Who does not need a primary preventive ICD?

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  Biotronik
  Boston Scientific
  Medtronic
  St. Jude Medical
Who does not need a primary preventive ICD?
Benefit – risk assessment

♦ Cause and extent of cardiac disease
♦ Timing
♦ Competing risk factors: expected survival < 1 year, NYHA class IV
♦ Other patient specific factors:
  Informed consent, compliance, severe mental illness, dementia, current drug abuse
Sources

- Guidelines of the European Society of Cardiology 2006:
  - Randomized controlled trials
  - Metaanalysis
  - Subgroup analysis
  - Retrospective studies
  - Observational studies
  - Expert opinion - consensus

- ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013
  Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy
Class III Indication of ESC Guidelines 2006

◆ Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

◆ ICD implantation is not indicated during the acute phase of myocarditis. (Level of Evidence: C)

◆ Elderly patients with projected life expectancy less than 1 y due to major comorbidities should not receive ICD therapy. (Level of Evidence: C)

ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of SCD. Europace (2006) 8, 746–837
Coronary artery disease (CAD): MADIT II, LVEF <30%

- N = 1232
- Age = 64 ± 10
- LVEF = 23 ± 6%
- 37 NYHA I
- 63 NYHA II+III

Mortality Reduction 31%, p = 0.016
Reduction of SCD 66%, p < 0.0001

Who does not need a primary preventive ICD?/Hildegard Tanner

DCM and CAD: SCDHeFT, LVEF<35%

Amiodarone vs. Placebo

ICD Therapy vs. Placebo

<table>
<thead>
<tr>
<th></th>
<th>HR</th>
<th>97.5% CI</th>
<th>P-Wert</th>
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</thead>
<tbody>
<tr>
<td>Amiodarone vs. Placebo</td>
<td>1.06</td>
<td>0.86, 1.30</td>
<td>0.53</td>
</tr>
<tr>
<td>ICD Therapy vs. Placebo</td>
<td>0.77</td>
<td>0.62, 0.96</td>
<td>0.007</td>
</tr>
</tbody>
</table>

N = 2521
Age = ? J.
LVEF = ?%
70% NYHA II
30% NYHA III
CAD 51%
DCM 49%

Coronary artery disease (CAD): MUSTT, LVEF<40% ns VT and inducibility of VT/VF during EP Study

Survival Rate

- N = 704
- Age = 66 (58-72) J.
- LVEF = 30 (20-35)%
- 36% NYHA I
- 38% NYHA II
- 25% NYHA III
- 0% NYHA IV


72% Risk reduction of arrhythmic death or cardiac arrest, $p < 0.001$
Who does not need a primary preventive ICD?

- **MADIT (>3 Wo, 75% > 6 Mo)**
  - (After surgery)

- **MADIT II (>1 Mo, 87% > 6 Mo)**
  - (6-40 d after MI)

- **DINAMIT**
  - (6-40 d after MI)

- **DEFINITE Mean 2.8 Jahre**
  - (Median 3 Mo, < 9 Mt)

- **CAT**
  - (Median 3 Mo, < 9 Mt)
## HCM risk score for probability of SCD at 5 years

### HCM Risk-SCD Calculator

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>Years</td>
</tr>
<tr>
<td><strong>Maximum LV wall thickness</strong></td>
<td><strong>mm</strong></td>
</tr>
<tr>
<td><strong>Left atrial size</strong></td>
<td><strong>mm</strong></td>
</tr>
<tr>
<td><strong>Max LVOT gradient</strong></td>
<td><strong>mmHg</strong></td>
</tr>
<tr>
<td><strong>Family History of SCD</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Non-sustained VT</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Unexplained syncope</strong></td>
<td>No</td>
</tr>
</tbody>
</table>

**Risk of SCD at 5 years (%)**: [ ]

**ESC recommendation**: [ ]

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Hypertrophic cardiomyopathy: ICD indications

- LOW RISK
  5-year risk <4%
- INTERMEDIATE RISK
  5-year risk ≥4-<6%
- HIGH RISK
  5-year risk ≥6%

- ICD generally not indicated
- ICD may be considered
- ICD should be considered

ICD implantation is not recommended in patients with an estimated 5-year risk of SCD of <4% and no other clinical features that are of proven prognostic importance.

Who does not need a primary preventive ICD?/Hildegard Tanner

**Appropriate Use Criteria (AUC)**

- **Median Score 7 to 9:** Appropriate Care
- **Median Score 4 to 6:** May Be Appropriate Care
- **Median Score 1 to 3:** Rarely Appropriate Care

R: Post-Acute MI (< 40 Days) and LVEF <30-40%

- No NSVT

- After or before revascularization:
  Asymptomatic NSVT > 4d and no EPS, or EPS with inducibility within 30-40d

- Not amenable for revascularization:
  No NSVT

Appropriate Use Criteria for ICD and CRT. Heart Rhythm 2013;10.
R: Not-ischemic CMP (< 3 months of diagnosis) and narrow QRS

- LVEF ≤ 30% and NYHA I
- LVEF 31% to 35% and NYHA II and III
- NYHA IV: no scoring

*Appropriate Use Criteria for ICD and CRT. Heart Rhythm 2013;10.*
R: Specific etiologies

- Acute lymphocytic myocarditis (< 3 months ago) irrespective of LVEF

- Asymptomatic Brugada Typ I ECG, without family history of SCD:
  - without EPS or without inducible VT or VF at EPS

*Appropriate Use Criteria for ICD and CRT. Heart Rhythm 2013;10.*
R: Life Expectancy

- Life expectancy <1 year from cardiac or noncardiac conditions
- ≥ 90 years old and NYHA I
- Not able to understand or provide informed consent and no healthcare proxy can be identified
- Significant psychiatric illnesses that may be aggravated by device implantation or that may preclude regular follow-up

Appropriate Use Criteria for ICD and CRT. Heart Rhythm 2013;10.
R: Other Comorbidities

- IV drug abuse (ongoing)
- Unresolved infection associated with risk for hematogenous seeding
- Noncompliance with medical therapy and follow-up
R: Class IV Heart Failure

- Not candidate for cardiac transplantation, CRT, or VAD
  Refractory symptoms on oral therapy

- Not a candidate for transplant or VAD
  Does not meet CRT criteria
  Planned outpatient continuous i.v. inotropic therapy for palliation

*Appropriate Use Criteria for ICD and CRT. Heart Rhythm 2013;10.*
Summary: Who does not need a primary preventive ICD?

- In patients where benefit-risk assessment does not support the implantation of an ICD
- CAD and DCM patients with LVEF > 40/35%
- HCM patients with a low risk score
- Competing risk factors: expected survival < 1 year, NYHA class IV, not candidate for cardiac transplantation
- Acute myocarditis
- Missing informed consent, compliance, severe mental illness, dementia, current drug abuse