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Original Article

Endocardial Versus Epicardial Ventricular Radiofrequency Ablation

Utility of In Vivo Contact Force Assessment

Frederic Sacher, MD; Matthew Wright, MRCP, PhD; Nicolas Derval, MD; Arnaud Denis, MD; Khaled Ramoul, MD; Laurent Roten, MD; Patrizzio Pascale, MD; Pierre Bordachar, MD; Philippe Ritter, MD; Meleze Hocini, MD; Pierre Dos Santos, MD, PhD; Michel Haissaguerre, MD; Pierre Jais, MD

Background**—**Contact force (CF) is an important determinant of lesion formation for atrial endocardial radiofrequency ablation. There are minimal published data on CF and ventricular lesion formation. We studied the impact of CF on lesion formation using an ovine model both endocardially and epicardially.

Methods and Results**—**Twenty sheep received 160 epicardial and 160 endocardial ventricular radiofrequency applications using either a 3.5-mm irrigated-tip catheter (Thermocool, Biosense-Webster, n=160) or a 3.5 irrigated-tip catheter with CF assessment (Tacticath, Endosense, n=160), via percutaneous access. Power was delivered at 30 watts for 60 seconds, when either catheter/tissue contact was felt to be good or when CF>10 g with Tacticath. After completion of all lesions, acute dimensions were taken at pathology. Identifiable lesion formation from radiofrequency application was improved with the aid of CF information, from 78% to 98% on the endocardium (P<0.001) and from 90% to 100% on the epicardium (P=0.02). The mean total force was greater on the endocardium (39±18 g versus 21±14 g for the epicardium; P<0.001) mainly because of axial force. Despite the force–time integral being greater endocardially, epicardial lesions were larger (231±182 mm^3 versus 209±131 mm^3; P=0.02) probably because of the absence of the heat sink effect of the circulating blood and covered a greater area (41±27 mm^2 versus 29±17 mm^2; P=0.03) because of catheter orientation.

Conclusions**—**In the absence of CF feedback, 22% of endocardial radiofrequency applications that are thought to have good contact did not result in lesion formation. Epicardial ablation is associated with larger lesions. (***Circ Arrhythm Electrophysiol*****. 2013;6:144-150.**)

Key Words: ablation ■ contact force ■ endocardium ■ epicardial ■ ventricular tachycardia

Contact force (CF) is an important determinant of lesion formation for endocardial atrial catheter ablation.[1] However, little is known about its impact on ventricular radiofrequency (RF) ablation (particularly epicardial ablation). We investigated ventricular lesion formation after RF ablation on the epicardium (EPI) and endocardially (ENDO) in a sheep model using standard irrigated-tip catheter versus a CF-sensing catheter.

Clinical Perspective on p 150

Methods

Animal Preparation

The experimental protocols were handled in compliance with the Guiding Principles in the Use and Care of Animals published by the National institutes of Health (NIH Publication No. 85-23, Revised 1996).

Twenty-two sheep (6±1years, 55±10 kg) were sedated with an intramuscular injection of 20 mg/kg ketamine hydrochloride and anaesthetized with sodium pentobarbital (10 mg/kg). Slow intravenous infusion of saline maintained hydration throughout surgery, and anesthesia was maintained using continuous intravenous infusion of ketamine (500 mg/hour) and pentobarbital (150 mg/hour). The trachea was intubated through a midline cervical incision for connection to a respirator (Siemens Servo B, Berlin, Germany). Sheep were then ventilated using room air supplemented with oxygen. An intravenous access was placed in the internal jugular vein for infusion of drugs and fluids. Arterial blood gases were monitored periodically (Radiometer, Copenhagen, Denmark), and ventilatory parameters were adjusted to maintain blood gases within physiological ranges.

Access to the right ventricle (RV) was performed via femoral vein and a long steerable 8.5 Fr sheath (Agilis, St Jude Medical) was inserted. The left ventricle (LV) was accessed via a retrograde aortic approach, and a short 7 or 8 Fr sheath was placed in the femoral artery. Epicardial access was performed with a tuohy needle (Braun, Germany) via a subxyphoid approach, as previously described.[2,3] A 8.5 Fr Agilis (St Jude Medical) sheath was used to manipulate the

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ablation catheter in the pericardium. Intrapericardial fluid was drained continuously with a vacuum system connected to the epicardial sheath.

Two sheep were excluded from this study: one because of an epicardial access problem, and the second one because of intractable ventricular fibrillation that could not be converted by several direct current shocks after the initial endocardial LV lesion.

CF Measurement

The Tacticath catheter (Endosense, Switzerland) displays CF information due to a force sensor incorporated into its distal part between the second and third electrode. The force sensor consisted of a deformable body and 3 optical fibers to measure microdeformations that correlate with force applied to the catheter tip. Infrared laser light is emitted through the proximal end of the 3 optical fibers. The light is reflected by fiber Bragg gratings on the deformable body at the distal end of the optical fibers, near the tip of the catheter. Applying CF to the tip of the catheter produces a microdeformation of the deformable body, causing the fiber Bragg gratings to either stretch or compress, which changes the wave length of the reflected light. The change of wave length is proportional to the CF applied to the tip. By monitoring the wave length of the reflected light in the 3 fibers, the system is able to calculate and display the vector of the CF (magnitude and angle).

Ablation

Two operators (F.S. and P.J.) performed both endocardial and epicardial ablation of the RV and LV with a 3.5-mm open irrigated-tip catheter (Thermocool, Biosense Webster, Diamond Car, CA; THERM group) or a 3.5-mm open irrigated-tip catheter enabling CF information (Tacticath, Endosense, Switzerland; Tacticath group). In each sheep, a mean of 16 RF applications were performed (4 at the ENDO of the LV, 4 at the ENDO of the RV; 4 at the EPI of the RV and 4 at the EPI of the LV, going from apical to basal for each series of 4; Figure 1A). Epicardial lesions were performed anteriorly and endocardial lesions were performed inferiorly to give separation between the lesions at pathology, ensuring a perfect match between RF applications and lesions found at necropsy in the absence of electroanatomic system. The order of RF application (RV versus LV, ENDO versus EPI) was randomized for each animal.

RF was delivered when electrode contact was achieved as assessed by recording high-amplitude potentials, tactile feedback, and fluoroscopy, or when CF>10 g (when possible) for the Tacticath group. Energy was delivered in power control mode at 30 W for 60 seconds, with a flow rate titrated to obtain a target temperature between 39 to 43°C.

Impedance was recorded and the percentage of impedance drop at 10 seconds was calculated. Impedance was taken before RF delivery (baseline impedance) and 10 seconds after RF start (impedance t10). Difference of local ventricular bipolar amplitude before and after each application was measured with the caliper function of the

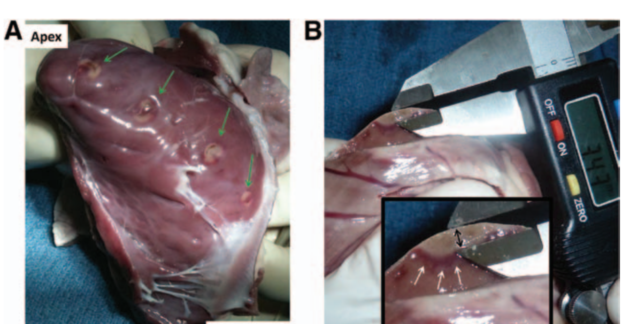

Figure 1. A, Represents 4 endocardial lesions performed on the inferior wall of the left ventricle. **B**, Endocardial and epicardial lesions were then sliced in the middle and the depth was measured (**black arrow**) without taking into account the inflammation (red collar: **white arrows**).

Labsystem Pro (Bard). A cutoff value of 50% amplitude reduction was arbitrarily chosen to identify a presumed effective lesion. In the Tacticath group, CF as well as force–time integral (FTI; area under the curve of CF for the duration of RF delivery)[4] were monitored continuously.

In case of steam pop or sustained polymorphic ventricular tachycardia/ventricular fibrillation requiring defibrillation, RF was stopped immediately and the RF duration was noted.

Necropsy

After completion of the lesion set, the sheep was euthanized and the heart explanted. In situ lesions on lung or mediastinum were examined. Gross anatomic examination was performed immediately to identify and measure lesions. Measurements were performed with a micrometer (±0.1 mm). Inflammation (red collar; Figure 1B) was excluded from the lesion size. In case of RF application on epicardial fat, the myocardial lesion sizes were not included in the analysis.

Lesions volume was calculated according to the formula of Yokoyama et al.[6] The maximum depth (a), maximum diameter (b), depth at the maximum diameter (c), and surface diameter (d) of the lesion were measured. Lesion volume was calculated as follows: volume = $(1/6)\times(A\times B^2+C\times D^2/2)$.[5,6]

Statistical Analysis

Quantitative variables were expressed as mean±standard deviation. We compared characteristics of RF applications/lesions performed with the 2 types of catheters (Thermocool and Tacticath) on the endocardium, and then on the EPI. We also compared all RF applications/lesions performed on the endocardium (whatever catheter used) to those performed on the EPI. Comparisons of quantitative variables between groups were performed using linear mixed models, where correlations between animal values were handled through the unstructured covariance matrix of random effects through autocorrelated error structures. Comparison of the number of lesions found at necropsy and transmurality of the lesions between groups were performed using marginal logistic regression models. Bivariate correlation between axial force and lesion depth, lateral force and lesion depth/surface area/volume were performed with the Pearson test. A value $P<0.05$ was considered statistically significant.

Results

A total of 320 RF applications were performed (80 on the endocardium and 80 on the EPI with each catheter). There were no differences in terms of actual power delivery, RF duration, and irrigation rate, according to either catheter or ventricular surface (Table 1). CF achieved was greater ENDO with a total CF of 39±18 g versus 21±14 g epicardially ($P<0.001$) and a FTI of 2338±1076 g second versus 1163±705 g second. This was mainly because of axial force (28±19 g versus 11±9 g; $P=0.005$), although lateral force was also higher ENDO (22±12 g versus 16±10 g; $P=0.008$). Of note, catheter orientation was mainly parallel to the tissue epicardially, whereas, ENDO, it was predominantly perpendicular to the tissue.

Mean impedance drop at 10 seconds was lower on the endocardium (12±7%) versus EPI (17±10%; $P<0.001$), as well as the percentage of applications with an impedance drop >10% at 10 seconds (54% versus 71%; $P=0.004$). No difference was found, between EPI and ENDO, in terms of electrogram (EGM) decrease.

Steam pops occurred 13 times in 4 sheep (ENDO=7 and EPI=6) during RF application, predominantly with the thermocool catheter (12 versus 1 with Tacticath). When the

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Table 1. Electrophysiological Parameters During Ablation and Lesion Characteristics at Necropsy Depending Site of Ablation

		THERM Group		Tacticath Group		*P* Value		
		ENDO	EPI	ENDO	EPI	ENDO THERM vs ENDO Tacticath	EPI THERM vs EPI Tacticath	ENDO vs EPI Tacticath
RF parameters	No. of RF applications	80	80	80	80	-	-	-
	Power (W)	30±2	30±1	30±2	30±1	NS	NS	NS
	RF duration (s)	57±14	55±13	59±5	58±7	NS	NS	NS
	Mean pump flow rate during ablation (mL/min)	25±11	23±11	25±14	21±15	NS	NS	NS
	Percentage of Impedance drop at 10 s (%)	13±8	18±10	10±6	14±9	$P<0.001$	$P=0.009$	$P<0.001$
Contact force data	Total force (g)	-	-	39±18	21±14	-	-	$P<0.001$
	Axial force (g)	-	-	28±19	11±9	-	-	$P=0.005$
	Lateral force (g)	-	-	22±12	16±10	-	-	$P=0.008$
	Force time integral (g s)	-	-	2338±1076	1163±705	-	-	$P<0.001$
Necropsy	No. of lesions	62 (78%)	61/68 (90%) [12 on fat]	78 (98%)	72/72 (100%) [8 on fat]	$P=0.007$	$P=0.02$	NS
	Lesion depth (mm)	4.7±2.1	4.1±1.6	4.4±1.4	4.0±1.4	NS	NS	NS
	Lesion width (mm)	5.3±1.7	6.3±1.9	5.1±1.6	5.9±1.9	NS	NS	NS
	Lesion length (mm)	7.7±2.2	8.4±2.6	7.2±1.9	8.1±2.7	NS	NS	$P<0.001$
	Volume (mm^3)	229±147	249±183	209±131	231±182	NS	NS	$P=0.02$

ENDO indicates endocardium; EPI, epicardium; RF, radiofrequency; and THERM, Thermocool.

steam pop occurred with the Tacticath catheter, the total force was 60 g and FTI 3300 g second.

Thirteen applications (ENDO=5 and EPI=8) in 6 sheep induced ventricular tachycardia/ventricular fibrillation that required external cardioversion.

Necropsy

A total of 293 RF applications were identified at necropsy (92%). On the endocardium, 62 ventricular lesions were identified on 80 RF (78%) applications in the THERM group, whereas 78 of 80 (98%) were identified in the Tacticath group ($P=0.007$; Table 1). Epicardially, 20 ablation sites were identified on fat, and therefore were not included in the analysis (12 in the THERM group and 8 in the Tacticath group). Sixty-one of 68 (90%) RF applications in the THERM group versus 72 of 72 (100%) in the Tacticath group ($P=0.02$) were identified. Of note, when local fat thickness was ≤1 mm, 6 myocardial lesions out of 7 RF applications could be identified. Maximal myocardial lesion depth was 2 mm. But when fat thickness was >1 mm, no myocardial lesion could be identified (maximal CF 16 g).

A 50% decrease in electrogram amplitude (before and after RF applications) was in favor of lesions found at necropsy: 156 of 159 (98%) versus 80 of 114 (70%) in the absence of EGM amplitude decrease ($P<0.001$). However, lesion sizes were not statistically different depending on this decrease or on the impedance drop.

Lesions were larger epicardially (231±182 mm^3 versus 209±131 mm^3; $P=0.02$) and covered a greater area (41±27 mm^2 versus 29±17 mm^2; $P=0.03$). There was a trend toward deeper lesions, when applications were performed ENDO (4.6±1.7 mm versus EPI: 4.1±1.5 mm; P=NS), with a weak correlation ($r=0.19$; $P=0.03$) between axial force and lesion depth, but not between lateral force and lesion depth, surface area, or volume. There was no difference in achieving transmural lesions between EPI and ENDO RF delivery (ENDO: 23% of transmural lesion versus EPI: 13%; P=NS) nor depending on the catheter used. Transmural lesions were mainly found in the RV (n=40) or at the left ventricular apex (n=17), where ventricular wall are thinner. Endocardial LV lesions were larger than RV endocardial ones, despite identical RF settings (irrigated-tip catheter, 30 W for 60 seconds), but with a trend to higher CF (mainly because of axial force) and FTI (Table 2).

In the CF group alone, the mean total CF and FTI were higher in RF applications with lesions found at necropsy, than those where no lesion was identified (33±18 g versus 7±0.5 g; $P<0.001$ and 1941±1068 g second versus 404±32 g second; $P<0.001$). The relationships between CF, FTI, and lesion depth/volume are reported in Figure 2. On the endocardium, the mean lesion depth and size increase with the FTI (Figure 2A). However, this visual correlation was not present on the EPI (Figure 2B), where a FTI between 1000 and 2500 g second resulted in the same lesion volume on average. The maximal total CF and FTI for RF applications not resulting in

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Table 2. Contact Force Information and Lesion Size Depending on RF Application Site

		Endocardium			Epicardium		
		RV	LV	*P* Value	RV	LV	*P* Value
CF data	Total force (g)	36±15	43±20	NS	20±12	22±10	NS
	Axial force (g)	23±16	34±21	0.006	10±9	11±9	NS
	Lateral force (g)	24±12	20±13	NS	15±10	16±10	NS
Necropsy	Force time integral (g s)	2133±881	2549±1220	NS	1063±724	1240±649	NS
	Lesion depth (mm)	4.0±1.4	5.0±2.0	0.001	3.6±1.3	4.5±1.6	0.02
	Volume (mm^3)	179±134	249±136	0.003	221±178	261±186	NS

LV indicates left ventricle; and RV, right ventricle.

lesions at necropsy were 7 g and 439 g second. The minimal total CF and FTI for RF applications resulting in lesions at necropsy were 10 g/609 g second on the endocardium and 5 g/273 g second on the EPI.

Of note, in 3 sheep (2 with Thermocool, 1 with Tacticath), pulmonary lesions facing the epicardial RF ablation site were identified (Figure 3). For the Tacticath patient, the force was not directed toward the heart.

Discussion

This study provides a number of unique insights into acute ventricular lesion formation:

1. Even with experienced operators a fifth of ventricular endocardial RF applications do not result in lesion formation when fluoroscopy, tactile feedback, and EGM amplitude are used to assess contact.
2. The addition of CF information dramatically decreases the number of RF applications that do not result in lesion formation.
3. Absence of circulating blood on the EPI (no heat sink effect) allows creating larger lesion on the EPI. Lower axial CF achieved epicardially associated with parallel catheter orientation alters the lesion geometry to being broad and shallow. These changes in geometry could have important implications for ventricular tachycardia ablation.

Lesion Formation

In the Thermocool group, 22% of RF applications did not result in lesion formation. This was despite the impression of being in good contact based on tactile feedback, fluoroscopy, and high-amplitude electrograms. The 2 RF applications with CF information (Tacticath group), which did not result in lesion at necropsy, had a low CF <10 g and a FTI <500 g second because of catheter instability or displacement meaning that the amount of energy received to the tissue was too low to create lesion. Interestingly in the Toccata study,[1] 12% of RF applications (operator blinded to CF information) were performed with a CF<5 g. In an oral communication, showing the 12-months follow-up of the atrial fibrillation population of this Toccata study, all patients with a mean CF<10 g during RF applications experienced atrial fibrillation recurrence. CF feedback seems less crucial in the pericardial space because this is a virtual space, so in the absence of fluid, the catheter is in contact with the tissue. Whereas a CF<10 g resulted in the absence of lesion on the endocardium, this was not the case on the EPI. On the EPI, limitation of RF efficacy by fat occurred for 20 of 160 RF applications. However, these 20 applications could be identified on epicardial fat. A limited myocardial lesion could even be identified when local fat thickness was <1 mm, but in these cases, the maximal lesion depth seen was 2 mm.

The mean impedance drop during the first 10 seconds was more important during ablation on the EPI versus endocardium whatever the catheter used (Thermocool $P<0.001$ and Tacticath $P<0.001$), but was not able to predict lesion size. A decrease ≥10% of impedance during the first 10 seconds of RF application was not able to predict lesion at necropsy, neither was the decrease >50% of the electrogram. Yokoyama et al[6] emphasized that the magnitude of impedance decrease during RF applications increased significantly with increasing CF. However, at the same CF, there was no difference in the magnitude of impedance decrease between 30 and 50 W, whereas these applications resulted in different lesion volume. We also reported a poor correlation between impedance drop and lesion depth.[7] Concerning the EGM amplitude, although a reduction of electrogram amplitude was in favor of lesion formation, 2% of applications with lesion found at necropsy did not have a EGM amplitude reduction >50%. This may be because of the fact that RF applications were performed in healthy ventricular myocardium, whereas spatial resolution of the catheter allows recording of normal tissue activities outside the lesion. Looking at CF information, total force was much higher when ablation was performed on the endocardium (39±18 versus 21±14g) predominantly because of an increased axial force, whereas on the EPI, lateral force was superior to axial force (Table 1). Whereas the catheter tip was mainly oriented parallel on the EPI because of its constraint from the parietal pericardium, this was not the case on the endocardium. The electrode orientation has previously been shown to influence lesion characteristics in a bench model.[8] In atrium, optimal CF has been evaluated around 20 g.[6,9–11] Concerning safety, minimal forces to perforate ventricles mechanically (without RF delivery) are higher than for atria (131 g [RA], 159 g [LA], 168 g [RV], and 227 g [LV])[12]; however, the force required to perforate when RF is delivered can be as low as 77 g in the atrium.[13]

Whereas it has been shown that CF was correlated with lesion volume,[6] it seems that a parameter coupling instantaneous total force and application duration (FTI)[4] was more accurate to predict lesion size. This was visually verified

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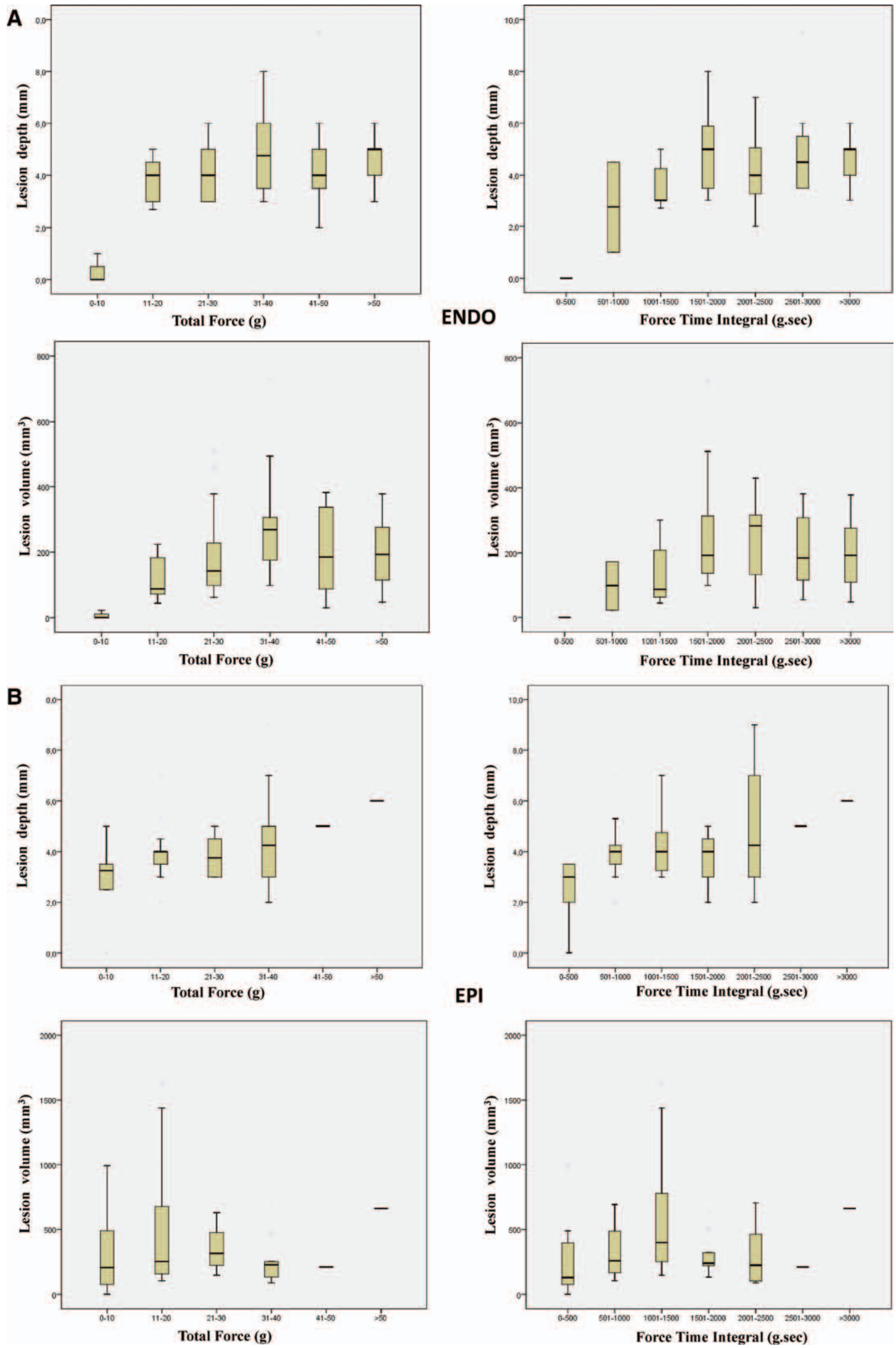

Figure 2. Mean lesion depth and volume of lesions performed with the Tacticath catheter depending on contact force (CF) and force–time integral (FTI) applied on the endocardium (**A**) vs epicardium (**B**).

for endocardial ventricular applications in this study, but not for epicardial ones. Moreover, in the Tacticath group, FTI was twice lower when applications were performed on the EPI compared with the endocardium, however, lesions volume were larger on the EPI (231±182 mm^3 versus 209±131 mm^3; *P*=0.02; Table 1). This was possibly because of the absence of the heat sink effect of circulating blood on the EPI, where energy stays locally.

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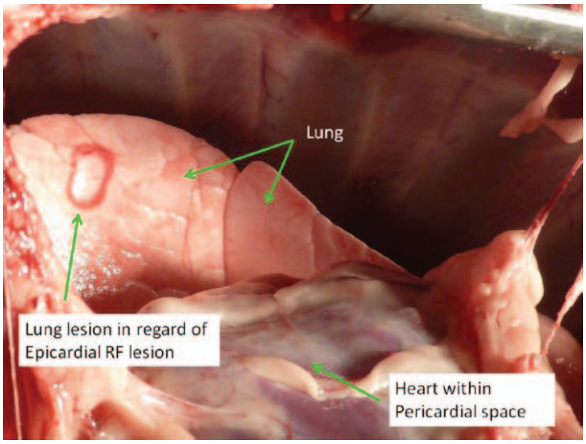

Figure 3. Lung lesion because of radiofrequency (RF) delivered on the epicardium with the catheter not well applied toward the heart.

On the ventricular endocardium, as earlier demonstrated for the atria, a total force<10 g or a FTI<500 g second results in no lesion being identifiable. However, optimal CF for ablation seems to be higher than for atria, based on Figure 2A. A total force of 30 to 40 g and a FTI between 2000 and 2500 g second seem to create optimal lesion.

On the epicardial side, CF information may not be as useful as ENDO, CF<10 g or an FTI<500 were enough to create lesion and there was no clear difference of lesion depth or volume using 11 to 20, 21 to 30, or 31 to 40 g of force. Moreover, it was infrequent to obtain a force >40 g on the pericardium, when the catheter lay on the ventricles in the absence of adherences. CF>40 g was obtained mainly when catheter faced the concavity of the pericardial space. Applying energy when the force is not directed toward the heart may result in lung lesion (Figure 3). It is particularly important that the vector of force is pointing toward the myocardium and not the lung, to prevent/minimize pulmonary lesions.

Limitations

Because of the design of the study, the operators were not blinded to the catheter type. To ensure recognition of the different ablation site at necropsy, a systematic approach was performed. Lesions characteristics, if RF had been applied at different sites, may have been different because of differing loads on the catheter dependent on the angle at which the catheter tip makes contact with the tissue.[8] Other variables such as electrode surface area in contact with the tissue and local blood flow known to effect lesion formation could not be controlled. Prevalence of ventricular arrhythmias during RF application is much higher in animal model compared with patients.

Conclusions

More than 20% of endocardial ventricular RF applications are not associated with tissue lesion in the absence of CF information with experienced operators. Epicardial ablation is associated with wider and larger lesions, whereas endocardial ablation results in deeper lesions.

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CLINICAL PERSPECTIVE

Although radiofrequency (RF) catheter ablation is well established, the operator has minimal information to guide actual lesion formation. This is of more importance for ventricular tachycardia than for simple supra ventricular tachycardia ablations, where the effect of ablation is immediately apparent, for example, loss of delta wave. This study demonstrates that even in experienced hands, 20% of lesion deliveries do not result in any myocardial lesions being formed. Contact force feedback dramatically improved the ablation results on the ventricular endocardium and epicardium, and a contact force threshold was defined for effective lesion formation. In addition, the vector of the catheter force (axial versus lateral) critically influenced lesion geometry and depth. The force–time integral (FTI) throughout RF application correlates to lesion volume in the atria, and this was also the case in the ventricle especially with endocardial lesions. Interestingly, epicardial RF applications required less contact force for similar lesion size, possibly due to less convective cooling on the epicardial surface. These data suggest that contact force feedback can dramatically increase the efficiency of lesion delivery for the operator. Although we are still unable to visualize lesion formation in real-time, the addition of contact force as another surrogate of lesion formation is an important step forward for catheter ablations.

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