Comparison of Electrode Cooling Between Internal and Open Irrigation in Radiofrequency Ablation Lesion Depth and Incidence of Thrombus and Steam Pop

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Background—Electrode cooling by circulating fluid within the electrode (closed loop) or open irrigation facilitates radiofrequency (RF) ablation. This study compared lesion parameters between closed loop and open irrigation with the use of a canine model.

Methods and Results—In 8 anesthetized dogs, the skin over the thigh muscle was incised and raised, forming a cradle superfused with heparinized blood (activated clotting time >350 seconds) at 37°C. A 7F 4-mm closed loop electrode (irrigation 36 mL/min) and 7.5F 3.5-mm open irrigation electrode (irrigation 17 mL/min) were positioned perpendicularly to the thigh muscle at 10 g contact weight. RF was applied (n=121) at 20 or 30 W for 60 seconds in low (0.1 m/s) or high (0.5 m/s) pulsatile blood flow. Temperatures were measured in the electrode, electrode-tissue interface, and within the tissue at 3- and 7-mm depths. After each RF, the cradle was emptied to examine the electrode and interface for thrombus. There was no difference between closed loop and open irrigation in impedance, lesion depth, or tissue temperature at 20 or 30 W. Interface temperature and electrode temperature were greater in the closed loop application. Thrombus occurred in 32 of 63 closed loop versus 0 of 58 open irrigation RF applications (P<0.05) with interface temperature ≥80°C in all 32 (electrode temperature <40°C in 1, 40°C to 50°C in 26, and ≥50°C in 5). With closed loop, interface temperature and thrombus incidence were greater at 30 W and low blood flow. With open irrigation, interface temperature remained low (≤71°C) with no difference between 20 and 30 W or between low and high blood flow. Steam pop occurred at 20 W in 4 of 35 closed loop and 0 of 30 open irrigation and at 30 W in 15 of 28 closed loop and 4 of 28 open irrigation applications (P<0.05).

Conclusions—Lower interface temperature, thrombus, and steam pop, especially in low blood flow, indicate greater interface cooling with open irrigation. (Circulation. 2006;113:11-19.)

Key Words: catheter ablation ■ radiofrequency ■ tachyarrhythmias ■ thrombus

Radiofrequency (RF) catheter ablation is most often performed in the temperature control mode.1–7 Under temperature control, RF power is regulated to maintain a constant electrode temperature (commonly 55°C or 60°C), which is generally thought to limit the temperature at the electrode-tissue interface to a level that will prevent an impedance rise, the formation of soft thrombus, and a steam pop. The ablation electrode temperature is dependent on the opposing effects of heating from the tissue and cooling by the blood flowing around the electrode.8–14 At any given electrode temperature, the RF power delivered to the tissue is significantly reduced in areas of low blood flow.10 The reduced cooling associated with low blood flow causes the electrode to reach the target temperature at lower power levels. Because lesion size is primarily dependent on the RF power delivered to the tissue,12,14 lesion size will vary with the magnitude of local blood flow. Areas where lesion size is adversely affected because of low local blood flow (poor electrode cooling) include a deep pouch in the subeustachian isthmus (ablation of atrial flutter); dilated and poorly contracting atria (ablation of chronic atrial fibrillation or macroreentrant atrial tachycardia in patients after surgically repaired congenital heart disease or mitral valve disease); and dilated and poorly contracting ventricles (ablation of ventricular tachycardia associated with a postinfarction left ventricular aneurysm).6,15 In these locations, increasing electrode temperature to 65°C or 70°C only minimally increases RF power and increases the risk of thrombus formation and impedance rise.6,10,16–18

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Two approaches have been developed to increase electrode cooling to allow RF power to be maintained in a desirable

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range in areas of low blood flow. One approach is to increase the electrode surface area exposed to the blood by increasing electrode circumference and length (8 to 10 mm). The greater surface area increases convective cooling in the same level of blood flow. The second, and potentially more effective, approach is fluid irrigation of the electrode either by circulating fluid within the electrode (closed loop system) or flushing saline through openings in the electrode (open irrigation system). The “active electrode cooling” by irrigation allows sustained RF power, even at sites with low blood flow, to produce deeper lesions. We hypothesized that, at the same constant RF power, lesion depth would be similar between closed loop and open irrigation electrodes, but the effect of flushing around the electrode at the surface of the tissue by the open irrigation system (external cooling) would decrease the formation of thrombus during ablation. The purpose of this study was to use an established canine model to compare between closed loop and open irrigation electrodes the RF lesion depth, incidence of thrombus formation, and steam pop at the same RF power in both low–blood flow and high–blood flow conditions.

Methods

Irrigation Ablation Catheters

The closed loop irrigation catheter has a 7F, 4-mm length tip electrode (Chilli, Boston Scientific; Figure 1A). A solution of 5% dextrose at room temperature was circulated continuously through the tip electrode at a flow rate of 36 mL/min, cooling the ablation electrode internally. The open irrigation catheter has a 7.5F, 3.5-mm tip electrode with an internal thermocouple and 6 irrigation holes (0.4-mm diameter) located around the electrode, 1.0 mm from the tip. Heparinized (1 U/min) normal saline at room temperature was irrigated through the electrode and 6 irrigation holes at a flow rate of 17 mL/min during each RF application, providing internal and external electrode cooling.

Experimental Preparation

The experimental protocol was approved by the University of Oklahoma Committee on the Use and Care of Animals. Eight mongrel dogs weighing 25 to 32 kg were anesthetized with sodium pentobarbital (25 mg/kg) and ventilated mechanically with room air. The right carotid artery was cannulated for monitoring arterial pressure.

The canine thigh muscle preparation has been described previously. Each dog was placed on its right side. A 20-cm skin incision was made over the left thigh muscle. The skin on each side of the incision was dissected free of the connective tissue. The skin edges were raised to form a cradle that was filled with heparinized blood (activated clotting time [ACT] >350 seconds) from the same animal at 37°C to 38°C. Two fluoroptic temperature probes were positioned on opposite sides of the electrode-tissue interface. Two other fluoroptic temperature probes were positioned within the tissue, adjacent to the electrode at depths of 3 and 7 mm. Pulsatile blood flow was directed around the electrode at either low (0.1 m/s) or high (0.5 m/s) velocity.
the pulsatile blood flow (Figure 2B). The electrode-tissue interface temperature was taken as the higher of the 2 temperatures. Two additional fluoroptic temperature probes were bundled together with shrink tubing and inserted into the thigh muscle adjacent to the ablation electrode at 3 and 7 mm below the muscle surface. The electrode-tissue interface and 2 tissue temperatures were measured at 125-ms intervals (Figure 3).

Ablation Protocol

Radiofrequency energy (500 kHz) was delivered between the ablation electrode and an adhesive electrosurgical dispersive pad (20×10 cm) applied to the shaved skin of the opposite thigh. A custom RF generator (Radionics, model RFG-3DJ) was used that allowed the recording of power, impedance, and electrode temperature at 20-ms intervals (Figure 3). The root-mean-square power and impedance and the electrode temperature, interface temperature, and tissue temperature were monitored continuously and recorded (Bard Lab-System). RF applications were delivered at constant power of 20 or 30 W for 60 seconds but were terminated immediately in the event of an impedance rise of ≥10 Ω above the lowest impedance during the RF application.

After each RF application, the catheter was left in place, and the cradle was emptied of blood. The ablation electrode and the electrode-tissue interface were examined for thrombus (Figure 4). The electrode was then removed, cleaned, and positioned at a new site for another RF application. RF current was delivered at 6 to 8 sites along the surface of the left thigh muscle. The skin incision was then closed, and the animal was rotated to expose the right thigh muscle. The right thigh muscle was prepared with the same procedure, and 6 to 8 applications of RF current were delivered.

Two hours after the ablation procedure, 20 mL of 10% triphenyl tetrazolium chloride was administered intravenously. Triphenyl tetrazolium chloride stains intracellular dehydrogenase a deep red color, distinguishing viable (red) and necrotic (pale) tissue. The animals were euthanized, and the thigh muscles were excised and fixed in 10% formalin. The thigh muscles were sectioned to measure lesion size.

Measurements of Lesion Size

The maximum depth, maximum diameter, depth at the maximum diameter, and lesion surface diameter were measured (Figure 5).

Statistical Analysis

Values are presented as mean±SD. The factorial design of the study involved 2 catheter types (closed loop and open irrigation), 2 blood flow levels (0.1 and 0.5 m/s), and 2 power levels (20 and 30 W) for a total of 8 conditions. The mean electrode temperature, interface temperature, and tissue temperature at 3.0- and 7.0-mm depths and lesion dimensions were calculated for each of the 8 conditions in each dog. The means among the 8 dogs of electrode temperature, interface temperature, and tissue temperature at 3.0- and 7.0-mm depths and lesion dimensions for RF applications at constant power (20 and 30 W) in low and high blood flow (0.1 and 0.5 m/s) were compared between the closed loop catheter and open irrigation catheter by repeated-measures ANOVA. The significance of the difference between the closed loop catheter and open irrigation catheter in incidence of thrombus formation and steam pop was assessed by McNemar tests for paired observations. The significance of the relationship between electrode temperature and interface temperature and between electrode temperature and lesion depth among the 8 dogs was assessed by a simple linear regression analysis for the closed loop and open irrigation catheters at constant power (20 and 30 W). A probability value <0.05 was considered statistically significant.

Results

A total of 121 RF applications were delivered in the 8 dogs with the use of either the closed loop electrode (n=63) or open irrigation electrode (n=58), at power of 20 or 30 W and in either low (0.1 m/s) or high (0.5 m/s) pulsatile blood
flow (Table). The impedance at the onset of the RF applications was similar for the closed loop and open irrigation electrodes (94 ± 7 versus 94 ± 6 Ω, respectively), and the surface areas of the electrodes were similar, suggesting that a similar ratio of RF power was delivered between the tissue and blood for the 2 electrodes. As a result, for RF applications at the same constant power (20 or 30 W), there was no difference between the closed loop and open irrigation electrodes in tissue temperatures at depths of 3 and 7 mm or in maximum lesion depth in the setting of either low (0.1 m/s) or high (0.5 m/s) blood flow (Table and Figure 5). The maximum diameter was slightly smaller with open irrigation. The diameter at the surface of the lesion was smaller and the depth at the maximum lesion diameter was greater in lesions produced by the open irrigation electrode (Figure 5).

Figure 4. Thrombus at the electrode-tissue interface produced by the RF application shown in Figure 3A, delivered with the closed loop electrode at 20 W in low blood flow. The thrombus formed on the electrode-tissue interface surrounding the ablation electrode despite the absence of an impedance rise. The size of soft thrombus was 7×4 mm.

Figure 5. A, Lesion dimensions for RF applications in low blood flow (0.1 m/s). Values are expressed in millimeters (mean ± SD). A, Maximum lesion depth; B, maximum lesion diameter; C, depth at maximum lesion diameter; and D, lesion surface diameter. B, Lesion dimensions for RF applications in high blood flow (0.5 m/s). *P<0.05, comparison between the closed loop electrode and open irrigation electrode at the same RF power (20 or 30 W) and same blood flow (0.1 or 0.5 m/s). †P<0.05, comparison between blood flow of 0.1 and 0.5 m/s at the same RF power (20 or 30 W).
Thrombus Formation and Steam Pop: Relationship to Electrode and Electrode-Tissue Interface Temperatures

**Closed Loop Electrode**

For the closed loop electrode, there was no difference in the peak electrode temperature between RF applications in low blood flow and high blood flow at the same power (20 or 30 W). The peak interface temperature was significantly greater in low blood flow than high blood flow (Table). There was no significant relationship between the peak electrode temperature and the peak interface temperature for RF applications at 20 or 30 W in low blood flow or high blood flow among the 8 dogs.

Thrombus occurred in 32 of the 63 RF applications (51%) with the closed loop electrode (Table, Figures 4 and 6). The peak interface temperature was \( \geq 80°C \) in all 32 RF applications with thrombus. All but 1 of the 33 RF applications with peak interface temperature \( \geq 80°C \) produced thrombus (Figures 3A and 6A). Only 8 of the 32 RF applications with thrombus had a peak interface temperature of \( \geq 100°C \). An impedance rise (\( \geq 10 \Omega \)) occurred in only 6 (19%) of the 32 RF applications with thrombus.

In high blood flow, thrombus occurred in RF applications with electrode temperature \( \geq 43°C \). In low blood flow, thrombus occurred at any electrode temperature (Figure 6). For low and high blood flow combined, thrombus occurred in 1 of 6 RF applications (17%) with peak electrode temperature \( <40°C \), 26 of 50 RF applications (52%) with peak electrode temperature \( 40°C \) to \( 50°C \), and 5 of 7 RF applications (71%) with peak electrode temperature \( >50°C \) (Figure 6B).

Steam pops were identified by an audible pop or small (3 to 5 \( \Omega \)), brief (usually in the range of 50 ms) increase in impedance. A steam pop occurred in 19 of the 63 RF applications (30%) with the use of the closed loop electrode: 4 of 35 RF applications (11%) at 20 W and 15 of 28 RF applications (54%) at 30 W (\( P<0.05 \); Table, Figure 6). At 30 W, RF applications with and without a steam pop were similar in electrode temperature (49±5°C versus 48±5°C) or interface temperature (86±18°C versus 88±20°C), but there was a trend toward higher tissue temperature at depths of 3 mm (94±19°C versus 83±22°C) and 7 mm (58±16°C versus 49±12°C). There was no significant difference between low blood flow and high blood flow in the incidence of a steam pop. An impedance rise of \( \geq 10 \Omega \) occurred in only 5 of 19 RF applications with a steam pop (Figure 6).

**Open Irrigation Electrode**

The peak electrode temperature and interface temperature were lower at each RF power and blood flow rate for the open irrigation electrode than for the closed loop electrode (Table). The peak interface temperature was \( \leq 71°C \) in all 58 RF applications with the open irrigation electrode, with no thrombus or impedance rise (Figure 6 and Table). The range of peak electrode temperature was narrow (30°C to 44°C), and there was no significant relationship between peak electrode temperature and peak interface temperature in RF applications at 20 or 30 W in low or high blood flow among the 8 dogs. There was no significant difference in electrode temperature or interface temperature between RF applications in low- and high-blood flow conditions (Table).

A steam pop occurred in 4 of 58 RF applications (7%) with the open irrigation electrode (none of 30 RF applications at 20 W and 4 of 28 RF applications at 30 W; Figure 6 and Table). The incidence of steam pop at 30 W was significantly lower with the open irrigation electrode than with the closed loop electrode (14% versus 54% of applications; \( P<0.05 \)) (Table). The open irrigation RF applications associated with a steam pop had peak electrode temperature ranging from only 36°C to 40°C and peak interface temperature ranging from only 38°C to 50°C, with tissue temperatures at 3-mm depth ranging from 91°C to 100°C and at 7-mm depth ranging from 47°C to 72°C. As demonstrated for the closed loop electrode, electrode temperature or interface temperature was similar between RF applications with and without steam pop (Figure 6).

Relationship Between Electrode Temperature and Lesion Depth

Among the 8 dogs, there was no significant relationship between peak electrode temperature and lesion depth, except for RF ablations with the closed loop electrode at 20 W in high blood flow.
In this study RF ablation with closed loop and open irrigation electrodes produced lesions of comparable depth at the power range tested, in both low- and high-blood flow conditions. This is due to the similar electrode surface area, contact force, and overall impedance resulting in similar power delivered to the tissue. Open irrigation was more effective in cooling the electrode-tissue interface, reflected by (1) lower interface temperature; (2) lower incidence of thrombus; and (3) and smaller lesion diameter at the surface (with the maximum diameter produced deeper in the tissue). These differences between the 2 electrodes were greater in low blood flow, presumably because the flow of saline irrigation out of the electrode provides additional cooling of the electrode-tissue interface (“external cooling”). Ablation with the closed loop electrode (with irrigation providing only internal cooling) in low blood flow frequently resulted in high electrode-tissue interface temperature (despite low electrode temperature) and thrombus formation. The lower interface temperature at the same electrode temperature in higher blood flow with the closed loop electrode suggests that much of the interface cooling is derived from surrounding blood flow (Figure 1A). In contrast, with the open irrigation electrode, the interface temperature was similar in low and high blood flow, suggest-
ing that interface cooling was independent of the local blood flow.

This study provides strong evidence that interface temperature is the major determinant of thrombus formation. Thrombus occurred consistently at an interface temperature of ≥80°C (Figure 6). Although it is frequently thought that thrombus occurs at an interface temperature of 100°C, only 8 of the 32 RF applications producing thrombus had an interface temperature ≥100°C. The critical interface temperature of 80°C for thrombus formation is the same as previously found for 4- and 8-mm length nonirrigated electrodes. Thrombus formation was not dependent on an impedance rise. An impedance rise of ≥10Ω occurred in only 6 of 32 RF applications (19%) producing thrombus (Figure 6). Therefore, monitoring electrode temperature and impedance during ablation may not predict the presence or absence of thrombus formation.

None of the RF applications using the open irrigation electrode reached an interface temperature of 80°C, and none produced thrombus. Despite the lower interface temperature, tissue temperatures at depths of 3 and 7 mm and lesion depth were similar to RF applications in which the closed loop electrode with higher interface temperature was used. This demonstrates that interface temperature is not a determinant of lesion size.

A recent study from Demolin et al found that delivering RF current within a beaker of freshly drawn heparinized human blood consistently produced a soft thrombus around the ablation electrode at an electrode temperature of 80°C. This thrombus was similar in appearance to the thrombus occurring in the thigh muscle preparation in the present study. Scanning electron microscopy of the thrombi in human blood revealed a dense mesh of denaturized blood protein with entrapped and damaged red blood cells. This study also included RF ablation in heparinized human serum. “Thrombi” also occurred in human serum, and scanning electron microscopy images revealed a similar structure, without entrapped red blood cells. These observations suggest that the thrombus during RF ablation is related to heat-induced denaturation of blood proteins. Importantly, human blood developed thrombus at the same temperature (80°C) as canine blood in the present study.

The thermal effects on the thermocouple embedded in the electrode (electrode temperature) are dependent on electrode heating from the tissue, internal cooling by the irrigation fluid, and external cooling from blood flow or open irrigation. The difference between the electrode temperature and interface temperature was greater with the closed loop electrode than with the open irrigation electrode, and the difference increased with higher power and lower blood flow (Table). There was no significant correlation between the peak electrode temperature and the peak interface temperature with the closed loop catheter in low or high blood flow, which limits use of the electrode temperature as a guide of interface temperature. With open irrigation, the additional cooling of the electrode-tissue interface by the fluid exiting the irrigation holes narrows the range of electrode temperature and further decreases the correlation between electrode temperature and interface temperature.

A steam pop is the result of rupture of the tissue surface by steam produced within the tissue. This study found a lower incidence of steam pop with open irrigation compared with the closed loop system for RF applications at 30 W. The reduction in steam pop with open irrigation may be due to greater cooling of the tissue at shallow sites. There was a trend toward lower tissue temperature at 3-mm depth with the open irrigation electrode (Table). This would suggest that most of the steam pops with the closed loop system result from steam formation close to the surface. The incidence of steam pop would be expected to increase at higher power (such as 50 W) for both electrodes.

A recent study in which the closed loop electrode was used in swine hearts found that only 3 of 21 steam pops occurred at electrode temperature <40°C. The authors suggested that maintaining electrode temperature <40°C would reduce the risk of steam pop. However, in the present study 56% of RF applications maintaining just 20 W in low blood flow resulted in an electrode temperature ≥40°C, limiting the use of electrode temperature monitoring to prevent steam pops in low–blood flow areas.

There was no significant relationship between lesion depth and electrode temperature except for RF applications in which the closed loop electrode at 20 W in high blood flow was used. These findings indicate the limited value of using electrode temperature to predict lesion depth during clinical ablation procedures.

The lesion geometry differed between the open irrigation and closed loop systems. With the closed loop system, the diameter of the lesion was greatest close to the surface, especially in low blood flow. With open irrigation, the diameter of the lesion at the surface was significantly smaller than with the closed loop system, and the maximum diameter was displaced 1.6 to 4.2 mm (median 2.8 mm) below the surface, consistent with greater surface cooling (lower electrode-tissue interface temperature).

**Clinical Implications**

The most important clinical implication of this study is the difference in the potential for thrombus formation between the closed loop and open irrigation electrodes, especially in conditions of low blood flow and at higher power. The potentially higher risk of a thromboembolic event with the closed loop electrode is suggested in the following 2 studies. The incidence of stroke or transient ischemic attack was 2.7% in a series of patients undergoing RF ablation of ventricular tachycardia associated with structural heart diseases and 3.2% in another series of patients undergoing ablation of atrial fibrillation. In the second study, reducing RF power on detection of microbubbles eliminated embolic events, suggesting that microbubble formation was a reliable guide to thrombus formation. Importantly, there was no correlation between microbubble formation and electrode temperature. In agreement with our findings, electrode temperature was not a reliable guide to thrombus formation with the closed loop electrode system (Figure 6).

In contrast, there was no occurrence of cerebrovascular embolism in a study of 240 patients undergoing ablation of ventricular tachycardia associated with prior myocardial in-
fraction with the use of the open irrigation catheter.28 Definite conclusions cannot be derived from comparisons between different series, but these clinical observations are in accordance with the findings in our experimental model.

Study Limitations
The primary limitation of this study is that it was performed in a canine thigh muscle preparation instead of a beating heart. This preparation was chosen to control electrode orientation, contact pressure, and local blood flow and allowed the correlation of electrode temperature with interface temperature and temperatures within the tissue. This correlation would be very difficult in a beating heart because of limitations in measuring interface temperature and tissue temperature. Most importantly, it allowed the identification of thrombus on the electrode-tissue interface after each RF application. This preparation also provided the conditions of low blood flow, simulating commonly encountered clinical conditions in which sustained RF power is required to create adequate lesions and either of the 2 types of irrigation catheters would be used (such as ablation of chronic atrial fibrillation and ventricular tachycardia associated with prior myocardial infarction).6,7,15

The findings in previous studies in which the thigh muscle preparation was used have correlated with clinical experience. With the use of a 4-mm nonirrigated electrode, thrombus occurred at interface temperature ≥80°C. Maintaining electrode temperature ≤55°C was required to keep interface temperature <80°C and prevent thrombus.10 Clinical studies have suggested a reduction in electrode temperature to ≤55°C for ablation in the left atrium to minimize the risk of thrombus formation.6

Conclusions
RF lesion parameters were compared between 2 methods of electrode irrigation (closed loop and open irrigation electrodes) at constant power of 20 and 30 W and in low- and high–blood flow conditions. The similar electrode surface area produced similar tissue power, resulting in similar tissue temperatures (3- and 7-mm depths) and lesion depth. The occurrence of thrombus at the electrode-tissue interface correlated highly with interface temperature (≥80°C) and not with electrode temperature. Thrombus occurred frequently with the closed loop electrode (interface temperature ≥80°C), despite low electrode temperature. The interface temperature and the incidence of thrombus were greater in low blood flow, suggesting that local blood flow significantly contributes to electrode-tissue interface cooling with the closed loop electrode. With the open irrigation electrode, interface temperature was low (all ≤71°C) in low blood flow as well as in high blood flow, with no occurrence of thrombus. The low interface temperature indicates that open irrigation provides additional external cooling of the electrode-tissue interface, which is independent of local blood flow.

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Disclosures
Dr Nakagawa is a consultant for Biosense Webster, Inc and Boston Scientific Japan. Dr Jackman is a consultant for Biosense Webster, Inc. Dr Wittkampf has served as an advisor to Endocardial Solutions, Inc., which is now a part of St. Jude Medical. The other authors report no conflicts.

References
Thromboembolism is one of the most feared complications of catheter ablation in the left atrium and ventricle. With conventional radiofrequency (RF) ablation, this risk is small when electrode temperature is limited to $\sim 60^\circ\text{C}$. Two RF ablation systems that use irrigation to cool the electrode to allow greater power application and increased lesion size are now in clinical use: a closed loop system and an open system in which saline washes over the electrode into the blood stream. Parameters to guide use for optimal safety and efficacy are still being defined. Although the operator reads temperature measured from the electrode, this study again demonstrates that tissue temperature can be substantially greater than temperature measured from the electrode with either closed loop or open irrigation. Thrombus formation consistently occurs when the electrode-tissue interface temperature reaches $80^\circ\text{C}$ and unfortunately cannot be predicted from the measured electrode temperature or the change in impedance measured during ablation. In contrast to the closed irrigation system, the electrode-tissue interface temperature never reached $80^\circ\text{C}$ with open irrigation, and therefore no thrombus was produced. We also show that local blood flow over the electrode significantly contributes to electrode-tissue interface cooling with the closed loop electrode. Open irrigation provides additional external cooling of the electrode-tissue interface that is hoped to reduce the risk of thromboembolism during catheter ablation.
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