Importance of Catheter Contact Force during Irrigated Radiofrequency Ablation: Evaluation in a Porcine *Ex Vivo* Model Using a Force-Sensing Catheter

ARAVINDA THIAGALINGAM, M.B., CH.B., PH.D.,* ANDRE D'AVILA, M.D.,*
LORI FOLEY, B.S., J. LUIS GUERRERO, B.S., HENDRIK LAMBERT, PH.D.,‡
GIOVANNI LEO, M.S.,‡ JEREMY N. RUSKIN, M.D.,* and VIVEK Y. REDDY, M.D.*

From the *Cardiac Electrophysiology Department; †Cardiac Ultrasound Laboratory and Cardiovascular Surgical Unit, Massachusetts General Hospital, Boston, Massachusetts, USA; and ‡Endosense SA Endosense SA 42, Chemin de Grand-Puits, Geneva, Switzerland

Effect of Ablation Electrode Contact Force. ***Introduction:*** **Ablation electrode–tissue contact has been shown to be an important determinant of lesion size and safety during nonirrigated ablation but little data are available during irrigated ablation. We aimed to determine the importance of contact force during irrigated-tip ablation.**

Methods and Results: **Freshly excised hearts from 11 male pigs were perfused and superfused using fresh, heparinized, oxygenated swine blood in an ex vivo model. One-minute ablations were placed using one of 3 different power control strategies (impedance control—15 Ω target impedance drop, and 20 W or 30 W fixed power) and 3 different contact forces (2 g, 20 g, and 60 g) to give a grid of 9 ablation groups. The force sensing catheter (Tacticath^{TM}, Endosense SA) was irrigated at 17 mL/min for all of the ablations.**

Of a total 101 ablations, no thrombus formation was noted but popping was seen in 17 lesions. The lesion depth and incidence of pops was 5.0 ± 1.3 mm/0%, 5.0 ± 1.6 mm/10% and 6.7 ± 2.5 mm/45% for the 15 Ω, 20 W, and 30 W groups ($P < 0.01$), respectively, and 4.4 ± 1.8 mm/3%, 5.8 ± 1.6 mm/17% and 6.6 ± 2.0 mm/37% for the 2 g, 20 g, and 60 g groups, respectively ($P < 0.01$). The impedance drop in the first 5 seconds was significantly correlated to catheter contact force: 9.7 ± 9.9 Ω, 22.3 ± 11.0 Ω, and 41.7 ± 22.1 Ω, respectively, for the 2 g, 20 g, and 60 g groups (Pearson's $r = 0.65$, $P < 0.01$).

Conclusion: **Catheter contact force has an important impact on both ablation lesion size and the incidence of pops.** *(J Cardiovasc Electrophysiol, Vol. pp. 1-6)*

ablation, arrhythmia, atrial fibrillation, irrigated-tip catheter, ventricular tachycardia

Introduction

Irrigated-tip catheter ablation allows more power to be delivered, therefore enabling larger ablation lesions to be created,[1] but also decreases the accuracy of catheter tip temperature monitoring.[2] It is not clear which parameters are useful to monitor during irrigated-tip ablation to safely create the largest possible lesion. Catheter contact force has been shown to be an important determinant of lesion size and incidence of ablation complications during nonirrigated-tip catheter ablation, but there are little data on the effect of catheter contact force during irrigated-tip catheter ablation. Since accuracy of temperature monitoring is reduced during irrigated ablation, we hypothesized that further information on the interaction of catheter contact force with delivered power on irrigated-tip radiofrequency (RF) ablation efficacy and safety would be particularly relevant.

Recently, a novel externally irrigated-tip catheter has been introduced that allows monitoring of *in vivo* catheter-tissue contact force using 3 embedded optical sensors. This catheter was used to perform an *ex vivo* study investigating the effect of catheter contact force using various ablation strategies with safety (i.e., prevention of steam pops and thrombus formation) as a prime consideration.

Methods

Procedural Details

The experimental protocol was approved by the Massachusetts General Hospital Subcommittee on Research Animal Care. *Ex vivo* ablation was performed on 11 male pigs (weight 47.1 ± 4.1 kg). After an overnight fast and premedication with acetylpromazine (1.1 mg/kg), animals were anesthetized and ventilated mechanically with 100% oxygen. General anesthesia was maintained with isoflurane 1.5–3%. A left thoracotomy was performed and the pig was anticoagulated with 10,000 U heparin (IV). The heart was then

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Address for correspondence: Vivek Y. Reddy, M.D., Cardiac Arrhythmia Service, Mount Sinai School of Medicine, One Gustave L. Levy Place, Box 1030, New York, NY 10029. Fax: 646-537-9691; E-mail: Vivek.reddy@mountsinai.org

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excised and immediately chilled in iced saline. Blood was drained via a suction catheter from the thoracic cavity into a heparinized (10,000 U) reservoir.

As previously described, all of the ablations were performed on the endocardial surface of the *ex vivo* perfused heart preparation within a tissue bath (see Fig. 1 for a schematic representation).[3] A standard cardiopulmonary bypass pump circulated the heparinized blood through a heat exchanger, oxygenator and tissue bath at a rate of 3 L/min. The heat exchanger was adjusted to ensure that the blood temperature was maintained at 37°C. The coronary arteries were retrogradely perfused at 125 mL/min via a catheter in the ascending thoracic aorta. The posterior left ventricle was opened with a vertical incision from below the circumflex artery to the apex and a horizontal incision, below the circumflex artery.

Force Sensing Catheter

All ablations were performed with the force sensing catheter (Tacticath^{TM}, Endosense SA), which is a 7 French, 3.5 mm tip open irrigation catheter. Except where specified, the catheter was continually irrigated at 17 mL/min with 0.9% NaCl. The catheter has embedded 3 optical sensing fibers that allow measurement of both the magnitude and direction of the catheter contact force (see Fig. 1).

A RF generator (Stockert 70, Biosense Webster, USA) was used to deliver RF current. A standard dispersive electrode (E7506, Valley Lab, Boulder, CO, USA) was placed within the ablation tank to provide the return path for RF current. The RF generator was connected to an IBM–PC compatible computer via a serial data cable, and data (impedance, temperature, and power) was logged 10 times per second using the EpWin software (version 5.011, Biosense Webster, USA). The data were then exported into CSV files and analyzed using custom software written in the Matlab programming language.

Left Ventricular Ablations

Ablations were performed for 1 minute using one of 3 different power control strategies (impedance control—to a 15 Ω target impedance drop, and 20 W or 30 W fixed power) and 3 different contact forces (2 g, 20 g, and 60 g) to give a grid of 9 ablation groups.

15 Ω Impedance drop: The RF generator was set to power control with an initial power of 15 W and then titrated to achieve a target 15 Ω impedance drop. The initial impedance that was used to calculate the 15 Ω drop was measured 2 seconds after the start of the ablation (note that this value is lower than the value measured before commencing RF power or the first impedance recorded by the RF generator on the data file at 0.1 second). The power was increased by 5 W every 5 seconds if the target impedance drop had not been achieved. If the impedance drop exceeded 25 Ω the power was reduced by 5 W.

The desired catheter-tissue contact force (2, 20, and 60 g) was applied using a lever system that was attached to the distal tip of the catheter. The accuracy of the lever was checked before each set of ablations using a digital scale.

A total of 9 ablation lesions (i.e., 1 ablation lesion from each protocol group) were created on the left ventricular endocardium of each heart. Ablation sites were chosen to ensure that the lesions did not overlap. If there was insufficient endocardial surface to allow all of the ablation lesions to be placed without risk of lesion overlap, only 8 ablation lesions were delivered. The ablation was terminated by the Stockert RF generator in the event of excessive impedance rise. Each ablation lesion site was then examined for the presence of thrombus. A numbered marker was then sutured

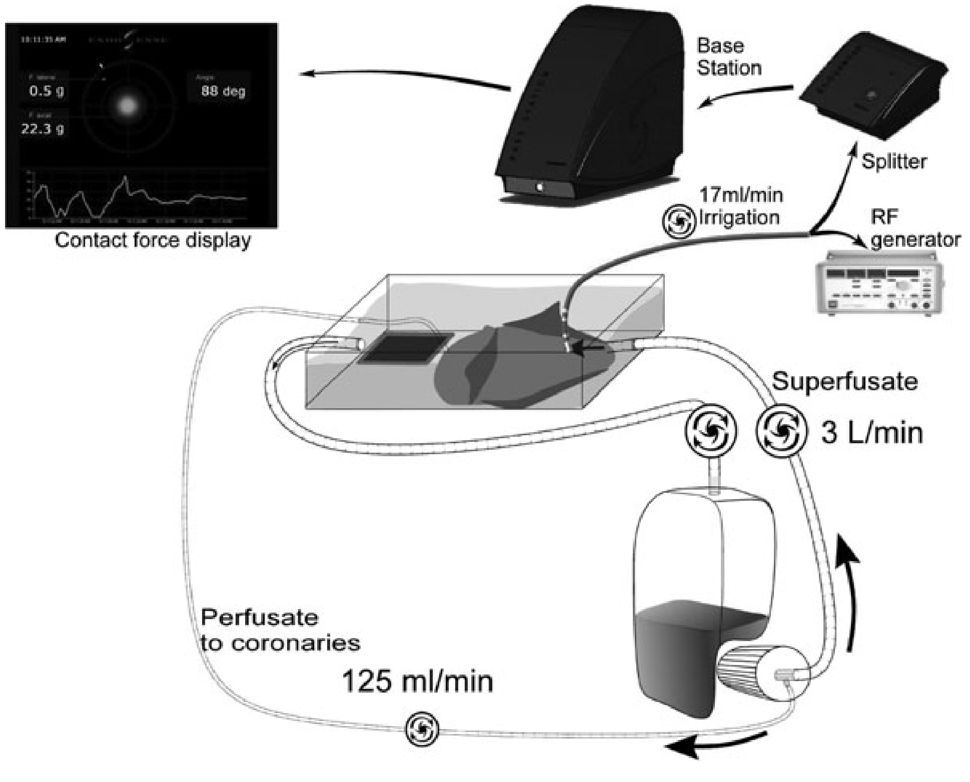

Figure 1. *Schematic of the ex vivo preparation. Fresh oxygenated blood was superfused over the endocardial surface of the left ventricle at 3 L/min. The force sensing catheter catheter was orientated perpendicularly to the endocardial surface during RF ablation using a calibrated scale to apply varying levels of force (2, 20, and 60 g). The catheter was connected through the splitter unit simultaneously to the RF generator and the force sensing base system.*

on the endocardial surface to allow the lesion to be accurately identified.

Each ablation site was dissected out as a block and bisected through the center of the ablation along its long axis and then incubated for 30 minutes using a viability stain to enhance lesion definition (triphenyltetrazolium choride 1%). The ablation lesion could be clearly identified as a white, nonstaining zone, surrounded by a border zone that often exhibited hyperpigmentation. We measured the ablation lesion as only the white (nonviable) tissue. The ablation lesions were photographed using a digital camera and macro lens (Nikon D50, Micro Nikkor 60 mm f2.8, Nikon Corporation, Melville, NY, USA). The lesion characteristics (lesion depth and maximum lesion width) were measured from the digital images using a custom program written in Matlab^{TM} (Version 6.0, The Mathworks, Natick, MA, USA).

Statistical Analysis

Statistical analysis was performed using R for Mac OS X (Version 2.5.1: The R Foundation for Statistical Computing, http://www.R-project.org.). Except where stated otherwise, data are reported in the tables as means ± standard deviations. Student's *t*-test was used to test the difference between the means. Tukey's honest significant difference (HSD) was used for multiple comparisons between ablation groups.

Results

A total of 101 RF ablation lesions were created using the 9 ablation protocols.

Ablation Characteristics by Ablation Protocol

The ablation duration was 60 seconds in all of the groups except the 30 W/60 g group in which 6 of 10 ablation lesions were automatically terminated early by the RF generator due to excessive impedance rise (mean duration 45.6 ± 13.9 seconds). The mean power varied from 12.6 ± 1.7 W to 27.6 ± 1.7 W in the 15 Ω/60 g and 30 W/60 g groups, respectively. There was a significantly lower power required in the 15 Ω impedance control groups with higher contact force: 19 ± 4.5 W for 2 g, 13.6 ± 1.2 W for 20 g, and 12.6 ± 1.7 W for 60 g contact force ($P < 0.001$). See Table 1 for detailed results of average power across the 9 groups. See Figure 2 for lesion parameters and ablation complication data summarized by ablation group and Figure 3 for ablation parameters by ablation group.

TABLE 1

The Actual Delivered Power and Maximum Temperature is Given for Each of the 9 Ablation Groups

	Power Titration Strategy		
Contact Force	**15 Ω drop**	**20 W**	**30 W**
2 g	19 ± 4.5 W 45.1 ± 5.3°C	17.5 ± 1 W 42.3 ± 2.7°C	25.1 ± 3.2 W 47.4 ± 5.7°C
20 g	13.6 ± 1.2 W 45.2 ± 4.3°C	18.5 ± 1.3 W 45.2 ± 4.4°C	25.6 ± 1.6 W 51.8 ± 6.2°C
60 g	12.6 ± 1.7 W 43.2 ± 3.5°C	18.5 ± 0.8 W 48.7 ± 5.1°C	27.6 ± 1.7 W 52.2 ± 5.7°C

The power was titrated in the impedance control strategy to achieve a 15 Ω impedance drop resulting in a higher delivered power in the low contact (2 g) group than the moderate or high contact groups. The actually delivered power was constant in the fixed power groups, as expected, and marginally lower than the programmed power.

Ablation at ''Moderate'' Catheter Contact Force (20 g)

Ablation lesions created using ''moderate'' (20 g) force created midsized ablation lesions (8.3 mm wide by 5.2 mm deep) without any incidence of pops using the 15 Ω impedance controlled strategy or 20 W fixed power. However, higher power (30 W fixed power) created significantly larger ablation lesions (12.4 mm wide × 7.1 mm deep) with a high rate of popping phenomena (50%).

Ablation at ''Low'' Catheter Contact Force (2 g)

Ablation lesions created using ''low'' (2 g) force created significantly smaller ablation lesions in comparison with moderate catheter contact force (lesion depth: $P = 0.014$ Tukey HSD) without any pops. However, higher power (30 W fixed power) low contact ablation created lesions that were comparable in size to ablation with moderate power, moderate contact but with a 9% risk of pops (high power low contact lesions 9 × 5.2 mm vs 8.8 × 5.1 mm for moderate power moderate contact).

Ablation at ''High'' Catheter Contact Force (60 g)

Ablation lesions created using ''high'' (60 g) force created large ablation lesions in comparison (lesion depth: $P = 0.2$ in comparison with moderate catheter contact and $P < 0.001$ in comparison with low contact force Tukey HSD). At 20 W power, lesion size was 7.7 × 3.8 for low contact, 8.8 × 5.1 for moderate contact, and 11.0 × 6.2 for high contact force. There was a high incidence of pops in the 2 fixed power ablation groups (30% for 20 W and 80% for 30 W) but no pops when power was titrated by the impedance drop during ablation.

Factors Affecting Ablation Safety

Thrombus formation was not seen in any of the lesions, but popping phenomena were noted in 17 of the 101 RF ablations. The incidence of popping was associated with both the contact force ($P = 0.003$) and delivered RF power ($P < 0.001$) when analyzed using univariate Fisher's test. In the groups in which a fixed power was delivered regardless of the impedance drop (i.e., fixed power 20 W and 30 W groups) the maximal impedance drop recorded was 41.1 ± 28.1 Ω in the ablations without pops and 70.4 ± 23.1 Ω in the ablations with pops ($P = 0.001$).

Factors Affecting Ablation Lesion Size

Ablation lesion depth was highly correlated with catheter tip temperature (Spearman's rho = 0.42 and $P < 0.001$), but the impedance drop during the ablation had a higher correlation (Spearman's rho = 0.72 and $P < 0.001$).

Effect of Catheter Contact Force on Ablation Impedance

The impedance at the initiation of the RF ablation was highly correlated with the contact force ($r = 0.73$). The initial impedance was 104.7 ± 19.5 Ω for 2 g contact, 139.1 ± 25.2 Ω for 20 g contact, and 171.2 ± 31.1 Ω for 60 g contact. The impedance drop during the first 5 seconds of the ablation also significantly correlated with the contact force Pearson's $r = 0.65$ $P < 0.01$ (drop of 9.7 ± 9.9 Ω for 2 g, 22.3 ± 11.0

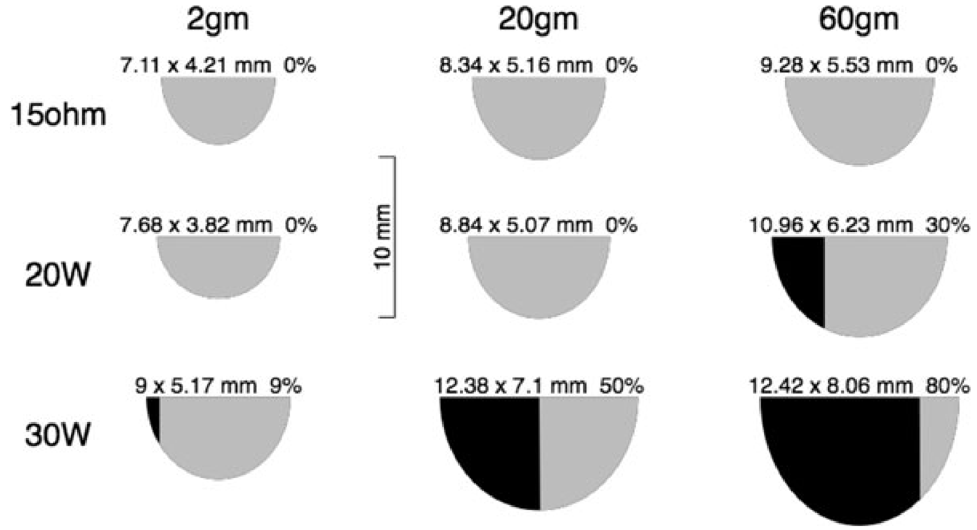

Figure 2. *Ablation lesion size and safety data for the 9 different ablation groups are summarized. Mean lesion width and depth for each group is shown graphically by the width and depth of the idealized ablation lesion as well as numerically in the associated text on a per group basis. The proportion of ablation lesions in which a pop was noted is also shown by the proportion of black in each of the lesion models and numerically in the text. The ablation groups are arranged by increasing contact pressure (columnwise from left to right) and power (by rows). The lesion size can be seen to increase with increases in the delivered power (i.e., for the 6 fixed power ablation groups in the lower 2 rows) and increasing contact pressure. Titrating power depending on the impedance fall during the ablation reduced the effect of catheter contact pressure on lesion size.*

Ω for 20 g, and 41.7 ± 22.1 Ω for 60 g). These groups all significantly differed from each other.

Discussion

In this *ex vivo* model, catheter-tissue contact force was an important determinant of both lesion size and complications. The effect of increasing contact force on lesion size and complications was as large as the effect of increasing ablation power, and this relationship was maintained for low, moderate, and high contact forces. The impedance drop during the first 5 seconds correlated with catheter contact force. In the absence of a force sensor, monitoring for excessive early impedance fall might help to reduce pops during high contact ablations.

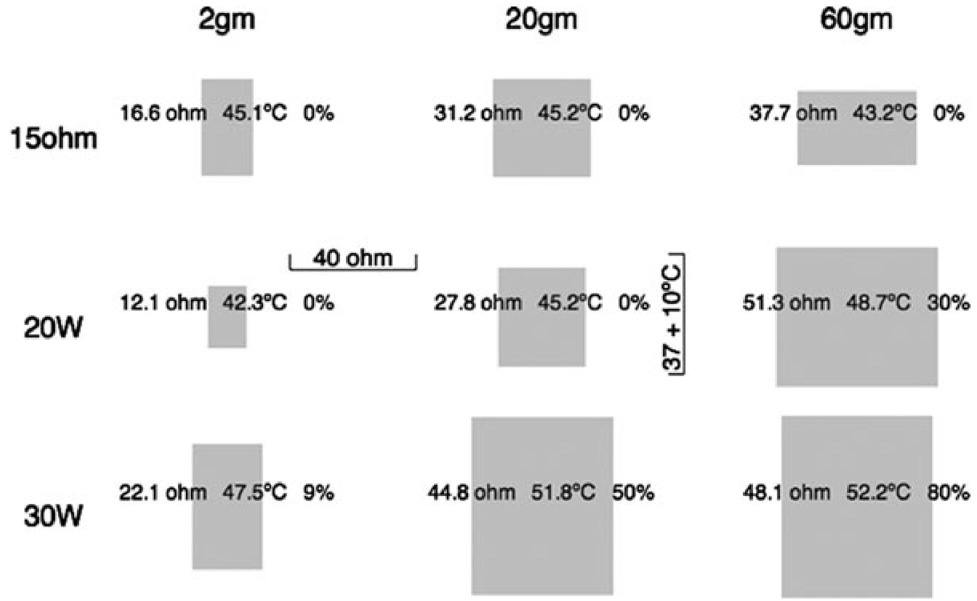

Figure 3. *Summary ablation parameters for the 9 ablation groups is again represented both graphically and numerically (see Figure 2 legend for further explanation). The impedance drop (from the impedance at 2 seconds to the minimum impedance recorded during the ablation) is shown by the width of the rectangle for each group. The height of the rectangle for each group displays the maximum catheter tip temperature rise above basal blood temperature (37° C) recorded during the ablation. In the 6 fixed power ablation groups the temperature rise and impedance drop appear to increase relatively symmetrically with increasing catheter contact pressure. However, in the impedance controlled ablation group the impedance does not change as markedly with different contact pressures but the temperature decreases with increasing contact pressure.*

Influence of Catheter Contact Force on Lesion Characteristics

In these ablation experiments, we used a symmetrical grid of ablation parameters (3 different power and catheter contact forces to give a total 9 ablation groups) so that the interaction between ablation power and catheter tip contact could be studied. We chose these 2 parameters as it is possible to measure them both with accuracy with the introduction of ablation catheters with contact force sensing technology. The introduction of irrigated-tip catheter ablation has been a major advance allowing larger ablation lesions to be created, but irrigated-tip ablation has the disadvantage of reducing the effectiveness of catheter tip temperature measurements. Therefore, any further information that can be obtained during the ablation becomes more important.

The effect of catheter contact force on ablation lesion size has been studied extensively during conventional (i.e., noncooled electrode) ablation.[4-7] These studies have shown that the temperature response during noncooled ablation is a good indicator of catheter tip contact—with increasing catheter tip contact there is an increased temperature response to a given RF ablation power.

The interaction between catheter contact and lesion characteristics during cooled tip ablation has been studied with varied results. Stagegaard[8] and colleagues performed irrigated-tip ablation on isolated porcine myocardium and found that increasing catheter contact from 10 to 30 g increased ablation lesion depth from 5.0 ± 1.1 mm to 7.3 ± 1.2 mm. Weiss[9] and colleagues performed irrigated-tip (30 W with 5, 10, 30, and 50 g) ablation using an ovine thigh model and found that lesion width was unaffected by varying contact force. The lesion depth, however, did increase with increasing contact force (5.5–9 mm for perpendicular catheter orientation). In this study, we observed a similar relationship between catheter contact and lesion depth but also found that the lesion width was similarly affected by catheter contact, and that this relationship remained intact with variations of the delivered power. Everett *et al.*[10] investigated the effect of 4 different contact conditions (10 g weighted contact, nonweighted contact, no contact, and side contact) on lesion size and complications using a variety of different ablation catheters (4 mm tip open and closed irrigation, 4 mm tip conventional, and 10 mm tip conventional with either a single or multiple temperature sensors). They found that there were significantly less complications in the noncontact group (except for thrombus formation that occurred at a similar rate). The nonweighted and 10 g contact group appeared to have similar complications and similar lesion sizes. These findings are discordant with the current study that showed a strong effect of contact force on lesion size and complications, and this relationship showed a clear dose–response characteristic. It is possible that this discordance may be the result of the large number of different factors and catheters that were studied by Everett *et al.*, which made evaluation of the role of contact force alone more difficult. Okumura and colleagues[11] used the Sensei robotic navigation system (Hansen Medical), which measures the catheter contact force from the catheter shaft (i.e., there is no direct pressure sensor at the tip) catheter contact force on lesion size during *in vivo* left atrial ablations. They showed a clear relationship between increasing catheter contact force and ablation lesion size with catheter contact force being the most important predictor of lesion size (above impedance drop, voltage reduction, and catheter orientation). Yokoyama *et al.*[12] performed irrigated-tip ablation at 2 power settings (30 W and 50 W) and 5 contact forces (2, 10, 20, 30, and 40 g) using the canine thigh model. They found that increasing contact force was associated with significantly larger lesions and a higher incidence of complications. The effect of catheter contact was a more important determinant of lesion size than the delivered power. Di Biase and colleagues[13] also investigated the effect of catheter contact force on RF ablation using a canine *in vivo* model and the Hansen Robotic system. They found that open irrigation RF ablation with 45 W of delivered power and 20 g of contact force was the best compromise between safety and efficacy (83.3% transmural lesions in the left atrium and 33.3% complications).

Effect of Catheter Contact Force on Impedance

The initial impedance at the start of ablation correlated with the contact force suggesting that this may be a useful measure to monitor if a contact force sensing catheter is not being used. Previous researchers have found a relationship between impedance and catheter contact force. Zheng and coworkers[14] investigated the effect of catheter contact (0, 10, 30, 60, and 90 g) on ablation impedance and lesion volume during *in vivo* ablation in a pig thigh model. They found that increasing contact force increased the initial impedance ($r = 0.85$). Strickberger and colleagues[15] investigated the effect of tissue contact on the initial impedance during ablation in 25 patients. They identified light or firm catheter on contact on the basis of radiographic appearance, electrogram voltage, and pacing threshold. They found that the impedance was 27% higher during firm catheter contact than during light catheter contact. These results are consistent with finite element modeling[16,17] studies and are the result of higher myocardial impedance in relation to blood impedance.

Clinical Use of Impedance Monitoring During Radiofrequency Ablation

We have previously shown that an excessive impedance drop during RF ablation is associated with a higher incidence of complications.[18] In this study, impedance-controlled ablation was associated with a low risk of popping regardless of catheter contact. In situations with a high catheter contact force, the initial impedance drop was noted to be high and the power delivery was reduced—thereby reducing the incidence of popping. Conversely, during poor tissue contact, the delivered power was increased.

Catheter Contact Force—How Much is Enough?

These data may provide some guidance for setting the delivered power during ablation with a contact catheter. The ‘‘moderate’’ catheter contact force (20 g) was associated with reasonable lesion size (~8.5 mm wide × 5.5 mm deep) with a low risk of popping during low power ablation (impedance control and fixed power 20 W). However, there was a risk of popping during high power ablation even with only moderate contact force. It will not always be possible to achieve adequate contact force in all myocardial areas. If only ‘‘light’’ catheter tip contact is achievable, the use of higher power (30 W) appears to create similar sized lesions to lower power ablations with moderate catheter tip contact, although there was a small risk of popping. The data from excessive catheter-tissue contact are also relevant for incidence of popping. These data suggest that the main utility of catheter contact sensors will be to allow the creation of more uniform ablation lesions and increase the safety of RF delivery. However, the creation of larger or deeper ablation lesions will require a change in the ablation technology as the parameter settings associated with large RF lesions were also associated with a high incidence of popping.

Limitations

This study was performed using an *ex vivo* model that differs from clinical RF ablation in a number of significant parameters including the absence of cardiac motion. In this study, the catheter was orientated perpendicular to the myocardium, and it is possible that other catheter orientations may change the accuracy of the various parameters to predict ablation related complications.

The changes in impedances observed during RF ablation in this model are more pronounced than are usually observed clinically. This may be the result of differences in the ablation circuit between *in vivo* and *ex vivo* ablation (including the absence of noncardiac soft tissue within the ablation circuit).

Conclusion

Catheter tip–tissue contact force was determined to be as important a factor in determining final lesion size as delivered RF power and was also correlated with a higher initial impedance drop. This relationship between catheter contact force and lesion size/safety was present for light, moderate, and heavy catheter contact forces.

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