Characterization of Catheter–Tissue Contact Force During Epicardial Radiofrequency Ablation in an Ovine Model

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Background—Contact force (CF) during radiofrequency ablation (RFA) is an important determinant of endocardial lesion size with limited data on epicardial RFA and CF. We evaluated CF characteristics using irrigated RFA on the epicardium in an ovine model.

Methods and Results—In 12 sheep, a 7-F irrigated RFA catheter with CF sensor was introduced via a pericardial incision onto/in parallel with ventricular epicardium. RFA (30 W per 30 second duration) was applied at 5g, 10g, 20g, 40g, and 70g: (1) over left and right ventricular myocardium with or without fat, (2) either directly over or adjacent to a coronary artery, or directly over the phrenic nerve. Force–time integral, lesion dimensions, and coronary artery/phrenic nerve injury were recorded. Lesion size, volume, and force–time integral progressively increased with higher CF (P<0.05). Steam pops occurred with high CF. Epicardial fat had an attenuating effect on RF penetration into myocardium (P<0.05); however, myocardial RF lesions could be created at sites with >3.5 mm epicardial fat. At sites with epicardial fat, each 10g increment in CF led to a 0.6 mm increase in lesion depth, whereas each 1 mm of fat reduced lesion depth into underlying myocardium by 0.7 mm. Extent of acute coronary injury with direct and indirect RFA and phrenic nerve palsy occurrence was proportional to CF.

Conclusions—CF is a determinant of epicardial RF lesion size, steam pops, acute coronary artery injury, and phrenic nerve injury. Although epicardial fat limits lesion size, RFA with high CF can produce small myocardial RF lesions at sites of thick epicardial fat. (Circ Arrhythm Electrophysiol. 2013;6:1222-1228.)

Key Words: catheter ablation ■ models, animal

Recent studies have demonstrated the importance of catheter–tissue contact force (CF) during radiofrequency ablation (RFA). A novel CF-sensing ablation catheter that allows real-time assessment of CF between an open irrigated catheter tip and target tissue interface has been shown to provide additionally useful information during endocardial catheter ablation procedures to treat atrial flutter and atrial fibrillation (AF). CF seems to have a relationship with the force–time integral, lesion size formation, acute procedural success, and recurrence rates.

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There remains a paucity of literature on the impact of CF during epicardial ablation procedures. It can be problematic when using traditional epicardial ablation techniques to determine ablation catheter–tissue contact. Furthermore, the impact of applied CF during RF application at sites over or adjacent to epicardial fat, coronary vessels, or the phrenic nerve (PN) has not been systematically described. Therefore, CF-sensing ablation catheters could potentially improve epicardial RFA efficacy.

The aims of this study were to evaluate and characterize the effect of CF-sensing technology on RF epicardial lesion size in an ovine beating heart model, and the effect of RF application with increasing CF over or adjacent to epicardial fat, coronary arteries, and the PN.

Methods
This study was approved by the Faculty of Veterinary Science Animal Research Ethics Committee of the University of Melbourne.

Procedure
Ovine Model Preparation—General Anesthesia
Twelve female crossbred sheep weighing 34±5.7 (range 30–40) kg were studied. Each animal underwent induction of general anesthesia (mean anesthetic time, 153±18.4 minutes) with

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thiopentone sodium 20 mg/kg and buprenorphine 0.01 mg/kg followed by a continuous infusion of fentanyl. Sheep were intubated and mechanically ventilated with oxygen and nitrous oxide. An intravenous bolus of lignocaine 40 mg was administered at the start of each case followed by a continuous infusion throughout the procedure as prophylaxis against ventricular arrhythmias.

Access to Pericardial Cavity
A left open thoracotomy was performed. The left and right ventricular (LV/RV) aspects of the beating heart were exposed and a 1-cm incision into the parietal pericardium was performed under direct vision. Prewarmed (37°C) normal saline was introduced into the pericardial space to allow for zero calibration of CF when there was no electrode-tissue contact (ie, catheter floating) as visualized by the operator. The CF-sensing catheter was then inserted via the pericardial incision into the pericardial space.

CF RFA Protocol
A novel CF-sensing 7-F quadrupolar ablation catheter (TactiCath; Endosense SA, Geneva, Switzerland; distributed by Biotronik, Germany) with 3.5 mm open irrigation tip electrode (total catheter length, 115 cm) was used. The interelectrode distance was 2-5.2 mm with a thermocouple positioned at the tip. The CF-sensing catheter contains a triaxial sensor located between the second and third electrode, which measures the force (amplitude and direction) of contact between tissue and catheter tip electrode. The sensor measures the lateral and axial force every 100 ms and displays this on a viewing station that is integrated into the electrophysiology laboratory.

An 8.5-F steerable long sheath (Agilis NxT; St Jude Medical, St Paul, MN) was used to improve catheter tip stability and facilitate optimal transmission of CF to the target epicardial structures during each RFA application. A Stockert Radiofrequency Power Generator (Biosense-Webster Inc, Diamond Bar, CA) was used for radiofrequency energy delivery. Power, temperature, and impedance were continuously monitored throughout each RFA application and stored on a computer-based digital amplifier/recorder system (Bard LabSystem Pro; Lowell, MA) for offline data analysis. The catheter was positioned parallel to the epicardial surface structures under the overlying pericardium. The operator ensured that the point of contact was against the epicardial surface and not against overlying lung or pericardium. Catheter-tissue CF was applied at the following predetermined sites: LV myocardium at a site without epicardial fat; RV myocardium at a site without epicardial fat; LV myocardium at a site with visible overlying epicardial fat; RV myocardium at a site with visible overlying epicardial fat; directly overlying a coronary artery (usually the left anterior descending artery); directly adjacent to, but not in immediate contact with, a coronary artery (usually the left circumflex artery); and directly onto the left PN.

Predefined constant CF was applied at 5g, 10g, 20g, 40g, and 70g at each of the above sites as measured by the catheter contact sensor. Each RFA application was delivered at 30 W for 30 seconds (17 mL/min irrigation) at a temperature limit of 48°C unless an impedance rise occurred first. The RF application was not terminated prematurely in the event of a steam pop occurring without impedance rise, and the total number of steam pops was recorded for each application.

It was observed in preparing the model that basal epicardial fat was thicker and became progressively thinner toward the apex. Therefore, when performing RF over fat, the highest CF was applied at the most basal site and CF reduced over each subsequent more apical location.

Direct application of RF energy over the PN was commenced at the most cranially accessible site that ensured consistent stability of applied CF. Diaphragmatic stimulation was observed with PN pacing during each RF application over the PN with loss of diaphragmatic contraction indicative of significant PN injury. Each subsequent RF application over the PN was applied in a more caudal site to the previous application to evaluate intact PN function.

Postprocedure Preparation of Ovine Heart
At the end of ablation procedure, the aorta was cannulated and 20 mL of 1% 2,3,5-triphenyl-tetrazolium chloride (TTC) solution was administered via the coronary arteries. The animal was euthanized and its heart harvested, immediately immersed in TTC solution for 20 to 30 minutes at room temperature to ensure adequate staining of the epicardium, and subsequently transferred to 10% formalin solution for fixation before subsequent macroscopic and microscopic histopathologic analysis.

CF Sensing Data
Data consisting of force characteristics (amplitude and direction) from catheter tip electrode and target tissue were recorded by Endosense software and exported for offline analysis. Visual display of tip-to-tissue orientation of the catheter was available to the operator to ensure that adequate catheter-tissue contact was maintained during each CF application.

Pathological Analysis
Lesions made over the myocardium and epicardial fat were measured macroscopically with a surgical ruler to determine diameter and depth. Baseline myocardial and epicardial fat thickness was measured immediately adjacent to each lesion. Lesion dimensions and lesion volume were measured and determined using a previously published formula. Lesion volume at sites where RF was applied over fat could not be accurately assessed with this formula. At sites of epicardial fat, the lesion size was determined from the amount of ablated myocardium directly underlying the fat. For example, if the epicardial fat was 5 mm thick and the lesion 7 mm deep, the depth of lesion was recorded as 2 mm to account only for the extent of myocardial ablation.

Sections from lesions made over or adjacent to coronary arteries and over the PN and adjacent to the left circumflex artery were taken and fixed in 10% neutrally buffered formalin. The tissue was dehydrated, embedded in paraffin, sectioned at 2 mm thickness, and stained with hematoxylin and eosin. Coronary lesions were analyzed by assessing for evidence of vacuolation within the tunica media and disruption of the tunica intima (internal elastic lamina and endothelium), perivascular edema, and fat necrosis.
Specimens were examined under light microscopy with microscopic measurements performed using the ScanScope XT system and analyzed with proprietary software.

Statistical Analysis
Data analysis was performed using the statistical package SPSS (release 17.0: IBM). Continuous variables were expressed as mean±SD. Means of lesion depth with versus without fat were compared at each CF using an independent samples t-test. A Mann–Whitney U-test was used when the normal distribution assumption was questionable. A linear mixed model was fitted across the entire data to determine the relationship between lesion depth into myocardium (response), fat thickness (covariate), and CF (continuous covariate). In addition to the above fixed effects, sheep was fitted as a random effect in the mixed model, with lesions nested within sheep. A 2-tailed P value <0.05 was considered statistically significant.

Results
A total of 420 lesions were analyzed. Twenty applications were excluded because of impedance rise prematurely terminating the RFA application, occurrence of ventricular fibrillation, or inconsistent CF during RFA application.

Baseline Tissue Characteristics
Of the areas targeted by ablation, the baseline LV wall thickness was 15±3.2 (range 11–22) mm and RV wall thickness was 5.6±0.9 (range 3–6.5) mm. For sites of ablation, the mean thickness (depth) of the fat layer underlying myocardium was 3.7±2.2 mm over the LV (range 0.5–8 mm) and 4.5±2.7 mm over the RV (range 1–7 mm). LV myocardium was up to 3 times thicker compared with RV myocardium. As expected, there was variability in the thickness of epicardial fat over different ventricular sites (Table 1).

Effect of RF Over Epicardial Sites Without Fat
There was a progressive increase in lesion size according to the delivered CF (Table 2; Figures 1 and 2). The smallest lesion depth (LV: 2.2±0.6 mm; RV: 1.8±0.5 mm) and width (LV: 2.8±0.9 mm; RV: 1.8±0.8 mm) occurred with the lowest CF of 5 g, which significantly increased with higher CFs up to 70 g (LV: 7.3±1.4 mm; RV: 6.4±1.0 mm; width: LV: 10.3±1.6 mm; RV: 9.9±1.9 mm). This resulted in an approximate doubling of lesion volume for each step-up in CF from 5 g to 40 g. Between 40 g and 70 g, lesion volume increased by 1 to 1.5 times. In the LV, even the largest lesions were not transmural because of the significant baseline wall thickness.

However, transmural lesions were frequently seen at 70 g applications over the RV and occasionally at 40 g applications (Figure 3A).

Steam pops were observed rarely at 5 g or 10 g CF, but frequently at 40 g (12%) and 70 g (33%). In no cases was there myocardial perforation with any steam pop. However, tissue cavitation or cratering was evident at RF lesion points that correlated with steam pop occurrence (Figure 3B).

Effect of RF Lesions Applied at Sites Covered by Epicardial Fat
Lesions were substantially smaller in depth of penetration into myocardium underlying areas of fat; however, even with a mean fat thickness 5.1±2.6 mm overlaying the LV, 70 g of CF during RF did produce a mean 1.4±2.0 mm deep myocardial lesion under the fat. Comparing myocardial lesion depth at LV or RV sites with and without epicardial fat (Figures 1 and 2), there was a highly significant difference. There was a strong relationship between both applied CF and lesion depth at sites with and without fat. There was a statically significant relationship between fat thickness and lesion depth across all CFs (P<0.05). The mixed model using CF and fat thickness as covariates for all lesions (at all forces and fat thickness) resulted in estimated coefficient of 0.064 for force and −0.670 for fat thickness. This showed that, on average, for each additional 10 g of force there was a 0.6 mm increase in lesion depth; however, for each additional 1 mm of fat, there was a 0.7 mm reduction in lesion depth. See Figure 4 and Table 1 (online-only Data Supplement) for details.

Effects of RF Delivered Over PN and Coronary Arteries
PN paralysis was seen for almost all applied lesions with applied force of >200 g (Table 2) but in no case at 5 g CF and 2 of 12 cases using 10 g CF.

Direct RF application over the left anterior descending coronary artery at forces from 5 g to 70 g did not result in vascular occlusion. However, marked acute coronary vessel injury was observed on histopathology at 70 g CF and moderate injury at 40 g CF (Table II in the online-only Data Supplement).

At the highest forces (Figure 4D), transmural vacuolation of the tunica media and disruption of the internal elastic lamina and endothelium were clearly observed in 9 cases. Even when RF was applied adjacent to but not directly over the coronary artery, there was evidence of vessel injury (Table III in the online-only Data Supplement). Fat necrosis around the vessels, perivascular edema, and perivascular

Table 1. Baseline Characteristics

<table>
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<th>5g</th>
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<th>20g</th>
<th>40g</th>
<th>70g</th>
<th>P Value</th>
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<tr>
<td>Mean LV wall thickness, mm</td>
<td>15.8±4.4</td>
<td>14.8±2.8</td>
<td>14.3±2.5</td>
<td>15.4±2.7</td>
<td>17.0±3.1</td>
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<tr>
<td>Mean RV wall thickness, mm</td>
<td>5.4±0.6</td>
<td>5.7±1.1</td>
<td>5.5±1.0</td>
<td>5.9±0.8</td>
<td>6.1±1.4</td>
<td>0.59</td>
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<tr>
<td>Mean LV fat layer, mm</td>
<td>2.7±2.1</td>
<td>2.9±1.8</td>
<td>3.3±1.4</td>
<td>4.0±2.0</td>
<td>5.1±2.6</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Mean RV fat layer, mm</td>
<td>2.6±1.1</td>
<td>3.5±1.3</td>
<td>4.5±1.7</td>
<td>6.0±3.4</td>
<td>6.2±3.8</td>
<td>&lt;0.05</td>
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Values are expressed as mean±SD. LV indicates left ventricular; and RV, right ventricular.
hemorrhage into the epicardial fat layer were frequently observed. Although not systematically assessed, the presence of an overlying (as opposed to adjacent) coronary vein did seem to reduce the degree of arterial injury in 5 cases.

Discussion
This study of epicardial RF application in an ovine model using a novel CF-sensing catheter provided the following main findings:

1. Epicardial lesion volume is related to increasing CF when this CF is applied directly over the myocardium with the catheter tip lying parallel to the surface as would usually be the case in clinical epicardial VT ablation in humans.

2. For each doubling of tissue contact between 5g and 40g of applied CF, there was a corresponding doubling in the absolute lesion volume.

3. At sites of thinner myocardium (in this model, RV with mean wall thickness 5.6±0.9 mm), transmural lesions can be created with epicardial RF applications.

4. Epicardial fat attenuates the effect of RF penetration into underlying myocardium, but myocardial ablation does still occur and is proportional to the applied CF and thickness of the fat layer.

5. PN injury occurs with increasing directly applied CF. At CF of ≥20g, this injury was virtually universal.

6. Acute coronary artery injury was also related to the delivered CF. Even at sites where RF was applied adjacent to the coronary artery, lesions with higher CF produced vessel wall injury as evidenced by vacuolation of the tunica media. When RF was directly applied over a coronary vessel at high CF, these changes were frequently transmural and extended to the tunica intima (endothelium).

Epicardial Lesion Volume and Applied CF
Previous experimental studies have demonstrated the influence that CF has on lesion size formation during RF applications. In clinical studies, sites of low applied CF have been shown to correlate with sites of less effective ablation and sites more likely to demonstrate tissue recovery with recovery of functional conduction properties. Similarly, in this study CF has a significant effect on lesion size. In sheep, the RV wall is thinner than the LV wall and transmural lesions were produced here when using higher CF. The application of strong CF on the epicardium was also more likely to produce steam pops and cavitation. It has been shown previously that impedance-controlled ablation was associated with a low risk of popping regardless of catheter-tissue contact when compared with fixed power ablation. However, given the importance of catheter contact for adequate lesion formation through tissue heating, CF represents another indicator of steam pop risk. We demonstrated that at

| Table 2. Radiofrequency Application Over Sites Not Covered With Epicardial Fat |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Lesion depth in LV, mm       | Contact Force                 | P Value                      |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| 5g                            | 2.2±0.6                      | 1.0±1.4                      | 5.5±1.0                      | 7.3±1.4                      | <0.05                        |
| 10g                           | 2.9±0.9                      | 4.1±1.5                      | 7.9±2.0                      | 10.3±1.6                     | <0.05                        |
| Mean LV lesion volume, mm³    | 4.3±2.5                      | 11.4±10.8                    | 22.3±17.4                    | 47.0±0.1                     | <0.05                        |
| RV lesion depth, mm           | 1.8±0.5                      | 3.0±0.9                      | 4.1±0.8                      | 5.0±0.6                      | <0.05                        |
| RV lesion width, mm           | 1.8±0.8                      | 4.1±1.0                      | 6.4±1.5                      | 7.9±2.3                      | <0.05                        |
| Mean RV lesion volume, mm³    | 3.1±2.0                      | 8.4±4.9                      | 19.0±10.6                    | 35.7±23.6                    | <0.05                        |
| Steam pop LV/RV (n lesions)   | 0 (84)                       | 1 (84)                       | 9 (84)                       | 10 (84)                      | 28 (84)                      |
| PN paralysis (n sheep)        | 0 (12)                       | 2 (12)                       | 11 (12)                      | 12 (12)                      | 12 (12)                      |
| Vessel injury present (n sheep)| 0 (12)                       | 3 (12)                       | 5 (12)                       | 11 (12)                      | 12 (12)                      |

Values are expressed as mean±SD. LV indicates left ventricle; PN, phrenic nerve; and RV, right ventricle.
lower CFs the chance of steam pops occurring is small but this risk increased significantly with higher CFs (ie, >20g).

Sacher et al. recently demonstrated larger epicardial than endocardial lesion formation in an ovine model with 60 seconds of irrigated RF at 30 W (mean total epicardial CF of 21g). The present study does not point to the optimal CF when performing ablation with 30 W irrigated RF (30-second duration), but even at 10g and 20g, significant lesions were created.

Influence of Epicardial Fat
Previous studies have reported on the protective role epicardial fat may have during RF ablation, and this may limit the use of epicardial RF. This can be particularly challenging in patients with nonischemic cardiomyopathy where there may be a predominance of low bipolar voltage correlating with scar substrate in the perivalvular regions that have extensive fat distribution epicardially. Moreover in humans, fat volumes around the heart have been found to correlate with advancing age and are larger in men compared with women.

The low electric and thermal conductivity properties of fat reduce the penetrating effect of RF current and heat to the underlying myocardium, thereby creating shallower lesions compared with epicardial areas without fat. It has been found that irrigated tip RFA was unable to produce epicardial lesions

![Image of epicardial fat and lesion formation](image_url)

Figure 4. Hematoxylin and eosin–stained epicardial lesions. A. Layer of overlying thin fat with significant lesion formation into underlying myocardium at 70g contact force (CF). B. Medium fat with moderate myocardial lesion formation at 70g CF. C. Thick fat with reduced but still significant lesion penetration into underlying myocardium at 70g CF. D. Radiofrequency lesion directly over coronary artery at 70g CF showing extensive tunica media injury with transmural vacuolation and fat necrosis.
through fat thicker than 3.5 mm, but this is dependent on power/temperature settings and does not take into account the amount of CF involved.17

The present study has shown that RF lesions using high CF can produce small myocardial lesions of mean depth 1 to 2 mm at sites of even the thickest fat (>5 mm). Whether these small lesions produce clinically relevant effects on epicardial circuits is unknown. The ANOVA model demonstrated that, on average, for each 10g of force there was a 0.6 mm increase in lesion depth; however, for each 1 mm of fat, there was a 0.7 mm reduction in lesion depth. Therefore, at 40g applied force over 4 mm of fat, there would be no lesion (2.4 mm calculated depth attenuated by 2.8 mm reduction in lesion penetration). However, at 3.5 mm of fat thickness (2.45 mm lesion depth attenuation), a 50g CF lesion (3.0 mm predicted lesion depth below fat) would produce a 0.5 mm lesion. In other words, a high CF would be required to create a meaningful lesion below 3.5 mm of fat.

Neurovascular Injury and Epicardial Ablation

Coronary vessel injury has been reported in rare cases of epicardial ablation.17 18 A large clinical case series reported acute coronary injury in 2 of 131 epicardial ablation procedures with both involving small branch vessel occlusion.18 Several studies have demonstrated that acute vascular wall changes, including endothelial disruption, neointimal thickening, and intravascular thrombosis, occur when delivering RFA in the vicinity of a coronary artery with risk of chronic vascular damage inversely proportional to vessel size.19 20 Moreover, more significant changes were noted to only occur in vessels of small calibre with the suggestion that larger vessels are protected from such changes due to greater blood flow.18

RF application over or immediately adjacent to a coronary artery is best avoided, and based on our data, coronary injury is greater when CF is high.

PN injury is an uncommon complication of epicardial ablation. Our study showed that PN injury appeared unlikely at 5g or 10g of CF but that it was consistently injured at forces >20g. Importantly in our model, RF was directly applied over the PN, whereas clinically, the PN sits on the external surface of the fibrous pericardium. It is not known what CF can be applied/transmitted to the PN during clinical epicardial ablation procedures.

Study Limitations

The use of an open left thoracotomy approach with saline-filled pericardium was chosen as our model of epicardial ablation, but this may be limiting the clinical relevance of our results. The model was chosen to (1) ensure optimal and consistent positioning of the CF catheter tip, (2) permit reliable application of RFA across all levels of CF, and (3) facilitate reproducible lesion formation over fat/coronaries and PN. Different results might have been achieved if perpendicular or angled catheter orientation had been attempted; however, applying the catheter tip parallel to the tissue surface in this study did reflect the usual epicardial ablation technique in humans.

Conclusions

CF is a major determinant of epicardial RF lesion size. occurrence of steam pops, coronary artery injury, and PN injury.

The epicardial fat layer has an important role in limiting the penetrating depth of ablation into the underlying myocardium. At sites of thickest epicardial fat, applying RF with the highest CF can produce small myocardial RF lesions.

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References


CLINICAL PERSPECTIVE

Contact force (CF) has been established as an important determinant of endocardial lesion formation during radiofrequency ablation (RFA). This study demonstrates the use of novel CF catheter technology during epicardial RFA in an ovine open beating heart model and how it can influence lesion size and geometry over areas with or without epicardial fat as well as potential injury to critical vascular/neural structures. The presence of thick epicardial fat is shown to attenuate the effect of RF penetration into underlying myocardium, but contrary to previous suggestion that myocardial lesion formation does not occur under areas with >3.5 mm overlying fat, we have shown that higher levels of CF can overcome this issue. Our data further quantify the incremental effect of every 10 g CF and 1 mm of fat thickness on lesion depth penetration, although it is important to remember that our model differs from the typical percutaneous approach of clinical epicardial RFA. Although higher CF can lead to effective lesion formation, potential pitfalls that remain include higher incidence of steam pops and greater extent of acute coronary and phrenic nerve injury, both of which have been reported to occur rarely but remain important considerations during clinical epicardial VT ablation. CF, therefore, can play an important role in reducing complications and improving epicardial RFA efficacy.