# Baroreflex activation therapy for resistant hypertension: results from mid-term prospective ambulatory blood pressure registry

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**Objectives:** First generation baroreflex activation therapy (BAT) devices showed clinical efficacy in patients with drug-resistant arterial hypertension (AHT), but the safety profile was insufficient. Data regarding efficacy of second-generation devices were generated mostly from office blood pressure (BP) measurements or short-term 24-hour ambulatory blood pressure measurements (ABPM). We present a mid-term prospective registry to evaluate the efficacy and safety of recent BAT devices.
**Purpose:** The purpose of our study was to find a method that helps patients with drug-resistant arterial hypertension to control their blood pressure. Further we sought to reduce the overall amount of antihypertensive drugs to lessen side effects, as well as the effects of polypharmacy.
**Methods:** All patients receiving Barostim neo between November 2013 and June 2019 for resistant AHT were prospectively included into this observational study. ABPM was performed at baseline, in 3-month intervals in the first year after BAT implantation and in 6-month intervals afterwards for up to 42 months. Patients were assigned into two groups of responders and non-responders. Non-responders had a mean blood pressure drop (BPD) below 5mmHg. Responders in turn were categorized into 3 sub-groups (low-BPD between 5–9 mmHg, medium-BPD between 10–19 mmHg and high-BPD ≥20 mmHg). The primary efficacy end-points were changes in systolic and diastolic BP and number of antihypertensive medications. The primary safety end point was BAT-related major adverse events (MAE).
**Results:** 64 patients (mean age 63 years, 67% males) were included. Only patients who completed a 24-hour ABPM during a follow up were counted in the statistical analysis. We had an overall responder rate of 67.8%. Out of those 15.4% had low-BPD, 38.4% medium-BPD and 46.2% had a high-BPD. Systolic BP decreased over the 3.5-years period from 168±17 mmHg to 149±19 mmHg (n=19, mean change −18.8 mmHg; 95% confidence interval [CI]: −29.32 to −8.36; $p<0.0007$). Diastolic BP decreased from 97±16 to 85±12 mmHg (n=19, mean change −11.7 mmHg; 95% CI: −19.2 to −4.2; $p<0.0021$). The mean number of antihypertensive drugs was reduced from 6.9±1.3 to 5.2±1.5 (n=19, mean change −1.7; 95% CI: −0.8 to −0.27; $p<0.0009$). The time course of primary end-points is shown in Fig.1. Freedom from BAT-related MAE was 93.5%. 4 perioperative complications (1 pocket bleeding, 1 pocket infection, 1 N. hypoglossus palsy, 1 hoarseness) resolved without residual side effects. There were five non BAT related deaths (7,8%) in the follow up period.
**Conclusion:** Systolic and diastolic ABP, as well as number and dosage of antihypertensive drugs decreased significantly during 3.5-years follow-up after Barostim neo implantation in 64 consecutive patients (of whom 62 completed at least one follow-up). No MAE associated with BAT were observed after the perioperative period. However, further controlled trials are needed to confirm the long-term efficacy of BAT.

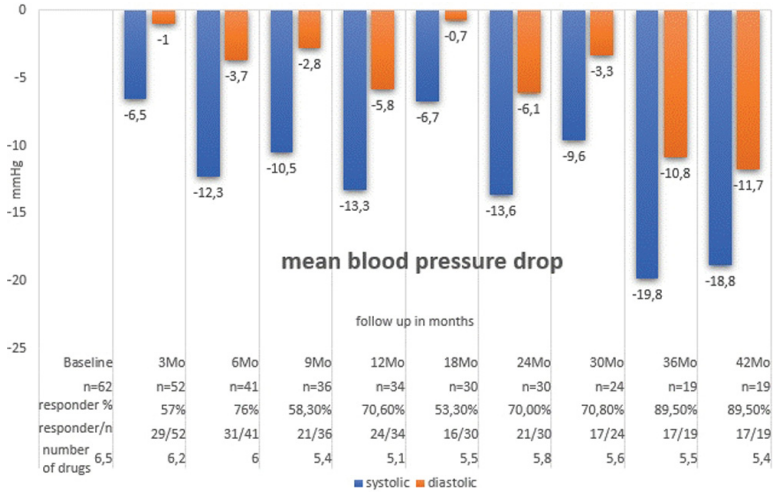


Figure 1. Mean blood pressure drop