

ESC Guidelines

Heart failure update 2008

For internal training purpose.

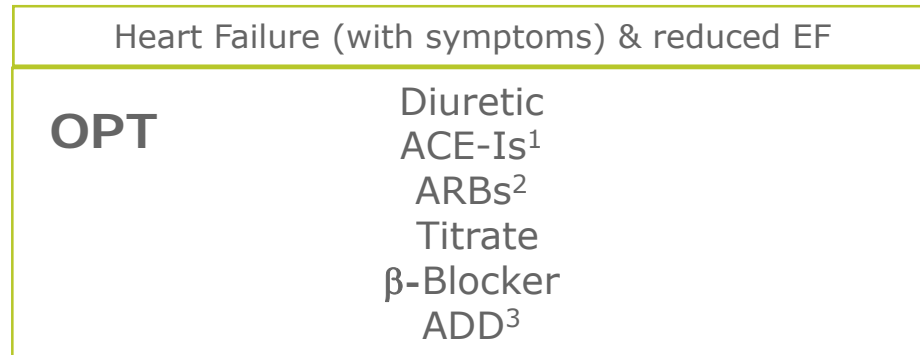
Agenda

- **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.

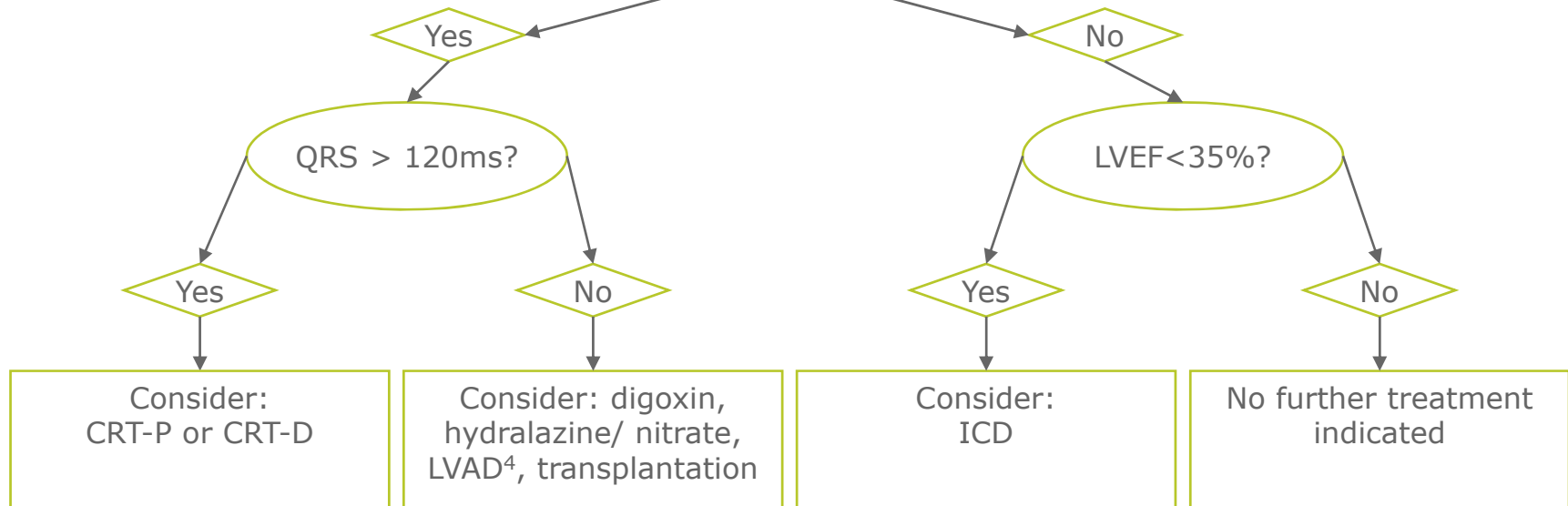
- **CRT-D recommended as routine therapy in heart failure patients to reduce mortality and morbidity**
Class I – Level of evidence A (*previously Level of evidence B*)
 - NYHA III-IV class
 - OPT, LVEF \leq 35%
 - QRS \geq 120 ms
- **CRT-P**
Class IIb Level C (*previously in NYHA III-IV*)
 - Concomitant indication for permanent pacing in NYHA II-IV
 - LVEF \leq 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



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

Persisting signs and symptoms?



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Classes of recommendations

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.

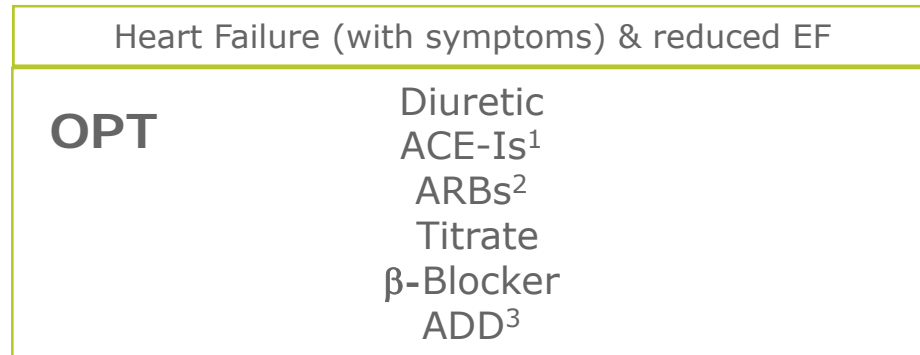
Level of evidence C

Consensus of opinion of experts and/or small studies, retrospective studies, and registries.

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- 1 Angiotension-converting enzyme inhibitors
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- 4 Left ventricular assist device

Persisting signs and symptoms?

Yes / No

QRS > 120ms?

LVEF < 35%?

Yes

No

Yes

No

Consider:
CRT-P or CRT-D

Consider: digoxin,
hydralazine/ nitrate,
LVAD⁴, transplantation

Consider:
ICD

No further treatment
indicated

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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 $\leq 35\%$, 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.
- COMPANION¹ demonstrated a significant decrease in total mortality in CRT-D patients.

¹ Bristow MR et al.; N Engl J Med 2004;350:2140–2150.

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:
(Wilkoff B. et al.; HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. Heart Rhythm. 2008; 5(6):907-25.)

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 $\leq 35\%$
- QRS ≥ 120 ms

Clinical benefit

- Improve symptoms /reduce hospitalizations
- Reduce morbidity and mortality

ICD 1/3

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 \leq 40%
- Survival expectation > 1year

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 \leq 35%
- LV dysfunction due to MI >40 days
- Survival expectation > 1year

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 \leq 35%
- Non-ischemic cardiomyopathy
- Survival expectation > 1year

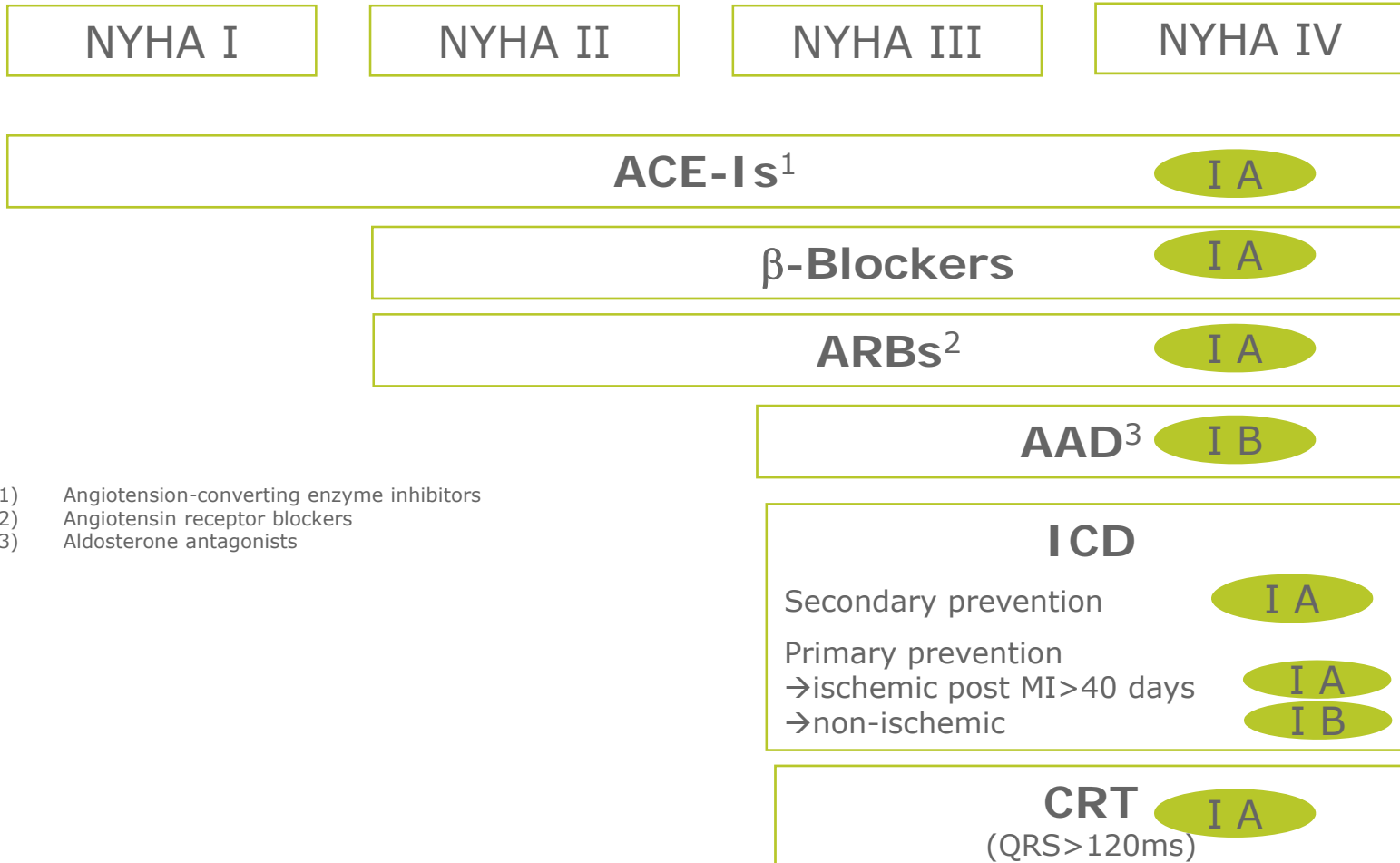
Clinical benefit

- Reduce mortality

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Treatment overview in heart failure patients (1/2)



- 1) Angiotension-converting enzyme inhibitors
- 2) Angiotensin receptor blockers
- 3) Aldosterone antagonists

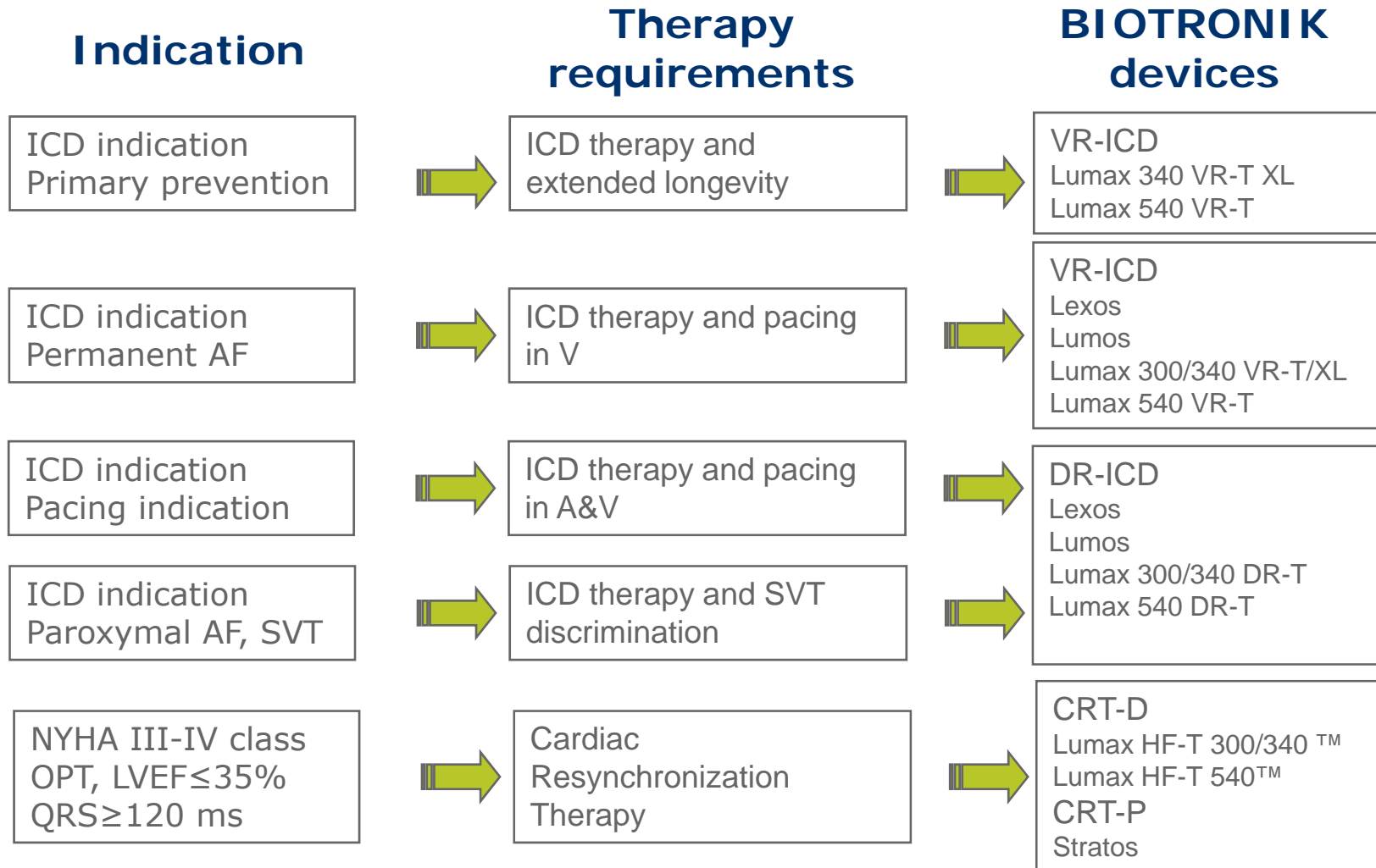
Treatment overview in heart failure patients (2/2)

Drug/Device	Class/Evidence	Clinical benefit
ACE-I	I A	→Improves ventricular function and patient well-being
β-Blockers	I A	→Reduces hospital admission for worsening HF
ARBs	I A	→Increases survival
AADs	I B	
ICD		
→Secondary prevention	I A	→Reduces mortality
→Primary prevention	I A	
-ischemic post MI>40 d	I B	
-non-ischemic		
CRT	I A	→Improves symptoms/reduces hospitalizations →Reduces mortality

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BIOTRONIK provides a complete ICD/CRT product portfolio according to the ESC guidelines



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.