Irrigated Needle Ablation Creates Larger and More Transmural Ventricular Lesions Compared With Standard Unipolar Ablation in an Ovine Model

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Background—Ventricular tachycardia recurrence can occur after ventricular tachycardia ablation because of incomplete and nontransmural ventricular lesion formation. We sought to compare the lesions made by a novel irrigated needle catheter to conventional radiofrequency lesions.

Methods and Results—Thirteen female sheep (4.6±0.7 years, 54±8 kg) were studied. In 7 sheep, 60-s radiofrequency applications were performed using an irrigated needle catheter. In 6 sheep, conventional lesions were made using a 4-mm irrigated catheter. 1.5T in vivo and high-density magnetic resonance imaging (9.4T) were performed on explanted hearts from animals receiving needle radiofrequency. Conventional lesion volume was calculated as \((1/6) \times \pi \times (A \times B^2 + C \times D^2)/2\). Needle lesion volume was measured as \(\Sigma (\pi r^2)/2\) with a slice thickness of 1 mm. The dimensions of all lesions were also measured on gross pathology. Additional histological analysis of the needle lesions was performed. One hundred twenty endocardial left ventricular ablation lesions (conventional, n=60; needle, n=60) were created. At necropsy, more lesions were found using needle versus conventional radiofrequency (90% versus 75%; \(P<0.05\)). Comparing needle versus conventional radiofrequency: lesion volume was larger (1030±362 versus 488±384 mm\(^3\); \(P<0.001\)), and more transmural lesions were created (62.5% versus 17%; \(P<0.01\)). Pericardial contrast injection was observed in 4 apical attempts using needle radiofrequency, however, with no adverse effects. Steam pops occurred in 3 attempts using conventional radiofrequency.

Conclusions—Irrigated needle ablation is associated with more frequent, larger, deeper, and more often transmural lesions compared with conventional irrigated ablation. This technology might be of value to treat intramural or epicardial ventricular tachycardia substrates resistant to conventional ablation. (Circ Arrhythm Electrophysiol. 2015;8:1498-1506. DOI: 10.1161/CIRCEP.115.002963.)

Key Words: ablation techniques ▪ arrhythmias, cardiac ▪ catheter ablation ▪ magnetic resonance imaging ▪ models, animal

Ventricular tachycardia (VT) ablation is associated with a relatively high recurrence rate. Outcomes of VT ablation are worse in nonischemic cardiomyopathy when compared with ischemic cardiomyopathy.\(^1\)\(^2\) One of the factors contributing to high recurrence rates may be the inability to perform transmural lesions. Formation of transmural lesions is particularly important in patients with intramural arrhythmogenic substrates and preserved wall thickness. In this context, techniques such as selective intracoronary ethanol injection or bipolar ablation, have demonstrated promise, however, have not been widely adopted.\(^3\)\(^6\)

A promising novel technology for ablation of intramural VT circuits of foci is the retractable needle catheter technique. Several recent studies have demonstrated that the technique may be useful in patients with VT resistant to conventional ablation.\(^7\)\(^8\)\(^9\)\(^10\) However, characteristics of lesions after needle ablation, both in healthy and scarred tissue, have not been fully defined. Furthermore, optimal ablation settings are not yet established (saline infusion rate through the needle and the catheter, power titration, and ablation time). The aim of this study was (1) to evaluate lesion formation

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WHAT IS KNOWN

- VT recurrence can occur after VT ablation due to nontransmural lesion formation.
- Irrigated needle ablation creates large ventricular lesions.

WHAT THE STUDY ADDS

- Prospective comparison between needle ablation and conventional ablation shows superior lesion size, depth and transmurality from irrigated needle ablation.
- Needle RF lesions are visible on both 1.5T and 9.4T DE-MRI but 9.4T DE-MRI delivers high density, histology-like lesion information.

using a retractable needle catheter versus conventional ablation and (2) to evaluate the safety of VT ablation using the needle catheter.

Methods

Animal Preparation

The experimental protocol was compliant with the Guiding Principles for the Use and Care of Animals published by the National Institutes of Health (NIH Publication no. 85-23, Revised 1996). Animals were sedated with an intramuscular injection of 20 mg/kg ketamine hydrochloride and anesthetized 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/h) and pentobarbital (150 mg/h). 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 catheter was placed in the internal jugular vein for infusion of drugs and fluids. Arterial blood gases were monitored at 30-minute intervals (Radiometer, Copenhagen, Denmark), and ventilation parameters were adjusted to maintain blood gases within physiological ranges.

Substrate Mapping

The left ventricle was accessed via a retrograde aortic approach, and a short 7 or 8F sheath was placed in the right femoral artery. In both groups, bipolar voltage map of left ventricular endocardium was acquired using ablation catheters (Thermocool or needle catheter, Biosense Webster, Diamond Bar, CA) and a CARTO system. Conventional voltage thresholds were applied (<0.5 mV as dense scar, 0.5–1.5 mV as border zone, >1.5 mV as normal tissue). All ablation lesions were created in healthy tissue (normal voltage) and were manually annotated as 3-dimensional (3D) tags on the map to compare the lesions with the magnetic resonance imaging (MRI) data after postprocedural image integration.

Catheter Ablation

The deflectable needle catheter has a distal bipole with an extendable/retractable 27 gauge nitinol needle. The needle has an embedded thermocouple and has a central lumen through which saline can be infused, and the lumen of the catheter is flushed separately. A position sensor within the catheter tip is compatible with the CARTO system (Biosense Webster). The needle can be retracted completely within the catheter tip and completely expanded has a needle length of 12 mm (common used lengths vary between 4 and 8 mm). At the distal handle, a manual adjustable system can adjust the wanted needle length in mm and enables retraction and expansion of the needle. The bipolar recordings Abl1-2 were made between the needle and the distal electrode. Abl3-4 was made between the ring electrode and the distal electrode. Abl1-2 was noisy and not interpretable with the needle retracted, but became visible after needle deployment. Impedance was only recorded with the needle extracted. Pacing in both unipolar (0.5–500 Hz, between needle tip and catheter electrode in the inferior caval vein) and bipolar (30–500 Hz, between needle tip and distal electrode) mode and electrogram recordings are possible from the catheter electrodes and the needle tip.

Needle Ablation Group

The needle was fully retracted during manipulation within the left ventricle. Ablation sites were tagged on the substrate map. In an attempt to comprehensively analyze the effect of needle ablation, lesions were delivered in multiple different areas of the left ventricle.

When good contact and perpendicular tip position were expected by tactile feedback and fluoroscopy, the needle was expanded during fluoroscopy to evaluate needle deployment. ST elevation on the unipolar tip electrode and ectopic beats were frequently observed during this maneuver. Contrast injection of 1 to 2 mL of Omnipaque 300 mg/mL was performed under fluoroscopic view to evaluate contrast staining and to rule out perforation. After contrast injection, the needle was flushed during 60 to 90 s (defined as waiting time). Ablation was then performed, using a power controlled mode (25–35 W) with an ablation duration of 60 s at an infusion rate of 2 mL/min flow through the needle lumen and 1 to 2 mL/min flow rate through the catheter lumen. Ablation was started at 25 W and up titrated to 35 W if a stable decline in impedance was observed. An application was considered if radiofrequency was delivered for ≥10 s. The choice of flow settings was based on the available data from animal and clinical studies and from our own experimental data demonstrating larger needle lesions using 2 mL/min versus 1 mL/min flow (unpublished data). From a theoretical perspective, the saline infusion acts as a virtual electrode and potentially cools the needle tip. Needle perforations with contrast injection into the pericardial space were not considered as radiofrequency applications because radiofrequency was not delivered in this situation.

In case of stable sinus rhythm, bipolar electrogram voltage was measured before and after ablation, with the needle deployed in the myocardium, using an EP Recording System (LabSystem PRO, Bard EP, Lowell, MA). Pacing thresholds were also analyzed before and after ablation using a stimulator (UHS 3000, Biotronik, Berlin, Germany). Because this device has a maximal limit on pacing thresholds of 10 mA, we considered any threshold >10 mA as 11 mA.

Conventional Ablation Group

Endocardial ablation sites were selected on the substrate map in healthy left ventricular areas. Each ablation site was tagged on the substrate map. When good contact was expected by tactile feedback and fluoroscopy, a conventional ablation (Thermocool, Biosense Webster, Diamond Bar, CA) was performed for a duration of 60 s using a power-controlled mode (30–35 W) and 30 mL/min irrigation rate. An application was considered if radiofrequency was delivered for ≥10 s.

Magnetic Resonance Imaging

MRI was performed in 5 of 7 animals from the needle ablation group. In vivo late gadolinium–enhanced MRI was performed immediately after the ablation procedure to assess whether acute lesions could be assessed noninvasively. Imaging was performed using a 1.5T device (Avanto, Siemens Medical Systems, Erlangen, Germany) equipped with a 32-channel cardiac coil. Late gadolinium–enhanced imaging was initiated 15 minutes after the injection of 0.2 mmol/kg gadodiamide meglumine (Dotarem, Laboratoires Guerbet, Aulnay-sous-Bois, France). Images were acquired using a 3D, ECG-gated, respiratory-navigated, and inversion recovery-prepared turbo fast low angle shot sequence with fat saturation. Sequence parameters were—voxel size
1.25×1.25×2.5 mm, TR/TE 6.1/2.2 ms, flip angle 22°, inversion time 260 to 320 ms depending on the results of a T1 scout scan performed immediately before acquisition, parallel imaging with GRAPPA technique with K=2, 42 reference lines, and acquisition time 5 to 10 minutes depending on the animal’s heart and breath rate.

Ex vivo high-resolution MRI (9.4T) was performed on explanted hearts from the same animals. The aim was to assess tissue characteristics at lesion site (needle trajectory, necrotic core, and hemorrhagic halo) and to enable accurate 3D lesion measurement (volume, transmurality). Animals were euthanized after in vivo MRI acquisitions, and the hearts were rapidly removed and flushed with cold cardioplegic solution, followed by a fixed perfusion during 1.5 hours with a 1 L solution of 4% formalin in PBS containing 2 mL gadodiamate meglumine (Dotarem, Guerbet). Imaging was performed with the heart removed from formalin and placed in a plastic container immersed with Fomblin (Aldrich), a perfluoropolyether for susceptibility matching. Imaging was performed on a 9.4T system (Bruker BioSpin MRI, Ettlingen, Germany) with an open bore access of 30 cm, using a 7-element transmit/receive array coil. The whole heart was imaged in short-axis orientation using a 3D turbo fast low angle shot sequence with the following parameters: voxel size 80×80×235 μm, TR/TE 25/9 ms, flip angle 30°, and acquisition time of ≈110 hours per animal.

On these high-resolution images, lesions were identified and labeled by reviewing the lesion tags on the 3D electroanatomic map. MRI signal characteristics were assessed at each lesion site. Lesions were described as present or absent, transmural or nontransmural. Lesions were considered as transmural when extending from the endocardium to <2 mm from the epicardium. In addition, lesion volume was measured by 3D manual segmentation using the software OsiriX 3.9.4 (Osirix Foundation, Geneva, Switzerland).

Gross Pathology and Histology
Gross anatomic examination was performed immediately after animal euthanize, in all animals from the conventional ablation group (n=6) and in 2 animals from the needle ablation group. In the 5 animals from the needle group, who underwent MRI, gross pathology examination was performed after fixation. Lesions were identified and labeled by reviewing the lesion tags on the 3D electroanatomic map. Lesions were described as present or absent, transmural or nontransmural. Lesions were considered as transmural when extending from the endocardium to <2 mm from the epicardium. The 3 dimensions were measured on each lesion using a micrometer (±0.1 mm), with surrounding inflammation being excluded from lesion sizing.

The volume of conventional radiofrequency lesions was considered as half a prostate ellipsoid (missing cap) and computed as follows: lesion volume = (π/6) × (A × B × C) where A, B, and C are the dimensions in millimeters. The volume of needle radiofrequency lesions was calculated as the sum of all slice surfaces (π×width²/2 for each slice) of 1-mm section thickness on ex vivo high resolution 3D MRI data (surrogate for histological slices), as described by Sapp et al.11 Hence, high-field MR lesion volume measurements were only available in 5 of 7 animals from the needle ablation group.

Histological assessment was performed in 5 animals from the needle ablation group (the same that underwent MRI). After fixation in formaldehyde, explants were processed using an automatic tissue treatment (LEICA TP1020) for embedding in paraffin (LEICA EG1150H). Serial 6-μm thick sections were cut using a Microtome (LEICA RM2255) and stained with Masson trichrome, after standard procedures. Paraaffin sections were deparaffinized with toluene and rehydrated in graded series of ethanol and distilled water before staining (tissue coloring using HMS70 from MicroMicrom). After staining, the sections were analyzed by a certified anatomic pathologist using a dedicated Microscope (NIKON Eclipse) and imaging software (NIS Elements D version 4.12).

Statistical Analysis
Continuous data are expressed as mean±SD. The one-sample Kolmogorov–Smirnov test was used to ensure a normal distribution of the measurement data. Continuous variables were compared between groups using parametric (Student t) or nonparametric (Mann–Whitney) tests, depending on data normality. Specifically, a linear mixed model analysis was used to identify statistically significant differences in lesions measurements between the 2 groups (needle versus conventional), taking lesions as repeated measures. A paired analysis was performed when data were compared before and after radiofrequency. Categorical variables were compared using Fisher exact tests. A P value <0.05 was considered to indicate statistical significance. Statistical analyses were performed using PASW Statistics 18 (version 18.0.0).

Results
Population Characteristics
Thirteen female sheep (4.6±0.7 years, 54±8 kg) were included and divided into 2 groups, one undergoing ablation with the conventional irrigated catheter (n=6) and the other undergoing ablation with the needle irrigated ablation catheter (n=7).

A total of 120 ablation lesions (conventional radiofrequency, n=60; needle radiofrequency, n=60) were created in the 13 sheep. A mean waiting time between contrast staining and radiofrequency application in the needle radiofrequency group was 79±23 s. The needle was deployed from 3 to 8 mm in all animals with a mean length of 6±1 mm. Apical lesions were performed with 3 mm deployment length in all cases. Baseline characteristics are presented in Table 1. Macroscopic lesion assessment was feasible in all 13 animals. It was performed on wet tissue in 8 animals, and after fixation in the 5 animals that underwent MRI. In vivo and ex vivo MRI studies were feasible in all 5 animals in which they were attempted. Histological analysis was feasible in all of these 5 animals.

Procedural Data
Among the 120 radiofrequency applications, there were no differences in radiofrequency duration between groups (58±10...
s in needle group versus 55±13 s in conventional group; \( P=0.33 \), and effective mean power delivered between both groups (29±5.8 W in needle group versus 30±1.8 W in conventional group; \( P=0.39 \)). Using the needle catheter, contrast injection into the pericardial space occurred in 4 attempts at the apex, whereas the needle was deployed at 3 mm. After the identification of pericardial injection, the needle was retracted, and the animal was observed during 10 minutes. There was no evidence of tamponade in any of the 4 cases. Short runs of ventricular tachycardia were frequently observed during radiofrequency application. Sustained ventricular arrhythmias were observed in 4 cases (3 monomorphic VT and 1 VF) In these 3 cases of sustained ventricular tachycardia, the needle was retracted and no further measurements were performed (sinus rhythm was necessary for bipolar voltage measurement). In the case of ventricular fibrillation, the needle was retracted and the animal received 1 direct current shock and returned into sinus rhythm.

Pacing thresholds and voltage measurements are shown in Table 2 and an example is given in Figure 1. Pacing threshold measurement was feasible both before and after ablation on 53 needle radiofrequency applications sites. Thresholds increased from 6.2±2.9 mA before ablation to 9.8±2.5 mA after ablation (\( P<0.001 \)). A threshold above >10 mA was observed on 2 of 53 sites before ablation and 19 of 53 sites after ablation (\( P<0.001 \)). Bipolar voltage could be reliably measured before and after radiofrequency on 28 needle radiofrequency applications sites. A decrease in bipolar voltage was consistently observed after ablation (2.7±2.7 mV before radiofrequency versus 0.7±0.4 mV after radiofrequency; \( P<0.001 \)). In the conventional radiofrequency group, 3 steam pops occurred during ablation, however, no tamponade was observed. One episode of ventricular fibrillation was observed during ablation, requiring multiple shocks. All 13 animals survived the complete ablation procedure.

Table 2. Electrogram and Threshold Measurements

<table>
<thead>
<tr>
<th></th>
<th>Needle RF</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of RF applications</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>No. of threshold measures</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td>Unipolar threshold before RF</td>
<td>6.2±2.9 mA</td>
<td></td>
</tr>
<tr>
<td>Unipolar threshold after RF</td>
<td>9.8±2.5 mA</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No capture &gt;10 mA before RF</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>No capture &gt;10 mA after RF</td>
<td>19</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No of electrogram measurements</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Bipolar voltage before RF</td>
<td>2.7±2.7 mV</td>
<td></td>
</tr>
<tr>
<td>Bipolar voltage after RF</td>
<td>0.7±0.4 mV</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bipolar voltage reduction</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

RF indicates radiofrequency

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Figure 1. Fluoroscopic image and electrogram recording of a needle ablation procedure. A, Irrigated needle catheter with extracted needle (white circle) inside the myocardium using retrograde aortic access. Another bipolar diagnostic catheter is positioned in the inferior caval vein for unipolar needle tip recording. B, Intramyocardial contrast staining (white outline) after injection of 1 mL Omnipaque contrast through the needle tip. No contrast perfusion into the pericardial space. C, Electrogram recordings: the first 3 lines are 3 different ECG derivations, the second 2 lines are bipolar recordings between the needle tip and ring electrode, and the last 2 lines are unipolar recordings of the needle tip and the ring electrode. Top, Sinus rhythm. Before ablation, a bipolar voltage of 3.16 mV was measured. An R wave was observed on the unipolar recording before the application. Middle, An ST elevation was seen on the unipolar recordings during contrast injection. Often, premature ventricular contractions are seen, when the needle enters the myocardium. Bottom, Sinus rhythm with multiple premature ventricular contractions. After ablation, 1.5 mV bipolar voltage was measured. A QS pattern on the unipolar recording was seen after the application. RF indicates radiofrequency.
Lesion Characteristics on Gross Pathology and MRI

After the ablation procedure, more lesions were found on necropsy in the needle radiofrequency group when compared with the conventional ablation group (needle versus conventional: 54/60 [90%] versus 45/60 [75%]; P<0.05). Furthermore, lesion volume was more than twice as large in the needle radiofrequency group (needle versus conventional: 1030±362 versus 488±384 mm³; P<0.001). Needle radiofrequency lesions were also deeper (needle versus conventional: 9.9±2.7 versus 5.2±2.4 mm; P<0.001) and more likely to be transmural (needle versus conventional: 62.5% versus 17%, P<0.01). All transmural lesions using conventional radiofrequency were found near the left ventricular apex where a wall thickness of ≤3 mm was measured. Ablation and lesion characteristics are outlined in Table 3. A comparison between conventional and needle radiofrequency lesions is given in Figure 2. Mixed-model analysis demonstrated that the lesion size was solely dependent on the method used (conventional radiofrequency versus needle radiofrequency, F=11.422 and P=0.001). The results are summarized in Table I in the Data Supplement.

In Vivo and Ex Vivo Imaging Features

In vivo MRI studies were feasible using a clinical 1.5T scanner in all 5 animals from the needle ablation group. In these animals, radiofrequency applications had been performed on 50 sites. Late gadolinium–enhanced imaging was performed within 60 minutes of the ablation procedure in all animals and allowed for the visualization of lesions at all sites of radiofrequency application (50/50). All lesions demonstrated characteristics consistent with coagulative necrosis, that is, a halo of intense enhancement surrounding a dark core. Lesions were of ellipsoid shape, with a center located within midwall layers.

Ex vivo MRI studies with a 9.4T scanner were feasible in all 5 animals. Of note, however, the size of the hearts did not enable a complete left ventricular coverage. Therefore, the apex was not included in the field of view, and apical radiofrequency application sites could not be analyzed. Nonetheless, lesions were identified at all radiofrequency application sites present in the imaging field of view (41/41). All lesions showed similar features, that is, a halo of hypointense signal compatible with hemorrhagic tissue, surrounding a highly heterogeneous necrotic core. Lesions appeared to be of ellipsoid or teardrop shape, with a center located within midwall layers. The needle trajectory was clearly visible in all cases. Comparative examples of in vivo and ex vivo MRI are illustrated in Figure 3, and additional examples of 9.4T ex vivo MRI are shown in Figure 4.

Histological Features

Histological abnormalities were observed in all 54 lesions identified on gross pathology. At the core of the ablation lesions, hyper contracted muscle fibers (monophasic muscular degeneration) were observed. In some cases, fragmented sarcoplasm with an intact nucleus was observed. In addition, discrete microhemorrhage and vascular congestion were seen. When present, Purkinje fibers were vacuolated and fragmented.

At the lesion border zone, muscle fibers appeared less contracted and were characterized with a brilliant red appearance of the sarcoplasm with Masson trichrome staining. The needle trajectory after radiofrequency delivery, when visible, was characterized by torn and hyper contracted fibers (boiled appearance of the fibers). The needle trajectory of a puncture attempt without radiofrequency delivery was characterized by small amount of mechanical tearing of myofibers, but not the brilliant red appearance of the sarcoplasm and the disarray of the Purkinje fibers. These findings suggest that the latter

Table 3. Ablation Data

<table>
<thead>
<tr>
<th></th>
<th>Conventional RF</th>
<th>Needle RF</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of RF applications</td>
<td>60</td>
<td>60</td>
<td>NS</td>
</tr>
<tr>
<td>RF duration, s</td>
<td>55±13</td>
<td>58±10</td>
<td>0.33</td>
</tr>
<tr>
<td>Mean power delivery, W</td>
<td>30±1.8</td>
<td>29±5.8</td>
<td>0.39</td>
</tr>
<tr>
<td>No. of lesions found</td>
<td>45 (75%)</td>
<td>54 (90%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Lesion depth, mm</td>
<td>5.2±2.4</td>
<td>9.9±2.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td>5.2±1.7</td>
<td>8.5±2.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lesion width, mm</td>
<td>7.9±2.4</td>
<td>8.5±2.5</td>
<td>0.33</td>
</tr>
<tr>
<td>Lesion volume, mm³</td>
<td>488±384</td>
<td>1030±362</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No. of RF applications</td>
<td>60</td>
<td>60</td>
<td>NS</td>
</tr>
<tr>
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<td>0.33</td>
</tr>
<tr>
<td>Lesion volume, mm³</td>
<td>488±384</td>
<td>1030±362</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Transmural lesion, %</td>
<td>17%</td>
<td>62.5%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>T₀s and T₃₀s impedance, ohms</td>
<td>134±31 and 16±21</td>
<td>109±13 and 94±8</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

NS indicates not significant; RF, radiofrequency; T₀s, after 0 s; and T₃₀s, after 30 s.
changes are because of tissue heating of radiofrequency delivery on top of the mechanical disruption of myofibers. Necrosis but no fibrosis was seen within the lesions, as the specimens were fixated at the acute phase.

Finally, a degenerated musculature was seen from the center toward the borderzone. Macroscopic, histological, and MRI appearance of the same radiofrequency lesion are illustrated in Figure 5. Additional histological examples are demonstrated in Figure 6.

Discussion
The main findings of this study are (1) radiofrequency deliveries by an irrigated needle ablation catheter result in more frequent lesions. The lesions are larger, deeper, and more often transmural than those induced by conventional irrigated catheters, (2) needle radiofrequency ablation seems to be feasible and safe in the left ventricle, and (3) these lesions can be qualitatively and quantitatively assessed with the use of in vivo and ex vivo MRI.

Lesion Size in Needle Versus Conventional Radiofrequency Catheters
Multiple previous studies have reported that conventional ablation catheters fail to create deep or transmural lesions.8,12 This study demonstrates that lesions created by the irrigated needle catheter are significantly larger and deeper than those created by a conventional irrigated catheter. This finding may be of interest for ablation of VT circuits refractory to conventional ablation because of deep intramural locations. It also offers the possible treatment of epicardial targets from the endocardium, sparing the need for epicardial access. This could be of major interest particularly when epicardial targets are covered by coronary artery branches.

In addition to needle catheters, several techniques have attempted to overcome the challenges of ablating intramural VT circuits. Sacher et al13 reported that the use of contact force sensing catheters is associated with a higher prevalence of lesions at necropsy in animal models. However, the size and depth of the lesions was not significantly improved (<5 mm). Transcoronary ethanol ablation has been reported to be effective for the management of intramural VT resistant to conventional radiofrequency ablation.14 However, ethanol ablation is limited by the anatomy of the coronary artery system and the challenge of controlling lesion size.5

Bipolar ablation is another technique that has been demonstrated to increase lesion size. The ability of the method to induce transmural lesions has been demonstrated in animal and computer modeling studies.14 However to this day, the use of bipolar ablation in humans has only been evaluated in small case series with heterogeneous clinical results.4,6,15

Preliminary results of epicardial ablation using an open-chest approach are included as Data Supplement (Figure I in the Data Supplement). The needle catheter was held manually with moderate pressure, ≈3 cm from the needle tip. This technique could be used during a hybrid surgical approach using a minithoracotomy. We have however not investigated the possibility of needle ablation using a subxyphoid approach because we hypothesized that we could not have a favorable angulation toward the epicardium and the potential harm of direct puncture of coronary arteries with the needle tip. With direct optical visualization, it could be investigated, however, once again, we believe correct angulation maybe a challenge.

Because our results indicate that irrigated needle ablation catheters are able to create intramural lesions of consistent size, this technique can be viewed as a promising alternative in patients refractory to conventional ablation, as recently suggested by the results of a first clinical study.10

In Vivo Lesion Efficacy Evaluation of Needle Ablation
Sacher et al previously demonstrated an electrogram reduction >50% in approximately half of applications using

Figure 3. Macroscopic, histological, and magnetic resonance imaging (MRI) comparison of the same needle radiofrequency (RF) lesion. A, Histological analysis with a visible needle trajectory (arrow). No fibrosis is observed in the acute phase. B, Macroscopic evaluation of the same needle RF lesion with a 2-mm gap toward the epicardium. These gaps (1–2 mm) are often seen on purpose to avoid complications of needle perforation, without information on local wall thickness. The needle trajectory is also macroscopically visible (arrow). C, High-density ex vivo (9.4T) MRI image—short-axis plane—of the same needle lesion with visualization of the needle trajectory (arrow).
conventional ablation. Electrogram reduction was more frequent when a lesion was found at necropsy compared with the absence of lesion.16 Our findings relating to needle radiofrequency application compare favorably with this report. We demonstrated an electrogram reduction of >50% during all radiofrequency applications. Potential explanations for these findings include the fact that we used contrast staining and we evaluated ventricular premature beats with needle extraction and ST elevation before radiofrequency delivery. We think that these measures help to select for potential effective radiofrequency applications. Consistent with the findings relating to electrogram reduction, 100% of needle radiofrequency lesions were identified using MRI. Intramural bipolar pacing did increase after ablation when feasible. All these measurements can potentially help to evaluate efficacy of lesion formation, but this has to be further investigated.

Safety of Needle Ablation
This animal study did not demonstrate major complications associated with needle ablation. To avoid perforation, the needle deployment did not exceed 8 mm. At apical sites, needle length was limited to 3 mm. However, 4 perforations were observed, as identified by iodine contrast injection. The small size of the needle probably explains the absence of tamponade in such situation. All pericardial contrast bluses occurred at apical needle positions. These findings suggest that radiofrequency application with the needle should be avoided or limited to <3 mm needle length in structurally remodeled areas with severe wall thinning. Furthermore, in area with thinner myocardial tissue, such as the left ventricular apex and right ventricular free wall, needle radiofrequency should be delivered with caution.

Two VF episodes were observed in this series, 1 because of needle deployment and 1 because of radiofrequency delivery with conventional catheter. Sheep are prone to develop VF when the ventricles are targeted and this risk should probably not be extrapolated to humans.

Interestingly, in a recent feasibility study in humans, Sapp et al reported complications in 3 of 8 patients (1 tamponade and 2 heart block).10 These findings highlight the point that the safety of needle ablation should be further studied in larger cohorts of patients undergoing VT ablation. In this context, the integration of wall thickness maps derived from preprocedural imaging into 3D mapping systems might be helpful to define the needle deployment length that is most appropriate for a given site.17

The appearance of the needle trajectory on high-density MRI and histology, could potentially raise concerns regarding fistula creation following needle ablation. Of note however in their limited clinical series Sapp et al10 did not report any clinical fistulae after a mean follow-up of 12 months. Further studies in larger cohorts of patients are necessary to fully address this question.

Finally, coronary injury may remain a concern, as the lesions are often transmural. Needle ablation may not obviate the need for performing a coronary angiogram before and after ablation. Even if preliminary clinical data from Sapp et al did not show acute coronary syndromes, more data are needed.10
Use of MRI to Characterize Ablation Lesions
Our results demonstrate that both in vivo and ex vivo MRI can be used to identify radiofrequency lesions and quantify lesion size. In this study, in vivo MRI was performed on a clinical scanner using a clinically available imaging protocol. This free-breathing method, initially developed to image atrial fibrosis, was chosen because of its higher spatial resolution when compared with conventional late gadolinium–enhancement methods acquired during 1 breath-hold. Using this method, lesions were depicted on all sites of needle radiofrequency application. This finding suggests both that myocardial damage is consistently observed after needle radiofrequency ablation and that in vivo MRI can identify these lesions with high sensitivity. The ability of MRI to assess acute ablation lesions is consistent with prior reports using conventional ablation in humans and to a recent animal study.

In this study, we also performed ex vivo MRI on explanted hearts using a high field strength MRI system (9.4T). The rationale to add ex vivo MRI data was to provide structural information on ablation lesions with high spatial resolution and with minimal organ deformation. Indeed, accurate sizing of needle ablation lesions could not be directly derived from the lesion dimensions measured on gross pathology, because the shape of the lesions was highly variable, as opposed to conventional ablation lesions that can be considered as half a prolate ellipsoid. Therefore, 3D segmentation was considered more robust. In addition, ex vivo MRI facilitated the comparison to electroanatomical map and the labeling of ablation sites because the global shape of the organ was preserved.

We think that our MRI results illustrate the use of MRI in the postablation setting either in vivo to document lesion formation and transmurality at the acute stage or ex vivo as a surrogate for histology to overcome the issue of spatial registration with procedural data.

Limitations
The first limitation of this study is that ablation was performed in healthy tissue only. Therefore, the reported lesion size might apply to patients with nonscar-related VT, but lesion formation in patients with scar-related VT should be addressed in future studies. However, scar-related VT is usually associated with thinner myocardium, and conventional radiofrequency is more likely to create transmural lesions. Furthermore, lesions were characterized at the acute stage, and further research is therefore required to describe the definite result of needle radiofrequency ablation at the chronic stage. Another potential limitation is the absence of contact force in the group with conventional ablation catheters. However, although this contact force was shown to be associated with a higher rate of lesions on pathology, the size of the lesions do not seem to be improved. Finally, MRI characterization was only used in the needle ablation group, given the limited availability of MRI, prolonged scanning times (>120 hours), and the fact that previous studies have reported on MRI imaging after conventional ablation, we focused our imaging on the needle group. The description of conventional ablation lesions on MRI has already been reported, and the sizing of these lesions from gross pathology measurements was shown to be similar and feasible.

Conclusions
Needle radiofrequency ablation seems to be feasible and safe in the left ventricle. Lesions induced by an irrigated needle ablation catheter are more frequent, larger, deeper, and more often transmural than those induced by conventional irrigated catheters. These lesions can be qualitatively and quantitatively assessed at the acute stage with the use of in vivo and ex vivo MRI.

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References


Irrigated Needle Ablation Creates Larger and More Transmural Ventricular Lesions Compared With Standard Unipolar Ablation in an Ovine Model

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**Supplemental Table 1:** Mixed analysis of lesion size.

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*a. Dependent Variable: Volume.*

**Abbreviations:** df, degrees of freedom; F, F-statistic; Sig., p-value; lesion #, lesion number.
**Supplemental Figure 1:** Two examples of epicardial needle ablations using an open-chest approach. Two ex-vivo freshly explanted sheep hearts after epicardial needle ablation (4 lesions in Figure A and 4 lesions in Figure B). Access was obtained by a surgical sternotomy. Saline infusion into the pericardial sac was performed (under hemodynamic monitoring) to ensure constant covering by saline of the needle tip during ablation. **A.** The results of 4 needle ablation lesions are shown here. Power was increased in steps of 5 Watts (20-25-30-35 Watts) from left to right (yellow arrow) during 60sec ablation duration and fixed gap and needle irrigation rate at 2ml/min. Lesion size increased from left to right from 6mm depth and 5mm width to 10mm depth and 9mm width. **B.** The results of 4 needle ablation lesions are shown here. Power was delivered at 35 Watts and fixed needle irrigation rate at 2ml/min. Ablation duration and gap flow rate was increased from left to right (yellow arrow). RF energy for the first two lesions was delivered during 30 seconds and RF energy was delivered during 60 seconds for the last two lesions. Gap flow rate was 1ml/min for lesion 1 and 3 and 2ml/min for lesion 2 and 4. Lesion depth for all lesions was constant at 10±1mm but lesion width increased from 4mm to 8mm.