Is not Defibrillation Threshold Testing really necessary during ICD implantation?

경북의대 배명환
Defibrillation Threshold (DFT) Testing

- DFT is the lowest amount of energy needed to successful defibrillate the heart

![Graph showing T-wave shock and Burst pacing]
Defibrillation Threshold (DFT) Testing

• Ensuring electric integrity of ICD generator and leads, reliable sensing, appropriate detection and termination of ventricular arrhythmias

• Perceived lack of benefit

• lack of correlation between induced and spontaneous VF

• Potential for complication
  - anesthesia-related risk
  - systemic embolization in AF and severe LV dysfunction
Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE)

- 1,253 DFT versus 1,247 no DFT, 2009-2011, 3.1yrs F/U
- Primary outcome: arrhythmic death or failed appropriate shock

Routine DFT testing at the time of ICD implantation does not improve shock efficacy or reduce arrhythmic death

P<0.0001 for non-inferiority

*Figure 2: Failed appropriate shock or arrhythmic death*
Systematic Review of Defibrillation Threshold Testing at De Novo Implantation

- DFT versus no DFT, 13 studies, 9,740 patients

Arrhythmic death
Ineffective shocks

Phan K, ET AL. Circ Arrhythm Electrophysiol. 2016;9:2003357
Benefit of DFT testing

• SIMPLE
  - A single-blind, non-inferiority, randomised controlled trial
  - not improved shock efficacy or reduced arrhythmic death

• Meta-analysis
  - 13 studies, 9,740 patients
  - not reduce the risk of failed shocks or prolong survival

→ Benefit of DFT testing has not been proven
Induced VF vs. Spontaneous VF

- Myocardial ischemia or scar vs. Electric stimulation
- Features of induced VF differ according to the mode of induction in animal study
- Spontaneous VF is faster and has lower degree of regularity than induced VF
- Ischemic VF leads to lower resuscitation rates than electrically induced VF in animal models

Complications associated with defibrillation threshold testing: The Canadian experience

- 19,067 ICD in Canada
- Death 3, stroke 5, prolonged resuscitation 27

<table>
<thead>
<tr>
<th>Age, years</th>
<th>Gender</th>
<th>EF</th>
<th>NYHA class</th>
<th>Heart disease</th>
<th>Chronic rhythm</th>
<th>Pre- and postoperative anticoagulation</th>
<th>Rhythm at induction</th>
<th>Did AF cardiovert with DFT testing?</th>
<th>Details of CVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>82</td>
<td>Female</td>
<td>20%</td>
<td>II</td>
<td>Nonischemic CM</td>
<td>AF (?paroxysmal)</td>
<td>IV heparin</td>
<td>AF</td>
<td>Yes</td>
<td>Died 4 days after</td>
</tr>
<tr>
<td>72</td>
<td>Male</td>
<td>40%</td>
<td>II</td>
<td>Ischemic CM</td>
<td>Persistent AF</td>
<td>Coumadin and bridging IV heparin</td>
<td>AF</td>
<td>No</td>
<td>Cerebellar ischemic CVA 12 hours after; no recovery MCA ischemic CVA; no recovery</td>
</tr>
<tr>
<td>72</td>
<td>Male</td>
<td>21%</td>
<td>IV</td>
<td>Ischemic CM</td>
<td>Persistent AF</td>
<td>Coumadin and bridging IV heparin</td>
<td>AF</td>
<td>Yes</td>
<td>TIA</td>
</tr>
<tr>
<td>58</td>
<td>Male</td>
<td>33%</td>
<td>II</td>
<td>Ischemic CM</td>
<td>Persistent AF</td>
<td>Coumadin and bridging IV heparin</td>
<td>AF</td>
<td>Yes</td>
<td>MCA ischemic CVA; no significant recovery</td>
</tr>
<tr>
<td>53</td>
<td>Female</td>
<td>30%–35%</td>
<td>II</td>
<td>Nonischemic</td>
<td>Persistent AF</td>
<td>Coumadin and bridging IV heparin</td>
<td>AF</td>
<td>Yes</td>
<td>MCA ischemic CVA; no significant recovery</td>
</tr>
</tbody>
</table>
# Safety of DFT testing

<table>
<thead>
<tr>
<th>Primary safety Composite*</th>
<th>Secondary safety composite†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Stroke</td>
</tr>
<tr>
<td>Non-CNS systemic embolism</td>
<td>Pulmonary embolism</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>Heart failure needing inotropes or diuresis</td>
</tr>
<tr>
<td>Intraoperative hypotension</td>
<td>Need for chest compression</td>
</tr>
<tr>
<td>Non-elective intubation</td>
<td>Aspiration pneumonia</td>
</tr>
<tr>
<td>Unplanned stay in ICU</td>
<td>Pneumothorax</td>
</tr>
<tr>
<td>Pericarditis, cardiac perforation, or cardiac tamponade</td>
<td>Device infection</td>
</tr>
<tr>
<td>Arterial-line complication</td>
<td>Anoxic brain injury</td>
</tr>
</tbody>
</table>

*ICU-intensive-care unit, †Includes all adverse events apart from other anoxic brain injury, aspiration pneumonia, and device infection. Two patients had both non-CNS systemic embolism and pulmonary embolism.

## Table 3: Safety outcomes

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>DFT Events</th>
<th>Total Events</th>
<th>Total Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior studies</td>
<td>Arnson</td>
<td>0</td>
<td>352</td>
<td>1214</td>
</tr>
<tr>
<td></td>
<td>Calvi</td>
<td>0</td>
<td>42</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Codner</td>
<td>0</td>
<td>80</td>
<td>133</td>
</tr>
<tr>
<td></td>
<td>Healey</td>
<td>3</td>
<td>75</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Kovacevic-Kostic</td>
<td>0</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Michowitz</td>
<td>7</td>
<td>204</td>
<td>2</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>Random</td>
<td>773</td>
<td>1569</td>
<td>4.9%</td>
</tr>
<tr>
<td></td>
<td>Fixed</td>
<td>10</td>
<td>2</td>
<td>95%</td>
</tr>
</tbody>
</table>

**Composite safety outcome**

- Tau²: 0.67; Chi²: 1.47, df = 1 (P = 0.23); I²: 32%
- Test for overall effect: Z = 0.52 (P = 0.60)

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**Simple RCT**

- Subtotal (95% CI) Random: 81/2015
- Subtotal (95% CI) Fixed: 81/2015

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- Heterogeneity: Not applicable
- Test for overall effect: Z = 0.98 (P = 0.33)
- Total events: 81/2015
- Heterogeneity: Tau²: 0.00; Chi²: 1.44, df = 2 (P = 0.49); I²: 0%
- Test for overall effect: Z = 1.06 (P = 0.29)
- Test for subgroup differences: Chi²: 0.12, df = 1 (P = 0.72); I²: 0%

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**Favours DFT Favours no-DFT**

- Risk Ratio M-H, 95% CI: 1.17 [0.86, 1.60]
- Risk Ratio M-H, 95% CI: 1.18 [0.87, 1.60]
EDITORIAL COMMENTARY

The top 10 reasons to avoid defibrillation threshold testing during ICD implantation

Sami Viskin, MD, Raphael Rosso, MD

From the Tel-Aviv Sourasky Medical Center and Sackler-School of Medicine, Tel Aviv University, Israel

To DFT, or not to DFT...

Sami Viskin 2010
1. The majority of implanted ICDs will never treat spontaneous VF.
2. Induction of VF is a poor model of the spontaneous VF.
3. Not all VF-arrhythmias are created equal.
4. Inducible VF and spontaneous VF are two different arrhythmias.
5. Patients are so likely to have a successful DFT test that actually performing the test adds little information.
6. Low DFTs during ICD implantation do not guarantee termination of spontaneous VF.
7. The very low sudden-death rate in patients with implanted ICD is not necessarily attributable to DFT testing.
8. Long-term survival may not necessarily be affected by DFT testing.
9. DFT testing is not without risk.
10. The road to hell is paved with good intentions.
CASE 1

- 남자 30세
- Sudden cardiac arrest due to ventricular fibrillation
- HTN/DM (-/-), SCD FHx (-)
- ECG normal sinus rhythm
- 2D-UCG EF 60%, No RWMA of LV
- CAG coronary artery stenosis (-), ergonovine test (-)

# Idiopathic VF

→ ICD insertion
ICD

- VR, single coil
- R wave sensing 5.6 mV
- Pacing Impedance 620 ohms
- Pacing threshold 0.5V@0.4ms
- Defibrillation impedance 80 ohms

→ defibrillation threshold test
Defibrillation threshold test (#1)

- EGM1 RV tip to RV ring
- EGM2 CAN to RV coil

External defibrillation 200J
Defibrillation threshold test (#2)

Failed DFT testing

External defibrillation 200J
CASE 2

- 남자 56세
- Sudden cardiac arrest, ventricular fibrillation
- 내원 10년 전 타병원에서 IHD로 pLAD stent #1
  내원 2년 전 CAG상 significant stenosis 없음. 당시 LVEF 50%
- HTN/DM (+/+), AF (+)
- Current medication
  Aspirin, atorvastatin, warfarin, lasix, bisoprolol, digoxin
CASE 2

2D-UCG

- 내원 20일 mechanical ventilator weaning
- CAG no significant stenosis

# Ventricular fibrillation
# Ischemic CMP, AF
→ ICD insertion
R wave sensing 20.6 mV
Impedance 459 ohms
Pacing threshold
0.6V@0.4ms
Shock impedance 78 ohms
DFT (-)

VT monitor only
VF 220회 이상, 31J, 41J, 41J 6회

Warfarin titration 후 퇴원 예정
• 퇴원 전일 18시 24분 병동에서 워킹바 밀면서 걸어가던 중 의식 소실, 18시 27분 monitor상 VF, external defibrillation 200J후 sinus rhythm으로 conversion

왜? ICD가 들어가 있는 데 VF이 termination 되지 않았나?
ICD interrogation

- VT 31J shock 후 VF, 41J shock 7회 후에도VF persistent, external defibrillation 후 sinus conversion

Failed defibrillation by ICD
Reassessing Risk Factors for High Defibrillation Threshold: The EF-SAGA Risk Score and Implications for Device Testing

- 1,642 ICD, high DFT (safety margin <10J) 2.3%

<table>
<thead>
<tr>
<th>Number of variables</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4 or 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>High DFT (#)</td>
<td>0</td>
<td>1</td>
<td>8</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>Normal DFT (#)</td>
<td>69</td>
<td>272</td>
<td>475</td>
<td>323</td>
<td>92</td>
</tr>
</tbody>
</table>

EF-SAGA score predictive variables:
- Ejection Fraction less than 20%
- Secondary prevention indication for defibrillator
- Age less than 60 years
- Gender, male
- Amiodarone use

Predictors of a high defibrillation threshold test during routine ICD implantation

- 788/864 DFT testing
- 76 no DFT testing: AF, intra-cardiac thrombus, hemodynamic instability
- High DFT: 44 (5.6%) patients
- QRS duration ≥150ms, LVEDD ≥60mm, LVEF ≤25%, right side implantation

Systematic Review of Defibrillation Threshold Testing at De Novo Implantation

Conclusions—This systematic review of contemporary data suggests a modest average effect of DFT, if any, in terms of mortality, shock efficacy, or safety. Therefore, DFT testing should no longer be compulsory during de novo implantation. However, DFT testing may still be clinically relevant in specific patient populations. (Circ Arrhythm Electrophysiol. 2016;9:e003357. DOI: 10.1161/CIRCEP.115.003357.)

- HCM, channelopathy, congenital heart disease
- Right-side implantation
- Generator replacement (aging lead components)
- Subcutaneous ICD
CASE 1: failed DFT testing

- Single coil
  → dual coil

VF termination
### SIMPLE trial

<table>
<thead>
<tr>
<th></th>
<th>No defibrillation testing (n=1247)</th>
<th>Defibrillation testing (n=1253)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>62.6 (11.5)</td>
<td>63.0 (11.7)</td>
</tr>
<tr>
<td>Male</td>
<td>1015 (81.4%)</td>
<td>1009 (80.5%)</td>
</tr>
<tr>
<td>ICD implanted for primary prevention</td>
<td>889 (71.3%)</td>
<td>924 (73.7%)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>821 (65.8%)</td>
<td>799 (63.8%)</td>
</tr>
<tr>
<td>Non-ischaemic dilated cardiomyopathy</td>
<td>392 (31.4%)</td>
<td>414 (33.0%)</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>42 (3.4%)</td>
<td>53 (4.2%)</td>
</tr>
<tr>
<td>Long QT, Brugada syndrome, or CPVT</td>
<td>24 (1.9%)</td>
<td>29 (2.3%)</td>
</tr>
<tr>
<td>Previous PCI or CABG</td>
<td>651 (52.2%)</td>
<td>622 (49.6%)</td>
</tr>
<tr>
<td>Heart failure class NYHA II</td>
<td>404 (32.4%)</td>
<td>410 (32.7%)</td>
</tr>
<tr>
<td>Heart failure class NYHA III</td>
<td>365 (29.3%)</td>
<td>387 (30.9%)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, %</td>
<td>31.6% (12.4%)</td>
<td>32.0% (12.8%)</td>
</tr>
<tr>
<td>History of atrial fibrillation</td>
<td>285 (22.9%)</td>
<td>299 (23.9%)</td>
</tr>
<tr>
<td>Persistent or permanent atrial fibrillation</td>
<td>141 (11.3%)</td>
<td>139 (11.1%)</td>
</tr>
<tr>
<td>Previous stroke or transient ischaemic attack</td>
<td>133 (10.7%)</td>
<td>127 (10.1%)</td>
</tr>
<tr>
<td>Amiodarone use</td>
<td>182 (14.6%)</td>
<td>190 (15.2%)</td>
</tr>
<tr>
<td>ACE inhibitor use</td>
<td>891 (71.5%)</td>
<td>888 (70.9%)</td>
</tr>
<tr>
<td>Angiotensin receptor blocker use</td>
<td>213 (17.1%)</td>
<td>205 (16.4%)</td>
</tr>
<tr>
<td>β-blocker use</td>
<td>1100 (88.0%)</td>
<td>1088 (86.8%)</td>
</tr>
<tr>
<td>Aldosterone antagonist use</td>
<td>479 (38.4%)</td>
<td>445 (35.5%)</td>
</tr>
<tr>
<td>No device implanted</td>
<td>11 (0.9%)</td>
<td>11 (0.9%)</td>
</tr>
<tr>
<td>Single chamber ICD implanted</td>
<td>569 (45.6%)</td>
<td>552 (44.1%)</td>
</tr>
<tr>
<td>Dual chamber ICD implanted</td>
<td>319 (25.6%)</td>
<td>324 (25.9%)</td>
</tr>
<tr>
<td>Resynchronisation ICD implanted</td>
<td>348 (27.9%)</td>
<td>366 (29.2%)</td>
</tr>
<tr>
<td>Right-sided device implant</td>
<td>15 (1.2%)</td>
<td>13 (1.0%)</td>
</tr>
<tr>
<td><strong>Dual coil ICD lead</strong></td>
<td>733 (58.8%)</td>
<td>717 (57.2%)</td>
</tr>
<tr>
<td><strong>Implant R-wave voltage mV</strong></td>
<td>15.1 (6.3)</td>
<td>14.9 (6.2)</td>
</tr>
</tbody>
</table>
**SIMPLE trial**

- **DC-leads** were associated with a **reduction** in the composite of **failed appropriate shock or arrhythmic death** in the subgroup of **non-HF** patients (SC-leads: 2.31%/year; DC leads: 0.73%/year; adjusted HR 7.02; CI, 2.41-20.5; p<sub>interaction</sub> < 0.001)

J Cardiovasc Electrophysiol. 2019 Apr 4. [Epub ahead of print]
Case 2: Failed appropriate shock

- Dual coil lead change
- Shock vector change

After shock vector change, DFT test → 41J VF termination
2년 후

• VF→41J termination
Role of ICD

• Sudden arrhythmic death↓
  → DFT testing may still be clinically relevant in specific patient populations
Role of ICD

- Efficacy ≥ leads extraction

→ Dual coil leads in high risk patients for high defibrillation threshold and short expected life span
경청해 주셔서 감사합니다.