Effects of radiofrequency energy delivered through partially insulated metallic catheter tips on myocardial tissue heating and ablation lesion characteristics

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BACKGROUND Cardiac radiofrequency (RF) ablation is typically achieved using symmetric catheter tips, which may result in unintended heating adjacent to targeted tissue. Partial insulation may alter lesion geometry and prevent collateral heating.

OBJECTIVE The purpose of this study was to assess partially insulated focused ablation (PIFA).

METHODS Partial insulation using thermally conductive materials was applied to a 4-mm or 8-mm nonirrigated catheter and a 3.5-mm open-irrigated catheter. These PIFA tips, or their noninsulated counterparts, were applied to *ex vivo* viable bovine myocardium. Ablations were delivered at various powers and under temperature control. Potential clinical applicability was evaluated *in vivo* by targeting porcine epicardium with irrigated PIFA and assessing its protective effects on the pericardium.

RESULTS PIFA catheters exhibited different properties and produced asymmetric lesions compared with corresponding standard ablation catheters. Temperatures at 3- and 5-mm depths were higher for PIFA catheters, with a temperature increase measured at the catheter tip–tissue interface; however, in temperature control ablation, tip–tissue temperature increases did not limit power delivery. Furthermore, temperatures were lower on the insulated surface and were significantly higher on the noninsulated PIFA side. Impedance changes were significantly larger; more steam pops were observed with PIFA but were mitigated by external irrigation, a larger tip electrode, and use of more thermally conductive insulation. In contrast to standard ablation, open-irrigated PIFA created larger asymmetric lesions *in vivo* over porcine epicardium, without evidence of pericardial injury.

CONCLUSION PIFA ablation has different characteristics compared with symmetrically conductive ablation. Further research is needed to assess the clinical implications of insulated catheter ablation.

KEYWORDS Radiofrequency ablation; Ablation biophysics; Epicardial ablation; Atrioventricular node; Ablation complications; Insulation; Facilitated ablation

ABBREVIATIONS AV = atrioventricular; **PIFA** = partially insulated focused ablation; **RF** = radiofrequency

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Introduction

Cardiac ablation using radiofrequency (RF) energy is the standard treatment of most arrhythmias refractory to medical therapy. RF current heats tissue via resistive heating of a thin rim of tissue that is in direct contact with the ablation tip.[1] Deeper tissue heating is the result of passive thermal conduction from this small area of volume heating,[2] and ablation lesion size is related to the temperature at the electrode–tissue interface, size of the ablation tip, RF duration, and tissue contact.[3–5]

One limitation of RF ablation is the inability to achieve durable lesions with the safe delivery of low power to myocardial tissue. Furthermore, ablation may be constrained because of anatomic considerations, such as proximity to critical structures including the atrioventricular (AV) node, phrenic nerve, or pericardium.[6–8] In addition, when ablating myocardial tissue, only 1 side of the ablation catheter is adjacent to the tissue being targeted; RF from the contralateral side either is lost because of circulating blood or can potentially injure adjacent tissue.

We hypothesized that selective electrical insulation applied to an ablation electrode to protect nontargeted myocardial tissue or structures would alter RF lesion geometry with minimal effect on tip temperatures. In order to influence RF energy delivery, we modified existing catheters by coating a portion of the metallic tip using a thin layer of electrical insulation that also

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is thermally conductive. This modification 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. Partially insulated focused ablation (PIFA) catheters were created whereby 1 side of various ablation catheter tips (4-mm, 8-mm, and open-irrigated) was insulated with a very thin layer of thermal adhesive coating to eliminate RF conductivity on this side while also allowing for convective cooling of the catheter tip to prevent tip temperature limitations.

We sought to characterize myocardial tissue heating and ablation lesion formation characteristics using these novel partially insulated catheters using power and temperature control RF ablation modes. We hypothesized that the insulated sides of the PIFA catheters would have minimal tissue injury when RF ablation was delivered. Second, we further hypothesized that the noninsulated sides of these catheters would deliver a greater degree of tissue heating with less power and result in larger, asymmetric ablation lesions without the limitation of higher tip temperatures.

Methods

Ex vivo model

The experimental protocols were approved by the Institutional Animal Care and Use Committees of the University of Colorado and University of Chicago. An *ex vivo* model was used, as previously validated and described in detail elsewhere.[9,10] In brief, viable bovine myocardium was placed on top of a submersible load cell in a circulating saline bath at 37°C. Fluid was circulated in a saline bath at a rate of 5 L/min using a perfusion pump designed for cardiac bypass. By measuring force applied to the overlying myocardial tissue, the load cell was used to standardize application of energy.

Catheter modification with electrical insulation using thermally conductive materials

A nonirrigated 4-mm RF catheter, a nonirrigated 8-mm RF catheter, and an open-irrigated RF ablation catheter (Biosense Webster, Diamond Bar, CA) were partially insulated by coating half their surfaces with a thin layer of thermally conductive material, either silicone–vinyl or a composite of aluminum oxide and boron nitride. The coatings were created with an epoxy that was allowed to dry, leaving a thin (<0.1 mm) layer covering half of the metallic tip. For the externally irrigated catheter, the existing tip fenestrations were preserved to allow 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, Sylmar, CA).

Delivery of RF energy applied to myocardium

Using varying powers (20, 30, and 40 W) under power control mode, a series of ablation lesions with each catheter was created on the recently excised bovine myocardium, with the insulated or noninsulated side parallel to the myocardium. A separate set of lesions was created using temperature control mode for maximum power (50 W for 4 mm and irrigated tip, and 70 W for 8 mm), with tip temperature limits set at ≤55°C (4 mm), ≤60°C (8 mm), and ≤45°C (irrigated tip), for 60-second ablations. Lesions applied per ventricular section depended on the available endocardial surface. Lesions were not placed over or in close proximity to papillary muscles (5 mm) or within proximity to other lesions. Furthermore, section edges were avoided.

In vivo epicardial ablation and assessment of pericardial injury

Three Yorkshire pigs were anesthetized, and intravenous lidocaine (50–100 mg) was used intraoperatively for prophylaxis of ventricular arrhythmias. Epicardial access was obtained under fluoroscopy using a 17-gauge Pajunk needle (Pajunk Medical Systems, Norcross, GA), and a 9Fr sheath was placed in the epicardium. An electroanatomic map of the entire epicardium was created using the CARTO3 mapping system (Biosense Webster). Via the 9Fr sheath, a PIFA irrigated tip catheter and a standard irrigated tip catheter were used to deliver PIFA and standard irrigated "control" ablation lesions on the epicardium in each pig. Ablations were delivered at 50 W for 30 seconds with the same amount of force as measured by SmartTouch technology on the RF catheters (Biosense Webster). Ablation lesions were tagged by the electroanatomic mapping system. Ablations with both PIFA and standard catheters were performed in the same epicardial region. Saline irrigant was suctioned from the epicardium after each ablation. After ablation, animals were sacrificed, and the hearts and their pericardium were immediately explanted and fixed in formalin. Gross pathology was performed, pericardial tissue was assessed for injury, and epicardial ablation lesions were analyzed.

Ablation lesion volume measurements

A digital micrometer was used to analyze tissue sections, and single lesion volumes were calculated using the equation for an ellipsoid, as described and validated in previous studies.[9,10] For each lesion, maximum depth (A), maximum width (W), and lesion surface diameter (D) were measured.

Volume of an ellipsoid ablation lesion

$$\textit{Lesion Volume} = \left[1.33\pi(D)\left(\frac{W}{2}\right)\left(\frac{L}{2}\right)\right]/2$$

where D = maximum depth, W = maximum width, and L = lesion surface diameter

Tissue temperature analysis

Figure 1 shows how thermocouple wires were placed into myocardium at 3- and 5-mm depths during ablations with the standard catheter or noninsulated aspect of the PIFA catheter parallel to the myocardium. Furthermore, these T-type thermocouple wires were placed horizontally into myocardium on the tissue surface at distance of 1, 2, and 4 mm from each side of the ablation catheter, with the ablation catheter oriented as shown in Figure 2 in relationship to the myocardium. Thermocouple