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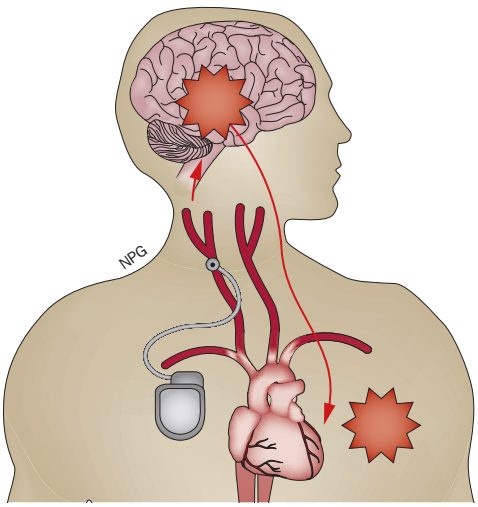
HEART FAILURE

BAT safe and effective in patients with HF

In 2014, a small, single-centre, proof-of-concept study indicated that baroreflex activation therapy (BAT) might be safe and effective in patients with NYHA class III heart failure (HF) and left ventricular ejection fraction (LVEF) <40%. Findings from a larger, multinational, prospective, randomized trial, presented at the 2015 ACC Scientific Sessions and published in *JACC Heart Failure*, have now confirmed these intial results and open the way for larger, prospective, clinical outcome studies.

In total, 146 patients with NYHA class III HF with LVEF ≤35% were randomly assigned to guideline-directed medical therapy alone or in combination with BAT. At baseline, 79% of participants were taking an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker, 86% were taking a β-blocker, and 86% were taking a diuretic.



Of note, 87% also had implantable cardioverter-defibrillator devices, and 32% had devices for cardiac resynchronisation therapy. Rigorous testing at the time of BAT device implantation revealed no device–device interactions that impeded the performance of these devices. In their discussion of the findings, the investigators point out that "this observation is important, since a majority of HF patients with reduced [LVEFs] are indicated for such devices."

The primary safety outcome—event-free rate of all system-related and procedure-related major adverse neurological and cardiovascular events at 6 months—was 97.2%. Two haematomas were found to be related to the procedure. In their study report, the investigators highlight that "the safety profile of BAT in HF is ... similar to a pacemaker."

Importantly, since lower blood pressures (BPs) are associated with poorer outcomes in patients with HF, BAT was associated with statistically significant increases in systolic BP (8.5 ± 3.8 mmHg, $P = 0.03$) and pulse pressure (9.6 ± 3.2 mmHg, $P = 0.004$). These findings contrast with the known BP-lowering effects of BAT in hypertensive patients, and the investigators postulate that they are perhaps a result of improved stroke volume owing to reduced vascular resistance.

At the 6-month follow-up, BAT was associated with statistically significant improvement in all three primary efficacy end points. For patients in the control and BAT groups, respectively, NYHA class improved in 24% and 55%, remained the same in 67% and 42%, and worsened in 9% and 3%. The Minnesota Living with Heart Failure Questionnaire Quality of Life score improved by –17.4 ± 2.8 in the BAT group, but within-group change in the controls was not significant. Similarly, the patients who received BAT, but not the controls, experienced a significant improvement in 6 min hall walk distance (59.6 ± 14.1 m). The investigators note that "the magnitude of these benefits was similar to, if not greater than, that reported with currently available effective drug and device therapies for HF, and yet they were seen in patients already receiving these therapies".

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"Our results indicate that HF therapy can be improved in an already very well treated, but very symptomatic, HF population," write the investigators. The study was not adequately powered to evaluate clinical outcomes, and larger, prospective studies are, therefore, needed to evaluate the impact of BAT on mortality as well as hospitalization for HF.

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Original article Abraham, W. T. *et al.* Baroreflex activation therapy for the treatment of heart failure with a reduced ejection fraction. *JACC Heart Fail.* doi:10.1016/j.jchf.2015.02.006