

# Quality of life response to BAROSTIM Therapy

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## OBJECTIVE

Evaluate the quality of life in subjects with and without baroreflex activation therapy (BAT) at six months who have heart failure with reduced ejection fraction.

## BACKGROUND

Patients with heart failure with reduced ejection fraction (HFrEF) have poor quality of life as measured by both physical and emotional dimensions.

## METHODS

In a multicenter randomized trial conducted in subjects with NYHA class II (recently III) or III HFrEF, left ventricular ejection fraction  $\leq$  35%, stable optimal guideline directed medical HF therapy (GDMT), no Class 1 indication for cardiac resynchronization therapy (CRT), and NT-proBNP < 1600 pg/ml, a total of 264 subjects were randomized to BAROSTIM therapy plus GDMT (BAT group) or GDMT alone (Control group). Quality of life was measured at baseline and six months using the Minnesota Living with HF Questionnaire (MLWHF) and the EuroQol 5-Dimension Long (EQ-5D) tool. From the MLWHF questionnaire, both a physical and an emotional dimension was analyzed using subsets of the 21 questions. From the EQ-5D, the five individual dimensions and the overall health status (0-100, where 100 is best) was analyzed.

## RESULTS

Of the 264 randomized subjects, 120 BAT and 125 Control subjects had 6-month quality of life data. Treatment with BAT resulted in significant improvements in quality of life overall, as well as in the specific dimensions of the quality of life questionnaires, compared to Control.

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Table: Quality of Life at Six Months

Minnesota Living with Heart Failure	BAT N=120	Control N=125	Difference
Overall Score	-20.7 $\pm$ 25.4	-6.2 $\pm$ 20.1	-14.1*
Physical (8 questions)	-8.8 $\pm$ 11.8	-3.3 $\pm$ 9.0	-5.3*
Emotional (5 questions)	-4.8 $\pm$ 7.2	-1.0 $\pm$ 6.2	-3.8*
EuroQol 5-Dimension	BAT	Control	Difference
Overall health today (0-100, 100 best can imagine)	16.3 $\pm$ 19.6	5.3 $\pm$ 19.2	10.0*
Mobility (% improved)	48%	28%	20%
Self-Care (% improved)	23%	15%	8%
Usual Activities (% improved)	59%	36%	23%
Pain/Discomfort (% improved)	43%	24%	19%
Anxiety / Depression (% improved)	44%	18%	26%

All p-values < 0.01

\*The difference is evaluated based on an ANCOVA model adjusting for the baseline value.

## CONCLUSION

Among subjects with symptomatic HFrEF, treatment with BAT resulted in significant improvement in all quality of life dimensions at six months. Quality of life benefits were congruent with improved six-minute hall walk distance and decrease in NTproBNP.

REFERENCES: Zile et al. J Am Coll Cardiol 2020;76:1-13