In-Vivo Safety and Efficacy of the Hood: A Novel Cardio-embolic Protection Device for Catheter-Based Ablation

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Introduction: Radiofrequency (RF) ablation of cardiac arrhythmias is associated with a risk of stroke or silent brain lesions detected on MRI despite peri and intraprocedural anticoagulation. These result from thermal coagulum and microbubble formation at the ablation site. We previously demonstrated the potential benefit of a novel “hood” device that can contain thermal coagulum and microbubbles at the catheter-tissue interface which can thereby decrease the rate of embolization (Figure1A). In this study, we aim to demonstrate the safety of this device in chronic in-vivo animal studies. We hypothesize that ablation using the hood device is not associated with increased risk of stroke, brain infarcts and silent brain lesions detected on MRI.

Methods: RF ablation was performed in the left atria of three canine animals through trans-septal access after heparin was administered for goal activated clotting time of 300 seconds. Each animal had 5 total ablations using non-irrigated standard ablation catheters. Two of the three animals had ablations with our hood device at 30 watts, 35 seconds, and temperature control at 50°C in animal 1 and 30 watts, 45 seconds and 50°C in animal 2. Adequate positioning of our device to encompass the ablation site was confirmed on Fluoroscopy and intra-cardiac echocardiogram (Figure1B). One animal served as control and RF ablation was performed without the hood at 30 watts, 45 seconds and 50°C. Each animal underwent MRI of the brain at baseline and three days after the procedures. Diffusion-weighted imaging, T2 FLAIR, gradient echo and gadolinium enhanced T1 sequences were included. The frequency of brain lesions on MRI was compared before and after the procedure for each animal and with control.

Result: Baseline brain MRI did not show infarcts in the animals (Figure 1C&E). All five ablation procedures were performed successfully in each animal model and all animals survived with no signs of stroke or any obvious signs of embolic phenomena. Follow up MRI did not show evidence of infarct in either of the two experimental animals or the control animal (Figure1D&F). Left atrial ablation lesions were confirmed on gross examination of the explanted heart after day 3.
Conclusion: The use of our hood cardio-embolic protection device is feasible and did not show increased risk of acute peri-procedural stroke or silent brain lesions detected on MRI following non-irrigated left atrial ablation.