Feasibility of the Radiofrequency Hot Balloon Catheter for Isolation of the Posterior Left Atrium and Pulmonary Veins for the Treatment of Atrial Fibrillation

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Background—Atrial fibrillation originates mostly from the pulmonary vein (PV) foci or non-PV foci in the posterior left atrium (LA). The present study was designed to evaluate the feasibility and safety of a novel radiofrequency hot balloon catheter for the treatment of patients with atrial fibrillation by electrically isolating the posterior LA, including all PVs.

Methods and Results—One hundred consecutive patients with drug-resistant atrial fibrillation (63 paroxysmal, 37 persistent) were enrolled. The isolation of the PVs was performed by wedging the balloon at each PV antrum to create circumferential lesions in each case. Contiguous linear lesions were also created at the roof between the superior PVs and at the bottom of the posterior LA between the inferior PVs by dragging the balloon along the endocardium. Complete elimination of the posterior LA and PV potentials was achieved in all 100 cases, confirmed by either conventional or electro-anatomic mapping system. The total procedure time was 129 ± 26 minutes, inclusive of 29.9 ± 7.3 minutes of fluoroscopy time. Follow-up during 11.0 ± 4.8 months confirmed that 92 patients (60 paroxysmal, 32 persistent) were free from atrial fibrillation without antiarrhythmic drugs, and in the remaining patients except for 2 with LA tachycardia, sinus rhythm was maintained with antiarrhythmic drugs. With precautions of esophageal cooling by irrigation dictated by temperature monitoring and monitoring phrenic nerve pacing, no LA-esophageal fistula or permanent phrenic nerve injury occurred.

Conclusion—This feasibility study supports the safety and efficacy of radiofrequency hot balloon catheter for complete isolation of the posterior LA and PVs. (Circ Arrhythmia Electrophysiol. 2009;2:225-232.)

Key Words: atrial fibrillation ■ posterior left atrium ■ catheter ablation ■ radiofrequency current ■ balloon catheter

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Methods

Study Population
One hundred consecutive patients (77 men and 23 women; mean age, 65 ± 7 years) with drug-resistant paroxysmal (n=63) or persistent...
Ablation System

The ablation system is composed of a 12F RHB (Hayama Arrhythmia Institute, Kanagawa, Japan), a 13F deflectable guiding sheath, an intraballoon agitation device, and a specially manufactured RF generator with maximum output of 200 W (Hayama Arrhythmia Institute). The balloon and the catheter shaft are made of polyurethane. The balloon membrane, 50 μm in thickness, is very elastic (Figure 1). The catheter shaft has 2 lumens. The inner lumen is for the guide wire and the outer lumen is for balloon inflation/deflation and also incorporates the electric cable. The balloon is inflated up to 25 to 35 mm in diameter by contrast medium diluted 1:1 with normal saline. A coil electrode is mounted on the shaft within the balloon for the delivery of RF energy, and a thermocouple is attached to the coil electrode for monitoring the central balloon temperature. RF current of 1.8 MHz is delivered between the coil electrode inside the balloon and the 4 cutaneous electrode patches on the patient’s back to induce capacitive-type heating of the balloon. The balloon central temperature is maintained at a selected value by automatic regulation of RF energy output. The agitation device delivers vibratory wave through the outer lumen into the balloon to mix the inner fluid with eliminating the temperature gradient. As a result, temperature uniformity is maintained in the hot balloon.

Electrophysiological Studies and Ablation Method

The entire procedure was performed under general anesthesia with propofol and short-acting fentanyl derivative. The trachea was intubated and maintained on the respirator. Esophageal temperature (ET) was monitored by means of a probe inserted through a nasogastric tube. The LA was entered by transseptal approach, and the 13F deflectable guiding sheath was advanced before the insertion of the RHB. A steerable quadripolar electrode was positioned at the right ventricular apex, a 20-polar catheter within the right atrium, a sheath catheter (EP Technology or Yamaoka Technology, Tokyo, Japan) at the PV region. The most proximal electrode of the basket catheter was positioned at the PV-LA junction, based on the PV angiogram (Figure 2A through 2C). The activated clotting time was maintained between 300 and 400 seconds by intravenous heparin during the procedure.

The diameter of each PV ostium and the thickness of each PV-LA junction or PV antrum were measured by intracardiac echocardiography. Patients who had intra-atrial thrombus, dilated LA >55 mm in diameter on M-mode echocardiography, severe structural heart disease, or severe pulmonary disease were excluded. Written informed consent was obtained from all the registered patients according to the protocol approved by the Human Research Committee of Hayama Heart Center.
At the start of the ablation procedure, contiguous lesions were initially created at the roof of the LA between the superior PVs by applying the lateral aspect of the balloon to the wall of the roof, and then dragging the balloon with the support of a spiral guide wire (Figure 2A). The guide wire was subsequently exchanged for a J-shaped wire enabling the gentle selection of each PV without injury of the distal PV bed. Then the PV antrum was ablated, followed by the ipsilateral carina by dragging the balloon. Finally, a contiguous lesion was also created at the bottom of the LA by dragging the balloon, thereby connecting both inferior PVs.

To avoid the complication of PV stenosis, the balloon was inflated 5 to 10 mm larger than that of each PV ostium measured by ICE and wedged at the antrum around the PV ostium with backup support provided by the deflectable guiding sheath (Figure 2B). Regarding uniform tissue contact, it was confirmed by the occlusive pulmonary venography without any leakage into the LA after injecting contrast. When the inflated balloon was in contact with the roof, the indentation at the top of the balloon confirmed that almost full expansion without indentation. If the balloon was inserted too deeply into the PV across the antrum, it showed an indentation at the LA-PV junction, which indicated the necessity of repositioning the balloon. When the inflated balloon was in contact with the roof, the ET was still higher than 41°C despite such maneuver, cooling saline (20 to 30 mL/bolus) was infused into the esophagus through a tube to avoid heating injury.

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When the PV potential was not completely abolished after the first energy delivery, the balloon was advanced a little across the LA-PV junction to create a small indentation and the lower balloon temperature was selected.

If the esophagus was located adjacent to the balloon, we carefully inflated the balloon to avoid compressing the esophagus extensively, and the ET was monitored during the energy delivery (Figure 2 and Figure 3). When the ET exceeded 41°C, the output of RF energy was lowered to decrease the balloon central temperature to 60°C. If the ET was still higher than 41°C despite such maneuver, cooling saline (20 to 30 mL/bolus) through the gastric tube just above the balloon was infused into the esophagus repeatedly, until the ET was lowered below 40°C in an attempt to avoid esophageal damage (Figure 3B). The saline was aspirated out the stomach after the procedure.

During the ablation of the right superior PV (RSPV) antrum, the right phrenic nerve was paced at a rate of 40/min using a bipolar electrode positioned at the superior vena cava, using a stimulator (esophageal pacer; FIAB, Florence, Italy) with wide pulse (4 to 20 ms) and high output (2 to 40 mA). If the right phrenic nerve was captured and the right diaphragmatic excursion was observed. When it disappeared during ablation, RF energy delivery was stopped immediately, and the balloon was repositioned.

A contiguous lesion was also ablated at the bottom of the posterior LA between the 2 inferior PVs by dragging the balloon (Figure 2). The left half of the bottom lesion was created by applying the lateral aspect of the balloon with clockwise rotation of the catheter shaft while leaving a guide wire inside the left inferior PV (LIPV). The remaining right half of the bottom lesion was created with counterclockwise rotation of the shaft while leaving a guide wire inside the right inferior PV (RIPV).

After the ipsilateral PV isolation was performed by HBC and confirmed by a basket catheter, it was followed by isolation of the contralateral PV. After all the ablation procedures were finished, we elected to remap the whole PLA including all PVs and the ablation line at the roof and the bottom, using a conventional 4-mm-tipped ablation catheter or an electro-anatomic mapping system (Figures 4, 5, and 6). The ablation procedure was repeated until all the posterior LA and PV potential decreased to <0.05 mV during sinus rhythm, and exit block at the ablation site was confirmed by pacing inside the PVs and the posterior LA. Esophageal endoscopy was performed within 1 week of the session, before discharge in all the patients.

**Follow-up**

All patients were followed up for more than 10 months. The antiarrhythmic agents were withdrawn 4 to 12 weeks after ablation if the patient was free from AF or atrial tachycardia. The patients were educated to record the ECG at a fixed time every day and also during any symptoms for 3 to 6 months with a mobile ECG (Omron, Tokyo, Japan). Multislice computed tomography scanning was performed 3, 6, and 12 months after the session for the sequential measurement of the PV ostial diameter. Clinical success was defined as the absence of AF during regular ECG examination, Holter monitoring, and the mobile ECG during 3 to 6 months, excluding the 3-month blanking period after the session.

**Statistical Analysis**

Continuous variables are expressed as mean±SD. Probability values <0.05 with 1-way ANOVA and Scheffe test were considered statistically significant.

**Results**

In all patients, the entire ablation procedure was completed without acute major complications. The ostial diameter was...
21.4±3.2 mm for the left superior PV (LSPV), 19.1±3.0 mm for the LIPV, 21.0±3.0 mm for the RSPV, and 18.8±3.1 mm for the RIPV (Table). The wall thickness at the LA-PV junction was 2.2±0.4 mm for the LSPV, 1.9±0.3 mm for the LIPV, 2.0±0.4 mm for the RSPV, and 1.8±0.3 mm for the RIPV. During ablation, the central balloon temperature was maintained at 60° to 75°C. The output of RF energy required to maintain optimal balloon temperature was 130±16 W for the LSPV, 107±19 W for the LIPV, 122±17 W for the RSPV, 78±18 W for the RIPV, 110±13 W for the roof, 123±11 W for the carina, and 135±8.0 W for the posterior LA (Table). The central balloon temperature was 69±2.9°C for the LSPV, 67±7.4°C for the LIPV, 70±2.6°C for the RSPV, 67±2.9°C for the RIPV, 69±3.1°C for the roof, 68±2.6°C for the carina, and 65±3.3°C for the posterior LA. The total RF current delivery time was 10.0±2.7 minutes for the LSPV, 6.9±2.5 minutes for the LIPV, 8.1±2.7 minutes for the RSPV, 5.7±2.1 minutes for the RIPV, 7.8±2.0 minutes for the roof, 6.6±0.9 minutes for the carina, and 9.6±2.1 minutes for the posterior LA. The balloon diameter was 28.6±1.8 mm for the LSPV, 28.3±1.8 mm for the LIPV, 28.3±1.5 mm for the RSPV, 27.6±1.9 mm for the RIPV.

Figure 4. Electroanatomic bipolar voltage mapping after balloon-based “box” isolation. Red color shows low voltage area <0.04 mV, indicating electrically silent area created by balloon-based ablation, consistent with isolation of the posterior LA, including 4 PVs. Left panel, Posteroanterior view; right panel, right lateral–slight cranial view.

Figure 5. Elimination of all LA-PV potentials after balloon ablation of the left PV antrum. All left inferior (left panel) and left superior (right panel) PV potentials and adjacent LA potentials were eliminated by the application of balloon ablation.
28.2±1.2 mm for the roof, 28.5±1.6 mm for the carina, and 28.2±1.6 mm for the posterior LA. There was significant difference in the output of the RF energy and the delivery time between LSPVs and the other regions except for the posterior wall \((P<0.0001)\). Successful isolation of the posterior LA including all the PVs was achieved in all patients. The common ostium variant of LSPV and LIPV was observed in 3 cases, which could be successfully isolated by ablating separately at the bifurcation of the LSPV and the LIPV, with the guide wire inserted into each PV. Branching of the right middle PV (RMPV) from the antrum of the RSPV was commonly observed. In such case, single RSPV antral ablation could isolate both RSPV and RMPV simultaneously. If RMPV potential persisted, it was successfully ablated in the same manner as the other PVs.

After ablation, the maximal amplitude of the potential of posterior LA and 4 PV became <0.05 mV in all cases. Furthermore, pacing with maximal output (9.9 V) at the center of the posterior LA and within the PV did not propagate beyond the ablation lesions, which indicated exit block. The total procedure time was 129±26 minutes, inclusive of 29.9±7.3 minutes of fluoroscopy time.

During the application of RF energy, especially during LSPV antral ablation, transient sinus bradycardia, sinus arrest, and atrioventricular (AV) block was observed. It was managed by backup pacing and was resolved spontaneously in 5 to 10 seconds with continuation of the RF application. In the early 36 cases, the ET was only monitored during ablation at the left PV near the esophagus without special care for the protection of the esophagus. ET rose gradually to reach the plateau, 41.4±1.6°C (range, 38–44°C) during LSPV isolation, and 40.8±1.6°C (range, 38–45°C) during LIPV isolation (Figure 3A). Shallow esophageal ulceration was observed in 3 cases during this early period. Therefore, in the latter 64 cases, the output of RF energy was controlled as mentioned above. Cooling saline was infused in 58 of the latter 64 cases (Figure 3B). After adopting this strategy, only 1 case of shallow esophageal ulcer was found in a

### Table. Baseline and Procedure Characteristics During Ablation to Create Box Isolation

<table>
<thead>
<tr>
<th></th>
<th>LSPV</th>
<th>LIPV</th>
<th>RSPV</th>
<th>RIPV</th>
<th>Roof</th>
<th>Carina</th>
<th>PLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max output, W</td>
<td>130±16*</td>
<td>107±19</td>
<td>122±17</td>
<td>78±18</td>
<td>110±13</td>
<td>123±11</td>
<td>135±8.0</td>
</tr>
<tr>
<td>Max temperature, °C††</td>
<td>69±2.9†</td>
<td>67±7.4</td>
<td>70±2.6</td>
<td>67±2.9</td>
<td>69±3.1</td>
<td>68±2.6</td>
<td>65±3.3</td>
</tr>
<tr>
<td>Energy delivery time, min</td>
<td>10±2.7‡</td>
<td>6.9±2.5</td>
<td>8.1±2.7</td>
<td>5.7±2.1</td>
<td>7.8±2.0</td>
<td>6.6±0.9</td>
<td>9.6±2.1</td>
</tr>
<tr>
<td>Balloon diameter, mm</td>
<td>28.6±1.8§</td>
<td>28.3±1.8</td>
<td>28.3±1.5</td>
<td>27.6±1.9</td>
<td>28.2±1.2</td>
<td>28.5±1.6</td>
<td>28.2±1.6</td>
</tr>
<tr>
<td>PVo diameter, mm</td>
<td>21.4±3.2‡</td>
<td>19.1±3.0</td>
<td>21.0±3.0</td>
<td>18.8±3.1</td>
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<tr>
<td>Wall thickness, mm</td>
<td>2.2±0.4‡</td>
<td>1.9±0.3</td>
<td>2.0±0.4**</td>
<td>1.8±0.3</td>
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*\(P<0.0001\) versus other site, except PLA and carina.
†\(P<0.01\) versus LIPV, RIPV, and PLA.
‡\(P<0.0001\) versus other site, except PLA.
§\(P<0.005\) versus RIPV.
‖\(P<0.0001\) versus other site and other PV.
¶\(P<0.001\) versus RIPV.
**\(P<0.001\) versus LIPV and RIPV.
††Temperature of the coil electrode inside the balloon.
PVo indicates pulmonary vein ostium; PLA, posterior LA.
75-year-old patient, which was cured by proton pump inhibitor for 4 weeks.

Right phrenic nerve pacing with diaphragmatic excursion could be performed in 96 of 100 patients without previous phrenic nerve paralysis. Right phrenic nerve paralysis occurred in 1 patient (a 70-year-old man), which could not be captured during RSPV ablation, but the patient recovered within 3 months.

During the 11.0±4.8 month follow-up period, 92 (60 paroxysmal, 32 persistent) of 100 (63 paroxysmal, 37 persistent) patients were free from AF without antiarrhythmic drugs, and the remaining patients maintained sinus rhythm with antiarrhythmic drugs except for 2 cases with LA flutter. In these 2 cases, the arrhythmogenic foci at the LIPV bottom near the Marshall vein was successfully ablated on the second session.

During the follow-up period, there were no severe complications such as cerebral embolism, spastic pyloric stenosis, or LA-esophageal fistula. However, 3 patients had nonsymp-

tomatic PV stenosis (<50%).

Discussion

Main Findings

The present study showed that the isolation of the posterior LA including all PVs was successfully achieved in all patients, using our RHB system, by wedging the elastic thermal balloon at each PV antrum and dragging the balloon at the roof and the bottom of the posterior LA. After the first session, 92 (60 paroxysmal, 32 persistent) of 100 (63 paroxysmal, 37 persistent) patients were free from AF without antiarrhythmic drugs, and the remaining patients maintained sinus rhythm with antiarrhythmic drugs except for 2 cases with LA tachycardia during 11.0±4.8 months of follow-up.

Mechanism and Advantage of the RHB

Ablation System

Mechanism

A very high-frequency current (1.8 MHz) of RF energy produces a capacitive type heating of the fluid surrounding the coil electrode within the balloon. In addition, an agitation system mixes inner fluid, thereby eliminating the temperature difference within the balloon due to convection. As a result, the entire balloon membrane is uniformly heated, so the LA tissue in contact with the balloon can be uniformly ablated. In contrast, tissue that is not directly in contact with the balloon such as the endothelium of the PV distal to the balloon is exposed to much less heat than tissue in the contact area, due to large heat capacity of the blood surrounding the balloon. Therefore, only the tissue in direct contact with the balloon is selectively ablated.

Advantages

The present balloon membrane is so thin (50 μm) that the property of heat conductivity is excellent, and it is so elastic that it conforms even to irregularly shaped target tissue. Furthermore, the frequency of RF energy of the present balloon was reduced from 13.56 to 1.8 MHz, thereby reducing leakage current and improving the efficiency of RF heating. These design improvements are expected to further enhance the performance of the RHB.

Advantages of Isolation of the Posterior LA Including PVs Using an RHB

The PVs and the posterior LA are both developed from the sinus venosus, where there are many pacemaking cells with spontaneous rhythmic activity in the early embryonic heart. The discrete site of high-frequency periodic activity is localized most often to the posterior LA, including the PV during AF in sheep hearts. Non-PV foci originated mainly from the PV ostium or from the posterior LA, and the LA and the LA roof serve as a substrate for maintenance of AF in the patients with paroxysmal AF. LA maze surgery with isolation of the posterior LA and PVs could cure AF in 93% of the patients with lone AF and 86% with chronic AF. These findings support that isolation of not only PVs but also the whole posterior LA can result in a much better cure rate in the patients with paroxysmal and persistent AF. In this regard, the ablation methods using a conventional ablation catheter were reported by Lim and Kumagai. However, making contiguous linear lesions by the point-by-point ablation technique is technically difficult, and it frequently results in electric reconnection at the ablation line with reentrant atrial tachycardia, which requires a second session, including the epicardial ablation procedure to abolish the gap. We have already reported that successful PV antral isolation can be achieved using the RF thermal balloon catheter without major complications such as PV stenosis or cerebral embolism. For the present study, we have improved the balloon membrane to be much thinner than before (ie, 50 μm versus 150 μm) with a more compliant and elastic balloon, and have also developed a 13F deflectable guiding sheath suitable for this RHB. The high success rate of the present study may be attributable to the combination of these improvements. During the present study, we could obtain good thermal contact of the balloon with a variety of PV antrum sizes and shapes (eg, funnel shape or early branching of the PV, the roof, the carina, and the posterior LA wall) by using a very compliant balloon and by support of the deflectable guiding sheath. In the present study, all PV potentials as well as adjacent LA potential were eliminated (Figures 5 and 6); it indicates that there is extensive tissue destruction of a large area outside the vein. In addition, we measured the wall thickness of each LA-PV junction using ICE and determined the minimum RF energy output and delivery time to make a transmural lesion around the PV ostium. Compared with the conventional 4- or 8-mm-tipped ablation catheter, it may be obvious that the 25-mm balloon-based ablation may result in far less possibility of gap formation, which may be the cause of reentrant atrial tachycardia due to reconnection at the ablation site as shown by the previous study. The other balloon-based ablation systems using ultrasound, laser, or cryogenic energy were reported only for the ablation at LA-PV junction, and extensive antral isolation was not possible with these devices. The reason for insufficient antral isolation may be due to the use of noncompliant balloons, which did not always allow a good fit for the various sizes and shapes of the PV antrum with differing anatomy of the LA-PV junction. In this regard, our thermal balloon ablation system may have a major advantage.
Clinical Outcome and Safety

This approach was very effective not only for paroxysmal AF but also for persistent AF, perhaps due to the complete isolation of the posterior LA, which may contain a triggering focus or foci and may become the substrate for the maintenance of AF. The results may be attributed to the creation of broad, not linear, ablation bands with far less possibility of electric reconnection.

There was no major collateral damage such as severe PV stenosis or permanent phrenic nerve paralysis. This may be partly due to the heating characteristics of RHB and the precautions of esophageal cooling and phrenic nerve pacing during the procedure. Also, the risk of esophageal cooling (such as aspiration) might be avoided by general anesthesia. The temperature of the balloon of RHB rises by warming the intraballoon fluid by means of a very high-frequency electric field from the central coil electrode, so that there is always a negative temperature gradient from the balloon center to the surface (ie, the temperature at the tissue interface is approximately 10°C cooler than the temperature of the coil at the center of the balloon). As the tissue is heated by thermal conduction from the contact surface of the balloon to the tissue, a longer delivery time of RF energy drives the lesion deeper into the tissue. In other words, the lesion depth may be predictable with this RHB system. We measured the wall thickness of the target site to determine the balloon central temperature and the delivery time of RF energy for creating a transmural ablation lesion. Results of these measurements indicate that collateral damage due to overheating may be prevented by controlling the balloon temperature and the RF delivery time. In contrast, conventional ablation procedures may occasionally cause collateral damage by overheating the tissue, because the temperature measured at the tip of the conventional ablation electrode underestimates the deep tissue temperature rise due to the cooling effects of high blood flow around the electrode.

Asymptomatic esophageal ulceration was reported with high incidence after PV antral isolation by Nakagawa et al Therefore, as Singh et al pointed out, it is thought that the ET should be kept under 41°C, which is crucial for avoiding esophageal damage. Because the temperature gradient from the balloon center to the surrounding tissue during RHB ablation was always negative during this study, we could maintain the ET under 41°C by controlling the balloon temperature and by infusing cooling saline into the esophageal mucosa, due to the variable anatomic structures. The measurement of ET was prone to be inaccurate because the temperature probe may not always be in contact with the esophageal mucosa. However, we paid attention to the position of the temperature probe as it was close to the balloon. There may be some controversy about the appropriateness of ablating the entire posterior LA because it might impair LA function. This issue is being investigated.

One limitation of this approach may be the techniques for determining the location of the LA-PV junction and the diameter of the ostium, using ICE, a PV angiogram, and fluoroscopic analysis of the shape of the inflated balloon. Although we assumed that the indentation of the balloon showed the location of PV-LA junction, we recognize that this approach may be inaccurate, particularly for those cases with funnel-shaped continuation of the PV and PV antrum. However, the fact that no severe PV stenoses were observed after ablation indicates that our determination of the LA-PV junction was clinically correct. Further investigation is needed to clarify this issue.

The measurement of ET was prone to be inaccurate because the temperature probe may not always be in contact with the esophageal mucosa, due to the variable anatomic structures. However, we paid attention to the position of the temperature probe using biplane fluoroscopic views to ensure placement as close as possible to the balloon. There may be some controversy about the appropriateness of ablating the entire posterior LA because it might impair LA function. This issue is being investigated.

Conclusion

The electric isolation of the posterior LA including all the PVs using an RHB with very elastic balloon was feasible and safe in all the enrolled patients. This ablation strategy using an RHB system is a promising approach for the treatment of drug-resistant paroxysmal or persistent AF.

Disclosures

None.

References

Present techniques for atrial fibrillation catheter ablation that use large-tip or irrigated-tip electrodes for pulmonary vein antral isolation and ablation at additional areas require substantial technical skill, procedure times can be long, and multiple procedures are not uncommonly required. Recently, several balloon-based ablation devices using cryogenic, ultrasound, or laser energy have been developed; however, in general, these balloons are relatively noncompliant, and isolation of the entire pulmonary vein antral region may be difficult. Therefore, we developed a novel radiofrequency hot balloon catheter, with a more compliant balloon that can be wedged in the pulmonary vein antra and dragged across the atria to create additional ablation. In 100 patients, complete elimination of potentials in the pulmonary vein antra and posterior left atrium was achieved, with an average procedure time slightly more than 2 hours. During a mean follow-up of 11 months, 92 patients were free from recurrent arrhythmias. With precautions of cooling the esophagus as needed with irrigation and phrenic nerve pacing, 1 transient phrenic nerve injury was the only complication related to these structures. The radiofrequency hot balloon catheter is a promising ablation device for the treatment of atrial fibrillation.
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