

**SUSTAINED BLOOD PRESSURE REDUCTION BY BAROREFLEX HYPERTENSION THERAPY WITH A CHRONICALLY IMPLANTED SYSTEM: 2-YEAR DATA FROM THE RHEOS DEBUT-HT STUDY IN PATIENTS WITH RESISTANT HYPERTENSION.**

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**Objective:** The Device Based Therapy of Hypertension (DEBuT-HT) study uses an implantable pulse generator and electrodes implanted around the carotid sinus to electrically activate the carotid baroreflex chronically. The long-term (>2 year) blood pressure (BP) data in a cohort of patients who underwent chronic therapy were assessed to analyse if therapeutic responsiveness was sustained.

**Design and Method:** Of 45 patients currently enrolled in DEBuT-HT, a cohort of 16 patients (8f / 8m, age: 52 ± 9 yrs, BMI: 31 ± 6 kg/m<sup>2</sup>) from 4 European centers has completed > 2 years of chronic therapy with the device; activated one month after successful surgical implantation (baseline). This cohort's mean duration of device based treatment is currently 33 ± 5 months.

**Results:** During the total observation period of this cohort (534 patient months), there were no unexpected system- or procedure related serious adverse events. The BP- and heart rate reductions at 3 months, 1 year and 2 years for efficacy were significant compared to baseline.

**Office-based mean±SD baseline and mean±SE deltas**

<b>N=16</b>	<b>Baseline</b>	<b>Δ 3 Months</b>	<b>Δ 1 year</b>	<b>Δ 2 year</b>
Systolic BP (mmHg)	191 ± 32	-34 ± 7 (p<0.001)	-38 ± 7 (p<0.001)	-35 ± 8 (p<0.001)
Diastolic BP (mmHg)	116 ± 22	-20 ± 4 (p<0.001)	-27 ± 5 (p<0.001)	-24 ± 6 (p<0.001)
Heart rate (bpm)	81 ± 11	-14 ± 3 (p<0.001)	-12 ± 3 (p<0.001)	-12 ± 4 (p=0.004)

A drop in systolic BP of at least 20 mmHg was achieved in 12 of 16 (75%) patients at 2 years and 5 of 16 (31%) achieved a systolic BP of less than 140 mmHg at 2 years. At 2 years, these reductions were sustained while the number of antihypertensive medications remained stable at 4.8 at baseline and 4.8, 4.7 and 4.6 at 3 months, 1 year and 2 years respectively.

**Conclusions:** The Rheos system is a novel implantable device under investigation for the chronic treatment of resistant hypertension. These 2-year results indicate that the response to the Rheos system therapy is sustained and support that such a device-based approach to blood pressure control may be a future therapeutic option in patients with resistant hypertension.