Chairside I, v1
Completed 2-26-2021
N = 13

Chairside I, v1 was an open label prospective study of a PressurePace™ simulation (manual pacemaker programming) in 13 subjects with hypertension and dual-chamber pacemakers implanted for standard indications. The purpose of the study was to:

1. Demonstrate the feasibility of significantly lowering blood pressure (systolic blood pressure = to or > 10 mmHg and diastolic blood pressure = to or > 5 mmHg) using the PressurePace™ algorithm.

2. Study the dose-response relationship of the BaroPace™ effect.

3. Gain insights into potential causal mechanism(s). Specifically, further evaluate the negative influence of Sympathetic Nervous System blockade induced by the therapeutic use of beta-adrenergic blocking drugs ("beta blockers") and the role of neuro-modulation.

The results of Chairside I, v1 satisfied all three goals:

1. Nine out of nine patients not being administered beta-adrenergic blocking drugs showed a drop in systolic blood pressure = or > 10 mmHg ($p < 0.01$). Diastolic blood pressure was also significantly reduced, (= or > 5 mmHg, $p < 0.05$).

2. Successful reduction in blood pressure was achieved within 30 minutes and required no more than two adjustments of the Right Atrial Pacing Rate in all patients not being administered beta-adrenergic blocking drugs.

3. In four patients treated with beta-adrenergic blocking drugs, the blood pressure lowering effect of PressurePace™ was completely negated, further confirming the causal relationship between the BaroPace effect and the Sympathetic Nervous System. Because many clinicians administer beta-adrenergic blocking drugs for DRH and HFpEF, this finding has important clinical implications. It builds on the retrospective data reported by Ngyuen et al (HRS 2021) who reported that the improvement in NYHA class and blood pressure associated with dual chamber pacing in patients with HFpEF was significantly reduced in the presence of beta-adrenergic blocking drugs.