

Symptomatic endpoint responder rates to BAROSTIM Therapy

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OBJECTIVE

Evaluate the symptomatic response to baroreflex activation therapy (BAT) at six months.

BACKGROUND

Patients with heart failure with reduced ejection fraction (HFrEF) have varying responses to symptomatic endpoints with device-based HF therapies.

METHODS

In a trial of subjects with NYHA Class II (recently III) or III HFrEF, left ventricular EF \leq 35%, guideline directed medical HF therapy (GDMT), no indication for cardiac resynchronization therapy, and NT-proBNP $<$ 1600 pg/ml, 264 subjects were randomized to BAROSTIM therapy plus GDMT (BAT group) or GDMT alone (Control group). Six-minute hall walk (6MHW), Minnesota Living with HF (QOL) and NYHA Class were analyzed. Clinically relevant responders were defined by 6-month improvement in 6MHW $>$ 10%, QOL $>$ 5 points or improvement in at least one NYHA class; super responders were defined by 6-month improvement in 6MHW $>$ 20%, QOL $>$ 10 points or improvement to NYHA class I.

RESULTS

Both clinically relevant and super responders were significantly higher in BAT versus Control subjects for all symptomatic endpoints. In BAT subjects, 72% had clinically relevant improvements in \geq 2 endpoints compared to 29% of Control subjects ($p<0.001$), and 28% of BAT subjects had super responder improvements in \geq 2 endpoints versus 10% of Control subjects ($p<0.001$).

CONCLUSION

Among subjects with symptomatic HFrEF, treatment with BAT resulted in higher clinically relevant and super responder rates. The BAT clinically relevant and super responder rates are similar to those seen with CRT, in CRT-indicated patients.

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REFERENCES

Table: Response Rates at Six Months

Clinically Relevant Responder	BAT N=120	Control N=125
6MHW $>$ 10%	73 (62%)	37 (31%)
NYHA Improve \geq 1 Class	78 (65%)	39 (31%)
QOL $>$ 5 Points	82 (68%)	55 (44%)
Clinically relevant response in \geq 1	111 (94%)	85 (71%)
Clinically relevant response in \geq 2	85 (72%)	35 (29%)
Clinically relevant response in all 3	35 (30%)	10 (8%)
Super Responder	BAT	Control
6MHW $>$ 20%	40 (34%)	22 (18%)
NYHA Improve to Class I	19 (16%)	3 (2.4%)
QOL $>$ 10 Points	73 (61%)	45 (36%)
Super response in \geq 1	93 (79%)	58 (48%)
Super response in \geq 2	33 (28%)	12 (10%)
Super response in all 3	5 (4%)	0 (0.0%)

All p-values $<$ 0.025