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**Symptomatic Responder Rates To Barostim Therapy**

**Author Block:** William T.. Abraham, MD, JoAnn Lindenfeld, MD, Fred Weaver, MD, Faiez ZANNAD, MD, Michael R.. Zile, MD, Elizabeth Galle, Jill Schafer, MS and Marwan M.. Bahu, MD, FHRS. The Ohio State University, , Vanderbilt University, Nashville, TN, Division of Vascular Surgery and Endovascular Therapy, Keck School of Medicine, University of Southern California, Los Angeles, CA, Centre Hospitalier Universitaire de Nancy, Vandoeuvre les Nancy, France, MUSC, Charleston, SC, CVRx Inc., Minneapolis, MN, NAMSA, Inc., Minneapolis, MN, Biltmore Cardiology, Paradise Valley, AZ

**Abstract:**

**Background:** Patients with heart failure with reduced ejection fraction (HFrEF) have varying responses to device-based heart failure therapies.

**Objective:** Evaluate the symptomatic response rate to baroreflex activation therapy at 6 months.

**Methods:** In a trial in subjects with NYHA class II (recently III) or III HFrEF, left ventricular ejection fraction  $\leq$  35, stable optimal guideline direct 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 either BAROSTIM therapy plus GDMT (BAT) or GDMT alone (Control). Six-minute hall walk distance (6MHW), Minnesota Living with HF Questionnaire (QOL) and NYHA Class (NYHA) was analyzed. Responders were defined by a 6-month improvement in 6MHW of > 10%, QOL improvement of > 5 points and/or improvement of one NYHA; super-responders were defined by an improvement in 6MHW of > 20%, QOL improvement of > 10 points and/or improvement to NYHA class I.

**Results:** Of the 264 randomized, 120 BAT and 125 Control had 6-month data. As shown in the Table 1, responder and super-responder rates were significantly higher in BAT versus Control subjects for all endpoints. In BAT subjects, 72% responded to at least two symptomatic endpoints compared to 29% of Control subjects ( $p < 0.001$ ). For super-responders, 28% of BAT subjects had large improvements in at least two symptomatic endpoints versus 10% of Control subjects.

**Conclusion:** Among subjects with symptomatic HFrEF, treatment with BAT resulted in high responder and super-responder rates of 72% and 28%, respectively. These responder and super-responder rates are similar to those seen with CRT, in CRT-indicated patients.

Responder Rate by Randomized Group

<b>Responder</b>	<b>BAT</b>	<b>Control</b>	<b>P-value</b>
6MHW > 10%	73 (62%)	37 (31%)	<0.001
NYHA Improve $\geq$ 1 Class	78 (65%)	39 (31%)	<0.001
QOL > 5 Points	82 (68%)	55 (44%)	<0.001
At least 2 of the following: 6MHW > 10%, NYHA Improve $\geq$ 1, QoL > 5	85 (72%)	35 (29%)	<0.001
<b>Super Responder</b>	<b>BAT</b>	<b>Control</b>	<b>P-value</b>
6MHW > 20%	40 (34%)	22 (18%)	0.006
NYHA Improve to Class I	19 (16%)	3 (2.4%)	<0.001
QOL > 10 Points	73 (61%)	45 (36%)	<0.001
At least 2 of the following: 6MHW > 20%, NYHA Class 1, QOL > 10	33 (28%)	12 (10%)	<0.001

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