ESC Guidelines
Heart failure update 2008

For internal training purpose.
Agenda

- Introduction
- Classes of recommendations
- Level of evidence
- Treatment algorithm
- Changes to ESC guidelines in 2008
- Recommendations for device in patients with LV systolic dysfunction
- Treatment overview in CHF
- BIOTRONIKs CRT/ICD products
In the new ESC CHF guidelines there are four revised recommendations related to CRM device therapy.

- **CRT-D** recommended as routine therapy in heart failure patients to reduce mortality and morbidity
  
  Class I – Level of evidence A *(previously Level of evidence B)*
  
  - NYHA III-IV class
  - OPT, LVEF ≤ 35%
  - QRS ≥ 120 ms

- **CRT-P**
  
  Class IIb Level C *(previously in NYHA III-IV)*
  
  - Concomitant indication for permanent pacing in NYHA II-IV
  - LVEF ≤ 35% or LV dilatation

- **DDD-pacemakers**
  
  Class IIb Level C *(first time recommended)*
  
  - Heart failure and sinus rhythm

- **Remote monitoring**
  
  Class IIa Level of evidence C *(first time recommended)*
Treatment algorithm for patients with symptomatic heart failure & reduced ejection fraction

Heart Failure (with symptoms) & reduced EF

**OPT**
- Diuretic
- ACE-I$^1$
- ARBs$^2$
- Titrate
- β-Blocker
- ADD$^3$

Persisting signs and symptoms?

- **Yes**
  - QRS > 120ms?
    - **Yes**
      - Consider: CRT-P or CRT-D
    - **No**
      - Consider: digoxin, hydralazine/ nitrate, LVAD$^4$, transplantation

- **No**
  - LVEF<35%?
    - **Yes**
      - Consider: ICD
    - **No**
      - No further treatment indicated

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1 Angiotension-converting enzyme inhibitors
2 Angiotensin receptor blockers
3 Aldosterone antagonists
4 Left ventricular assist device

ESC Guidelines 2008
European Heart Journal, doi: 10.1093/eurheart/ehn309
European Journal of Heart Failure, doi: 10.1016/j.ejheart.2008.08.005
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## Classes of recommendations

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
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</thead>
</table>
| **Class I** | Evidence and/or general agreement that a given treatment or procedure is beneficial, and effective.  
→ Is recommended/ is indicated |
| **Class II** | Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.  

  - II A: Weight of evidence/opinion is in favour of usefulness/efficacy.  
→ Should be considered.  

  - II B: Usefulness/efficacy is less established by evidence/opinion.  
→ May be considered. |
| **Class III** | Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful.  
→ Is not recommended. |
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Level of evidence

Level of evidence A Data derived from multiple randomized clinical trials or meta-analyses.

Level of evidence B Data derived from a single randomized clinical trial or large non-randomized studies.

Level of evidence C Consensus of opinion of experts and/or small studies, retrospective studies, and registries.
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Heart Failure (with symptoms) & reduced EF

**OPT**
- Diuretic
- ACE-Is\(^1\)
- ARBs\(^2\)
- Titrate
- \(\beta\)-Blocker
- ADD\(^3\)

Persisting signs and symptoms?

Yes

QRS > 120ms?

Yes

Consider: CRT-P or CRT-D

No

Consider: digoxin, hydralazine/ nitrate, LVAD\(^4\), transplantation

No further treatment indicated

No

LVEF<35%?

Yes

Consider: ICD

No

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CRT-P and CRT-D(new)
Guidelines recommend Class I Level of evidence A

Now CRT-D is also recommended as Class I Level of evidence A.

Patient population
- NYHA class III/IV, OPT, LVEF ≤35%, QRS≥120 ms

Clinical benefit
- Improve symptoms/reduce hospitalization
- Reduce mortality

Clinical trial evidence
- CRT-D indications have been changed according to the results of COMPANION.
- COMPANION\(^1\) demonstrated a significant decrease in total mortality in CRT-D patients.

Remote monitoring

Guidelines recommend Class IIb Level of evidence C

Based on the Wilkoff et al. consensus paper remote monitoring has been recommended for the first time.

“Remote monitoring is the continuous collection of patient information and to review this information without patient present.

...remote monitoring may decrease healthcare utilization through fewer hospital admissions for chronic HF, fewer heart failure-related re-admissions, and more efficient device management.

Ongoing trials will assess the clinical utility of such an approach.”

Based on the consensus paper:
Pacemakers
Guidelines recommend **Class IIa Level of evidence C.**

**CRT-P recommendation addresses new patient population in NYHA II.**

**CRT-P devices**

**Patient population**
- Patients with concomitant indication for permanent pacing (first implant or upgrading of a conventional pacemaker) in NYHA II-IV, LVEF≤35%, or LV dilatation.

**Clinical benefit**
- Avoid deleterious or increase dyssynchrony due to right ventricular pacing.

**DDD-pacemakers**

**Patient population**
- Patients with heart failure and sinus rhythm.

**Clinical benefit**
- Maintain normal chronotropic response and coordinate the atrial and ventricular contraction.
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**CRT-P and CRT-D**

**Guidelines recommend** *Class I Level of evidence A.*

**Patient population**
- NYHA III-IV class with symptoms
- OPT, LVEF≤35%
- QRS≥120 ms

**Clinical benefit**
- Improve symptoms /reduce hospitalizations
- Reduce morbidity and mortality

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Guidelines recommend **Class I Level of evidence A.**

**Patient population**

- Secondary prevention (survivor of ventricular fibrillation, patients with documented haemodynamically unstable VT and/or VT with syncope)
- OPT, LVEF ≤ 40%
- Survival expectation > 1 year

**Clinical benefit**

- Reduce mortality
ICD 2/3

Guidelines recommend Class I Level of evidence A.

Patient population
- Primary prevention in NYHA II/III
- OPT, LVEF ≤ 35%
- LV dysfunction due to MI > 40 days
- Survival expectation > 1 year

Clinical benefit
- Reduce mortality
ICD 2/3

Guidelines recommend Class I Level of evidence B.

Patient population

- Primary prevention in NYHA II/III
- OPT, LVEF ≤ 35%
- Non-ischemic cardiomyopathy
- Survival expectation > 1 year

Clinical benefit

- Reduce mortality
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Treatment overview in heart failure patients (1/2)

NYHA I | NYHA II | NYHA III | NYHA IV

**ACE-Is**
1. Angiotensin-converting enzyme inhibitors

**β-Blockers**
1. Angiotensin receptor blockers

**ARBs**
1. Aldosterone antagonists

**AAD**
1. Ischemic post MI>40 days
2. Non-ischemic

**ICD**
1. Secondary prevention
2. Primary prevention
  - Ischemic post MI>40 days
  - Non-ischemic

**CRT**
1. (QRS>120ms)
## Treatment overview in heart failure patients (2/2)

<table>
<thead>
<tr>
<th>Drug/Device</th>
<th>Class/Evidence</th>
<th>Clinical benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE-I</td>
<td>I A</td>
<td>Improves ventricular function and patient well-being</td>
</tr>
<tr>
<td>β-Blockers</td>
<td>I A</td>
<td>Reduces hospital admission for worsening HF</td>
</tr>
<tr>
<td>ARBs</td>
<td>I A</td>
<td>Increases survival</td>
</tr>
<tr>
<td>AADs</td>
<td>I B</td>
<td></td>
</tr>
<tr>
<td>ICD</td>
<td>I A</td>
<td>Reduces mortality</td>
</tr>
<tr>
<td>CRT</td>
<td>I A</td>
<td>Improves symptoms/reduces hospitalizations, Reduces mortality</td>
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</tbody>
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BIOTRONIK provides a complete ICD/CRT product portfolio according to the ESC guidelines

<table>
<thead>
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<th>Indication</th>
<th>Therapy requirements</th>
<th>BIOTRONIK devices</th>
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<tbody>
<tr>
<td>ICD indication Primary prevention</td>
<td>ICD therapy and extended longevity</td>
<td>VR-ICD</td>
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<td>Lumax 340 VR-T XL</td>
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<td>Lumax 540 VR-T</td>
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<td>ICD indication Permanent AF</td>
<td>ICD therapy and pacing in V</td>
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<td>Lumax 540 VR-T</td>
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<tr>
<td>ICD indication Pacing indication</td>
<td>ICD therapy and pacing in A&amp;V</td>
<td>DR-ICD</td>
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<td>CRT-P</td>
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<td>NYHA III-IV class OPT, LVEF≤35%</td>
<td>Cardiac Resynchronization Therapy</td>
<td>Stratos</td>
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<td>QRS≥120 ms</td>
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Conclusion

- Guidelines now recommend CRT-D and CRT-P as routine heart failure therapy with Class I Level of evidence A.
- Remote monitoring of patients with CRM devices is recommended for the first time in the ESC guidelines.
  - BIOTRONIK Home Monitoring®, TRUST and REFORM trials will provide further clinical evidence of the benefits of remote monitoring.
- New option of Stratos therapy, CRT-P, in NYHA II patients.
- BIOTRONIK ICD/CRT devices provide the advanced technology to fulfil guidelines recommendations.