ORAL SESSION

ORAL SESSION 8D
INNOVATIVE TECHNIQUES AND DEVICES

OP.8D.01 CONTROLLING AND LOWERING BLOOD PRESSURE WITH THE MOBIUSHD DEVICE: FIRST-IN-MAN INTERIM RESULTS (CALM-FIM STUDY)

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Objective: To evaluate the safety and performance of the MobiusHD system in patients with resistant hypertension.

Design and method: This is a multi-center (9 centers) non-randomized, first-in-man assessment of a nitinol self-expanding rectangular cuboid implant (MobiusHD) designed to increase carotid sinus arterial wall strain without impacting pulsatility or laminar flow. The geometric changes of the carotid sinus enhance baroreceptor sensitivity thus decreasing sympathetic activity and lowering BP. Patients with resistant hypertension (> 3 antihypertensives, of which one is a diuretic, and office SBP > 160 mmHg), without obstructive carotid disease received a unilateral carotid sinus MobiusHD implant. Incidence of serious adverse events and unanticipated adverse device effects were collected along with changes in blood pressure (BP) measured during 1.5-year follow-up.

Results: So far 31 patients, mean age 52 (range 21–76) years, of the anticipated 50 patients received a MobiusHD implant of which 9 patients had failed on renal denervation. Mean pretreatment office BP was 182/107 (±18/15) mmHg with a median of 4.4 prescribed antihypertensives [daily defined dose (DDD): 7.4]. During follow-up 3 patients had serious adverse events (as adjudicated by the data safety monitoring board) related to procedure or device: hypotension (n = 2) and closure device failure, requiring repair (n = 1). At 180 days, 17 of the 20 patients had a reduction in office SBP > 10 mmHg and/or 24-hr SBP > 5 mmHg. Eight of these 17 patients had a reduction in DDD of antihypertensive medications.

Changes in DDD and BP after MobiusHD implant

	Pre-implant	Δ Day 7	Δ Day 30	Δ Day 90	Δ Day 180	Δ Day 365	Δ Year 1.5
Patients (n)	31	31	27	25	20	9	5
DDD (n)	7.4	7.1	5.9	5.8	6.1	7.2	7.3
Office BP (mmHg)	182/107	-29/-15	-25/-12	-25/-11	-24/-11	-26/-11	-33/-16
24h SBP (mmHg)	165/98	-	-	-12/-6	-16/-9	-	-

Conclusions: So far, implanting the MobiusHD device in patients with resistant hypertension seems to be safe and shows promising results in BP lowering.

OP.8D.02 FIRST IN MAN TREATMENT OF SEVERE BP VARIABILITY WITH BAROREFLEX ACTIVATION THERAPY

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Objective: Profound BP variability (BPV) is a major cause of cardiovascular morbidity and poor quality of life as there are no optimal pharmacological strategies to help patients. We hypothesised that in a patient with baroreflex dysfunction and preserved efferent baroreflex pathway, carotid sinus stimulation may help control BP, BPV and heart rate variability (HRV).

Design and method: A 52 year old man was referred with profound HR and BPV. Home SBPs were in a range of 60–250 mmHg and DBPs were 40–130 mmHg and heart rate (HR) of 60–200 bpm (confirmed with ABPM, see Figure) despite multiple medications including felodipine 30 mg daily, terazosin 16 mg daily, doxazosin 8 mg daily, bisoprolol 20 mg daily and butrans patch 17.5 mcg/hr.
After extensive multi-disciplinary investigations the diagnosis was progressive central and peripheral dysautonomia consequent upon immune-mediated neuropathy secondary to undifferentiated connective tissue disease with Sjogren's syndrome. It was not possible to improve BP control with use of clonidine patches and he had frequent severe epistaxes due to hypertensive surges and blackouts due to hypotension and was therefore retired from work on medical grounds.

Results: Autonomic function tests confirmed widespread dysautonomia with preserved but attenuated vasodepressor response to carotid sinus massage. Baroreflex activation therapy (BAT) was undertaken after numerous in-patient attempts to control BPV pharmacologically had failed. The Barostim Neoâ device was implanted with a right carotid sinus electrode in March 2015 and subsequently device settings were reprogrammed on several occasions to optimise BP control.
The patient's BP profile improved considerably following BAT but significant hypotensive episodes continued and thus all antihypertensives were stopped with substantial improvement in HR and BP and halving of BPV and concomitant reduction in epistaxes and syncopal episodes.

Conclusions: Severe BPV is uncommon and challenging to manage when caused by baroreflex failure. Some antihypertensive drugs can increase BPV and elevate sympathetic tone which could further impair BP control in patients with this diagnosis. Use of BAT in this setting may be of benefit as long as the carotid sinus nerve and vasodepressor component of the baroreflex still function.

OP.8D.03 MEASUREMENT OF ARTERIAL STIFFNESS BY ULTRAFAST ECHO: COMPARISON WITH ECHOTRACKING IN NORMOTENSIVE SUBJECTS AND HYPERTENSIVE PATIENTS

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Objective: The question whether arterial stiffness in hypertension is increased solely because of increased arterial pressure is not solved. Because measurement of arterial stiffness is highly dependent on measurement of blood pressure (BP), the development of methods independent of BP is necessary for clarifying this question. Ultrafast echography (UFE, Supersonic Imagine, Aix en Provence, France) makes use of very fast sampling rate (up to 10 kHz), so transient events such as pressure wave arrival can be tracked. From the spontaneous pressure wave transit time, the stiffness of the wall material can be measured with no need of BP. This method has never been tested against classical echotracking (Artlab, Esaote, Maastricht, NL) and carotid to femoral pulse wave velocity (cf-PWV, Sphygmocor, AtCor, Sydney, Australia).

Design and method: We included 56 subjects, 27 normotensives (NT) and 29 essential hypertensives (HT), matched for age and sex. We compared UFE to echotracking and cf-PWV. Measurements were performed in resting conditions.

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