Wearable Cardioverter Defibillators

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Aarau
Speakers fee from ZOLL
Technology Overview
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Arrhythmia detection

- Sinus
- Ventricular Arrhythmia
- Sinus
- Vibration Alert
- Siren
- Loud Siren Alert
- Patient Audible Prompt
- Gel
- Bystander Alert
- Shock

Time (s) 0 15 30 45
<table>
<thead>
<tr>
<th>Study/Year</th>
<th>No of pts</th>
<th>Inclusion Criteria</th>
<th>Design</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auricchio et al, 1998</td>
<td>10</td>
<td>Pts undergoing EPS for VT/VF</td>
<td>Observational, clinical testing</td>
<td>10/10 episodes of induced VT/VF were successfully terminated with first 230J monophasic shock in 10 Pts</td>
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<tr>
<td>Reek et al, 2002</td>
<td>84</td>
<td>High-risk after MI/CABG, Pts awaiting HTX</td>
<td>Retrospective, registry data</td>
<td>7/7 episodes of VT/VF were successfully terminated during mean FU of 116 days</td>
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<tr>
<td>Reek et al, 2003</td>
<td>12</td>
<td>Pts undergoing EPS for VT/VF</td>
<td>Observational, clinical testing</td>
<td>22/22 episodes of induced VT/VF were successfully terminated with first 70J or 100J biphasic shock in 12 Pts</td>
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<td>Feldman et al, 2004</td>
<td>289</td>
<td>WEARIT: heart failure NYHA III/IV BIROAD: high-risk after MI/CABG</td>
<td>Prospective cohort study</td>
<td>6/8 episodes of spontaneous VT/VF were successfully terminated during mean FU of up to 4 months</td>
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<td>Klein et al, 2010</td>
<td>354</td>
<td>High-risk after MI/CABG, Pts awaiting HTX, delayed implant, risk stratification</td>
<td>Retrospective, registry data</td>
<td>20/21 VT/VF episodes were successfully terminated by 1st shock during a mean wear-time of 3 months</td>
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<td>Chung et al, 2010</td>
<td>3569</td>
<td>Various indications according to CMS coverage</td>
<td>Retrospective, registry data</td>
<td>Compliance was high and SCD mortality was low during WCD use comparable to that of ICD Pts; 79/80 VT/VF episodes were successfully terminated by 1st shock during a mean wear-time of 53 days</td>
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<tr>
<td>Rao et al, 2011</td>
<td>162</td>
<td>CSHD, IAS</td>
<td>Prospective observational, registry data</td>
<td>WCD can be safely used in high-risk adults with CSHD and IAS; 3 VT/VF episodes were successfully terminated by 1st shock during a mean wear-time of 29 days</td>
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<tr>
<td>Saltzberg et al, 2012</td>
<td>266</td>
<td>PPCM, NICM</td>
<td>Retrospective, registry data</td>
<td>No arrhythmic events and low mortality rate in Pts with PPCM</td>
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<tr>
<td>Zishiri et al, 2013</td>
<td>809</td>
<td>Pts after CABG/PCI with LVEF≤35%</td>
<td>Prospective observational, registry data</td>
<td>WCD use was associated with lower short- and long-term mortality than no WCD use in high-risk Pts after CABG or PCI; 12/18 (1.3% event rate) VT/VF episodes were successfully terminated</td>
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<tr>
<td>Epstein et al, 2013</td>
<td>8453</td>
<td>Recent MI with LVEF≤35%</td>
<td>Retrospective, registry data</td>
<td>133 Pts (1.6%) received 309 shocks for VT/VF during 40 day and 3 month waiting periods after MI; 91% were successfully resuscitated</td>
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<td>Duncker et al, 2014</td>
<td>7</td>
<td>PPCM</td>
<td>Prospective cohort study</td>
<td>4 episodes of VF were successfully terminated by 1st WCD shock in 3/7 Pts during mean wear-time of 81 days</td>
</tr>
<tr>
<td>Kutyifa et al, 2015</td>
<td>2000</td>
<td>High-risk ICM, NICM, CSHD/IAS</td>
<td>Prospective observational, registry data</td>
<td>VT/VF event rates of 3% in ICM and CSHD/IA, respectively and 1% in NICM during mean wear-time of 3 months; 30/30 episodes of spontaneous VT/VF successfully terminated by 1st shock</td>
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<tr>
<td>Singh et al, 2015</td>
<td>525</td>
<td>Newly diagnosed ICM and NICM</td>
<td>Prospective observational, registry data</td>
<td>Very low arrhythmic risk in Pts with NICM, 2.2% of ICM Pts received appropriate shock for VF</td>
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<tr>
<td>Salehi et al, 2016</td>
<td>127</td>
<td>Newly diagnosed NICM (ACM)</td>
<td>Retrospective registry data</td>
<td>9/9 episodes of spontaneous VT/VF successfully terminated by 1st shock in 7 Pts during mean FU of 51 days</td>
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</tbody>
</table>
• Prospectice registry to evaluate safety and efficacy of the WCD for SCD prevention
• High-risk pts without established ICD indication
  – Low LVEF after MI, coronary revascularization
  – New onset NICM
  – Inherited or congenital heart disease

Kutyifa et al, Circulation 2015
WEARIT II Registry

- 2000 pts enrolled between 2/2011 and 8/2014
- Age 62 years, 70% male
- LVEF 25%, 50% with symptomatic CHF

- Duration of WCD use 90 days
- Median daily use 22.5 hours
- 120 sustained VT/VF events in 41 pts
- 30 VT/VF episodes in 22 pts treated by WCD
- 30/30 first shock success
- 10 pts with inappropriate shocks (0.5%)
- 3/2000 pts died during WCD wearing (all had asystole)
- 42% (ICM), 36% (NICM) and 46% (CSHD/IAS) received ICD
- Most frequent reason for no ICD was LVEF improvement (41%)

Kutyifa et al, Circulation 2015
Summary of Clinical Experience

- >>100’000 pts with WCD (US>Europe)
- Treated Pts
  - who do not meet current guideline indications for ICD
  - with transient or unknown risk
  - awaiting ICD implantation
- High pts compliance, increasing with time of use
- Very high first shock success rate, low rate of inappropriate therapies (<1%)
- The rate of sustained VT/VF in WCD populations is significant
  - ICM 2-3%
  - NICM 1%
  - Highest rate in pts with ICD indication 5.2% (Chung et al, JACC 2010)
- About 40% in the high-risk population will receive an ICD
- Patient selection, training, and compliance are essential

Waessnig et al, 2015
Cost Effectiveness

Markov Models
• in the setting of ICD explant
  – ICER of WCD strategy was $26,436/QALY  Healy et al, Heart Rhythm 2015
• high-risk post MI or revascularization, low LVEF
  – ICER of WCD $60’600/QALY  Sanders et al, JICRM 2015

Dependent on indication/patient population, event rate, duration of use, cost of device, frequency of ICD implantation
## Representation in Guidelines

<table>
<thead>
<tr>
<th>Year</th>
<th>Reference</th>
<th>Key Points</th>
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<tbody>
<tr>
<td>2006</td>
<td>ACC/AHA/ESC 2006 Guidelines for management of patients with ventricular arrhythmias and prevention of sudden cardiac death.</td>
<td>Quotation of FDA approval of the WCD for cardiac patients with a transient high risk for VF such as those awaiting cardiac transplantation, those at very high risk after a recent MI or an invasive cardiac procedure, or those requiring temporary removal of an infected ICD for antibiotic therapy.</td>
</tr>
<tr>
<td>2006</td>
<td>International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates.</td>
<td>Class I indication for WCD prescription for status 1B patients who are discharged home given that the wait for transplantation remains significant.</td>
</tr>
<tr>
<td>2009</td>
<td>Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management.</td>
<td>Recommendation to consider the WCD as an alternative to early ICD re-implantation after device explant when there is concern of on-going infection.</td>
</tr>
<tr>
<td>2009</td>
<td>ACCF/AHA guideline for the management of ST-elevation myocardial infarction.</td>
<td>Usefulness of a WCD in high-risk patients during the first 4 to 6 weeks after ST-elevation myocardial infarction is under investigation.</td>
</tr>
<tr>
<td>2013</td>
<td>EHRA/HRS/APHRS Expert consensus on ventricular arrhythmias.</td>
<td>Patients with impaired LV function early after MI with or without revascularization are at increased risk for SCD and may benefit from WCD until reassessment of LV function.</td>
</tr>
<tr>
<td>2014</td>
<td>HRS/ACC/AHA Expert consensus statement on the use of ICD therapy in patients who are not included or not well represented in clinical trials.</td>
<td>The WCD may be an option as a “bridge to ICD” for selected patients at high risk of sudden cardiac death due to ventricular arrhythmias, although the data are scant.</td>
</tr>
<tr>
<td>2015</td>
<td>ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.</td>
<td>In patients with transient impaired LVEF, the WCD may be used until LV function has recovered sufficiently, following insults such as myocardial infarction, post-partum cardiomyopathy, myocarditis or interventions such as revascularization associated with transient LV dysfunction. Similarly, patients with a history or at risk of life-threatening VAs or who are scheduled for cardiac transplantation may be temporarily protected with the WCD.</td>
</tr>
<tr>
<td>2016</td>
<td>A science advisory from the American Heart Association. WCD therapy for the prevention of sudden cardiac death.</td>
<td>WCD use is reasonable when there is a clear indication for an ICD in the presence of a transient contraindication to an ICD. WCD use may be appropriate in clinical circumstances associated with transient increased arrhythmic risk.</td>
</tr>
</tbody>
</table>
**ESC Guidelines 2015**

- **Level IIb Recommendation**
  “...Adult patients with poor LV systolic function who are at risk of sudden arrhythmic death for a limited period, but are not candidates for an ICD...”
  - bridge to heart transplant
  - bridge to transvenous ICD implant
  - peripartum cardiomyopathy
  - active myocarditis
  - arrhythmias in the early post-myocardial infarction phase

**AHA Science Advisery 2016**

- **Level IIa Recommendation**
  - when there is a clear indication for an ICD accompanied by a transient contraindication or interruption
  - as bridge to cardiac transplantation

- **Level IIb Recommendation**
  - when there is concern about a temporarily heightened SCD risk
  - in situations with increased risk of death in which ICDs have shown to decrease SCD but overall mortality
Current Indications

ICM
Structural HD w/o PCI/CABG
LVEF <35%
Recent MI
Recent Revasc.

ROCM
Heart Failure
LVEF <35%

NICM
Myocarditis
Special forms of CM

Non-structural heart disease
IAS, Syncope of unknown origin

Awaiting transplantation
LVAD pts

WCD
Time for risk assessment

ICD infection
Delayed implant
Radio/Chemotherapy

Re-evaluate LVEF
Recovery >35%?

YES: consider medical Tx
NO: consider ICD

Alternative to ICD
1-2 months

Temporary Protection

40-90 days
3-6 months
Limitations...

- Lack of randomized trial(s)
- No pacing capabilities
- Patient compliance and comfort

...and Future Perspectives

- Completion of VEST study expected at the end of 2017
- WCD may be a tool for risk-stratification for primary prevention of SCD and may improve patient selection for prophylactic ICD
Anleitung:
Bitte das Formular ausfüllen

Bereich A – Patienteninformationen (Name, Adresse, Tel.-Nr., Versicherungsinformationen: wichtig für eine zügige Bearbeitung des Antrages).
Bereich C – Information zum verordnenden Arzt. Verordner muss unterschreiben und Datum angeben.
• Ausgefülltes Formular umgehend faxen an: Fax-Nr. 0800 820061.
• Aktuellen ärztlichen Bericht beilegen.
• Original wird vom ZOLL CMS Mitarbeiter bei Versorgung abgeholt.
[Original-Folgeverordnung bitte per Post an ZOLL Medical Switzerland AG, Vorstadt 26a, 6300 Zug versenden].

Indikationen laut MiGeL Eintrag vom 1. Juli 2014:

Die LifeVest ist indiziert
• als vorübergehende Therapiemassnahme, wenn eine Implantation eines implantierbaren kardiovertierenden Defibrillators (ICD) nicht sofort möglich ist
• bei Patienten mit einer geplanten Herztransplantation
• bei Patienten mit hohem Risiko für einen plötzlichen Herztodfall, insbesondere bei ventrikulärer Dysfunktion
• bei Patienten mit Kardiomyopathie
• bei Patienten mit Status nach Myokardinfarkt
• bei Patienten mit Myokarditis
• bei Patienten mit nach chirurgischer oder perkutaner Revaskularisierung
• bei Patienten mit einer linksv ventrikulären Ejektionsfraktion (LVEF) < 36%