Use of a Novel Irrigated Balloon Catheter to Generate Continuous Right Atrial Lesions by Radiofrequency Ablation

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Summary

Ablation catheters with multiple electrodes are effective for the creation of linear atrial lesions but are associated with an increased risk of coagulum formation. In an animal study, we used a novel 9Fr deflectable ablation catheter with two saline/foam electrode pocket covered with 20 mm tubing. Each pocket contained six 2-mm long electrodes with a 1-mm interelectrode distance. Bipolar electrograms between the 3 distal and 3 proximal composite electrodes were recorded, and the pacing threshold was determined before and after radiofrequency (RF) ablation. Long linear lesions were created by applying RF energy for 90 seconds at 50 W during saline irrigation (0.4 mL/sec) between 1) the superior vena cava (SVC) and inferior vena cava (IVC), 2) SVC, fossa ovalis, and IVC, 3) transverse loop from the crista terminalis to the tricuspid valve (TV), and 4) TV and the IVC. Continuous transmural lesions were created only in a minority of cases, and lesion gaps were noted in the free wall lesions. No coagulum formation was observed after RF energy delivery. A long lesion can be created in the right atrium by using an irrigated balloon catheter, but continuous lesion formation was achieved only in a minority of animals. (Int Heart J 2009; 50: 365-376)

Key words: Catheter ablation, Atrial fibrillation, Irrigation catheter, Maze procedure

Radiofrequency (RF) catheter ablation has been shown to be an effective method for curing supraventricular tachycardia and isthmus dependent atrial flutter.1-4) Catheter ablation for curing atrial fibrillation (AF) based on surgical maze has also been reported, but the success rate was low because of discontinuities within the lesions and an increased risk of coagulum formation leading to thromboembolic complications.5-7) Recently, catheter ablation of ectopic...
foci originating in the pulmonary veins was shown to be effective for curing paroxysmal AF.\textsuperscript{8} Isolation of at least 3 pulmonary veins was reported to be effective in 70\% of patients with paroxysmal AF but in only 22\% of patients with persistent AF.\textsuperscript{9} Thus, pulmonary vein isolation and the production of continuous linear lesions might be a prerequisite for successful RF ablation of chronic AF. Ablation catheters with flexible, multiple coiled electrodes have been developed to improve tissue contact along the entire length of the electrode and are effective for creation of linear atrial lesions. However, penetration into the atrial wall by RF ablation may be limited, particularly in regions of trabeculation and anatomic complexity. RF ablation with multiple coiled electrodes is also associated with an increased risk of coagulum formation.\textsuperscript{10} Irrigation of the electrodes may help reduce this risk.\textsuperscript{11} We conducted an animal study to assess the potential utility of a specially designed cooled RF catheter system using long saline/foam electrodes with a support loop for creation of transmural linear lesions in the right atrium without risk of coagulum formation.

**Methods**

The care of all animals in this study conformed to the American Heart Association policy on research animal use and was in accordance with accepted guidelines for the care and treatment of experimental animals at Nihon University School of Medicine.

**Experimental preparation:** Twelve domestic pigs weighing 30-35 kg (32.9 ± 3.3 kg) were immobilized with ketamine (15 mg/kg) and anesthetized with pentobarbital sodium (25 mg/kg). Anesthesia was maintained with pentobarbital sodium (100 mg) as needed. The animals were then intubated with a volume controlled animal ventilator (Model 613, Harvard Apparatus, South Natick, MA, USA). Intravenous Ringer’s solution was infused as needed to replace lost fluid. Cut-down was performed in the right thigh area to isolate the right femoral vein. An 11Fr long introducer sheath (Soft Tip Sheath, Boston Scientific/EP Technologies, San Jose, CA, USA) was positioned in the right atrium through the right femoral vein under fluoroscopic guidance. All animals were fully anticoagulated using intravenous heparin at the dosage needed to achieve and maintain an activated clotting time of 2.5 to 3.0 times the baseline value. Advancement and deployment of the catheter onto the right atrial wall was performed under fluoroscopic guidance and confirmed by the intracardiac electrogram signal and pacing threshold. All animals were fully anticoagulated with intravenous heparin at the dosage needed to achieve and maintain an activated clotting time of 2.5-3.0 times the baseline value. The 9 Fr catheter system (Nexus\textsuperscript{TM} Linear Ablation Catheter, Cardiac Pathways Corp., Sunnyvale, CA, USA) consisted of
an inner electrode catheter with an adjustable support loop, which is deflectable at its base and fitted through the long guiding sheath. Two saline/foam electrode pockets that allow saline to flow toward the tissue to be ablated through an array of holes on the side of the loop wire were each 2 cm long with a 1.5-mm interpocket distance. Each electrode contained six 2-mm electrodes with a 1-mm interelectrode spacing, allowing for intracardiac bipolar recording and pacing between the 3 distal and 3 proximal composite electrodes (Figure 1).

Four long linear right atrial lesions were produced; 1) from the superior vena cava (SVC) to the inferior vena cava (IVC), 2) in the right atrial septum (from the SVC to fossa ovalis and fossa ovalis to the IVC), 3) in the right atrial free wall (mid right atrial horizontal transverse loop from tricuspid annulus (TA) to the crista terminalis), and 4) at the TA - IVC isthmus. The saline/foam electrode pockets were positioned against the right atrial wall by deflecting the catheter through the long sheath (15°curve for SVC - IVC and RA septum and 120° curve for RA free wall and TVA - IVC isthmus) and orienting the loop. The de-
gree and extent of contact between the electrode pockets and the right atrial tissue were optimized by adjusting the size of the support loop. Room-temperature saline was circulated through a double inner lumen to both pockets at a rate maintained by a motor-driven pump. Prior to RF energy delivery, saline infusion was initiated at 0.4 mL/sec, and approximately 10 mL of saline was infused to ensure priming and evacuation of blood. Saline infusion was maintained at a steady rate of 0.4 mL/sec throughout the ablation procedure. The RF generator was a computer-controlled device (Cable IT, Japan Lifeline Co., Tokyo) capable of delivering up to 70 W of power and equipped for continuous digital recording of system impedance and energy output. Immediately after the ablation procedure, the animals were killed by intravenous administration of potassium chloride for observation of acute results.

**Electrophysiologic measurements:** All electrophysiologic studies were performed in sinus rhythm. Surface electrocardiogram (ECG) and endocardial electrocardiogram signals were monitored continuously and recorded on a polygraph (MIC-9800, Fukuda Denshi Corp., Tokyo). ECG lead II and composite endocardial electrograms from distal and proximal electrodes pockets were displayed simultaneously. Pacing thresholds of the right atrium in contact with each electrode pocket were determined by using constant atrial pacing at a cycle length of 400 msec. Endocardial atrial signal amplitudes and pacing thresholds were obtained before and after ablation. The pre- and postablation bipolar electrogram amplitudes and electrogram amplitude ratio (postablation/preablation amplitude) were compared on the basis of preablation pacing threshold and pacing threshold ratio (postablation/preablation threshold) to predict transmural lesion formation.

**Ablation:** For each ablation, RF energy was applied simultaneously to the 6 electrodes within each pocket with the use of an integrated control box (Cardiac Pathways Corp.). A lead plate was used for the indifferent electrode and placed on the animal’s back. RF energy was delivered to each pocket at 50 W for 90 seconds in each ablation. During ablation, impedance was monitored continuously.

**Pathological analysis:** Gross and histopathologic examinations were performed 30 minutes after ablation. Lesions within the right atrium were subjected to gross examination, lesion dimensions were determined, and any evidence of endocardial coagulum formation or trauma was documented. Specimens were then submerged in 10% neutral buffered formalin for histological examination. After sectioning, the tissues were routinely processed, embedded in paraffin, sectioned to 5-μm thickness, and treated with hematoxylin and eosin stain. Tissue was evaluated for lesion dimension, extent of ablation injury, and evidence of pericardial injury.
**Statistical Analysis:** Data are expressed as the mean ± SD. Differences were analyzed by Student’s paired or unpaired *t*-test. *P* < 0.05 was considered significant. StatView 5.0 (SAS Institute Inc.) was used for all statistical analyses.

**RESULTS**

**Catheter positioning:** Ablation of the right atrial free wall and isthmus was accomplished with a single catheter positioning in 8 and 9 pigs, respectively. In 1 pig, catheter pullback was necessary to ablate the right atrial free wall and isthmus. Ablation of the SVC - IVC and right atrial septum lines was accomplished with 1-2 catheter pullbacks in all 12 pigs.

**Ablation and electrophysiologic correlates:** RF energy was delivered first through the distal pocket and then through the proximal pocket. All ablations were carried out to completion of 90 seconds without impedance rise. The pacing threshold was measured in 0.5 V increments at a pulse width of 0.5 ms. Ablation resulted in a significant reduction in the atrial electrogram amplitude from an average of 1.55 ± 0.98 mV to 0.47 ± 0.24 mV (*n* = 43, *P* < 0.00001) and an increase in the atrial pacing threshold from 2.87 ± 1.67 mV to 8.92 ± 1.95 mV (*n* = 41, *P* < 0.00001). Examination of the catheter after each ablation showed no coagulum, blood penetration, or electrode damage. In 16 of the 41 ablations, atrial pacing became impossible at the maximum output of 10.5 V. In such cases, the atrial pacing threshold was recorded as 10.5 V. Local bipolar electrogram

<table>
<thead>
<tr>
<th>Preablation Pacing Threshold (V)</th>
<th>EG Amplitude (mV) Preablation</th>
<th>EG Amplitude (mV) Postablation</th>
<th>Amplitude Ratio Post / Pre</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5-2.0 V</td>
<td>2.09 ± 1.19</td>
<td>0.49 ± 0.28</td>
<td>0.30 ± 0.24</td>
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<tr>
<td>2.5-4.0 V</td>
<td>1.30 ± 0.64†</td>
<td>0.45 ± 0.21‡</td>
<td>0.41 ± 0.17</td>
</tr>
<tr>
<td>≥ 4.5 V</td>
<td>0.84 ± 0.46†</td>
<td>0.44 ± 0.23</td>
<td>0.60 ± 0.31†</td>
</tr>
</tbody>
</table>

* † *P* < 0.0001 versus preablation; ‡ *P* < 0.05 versus 0.5-2.0 V; † † P < 0.002 versus 2.5-4.0 V; ‡ † *P* < 0.02 versus 0.50-2.0 V; † † P = 0.05 versus 2.5-4.0 V.

<table>
<thead>
<tr>
<th>Pacing Threshold Ratio (Post / Pre)</th>
<th>EG Amplitude (mV) Preablation</th>
<th>EG Amplitude (mV) Postablation</th>
<th>Amplitude Ratio Post / Pre</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 4.0</td>
<td>1.80 ± 1.21</td>
<td>0.34 ± 0.17†</td>
<td>0.27 ± 0.19</td>
</tr>
<tr>
<td>3.0-4.0</td>
<td>1.56 ± 0.69</td>
<td>0.59 ± 0.21†</td>
<td>0.44 ± 0.22‡</td>
</tr>
<tr>
<td>&lt; 3.0</td>
<td>0.99 ± 0.41</td>
<td>0.61 ± 0.29†</td>
<td>0.67 ± 0.18†</td>
</tr>
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* † *P* < 0.0001 versus preablation; ‡ P < 0.02 versus preablation; † † *P* < 0.001 versus > 4.0; † † † *P* < 0.001 versus > 4.0; † † † † *P* < 0.0001 versus > 4.0; † † † † † *P* < 0.05 versus 3.0-4.0.
amplitudes before and after ablation were then compared on the basis of the preablation pacing threshold. The pre- and postablation bipolar electrogram amplitudes were 2.09 ± 1.19 mV and 0.49 ± 0.28 mV, respectively ($P < 0.0001$), at a pacing threshold of 0.5-2.0 V, 1.30 ± 0.64 mV and 0.45 ± 0.21 mV at a pacing threshold of 2.5-4.0 V ($P < 0.0001$), and 0.84 ± 0.46 mV and 0.44 ± 0.23 mV ($P = 0.09$) at a pacing threshold of ≥ 4.5 V. The bipolar electrogram amplitude

Figure 2. A: Superior vena cava-inferior vena cava linear ablation. B: Gross effects of ablation in acute study.
ratio (postablation/preablation amplitude) was $0.30 \pm 0.24$ at a pacing threshold between 0.5-2.5 V, was $0.41 \pm 0.17$ at 3.0-4.0 V, and $0.60 \pm 0.31$ ($P < 0.03$ versus 0.5-2.5 V; $P = 0.05$ versus 2.5-4.0 V) at a pacing threshold of $\geq 4.5$ V (Table I). Local bipolar electrogram amplitudes before and after ablation were $1.80 \pm 1.21$ mV and $0.34 \pm 0.17$ mV ($P < 0.001$ versus 3.0-4.0; $P < 0.02$ versus <3) at a pacing threshold ratio (postablation/preablation threshold) of $> 4.0$, $1.56 \pm 0.69$ mV and $0.59 \pm 0.21$ mV at a pacing threshold ratio of 3.0-4.0, and $0.99 \pm 0.41$ mV ($P < 0.05$ versus 3.0-4.0) and $0.61 \pm 0.29$ mV at a pacing threshold ratio of

Figure 3. A: Right atrial free wall linear ablation. B: Gross effects of ablation in acute study.
The bipolar electrogram amplitude ratio (postablation/preablation amplitude) was $0.27 \pm 0.19$ ($P < 0.03$ versus 3-4; $P < 0.0010$ versus < 3) at a pacing threshold ratio of > 4, was $0.44 \pm 0.22$ ($P < 0.05$ versus < 3) at a pacing threshold ratio of 3-4, and $0.67 \pm 0.18$ at a pacing threshold ratio of < 3 (Table II). Examination of the catheter after ablation showed no coagulum, blood penetration, or electrode damage.

**Gross and histologic data:** Upon macroscopic examination, linear lesions were noted in all animals (Figures 2-4). However, on macroscopic examination 1 or 2 gaps (Figure 5) were noted in the SVC-IVC line in 6 of 12 (50%) animals, in the septal line in 5 of 12 (42%) animals, in the RA free wall line in 9 of 12 (75%)
Figure 5. Gap in the ablation line between superior vena cava - inferior vena cava ablation line.

Figure 6. A: Right atrial free wall lesion. Gross effects of ablation in acute study. B: Low-power view of the lesion on the right atrial free wall in the acute preparation. Note the transmural coagulative necrosis with central myocyte pallor surrounded by a rim of contraction band injury.
animals, and in the tricuspid isthmus line in 3 of 12 (25%) animals. No mural thrombus was noted in any lesion. There was no structural damage noted on the valve leaflets or choral attachments. Histologic examination revealed a sharply delineated zone of coagulative necrosis with central myocyte pallor surrounded by a rim of contraction band injury (Figure 6).

**DISCUSSION**

RF ablation by means of cooled methods has been shown to produce lesions that are larger than those produced by the corresponding conventional RF method.\(^{12,13}\) It was shown that heating occurred more deeply with a saline-irrigated system than with conventional RF ablation.\(^{14}\) Thus, cooling allows delivery of RF energy at increased power and duration, therefore, delivery of RF energy can potentially be modified to suit the desired lesion geometry. In this study, saline-cooled RF ablation was applied through long electrode pockets to meet the need for creating 4 linear lesions. To further improve positioning of the electrode along the right atrial wall, a support loop system and a long sheath of a different distal angle was used that provided for stabilization and optimal electrode-tissue contact. For confirmation of sufficient contact with the atrial tissue, each pocket contained a bipolar electrode system for electrophysiologic measurement. Delivery of 50 W of RF energy for 90 seconds did not result in impedance rise or coagulum formation. Liem, *et al* produced transmural lesions across the cavo-tricuspid isthmus in all 7 of their sheep by this technique.\(^{15}\) Their results may be explained by the shorter distance, smooth surface, and easy positioning of the catheter at the cavo-tricuspid isthmus. We achieved a higher success rate (75%) for cavo-tricuspid isthmus ablation than for other lesions. However, in our study, creation of effective linear RF lesions was still problematic: continuous transmural lesions along all 4 ablation lines were achieved only in a minority (2/12 animals) of cases. Electrogram amplitude reduction and pacing threshold increase have been described as means to evaluate effective lesion creation.\(^{15,16}\) The present results also demonstrated that a lower atrial pacing threshold before ablation (0.5-2.0 V) correlates with higher atrial electrogram amplitudes and greater reduction of atrial electrogram amplitude by ablation, and a larger atrial pacing threshold ratio (> 4, postablation/preablation) correlates with greater reduction of atrial electrogram amplitudes and greater reduction of the atrial electrogram ratio (postablation/preablation) after ablation. However, their predictive accuracy was low regarding continuous and transmural lesion formation in our study. Van Rensburg, *et al*\(^{17}\) reported that 15 linear lines were created in the right atria of 13 sheep using 3 multielectrode catheters (8 × 4 mm 7Fr, 4 × 6 mm 7Fr, 8 × 4 mm 3.7Fr), but only 3 transmural and continuous
lesions were noted macroscopically. Furthermore, clear coagulum formation was noted on the active electrodes of the catheter in 60%. Thus, in the very least, our cooled RF catheter system using long saline/foam electrode might be advantageous for avoiding thromboembolic complications.

**STUDY LIMITATIONS**

In this study, we analyzed electrophysiologic parameters, which were readily available within the system, before and after ablation. However, we were unable to correlate changes in the electrophysiologic parameters to lesion depth and to gaps in the ablation line. Continuous linear and transmural lesion formation was achieved only in a minority of animals mainly because of the gap between the distal and proximal electrode pockets and because of skip areas at the right atrial free wall due to the presence of pectinate muscle. Noncontinuous lesions may be proarrhythmic, creating a substrate for reentry. This underscores the need to document complete conduction block by recording split potentials along the ablation line by conventional electrophysiology methods or a 3-dimensional electro-anatomical or noncontact mapping technique. The second limitation of this study was that the Nexus™ Linear Ablation Catheter was not able to monitor saline/foam electrode temperature, and thus we were unable to adjust the power to create a transmural linear lesion by monitoring electrode temperature.

**CONCLUSIONS**

The results of this study have shown that cooled RF ablation is promising for creating linear lesions. With this modification, RF energy can be delivered at increased power and duration, over a long electrode pocket system. Such a novel catheter system may be useful for the treatment of atrial fibrillation and flutter in humans.

**REFERENCES**


