

CCM-Reg – “Real-World” Registry Data

OBJECTIVE OF THE REGISTRY

This prospective European registry at 31 sites aims to show the longer-term impact of cardiac contractility modulation on hospitalizations and mortality in real-world experience of patients with moderate to severe heart failure with an EF between 25–45%. The registry population was the same as the FIX-HF-5C study population.

ENROLLMENT

A total of 140 patients with ejection fraction between 25 and 45% CCM-REG₂₅₋₄₅ Cohort received cardiac contractility modulation therapy for clinical indication, and were followed for two years with Minnesota Living with Heart Failure Questionnaire (MLWHFQ), LVEF, and hospitalization. Cardiovascular and HF hospitalizations were compared to hospitalizations during the year prior to CCM. Mortality was followed for three years, and compared with predictions by the Seattle Heart Failure Model (SHFM). In addition, a separate analysis was performed on patients with EF between 35 and 45% CCM-REG₃₅₋₄₅ Cohort.

RESULTS IN SUMMARY

Sustained improvements in Quality of Life and LVEF were shown. Cardiovascular and heart failure hospitalizations were decreased by 75%. The three-year mortality was similar to that predicted by the Seattle Heart Failure Model (SHFM) for the patient group with EF between 25 and 45%, but significantly lower in the patient group with EF between 35 and 45%.

Figure 1: Changes from baseline before CCM: Significant and sustained improvements in MLWHFQ, NYHA and LV EF in the entire CCM-REG₂₅₋₄₅ Cohort.

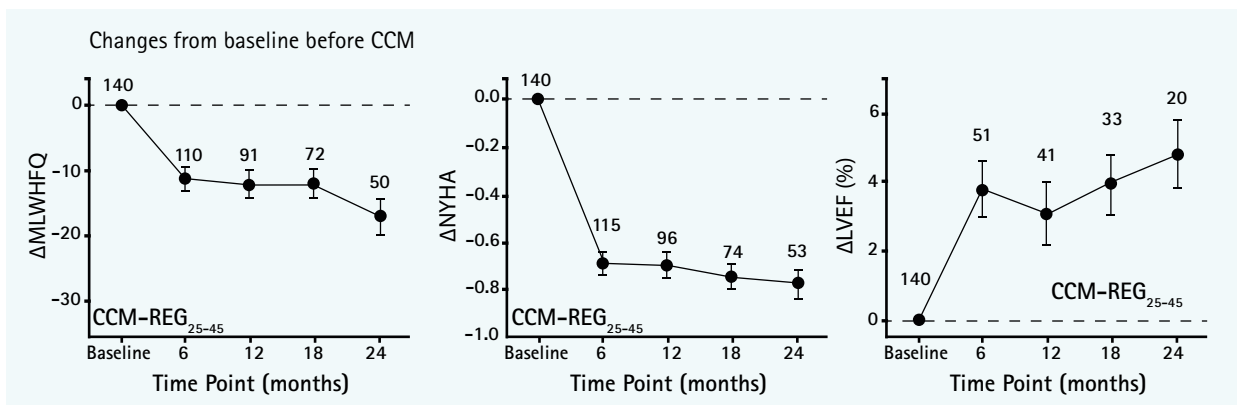
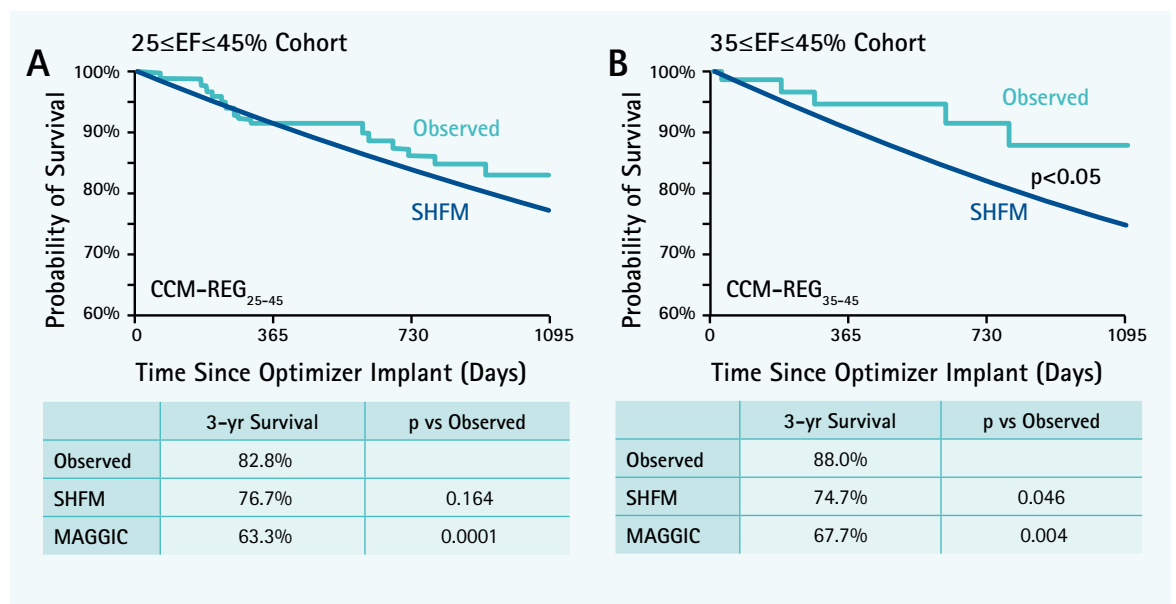


Table 1: CV and HF hospitalizations reduced by ~75%.

Cohort	EVENT	Pre-Enrollment			Post-Enrollment		
		Pt-Yrs	Events	Event-Rate	Pt-Yrs	Events	Event-Rate
CCM-REG ₂₅₋₄₅	HF	140.0	134	0.96	279.6	73	0.26*
	CV		34	0.24		24	0.09*
	HF+CV		168	1.20		97	0.35*
CCM-REG ₃₅₋₄₅	HF	57.0	47	0.82	113.5	18	0.16*
	CV		23	0.40		9	0.08*
	HF+CV		70	1.23		27	0.24*

*p<0.0001

Figure 2: Three-year mortality similar to prediction of SHFM for CCM-REG₂₅₋₄₅ cohort (A) and significantly lower than predicted for CCM-REG₃₅₋₄₅ cohort (B).



CONCLUSIONS

The results of this registry confirm results of the FIX-HF-5C and earlier studies: CCM improves exercise tolerance and quality of life in patients with EF ≥25% and ≤45%. The effects on QoL and LVEF are sustained over time, and have again shown to be stronger in the patient group with EF between 35 and 45%. The

cardiovascular and heart failure hospitalization rate was decreased by 75%, in line with the 73% reduction seen in the FIX-HF-5C study. The three-year mortality rate was similar to the prediction of SHFM for the CCM-REG₂₅₋₄₅ cohort, and significantly lower than predicted for CCM-REG₃₅₋₄₅ cohort.

Source:

Data was presented at European Heart Failure Congress, May 28th 2018 by Prof. Gerd Hasenfuß, and is submitted for publication.
https://www.escardio.org/Congresses-&-Events/ESC-TV/Heart-Failure-2018?utm_medium=Email&utm_source=ESC-TV&utm_campaign=ESC-TV-HF-2018-Day-2

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