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.

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.

New Devices and Innovation

First Percutaneous Transluminal Cavaflow Restriction in a Patient with Congestive Heart Failure

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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 histological (injury) cohorts (30, 90, 180 day follow-ups) had 4 RF-treated and 3 sham-treated animals (no RF energy delivered) and 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 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 34 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, pericardial fat, or intestine.

Conclusions: Safety of the Boston Scientific Vessix Renal Denervation System in 7F configuration was demonstrated for both single and overlap treatment.

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 using the method of renal frame count (RFC).

Methods: We studied the (RBF) before and after RDN by counting the numbers of frames (fr)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 owweheating due to loss of direct contact with intima.