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Advanced Heart Failure Swiss Webinar Series

Regaining quality of life - new device
opportunities

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Kompetenz, die lächelt.

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Disclosures Matthias Paul

Consultant fees / presentations for:

Novartis

Vifor

Servier

Astra Zeneca

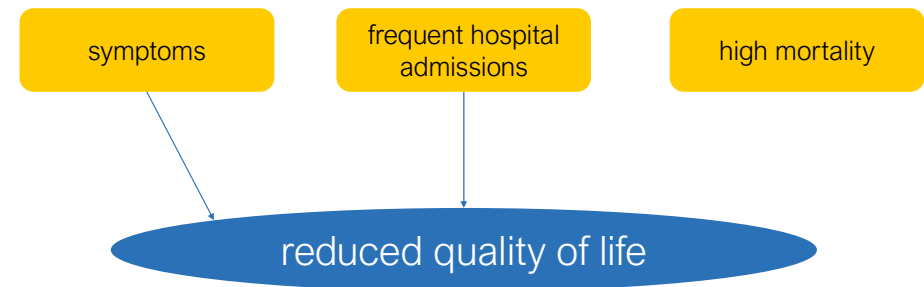
Boehringer-Ingelheim

Bayer

Disclosures Qian Zhou

- Research grant
Boehringer Ingelheim
- Consultant fees
Abbott, AstraZeneca, Bayer, Novartis, Vifor

Health related quality of life



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What matters to patients

- Health-related quality of life is reduced compared to «normal» people and compared to other chronic diseases
- Our goals: reduction of mortality and readmissions (hard endpoints in trials)
- Patient goals: Quality of life more important than longevity



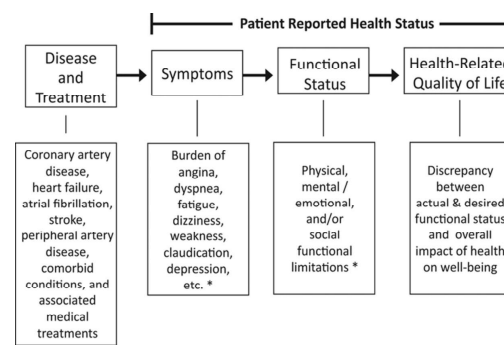
European Journal of Heart Failure (2013) 15, 1113–1121
doi:10.1093/ehj/ehf18071

Preferences of heart failure patients in daily clinical practice: quality of life or longevity?

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What is quality of life – how can we measure QoL?



Instrument	Population in Which Validated	# of Items Overall	Domains/Subscales (# of Items)	Scoring/Summary Score(s)
Minnesota Living with Heart Failure Questionnaire (MLHFQ)	NYHA class III patients in a clinical trial with pimobendan	21	Physical (8); emotional (5)	0–105, Best to worst, lower score is better
Kansas City Cardiomyopathy Questionnaire (KCCQ)	Stable and decompensated heart failure patients	23	Physical limitation (6); symptoms (8); self-efficacy (2); social limitation (4); quality of life (3)	Overall summary score and subscales scored 0–100; higher score is better
Chronic Heart Failure Questionnaire (CHQ)	Symptomatic patients with heart failure in RCT of digoxin	16	Dyspnea (5); fatigue (4); emotional (7)	16–122, Worst to best; higher score is better
Quality of Life Questionnaire for Severe Heart Failure (QLQ-SHF)	Patients with NYHA class III/IV symptoms in the Metoprolol in Dilated Cardiomyopathy (MDC) trial	26	Psychological (7); physical activity (7); life dissatisfaction (5); somatic symptoms (7)	0–190; Lower score is better

Rumsfeld, J. S. et al. Cardiovascular Health: The Importance of Measuring Patient-Reported Health Status. *Circulation* 127, 2233–2249 (2013).

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KCCQ scores

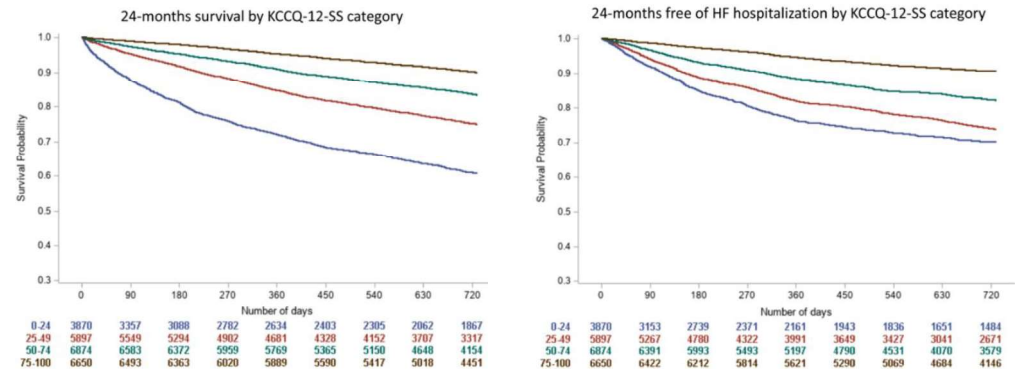
Health status	NYHA class	Change in KCCQ score
0-24	very poor to poor	III-IV
25-50	poor to fair	III
50-74	fair to good	II-II
75-100	good to excellent	I-II

5	small
10	moderate to large
20	large to very large

Speratus, J. A., Jones, P. G., Sandhu, A. T. & Arnold, S. V. Interpreting the Kansas City Cardiomyopathy Questionnaire in Clinical Trials and Clinical Care JACC State-of-the-Art Review. *J Am Coll Cardiol* 76, 2379–2390 (2020).

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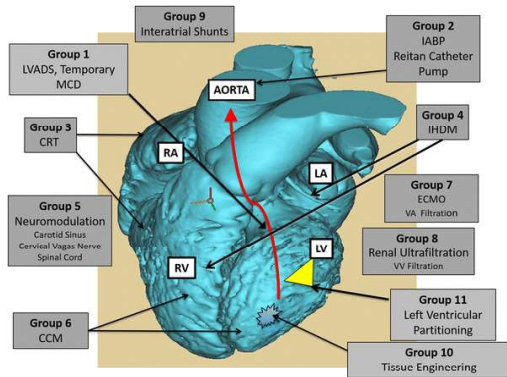
Association of QoL with prognosis



Johansson, I. et al. Health-Related Quality of Life and Mortality in Heart Failure: The Global Congestive Heart Failure Study of 23 000 Patients From 40 Countries. *Circulation* 143, 2129–2142 (2021).

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There are numerous cardiac devices offering potential benefits in HF



Murphy, C., Zafar, H. & Sharif, F. An updated review of cardiac devices in heart failure. *Ir J Medical Sci* 1971 - 186, 909-919 (2017).

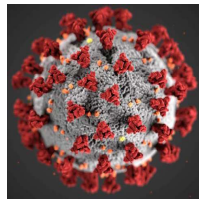
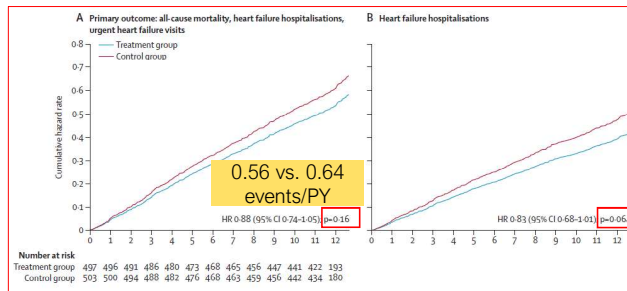
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GUIDE-HF

- 1:1 Randomisation to either hemodynamic-guided management or usual care
- Inclusion criteria:
NYHA II-IV, previous HF hospitalization OR elevated NT-pro/BNP, all EF (HFrEF, HFmrEF, HFpEF)
- Primary endpoint:
All-cause mortality, HF hospitalization or urgent HF visits

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GUIDE-HF



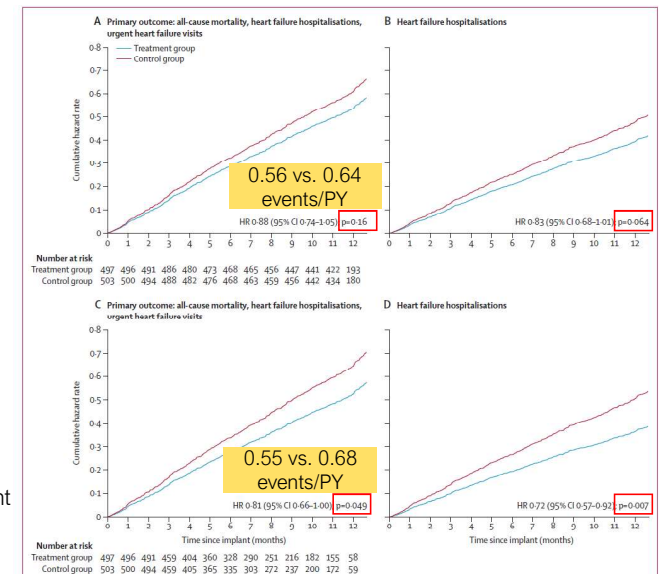
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GUIDE-HF prespecified pre-COVID-19 impact analysis

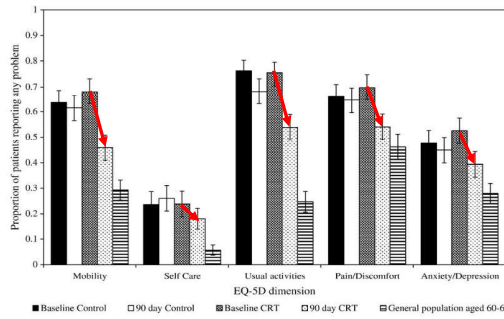
- After lockdown 21% decrease in events in the control group but virtually no change in the treatment group

Conclusion:

- The COVID-19 pandemic may have contributed to the negative finding.
- The pre-COVID-19 impact analysis indicated a possible benefit of haemodynamic-guided management



Cardiac resynchronization therapy

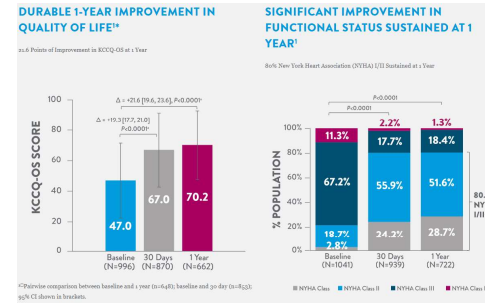


The proportion of patients reporting any problems in each of the EQ-5D dimensions at baseline and 3 months by treatment group (95% CI are indicated) compared to an age-matched sample of the United Kingdom general population.

Recommendations	Class ^a	Level ^b
CRT is recommended for symptomatic patients with HF in SR with a QRS duration ≥ 150 ms and LBBB QRS morphology and with LVEF $\leq 35\%$ despite OMT in order to improve symptoms and reduce morbidity and mortality. ²⁰⁵⁻²¹⁵	I	A
CRT rather than RV pacing is recommended for patients with HFrEF regardless of NYHA class or QRS width who have an indication for ventricular pacing for high degree AV block in order to reduce morbidity. This includes patients with AF. ²¹⁶⁻²¹⁹	I	A
CRT should be considered for symptomatic patients with I Lf in SR with a QRS duration ≥ 150 ms and non-LBBB QRS morphology and with LVEF $\leq 35\%$ despite OMT in order to improve symptoms and reduce morbidity and mortality. ²⁰⁵⁻²¹⁵	IIa	B
CRT should be considered for symptomatic patients with HF in SR with a QRS duration of 130–149 ms and LBBB QRS morphology and with LVEF $\leq 35\%$ despite OMT in order to improve symptoms and reduce morbidity and mortality. ^{211,220}	IIa	B
Patients with an LVEF $\leq 35\%$ who have received a conventional pacemaker or an ICD and subsequently develop worsening HF despite OMT and who have a significant proportion of RV pacing should be considered for 'upgrade' to CRT. ²²¹	IIa	B

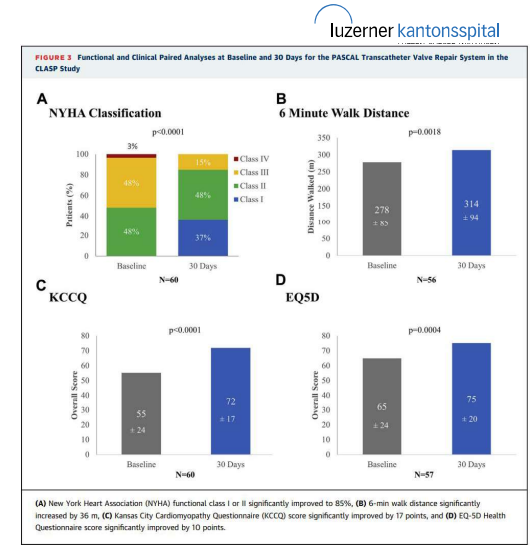
Cleland, J. G. F., Calvert, M. J., Verboven, Y., & Freemantle, N. Effects of cardiac resynchronization therapy on long-term quality of life: An analysis from the Cardiac Resynchronisation-Heart Failure (CARE-HF) study. *Am Heart J* 157: 457-466 (2009).

Transcatheter mitral valve repair



*p < 0.05 Points of Improvement in KCCQ-OS at 1 Year

¹Both New York Heart Association (NYHA) I/II Sustained at 1 Year



(A) New York Heart Association (NYHA) functional class I or II significantly improved to 85%, (B) 6-min walk distance significantly increased by 36 m, (C) Kansas City Cardiomyopathy Questionnaire (KCCQ) score significantly improved by 17 points, and (D) EQ-5D Health Questionnaire score significantly improved by 10 points.

<https://mitralclip.com/physician/safety/mitralclip-expand-study> (last visited 29.11.2021)

Amat-Santos, I. J., et al. Left atrial decompression through unidirectional left-to-right interatrial shunt for the treatment of left heart failure: first-in-man experience with the V-Wave device. *EuroIntervention* 10: 1127-1131 (2015).

Interatrial shunt devices

Mechanism of Action

- Excess LA volume shunted to RA
- ↓ Left atrial pressure (LAP)
- ↓ Pulmonary artery pressure

- Reduced pulmonary congestion and HF events
- Improved functional status and symptom relief
- Signs of potential reverse LV remodeling
- Maintenance of RV function

- Phase 1 trial showed safety and efficacy in HFpEF patients (REDUCE LAP-HF)
- First in man study with a V-Wave device showed feasibility in a HFrEF patient.

1. Hasenfuss, G. et al. A transcatheter intracardiac shunt device for heart failure with preserved ejection fraction (REDUCE LAP-HF): a multicentre, open-label, single-arm, phase 1 trial. *Lancet* 387, 1298-1304 (2016).

2. Amat-Santos, I. J., et al. Left atrial decompression through unidirectional left-to-right interatrial shunt for the treatment of left heart failure: first-in-man experience with the V-Wave device. *EuroIntervention* 10, 1127-1131 (2015).

Interatrial shunt devices

Ongoing trials:

<p>Corvia</p>	<p>Occlutech</p>	<p>V-Wave</p>
REDUCE LAP-HF II 2022	PRELIEVE 2022	RELIEVE-HF 2022