

Real-time Closed-Loop Regulation of Permanent Pacing Rate using External Home Blood Pressure Measurements in Patients with HFpEF and Hypertension: A First-in-Man Report

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Background

Patients with ‘heart failure with preserved ejection fraction’ (HFpEF) frequently manifest chronotropic incompetence as well as hypertension (HTN). It has been shown that cardiac pacing may improve clinical outcomes in these patients. To date, cardiac pacing has not been regulated by an external hemodynamic input. This study utilized a multicenter, randomized, double blind cross over design to assign patients with previously implanted permanent pacemakers (PM) and hypertension to two study arms: conventional clinical pacemaker setting (CPM), and a pacing arm in which the atrial pacing rate was regulated by twice a day BP measurements in the patient’s home (BPAP).

Method

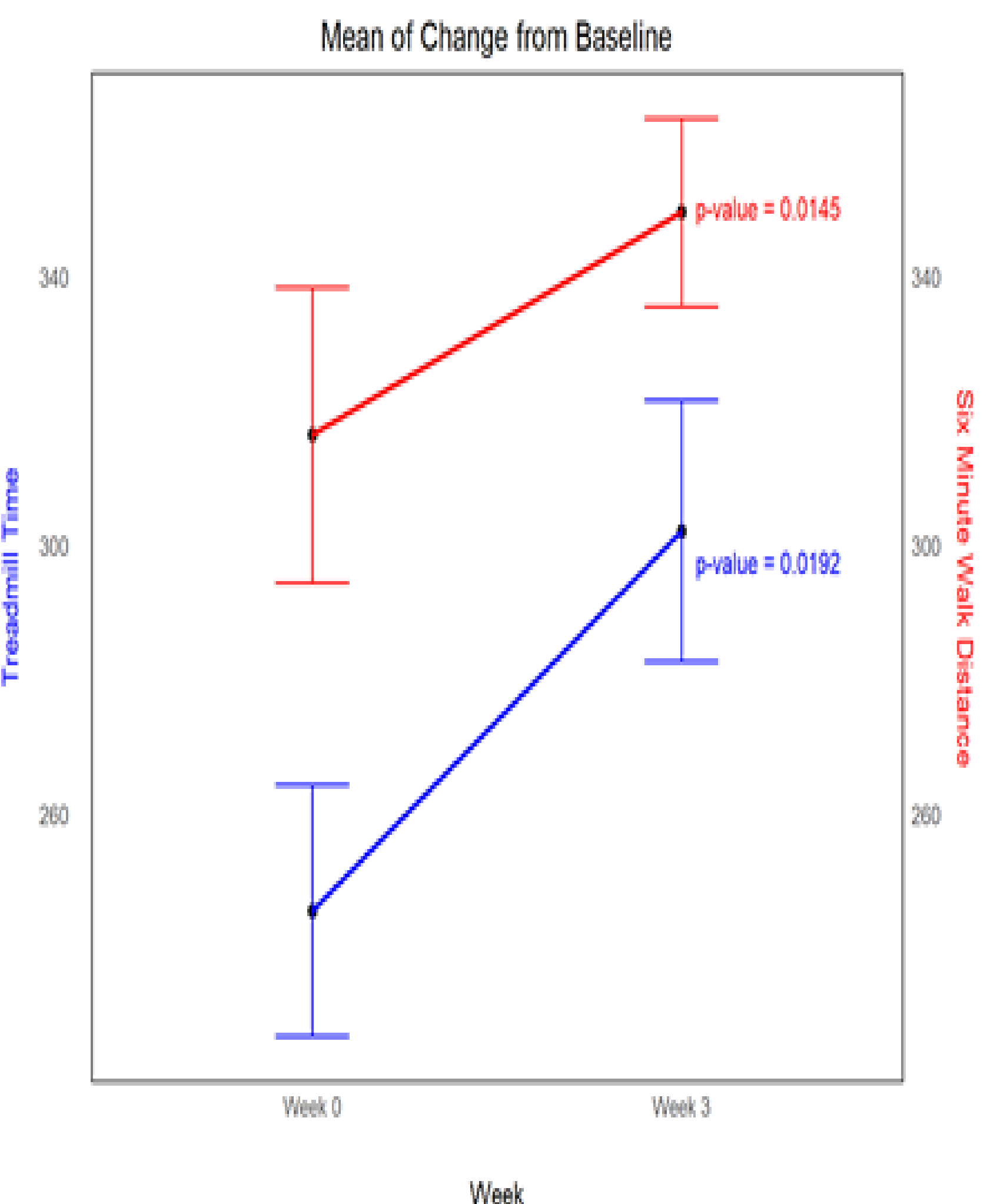
Blue tooth communication *between* a BP cuff, a computer tablet with proprietary algorithm, and a permanent dual chamber PM, was established twice/day. BP measurement quality and patient safety were monitored by a clinical associate in the patient’s home. Encrypted changes in atrial pacing rate, when indicated by the BPAP driven atrial pacing algorithm, were sent to the PM. Pacing rates were limited to 60-88/min. Study duration was 49 days: one week baseline observation and three weeks in each pacing treatment arm. Study endpoints were duration on Bruce low level treadmill (TM), six-minute walk (6 MW), Minnesota Quality of Life (QOL) and NYHA scores. All were obtained at baseline and at the completion of each phase, as were 24-hr BP measurements. Patients with atrial fibrillation were excluded. Patient subjective input at each session was recorded and all data stored on a secure cloud server.

Results

- 16 patients, mean age 63, ejection fraction: $54 \pm 5\%$, gender: 15/16 males. Pacing indication: heart block (14/16); sinus node dysfunction (16/16).
- TM time, 6MW, QOL and NYHA scores, were all significantly improved following BPAP: TM: 455 ± 64 vs 361 ± 32 sec, 6MW: 355 ± 18 vs 316 ± 32 meters, QOL: 7 ± 7 vs 22 ± 11 , NYHA: 9/16 vs 2/16, all $p < 0.05$.
- Compared to Baseline, these data represent a 35% increase in TM duration, a 72% improvement in QOL score, and 14% improvement in 6MW.
- Significant changes in these metrics were not detected when CPM was compared with baseline measurements.
- The sequence in which the pacing arms were chosen did not affect the results.
- Pacing with BPAP was well tolerated in all patients.

Conclusion

This is the first study to show safety and marked efficacy of a real-time, closed loop, in-home, BP-driven permanent pacing algorithm in patients with HFpEF and HTN. If these data are supported by a larger randomized trial, this may result in a new pacing therapy for many patients with HFpEF.



Disclosures / Acknowledgments

MB and ESG own shares in Baropace