Effect of radiofrequency energy delivery in proximity to metallic medical device components

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BACKGROUND Radiofrequency (RF) ablation of cardiac arrhythmias is often performed in the presence of metallic materials in the heart.

OBJECTIVES We hypothesize that metal objects in proximity to an RF ablation source can lead to ohmic heating of surrounding tissue. Furthermore, we hypothesize that insulation of the metal can mitigate this RF effect.

METHODS A model consisting of viable bovine myocardium or thermochromic liquid crystal medium, a circulating saline bath at 37°C, and a load cell was used. A 4-mm RF ablation catheter was positioned with 10 g of force over bovine myocardium and placed in proximity to a copper wire, a defibrillator lead, and a circular mapping catheter. RF was applied at 30 W, and tissue temperatures were measured. Ablation near insulated and noninsulated esophageal temperature probes was also performed.

RESULTS Ablation in proximity to metal resulted in higher temperatures. Average maximum distances for observed thermal changes to >45°C for the ± lead were 5.2 ± 0.3 mm and 5.7 ± 0.4 mm when metal was interposed between the catheter and the ground electrode. Presence of an esophageal temperature probe increased temperatures in tissues adjacent to the probe and caused lesions remote to the ablation site. Esophageal probe insulation prevented these tissue temperature increases and injury to nontargeted tissues.

CONCLUSION Effects of RF ablation are potentiated near metallic components of medical devices, leading to significant tissue heating. Further research is needed to assess the safety impact of RF in the myocardium near metallic objects, particularly esophageal temperature probes.

KEYWORDS Esophageal temperature probe; Metal proximity; Ohmic heating; Radiofrequency ablation; Remote heating

ABBREVIATIONS **ANOVA** = analysis of variance; **CMC** = circular mapping catheter; **ICD** = implantable cardioverter-defibrillator; **MSEP** = multisensor esophageal probe; **RF** = radiofrequency

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Introduction

Intracardiac medical devices, from implantable cardioverter-defibrillators (ICDs) to left ventricular assist devices, are increasingly being implanted and have transformed the treatment of cardiovascular diseases. However, medical devices present certain challenges during radiofrequency (RF) ablation, including risks of dislodgement and interference and impediment of access to potential sites of ablation.[1] Less is known about the effects that metallic objects have on RF parameters, including temperature and impedance changes, and how insulation of metal items can impact these changes.[2–4]

We hypothesize that RF ablation near metallic intracardiac materials will amplify current density around the metal and lead to ohmic heating of adjacent tissues, with the potential for unintended heating and even possibly injury. This potential scenario is commonly encountered during ablation near intracardiac leads and near multielectrode circular mapping catheters (CMCs) used for pulmonary vein isolation, as well as during posterior left atrial ablation with a temperature probe in the adjacent esophagus.

We hypothesize that the presence of metal within the RF field generated by an ablation catheter will lead to metallic heating remote from the source of RF energy. We sought to evaluate this phenomenon, to investigate the potential for unintended heating of tissue near metal, and to assess the effect of electrical insulation.

Methods

Temperature analysis using heat-sensitive thermochromic liquid crystal medium

Clinical devices with metallic parts were placed near an ablation catheter within a thermochromic liquid crystal medium designed to display color change between 45°C and 50°C (Edmund Optics, Barrington, NJ), allowing for a

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qualitative assessment of temperatures spatially and temporally. Orientation of the RF ablation field was adjusted by placing the RF grounding electrode in various locations with respect to the metal items, and heating patterns were assessed. The presence or absence of color change was assessed upon application of RF energy near the metallic device tested.

Ex Vivo Model

The experimental protocols have been approved by the Institutional Animal Care and Use Committees of the University of Colorado. An ex vivo model was used, as previously validated and described in detail elsewhere.[5–7] Viable bovine myocardium was placed in a circulating saline bath at 37°C on top of a submersible load cell. With the use of a perfusion pump designed for cardiac bypass, fluid was circulated in a saline bath at a rate of 5 L/min. By measuring force applied to the overlying myocardial tissue, the load cell was used to standardize application of energy.

Ablation in close proximity to metal

T-type thermocouple wires insulated with cyanoacrylate were inserted between an open irrigated catheter and the metal material being studied, including a copper wire, the tip electrode of a defibrillator lead, and the electrode of a CMC. The T-type thermocouple wires were placed horizontally at 1-mm, 2-mm, and 4-mm distances from each side of a 4-mm ablation catheter (Biosense Webster, Diamond Bar, CA), with the ablation catheter oriented as shown in Figure 1 in relationship to the metal item. Ablation was performed in power-control mode at 30 W.

Ex vivo model of esophageal probes during myocardial "left atrial" ablation

A stage that contained a section of bovine tissue of 5-mm thickness, similar to the thickness of the posterior left atrium, was submersed in a saline bath. Underneath the bovine tissue, either an insulated single sensor esophageal probe (Level 1 Esophageal Stethoscope with Temperature Sensor ES400–18; Smiths Medical, St Paul, MN) or noninsulated multisensor esophageal probe (MSEP) (Esotherm; FIAB SpA, Florence, Italy) was placed; a control, consisting only of insulation and no esophageal probe, was also tested. The insulation material for the control and for the insulated esophageal probe was 0.5-mm thick and was made from flexible polyvinyl chloride. A 4-mm ablation catheter was placed perpendicular to the "left atrial" myocardial surface. Thermocouples were placed between the left atrial tissue and the esophageal probe (5 mm from the ablation catheter), immediately below the esophageal probe (8 mm from the ablation catheter), and 3 mm from the esophageal probe (11 mm from the ablation catheter) (Figure 2A). A separate set of thermocouple wires was similarly placed for the control and aligned at the same distances from the left atrial tissue and ablation catheter. A 4-mm ablation catheter was used to deliver a set of RF energy applications at 50 W for 60 seconds. The catheter tip temperature limit was set at ≤ 55°C.

Tissue temperature analysis

Thermocouple analogue inputs were converted to digital signals using LabVIEW software (version 7.0).[8] Temperatures were recorded in a continuous fashion throughout the 60 seconds of RF application at a rate of 5 Hz. Peak tissue temperature was defined as the maximum temperature reading during RF application. RF applications that generated steam pops were excluded from the temperature curve analysis.

Statistical analysis

SPSS software[9] was used to perform all calculations. The analysis of variance (ANOVA) test was used to compare continuous variables, and the χ^2 test was used for dichotomous comparisons of tissue temperatures from ablated tissues near metals vs control tissues.

Results

Thermochromic heat patterns during RF ablation near metal

Using heat-sensitive thermochromic liquid crystal medium, we demonstrated that clinical devices with metallic parts,

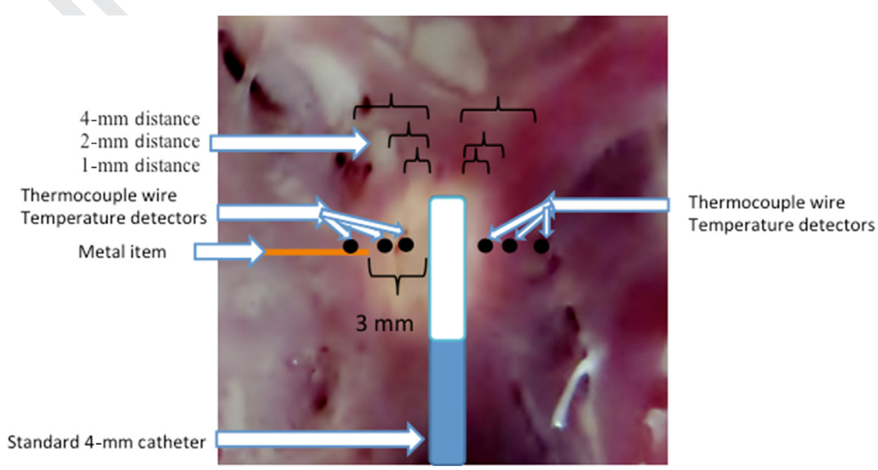

Figure 1 Thermocouple wires were inserted in the myocardium on both sides of the standard catheter at distances of 1, 2, and 4 mm. The metal item (copper wire, defibrillator lead, or CMC) was placed on 1 side of the standard catheter at a 3-mm distance.