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Effect of Charge Delivery on Thromboembolism During Radiofrequency Ablation in Canines

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ABSTRACT

OBJECTIVES This study investigated whether delivering negative charge to catheter tips reduces thromboembolism during catheter ablation.

BACKGROUND Radiofrequency (RF) ablation prevents atrial fibrillation that can cause stroke or death. However, ablation itself can cause stroke (2%) or silent ischemia (2% to 41%), possibly via particulate debris that embolizes after coagulum adherence to catheter surfaces. Coagulum formation on RF catheters can be prevented by applying negative charge, but it is unknown if charge reduces peripheral thromboembolism.

METHODS Paired (Charge ON vs. OFF) endocardial RF ablations were performed in 9 canines using nonirrigated RF catheters. Continuous negative charge was delivered via −100 μA of DC current applied to ablation catheter electrodes. Intracardiac echocardiography was used to navigate the catheter and to monitor coagulum formation. In a subset of 5 canines, microemboli flowing through polyester tubing between the femoral artery and vein (extracorporeal loop) were monitored with bubble counters and inline filter fabric. After each ablation, catheter-tip coagulum and blood particles deposited on the filters were quantified using photography and imaging software (ImageJ, U.S. National Institutes of Health, Bethesda, Maryland).

RESULTS Negative charge significantly decreased the extracorporeal loop median filter area covered by particles ($n = 19$ pairs) by 10.2 mm^2 ($p = 0.03$), and decreased median filter particles by 349 ($p = 0.03$). Negative charge also decreased the percentage of the catheter tip surface area covered by coagulum ($n = 39$ pairs) by 7.2% ($p = 0.03$).

CONCLUSIONS Negative charge delivery to ablation catheter tips during RF ablation can reduce particulate embolization material in an extracorporeal loop, and potentially reduce thromboembolic risk associated with RF ablation. (J Am Coll Cardiol EP 2018;■:■-■) © 2018 by the American College of Cardiology Foundation.

Radiofrequency (RF) catheter ablation is a common therapy to prevent a cardiac arrhythmia (atrial fibrillation) that can cause stroke or death. Although successful ablation may prevent stroke, the ablation procedure itself, paradoxically, can cause stroke in 0.6% (1) to 2% (2,3) of cases. Even if stroke symptoms are not detected post-ablation, studies have suggested that cognitive

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ABBREVIATIONS AND ACRONYMS

ACT = activated clotting time

DC = direct current

ICE = intracardiac echocardiography

RF = radiofrequency

dysfunction may arise in 13% to 20% of cases (4), and that these deficits may be associated with "silent" ischemic lesions in the brain (5). Magnetic resonance imaging (MRI) studies have reported incidences of "silent" ischemic brain lesions after ablation between 2% and 41% (6). Thromboembolic events may arise from coagulum formation on RF ablation catheters, and/or other catheters introduced into the left atrium, during the ablation procedures.

It has been previously demonstrated in bench and pre-clinical studies that coagulum formation on cardiac RF ablation electrodes can be prevented by applying a small negative charge (7,8). The hypothesized mechanism of action was that the negatively charged electrode surface repelled the negatively charged fibrinogen molecules, and consequently prevented fibrinogen adherence to the electrode. The effect was dose-dependent in that as the amplitude of electrical current was increased, the thickness of clots formed at the catheter tip decreased to a threshold of 100 μA of negative DC current, above which coagulum formation was prevented.

Reducing coagulum formation during RF ablation may reduce the risk of thromboembolic events (e.g., stroke, other cerebrovascular or peripheral vascular thromboembolic events), and potentially enable physicians to use higher RF energies, thereby increasing the efficacy and safety of cardiac RF ablation procedures. We sought to determine whether a reduction of catheter tip coagulum is associated with a reduction in thromboembolic events. The effect of negative charge on systemic embolization was quantified by monitoring embolic material flowing through an extracorporeal loop. Our hypothesis was that negative charge applied to nonirrigated catheters during RF ablation reduces embolic microparticles.

METHODS

The experimental protocol was approved by the Institutional Animal Care and Use Committee at American Preclinical Services, LLC (Minneapolis, Minnesota).

NEGATIVE CHARGE DEVICE. A standalone device that delivers negative charge via –100 μA of DC current to ablation catheter tips was developed (8). Briefly, the charge-application circuit was connected between the electrode tip of the ablation catheter and a ground patch electrode, in parallel with the RF generator. The circuit was powered by 9-V batteries, and had a knob to adjust the amount of charge applied to the ablation electrodes. The circuit design, in which its internal resistance is much larger than the resistance of its target load, is a simple means to convert a voltage source (battery) to a current source. The current applied to the electrode/tissue interface results in ionic charge movement in the blood and tissue. Typical variations in the electrode/tissue interface resistance have very little effect on the amount of charge being delivered to the tissue. The high internal resistance of the charge-application circuit in parallel with the ablation generator also limited shunting of the applied ablation energy away from the cardiac tissue. During experiments, continuous negative charge was delivered using –100 μA of DC current; a similar amount of DC current was effective at preventing coagulum formation in previous studies (8).

ANIMAL MODEL. The effects of negative charge on thromboembolism were assessed via two series of animals: in Series 1, emboli were evaluated via qualitative and semiquantitative assessments; in Series 2, emboli were quantified using an extracorporeal loop (9). For both series, canines (mongrel, >28 kg) were anesthetized using acepromazine and propofol, intubated, and subsequently maintained on 1% to 3% isoflurane during mechanical ventilation. An 11-F sheath was placed in the left femoral artery for blood pressure monitoring. Vital signs were monitored throughout the procedure including heart rate, blood pressure, temperature, SpO_2, and activated clotting time (ACT). An 11-F sheath was placed in the right external jugular vein for intracardiac echocardiography (ICE) access.

Both intracardiac and epicardial echocardiography were available to optimize near-field visualization of catheter tip and tissue for real-time coagulum monitoring. ICE was performed via 8- or 10-F AcuNav ICE catheters utilizing the Siemens Acuson Sequoia C512 system (Munich, Germany). Epicardial echocardiography was performed via an echocardiography probe placed on the left atrial epicardium via minithoracotomy performed in the left fourth intercostal space.

Transseptal puncture was performed using a transseptal needle (BRK, St. Jude Medical, St. Paul, Minnesota) under ICE and fluoroscopic guidance; after confirmation of tenting in the fossa ovalis, the transseptal needle was advanced through the septum. Subsequently, an 8.5-F deflectable sheath (Agilis NxT, St. Jude Medical, St. Paul, Minnesota) was inserted into the left atrium. An unfractionated heparin bolus was administered after left heart access was performed. The ACT was measured every 30 min, and additional boluses were given to maintain an ACT of >300 s. Supplemental fluids (saline

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