

Reference – February 2011 – Kadish, et al: "A randomized controlled trial evaluating the safety and efficacy of cardiac contractility modulation in advanced heart failure," American Heart Journal

Link to trial summary - <https://pubmed.ncbi.nlm.nih.gov/21315216/>

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Background: Cardiac contractility modulation (CCM) delivers nonexcitatory electrical signals to the heart during the absolute refractory period intended to improve contraction.

Methods: We tested CCM in 428 New York Heart Association class III or IV, narrow QRS heart failure patients with ejection fraction (EF) $\leq 35\%$ randomized to optimal medical therapy (OMT) plus CCM (n = 215) versus OMT alone (n = 213). Efficacy was assessed by ventilatory anaerobic threshold (VAT), primary end point, peak VO₂ (pVO₂), and Minnesota Living with Heart Failure Questionnaire (MLWHFQ) at 6 months. The primary safety end point was a test of noninferiority between groups at 12 months for the composite of all-cause mortality and hospitalizations (12.5% allowable delta).

Results: The groups were comparable for age (58 ± 13 vs 59 ± 12 years), EF ($26\% \pm 7\%$ vs $26\% \pm 7\%$), pVO₂ (14.7 ± 2.9 vs 14.8 ± 3.2 mL kg⁻¹ min⁻¹), and other characteristics. While VAT did not improve at 6 months, CCM significantly improved pVO₂ and MLWHFQ (by 0.65 mL kg⁻¹ min⁻¹ [P = .024] and -9.7 points [P b .0001], respectively) over OMT. Forty-eight percent of OMT and 52% of CCM patients experienced a safety end point, which satisfied the noninferiority criterion (P = .03). Post hoc, hypothesis-generating analysis identified a subgroup (characterized by baseline EF $\geq 25\%$ and New York Heart Association class III symptoms) in which all parameters were improved by CCM.

Conclusions: In the overall target population, CCM did not improve VAT (the primary end point) but did improve pVO₂ and MLWHFQ. Cardiac contractility modulation did not have an adverse effect on hospitalizations or mortality within the prespecified boundaries. Further study is required to clarify the role of CCM as a treatment for medically refractory heart failure. (Am Heart J 2011;161:329-337.e2.)