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Control/Tracking Number: 20-A-7224-HRS Response To Barostim Therapy By Atrial Fibrillation Status

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Abstract:

Background: Patients with heart failure (HF) with reduced ejection fraction (HFrEF) can have varying responses to device-based HF therapies particularly when comparing those with and without a history of atrial fibrillation (AF).

Objective: Evaluate the response to baroreflex activation therapy (BAT) at 6 months in subjects with and without AF.

Methods: A multicenter trial (BeAT-HF) conducted in subjects with HFrEF, currently or recently with NYHA class III symptoms, left ventricular ejection fraction (LVEF) \leq 35%, stable optimal medical HF management for at least 4 weeks, no class-1 indication for cardiac resynchronization therapy, and NT-proBNP<1600 pg/ml, randomized subjects 1:1 to receive BAROSTIM Therapy (BAT) or BAT plus guideline directed therapy (GDT) for HF. Change from baseline to 6 months data was collected in 120 BAT subjects and 125 BAT+GDT subjects for outcomes including: 6-minute hall walk distance (6MHW), Minnesota Living with HF Questionnaire (QOL), core lab read NT-proBNP and New York Functional Class (NYHA).

Results: A total of 87 (36%) of the 245 subjects had AF. A response to BAT was demonstrated with an improvement between the two arms for all endpoints, as shown in the Table below.

Conclusion: Among subjects with symptomatic HFrEF, treatment with BAT plus GDT, compared with GDT alone, demonstrates improvement in 6MHW, QOL, NT-proBNP, and NYHA in subjects with and without a history of AF.

Table: Improvement with BAT vs GDT by AF Status		
	Δ Means*	p-value
Six Minute Hall Walk		
AF	66	<0.001
No AF	57	< 0.001
Quality of Life		
AF	-12	0.002
No AF	-16	< 0.001
NT-proBNP (% change)**		
AF	-23%	0.10
No AF	-25%	0.02
NYHA (% Improved)		
AF	27%	0.015
No AF	37%	<0.001
*The difference is evaluated based on an ANC	OVA model adjusting for	the baseline value.

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