

Left Ventricular Reverse Remodeling with Chronic Treatment of Resistant Hypertension Using an Implantable Device: Results from European and United States Trials of the Rheos[®] Baroreflex Hypertension Therapy[®] System

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Objectives: Left ventricular hypertrophy (LVH) increases risk of myocardial ischemia, sudden death and heart failure in hypertension (HTN). Regression of LVH in HTN reduces risk. Anti-HTN drugs have demonstrated LVH reduction. It is unknown if device therapy to lower blood pressure (BP) impacts LVH.

Methods: Stage II HTN subjects (systolic BP ≥ 160 mmHg) taking ≥ 3 anti-HTN drugs (≥ 1 diuretic) were implanted with the Rheos Baroreflex Hypertension Therapy (BHT) System. Baseline data were acquired before implant. BHT was activated 1 month after implant. Follow-up occurred after 3 and 12 months of BHT. Echocardiograms were reviewed at a blinded core lab. Results were computed for all subjects with echocardiograms available at baseline and each follow-up.

Results: 16 subjects (12 Europe/4 US, 7 M/9 F, Age 50.4 ± 11.5 yr, BMI 33.1 ± 7.8 kg/m²) were implanted at 4 centers. Changes versus baseline were analyzed with paired t-tests after 3 and 12 months of therapy. BHT reduced BP and regressed LVH. LV mass index decreased in 15/16 subjects after a year of BHT. No unanticipated adverse events occurred.

Changes in BP, Heart Rate, Left Ventricular (LV) Structure & Medication

	Baseline	Δ 3 Months	Δ 12 Months
Office Cuff Systolic BP (mmHg)	178.9 \pm 24.5	-24.8 \pm 26.0 [†]	-29.3 \pm 23.0 [‡]
Office Cuff Diastolic BP (mmHg)	106.3 \pm 16.9	-12.9 \pm 19.9*	-15.7 \pm 20.6*
Heart Rate (bpm)	72.9 \pm 11.9	-3.6 \pm 8.9	-3.6 \pm 7.6
Septal Wall Thickness (mm)	13.4 \pm 2.9	-0.8 \pm 1.1*	-1.3 \pm 1.8*
LV Posterior Wall Thickness (mm)	13.0 \pm 2.3	-0.9 \pm 0.9 [‡]	-1.4 \pm 1.1 [‡]
LV Mass Index (g/m ²)	130.2 \pm 33.5	-14.9 \pm 14.4 [‡]	-24.1 \pm 18.7 [‡]
Relative Wall Thickness	0.52 \pm 0.11	-0.03 \pm 0.05*	-0.04 \pm 0.05 [†]
Anti-HTN Medications (number)	4.9 \pm 1.8	-0.3 \pm 1.9	-0.5 \pm 0.7*

Conclusions: Chronic treatment of drug-resistant HTN with Rheos BHT regresses LVH while reducing BP. BHT benefits are incremental to those achieved with aggressive medical therapy. These findings merit larger studies with long-term follow-up to assess cardioprotective effects of LVH reduction from Rheos BHT.