Conclusions: This initial feasibility and safety study of renal nerve denervation mediated by low and intermediate β -radiation dosages indicates that this approach can cause substantial nerve damage while avoiding significant damage to the renal artery.



TCT-208

Catheter-based renal sympathetic denervation – results of the heidelberg registry

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Background: Renal sympathetic denervation is a novel treatment option in patients with treatment resistant hypertension. Registry data allow to evaluate safety and efficacy in a real-world szenario.

Methods: 53 consecutive patients with treatment resistant hypertension underwent renal sympathetic denervation with the Symplicity radiofrequency based catheter. At baseline, mean office blood pressure was $171\pm22/93\pm17$ mm Hg. The mean number of antihypertensive agents was 5.0.

Results: At 6 months follow up, office systolic blood pressure improved to 151 ± 18 mm Hg (minus 20 mm Hg compared to baseline; p<0.0001), the diastolic blood pressure to 86 ± 11 mm Hg (minus 7 mm Hg compared to baseline, p<0.001). The response rate, defined as reduction of office systolic blood pressure of >10 mm Hg was 66%. In 9 Patients (17%), number of dosage of antihypertensive agents could be reduced. The mean number of ablations points per kidney was 4.3. There was no correlation between the number of ablation points and blood pressure response (r= 0,25, p=ns).

Conclusions: Renal sympathetic denervation with the Simplicity systems results in a significant reduction of office systolic and diastolic blood pressure reduction in patients with treatment resistant hypertension. Effects on blood pressure were somewhat less profound than reported in the Symplicity trial program, reflecting a real world szenario with more liberal use of the method. Interestingly, there was no correlation between the number of ablation points and blood pressure response.

TCT-209

Durable Reduction In Blood Pressure In the First Cohort of Patients Treated With Renal Sympathetic Denervation Therapy For Resistant Hypertension

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Background: Resistant hypertension is associated with significant cardiovascular morbidity and mortality and it poses a significant treatment challenge for physicians. The treatment of resistant hypertension by renal sympathetic denervation (RD) has demonstrated excellent short-term reductions in blood pressure (BP) at six-months as reported by the Symplicity HTN-2 Investigators. The future role of RD is evolving and long-term results will clarify it's durability. Here we assess the long-term results in the first cohort of patients to be treated with RD in Australia. Methods: We compared the baseline office-based BP to long-term follow-up office-based BP, number of prescribed anti-hypertensive medications, major adverse cardiac and cerebrovascular events (MACCE) and hospital admissions in 8 patients whom had undergone RD from July 2007 to January 2008.

Results: Our cohort had a mean follow-up of 43 months and we found that office-based BP measurements were reduced by a mean of 30/9 mmHg when compared to baseline measurements (p<0.003 systolic; p<0.09 diastolic). The mean number of prescribed anti-hypertensive medications remained stable throughout the follow-up period (4.88 medications pre-treatment vs 4.1 medications at follow-up; p=NS). Two patients required hospitalisation for late cerebrovascular events. There were no cardiac events reported. **Conclusions:** This is the longest reported follow-up of renal sympathetic denervation patients. We have demonstrated a significant and durable decrease in blood pressure. However, there has been no reduction in the number of prescribed anti-hypertensive medications.

Blood Pressure Before and After Renal Sympathetic Denervation

250 200 150 100 50 0 Pre Post Follow Up

TCT-210

Decrease of the norepinephrine release from sympathetic nerves during renal denervation

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Background: Renal denervation (RDN) is a promising new treatment option for pronounced hypertension refractory to medical therapy. Interestingly, only 70-80% of patients have a relevant reduction in blood pressure (BP) three to six months after RDN when assessed by systematic 24h BP measurements. No variables have been identified to date predicting the BP response.

Methods: We assessed 11 patients with bilateral renal denervation for the changes of preand postprocedural norepinephrine (NE) and epinephrine (E) levels measured directly from the renal artery (RA) and vein (RV). We defined the respective spillover for ΔNE and ΔE as the difference RV-RA and compared this difference before and after the procedure.

Results: We assessed NE and E for 88 probes (11 patients x 2 (bilateral probes) x 2 (RA and RV) x 2(pre- and post-procedural)). There was a significant decrease of the Δ NE RV-RA spill-over comparing pre- with post-procedural levels (184pg/ml±180 decrease to 97pg/ml±137, P=0.03 for paired t-test). There was no significant change in the epinephrine levels during the procedure under conscious sedation (56pg/ml±192 compared to 29pg/ml±171, P=0.62 for paired t-test). The pre-post Δ NE RV-RA was even more pronounced when the median values were compared (P = 0.02).

Norepinephrine Delta (Median)



Conclusions: The decrease of NE veno-arterial difference is a directly assessable physiologic marker reflecting the effects of RDN with reduced renal NE release from sympathetic nerves. The current systematic follow-up at 3 and 6 months of our patients will allow the evaluation for a possible association of the pre-post ΔNE RV-RA with the BP response.

TCT-211

Ambulatory blood pressure and dipping-pattern after catheter-based renal sympathetic denervation in patients with resistant hypertension

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Background: Ambulatory blood pressure monitoring (ABPM) is mandatory in every patient with uncontrolled hypertension. Nighttime blood pressure and non-dipping is associated with cardiovascular morbidity and mortality. Catheter-based renal sympathetic denervation (RD) in patients with resistant hypertension has been shown to reduce sympathetic drive and office blood pressure. The influence of RD on ambulatory blood pressure (ABPM) has not been studied in details.

Methods: One-hundert patients with resistant hypertension undergoing catheter-based renal denervation were included in the study. Systolic and diastolic blood pressure (SBP/DBP) as well as ABPM (SBP/DBP average, SBP/DBP daytime, SBP/DBP nighttime, heart rate (HR) average) and dipping-pattern were analyzed prior to, and at 3 and 6 months follow-up.

Results: RD reduced office SBP and DBP at 3 and 6 months by 22.9/8.1 mmHg and 26.6/9.3 mmHg (p for all <0.001), respectively. After 3 and 6 months 24-hour average SBP/DBP was reduced by 8.9/4.9 mmHg (p=0.019/0.025) and 11.9.5/6.9 mmHg (p=0.022/0.011), respectively. Average SBP/DBP were lowered at 3 and 6 months follow-up at daytime by 9.6/5.1 mmHg (p=0.010/0.001) and 12.1/8.1 mmHg (p=0.001/0.001) and at nighttime by 6.6/5.8 mmHg (p=0.003/0.005) and 11.3/4.7 mmHg (p=0.001/0.001), respectively. Renal denervation also reduced maximum SBP by -11.9 mmHg at 3 months and by -14.4 mmHg at 6 months follow-up (p=0.009 and 0.006) whereas maximum DBP was not changed.

Conclusions: Beside significant reductions in office SBP and DBP, RD also reduced 24-hour average, daytime and nighttime SBP and DBP as well as maximum SBP after 3 and 6 months.

TCT-212

First Report of the 6-Month First in Human results of the OneShot[™] Renal Denervation System: The RHAS Study

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Background: Catheter-based selective renal sympathetic denervation has emerged as a new therapeutic option for patients with resistant hypertension. Recent studies have shown that ablation of the renal sympathetic nerves using radiofrequency (RF) energy delivered from within the renal artery is safe and effective. The OneShotTM device (Covidien, Campbell, CA) is a balloon-based RF system using a mounted spiral electrode with a unique feature of irrigation of the vessel lumen during treatment. The non-compliant balloon is inflated under low pressure (1 atm) in the renal artery. The electrode delivers RF energy to ablate adjacent nerve bundles with a single 2-minute treatment.

Methods: The RHAS study was a single-center feasibility study performed at Mercy Hospital in Auckland, New Zealand. Eligible patients had an office systolic blood pressure (SBP) ≥ 160 mmHg (≥ 150 if diabetic) despite a drug regimen that included two or more antihypertensive medications. Renal artery diameters were 4-7mm. The primary endpoint was the ability to insert the OneShotTM device into each renal artery and deliver RF energy. Secondary endpoints included office SBP at 6 months.

Results: Nine patients were enrolled; baseline characteristics and outcomes are shown below. The technical success rate was 88.9%. One failure occurred in the first enrolled patient and was due to an incorrect software setting which inhibited delivery of RF energy. All remaining patients had both renal arteries treated with the OneShotTM device. The mean procedure time (device insertion to end of treatment) was 16 minutes. At 30 days, the mean office SBP was 155 \pm 19 mmHg, a change of $-31 \pm$ 14 mmHg. Six-month results are pending.

Characteristic/Outcome	Mean \pm SD or % (n/N)
Age (yrs)	58.0 ± 15.8
Male gender	55.6% (5/9)
Weight (kg)	$\textbf{84.1} \pm \textbf{16.5}$
# Anti-hypertensive meds	3.0 ± 0.7
Serious adverse events	0.0% (0/8)
Office SBP at baseline (mmHg)	186 ± 18
Office SBP at 1 month (mmHg)	155 ± 19
Change from baseline (mmHg)	$-$ 31 \pm 14
Office DBP at baseline (mmHg)	91 ± 14
Office DBP at 1 month (mmHg)	86 ± 14
Change from baseline (mmHg)	-6 ± 10

Conclusions: The RHAS trial demonstrated rapid delivery of RF energy for renal sympathetic denervation using the $OneShot^{TM}$ device with safe blood pressure reduction at 1 month. Six-month data will be available at time of presentation.

TCT-213

Safety And Efficacy Of A Novel Multi-Electrode Renal Denervation Catheter In Resistant Hypertension: 3 Month Data From The EnligHTN I Trial

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Background: Catheter-based renal artery denervation therapy has emerged as a novel therapy in patients with resistant hypertension (HTN). Although initially performed with a single electrode radiofrequency (RF) catheter, recent advances in catheter designs are using multiple pre-specified electrode positions. This theoretically could improve the safety and efficacy of this treatment. We present the 3-month safety and efficacy data from the international multicenter EnligHTN I trial.

Methods: Inclusion criteria include patients from 18-80 years of age with office systolic BP \geq 160 mmHg (\geq 150 for patients with Type 2 diabetes) on \geq 3 anti HTN agents (including a diuretic) and renal artery diameter \geq 4mm and length \geq 20mm. Patients with dual main renal arteries are excluded. The primary end-point is the change in office BP at 6 months from baseline. The safety endpoints include vascular and renal artery complications. Renal artery CT angiography is performed at baseline and repeated at 6 months. Utilizing femoral artery access with an 8Fr RDC guiding sheath the EnligHTN catheter is introduced into the renal artery, and RF energy delivered sequentially for 90 seconds per electrode. The catheter is repositioned, rotated and denervation repeated. Both renal arteries are treated.

Results: In total 46 patients underwent renal denervation. Mean age was 60 ± 10 yrs and baseline BP 176/96 mmHg. The median procedure time (from initiation to completion of RF delivery) was 34.0 min. The mean number of therapies delivered was 7.7 for the right and 7.4 for the left renal arteries. There was no change in renal function pre and post procedure (eGFR 76 and 75 mL/min/1.73m2 respectively). There were no renal artery or serious vascular complications through 3 months. The BP changes pre-discharge and at 1 month were -23/9(n=45, p<0.0001) and -28/10 mmHg respectively(n=46, p<0.0001). The preliminary 3-month BP change is -37/17 mmHg(n=24, p<0.0001).

Conclusions: Renal denervation was performed safely and swiftly in patients with resistant HTN using the EnligHTN catheter. Initial results show a significant early reduction in BP that continues to reduce further at 3 months.

TCT-214

Abstract Withdrawn