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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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Brief Title: Hot Balloon ablation for Atrial Fibrillation

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ABSTRACT

Background: Atrial fibrillation (AF) 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 (RHB) for the treatment of patients with AF, by electrically isolating the posterior LA including all PVs.

Methods and Results: One hundred consecutive patients with drug-resistant AF (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-anatomical mapping system. The total procedure time was 129 ± 26 minutes inclusive of 29.9±7.3 minutes fluoroscopy time. Follow-up during 11.0 ± 4.8 months confirmed that ninety-two patients (60 paroxysmal, 32 persistent) were free from AF without antiarrhythmic drugs, and in the remaining patients except for two 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 RHB for complete isolation of the posterior LA and pulmonary veins.

**Key Words:** Atrial fibrillation, posterior left atrium, catheter ablation, radiofrequency
Introduction

Atrial fibrillation (AF) is the most commonly encountered tachyarrhythmia in daily clinical practice in our aging society. Haissaguerre et al. clearly demonstrated that rapidly firing or triggered ectopic foci in and around the PV triggered AF. Based on such observation, radiofrequency (RF) catheter ablation of AF has been achieved by encircling each PV ostia using conventional ablation methods to electrically isolate the PVs. Recently, developed techniques have been employed to isolate the entire posterior LA including all PVs; so called single ring isolation and Box isolation. These approaches could decrease the risk of esophageal damage and to eliminate the extra-PV foci at the posterior LA beyond the PV antra. However, these procedures required extremely high
technical skill and long procedural time, and were frequently associated with reentrant LA tachycardia due to electrical reconnection at the point-by-point ablation sites. Several balloon-based ablation devices have been developed, incorporating ultrasound, laser, and cryogenic energy sources. However, the complete circumferential isolation of the entire PV antrum could not be achieved with these devices and the procedure was complicated by collateral damage such as phrenic nerve palsy or esophageal perforation. We previously developed a unique RF thermal balloon catheter and reported the successful isolation of the PVs without complications such as PV stenosis or thromboembolism. Recently, we have improved the catheter by incorporating a more elastic and compliant balloon material (radiofrequency Hot balloon catheter: RHB). Consequently, the hot balloon can achieve better thermal contact with irregular PV ostia or Left Atrial anatomies. In addition, we have
developed a deflectable guiding sheath enabling the delivery of the balloon to any position within the LA. In this study, we evaluated the feasibility and safety of this RHB system for the electrical isolation of the entire posterior LA including all PVs, for the treatment of AF.

Methods

Study Population

Consecutive 100 patients (77 men and 23 women; mean age 65 ± 7 years old) with drug–resistant paroxysmal (n=63) or persistent (n=37) AF were registered in this clinical study. The patients with paroxysmal AF had documented AF episodes with duration of 6.5 ± 3.3 hours per single episode and frequency of 6.8 ± 3.4 times per month, despite the use of various antiarrhythmic drugs (average number of drugs attempted=3.4) for 4.5 ± 3.6
(1~19) years period. In patients with persistent AF, the duration from the first onset of AF was 4.2±3.9 (1~20) years. Ten patients had hypertension and 2 had diabetes mellitus. All the patients were on anticoagulation therapy for more than 8 weeks just before the ablation session. The diameter of each PV ostium and the size of the LA were measured using multi-slice computed tomography. Patients who had intra-atrial thrombus, dilated LA more than 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.

Ablation System
The ablation system is composed of a 12F RHB (Hayama Arrhythmia Institute, Kanagawa, Japan), a 13F deflectable guiding sheath, an intra-balloon agitation device, and a specially manufactured RF generator with maximum output of 200W (Hayama Arrhythmia Institute, Kanagawa, Japan). The balloon and the catheter shaft are made of polyurethane. The balloon membrane with 50μm in thickness is very elastic (Figure 1). The catheter shaft has two 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 25-35 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 1.8MHz 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 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 prior to the insertion of the RHB. A steerable quadripolar
electrode was positioned at the right ventricular apex, a twenty-polar catheter within the right atrium, a decapolar electrode within the coronary sinus and a basket catheter (EP Technology, USA, 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 2-A, B, C). 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 echo (ICE). The central balloon temperature and the duration of RF energy delivery were determined according to the thickness of the wall (1.4 - 3.2 mm) and the location of esophagus (Figure 2-5,6,7,8). During a prior in vitro study, the temperature difference between the surface and the center of the balloon was 10.2±0.5°C.
So the temperature of the tissue surface in contact with the balloon was maintained at about 60-65 °C when the central balloon temperature was set to 70-75°C. The in vitro study also demonstrated that the lesion depth was 2.3, 3.2, and 3.8 mm, following RF energy delivery of 2, 3 and 5 minutes respectively, when the balloon diameter was 25 mm and the central temperature was set to 70°C.

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 2-3,4). The guide wire was subsequently exchanged for a J-shape wire enabling the gentle selection of the 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 5-10 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 2-5, 6, 7).

Regarding uniform tissue contact, it was confirmed by the occlusive pulmonary venography without any leakage into the LA after injecting contrast medium via the inner lumen of the catheter.

Optimal positioning of the balloon was determined under the biplane fluoroscopic view (Figure 2-1, 5, 7, 11). The contour of the inflated balloon showed the relationship between the balloon and the target tissue. When the inflated balloon was wedged optimally at the
antrum, it showed 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 indentation at the top of the balloon confirmed that position.

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 esophageal temperature (ET)
was monitored during the energy delivery (Figure 2,3). 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 in spite of such maneuver, cooling saline (20-30cc/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 3-B). And the saline was aspirated out the stomach following the procedure.

During the ablation of the right superior pulmonary vein (RSPV) antrum, the right phrenic nerve was paced at a rate of 40/minute using a bipolar electrode positioned at the superior vena cava, using a stimulator (Esophageal pacer; FIAB, Italy) with wide pulse (4-20 msec) and high output (2-40 mA). If the right phrenic nerve was captured, 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
two 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 pulmonary vein (LIPV). The
remaining right half of the bottom lesion was created with counter clockwise rotation of the
shaft, while leaving a guide wire inside the right inferior pulmonary vein (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 4mm-tip ablation catheter, or an electro-anatomical mapping system (Fig 4,5,6). The ablation procedure was repeated until all the posterior LA and PV potential decreased to less than 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 one week of the session, before discharge in all the patients.

Follow-up

All patients were followed up more than 10 months. The antiarrhythmic agents were withdrawn 4-12 weeks after ablation if the patient was free from AF or atrial tachycardia. The patients were educated to record the electrocardiogram at a fixed time every day and also during any symptoms for 3-6 months with mobile electrocardiograph
Multi-slice 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 electrocardiographic examination, Holter monitoring and the mobile electrocardiograph during 3-6 month excluding the 3 month blanking period after the session.

**Statistical Analysis**

Continuous variable was expressed as mean ± standard deviation (SD). P value less than 0.05 with one-way ANOVA and Scheffe’s test was 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 left superior pulmonary vein...
(LSPV), 19.1±3.0 mm for LIPV, 21.0±3.0 mm for RSPV, and 18.8±3.1 mm for RIPV (Table 1). The wall thickness at the LA-PV junction was 2.2±0.4 mm for LSPV, 1.9±0.3 mm for LIPV, 2.0±0.4 mm for RSPV, and 1.8±0.3 mm for RIPV. During ablation, the central balloon temperature was maintained at 60-75°C. The output of RF energy required to maintain optimal balloon temperature was 130±16 W for LSPVs, 107±19 W for LIPVs, 122±17 W for RSPVs, 78±18 W for RIPV, 110±13 W for roof, 123±11 W for carina, and 135±8.0 W for posterior LA (Table 1). The central balloon temperature was 69±2.9°C for LSPV, 67±7.4°C for LIPV, 70±2.6°C for RSPV, 67±2.9°C for RIPV, 69±3.1°C for roof, 68±2.6°C for carina, and 65±3.3°C for posterior LA. The total RF current delivery time was 10.0±2.7 min for LSPV, 6.9±2.5 min for LIPV, 8.1±2.7 min for RSPV, and 5.7±2.1 min for RIPV, 7.8±2.0 min for roof, 6.6±0.9 min for carina, and 9.6±2.1 min for posterior LA. The balloon
diameter was 28.6±1.8mm for LSPV, 28.3±1.8mm for LIPV, 28.3±1.5 mm for RSPV, 27.6±1.9 mm for RIPV, 28.2±1.2 mm for roof, 28.5±1.6 mm for carina, and 28.2±1.6 mm for 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 posterior wall (P< 0.0001).

Successful isolation of the posterior LA including all the PVs was achieved in all of the 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 was 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 less than 0.05 mV in all the cases. Furthermore, pacing with maximal output (9.9 V) at the center of the posterior LA and within the PVs 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 min fluoroscopy time.

During the application of RF energy, especially during LSPV antral ablation, transient sinus bradycardia, sinus arrest, and AV block was observed. It was managed by backup pacing, and was resolved spontaneously in 5-10 seconds with continuation of the RF application. In the early 36 cases, the ET was only monitored during ablation at the left PVs near the esophagus without special care for the protection of the esophagus. ET rose gradually to reach the plateau, 41.4±1.6 (38-44) °C during LSPV isolation, and 40.8±1.6
(38-45) °C during LIPV isolation (Fig 3-A). Shallow esophageal ulceration was observed in three 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 (Fig 3-B). After adopting such strategy, only one case of shallow esophageal ulcer was found in 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 one patient (70 y/o male), which could not be captured during RSPV ablation, but the patient recovered within 3 months.

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

During follow-up period, there were no severe complications such as cerebral embolism, spastic pyloric stenosis, or LA-esophageal fistula. However, three patients had nonsymptomatic PV stenosis (less than 50%).

**Discussion**

**Main findings**

The present study showed that the isolation of the posterior LA including all PVs was successfully achieved in all patients utilizing 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, ninety-two (60 paroxysmal, 32 persistent) of 100 (63 paroxysmal, 37 persistent) patients were free from AF without antiarrhythmic drugs and the remaining patients could maintain sinus rhythm with antiarrhythmic drugs except for two cases with LA tachycardia during $11.0 \pm 4.8$ months of follow-up.

**Mechanism and advantage of the RF Hot balloon ablation system**

**Mechanism**

A very high frequency current (1.8MHz) 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 (50μm) 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...
13.56MHz to 1.8MHz, 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 a 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. 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 posterior LA and the LA roof serve as a substrate for maintenance of AF in the patients with paroxysmal AF.

LA
maze surgery with isolating 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 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 electrical 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 (i.e., 50μm vs 150μm) with a more compliant and elastic balloon, and have also developed a 13 F 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 (e.g. funnel shape or early branching of the PV, the roof, the carina, and the posterior LA wall) by employing very compliant balloon and by support of the deflectable guiding sheath. In fact in the present study all PV potentials as well as adjacent LA potential were eliminated (Figure 5,6), 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-tip ablation catheter, it may be obvious that the 25mm 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.⁵ 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.⁷ The reason for insufficient antral isolation may be due to the use of non-compliant balloons, which did not always allow good fit for the various size and shape of the PV antrum with various anatomy of the LA-PV junction.¹⁹ 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 PAF 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 electrical 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 intra-balloon fluid by means of a very high frequency electric field from the central coil electrode, so that there is always
negative temperature gradient from the balloon center to the surface (i.e., 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.\textsuperscript{21}

Asymptomatic esophageal ulceration was reported with high incidence after PV antral
isolation by Nakagawa et al.\textsuperscript{22} Therefore, as Singh pointed out\textsuperscript{23}, it is thought that the ET
should be kept under 41{\degree}C, which is crucial for avoiding esophageal damage. As the
temperature gradient from the balloon center to the surrounding tissue during RHB ablation
was always negative during this study\textsuperscript{20}, we could maintain the esophageal temperature
under 41{\degree}C by controlling the balloon temperature and by infusing cooling saline into the
esophagus, resulting in no deep esophageal ulceration in all the cases except one case,
when the esophageal temperature rose transiently over 45{\degree}C during the early period.\textsuperscript{24}

During ablation of RSPV and RIPV antra, we paced the right phrenic nerve from
the superior vena cava with the esophageal stimulator for the early detection of right phrenic nerve palsy in all the patients. Transient right phrenic nerve palsy occurred in only one patient (1.0%), and resolved during follow-up. Although the sample size is small (i.e., n = 100), the incidence of phrenic nerve palsy appears to be lower than for other balloon-based ablation catheters (e.g., HIFU). To reduce the risk of PV stenosis, we employed minimal RF energy to isolate each PV and avoided positioning of the balloon beyond the LA-PV junction, using data obtained by ICE and PV angiography. This approach resulted in no cases of severe PV stenosis and only 3 cases with asymptomatic PV stenosis.

In addition, no, thromboembolic events were observed during the applications, using conventional anticoagulation with warfarin.
**Limitations:**

This was not a multi-center study and the follow-up period was not long enough to fully evaluate the efficacy of RHB for the treatment of AF. Nevertheless, 92 of 100 patients (92%) became free from AF without antiarrhythmic drugs and even the remaining patients showed dramatic improvement of sinus rhythm maintenance with the drugs, so a second session was not required.

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 PV and PV antrum. However, the fact that no severe PV stenoses were observed following ablation indicates that our determination of LA-PV junction was clinically correct. Further investigation is needed to clarify this issue.

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

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

Disclosures: None.
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Figure 1.

A: Schematic view of left atrium (LA), pulmonary vein (PV) system and the inflated balloon, wedged at the left superior PV (LSPV) antrum through trans-septal approach.

SVC: superior vena cava; LIPV: left inferior pulmonary vein; RIPV: right inferior pulmonary vein; IVC: inferior vena cava; RA: right atrium

B: Photograph of radiofrequency HOT balloon –RHB–catheter (Produced by Hayama institute, Kanagawa, Japan). (See details in the text)

Figure 2. Isolation of the posterior left atrium including all pulmonary veins (anterior posterior view).

(A), (B) and (C) show the positioning of the basket catheter and venography at RSPV,
RIPV and LSPV, respectively. Note the balloon indentation (black arrow in 4), which corresponded to the mid roof between superior PVs (black arrow in C). This balloon deformation indicates the potential elasticity of the balloon.

**Figure 3. Temperature profile during application of radiofrequency energy:**

**A:** The balloon central temperature and the mean esophageal temperature are shown as a function of time during LIPV isolation (n=36).

**B:** Balloon central temperature and esophageal temperature are also shown as a function of time for an LIPV ablation, during which cooling saline (20-30cc/bolus) was infused into the esophagus through a tube to avoid a heating injury.
Figure 4. Electroanatomical bipolar voltage mapping following balloon based “BOX” isolation

Red color shows low voltage area less than 0.04 mV, indicating electrically silent area created by balloon based ablation, consistent with isolation of the posterior LA including 4 PVs.

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.

Figure 6. Elimination of all the LA-PV potentials after balloon ablation of the right PV antrum

All right inferior (left panel) and right superior (right panel) PV potentials and adjacent LA potentials were eliminated by the application of balloon ablation.
Table 1: Baseline and procedure characteristics during ablation to create BOX isolation

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<th>RIPV</th>
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<td>PV a Dia. (mm)</td>
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<td>19.1±3.0</td>
<td>21.6±3.0</td>
<td>18.6±3.1</td>
<td>22.5±1.6</td>
<td>22.2±1.6</td>
<td></td>
</tr>
<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>
<td>2.0±0.4†</td>
<td>1.8±0.3</td>
<td></td>
</tr>
</tbody>
</table>

* p<0.0001 vs other site except PLA and CARINA
** p<0.01 vs LIPV, RIPV and PLA
*** p<0.0001 vs other site except PLA
† p<0.005 vs RIPV
†† p<0.0001 vs LIPV, RIPV
¶ p<0.0001 vs LIPV, RIPV
†‡ p<0.0001 vs RIPV

# Temperature of the cool electrode inside the balloon
PV: Pulmonary vein ostium
LSPV: left superior pulmonary vein
LIPV: left inferior pulmonary vein
RSPV: right superior pulmonary vein
RIPV: right inferior pulmonary vein
Dia: Diameter
PLA: posterior LA