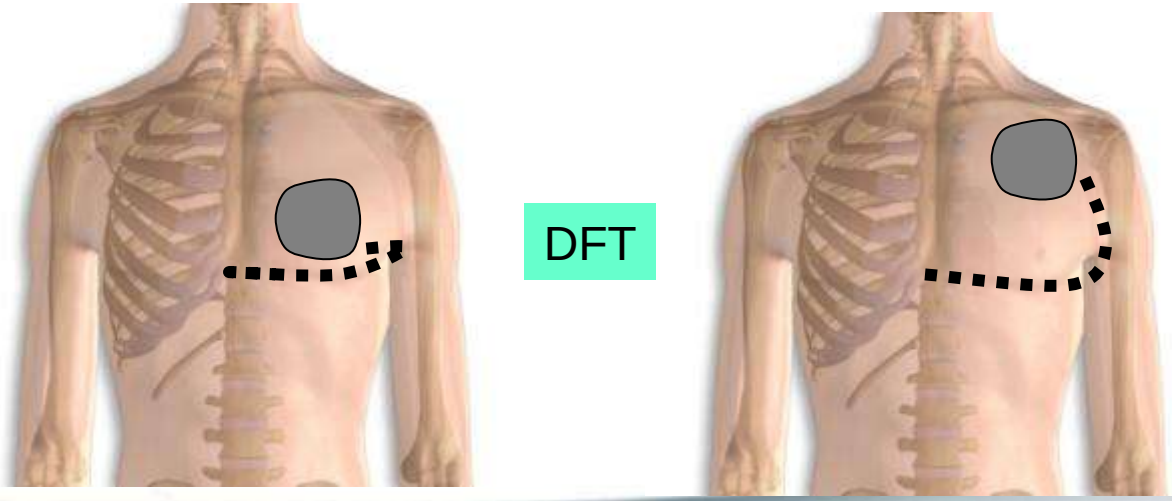
Background

- Non-transvenous implanted defibrillators offer potential advantages over transvenous ICDs
- Without a coil in the heart, more energy is needed to defibrillate

Medtronic, AHA 2009

Transvenous ICD defibrillation Efficacy is possible with a completely subcutaneous anterior-posterior shock pathway

to identify non-transvenous defibrillation configurations that provide efficacy comparable to transvenous devices with 70 Joules power

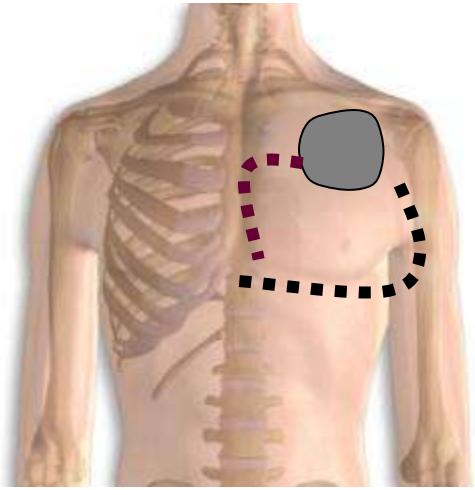


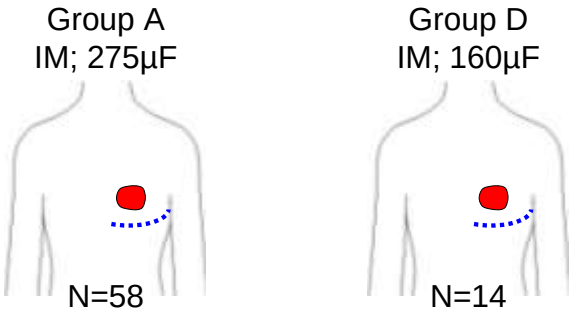
Medtronic, AHA 2009

2 changes throughout the study

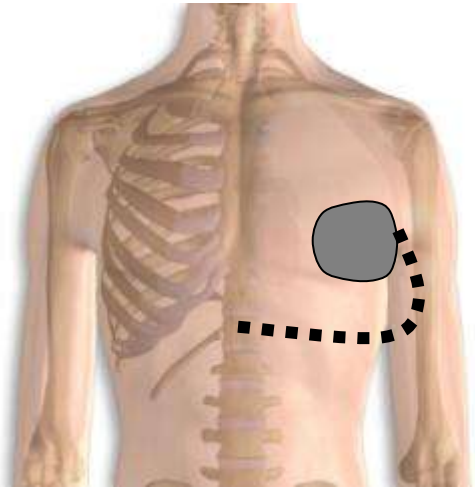
1. 2nd Auxiliary anterior coil added
2. Peak voltage increase to 1000 V
3. Lowered capacitance from 275 to 160 ηF

3.





Medtronic, AHA 2009

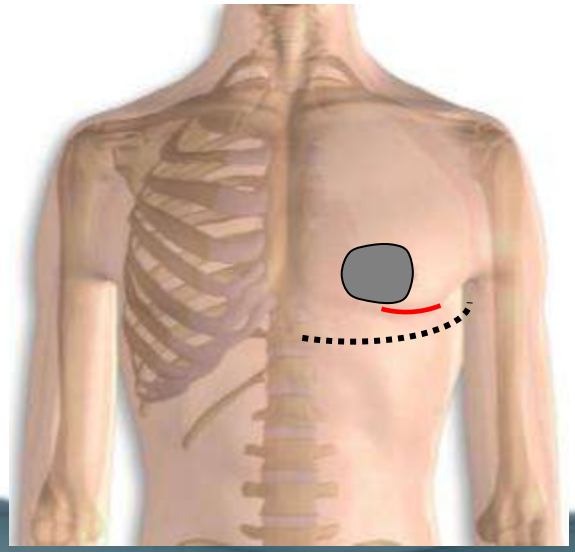


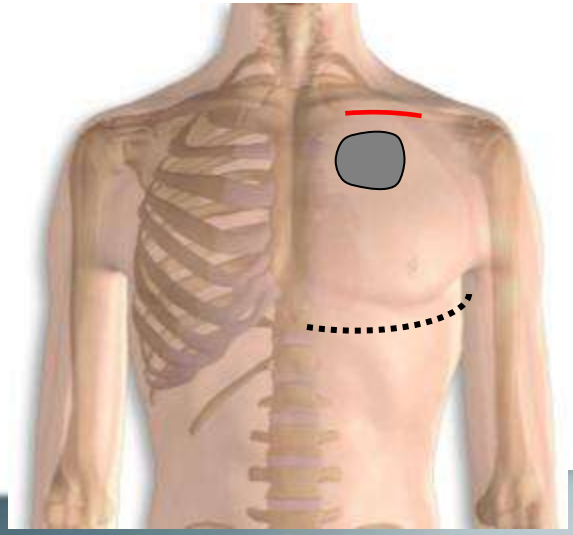
Methods

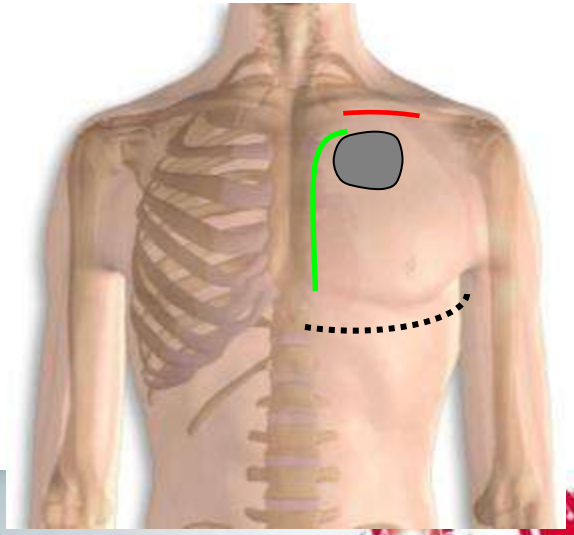
IM: Can implanted under pectoral muscle via inframammary incision

IC: Can implanted in conventional pocket via infraclavicular incision

IC-2: A 15-cm SQ coil connected to the can is added to the IC configuration





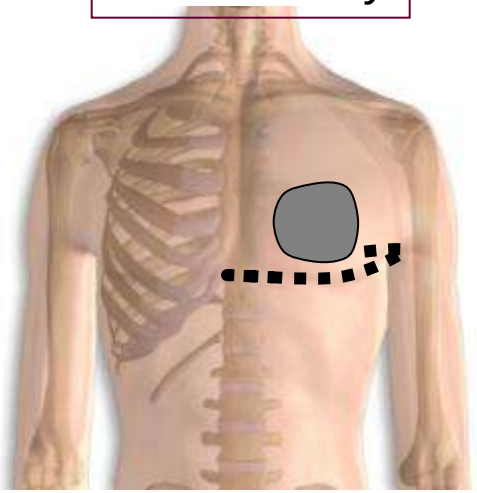


Medtronic, AHA 2009

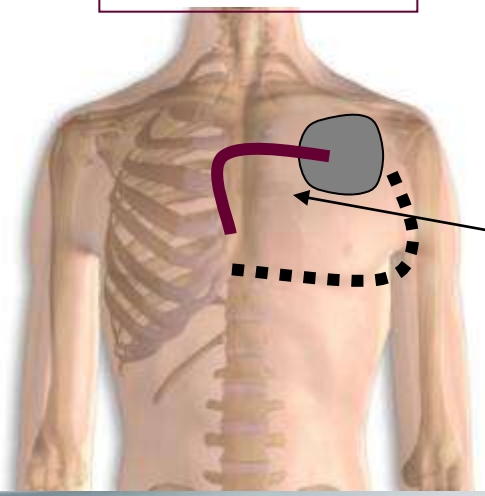
136 pts
VF to Shock time 20 sec.

70 Joules, 20 J. Safety Margin

93% Efficacy

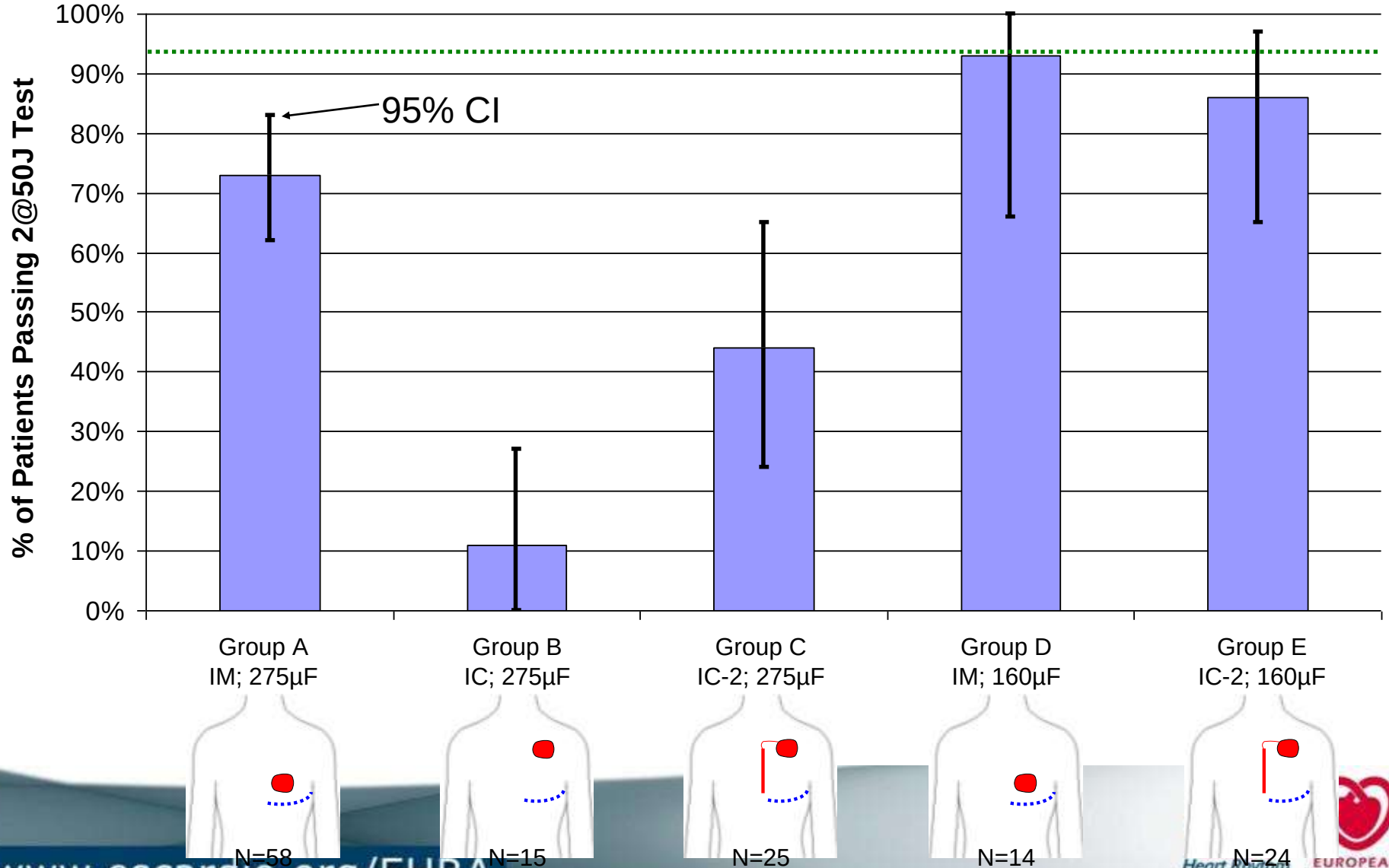


86% Efficacy

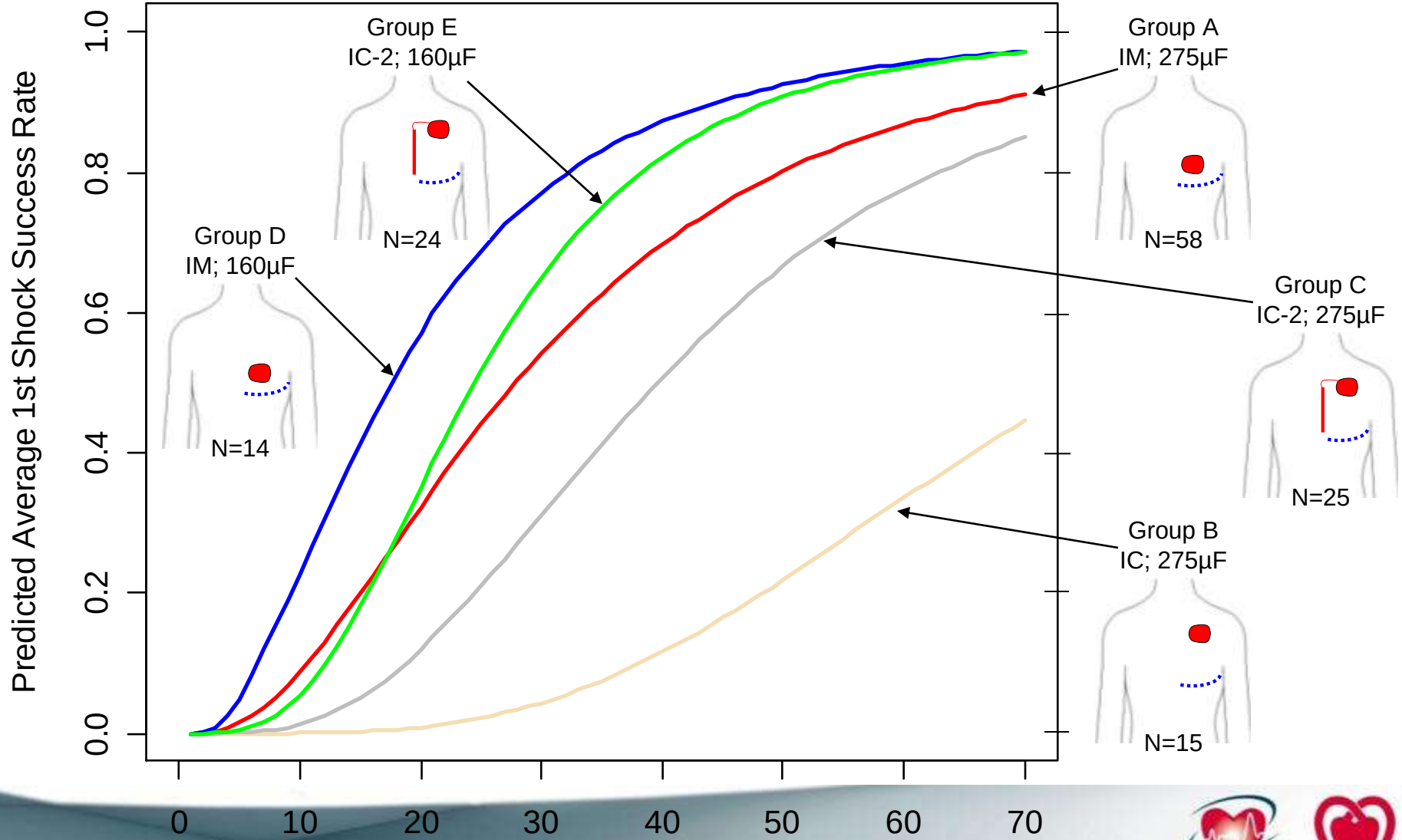


ASSURE trial: 94% Efficacy

Results: % Meeting Implant Testing



Results: Defibrillation Efficacy Curves



Discussion

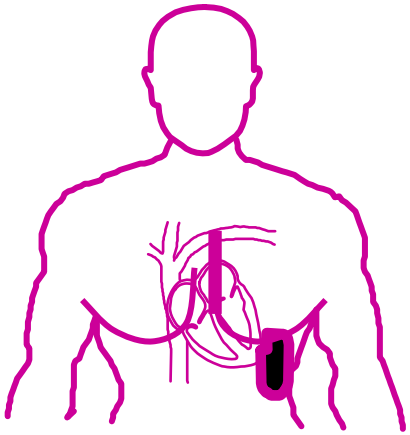
- Efficacy is highly dependent on can position
  - A conventional can position has poor efficacy
  - A sternally placed coil tied to the can improves efficacy
- Higher voltage, lowered capacitance improves efficacy

Conclusion

- Defibrillation efficacy comparable to a transvenous ICD was obtained with an anterior-posterior shock vector using a 160-μF capacitance and 70-J maximum output.

Cameron Health, HRS 2009

1st Clinical Evaluation of the Subcutaneous Implantable Defibrillator (S-ICD®) System



55 pts
Primary Objective: VF Detection + 65 J
No Fluoroscopy, 80 J power device

Results:
55/55 Detection, 53/55 (98%) VF Conversion
Mean time to therapy: 14±2,5 sec.
Implant time: 74±38 min.
Lead movement 4/53, Lead repositioning 2/53, 1/53 T-oversensing

Ian G. Crozier, MD, Iain C. Melton, Robert E. Park, Warren M. Smith, Margaret A. Hood, Luc Jordaens, Dominic Theuns, Lucas Boersma, Alexander H. Maass, Isabelle C. van Gelder, Arthur A. Wilde, Pascal van Dessel, Reinoud Knops, Gust H. Bardy, Riccardo Cappato, Pierpaolo Lupo, Craig Barr and Andrew A. Grace, HRS 2009, Boston, Late Breaking Trials

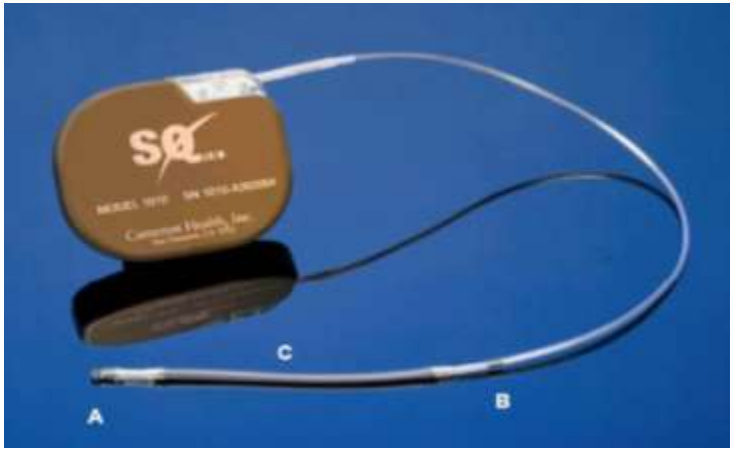
The NEW ENGLAND JOURNAL of MEDICINE

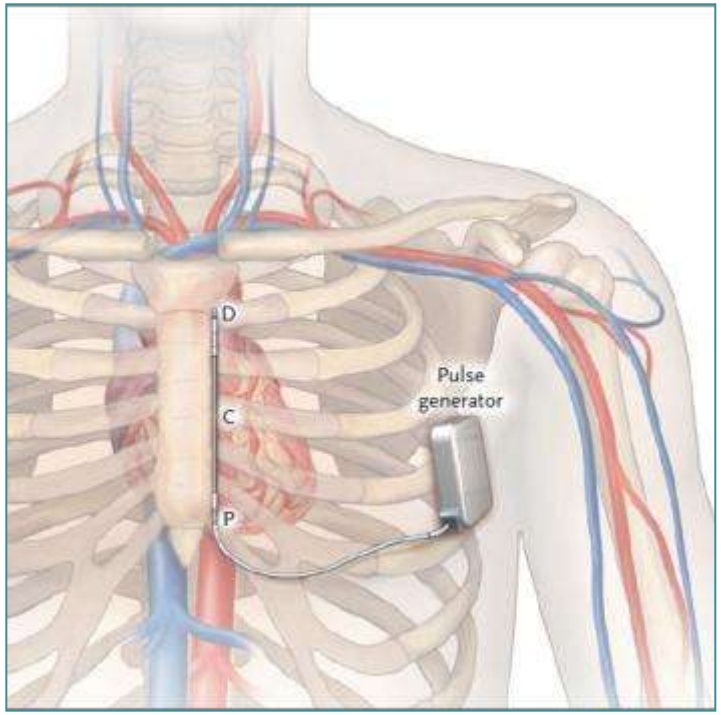
ORIGINAL ARTICLE

An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Amo Oduro, M.B., B.S., Lucas Boersma, M.D., Ph.D., Alexander H. Maass, M.D., Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wilde, M.D., Ph.D., Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D., Craig S. Barr, M.B., Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrew A. Grace, M.B., Ph.D.

Bardy G, et al. N Engl J Med 2010;363:36-44

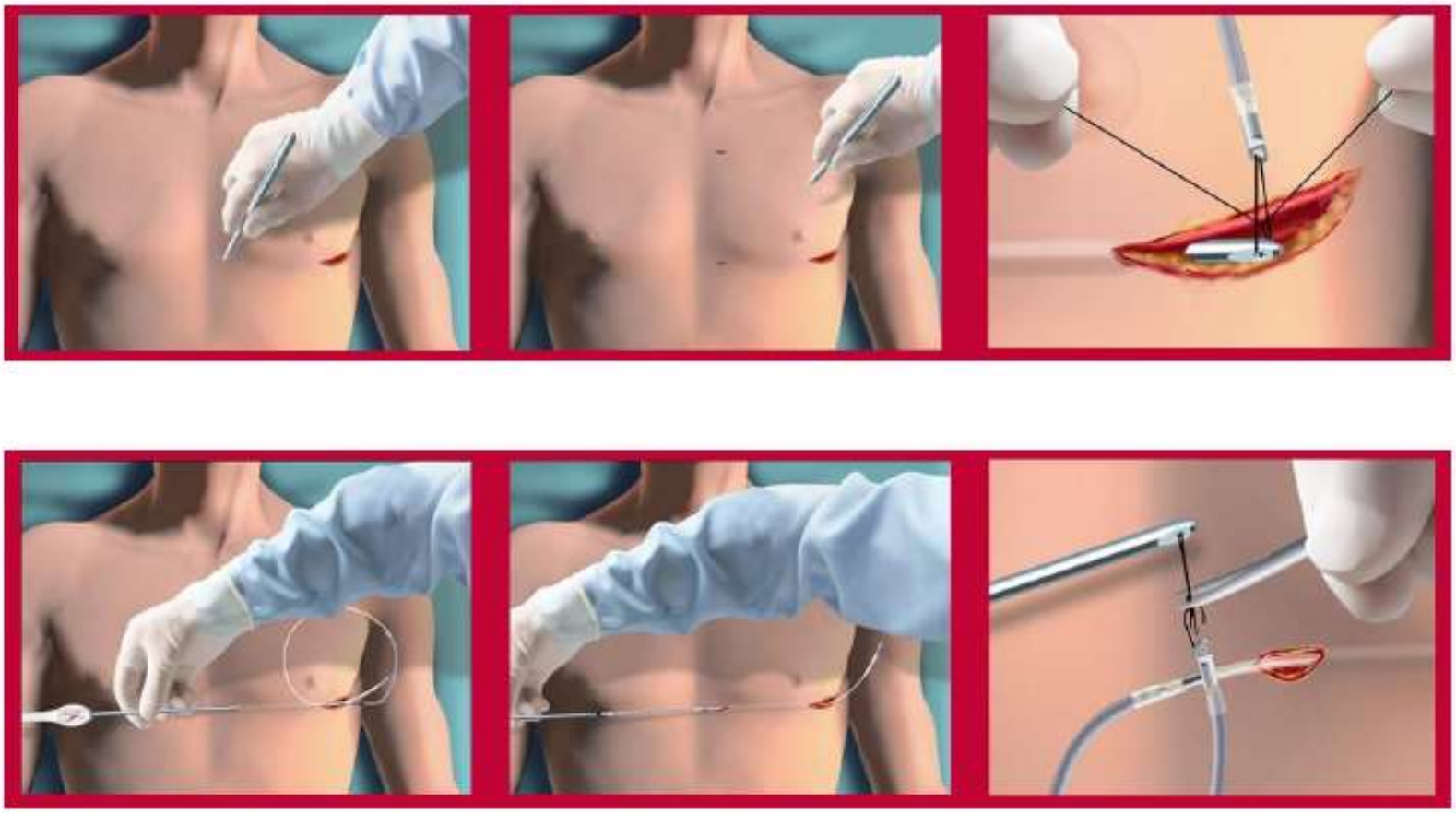




Tripolar parasternal lead (polycarbonate-urethane 55D, 3 mm diameter) + Active can PG

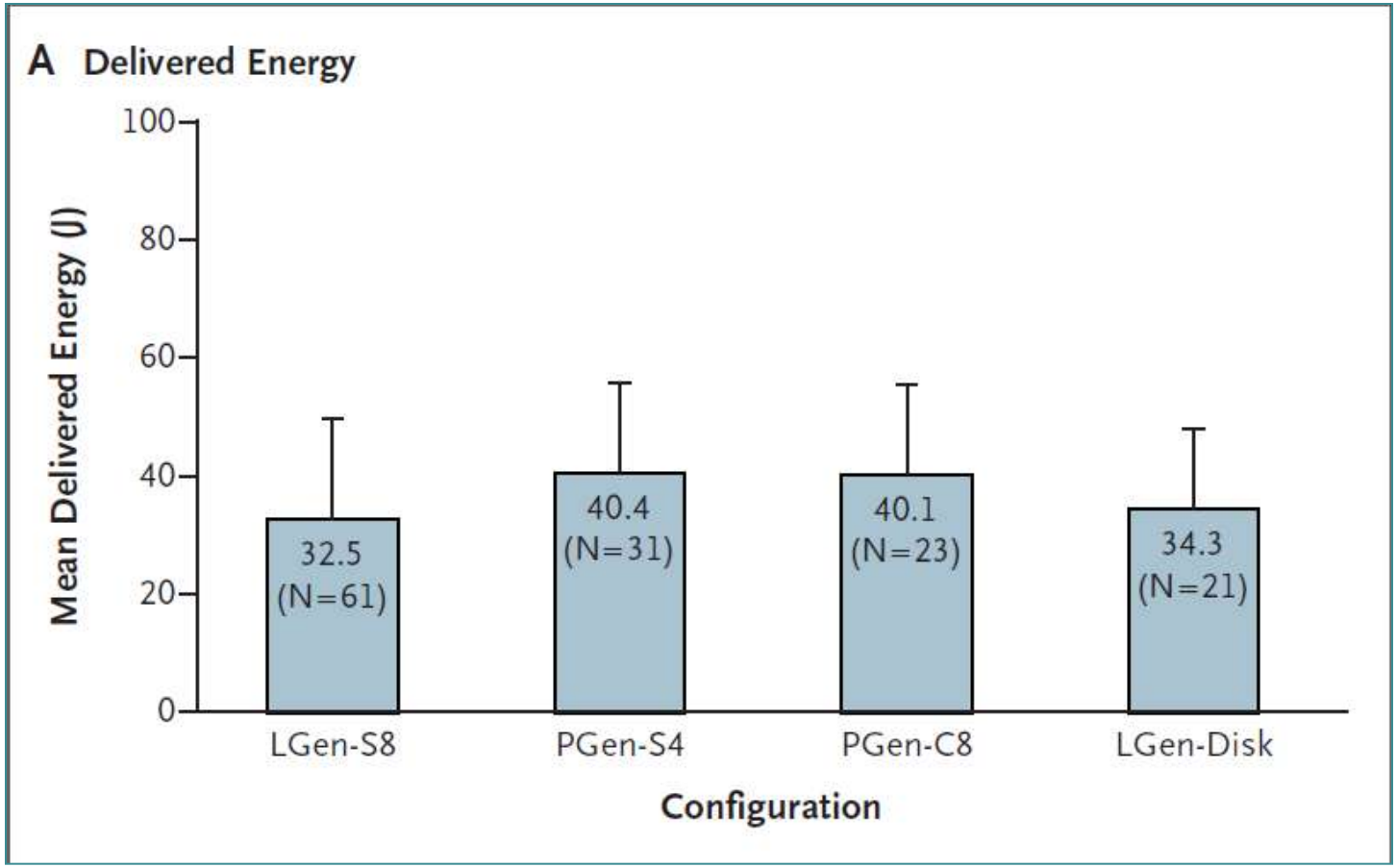
Bardy G, et al. N Engl J Med 2010;363:36-44

Implantation



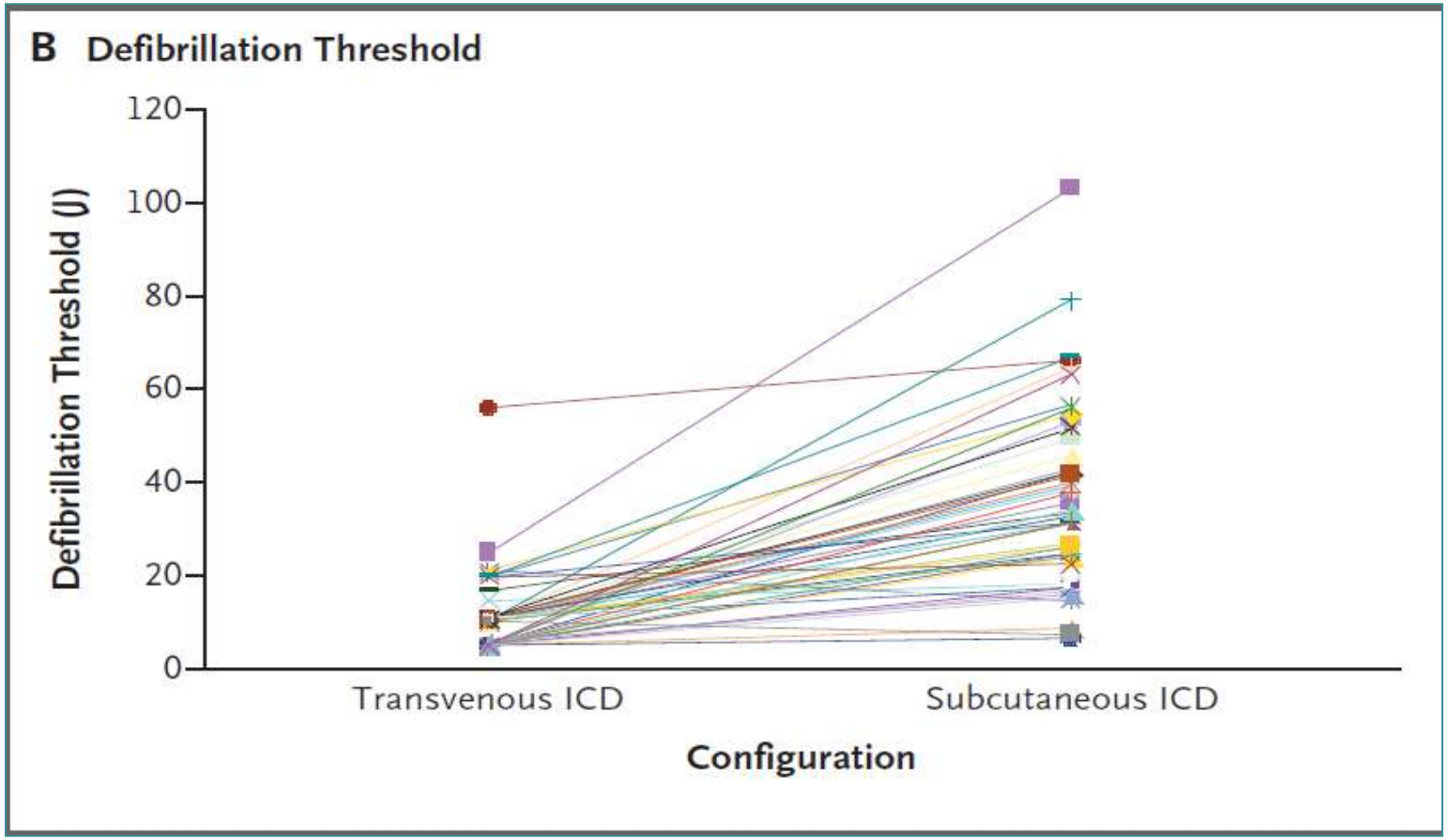
© Courtesy of Cameron Health

Energy Delivered



Bardy G, et al. N Engl J Med 2010;363:36-44

Energy Delivered



Bardy G, et al. N Engl J Med 2010;363:36-44

Detection

1. Signals - free of noise and double detection
2. Feature analysis: rate detection
3. Rhythm type - need for therapy
4. Arrhythmia reconfirmation to avoid shocking non-sustained ventricular arrhythmias
5. Capacitor charging
6. All shocks - 80J, reverse polarity possible
7. 50 bpm demand (>3 sec. pause) post-shock pacing (30 sec.) available: 200 mA biphasic transthoracic pulse - can to coil

S-ICD: Group questions
Patient Acceptance?

- 80 J output
- Potential erosion/migration issues (tunneling along rib margin and parasternally
- No painless therapies (ATP)
- No bradycardia support
- No heart failure monitors
- No remote patient follow up

General anesthesia to deliver subcutaneous lead?

- Do you typically implant devices under general anesthesia?
- What kind of anesthesia do you use to place subcutaneous leads?
- Would this affect your interest in this technology if general anesthesia was required?

Will longer time to therapy impact acceptance?

- Currently devices that delivery 36J can delivery therapy in <10 seconds
- These devices deliver nearly twice the energy and will take longer to charge, maybe 20 seconds
- At what time does syncope become a concern?

Conclusions:

- Development of an effective “leadless” (or totally extravascular) ICD system is a challenge, but not an insurmountable one

Conclusions:

- There may be potential advantages, including the ease of implantation, reduction in total therapy cost, and more widespread implantation capability due to the simplicity of the surgical approach

Conclusions:

- Further investigation is warranted to allow more widespread use of ICDs in patients who have indications for primary prevention devices