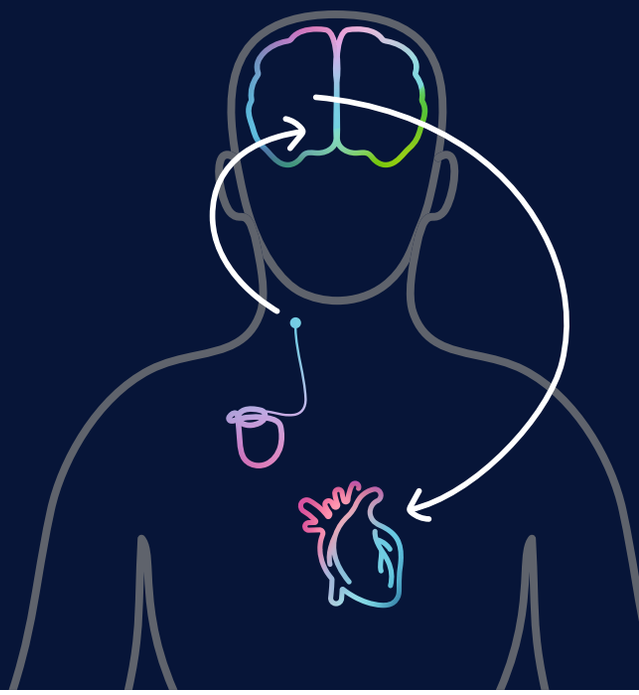
BeAT-HF Clinical Trial Summary

- Sustained and significant symptomatic improvements and safety at long-term follow-up
- Reduction in all-cause death, LVAD or transplant
- Improvement in the hierarchical composite (win ratio) of mortality, morbidity and QOL
- Improvement in clinical stability analysis, which include mortality, HF hospitalizations and symptoms



Unique post-market trial design

BeAT-HF was designed to provide additional long-term clinical evidence supporting Barostim

Design

- Prospective, multicenter, randomized 2-arm parallel-group, open-label with blinded endpoint evaluation
- 103 US Centers and 5 United Kingdom center
- Groups
  - Barostim plus GDMT (Barostim group)
  - GDMT alone (Control)
- FDA approval on safety and patient-centered symptomatic improvements in August 2019

Eligibility Criteria

- NYHA Class III or Class II (with a recent history of Class III)
- Left ventricular EF ≤ 35%
- 6MHW 150 – 400 m
- HF Hospitalization or NT-proBNP> 400
- Stable optimal management ≥ 4 weeks
- No class I indication for CRT
- NT-proBNP < 1600 pg/ml

Initial Enrollment
April 2016

6 month f/u
2019

>3.5 year f/u
2022

Endpoints @ 6 months for FDA approval
(n=264)

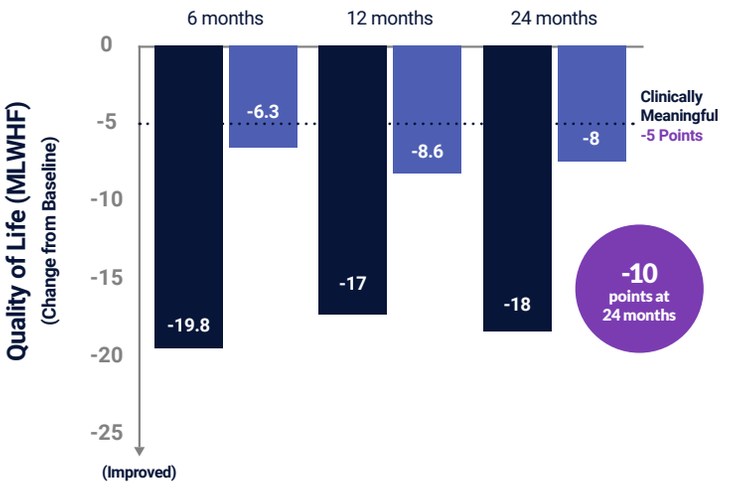
- Exercise capacity improvement (6MHW) @ 6 months
- Quality-of-life improvement (MLWHQ) @ 6 months
- NYHA class improvement @ 6 months
- Reduction in NT-proBNP @ 6 months

Long-term Follow-up
(n=264+59=323)

- CV mortality or morbidity
- Symptom improvement
- Additional clinical and economic endpoints

Durable symptom improvement & safety

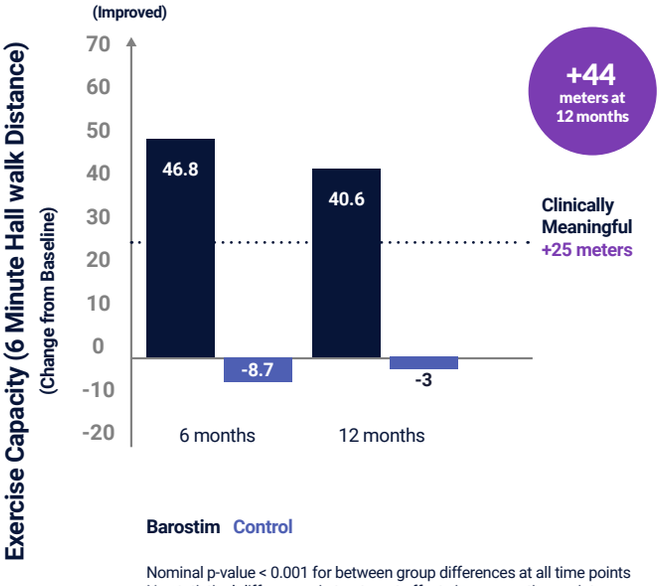
Quality of life (MLWHF)[1,2]



Barostim Control

Nominal p-value < 0.001 for between group differences at all time points
No statistical differences in treatment effect size across time points

Exercise Capacity (6MHW)[1,2]



Barostim Control

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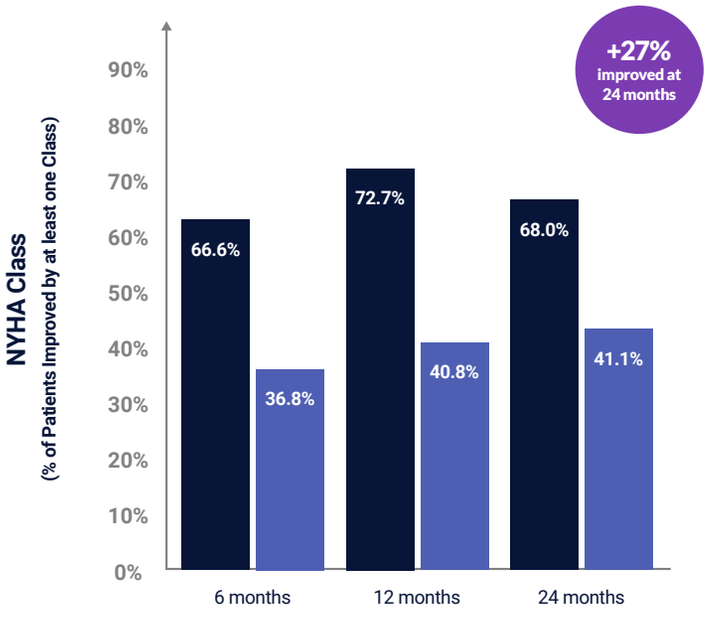
Functional Status (NYHA Class)[1,2]



Barostim Control

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No statistical differences in treatment effect size across time points

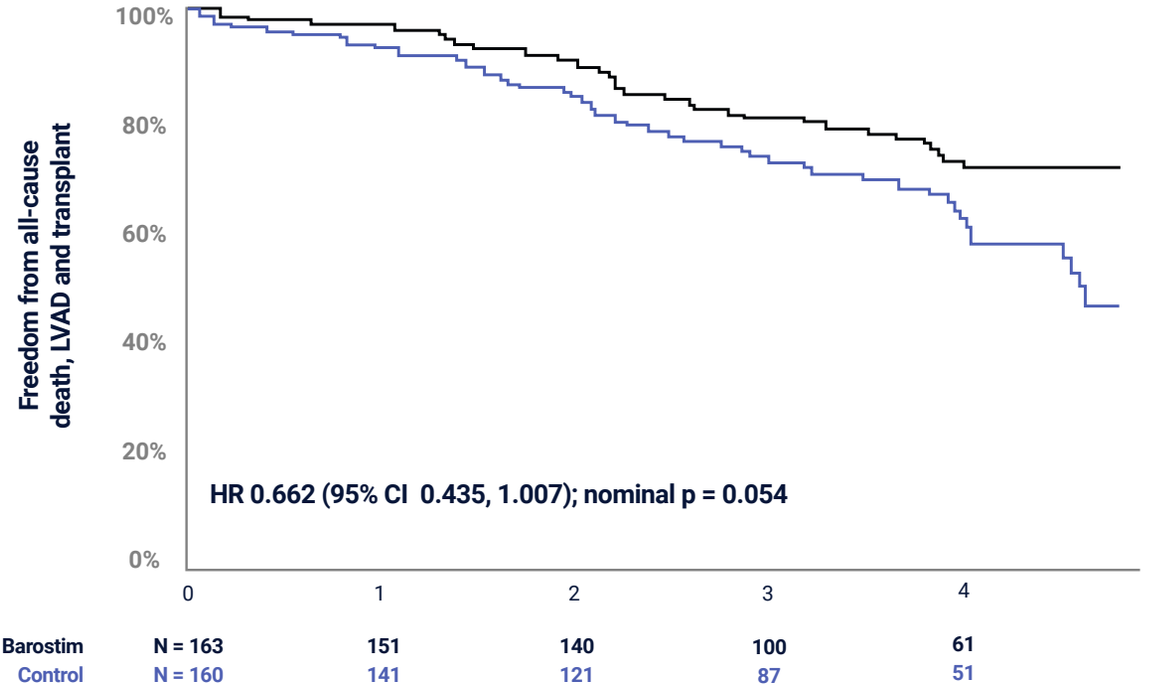
Safety Profile: MANCE*[,2]

97%

MANCE-free rate

* Major Adverse Neurological or Cardiovascular system or procedure-related event rate

Freedom From All-cause Death, LVAD, and Transplant[2]



34% reduction in relative risk

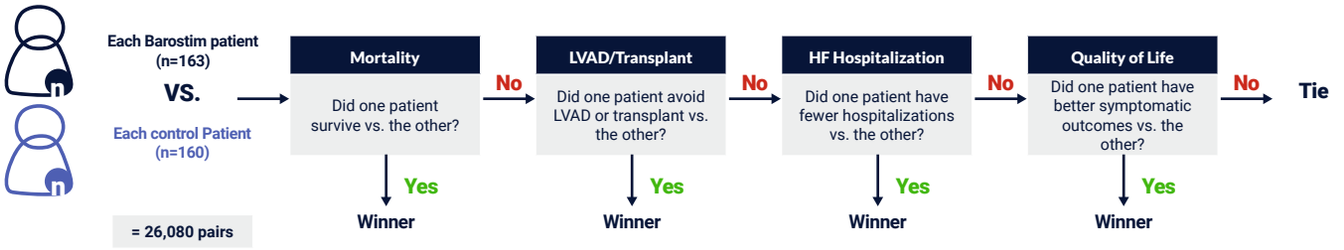
Curves estimated using Kaplan-Meier method. Hazard ratio and p-value from Cox proportional hazards model.

Hierarchical Composite Using Win Ratio Analysis[2]

Rationale:

- CV Mortality + HF Morbidity: 40% of patients contributed to the end point
- Win ratio: 100% of patients contribute to the end point

- Ranks events by severity
- Allows for patient-reported outcomes such as QOL



$$\text{Win Ratio} = \frac{\text{Total wins for treatment arm}}{\text{Total wins for control arm}}$$

1.26

nominal p = 0.04

Primary Composite Endpoint: CV Mortality & HF Morbidity*,[2]

- No statistically significant difference [Rate Ratio 0.94, (95% Confidence Interval 0.57, 1.57); p = 0.82]
- The COVID pandemic seems to have impacted the HF morbidity results of the study
- This COVID impact was stronger in the control group than the BAT group

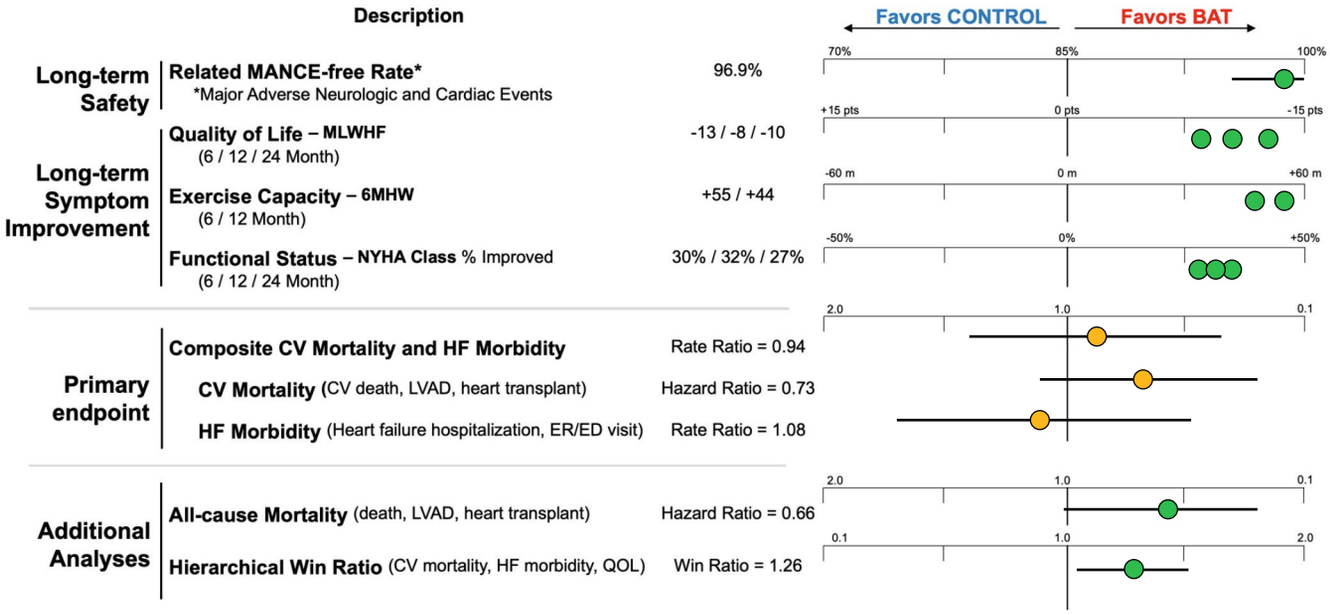
COVID as a Potential Confounder for Heart Failure Morbidity[2]

Time Period	BAT*	Control*
2020	0.28	0.07
2016, 2017, 2018, 2019, 2021, 2022	0.26	0.29

*Number of hospitalizations or emergency department visits for heart failure per patient-year of follow-up

*composite of CV mortality (cardiovascular death, LVAD, heart transplant) and HF morbidity (HF hospitalizations, ER visits)

BeAT-HF Summary of Key Evidence[2]



Conclusion[2]

The totality of evidence indicates that BAT is a safe, effective and durable treatment for patients with heart failure with reduced ejection fraction

References

1. Zile MR, et al. Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction. J Am Coll Cardiol 2020; 76:1-13.
2. Adapted from Dr Zile's presentation at DGK-Jahrestagung 2023, Mannheim (Germany): Baroreflex Activation Therapy (BAT) in Patients with Heart Failure and a Reduced Ejection Fraction (BeAT-HF) Trial – Long-Term Outcomes.

The Barostim™ System is CE marked and approved for sale for heart failure patients and hypertension patients in the European Union (EU).

For a complete listing of all risks and benefits, please visit www.cvrx.com/benefit-risk-analysis. For a list of all applicable patents, see www.cvrx.com/marking.

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