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Impact of monitoring surface temperature during pulmonary vein isolation in a second-generation hot balloon system

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ABSTRACT

Background: A surface temperature sensor can be used to visualize the effect of hot balloon (HB) catheters. This study evaluated the efficacy and safety of a second-generation HB system with surface temperature monitoring in patients with atrial fibrillation (AF).

Methods: Twenty patients (age: 69.6 ± 9.7 years, 11 male participants) who underwent first-time pulmonary vein isolation (PVI) using a second-generation HB were included. For each pulmonary vein (PV), the acute isolation rate and effective therapeutic range of surface temperature were investigated.

Results: Eighty-three PVs (including three right middle PVs) were isolated in 20 patients using an HB with a surface temperature sensor. Sixty-eight PVs were isolated using the first application. Fifteen PVs (left superior PV [LSPV], n = 7 [35%]; left inferior PV, n = 2 [10%]; right superior PV, n = 3 [15%]; right inferior PV, n = 3 [15%]) showed early intraoperative reconduction and required second applications. One LSPV required radiofrequency touch-up at the carina. The optimal balloon surface temperature and application time were evaluated, and a median value of 58 °C and integral value of 1000 °C·s were identified from the receiver operating characteristic curve to be useful effective indicators. However, for LSPV, the PV potential of carina or ridge likely often remained and needed to be independently considered. There was no periprocedural complication including severe pulmonary vein stenosis. During the observation period (median: 280 days, interquartile range: 261–318 days), 17 patients (85%) achieved and maintained sinus rhythm.

Conclusions: Second-generation HBs with a surface temperature sensor are expected to provide favorable outcomes in AF ablation treatment.

1. Introduction

Atrial fibrillation (AF) is the most common arrhythmia in the general population. It is a serious public health problem because it increases the risk of stroke, systemic embolism, and heart failure [1]. Catheter ablation for patients with paroxysmal AF has already been the standard treatment [2,3]. Since pulmonary vein isolation (PVI) has been established as the cornerstone of ablation for AF, several ablation techniques using balloon technology have been developed as an alternative therapy to conventional radiofrequency (RF) ablation. Moreover, the middle-term outcomes after performing these balloon modalities were not found to be statistically different [4–6]. RF hot balloon (HB) catheters (Hot-Balloon, Toray Industries, Inc., Tokyo, Japan) is a balloon-based ablation technology for AF treatment [4], and previous reports have shown the efficacy of this device for PVI [7,8]. However, the RF energy delivery time and central balloon temperature settings varied among facilities and operators, and indicators of effective ablation include the visualization of pulmonary vein (PV) occlusion using contrast media as well as the time to isolation using a circular mapping catheter [9]. Moreover, complications of severe PV stenosis and difficulty in isolating the left superior PV (LSPV) have been reported in cases where HBs were used [10,11] because there were no indicators of effectiveness during HB ablation. However, it has become possible to monitor the surface temperature of the HB as a new indicator in a second-generation HB. From the recent analysis of the thermo-fluid inside the catheter using computer-aided engineering (CAE) (Fig. 1A), it was found that the temperature of the inner surface of the balloon can be estimated accurately by measuring the temperature of the diluted contrast media sucked from the balloon into the catheter tube. As a result of this analysis, the second temperature sensor (intra-tube temperature sensor) was

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placed 15 mm from the proximal side of the balloon (Fig. 1B). This will allow us to obtain information from the tissue back to the balloon, and we may be able to make more effective and efficient ablation lesions with safety. The purpose of this study was to elucidate the efficacy and safety of a second-generation HB system with surface temperature monitoring for patients with AF.

2. Methods

2.1. Study population

This was a retrospective single-center study to evaluate the parameters of effective ablation using a second-generation HB with a surface temperature sensor. After it became possible to observe the balloon surface temperature, 20 patients underwent HB-PVI at Sakakibara Heart Institute from August 2020 to December 2020. Patients with first-time PVI were included in the study. Seven cases had paroxysmal AF, while 13 cases had persistent AF. In all cases, preoperative contrast-enhanced CT was performed to evaluate the figure of the left atrium and PVs before the ablation procedure, and the long and short diameters of each of the four PV were measured. In addition, the area of the ellipse was calculated from the long and short diameters, and the diameter calculated from the perfect circle of the area was defined as the mean diameter of each PV. All procedures were performed by three physicians with sufficient experience in the use of HB, and 20 consecutive cases were reviewed, excluding cases with missing data during treatment for any reason.

2.2. Ablation protocol

The procedures were performed by anesthesiologists under conscious sedation using pentazocine, dexmedetomidine hydrochloride, and propofol. The following three sheaths were inserted from the femoral vein: 17-F deflectable guiding sheath (TRESWALTZ; Toray Industries, Inc.), 8.5-Fr SL-0 (Abbott, St. Paul, MN, USA), and 9-Fr 25-cm sheath (Terumo Corp., Tokyo, Japan). After inserting these three sheaths, 3,000 units of heparin were administered. The atrial septum was observed using an AcuNav catheter (Siemens Medical Solutions Inc., Malvern, PA, USA) or ViewFlex ICE catheter (Abbott Laboratories, Chicago, IL, USA) from a 9-Fr sheath, and septal puncture was performed using an RF needle (NRG, Baylis Medical, Toronto, Canada) through an 8.5-Fr SL-0 sheath. After the septal puncture, a bolus of 7,000 units of heparin was immediately administered, and heparin was added as needed to achieve an activated clotting time of 300–350 s. Then, the deflectable guiding sheath was advanced into the left atrium over a J-tip guidewire (Spring Guide Wire; Toray Industries Inc.). The ICE catheter was replaced with a steerable mapping catheter (Bee AT®□; Japan Lifeline Co., Ltd., Tokyo, Japan), which was positioned in the right ventricle for bradycardia during left PVI. A second-generation HB (Toray Industries, Inc.) was delivered through the deflectable guiding sheath that was inflated to a diameter of 26–33 mm using the recommended injection volume (10–20 mL) of contrast media diluted 1:2 with saline. After the J-tip guidewire advanced into the targeted PV, the balloon was gradually inflated. The coaxial position of the HB to the PV antrum using the deflectable guiding sheath was confirmed by two different fluoroscopy angles (AP and RAO or LAO). The largest volume with complete occlusion using contrast media was considered as the optimal balloon size. To avoid PV stenosis, balloon occlusion was performed in the PV antrum as much as possible with a single application [12]. The energy applications were delivered as follows: right superior PV (RSPV; 70 °C, 2.5 min), right inferior PV (RIPV; 70 °C, 2–2.5 min), LSPV (73 °C, 3 min), and left inferior PV (LIPV; 70 °C, 2.0–2.5 min) [7,9]. When the balloon was in contact with the antrum, the shaft of the HB and PV were adjusted to be as parallel as possible. To avoid phrenic nerve injury, right phrenic nerve stimulation at the superior vena cava was performed using a Bee AT® catheter during HB energy applications to the right PVs

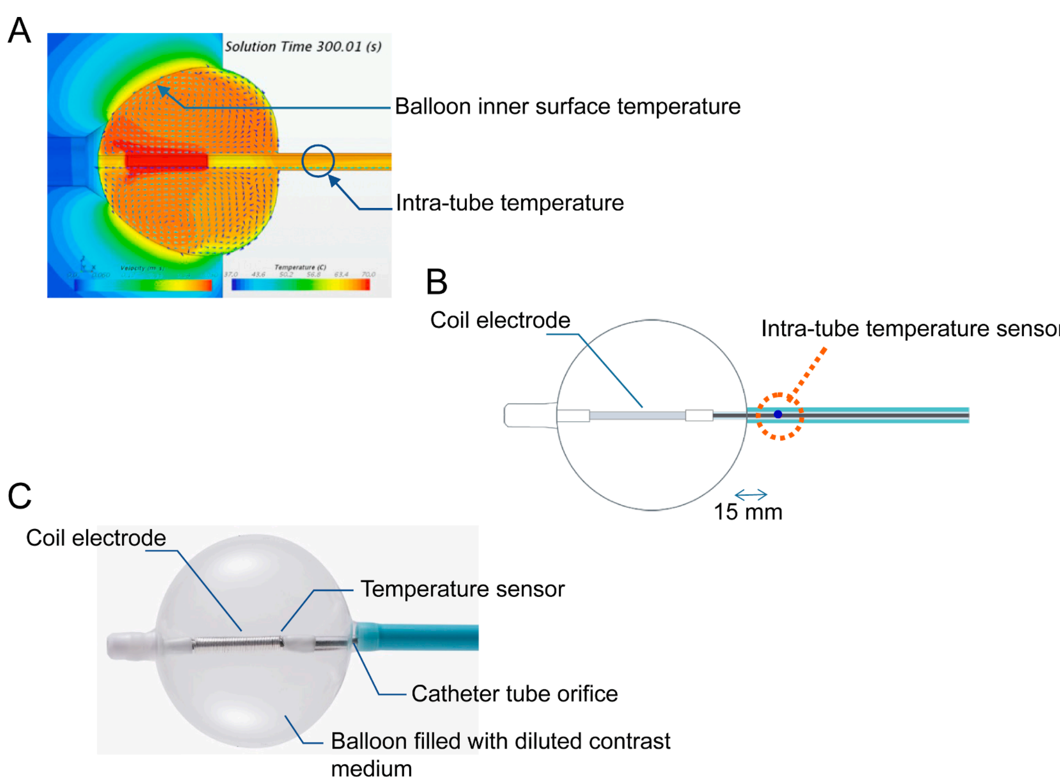


Fig. 1. Second-generation and conventional hot balloons. (A) Thermo-fluid analysis in the balloon by computer-aided engineering. The CAE analysis showed that the intra-tube temperature closely corresponded to the inner surface temperature of the balloon around the tissue contacting area. (B) Intra-tube temperature sensor. The intra-tube temperature sensor was placed 15 mm away from the proximal side of the balloon. (C) Conventional hot balloon catheter CAE, computer-aided engineering.

while the diaphragmatic compound motor action potentials (CMAPs) were monitored. If the CMAP amplitude declined by >30% of the initial amplitude, the application was stopped. PV potentials were recorded using a 5-Fr circular mapping catheter (EP star Libero; Japan Lifeline Co., Ltd., Tokyo, Japan) placed in the PV from the SL-0 sheath. During the HB ablation, an esophageal thermal sensor catheter (Esophastar; Japan Lifeline Co., Ltd.) with a gastric tube was placed into the esophagus behind the left atrium. If the esophageal temperature increases above 38 °C, cooling saline is injected through the gastric tube. The procedural endpoint was the disappearance of the PV potentials recorded by the circular mapping catheter. If the PV potential remained, a second application is performed. After two applications of HB, touch-up ablation with an irrigated ablation catheter (TactiCath; Abbott) was performed. After confirming the disappearance of PV potentials and bidirectional conduction block, high-dose isoproterenol (16–17 μg/min) was administered to check the PV reconnections and non-PV triggers.

2.3. Calculation of the median and integral values of surface temperature

In addition, the median surface temperature and integral of the surface temperature and time curves were calculated for each PV. The balloon temperature data were acquired every second from the balloon temperature monitor. A value of 50 was subtracted from the balloon temperature, and all values <0 were set to 0. All of the above values from the start to the end of ablation were added to obtain the integral value. Then, the integral value was obtained. The median value was calculated as the median of the balloon surface temperature after the balloon temperature reached the set point (70 °C or 73 °C). The integral value was calculated by subtracting 50 from the temperature at each time point from the time the balloon surface temperature reached 50 °C (Fig. 2, Fig. S1). If there were several applications of HB ablation, the integral value was defined as the sum of all procedures. For example, when the second application was successful, the median of the second application and sum of the two integrals were considered successful. In that case, the median and integral values of the first application were considered unsuccessful. In 83 PVs, including three right middle PVs in 20 cases, the median and integral values of the balloon surface temperature were calculated. Study patients were classified into the successful and unsuccessful PVI groups, and the differences between them were evaluated.

2.4. Follow-up

In all cases, antiarrhythmic drugs were discontinued after 3 months of the procedure. If the patient had an early recurrence within a blanking period—defined as 3 months after the procedure—antiarrhythmic drugs were prescribed at the physician's discretion and stopped at 3 months. As follow-up, clinical interviews, 12-lead electrocardiograms, and 24-h Holter electrocardiogram monitoring were performed at approximately 6 months. Recurrence was defined as any atrial tachyarrhythmia lasting for >30 s.

2.5. Statistical analyses

Continuous data were expressed as means ± standard deviations for normally distributed variables or as medians (interquartile ranges [IQRs]) for non-normally distributed variables. Differences in continuous variables were analyzed using Student's *t*-test or the Wilcoxon rank-sum test. All statistical analyses were performed using JMP® 15 (SAS Institute Inc., Cary, NC, USA), and $P < 0.05$ indicated statistical significance.

2.6. Ethical considerations

The study protocol was approved by the ethics committee of Sakakibara Heart Institute (IRB approval no.: 21–020), and written informed consent was obtained from all patients before the procedure.

3. Results

3.1. Patient characteristics

Patient characteristics and echocardiographic measurements are presented in Table 1. A total of 20 patients (11 male individuals; mean age: 69.6 ± 9.7 years) underwent PVI using the HB with a surface temperature sensor. Seven patients with paroxysmal AF and 13 patients with persistent AF were included in this study.

3.2. Analysis of procedures

The procedural characteristics of 83 PVs ablated by HB with a surface

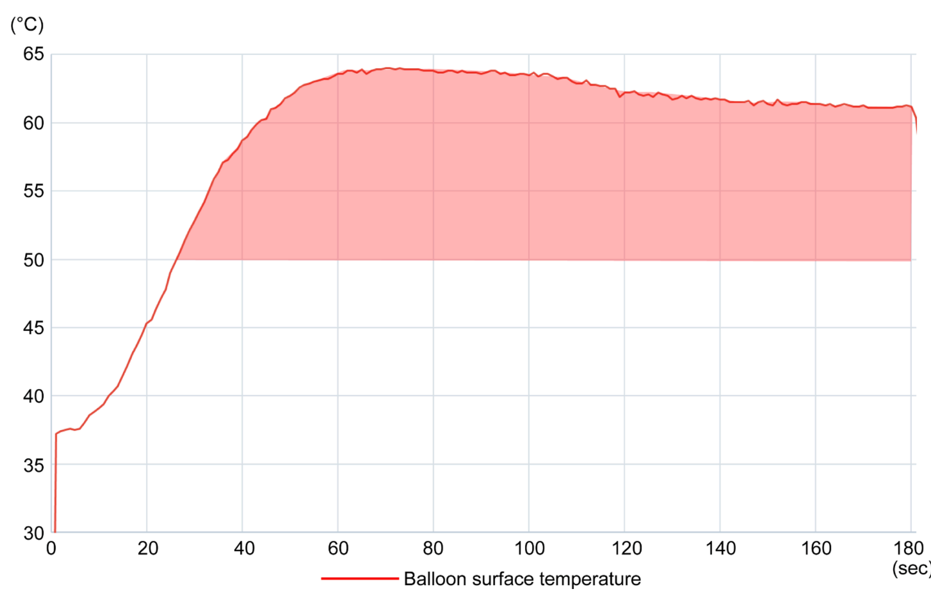


Fig. 2. The integral value of surface temperature above 50 °C. The balloon temperature data were acquired every second from the balloon temperature monitor. A value of 50 was subtracted from the balloon temperature, and all values <0 were set to 0. All of the above values from the start to the end of ablation were added to obtain the integral value.

Table 1
Baseline patient characteristics.

	n = 20
Age (years)	69.6 ± 9.7
Male (n [%])	11 (55)
AF type (n [%])	
Paroxysmal	7 (35)
Persistent	13 (65)
$CHADS_2$ score (n [%])	
0	4 (20)
1	10 (50)
2	4 (20)
3	2 (10)
LA (mm)	40.8 ± 5.4
LA volume (mL)	80.1 ± 27.5
LA volume index (mL/m^2)	46.8 ± 14.3
Ejection fraction (%)	58.9 ± 7.4

Abbreviations: AF, atrial fibrillation; $CHADS_2$ score, congestive heart disease, hypertension, age, diabetes, stroke/transient ischemic attack; LA, left atrium

temperature sensor are presented in Table 2. The mean diameter of each PV was as follows: 18.6 ± 3.85, 14.1 ± 3.52, 20.8 ± 3.69, 17.0 ± 3.43, and 6.33 ± 1.93 mm for the LSPV, LIPV, RSPV, RIPV, and right middle PV, respectively. The majority of PVs, excluding LSPV, were isolated using the first application. Two LIPVs, three RSPVs, and three RIPVs required a second application of HB ablation. However, seven PVs required a second application in LSPVs, and one of them required RF touch-up at the carina. Among the 20 patients included in this study, only one LSPV required RF touch-up, even though HB ablation for LSPV was performed at a higher temperature than other PVs and had a higher integral value. There was no statistically significant difference in the mean PV diameter and time of first application between the successful and unsuccessful PVI groups. The median balloon surface temperature and integrated value above 50 °C were significantly lower in the recurrence than in the non-recurrence group ($P < 0.05$, Table 3).

3.3. Gap sites immediately after the first application of HB ablation

Fifteen PVs (LSPV, n = 7 [35%]; LIPV, n = 2 [10%]; RSPV, n = 3 [15%]; RIPV, n = 3 [15%]) showed early intraoperative reconduction and required a second application (Table 3). The most frequent second application was required in LSPVs, and RF touch-up was required in only one of the PVs. The location required for RF touch-up was the anterior carina, which was the thickest part around the PV.

Table 2
Procedural characteristics of 83 PVs ablated by second-generation hot balloon.

	LSPV n = 20	LIPV n = 20	RSPV n = 20	RIPV n = 20	RMPV n = 3
Mean PV diameter (mm)	18.6 ± 3.85	14.1 ± 3.52	20.8 ± 3.69	17.0 ± 3.43	6.33 ± 1.93
Number of HB applications (n [%])					
1	13 (65)	18 (90)	17 (85)	17 (85)	3 (100)
2	7 (35)	2 (10)	3 (15)	3 (15)	0 (0)
RF touch-up (n [%])	1 (5)	0	0	0	0
Time of first application (s)	150 ± 34.3	141 ± 19.9	147 ± 21.3	140 ± 23.7	110 ± 17.3
The median value (°C)	61.5 ± 2.54	60.4 ± 2.04	59.3 ± 2.37	60.5 ± 2.74	59.6 ± 1.14
The integral value (°C·s)	1669 ± 459.8	1433 ± 271.4	1285 ± 382.4	1448 ± 381.9	1077 ± 200.7

Abbreviations: PV, pulmonary vein; LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; RSPV, right superior pulmonary vein; RIPV, right inferior pulmonary vein; RMPV, right middle pulmonary vein; HB, hot balloon. The median value (°C) was calculated as the median of the balloon surface temperature after the balloon temperature reached the set point (70 or 73°C). The integral value (°C·s) was calculated by subtracting 50 from the temperature at each time point from the time the balloon surface temperature reached 50 °C.

Table 3
Acute PV recurrence during hot balloon ablation.

	Recurrence n = 15	Non-recurrence n = 68	P-value
Mean PV diameter (mm)	19.1 ± 4.79	16.8 ± 4.67	0.11
Time of first application (s)	131.9 ± 43.4	145.7 ± 19.7	0.43
The median value (°C)	58.7 ± 0.61	60.7 ± 0.29	0.047
The integral value (°C·s)	1171 ± 603.9	1505 ± 311.2	0.026

Recurrence; PVI unsuccessful group required second HB application.
Non-recurrence; PVI successful group with first HB application.

3.4. Median and integral values of the balloon surface temperature

A total of 99 applications [LSPV: 20 (first) + 7 (second) + 1 (bonus); LIPV: 20 (first) + 2 (second), RSPV: 20 (first) + 3 (second), RIPV: 20 (first) + 3 (second)] were analyzed (Fig. 3). All procedures, including the LSPV, are shown in Fig. 3A. For LSPV, the result was expected to be different from that of the other three PVs. Therefore, all procedures except for LSPV were plotted, the result is shown in Fig. 3B. As shown in Fig. 3B, in the region with a median temperature of 58 °C and an integral value of ≥1000, 95% of the PVs (56/59) were isolated with a single application.

3.5. Acute complication and clinical outcome

In this study there was no acute complication, including pseudo aneurysm, phrenic nerve palsy, and cardiac tamponade. In addition, 15 of 20 patients underwent postoperative computed tomography examination to evaluate pulmonary vein stenosis at approximately 6 months after the procedure. Mild stenosis of <50% was observed, although severe stenosis of >70% was not observed in any case.

Patients were followed up for a median of 280 (IQR: 261–318) days and recurrence of atrial tachyarrhythmia was observed in three patients (15%) excluding the blanking period. The 12-lead electrocardiogram revealed atrial tachycardia in one patient and 24-h Holter electrocardiogram revealed atrial fibrillation in two patients.

4. Discussion

4.1. Main findings

This study provided several new findings:

First, it was important to maintain a stable surface temperature above a certain level to obtain a durable PVI. Second, constant attention must be paid to the stable coaxiality of the balloons to maintain a stable surface temperature. Third, LSPV had more acute reconduction or non-isolation and required more second application than the other three PVs.

4.2. Optimal surface temperature and application time

For the three PVs except LSPV, the receiver operating characteristic curve analysis results showed that the median and integral values of the balloon surface temperature were predictors of acute PVI (area under the curve = 0.766 and 0.833, respectively). The best cut-off value of the median value for acute PVI was 56.1 °C, and its sensitivity and specificity were 75.0% and 98.4%, respectively. Similarly, the integral value above 50 °C for acute PVI was 942.5° C · s, and its sensitivity and specificity were 75.0% and 98.4%, respectively. Based on these values, a median value of 58 °C and an integral value of 1000 °C · s are likely to be the reference values for no reconduction, as shown in Fig. 3-B. As for the three points that were not isolated after passing the two criteria, no special findings were found in the analyzed data. Therefore, it is possible that it was not isolated because of the thermal conductivity of the tissue.

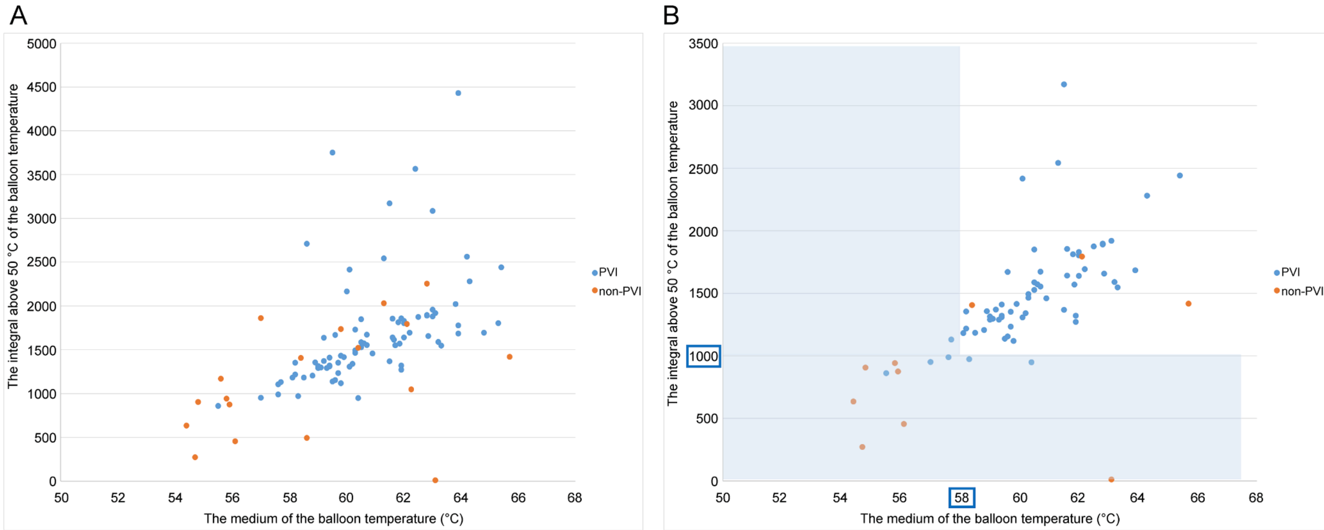
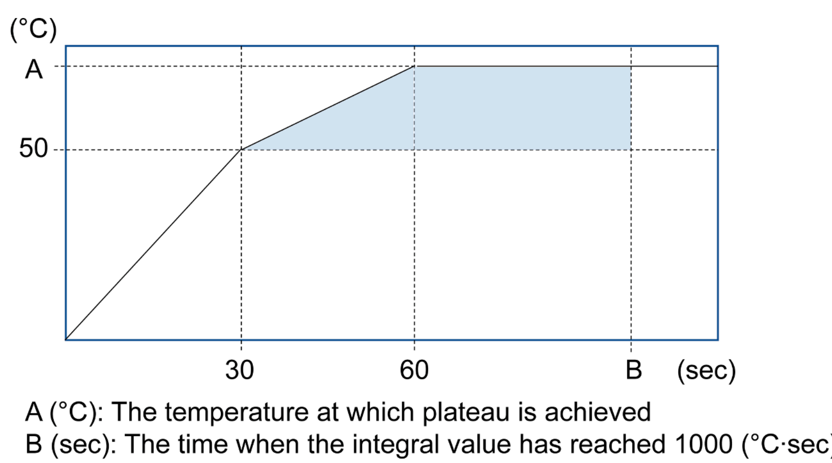


Fig. 3. The median and integral values of the balloon surface temperature. (A) The median and integral values of the balloon surface temperature in all procedures, including LSPV, are presented. (B) All procedures except for LSPV were plotted. In the region with a median temperature of 58 °C and an integral value of ≥1000, 95% of the PVs (56/59) were isolated with a single application LSPV, left superior pulmonary vein.

In all three PVs, complete isolation was obtained after the second application. Based on the accumulated data, a simplified graph is presented in Fig. 4. From this chart, 2–3 min of ablation by HB appears to be reasonable. However, a conventional balloon could not display the surface temperature, so blind ablation for a certain duration was performed. The incidence of severe stenosis (>70%) after HB ablation has been reported to be approximately 2–5% [10,13]. Some of these PVs may have been stenotic due to excessive ablation. Based on the results of this study, it is possible that PV stenosis can be prevented by setting an index of effective ablation and avoiding excessive ablation.



A (°C)	After achieved plateau (sec)	After reached 50°C (sec)	B (sec)
56	152	182	212
58	110	140	170
60	85	115	145
62	68	98	128
64	56	86	116
66	48	78	108

Fig. 4. Hypothetical time for an integral value >50 °C to reach 1000. Based on the data accumulated so far, a simplified graph was shown. A (°C): The temperature at which the plateau was achieved. B (s): Time when the integral value reached 1000 (°C·s).

4.3. Relationship between balloon surface temperature and balloon angle

The real-time balloon surface temperature accurately reflects the balloon angle (Fig. 5). As shown in Fig. 5A, even a slight deviation of the balloon axis caused the surface temperature to decrease rapidly. By re-adjusting the balloon axis shown in Fig. 5B, the surface temperature increased again. Therefore, maintaining coaxiality and stabilizing the surface temperature is required for more stable ablation.

As a result of more detailed thermo-fluid analyses inside the balloon using CAE (Fig. S2), it was found that the inner surface temperature of the balloon closely corresponds to the interface temperature between the balloon and tissue over time. However, comparing the coaxial state where the catheter tube orifice direction and coil electrode are linearly aligned and the non-coaxial state where they are not linearly aligned, it was found that the balloon surface temperature decreased in the latter state, because a unidirectional round flow was generated in the balloon and heated diluted contrast medium accumulated around the coil electrode.

4.4. Limitations and challenges of second-generation HBs

Three PVs (LIPV, RSPV, and RIPV), except for LSPV, had a low reconductivity of 10–15% compared with LSPV (35%) (Table 2), and almost all of them could be isolated by maintaining a surface temperature of 58 °C. However, for the LSPV, there were several cases that it could not be isolated even when the surface temperature was approximately 65 °C. It has been reported that the LSPV, especially the anterior aspect, often has residual pulmonary venous conduction and requires touch-up RF ablation [11]. The anterior ridge and carina were the locations that were not isolated. In these cases, temporary isolation was obtained when a high-frequency current was applied, although the phenomenon of reconduction was observed as soon as the current was stopped. In some cases, reisolation was possible with 1–2 points of RF ablation using TactiCath. It appeared that stronger contact or high-frequency energy would be required to obtain complete isolation with the balloon for LSPVs. However, considering that the HB is a compliant balloon with a maximum output of 73 °C, isolation with a balloon alone may be limited in cases with a thick tissue.

The HB system has a different energy source than other balloon systems and may not have much depth of penetration into myocardial tissue, which may lead to residual conduction in some cases. On the other hand, pulmonary vein stenosis caused due to HBs is a serious complication that requires further investigation. Our impression is that HBs cause shallow and widespread injury to the atrial tissue, and

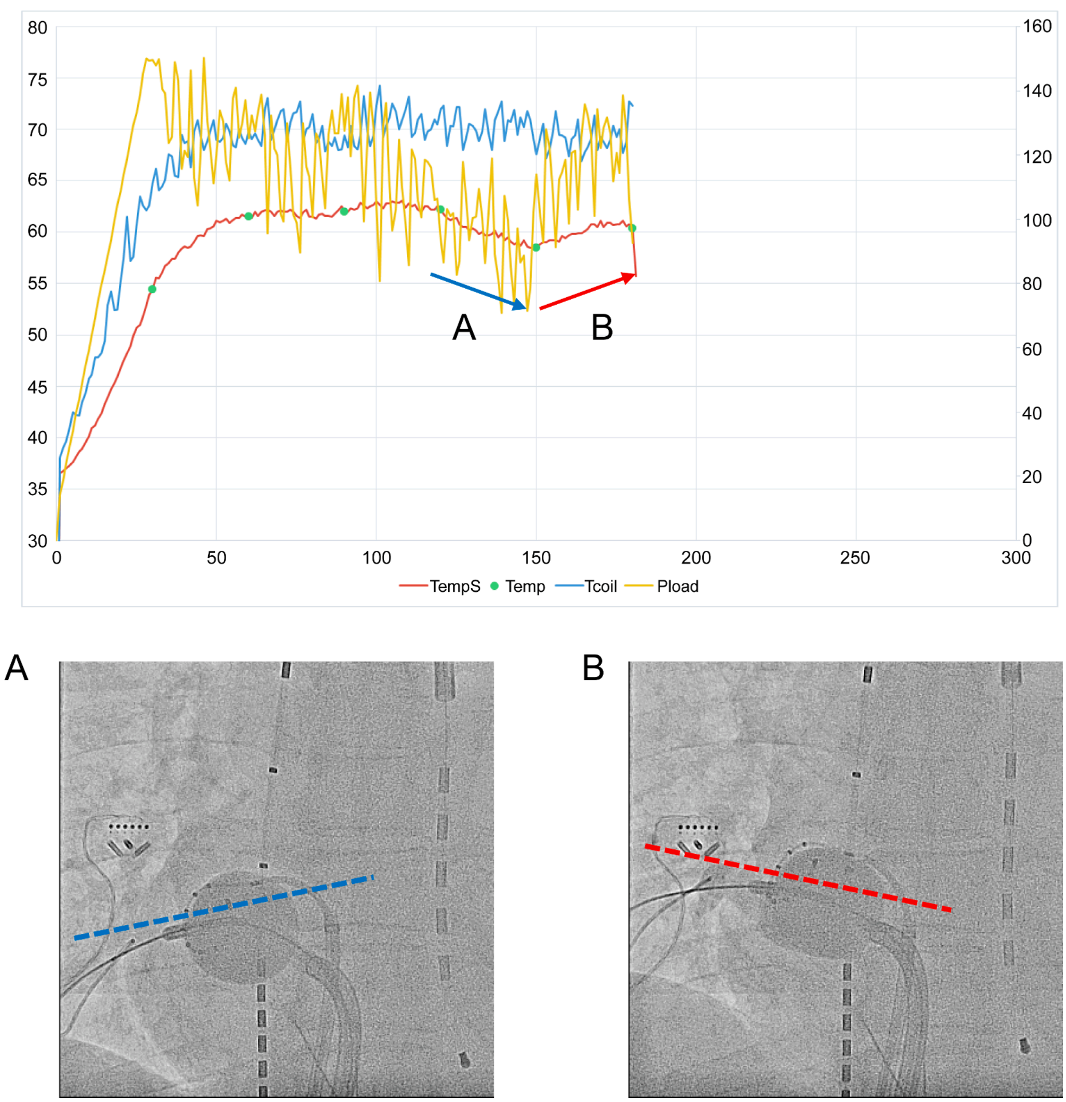


Fig. 5. Response of surface temperature to axis deviation. The relationship between the balloon surface temperature and balloon angle is presented. (A) A slight deviation of balloon axis to the PV affected the decrease in surface temperature. (B) By re-adjusting the balloon axis along the PV angle, the surface temperature increased again PV, pulmonary vein.

repeated application may cause additional injury and stenosis in thin areas without significantly affecting thick areas such as the anterior aspect of the left pulmonary vein. Multiple applications of a HB may increase the risk of severe pulmonary vein stenosis, and it may be preferable to convert to RF touch-up for the anterior aspect of the left pulmonary vein. Although monitoring surface temperature reduced the RF touch-up rate to LSPV by less than half (Fig. S3), the fact that touch-up is required in 10% of cases is a limitation of the second-generation balloon and may be a future challenge.

4.5. Comparison of conventional HB and second-generation HB with surface temperature sensor

The mechanism of conventional HB is shown in Fig. 1C. The balloon surface temperature was maintained uniformly at approximately 60 °C by heating and mixing the diluted contrast media filled in the balloon. A sensor of the conventional HB is attached to the proximal end of the coil electrode placed in the balloon to deliver an RF current, and the RF power was automatically controlled so that the temperature could reach the target temperature. The diluted contrast media heated in the vicinity of the coil electrode was agitated by periodic injection or suction from the catheter tube orifice to maintain a uniform balloon surface temperature. There is no temperature sensor on the surface of the balloon, and the surface temperature was estimated based on the results of pre-clinical bench testing. It may be predicted that the minimum temperature required at the electrode/tissue interface to achieve a permanent conduction block would be 50 °C [14]. Based on the experimental data using pseudo-biological tissue (gel), when the balloon was energized at a temperature of 70 °C for 3 min at a balloon injection volume of 12 mL, the temperature at 3 mm deep in the tissue reached 50 °C. Therefore, the balloon temperature was often set to 70 °C in previous reports. [12]

In this study, we used a second-generation HB with a surface-temperature sensor. With a conventional HB, we set the target internal balloon temperature of 70 °C or 73 °C maintained by delivery of RF current into the balloon to stir the fluid inside for 2–3 min for each PV. There was no information available from the conventional balloon, and the only way to confirm whether the ablation was effective was the pulmonary venous potential obtained from the circular mapping catheter [15]. However, the intra-tube temperature sensor, which is a new sensor, allows us to observe the balloon surface temperature, thereby increasing the information we can obtain. A comparison of the results between the first and second generation HBs at our institution is presented in Figs. S4 and S3. Basic experiments using a pseudo-biological model had shown that when the balloon surface temperature was 60–63 °C, the tissue depth of 3 mm reached approximately 50 °C. Therefore, with reference to the data, the procedure was performed to achieve a surface temperature of approximately 60 °C (2–2.5 min) in all PVs except for the LSPV. The LSPV was adjusted to maintain a surface temperature of approximately 63 °C (2.5 min), as previous reports have indicated that the LSPV has more reconduction [11,16].

5. Study limitations

This study described a single-center retrospective experience with a small number of patients reporting our initial experience with the HB with a surface temperature sensor. This study focused only on intra-operative PVI. In the future, it will be necessary to calculate indices that consider long-term durability and PV stenosis. In addition, acute isolation was determined by the loss of electrical potential acquired by the circular mapping catheter, and a voltage map was not created to understand the lesion formed on the surface. Of our sample of 20 patients, voltage mapping was performed in 12 patients after ablation with a second-generation balloon (Fig. S5). In the case of PVs with incomplete isolation, the size of the lesion formed by the balloon may have been the cause. Therefore, further studies are needed.

6. Conclusion

Observation of the second-generation HB surface temperature during PVI provides important information for effective and safe treatment. Except for the LSPV, PVs could be mostly isolated by maintaining a surface balloon temperature of 58 °C with a sensitivity of 75.0% and specificity of 92.1%. Although the surface balloon temperature setting of the LSPV has not been clarified, establishing an index for the HB setting is necessary, as this may affect the durability of PVI in the chronic phase.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability statement

The data underlying this article are available in the article and in its online supplementary material.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2022.100967.

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