**TCT-425**

**Innervation Patterns in the Renal Artery Ostium May Limit the Efficacy of Endovascular Radiofrequency Ablation**

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**Background:** Unconfirmed anecdotal evidence suggests that the superior aspect of the renal artery ostium is an attractive target for endovascular ablation.
**Methods:** Nerve and ganglion distribution was characterized in 16 renal arteries at 3 discrete distances from the aorta (Fig 1). RF ablation was performed in the renal ostium of another 8 arteries using a prototype renal/crescent multi-electrode RF catheter (Biosense Webster, CA) & treatments were confirmed by angiography. Renal norepinephrine (NEPI) levels were correlated with ablation zone geometries & nerve and ganglia injury 7d post denervation.
**Results:** Nerves & ganglia were more abundant but more distant from the lumen at locations closest to the aorta (Fig 1). At all 3 distances from the aorta, nerves and ganglia were distributed across all 4 quadrants. Efficacy was observed in 1 of 8 treated arteries where ablation area was 99.1mm2 & involved all 4 quadrants at a maximal depth of 9.1mm affecting 50% of nerves & reducing NEPI (37ng/g). In the other 7 arteries, no efficacy was observed, fewer than 20% of the nerves were affected, the ablation areas were smaller (16.2±10.9mm2) & present in only 1-2 quadrants at maximal depths of 3.8±2.7mm, and renal NEPI levels remained at baseline (620-991ng/g). Half of ablation zones did not contain ganglia, and the rest only 1 or 2 ganglia.

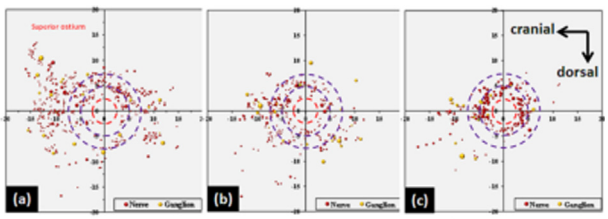

Fig 1 Composite distributions are depicted at 3 distances from the aorta: 0.3 mm (a) 3.0 mm (b) & 6.0 mm (c). Nerve & ganglia radii are based on measured sizes. Red dashes depict the location of an idealized lumen. Purple dashes depict the locus of points that are 2.5 mm and 5.0 mm away from the lumen.

**Conclusions:** Renal denervation therapies which specifically target the renal ostium must account for the unique anatomy and treatments localized to the superior aspect of the ostium alone will likely have limited added benefit as nerves are present in all quadrants.

**TCT-426**

**Bipolar Radiofrequency Renal Denervation With The Vessix Balloon Catheter System: Preclinical Safety Evaluation Through 180 Days**

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**Background:** A bipolar multi-electrode 7 Fr-compatible balloon catheter radiofrequency (RF) renal denervation system (Vessix, Boston Scientific, Natick, MA) with short procedure time was evaluated in a preclinical safety study in a domestic swine model.
**Methods:** Renal arteries of 27 swine received whole-artery treatment with overlapping treatments in the proximal 12 mm to mimic balloon overlap. Each of 3 histopathology cohorts (30, 90, 180 day follow-ups) had 4 RF-treated and 3 sham-treated (no RF energy delivered) animals; response of artery and surrounding nerves to bilateral treatment was examined (42 arteries). Scanning electron microscopy (SEM) was used to examine the renal artery flow surface for endothelialization in an additional 6 pigs (3 at each of 30 and 90 days: 12 arteries) following unilateral whole-artery treatment with proximal overlap: RF on one side and sham on the other. Power was ~1 watt, treatment duration 30 seconds, target temperature 68°C. Histology was done on all 54 kidneys and assessment for off-target injury was done in all 27 swine.
**Results:** One pig died due to spiral colon torsion unrelated to the device at 131 days, resulting in 6 arteries evaluated for the 180 day cohort. Renal artery injury was transmural and segmental, typically involving 30-60% of the circumference and demonstrating overlying nerve injury and associated segmental neointimal hyperplasia which was hemodynamically trivial (maximum stenosis 17.7% in any section). Healing of necrotic arterial media was by replacement fibrosis, essentially complete at 90 days and unchanged at 180 days. Overlying nerves also became fibrotic with no evidence of regeneration at 180 days by conventional histology. Endothelialization was focally incomplete at 30 days but confluent at 90 days. Sham-treated arteries showed only focal mechanical injury also seen with RF treatment. Kidney histology demonstrated no injury and there was also no injury to renal veins, ureters, adrenal glands, psoas muscles, peritoneum or intestine.
**Conclusions:** Safety of the Boston Scientific Vessix Renal Denervation System in 7F configuration was demonstrated for both single and overlap treatment.

**TCT-427**

**Second generation devices for renal denervation give better renal blood flow when compared with 1st generation catheters**

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**Background:** Renal Denervation (RDN) is an effective treatment for resistant hypertension. The procedure was done first with a single electrode catheter creating multiple intentionally spaced lesions. The catheter delivers 4-6 radiofrequency (RF) ablations at points distributed along the length of the renal artery. The procedure requires rotation and pull-back of the catheter between each hit. Second generation devices enable multiple simultaneous ablations at different points, allowing a single hit. RF is applied with pre-programmed time and intensity. The system provides same power regardless of catheter size eliminating the need for adjustment of the level. This gives a more predictable lesion pattern with single hit and a shorter time. This may reduce the risk of overheating and clot formation during RF delivery. The effect of RDN on renal blood flow (RBF) and the safety of the two generations of devices haven't been compared. We report the effect of those devices on RBF by using the method of renal frame count (RFC).
**Methods:** We studied the (RBF) before and after RDN by counting the numbers of frames (fr)on the renal angiogram from a beginning fr to an end fr. Fr1 is the fr that shows both edges of the ostium of the renal artery immediately after contrast injection. The end fr the fr which shows the contrast when it has reached the lateral edge of the renal cortex. RFC was calculated before and immediately after RDN in 10 cases done using 1st generation device. The results were compared with another 10 cases done using 2nd generation device.
**Results:** The mean RFC was 9.28 fr before RDN and increased to 13.71 fr after RDN in the cases that used 1st generation device ($p < 0.001$) suggesting slower (RBF) after RDN. The mean RFC was 9.44 fr before RDN and remained unchanged after the procedure in the cases that used 2nd generation device ($p=0.759$) suggesting no significant changes in (RBF) after the procedure.
**Conclusions:** 1st generation device causes significant increase in RFC reflecting deterioration in RBF when compared with 2nd generation. This can be explained by distal embolization due to catheter manipulation and micro clots formation from blood ovweheating due to loss of direct contact with intima.

## New Devices and Innovation

***Washington Convention Center, Lower Level, Hall A***

**Saturday, September 13, 2014, 5:00 PM–7:00 PM**

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**TCT-428**

**First Percutaneous Transluminal Caval flow Restriction in a Patient with Congestive Heart Failure**

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**Background:** So far, preload reduction in patients with Congestive Heart Failure (CHF) is performed by the use of high potency diuretics. We have previously reported that a Dynamic Stenosis of Inferior Vena Cava (IVC) associated with beneficial hemodynamic changes occurs, in some patients with CHF. Here, we are reporting one case of intermittent preload reduction by the use of an inflated balloon placed in the high IVC and guided by respiratory phases resulting in total occlusion during inspiration and subtotal occlusion during expiration.
**Methods:** 66 years-old Female patient with ischemic heart failure with severe left ventricular (LV) dysfunction (EF 39%), severe diastolic dysfunction with high LV filling pressure, NYHA class 2B, angina, scheduled for coronary angiogram. The patient was screened and enrolled in our caval flow protocol trial. An IVC balloon catheter for venous occlusion was introduced via right femoral vein, and was inflated up to 10 mm before the drainage of the Hepatic veins in the IVC. The IVC velocity was measured at 2 cm from the right atrium and caval flow velocity was 1.08 m/s, and then was inflated up to 13 to 14 mm achieving caval flow velocity up to 1.28 m/sec. The balloon remained inflated for 25 min.
**Results:** Right heart pressures and echocardiographic measurements showed: 44% reduction in pulmonary capillary pressure, 38% right ventricular pressure, and 60% reduction of the right atrium pressure compared with baseline. The LV diastolic diameter was reduced by 8% and systolic diameter decreased 18%, Ee' was reduced