Pre-Clinical Evaluation of a Novel Irrigated Radiofrequency Balloon Ablation Catheter for Pulmonary Vein Isolation in a Canine Model – Safety and Durability of Lesions

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Introduction : Durable Pulmonary vein isolation (PVI) is the cornerstone in the treatment of Drug-refractory Atrial Fibrillation. Biosense Webster Inc. has developed a novel radiofrequency (RF) irrigated balloon ablation catheter to create continuous circumferential lesions. Objective: In a preclinical model, assess the safety (incidence of char, steam pop, pulmonary vein stenosis, injury to cardiac tissue, pericardial effusion, collateral damage, peripheral thrombi) and ability of the novel irrigated RF balloon to electrically isolate PVs. The study also assessed the long-term durability of PVI at 30day and 90day follow up

Methods : In 7 canines, PVI procedure was performed using a 10F ablation catheter (Biosense Webster Inc.) with a 28mm balloon, containing a central lumen for external saline irrigation and 10 flexible gold electrodes (each: 14.5 m x 3mm with 4 irrigation holes and a thermocouple) surrounding the balloon surface (3mm spacing, Figure). All ablations were performed at 15W on all 10 electrodes, for a duration of 60sec, using an irrigation flow rate of 35ml/min and target electrode temperature of 55°. 6/8 canines were sacrificed following the acute ablation procedure. 2/8 canines were followed up until 90days, with an electrophysiological study performed at 30days and 90days to check for isolation of PVs and for presence of any PV stenosis or narrowing. Gross and histological examination of heart and surrounding organs (lungs, esophagus) was performed at necropsy for both acute and survival animals.

Result : All target PVs (n=7, 7/7, 100%) in the 7 canines were isolated acutely, requiring a mean of 3 RF applications per vein. No char, coagulum or steam pop were observed in this study. 5/7 animals were sacrificed acutely. No PV stenosis or narrowing was observed in these acute animals. 2/7 animals were survived and then sacrificed at 90days. In both animals, the PVs remained isolated at 30days and 90days, with no stenosis or narrowing of PVs observed in either animal. Gross pathological examination of the hearts revealed no thrombi, endothelial damage or hemorrhage. No incidence of clinically significant collateral damage, injury to cardiac tissue, or pericardial effusion were observed in these study animals. Histological examination revealed contiguous ablation lesion at treated PV sites (Figure)

Conclusion : This study demonstrates the safety and effectiveness of the novel irrigated RF balloon catheter to produce circumferential, contiguous transmural lesions that can isolate PVs in a canine animal model. The lesions created were safe and durable as demonstrated by the isolated PVs at 30 days and 90days post ablation procedure and the absence of any adverse events like PV stenosis or damage to surrounding organs.