

Comparison of Lesion Sizes Produced by Cryoablation and Open Irrigation Radiofrequency Ablation Catheters

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Radiofrequency Versus Cryoablation Lesion Sizes. *Introduction:* The relative lesion sizes created by large electrode cryoablation catheter and irrigated radiofrequency (RF) ablation are not known. The purpose of this study was to directly compare lesion sizes created by cryoablation and irrigated RF under controlled conditions.

Methods and Results: Ablation lesions were created in freshly harvested porcine left ventricular myocardium in a blood-filled tissue bath using an 8-mm-tip cryoablation catheter and a 3.5-mm-tip open-irrigated RF ablation catheter. Lesions were created under all permutations of the following conditions: electrode orientation vertical (perpendicular) or horizontal (parallel) to the tissue, electrode contact pressure at 6 or 20 g, and blood flow at 0.2 or 0.4 m/s over the electrode-tissue interface. The largest lesion volumes created with cryoablation were $961 \pm 103 \text{ mm}^3$, compared with the largest lesions volumes created with RF of $680 \pm 48 \text{ mm}^3$ ($P < 0.001$). The 3-way interactions among electrode orientation, contact pressure, and superfusate blood velocity accounted for the variation in lesion volumes for both catheters (both $r^2 = 0.97$, both $P < 0.0001$). The greater contact pressure increased lesion size for both cryoablation and RF. For cryoablation, lesion sizes were increased by the horizontal orientation and by the lower blood flow velocity. For open-irrigated RF, lesion sizes were significantly reduced by the horizontal orientation, however.

Conclusions: Depending on conditions of electrode orientation, contact pressure, and blood velocity, either 8-mm-tip cryoablation or open-irrigated RF may produce the larger lesion volumes. Open-irrigated RF lesion sizes are reduced in the horizontal catheter orientation. (*J Cardiovasc Electrophysiol*, Vol. 19, pp. 528-534, May 2008.)

cryoablation, open-irrigated radiofrequency ablation, lesion size

Introduction

Although cryoablation has the advantages of absolute catheter stability during energy delivery and the potential to produce transient electrophysiologic effects, there have been reduced success rates reported for some clinical applications.¹⁻⁵ This lower efficacy has been attributed to smaller lesion sizes than are possible with radiofrequency (RF) ablation.^{1,2} Lesion sizes created by catheter-based cryoablation are reportedly similar or smaller than noncooled RF lesions and smaller than irrigated RF lesions.^{1,2} Data from direct comparisons of cryoablation and RF ablation lesion sizes are very limited, however.^{1,2} The lesion sizes created by both cryoablation and RF are dependent on many factors, including electrode size, contact pressure, and the convective thermal effects of local blood flow.⁶⁻¹⁶ In vivo comparisons of cryoablation and RF lesion sizes are not able to control for all of these variables. From these in vivo studies, it is unknown

if the different lesion sizes are related to non-uniformity of these variables in vivo or to differences in the maximal lesion sizes possible with either energy source. The purpose of this study is to directly compare the lesion sizes created by commercially available cryoablation and open-irrigated RF ablation systems under strictly controlled experimental conditions. The open-irrigated ablation system was chosen because it has been shown to produce comparable lesion sizes with large tip catheters or closed irrigation catheters and is favored clinically when large lesions are desired due to fewer impedance rises and less coagulum formation.^{10,11,15-17} An 8-mm-tip cryoablation was chosen because this produces the largest lesion sizes for this energy source.¹²

Methods

Tissue Preparation

Fresh porcine hearts were harvested from pigs (30–35 kg) under general anesthesia according to a protocol approved by our Institutional Animal Care and Use Committee. The hearts were maintained in iced saline until sections of left ventricle (approximately $2 \times 2 \text{ cm}$ and 1-cm transmural thickness) were cut and pinned to the floor of a temperature-controlled bath (37°C). The bath was filled with heparinized blood collected from the animal at the time of cardiectomy. The bath rested on a waterproof digital scale with 2-g resolution (Fig. 1). By rezeroing the scale for each experiment, a precise amount of electrode contact pressure could be applied with

Cryoablation generator and/or catheters for this study were lent by CryoCath and Biosense-Webster.

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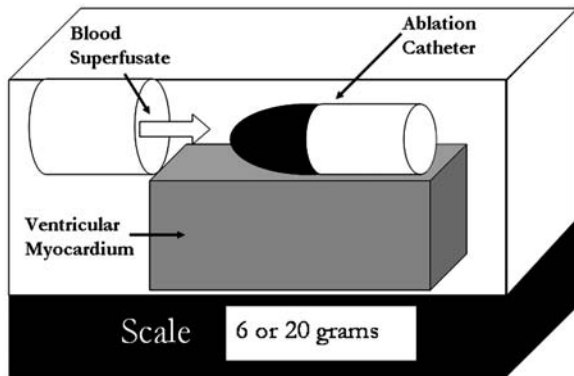


Figure 1. Schematic of tissue preparation. The blood-filled tissue bath rested on a digital scale that when rezeroed before placement of the catheter allowed precise control over the degree of contact pressure. The ablation electrode is shown in the horizontal position.

the catheters mounted in a micromanipulator.¹² The tissue was allowed to equilibrate to 37°C before ablation lesions were delivered. Blood from the bath was directed over the electrode-tissue interface through a plastic cannula (1-cm internal diameter) using a roller pump.

Cryoablation

A cryoablation catheter (Freezor Max 5, 9F diameter, 8-mm electrode length, CryoCath, Quebec, Canada) was positioned on the tissue surface using a micromanipulator. This catheter has a single thermocouple embedded on the inner surface of the tip of the electrode. The catheter utilizes the Joule-Thomson principle of refrigerant (nitrous oxide) expansion within the catheter tip to produce cooling. An irrigated, warmed (37°C) water jacket was fitted over the body of the catheter to simulate percutaneous use. Cryoablation (CryoCath console) was then delivered with target electrode temperature of -75°C for 300 seconds. This duration has been reported to produce maximal lesion dimensions during catheter cryoablation.^{12,13}

Radiofrequency Ablation

RF ablation was delivered with an open irrigation RF catheter (3.5 mm tip, Biosense-Webster Celcius Thermocool) and Stockert generator (BioSense-Webster, Diamond Bar, CA, USA). The catheter has a thermocouple embedded in the tip of the ablation electrode. Six side holes arranged symmetrically around the circumference of the electrode allow for irrigation of the electrode with normal saline. The saline was injected into the catheter via an external pump at the rate of 30 cc/min. Because the saline irrigation was pumped into the blood bath, the blood was replaced in the bath every 2–3 experiments. No systematic changes in impedance or lesion sizes were noted that could be attributable to a dilutional effect on the blood bath with consecutive experiments. After positioning the electrode against the tissue using a micromanipulator, RF current was delivered beginning at 25 W. Power was rapidly increased manually over 20–30 seconds to achieve an electrode temperature of 42°C or maximal power delivery of 50 W. This power setting was then continued for the remainder of the RF delivery and was recorded as the power level for statistical analysis. Sustained temperatures greater than 42°C frequently produced steam “pops” in this

preparation. The RF current was delivered for a total of 90 seconds allowing for at least 60 seconds of delivery at the maximal power. The long duration of total RF delivery was used to ensure that differences in lesion sizes were not due to insufficient energy delivery. The ablation impedance was recorded from the RF generator at the onset of ablation and at 1 second before the termination of RF delivery.

Protocols

Experiments for both cryoablation and RF were performed with the ablation electrodes either vertical (perpendicular) or horizontal (parallel) to the tissue, with blood flow over the electrode tissue interface at either 0.2 m/s or 0.4 m/s and with electrode contact pressure of either 6 or 20 g. For both cryoablation and RF ablation, 10 experiments were performed for all permutations of the experimental conditions (vertical vs. horizontal orientation, blood flow 0.2 or 0.4 m/s, contact pressure 6 or 20 g) for a total of 160 experiments. After lesions were created, the tissue was sectioned and stained with nitroblue tetrazolium (0.5 mg/mL). The lesion dimensions were measured using a digital caliper (0.01-mm resolution).

Data Acquisition and Analysis

The lesion geometries produced by the two ablation modalities had similar geometric shapes. For both catheters, lesions created in the vertical orientation were nearly symmetric in length and width. For the horizontal orientation the lesions from both catheters had longer dimensions along the axis of the electrode, compared with the dimension perpendicular to the electrode axis. This asymmetry was exaggerated for the 8-mm cryoablation catheter. For all lesions by both catheters, there was a slight reduction (about 0.5 mm) in the lesion dimensions measured at the surface compared to the same dimension measured 0.5–0.75 mm beneath the surface. This effect has been well described for cryoablation and irrigated RF catheters.^{7,8,10,17} Lesion volumes were calculated as half the volume of an oblate spheroid using the formula: lesion volume = $1/2 [4/3 \pi d(l/2)(w/2)]$ in which l = maximal lesion length, w = lesion width, and d = depth.¹² Electrode temperatures reported in this study represent the values displayed by the generators 2 seconds before termination of ablation.

Statistics

All values are reported as mean \pm SD. Paired comparisons between independent groups were made with the least square difference test to assure that an $\alpha < 0.05$ was maintained for these multiple comparisons. The effects of electrode orientation, contact pressure, superfusate blood velocity, and associated interactions on lesion size were assessed using analysis of variance. Resulting factors predicting lesion sizes were then described by fitting a linear regression model. A $P < 0.05$ was considered significant. Previous work with this preparation shows that 10 experiments per group has a power of 0.8 to detect a 54 mm³ difference in lesion volume between two groups.¹²

Results

The data for lesion dimensions for each catheter under all permutations of the experimental conditions are shown in Tables 1 and 2 and Figures 2 and 3.

TABLE 1
Radiofrequency Ablation

	Horizontal 20 g, 0.2 m/s	Horizontal 20 g, 0.4 m/s	Horizontal 6 g, 0.2 m/s	Horizontal 6 g, 0.4 m/s	Vertical 6 g, 0.2 m/s	Vertical 6 g, 0.4 m/s	Vertical 20 g, 0.2 m/s	Vertical 20 g, 0.4 m/s
Lesion depth (mm)	6.3 ± 0.5*††	5.9 ± 0.4*††	5.7 ± 0.8*§	5.0 ± 0.2*†	6.0 ± 0.3§	8.5 ± 0.5*	8.4 ± 0.6*†	8.7 ± 0.4*
Volume (mm ³)	245 ± 22*†§	171 ± 24*††	182 ± 32*†§	112 ± 9†	290 ± 24§	521 ± 44*	600 ± 59*†§	680 ± 48*†
Lesion length	11.6 ± 0.7*†§	9.9 ± 1.0*††	10.5 ± 1.4*†§	8.7 ± 0.4*†	11.3 ± 0.6*§	12.4 ± 0.8*	14.1 ± 0.8*†§	16.0 ± 0.5*†
Lesion width	7.4 ± 0.2*††§	6.6 ± 0.2*††	6.7 ± 0.3*††§	5.9 ± 0.3*†	8.2 ± 0.4§	9.5 ± 0.5*	9.8 ± 0.3†§	9.4 ± 0.3*
Power (W)	50 ± 0†	50 ± 0	49 ± 1†	50 ± 0	47 ± 2§	50 ± 0	44 ± 3†§	49 ± 2
Temperature (°C)	41 ± 1	41 ± 2	39 ± 2†	38 ± 1	42 ± 2§	39 ± 1†	41 ± 3	42 ± 3
Impedance (ohms)	98 ± 3	99 ± 1†	101 ± 5†	99 ± 3	93 ± 3§	99 ± 3	97 ± 4†	98 ± 5
Change impedance (ohms)	17 ± 4	19 ± 3	20 ± 6†	20 ± 3	13 ± 5	16 ± 3	13 ± 3	16 ± 6

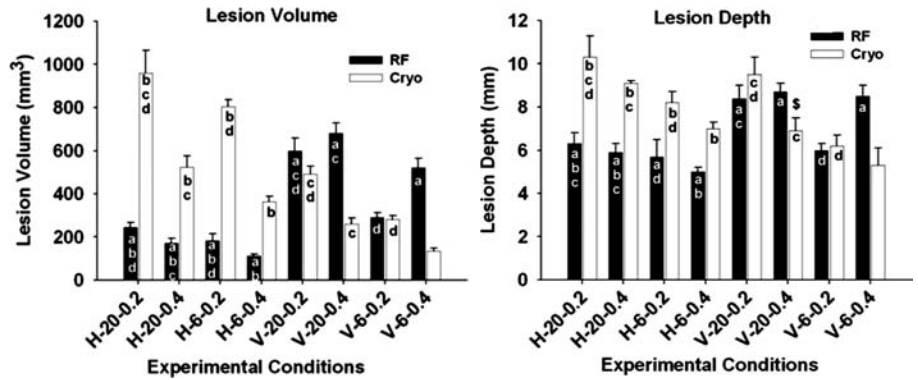
*P < 0.05 vs. same conditions except cryoablation (see Table 2), †P < 0.05 vs. same conditions except vertical orientation, ‡P < 0.05 vs. same conditions except 6-g contact pressure, §P < 0.05 vs. same conditions except 0.4 m/s blood velocity.

TABLE 2
Cryoablation

	Horizontal 20 g, 0.2 m/s	Horizontal 20 g, 0.4 m/s	Horizontal 6 g, 0.2 m/s	Horizontal 6 g, 0.4 m/s	Vertical 6 g, 0.2 m/s	Vertical 6 g, 0.4 m/s	Vertical 20 g, 0.2 m/s	Vertical 20 g, 0.4 m/s
Lesion depth (mm)	10.3 ± 1.0*††	9.1 ± 0.1*†	8.2 ± 0.5*††	7.0 ± 0.3*	6.2 ± 0.5†	5.3 ± 0.8	9.5 ± 0.8††	6.9 ± 0.6†
Volume (mm ³)	961 ± 103*††	523 ± 52*†	804 ± 33*†	363 ± 25*	281 ± 19†	135 ± 14	492 ± 37††	260 ± 29†
Temperature (°C)	- 88 ± 1.0*††	-87 ± 1*	-88 ± 1*†	-87 ± 1	-85 ± 1†	-86 ± 1	-85 ± 1.7†	-86 ± 1
Lesion length	14.9 ± 1.2*†	12.1 ± 0.8*	14.9 ± 0.6*†	12.3 ± 0.4*	10.5 ± 1.1†	7.7 ± 0.8	10.5 ± 0.7††	8.9 ± 0.4†
Lesion width	14.5 ± 0.7*††	10.4 ± 0.4*	13.6 ± 0.4†	10.1 ± 0.2*	8.5 ± 0.4†	6.6 ± 0.6	9.6 ± 0.4††	8.1 ± 0.4†

*P < 0.05 vs. same conditions except vertical orientation, †P < 0.05 vs. same conditions except 6-g contact pressure, ‡P < 0.05 vs. same conditions except 0.4 m/s blood velocity.

Figure 2. Lesion volumes and depths for irrigated RF ablation (dark bars) and cryoablation (white bars). Error bars represent one standard deviation. For the experimental conditions: H = horizontal orientation; V = vertical orientation; 20 = 20-g contact pressure, 6 = 6-g contact pressure, 0.2 = 0.2 m/s blood velocity, 0.4 = 0.4 m/s blood velocity. ^a*P* < 0.05 versus same conditions except cryoablation, ^b*P* < 0.05 versus same conditions except vertical orientation; ^c*P* < 0.05 versus same conditions except 6-g contact pressure, ^d*P* < 0.05 versus same conditions except 0.4 m/s blood velocity.



Cryoablation Lesions

For cryoablation, lesion depth ranged from 5.3 ± 0.8 mm to 10.3 ± 1.0 mm (*P* < 0.001) and lesion volume ranged from 135 ± 14 mm³ to 961 ± 103 mm³ (*P* < 0.001) depending on experimental conditions (Table 2 and Figs. 2 and 3). Lesion volume was related to catheter orientation, contact pressure, superfusate flow rate, and the 3-way interactions among these variables (*r*² = 0.97, *P* < 0.001). Horizontal catheter orientation and greater contact pressure were associated with larger lesion volumes, whereas higher blood flow velocity was associated with smaller lesion volumes (Tables 2 and 3, Fig. 2). The qualitative effects of these variables were consistent throughout all interactions, that is, a change in any one variable always increasing or decreasing lesion sizes (Fig. 4). Electrode temperature was not a significant determinant of lesion volume in the regression model (*P* = 0.38). Lesion depth was predicted by the same factors as lesion volume (Table 4). Electrode temperature was not a predictor of lesion depth in the regression model (*P* = 0.19, Table 4).

RF Lesions

For RF ablation, lesion depth ranged from 5.0 ± 0.2 mm to 8.7 ± 0.4 mm (*P* < 0.001) and lesion volume ranged from 112 ± 9 mm³ to 680 ± 48 mm³ (*P* < 0.001) depending on experimental conditions (Table 1, Figs. 2 and 3). RF lesion volume was related to electrode orientation, contact pressure, and blood flow velocity, and the 3-way interaction among these variables (Table 3, *r*² = 0.97, *P* < 0.001). For RF ablation, the vertical orientation was associated with greater lesion volume, compared with the horizontal orientation (Table 1 and 3, Fig. 2). RF lesion volume was not predicted by either electrode temperature or power (both *P* ≥ 0.30, Table 3).

The effect of blood velocity on RF lesion volume was dependent on catheter orientation (Table 1, Figs. 2 and 4). With the horizontal orientation, higher blood flow velocity reduced lesion volume, whereas in the vertical orientation higher blood flow velocity increased lesion volume (Table 1 and Fig. 4). In the vertical orientation, the higher blood velocity was associated with greater RF power delivery, compared with the lower blood velocity (Table 1, all *P* < 0.05). In the horizontal orientation, power delivery was at or near maximal for all conditions despite the creation of smaller lesions (Table 1). There were no consistent differences in electrode temperature, impedance, or change in impedance among the different conditions (Table 1).

All of the same factors predictive of RF lesion volume were also predictive of RF lesion depth (Table 4). Lesion depth was not predicted by RF power or electrode temperature (Table 4).

Comparison of RF and Cryoablation Lesion Sizes

There were significant differences in lesion volume and dimensions created by the RF and cryoablation catheters for almost all conditions (Tables 1 and 2, Fig. 2). The largest lesion depths (10.3 ± 1.0 mm) and volumes (961 ± 103 mm³) were created with the cryoablation catheter in the horizontal orientation with 20-g contact pressure and 0.2 m/s blood velocity. This compares with a depth of 6.3 ± 0.5 mm and a volume of 245 ± 22 mm³ for the open-irrigated RF catheter under the same conditions (both *P* < 0.05). Lesion volumes were always greater for the cryoablation catheter in the horizontal orientation, compared to the RF catheter in the horizontal orientation (Tables 1 and 2, Fig. 2, all *P* < 0.05). In contrast, lesion volumes were equal or greater for the RF catheter, compared to cryoablation with the catheters in the

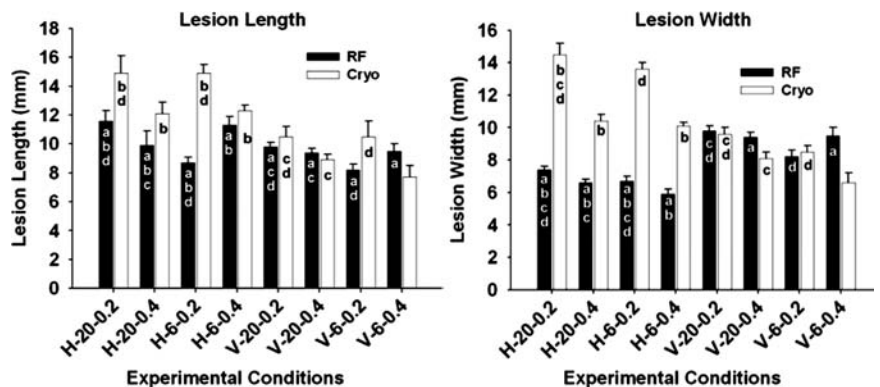


Figure 3. Lesion lengths and widths for irrigated RF ablation (dark bars) and cryoablation (white bars). Error bars represent one standard deviation. Abbreviations and annotations as per Figure 2.

TABLE 3
Predictors of Lesion Volumes

	Open-Irrigated RF		Cryoablation	
	Parameter Estimate	P Value*	Parameter Estimate	P Value*
Three-way interactions				
Orientation + contact pressure + blood velocity	130.5	<0.001	87.8	0.041
Two-way interactions				
Orientation + contact pressure	98.7	<0.001	-32.2	0.29
Orientation + blood velocity	170.2	<0.001	195.8	<0.001
Contact pressure + blood velocity	-132.4	<0.001	-88.3	0.004
One-way interactions				
Orientation (horizontal)	-509.8	<0.001	256.1	<0.001
Contact pressure (6 g)	-165.1	<0.001	-124.3	<0.001
Blood velocity (0.2 m/s)	-96.4	<0.001	236.3	<0.001
Electrode temperature	-2.1	0.30	-5.1	0.38
Power	-2.3	0.39	NA	NA

P values associated with *t*-test of significance for parameter estimate in fitted linear regression model.

vertical orientation (Tables 1 and 2, Fig. 2). Electrode orientation had the greatest influence on both lesion volume and depth for the RF catheter (parameter estimates, Tables 3 and 4). In contrast, blood velocity and orientation shared dominating influences on cryoablation lesion volume and depth (parameter estimates, Tables 3 and 4).

Discussion

The main findings of this study are that under controlled conditions: (1) both RF and cryoablation lesion sizes are influenced by catheter orientation, contact pressure, and velocity of blood flow over the electrode tissue interface; (2) the relative size of lesions created with these catheters depends upon the conditions under which energy is delivered; (3) catheter orientation and blood flow can have opposite effects on lesion size produced by RF and cryoablation catheters; and (4) lesion volumes produced by this open irrigation RF catheter are significantly smaller in the horizontal, as compared with vertical, catheter orientations.

It has been reported that cryoablation lesion sizes may be comparable with those of noncooled RF ablation but are smaller than those resulting from irrigated RF ablation.¹⁻⁵ Although our study demonstrates that under controlled conditions a commercially available cryoablation system can produce larger lesions than open-irrigated RF ablation, the relative lesion sizes depend on the conditions under which the lesions are created. Both RF and cryoablation are sensitive to electrode orientation, contact pressure, and convective

thermal effects from blood flow over the electrode-tissue interface.^{12,14,15}

Electrode Orientation

For cryoablation, the horizontal electrode orientation increases lesion size probably by enhancing thermal coupling with the tissue and by reducing the portion of the electrode exposed to convective warming from the blood pool.¹² The effect of electrode orientation on lesion size has not been previously reported for the open-irrigated RF electrode design.^{7,8,10,11,17} Surprisingly, our study shows that the horizontal electrode orientation produces significantly smaller lesion volumes than the vertical orientation.¹⁷ The reason for this finding is not clear from our study. With this open irrigation design, the irrigation fluid is discharged from six ports around the circumference of the electrode. In the vertical orientation, the fluid issues from the electrode above its interface with the tissue. In the horizontal orientation, however, some of these jets of irrigation fluid are discharged between the electrode and the tissue. Possibly, these fluid jets directly cool the tissue excessively or reduce the electrical coupling of the electrode with the tissue. This latter effect may shunt current through the blood pool and not the tissue. The greater electrode surface area in contact with the tissue may result in excessive tissue cooling regardless of whether the electrode is irrigated internally or externally. Possibly, the holes in the electrode surface alter the local electrical current density in an unfavorable manner. Our findings that the horizontal RF electrode failed to reach target temperature despite maximal

Figure 4. Graphical representations of interactions among electrode orientation, contact pressure, and blood velocity on lesion volume for cryoablation and open-irrigated RF ablation. For cryoablation, the qualitative effect of contact pressure and blood velocity are the same regardless of electrode orientation. For open-irrigated RF ablation, the effects of blood velocity are opposite for horizontal and vertical electrode orientations.

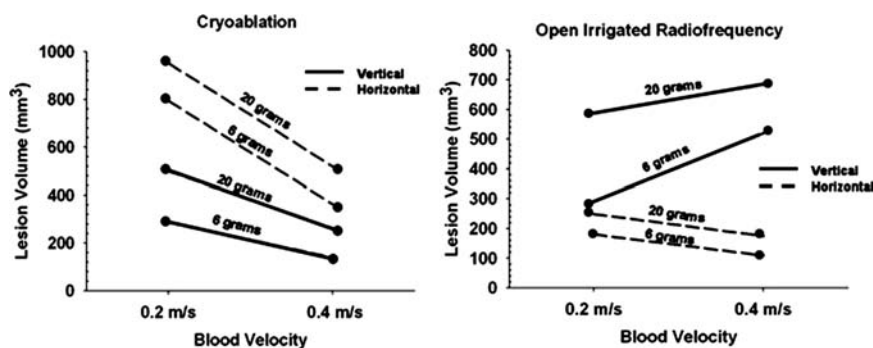


TABLE 4
Predictors of Lesion Depth

	Open-Irrigated RF		Cryoablation	
	Parameter Estimate	P Value	Parameter Estimate	P Value
Three-way interactions				
Orientation + contact pressure + blood velocity	2.35	<0.001	1.62	0.006
Two-way interactions				
Orientation + contact pressure	-0.56	0.08	-0.43	0.29
Orientation + blood velocity	0.78	<0.047	-1.12	0.01
Contact pressure + blood velocity	-2.09	<0.001	-1.55	<0.001
One-way interactions				
Orientation (horizontal)	-2.83	<0.001	2.26	<0.001
Contact pressure (6 g)	-0.26	0.27	-1.70	<0.001
Blood velocity (0.2 m/s)	-0.38	0.23	2.44	<0.001
Electrode temperature	0.01	0.74	0.11	0.19
Power	-0.11	0.77	NA	NA

P values associated with *t*-test of significance for parameter estimate in fitted linear regression model.

power and that increased blood flow over the electrode tissue interface further reduced lesion size are consistent with limited tissue heating by any of these proposed mechanisms. The clinical relevance of this finding is evident in a recent clinical study using this same open-irrigated RF catheter.¹⁸ This study found that tissue overheating and steam “pops” are much more common when the catheter is in the vertical orientation during left atrial ablation.¹⁸

Contact Pressure

Contact pressure is known to influence the size of RF lesions, and the importance of contact pressure has been recently described for cryoablation as well.^{12,14} Although unpublished, there may be some impression among the ablation community that cryoablation is contact insensitive. This impression may stem from the idea that ice formed about the cryoablation electrode acts as a thermal conductor even when contact with the tissue is poor. Our study is consistent with prior work that demonstrates that firm tissue contact improves lesion size for cryoablation.¹²

Blood Velocity

Our study reiterates the consistent detrimental effect of convective warming on cryoablation and reveals a variable effect of convective cooling on open-irrigated RF ablation. For the RF electrode in the vertical orientation, the higher blood velocity enhanced electrode cooling resulting in greater power delivery and larger lesion sizes. In the horizontal orientation, the greater blood velocity actually reduced lesion sizes. This is believed to be the result of reduced tissue heating in the horizontal orientation even at maximal power. The higher local blood velocity then could not have served to increase power delivery, but instead only produced additional tissue cooling.

Limitations

The relevance of in vitro experiments to clinical procedures can be questioned. Motion of the RF catheter over the myocardial surface during the cardiac cycle is absent in this study but may be a factor that enhances RF lesion size in vivo. The same mathematical equation was used to estimate lesion volumes for both RF and cryoablation lesions. This same equation is accurate for a broad range of geometric shapes

from spheres to ellipsoids and prolate spheroids. If differences exist between the energy sources in the fit of the actual lesion geometry to the model geometry, systematic errors in the relative lesion volumes may be created. The lesion volumes obtained in our study are comparable with those in previous reports, however.^{7,8,10,11,13,17} Only acute lesion sizes were determined. The relative sizes of chronic lesions created by these ablation modalities cannot be determined from this work; however, the strict control of variables achieved in this study is not possible with in vivo preparations.

Clinical Implications

The lesion sizes created by RF and cryoablation both depend heavily on electrode orientation, local blood flow, contact pressure, and interactions among these variables. The response of these two ablation modalities to electrode orientation and local blood velocity may be complimentary. For both energy modalities electrode orientation is a primary determinant of lesion sizes. Optimizing the electrode orientation in relation to the tissue may improve clinical success rates. Comparisons of lesion sizes by different energy sources are complex, and should consider all variables that are likely to affect lesion sizes.

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