


# European Society of Cardiology



**A Prospective, Randomised Comparison in  
Humans of Defibrillation Efficacy of a  
Standard Transvenous ICD System with a  
Totally Subcutaneous Implantable Defibrillator  
System (S-ICD<sup>®</sup>)**



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# **S-ICD<sup>®</sup> - Investigators**



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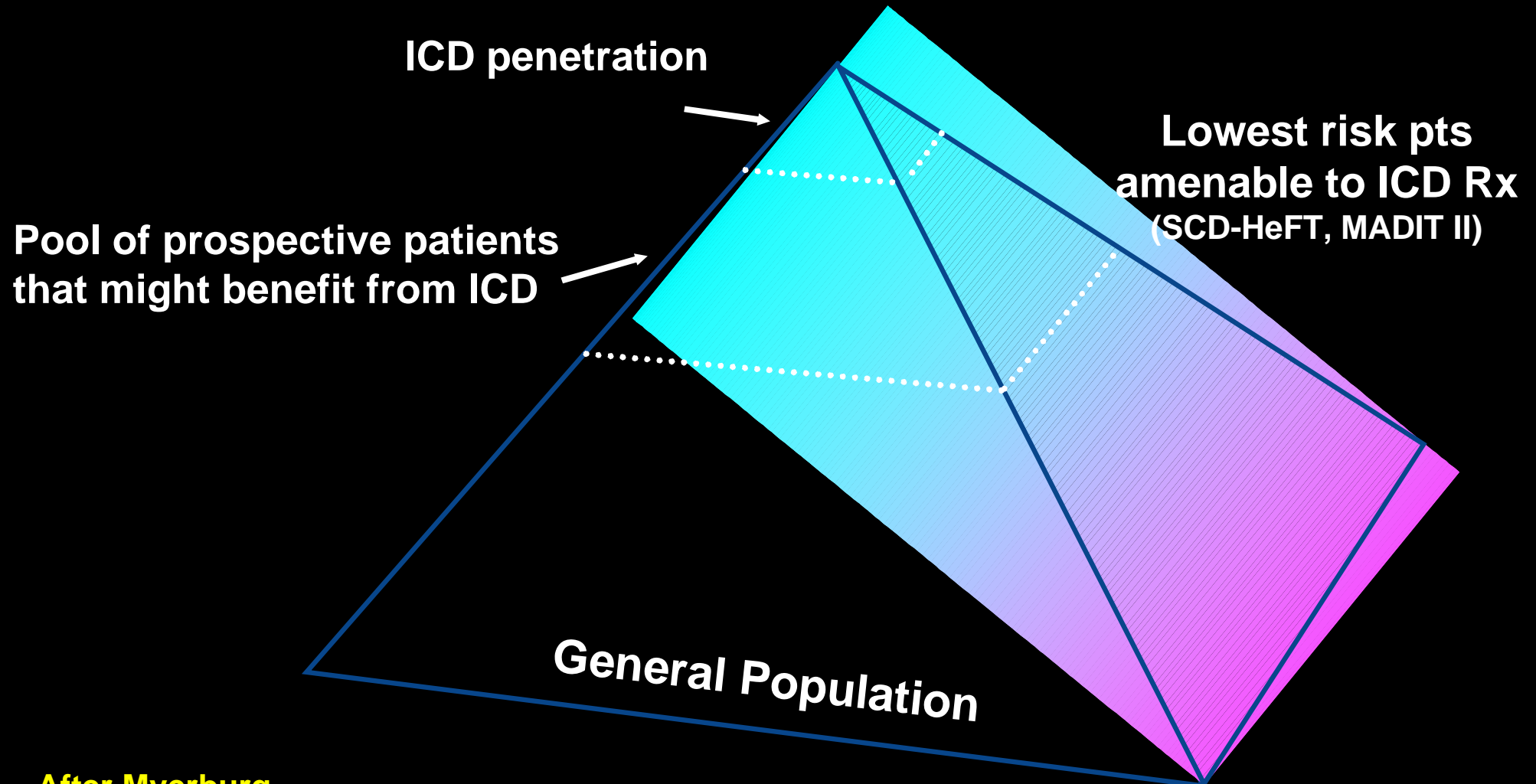
**Gust H. Bardy - Seattle**

# Traditional TV-ICD Issues

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- Lead complications, vascular access, surgical complications
- Young people - long-term ICD management
- Inappropriate detection
- Complex ICDs do not necessarily ↓ mortality
- Referral network bottleneck
- Special skills required
- Costly EP lab/OR, equipment & staff required
- No true prophylactic device for broad public use

# ICD Penetration vs. Population at Risk



After Myerburg

# Primary Study Goal



- To determine in a prospective, randomised within-subject study, DFTs for a totally subcutaneous implantable defibrillator system (S-ICD<sup>®</sup>) compared to a standard transvenous ICD system

# Study Onset and Termination



- Initial patient enrolled March 23, 2004
- Final patient enrolled June 3, 2005

# S-ICD<sup>®</sup> vs. TV-ICD

Standard ICD indications

↓  
Age  $\geq$  18

↓  
Informed Consent

↓  
R

N=53

← S-ICD<sup>®</sup> Testing First

N=26

→ TV-ICD Testing First

N=27

# Inclusion Criteria



- Any standard indication for TV ICD
- Age  $\geq$  18yrs
- Informed consent

# S-ICD<sup>®</sup> Testing Summary

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- 53 patients enrolled
- 4 patients did not complete DFT testing at physicians' discretion
- 165 VF inductions/defibrillations performed for the TV ICD system
- 172 VF inductions/defibrillations performed for the S-ICD<sup>®</sup> system

# TV ICD Guidelines

- Any market released TV ICD: 35 Medtronic, 16 Guidant, 2 St. Jude
- 32 single chamber, 16 dual chamber, and 5 bi-ventricular devices
- Lead system at discretion of investigator: 46 dual; 4 single (3 box changes, lead type unknown)
- Left subclavian/cephalic approach only
- Device based DFT testing

# S-ICD<sup>®</sup> Surgical Landmarks



# **S-ICD<sup>®</sup> Surgical Guidelines**

- **Lateral thoracic incision made along 5<sup>th</sup> ICS on left infra-mammary crease or vertically**
- **Subcutaneous pocket created and canister emulator electrode centred along 5<sup>th</sup> ICS**
- **Stab incisions x 2 left of xiphoid and manubrium**
- **Parasternal electrode inserted parallel to and 3 cm lateral to sternum with centre at 4<sup>th</sup> ICS**
- **Electrode and canister connected to custom high output defibrillator (Cameron Health, San Clemente)**
- **Pocket closed with temporary suture for DFT protocol**
- **ICD inserted - testing initiated**

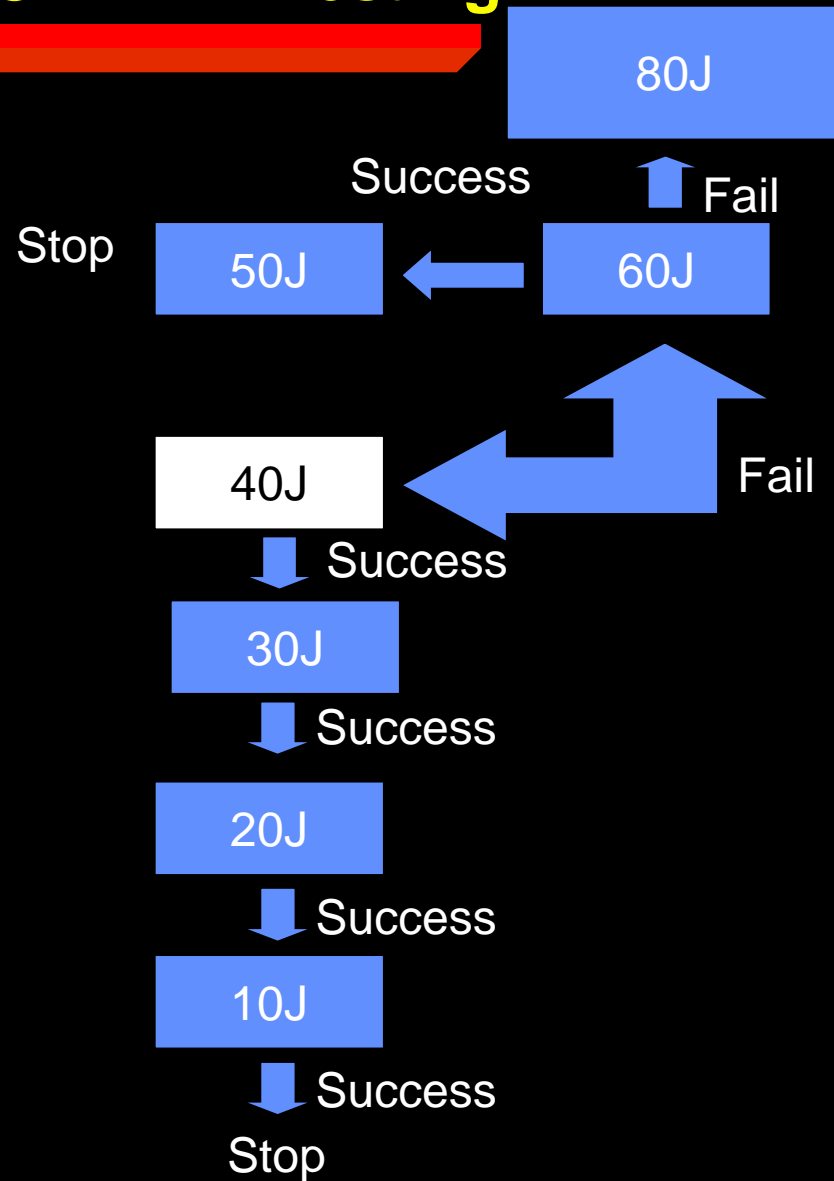
# S-ICD<sup>®</sup> Surgical Landmarks



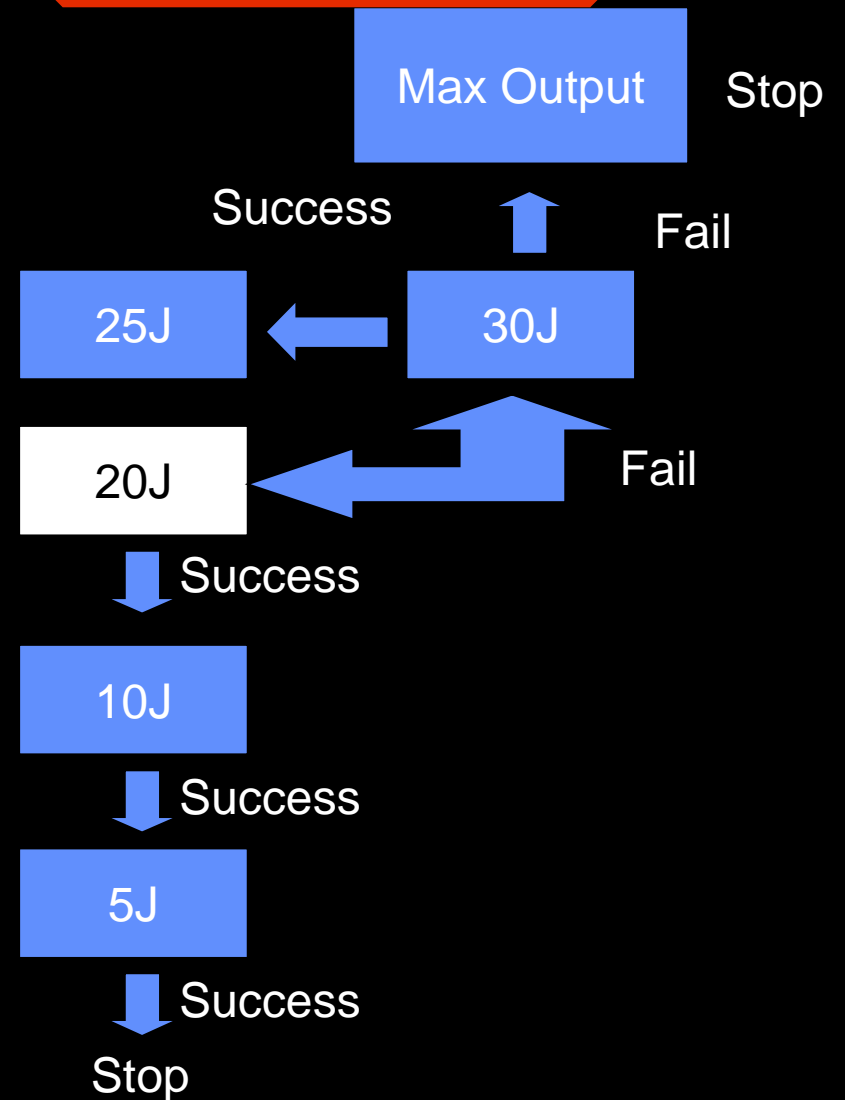
# S-ICD<sup>®</sup> Testing Rules

- No fluoroscopy allowed for temporary S-ICD<sup>®</sup> insertion
- Use of only sternal and 5<sup>th</sup> ICS anatomical landmarks
- Once placed, no system optimisation allowed
- Testing of S-ICD<sup>®</sup> was **prior to** fluoroscopic documentation of can/electrode position

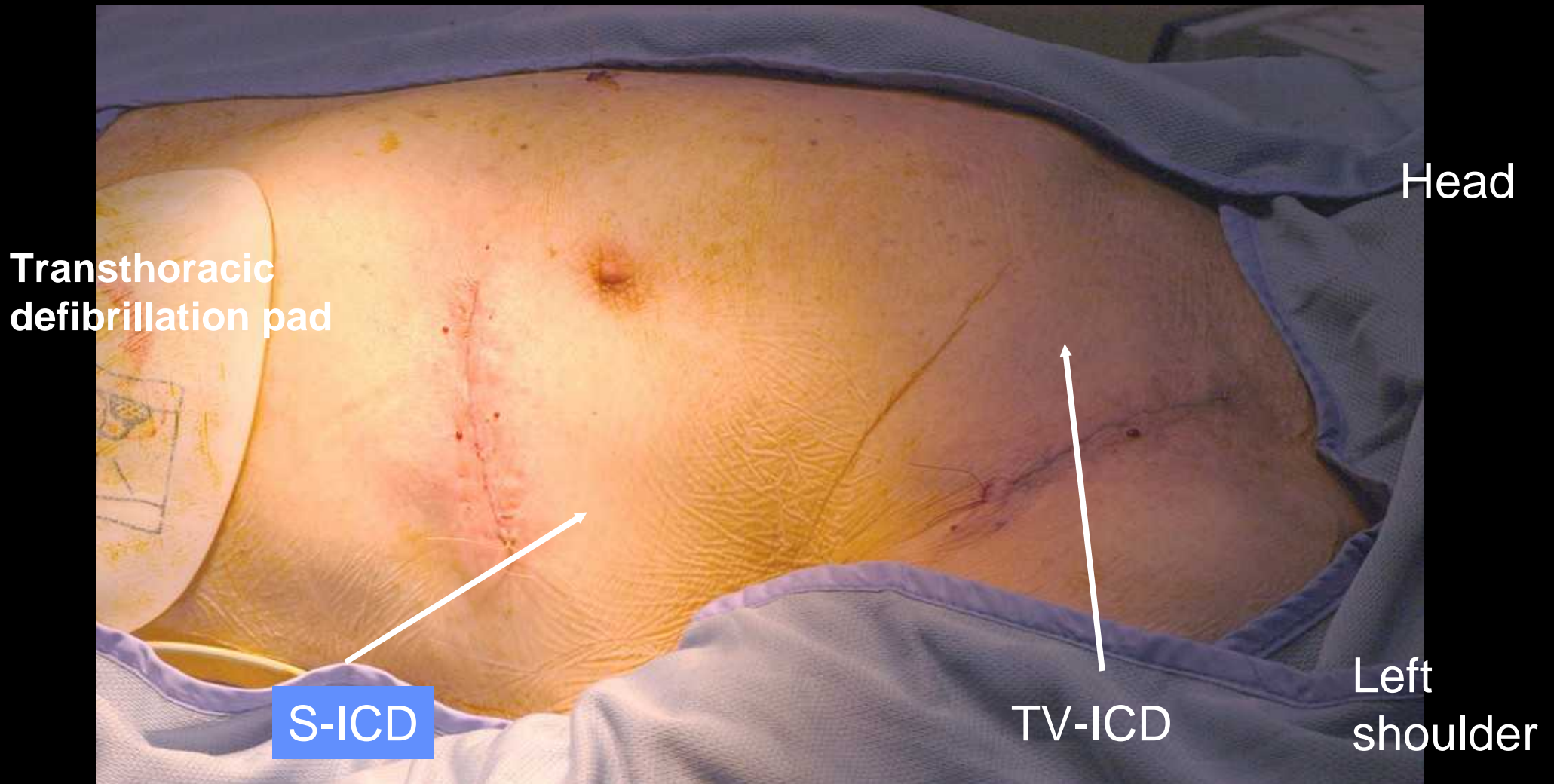
## S-ICD<sup>®</sup> DFT Testing



## TV-ICD DFT Testing



# Patient GLH-052



# Baseline Enrolment Characteristics

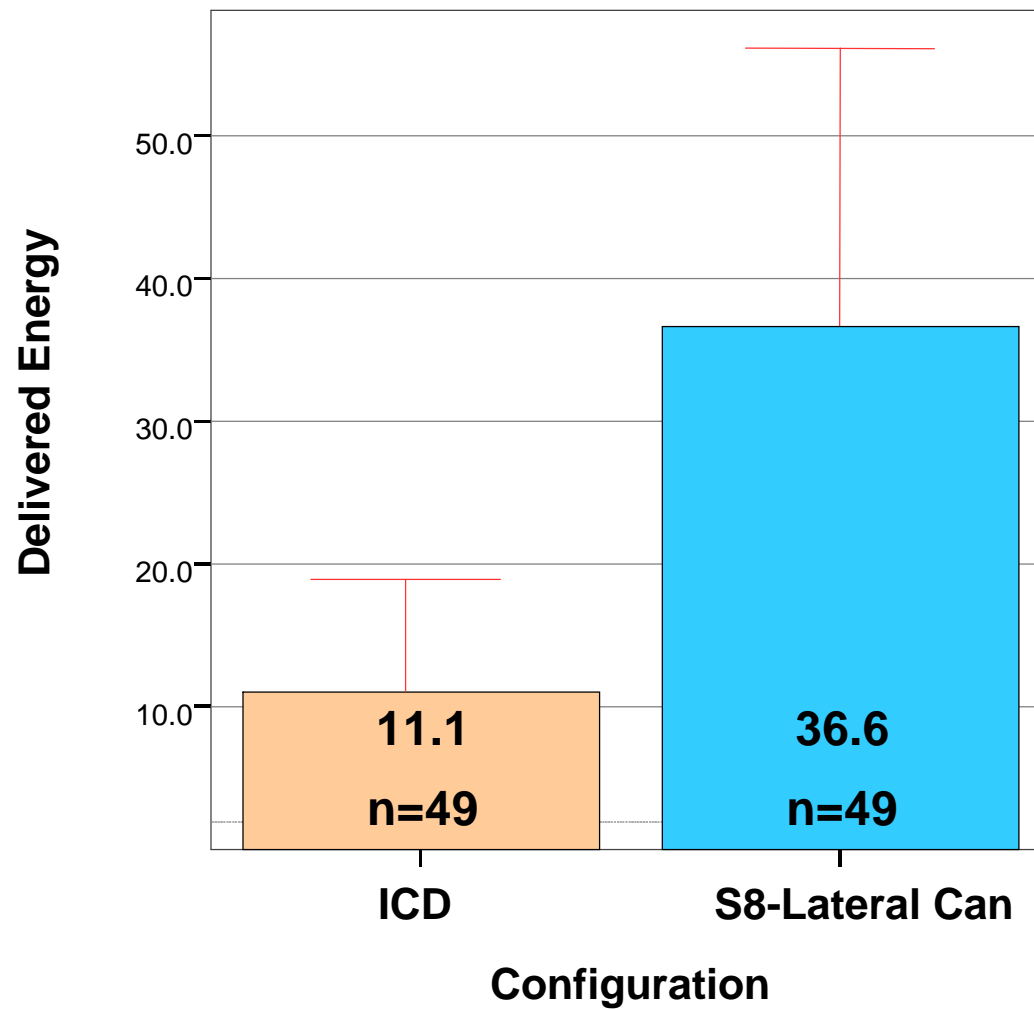
- **N** 53
- **Age** 63.6  $\pm$  10.5 yrs (Min-Max: 42-79)
- **Gender** M 51; F 2
- **Ischaemic/Non-ischaemic:** 27/16
- **Weight** 86.2  $\pm$  13.2 kg (61-114kg)
- **Height** 176  $\pm$  8.4 cm (159-198cm)
- **EF** 0.367  $\pm$  0.134 (0.19-0.70)
- **NYHA Class** I = 18, II = 17, III = 8

# Procedural Complications



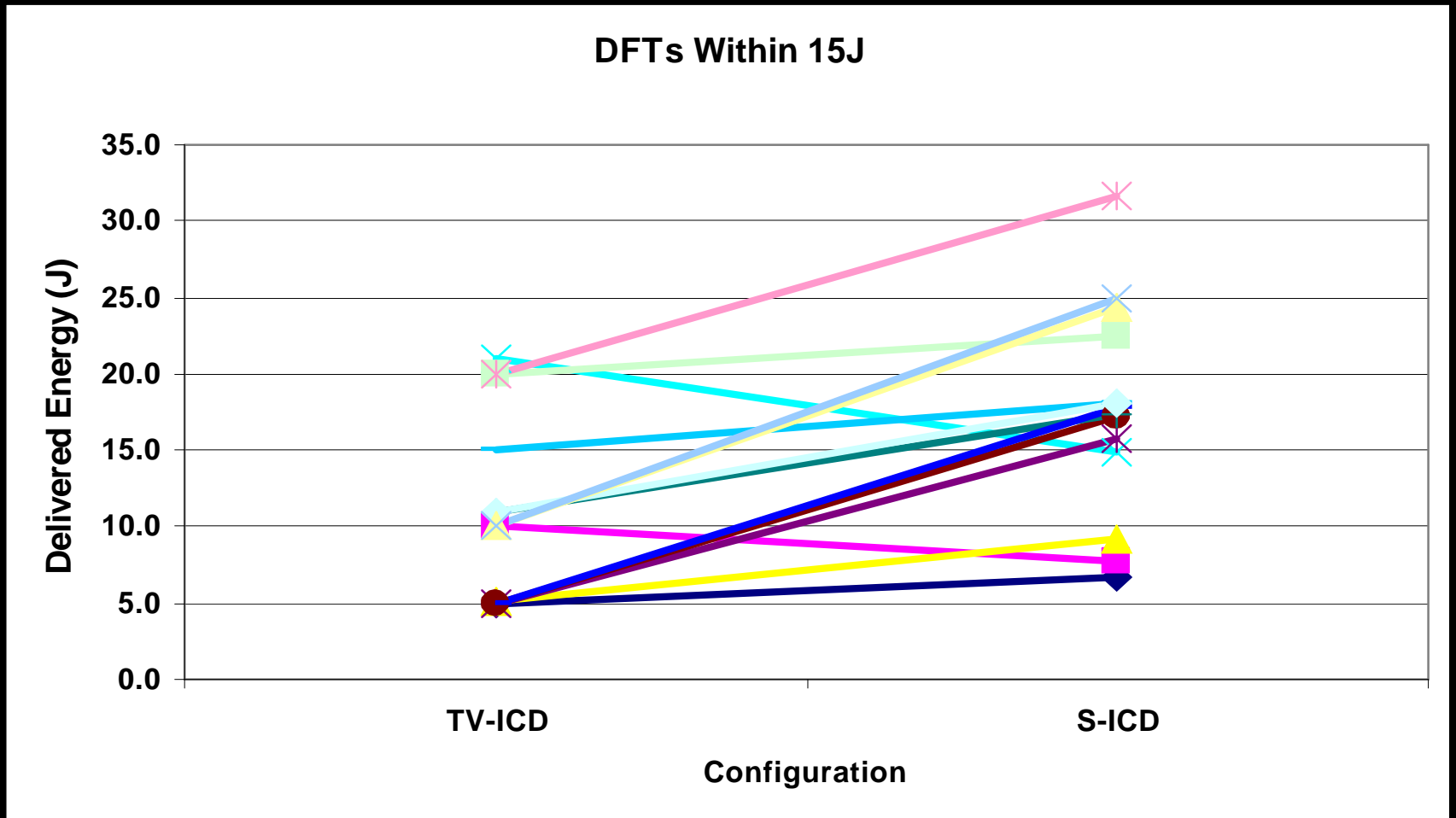
- **TV during implant: none**
- **S-ICD<sup>®</sup>: none**

# Comparative DFT data



# Paired DFTs within 15J for 14 patients

<u>TV-ICD</u>	<u>S-ICD</u>
5.0	6.7
10.0	7.7
5.1	9.2
21.0	14.9
5.0	15.7
5.0	17.2
11.0	17.4
5.0	17.8
15.0	18.1
11.0	18.1
20.0	22.4
10.0	24.3
10.0	24.9
20.0	31.7



# Specific Observations



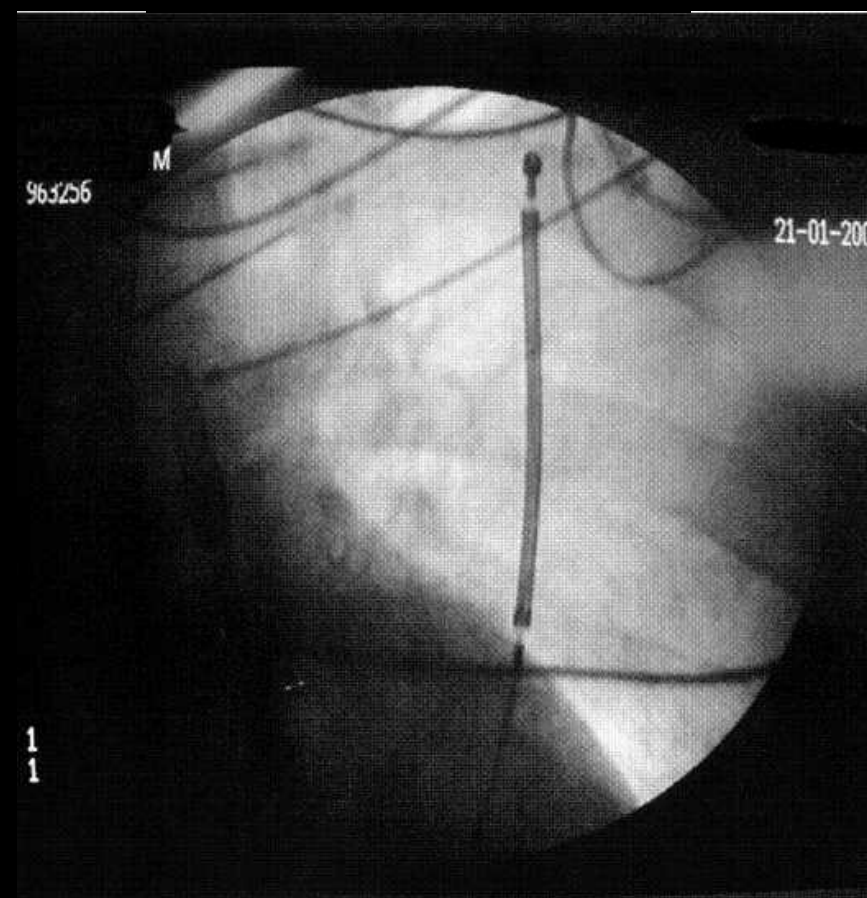
- **The S-ICD<sup>®</sup> configuration was never optimised with placement based solely on anatomical landmarks**
- **9 TV systems required optimising with leads re-positioned**
- **1 failure to defibrillate with TV-ICD**
- **1 failure to defibrillate with S-ICD<sup>®</sup>**

‘...the meat in the sandwich...’

GLH-043  
56.4J



PoH-435  
83J Failure



# Conclusions I



- **Using within-subject comparisons, the S-ICD<sup>®</sup> DFT's are approximately 3x TV defibrillation requirements**
- **The data suggests that subcutaneous defibrillation can safely be performed using a device with an output between 60-80J**
- **Fluoroscopy is not necessary for S-ICD<sup>®</sup> insertion as long as basic anatomic rules are followed using 5<sup>th</sup> ICS and sternum**

# Conclusions II



- **9 (17%) of TV – ICDs in this study required lead repositioning for system optimisation**
- **S-ICD<sup>®</sup> system has potential for very short insertion times**
- **S-ICD<sup>®</sup> may well serve as a viable alternative for TV-ICDs in many patients**