ESC Sudden Cardiac Death Guidelines:

*From the theory to the real life?*

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*President of EHRA*
Sudden cardiac death is defined as the unexpected death due to a cardiac cause, in patients with or without cardiac disease, which occurs within one hour from the appearance of the first clinical symptoms.
My task

- To briefly highlight the main messages derived from SCD Guidelines.
- I will focus on primary prevention of SCD and the use of ICD devices in patients with DCM (of ischemic and non-ischemic origin).
- I will also briefly discuss the varying implementation of these guidelines in different European countries and ICD cost-effectiveness issues.
SUDDEN CARDIAC DEATH

Primary prevention
The main Clinical Trials
The Guidelines Orders

MADIT-II

Defibrillator

Conventional
MADIT I

No. of patients

<table>
<thead>
<tr>
<th></th>
<th>Year</th>
<th></th>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>Defibrillator</td>
<td>5</td>
<td>31</td>
<td>17</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Conventional</td>
<td>5</td>
<td>48</td>
<td>29</td>
<td>17</td>
<td>0</td>
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P-value = 0.009

MADIT-II

Survival curves diverged at 9 months


No. At Risk

<table>
<thead>
<tr>
<th>Year</th>
<th>Defibrillator</th>
<th>Conventional</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>742</td>
<td>490</td>
</tr>
<tr>
<td>1</td>
<td>502 (0.91)</td>
<td>329 (0.90)</td>
</tr>
<tr>
<td>2</td>
<td>274 (0.94)</td>
<td>170 (0.78)</td>
</tr>
<tr>
<td>3</td>
<td>110 (0.78)</td>
<td>65 (0.69)</td>
</tr>
<tr>
<td>4</td>
<td>9</td>
<td>3</td>
</tr>
</tbody>
</table>

P = 0.007
Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)

ICD reduced mortality by 23%

<table>
<thead>
<tr>
<th>Group</th>
<th>HR</th>
<th>97.5% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone vs. Placebo</td>
<td>1.06</td>
<td>0.86, 1.30</td>
<td>0.529</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>

ICD mortality reductions in primary prevention trials are equal to or greater than those in secondary prevention trials.
POST-INFARCTION DILATED CARDIOMYOPATHY

Class I, level of evidence A

ICD therapy is recommended in patients with:

- Left ventricular dysfunction due to an earlier myocardial infarction, 40 days post MI
- An ejection fraction of ≤ 30 – 40 %
- NYHA class II or III
- Receiving optimal pharmaceutical therapy

Patients should have reasonable expectation of survival with a good functional status (> 1 year)
NON ISCHAEMIC CARDIOMYOPATHY

Class I, level of evidence B

ICD Therapy is recommended for primary prevention, to reduce total mortality by reducing SCD in patients with:

- Non ischaemic dilated cardiomyopathy
- LVEF ≤ 30 – 35 %
- NYHA class II – III
- Optimal Pharmaceutical Therapy

Patients should have reasonable expectation of survival with a good functional status (> 1 year)
Post MI cardiomyopathies

Class I, level of evidence A

- ICD therapy is indicated in patients with LVEF less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA II or III.

- ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30%, and are in NYHA I.
NON ISCHAEMIC CARDIOMYOPATHY

Class I, level of evidence A

ICD therapy is indicated in patients with non-ischemic DCM who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III.
SUDDEN CARDIAC DEATH

Primary prevention

Clinical practice in Europe
Clinical decisions that concern the use of ICD, CRT-P and CRT-D devices in the various European countries are characterized by significant heterogeneity.

The Guidelines that are followed are usually those of the ESC, in their unadulterated form or altered, sometimes national Guidelines (e.g. NICE) and not infrequently, the American Guidelines.

The patient access to advanced medical technology and especially ICD, CRT-P and CRT-D varies significantly in different European countries as a result of numerous causes and reasons.
ICD use in Europe vs USA
2004 - 2006

ICD Implants per 10^6 Inhabitants

European Average

US comparison
2004: 355 per 10^6 inhabitants
2005: 389 per 10^6 inhabitants
2006: 369 per 10^6 inhabitants

*Eucomed data from 04 to 06: Austria, Belgium (incl. Lux.), Denmark, Finland, France, Germany, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, UK. US analyst data from 04 to 06
ICD use in Europe
2005 - 2008

ICD Implant Rates per Million Inhabitants

<table>
<thead>
<tr>
<th>Country</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
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<tbody>
<tr>
<td>Austria</td>
<td>57</td>
<td>89</td>
<td>103</td>
<td>90</td>
</tr>
<tr>
<td>Belgium-Lux</td>
<td>90</td>
<td>55</td>
<td>120</td>
<td>110</td>
</tr>
<tr>
<td>Denmark</td>
<td>50</td>
<td>171</td>
<td>125</td>
<td>115</td>
</tr>
<tr>
<td>Finland</td>
<td>50</td>
<td>150</td>
<td>155</td>
<td>155</td>
</tr>
<tr>
<td>France</td>
<td>57</td>
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<tr>
<td>Germany</td>
<td>40</td>
<td>115</td>
<td>115</td>
<td>115</td>
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<tr>
<td>Greece</td>
<td>87</td>
<td>41</td>
<td>41</td>
<td>41</td>
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<tr>
<td>Ireland</td>
<td>98</td>
<td>51</td>
<td>51</td>
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<tr>
<td>Italy</td>
<td>141</td>
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<td>74</td>
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<tr>
<td>Netherlands</td>
<td>115</td>
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<td>45</td>
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<tr>
<td>Norway</td>
<td>149</td>
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<td>51</td>
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<tr>
<td>Portugal</td>
<td>171</td>
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<td>Sweden</td>
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<td>Switzerland</td>
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<tr>
<td>United Kingdom</td>
<td>198</td>
<td>98</td>
<td>98</td>
<td>98</td>
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</tbody>
</table>

Eucomed 2009
CRT-D use in Europe
2005 - 2008

CRT-Defibrillator Implant Rates per Million Inhabitants

Eucomed 2009
Regional differences in ICDs implantation in UK.

Data from Heart Rhythm Devices: UK National Survey 2007
We need to recognize that even in Germany there remains a significant difference in implantation rates in the various regions.
Pre SCD Registry

Risk stratification of patients post MI
Implantation rate

10,612 pts ≥ 1 month post AMI
(Mean LVEF 55.5% ± 11%)

Baseline
LVEF ≤30%
n=269 (2.5%) → Lost to FU
n=10

LVEF 31% - 40%
n=727 (6.9%) → Lost to FU
n=34

LVEF >40%
n=9,816 (90.6%) → Random selection
n=1,148 → Group 4
n=8,468

Follow-up (FU)
n=2,058
Group 1
n=259
ICD ≤ 4 months
n=57; 22.0%
ICD later
n=25; 9.7%

Group 2
n=693
ICD ≤ 4 months
n=15; 2.2%
ICD later
n=34; 4.9%

Group 3
n=1,106
ICD ≤ 4 months
n=3; 0.3%
ICD later
n=8; 0.7%

Voller H et al. ESC 2009
• Showed a reduction in total mortality of 20.2 % at 36 months post MI (in pts with LVEF ≤ 30 %)

• Benefit restricted mainly to those patients who received an ICD at 11 months post MI

• Few patients with guideline-based ICD indications received ICD therapy

Courtesy of C. Wolpert
European Heart Rhythm Association
Main Actions

- One of the main roles of EHRA, is to promote equal access to therapy for all patients across Europe.

- The first step was to compile data on the current situation in various ESC membership countries, compare them, and propose actions to move towards harmonization.
The European White Book of Electrophysiology:
The first necessary step towards equal access to therapy in Europe
Significant diversity exists among European countries in:

- The age distribution of the population
- Gross Domestic Product (GDP)
- The percentage of the GDP devoted to health expenditure
- Health systems (Private vs Public)
- Medical education and EP training
Significant diversity exists among European countries in:

- **Healthcare data**
  - Hospitals (per 100,000 population)
  - Beds (per 100,000 population)
  - Density of physicians (per 1,000 population)
  - Density of nurses (per 1,000 population)

- **Pacemaker – ICD-CRT implantation rates**

- **Number of Ablations performed**
## CRT-D use in Europe in 2007

<table>
<thead>
<tr>
<th></th>
<th>The highest CRT-D implantation rate per million (upper quartile)</th>
<th>The lowest CRT-D implantation rate per million (lower quartile)</th>
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</thead>
<tbody>
<tr>
<td>Italy</td>
<td>93,47</td>
<td>Georgia</td>
</tr>
<tr>
<td>Netherlands</td>
<td>85,63</td>
<td>Slovenia</td>
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<td>Germany</td>
<td>84,13</td>
<td>Tunisia</td>
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<td>Israel</td>
<td>68,33</td>
<td>Russian Federation</td>
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<tr>
<td>Czech Republic</td>
<td>58,57</td>
<td>Estonia</td>
</tr>
<tr>
<td>Austria</td>
<td>57,44</td>
<td>Lithuania</td>
</tr>
<tr>
<td>Denmark</td>
<td>50,11</td>
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<td>United Kingdom</td>
<td>38,83</td>
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</tbody>
</table>

EHRA White Book
<table>
<thead>
<tr>
<th>Country</th>
<th>Total expenditure on health as % of GDP</th>
<th>GDP/head ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>10.3</td>
<td>45,181</td>
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<tr>
<td>Croatia</td>
<td>7.7</td>
<td>14,414</td>
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<tr>
<td>France</td>
<td>10.5</td>
<td>41,511</td>
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<tr>
<td>Germany</td>
<td>10.6</td>
<td>40,415</td>
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<tr>
<td>Greece</td>
<td>9.9</td>
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<td>Norway</td>
<td>9.7</td>
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<tr>
<td>Russia</td>
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<tr>
<td>Spain</td>
<td>8.1</td>
<td>32,066</td>
</tr>
<tr>
<td>Turkey</td>
<td>7.7</td>
<td>9,629</td>
</tr>
</tbody>
</table>
SUDDEN CARDIAC DEATH

Primary prevention
Cost-Effectiveness Issues
IMPLANTABLE CARDIOVERTER DEFIBRILLATORS
Cost - Effectiveness Issues

- ICD therapy generally costs more than conventional management of cardiac arrhythmias but is more effective as compared to the therapy with amiodarone.

- The cost-effectiveness ratio of ICD therapy and Annual All Cause Cardiac Mortality has a U shape.

- The cause-effectiveness ratio becomes non-profitable at either low or very high percentages of Annual All Cause Cardiac Mortality.
PRIMARY PREVENTION OF SCD AND ICDs

Is the NNT too high?

This figure compares various therapy costs for 2004 in four major European countries.

SUDDEN CARDIAC DEATH

Implementation of ESC SCD Guidelines

Is it Primarily a Scientific, Political, or Financial Matter?
A large number of cardiologists, perhaps even the majority, in various European countries are unaware of significant parts of the guidelines.

It must become more widely known that the guidelines have been proved to contribute to improvement in patients’ quality of life and life expectancy.

We must overcome the reservations of those who question or reject the guidelines without providing clear justification, simply expressing their flat disbelief, for this or that reason.
Implementation of ESC SCD Guidelines
A political matter?

- Most governments in ESC countries give priority to limiting health care expenditure and are aggrieved when faced with the increased expenses that the guidelines often entail.

- It must be admitted here that the cost of implementing guidelines is indeed often insupportable for a significant number of countries in the European Union.

- Very often the policies of some governments disregard and diverge widely from the recommendations issued by their own national cardiological societies with regard to such topics.
Implementation of ESC SCD Guidelines
A financial problem?

- The cost of complete implementation of the guidelines often stands as an insurmountable obstacle for the economies of many countries of the European Union.

- The map of European economies shows material differences, where countries with a per capita income of €70,000 coexist besides those with a per capita income of €4,000.

- I personally believe that for countries with a per capita income below €25,000 the cost is the main reason for non-implementation of the guidelines.
Clinical effectiveness of ICD for the primary prevention of SCD is proven.

Therapy cost effectiveness continues to be a thorny issue.
CONCLUSIONS

- The implementation of the current guidelines is expensive.

- The MADIT II criteria can only be universally implemented in a limited number of countries.

- This life saving, but relatively expensive treatment with ICDs, needs to be implemented with caution, thoroughness and knowledge.
CONCLUSIONS

- The ESC has as a strategic priority, not only the production of high-quality guidelines, but also their correct implementation.

- The national societies have shown interest and understanding with regard to the need for implementation.

- What is needed is systematic and organised collaboration between national societies and the ESC and an assessment of the results on an annual basis.
Government dilemma
Spending the taxpayers’ money

- 4.5 million €
- 14-18 million €
- 14 million € annual front cost for UK