BIPOLAR MULTI-ELECTRODE BALLOON CATHETER RADIOFREQUENCY RENAL DENERVATION WITH THE VESSIX SYSTEM: PRECLINICAL SAFETY EVALUATION

Poster Contributions
Hall C
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Session Title: Renal Denervation and Critical Limb Ischemia: The Hottest Topics in Vascular Medicine
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Background: A bipolar multi-electrode balloon catheter radiofrequency (RF) renal denervation system offers advantages of short procedure time and low power to minimize risk of non-target tissue thermal injury. We report a preclinical safety study of a 7 French (F) system in a domestic swine model.

Methods: The 7F device was used to treat the renal arteries of 20 pigs, with overlapping treatments in the proximal 12 mm to mimic clinical balloon overlap. Each histopathology cohort (30 & 90 day follow-up) had 4 RF-treated and 3 sham-treated (no RF energy delivered) pigs and response of artery and surrounding nerves to bilateral treatment was examined (28 arteries). Scanning electron microscopy was used to examine the renal artery flow surface for endothelialization, with unilateral whole artery treatment with proximal overlap: RF on one side and sham on the other (3 pigs/cohort; 12 arteries). Treatment duration was 30 seconds. Animals received 2 to 3 treatments per artery depending on artery length. Histology on all 40 kidneys and assessment for non-target injury was undertaken in all 20 pigs.

Results: Renal artery injury was transmural and segmental, with variable percentages of the circumference (<10% to >90%, typically 30-50%) demonstrating overlying nerve injury and associated segmental neointimal hyperplasia. No increase in thermal injury was observed in overlapped vs single-treatment segments. At 30 days, “islands” of necrotic media remained, but at 90 days healing was essentially complete with mature replacement fibrosis. Inflammatory activity was mild at 30 days and minimal by 90 days. Maximum lumen stenosis (all sections, both time points) was 17.7%, hemodynamically trivial, and typically <10%. Endothelialization was focally incomplete at 30 days, but completely confluent at 90 days. Sham-treated arteries showed only mild focal mechanical injury, which was also seen with thermal treatment. Kidney histology demonstrated no injury, and there was no injury to renal veins, ureters, adrenal glands, psoas muscles, peritoneum or intestines.

Conclusions: Safety of the Boston Scientific Vessix renal denervation system in 7F configuration was demonstrated for both single and overlap treatment.