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Protection of Critical Structures During Radiofrequency Ablation of Adjacent Myocardial Tissue Using Catheter Tips Partially Insulated With Thermally Conductive Material

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ABSTRACT

OBJECTIVES This study sought to determine whether partially insulated focused ablation (PIFA) catheters can minimize risk of injury to critical structures, such as the phrenic nerve and atrioventricular (AV) node, during ablation of adjacent myocardial tissue.

BACKGROUND PIFA catheters using thermally conductive materials may have differential radiofrequency (RF) heating properties allowing for tailored RF application with more precision.

METHODS Open-irrigated, 4- and 8-mm RF ablation catheter tips were insulated partially by coating one-half of their surfaces with a layer of vinyl, silicone, vinyl-silicone, polyurethane, or a composite of aluminum oxide/boron nitride (AOBN). These coated catheters or corresponding noninsulated catheters were positioned with 10 g of force on viable bovine myocardial tissue during RF application in an ex vivo setup. Tip temperatures, power, and lesion volumes were compared. The most effective coating, AOBN, was modified further by adding fenestrations to aid in passive cooling. PIFA catheters with fenestrated AOBN coating were then tested in an in vivo porcine model to target myocardial tissue adjacent to the AV node and the phrenic nerve.

RESULTS PIFA catheters all demonstrated higher tip temperatures, although silicone- and AOBN-catheters demonstrated this to a lesser degree. Significant differences in lesion volumes and temperature-limited powers were noted between control, silicone, and AOBN tips. Steam pops were significantly higher for silicone but not AOBN. In contrast with non-PIFA catheters, injuries to the phrenic nerve and AV node during in vivo ablations with AOBN insulation positioned over these structures were reduced significantly.

CONCLUSIONS RF ablation using catheter tips partially coated with a thermally conductive insulation material such as AOBN results in larger ablation lesion volumes without temperature limitations. Partial insulation of the catheter tip will protect adjacent critical structures during RF ablation. (J Am Coll Cardiol EP 2016;■:■–■)

Effective radiofrequency (RF) ablation has been shown to be related to the size of the ablation catheter tip, temperature at the electrode-tissue interface, and duration and force of tissue contact (1-3). A limitation of RF ablation is the lack of durable lesions if only low powers, which may be safer, are delivered to myocardial tissue. In addition, anatomic considerations, such as proximity to critical structures including the atrioventricular (AV) node, phrenic nerve, or pericardium, can limit RF application. Furthermore, when ablating myocardial tissue, only 1 portion of the ablation catheter is in contact

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ABBREVIATIONS AND ACRONYMS

AOBN = aluminum oxide/boron nitride

AV = atrioventricular

PIFA = partially insulated focused ablation

RF = radiofrequency

with the tissue being targeted; RF from the contralateral side of the catheter is either dispersed due to circulating blood or can unintentionally harm adjacent tissue.

We have modified existing catheters by covering a portion of the metallic tip with electrical insulation that is also thermally conductive. Insulating 1 side of an ablation catheter may allow for a more tailored cardiac ablation by improving heating under the noninsulated side of the catheter while decreasing undesired RF-mediated injury from the insulated side (4).

When insulation is applied partially to an ablation electrode, it can alter RF lesion geometry. Although insulation may result in higher tip temperatures, this can be minimized by using a larger catheter tip, by irrigating the catheter tip, and by adding fenestrations or vents in the insulation to allow for thermal release.

We sought to determine the most effective insulation material that will allow for asymmetrical lesion formation while protecting the tissue adjacent to the insulated aspect of the ablation catheter tip. We also ascertained the effects of "venting," or interrupting the insulation to prevent tissue temperature limitations. Using what we found to be the most effective insulation, patterned with fenestrations to allow for additional cooling, we performed in vivo ablation near critical structures, such as the AV node and phrenic nerve, to determine the ability of PIFA to protect these structures.

METHODS

EX VIVO MODEL. Experimental protocols have been approved by the Institutional Animal Care and Use Committees of the University of Colorado and University of Chicago. An ex vivo model consisting of viable bovine myocardium, a submersible load cell, a circulating bath, and a deflectable sheath was assembled. A load cell was submersed in the bath and contained a section of viable bovine ventricular myocardium excised within 1 h of experimentation. This load cell measured force applied to the overlying myocardial tissue and was used to standardize application of energy. This ex vivo model has been validated and described in further detail elsewhere (5,6).

CATHETER MODIFICATION WITH ELECTRICAL INSULATION USING THERMALLY CONDUCTIVE MATERIALS. A nonirrigated 4-mm RF catheter, nonirrigated 8-mm RF catheter, and an open-irrigated RF ablation catheter (Biosense-Webster, Diamond Bar, California) were insulated partially by coating one-half of their surfaces with a thin layer of thermally conductive material; the insulation materials tested included vinyl, silicone, vinyl-silicone, polyurethane, or a composite of aluminum oxide/boron nitride (AOBN). The coating suspensions were created with an epoxy vehicle and allowed to dry, leaving a thin (<0.1 mm) layer covering one-half of the metallic tip. For the externally irrigated catheter, the existing tip fenestrations were preserved, allowing for active cooling with saline irrigant on all sides of the catheter. These PIFA catheters or their corresponding noninsulated catheters (Biosense-Webster) were positioned with 10 g of force in a parallel position using a deflectable sheath (Agilis, St. Jude Medical, Secaucus, New Jersey). The insulation coating that was found to be most effective, AOBN, was further modified by adding vents, or fenestrations, into the coating to allow for thermal release/venting (Figure 1). Ablation with this vented AOBN was compared with standard AOBN coating, and temperatures were recorded.

DELIVERY OF RF ENERGY APPLIED TO MYOCARDIUM. Using a temperature control mode, a series of RF lesions with each catheter was applied to recently excised bovine myocardium, with the noninsulated side parallel to and contacting the myocardium. Temperature limits for maximal power were set at 45°C for irrigated ablation and 55°C for 4- and 8-mm nonirrigated ablation. The number of lesions applied per ventricular section depended on the available endocardial surface. No lesions were placed over or in immediate proximity, defined as 5 mm, to papillary muscles or other lesions. Furthermore, no lesions were placed within 1 cm of section edge.

IN VIVO ABLATION OF AV NODE AND PHRENIC NERVE. Yorkshire pigs ($n = 12$) were anesthetized and intravenous lidocaine (50 to 100 mg) or amiodarone (150 mg IV bolus followed by a 1 mg/min infusion) was used intraoperatively for prophylaxis of ventricular arrhythmias. Epicardial access was obtained under fluoroscopy using a 17-gauge Pajunk needle (Pajunk Medical Systems, Norcross, Georgia) and a 9-F sheath was placed in the epicardium. An electroanatomic map of the superior vena cava, right atrium, and epicardium was created using the CARTO3 mapping system (Biosense-Webster).

A decapolar catheter was used to pace and capture the right and left phrenic nerves, either in the endocardium or epicardium. A force-sensing PIFA irrigated tip catheter and a standard force-sensing irrigated tip catheter were used to deliver alternating PIFA and standard irrigated "control" ablation lesions directly below the site of phrenic nerve capture. After each