



## ORIGINAL ARTICLE

# Effectiveness of a manual dragging laser irradiation technique using the first-generation endoscopic laser balloon ablation system for pulmonary vein isolation

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**Abstract**

**Background:** Although high efficacy of laser balloon (LB) ablation for atrial fibrillation (AF) has been shown, the conventional point-by-point technique requires a long procedure time. We investigated the clinical effectiveness of the manual dragging laser technique.

**Methods:** We enrolled 51 consecutive patients with paroxysmal AF who underwent pulmonary vein isolation (PVI) using first-generation LB (LB1) at our institution. The first 25 patients underwent PVI using a point-by-point laser irradiation maneuver (point-by-point group). The latter 26 patients underwent PVI using a manually dragging laser irradiation maneuver (dragging group). The power and delivery time for the laser energy were selected from a preset protocol with 5.5–12W and 20–30s for each application. The dragging irradiation method was performed by manually rotating approximately 1.5°/s during one irradiation application.

**Results:** PVI was successful in all cases. The duration of PVI was shorter ( $66 \pm 20$  vs.  $116 \pm 39$  min,  $p < 0.0001$ ), and the number of laser irradiations for the 4PVs were significantly less in the dragging group. There were four recurrent cases (16%) in the point-by-point group and 1 (4%) in the dragging group. There was no significant difference in the survival rate free from recurrence after the blanking period between the two groups (log-rank  $p = 0.1570$ ). The complications were similar between the groups (4% vs. 4%, ns).

**Conclusions:** The manual dragging laser irradiation technique using LB1 could shorten the PVI procedure time while preserving clinical effectiveness.

**KEYWORDS**

atrial fibrillation, catheter ablation, clinical outcome, dragging application, laser balloon catheter

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## Condensed abstract

Catheter ablation was performed using conventional point-by-point or dragging techniques using a first-generation laser balloon catheter in 51 patients with AF. The duration of pulmonary vein isolation and the number of laser irradiations for all four pulmonary veins were significantly lower in the dragging group. There was no significant difference between the two groups in terms of acute success and postoperative recurrence rates (log-rank  $p = 0.1570$ ). There were no severe complications in either group. Our study showed that the dragging irradiation technique was useful for reducing the procedure time while maintaining efficacy and safety.

## 1 | INTRODUCTION

Most ectopic beats triggering atrial fibrillation (AF) originate from the myocardial sleeves in the pulmonary veins (PVs).<sup>1</sup> Therefore, PV isolation is an essential procedure for catheter ablation of AF, especially paroxysmal AF.<sup>2,3</sup> Despite the high acute success rates of PV isolation, electrical reconnections of PV isolation are the most common causes of AF recurrence after ablation treatment.<sup>4</sup> This may be attributable to the technical difficulty in achieving a durable PV isolation using radiofrequency (RF) ablation. To perform PV isolation more easily, balloon technology-based catheters, including Cryoballoon, Hotballoon, and the first-generation Laser balloon (LB1), have been introduced.<sup>5-7</sup> Cryoballoon and Hotballoon catheters are single-shot energy delivery devices, whereas the LB1 catheter is a point-by-point energy delivery device. To create continuity and transmural ablation lesions using LB1, it is recommended to overlap the laser irradiation applications by 30–50%.<sup>8</sup> However, this conventional method leads to an increase in the frequency of laser irradiations and the duration of the procedure.<sup>9</sup> The third-generation LB (LB3) with an automated dragging system has been reported to shorten the duration of the procedure.<sup>10,11</sup> However, LB3 is not yet available everywhere in the world. The usefulness of the dragging technique for creating continuous lesions during RF ablation has been reported.<sup>12,13</sup> There has been no report on the manual dragging technique using the common type of LB catheter. Therefore, we retrospectively investigated the effectiveness and safety of the manual dragging technique using LB1.

## 2 | METHODS

### 2.1 | Study participants

A total of 51 consecutive patients with paroxysmal AF who underwent catheter ablation between July 2018 and February 2019 at our institution were retrospectively enrolled. The 1st to 25th patients who underwent laser irradiation by the conventional point-by-point technique were assigned to the point-by-point group. To exclude any learning curve bias, the 11th to 25th patients of the point-by-point

group were defined as the after-learning point-by-point group. The remaining 26 patients who underwent laser-irradiated ablation using the manual dragging technique were assigned to the dragging group. The study was approved by the Institutional Review Board of Kobe City Medical Center General Hospital, and an opt-out system was used to obtain the patients' consent for the use of their clinical data for research purposes. This study was conducted in accordance with the principles of the Declaration of Helsinki.

### 2.2 | Periprocedural management and electrophysiological study

The procedure was performed under deep sedation using dexmedetomidine hydrochloride. Fentanyl citrate was used as an analgesic. During the ablation procedure, heparin sodium was administered as a bolus or continuous administration to maintain an activated clotting time of >300 msec. A multielectrode catheter (BeeAT, Japan Lifeline, Japan) was inserted into the coronary sinus through the right jugular vein. A deflectable multipolar catheter was placed in the right ventricle or superior vena cava to pace the ventricle and phrenic nerve. The atrial septal puncture was performed using an RF transseptal needle (NRG™ RF Transseptal Needle, Baylis Medical Inc., Montreal, Canada, distributed by Japan Lifeline, Japan) under intracardiac ultrasound guidance. A three-dimensional voltage map of the left atrium and PVs was drawn using a multielectrode circular mapping catheter with an EnSite Precision mapping system (Abbott) before and after PVI. Adenosine triphosphate was administered to evaluate any dormant conduction in all patients except one with asthma.

### 2.3 | Laser balloon ablation

LB ablation was performed as described previously.<sup>9</sup> After voltage mapping in the left atrium (LA), a 12-Fr steerable sheath was placed in the LA. The LB1 catheter (Heartlight, CardioFocus) was positioned at each individual PV ostium, and an optimal PV occlusion with maximal exposure of the LA tissue was attempted by continuous flushing of the balloon with deuterium ( $D_2O$ ). LB1 was inflated to provide good tissue contact. Laser irradiation was performed at the site of best tissue contact. If PV isolation was not achieved after each initial circular irradiation, additional laser irradiation with real-time PV potential monitoring was performed. When the esophageal temperature exceeded 39°C, the energy delivery was stopped. Phrenic nerve stimulation was performed at the right subclavian vein to prevent phrenic nerve injury during anterior ablation of the right superior and inferior PVs.

### 2.4 | Irradiation technique

In the dragging group, the target marker of the laser irradiation was intermittently dragged at a speed of about 1.5°/sec during one

irradiation application by the operator (Figures 1A, 2). The overlap rate between the lesions was less than 30%, and the power setting was 12 W for 20 s. In the point-by-point group, the irradiation target during laser application was fixed for each lesion. To avoid creating gaps between each ablation lesion, we applied the applications with an overlap of 30%–50% (Figure 1B). If we could obtain good visualization, a higher power (12 W for 20 s) should be chosen as much as possible. In areas without a clear view (e.g., areas with overlapping moving blood), with a narrow view (e.g., carina sites), and with rising esophageal temperature, a lower power was chosen (5.5–8.5 W for 20 s).

## 2.5 | Follow-up

We evaluated the survival rate free from AF and atrial tachyarrhythmias (AT) without any antiarrhythmic drugs between the two groups. The definition of recurrence was that AF and AT exceeding 30 seconds were detected on a 12-lead or Holter electrocardiogram after the 3-month blanking period. All patients were required to self-examine their pulse daily. They visited our hospital at 1, 3, 6, and 12 months, and a 12-lead electrocardiogram was recorded. Cardiac ultrasound examination and 24-hour Holter recording were performed 6 and 12 months after the procedure. PV stenosis was assessed using computed tomography 3 months after the ablation. Severe PV stenosis was defined as a >75% decrease in the PV diameter 3 months after the ablation.

## 2.6 | Statistical analysis

Categorical variables were compared using Fisher's exact test. Continuous variables were first tested using the Shapiro–Wilk test to determine whether the data were normally distributed. Continuous data with a normal distribution are presented as the means and standard deviations. Continuous data with a skewed distribution are represented as the medians with interquartile ranges. Comparisons between the two groups were performed using Student's *t* test. Time-to-event analysis was performed using Kaplan–Meier curves, and a log-rank test and Cox proportional hazard regression analysis

were used to compare the differences between the groups. A two-sided alpha level of 0.05 was used for all superiority testing. Statistical analyses were performed using JMP version 13 (SAS Institute Inc.).

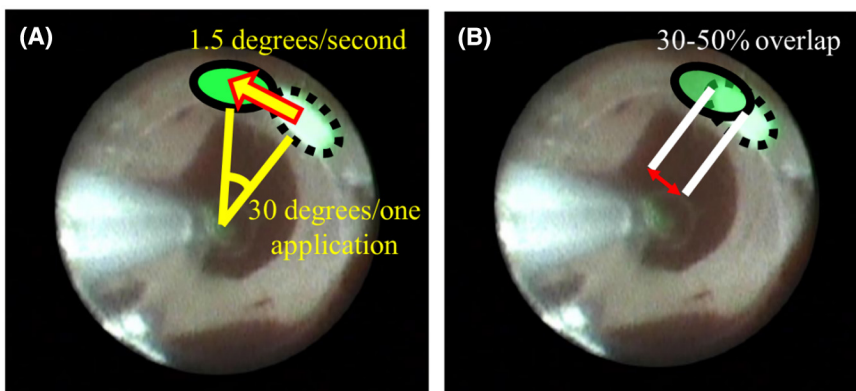
## 3 | RESULTS

### 3.1 | Patient characteristics

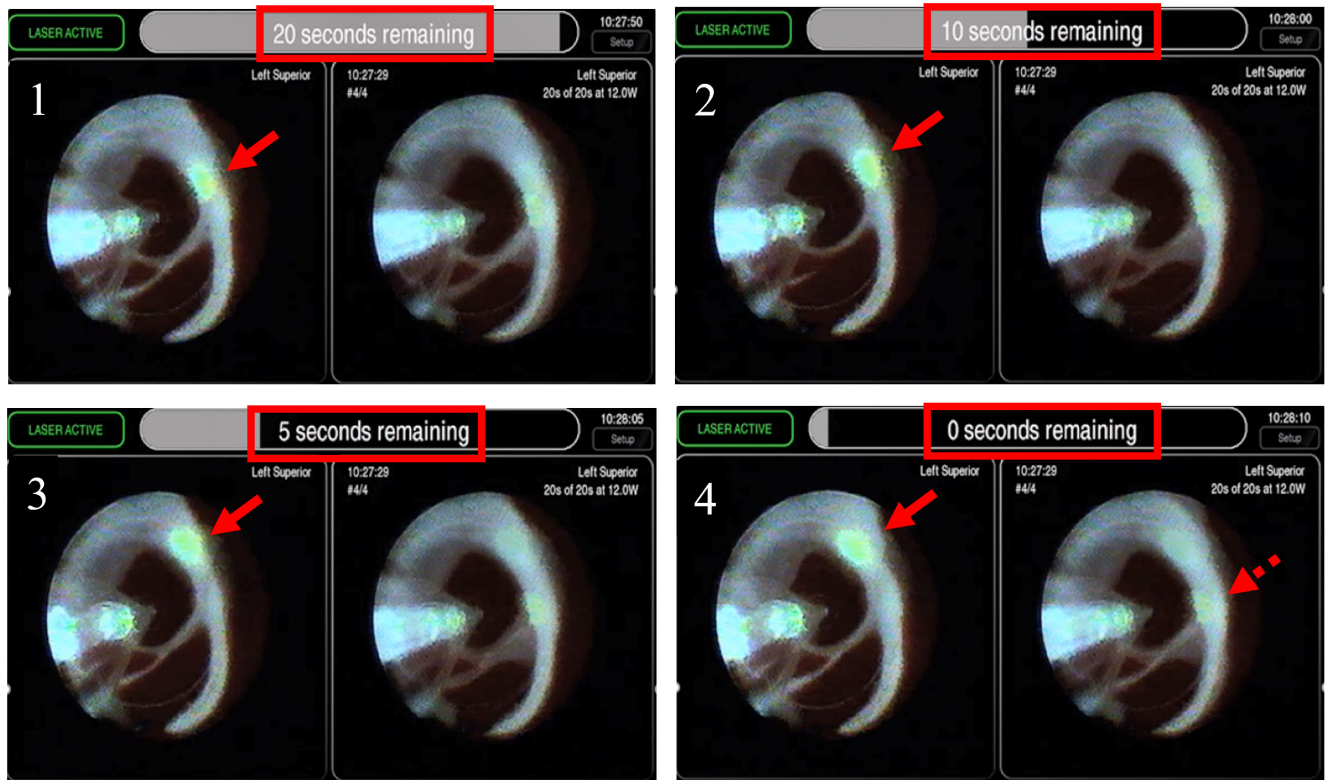
The baseline characteristics of the 51 patients from the two groups are shown in Table 1. No significant differences in the baseline characteristics were observed between the two groups. Two patients with a left common PV were included in the point-by-point group. There were no significant differences in the diameters of the four PVs between the two groups.

### 3.2 | Procedural characteristics

A total of 202 PVs were targeted in 51 patients. In both groups, the PV isolation was completed, including required touch-up procedures using an RF catheter. The rate of first-pass isolation of each PV was comparable between the groups (73% vs. 70% for LSPV, 88% vs. 96% for LIPV, 81% vs. 88% for RSPV, 85% vs. 92% for RIPV; ns, respectively) (Table 2). As an additional therapy with an RF catheter, a cavotricuspid isthmus line was performed in all patients, and a superior vena cava isolation was performed in three patients with an identified origin in the point-by-point group. The duration of PVI in the dragging group was significantly shorter than that in the point-by-point group ( $66 \pm 20$  min vs.  $116 \pm 39$  min,  $p < 0.0001$ ). The same trend was observed compared with the latter 15 cases in the postlearning point-by-point group ( $66 \pm 20$  min vs.  $105 \pm 32$  min,  $p < 0.0001$ ). The fluoroscopy time for the PVI in the dragging group was significantly shorter than that of in the point-by-point group ( $30 \pm 12$  min vs.  $40 \pm 18$  min,  $p = 0.0404$ ); however, there was no significant difference in the comparison with the postlearning point-by-point group ( $30 \pm 12$  min vs.  $35 \pm 13$  min,  $p = 0.2495$ ). In all PVs in the dragging group, the number of laser applications was significantly less than that of the point-by-point group. In all PVs in the dragging group, the average laser energy power was significantly higher than



**FIGURE 1** The dragging technique and conventional point-by-point technique. (A) In the dragging group, the target marker was continuously dragged for approximately 1.5 °/s during each 20 s application. (B) In the point-by-point group, the target marker was fixed for each application. Every lesion was created with an overlap of 30%–50%



**FIGURE 2** Endoscopic image of the dragging movement of the target marker during the application. As time passes, the laser marker moves counterclockwise. The solid arrows indicate the marker position in the real-time image and the dashed arrow indicates the start position of the laser irradiation in the review view

that in the point-by-point group. There was no significant difference in the frequency of touch-up ablation for each PV between the two groups (Figure 3). Three cases of PV reconnections with adenosine triphosphate were observed in the LSPV in the point-by-point group. There was no significant difference in the number of dormant conduction occurrences between the two groups (Figure 3). Touch-up and dormant conduction were frequently observed at the LSPV carina sites, especially at the anteroinferior sites (Figure 3).

### 3.3 | Clinical outcomes and safety

There was one case (4%) with recurrent atrial arrhythmias during the mean follow-up period of  $654 \pm 175$  days in the dragging group and four cases (16%) during  $640 \pm 216$  days in the point-by-point group. Figure 4 shows the Kaplan-Meier plot for freedom from AF and AT recurrences. There were no differences in the observation period ( $p = 0.7951$ ) and sinus rhythm maintenance rates between the two groups (log-rank  $p = 0.1570$ ). Compared with the postlearning point-by-point group, the same result was observed (Figure 4B). In the Cox regression model analysis for recurrence, the estimated hazard ratio in the dragging group compared with the point-by-point group was 0.23 (95% confidence interval [CI], 0.01–1.58;  $p = 0.1446$ ). Periprocedural complications occurred at a comparable rate between the groups (Table 3). No severe PV stenosis was noted

in either group. Phrenic nerve injury related to LB ablation occurred in one patient in the point-by-point group during the RSPV ablation and resolved during the outpatient follow-up. One vasospastic angina episode occurred in the dragging group before the LB ablation.

## 4 | DISCUSSION

### 4.1 | Major findings

The major findings of the present study are as follows<sup>1</sup>: The acute success rates of first-pass isolation and final isolation of each PV were comparable between the dragging and point-by-point groups.<sup>2</sup> The duration of PVI in the dragging group was significantly shorter than that in the point-by-point group.<sup>3</sup> For all PVs in the dragging group, the number of laser applications was significantly lower than that in the point-by-point group.<sup>4</sup> There were no differences in sinus rhythm maintenance rates between the two groups during the follow-up period.<sup>5</sup> No serious complications were observed in either group.

### 4.2 | Efficacy of the dragging method

Previous studies have reported that acute PV isolation using an LB1 alone with the point-by-point technique reached a

TABLE 1 Baseline patient demographics

Characteristic	Dragging (n = 26)	Point-by-point (n = 25)	p value
Age, years	65 ± 10	66 ± 11	0.6041
Male gender, n (%)	19 (73%)	21 (84%)	0.4986
Disease periods, months	40 ± 54	21 ± 28	0.1231
Weight, kg	65 ± 12	63 ± 15	0.6340
Height, cm	167 ± 9	166 ± 8	0.8410
CHADS <sub>2</sub> score	1.0 ± 1.0	1.0 ± 0.9	0.7686
CHA2DS2-Vasc score	1.9 ± 1.4	1.8 ± 1.4	0.6767
Hypertension, n (%)	12 (46%)	10 (40%)	0.7793
Heart failure, n (%)	0 (0%)	1 (4%)	0.4902
Diabetes, n (%)	2 (8%)	1 (4%)	1.0000
Valvular heart disease, (%)	0 (0%)	0 (0%)	–
Hemodialysis, n (%)	0 (0%)	1 (4%)	0.4902
Left ventricular ejection fraction, %	63 ± 5	62 ± 6	0.5101
Left atrial diameter, mm	35 ± 5	36 ± 6	0.3068
Left atrial volume index, ml/m <sup>2</sup>	34 ± 8	39 ± 9	0.0662
NT pro-BNP, pg/dL	97.8 ± 102.8	624.2 ± 2119.6	0.2117
Creatine, pg/dL	0.8 ± 0.2	1.1 ± 1.0	0.0709
Pulmonary vein diameter, mm			
Left superior	18 ± 3	19 ± 4	0.2426
Left inferior	17 ± 3	16 ± 2	0.1338
Right superior	19 ± 3	19 ± 4	0.8595
Right inferior	18 ± 2	17 ± 3	0.2976
Left common	–	26 ± 5	–

sufficiently high success rate even with a certain long procedure time.<sup>9,14</sup> In this study, the PV isolation rate using an LB1 alone with the novel dragging technique reached a comparably high rate with a shorter procedure time than the conventional point-by-point technique. In RF ablation, a certain number of PVs have been observed to reconnect after ablation due to a noncontiguity between the point-by-point lesions along the ablation line. Although a continuous RF catheter movement, such as a dragging maneuver, could increase the durable PVI rate, it may be difficult to maintain a constant contact force during an RF dragging maneuver.<sup>12</sup> However, because the laser irradiation dragging technique is not affected by the contact force, it is easier to obtain a continuous irradiation effect. Furthermore, it is important to create not only continuous lesions but also transmural lesions for a durable PVI, even with LB ablation. With the dragging method, the delivered energy density per lesion might be decreased compared to that with the conventional point-by-point method because the irradiation lesions per application are wider. Therefore, we selected a high-power setting (12 W) as much as possible to prevent insufficient lesion formation. Consequently, the first-pass PVI success rate and long-term outcome in the dragging group were comparable to those in the point-by-point group, showing the comparable efficacy of

the novel dragging technique. An experimental study by Nagase et al. also reported that dragging LB ablation with high power provides deep and continuous linear lesion formation comparable with that of point-by-point LB ablation. This finding could support our novel method.<sup>15</sup>

On the other hand, the most common residual gap and dormant conduction site in both groups were the LS carina, which was the thickest portion.<sup>16</sup> Therefore, fixed laser irradiation may be better for the LS carina than for the dragging method.

### 4.3 | Reduction in the procedure time

In this study, the reduced number of laser applications resulted in a decrease in the duration of the PVI, as expected. Since the point-by-point group included early cases, the learning curve may have had a large impact. However, in a comparison with the 15 patients in the postlearning point-by-point group, the procedure time was also significantly shorter in the dragging group. On the other hand, since it is not necessary to use fluoroscopy when a good visual field is obtained, there was no significant difference in the fluoroscopy time compared with the after-learning point-by-point group.

TABLE 2 Procedural outcomes

	Dragging	Point-by-point	p value
PVI success rate (%) (including touch-up with radiofrequency applications)	100%	100%	1.0000
First pass success rate			
Left superior, n/n (%)	19/26 (73)	16/23 (70)	1.0000
Left inferior, n/n (%)	23/26 (88)	22/23 (96)	0.6119
Right superior, n/n (%)	21/26 (81)	22/25 (88)	0.7030
Right inferior, n/n (%)	22/26 (85)	23/25 (92)	0.6680
Left common, n/n (%)	-	1/2 (50)	-
Touch-up with radiofrequency ablation, no. of pts (%)	2/26 (8)	4/25 (16)	0.4189
Left superior, n/n (%)	2/26 (8)	2/23 (9)	1.0000
Left inferior, n/n (%)	1/26 (4)	0/23 (0)	1.0000
Right superior, n/n (%)	1/26 (4)	1/25 (4)	1.0000
Right inferior, n/n (%)	1/26 (4)	2/23 (8)	0.6098
Left common, n/n (%)	-	1/2 (50)	-
PV reconnection with adenosine triphosphate test			
Left superior, n/n (%)	0/24 (0)	3/24 (13)	0.2340
Left inferior, n/n (%)	0/24 (0)	0/24 (0)	-
Right superior, n/n (%)	0/24 (0)	0/24 (0)	-
Right inferior, n/n (%)	0/24 (0)	0/24 (0)	-
Left common, n/n (%)	-	0/2 (0)	-
Time			
PV isolation, min	66±20	116±39	<0.0001
No. 1-10		133±45	<0.0001
No. 11-25		105±32	<0.0001
Total procedure, min	162±41	216±42	<0.0001
No. 1-10		230±51	0.0002
No. 11-25		207±34	0.0008
Fluoroscopy, min	30±12	40±18	0.0404
No. 1-10		46±24	0.0124
No. 11-25		35±13	0.2495
Number of laser applications			
Left superior, times	18±7	36±16	<0.0001
Left inferior, times	15±6	28±6	<0.0001
Right superior, times	18±8	30±10	<0.0001
Right inferior, times	15±6	27±8	<0.0001
Left common, times	-	45±9	-
Average energy power			
Left superior, W	11.5±0.7	10.8±1.0	0.0123
Left inferior, W	11.0±1.2	9.6±1.2	0.0004
Right superior, W	11.5±1.0	10.6±1.3	0.0090
Right inferior, W	11.1±0.9	9.9±1.4	0.0003
Left common, W	-	8.9±2.14	-
Total time of the laser application			
Left superior, s	346±129	704±283	<0.0001
Left inferior, s	254±125	508±109	<0.0001
Right superior, s	343±136	609±160	<0.0001
Right inferior, s	273±112	566±129	<0.0001
Left common, s	-	952±124	-

TABLE 2 (Continued)

	Dragging	Point-by-point	p value
Additional therapy			
Cavotricuspid isthmus line, n of pts (%)	26/26 (100)	25/25 (100)	-
Superior vena cava isolation, n of pts (%)	0/26 (0)	3/25 (12)	0.1104

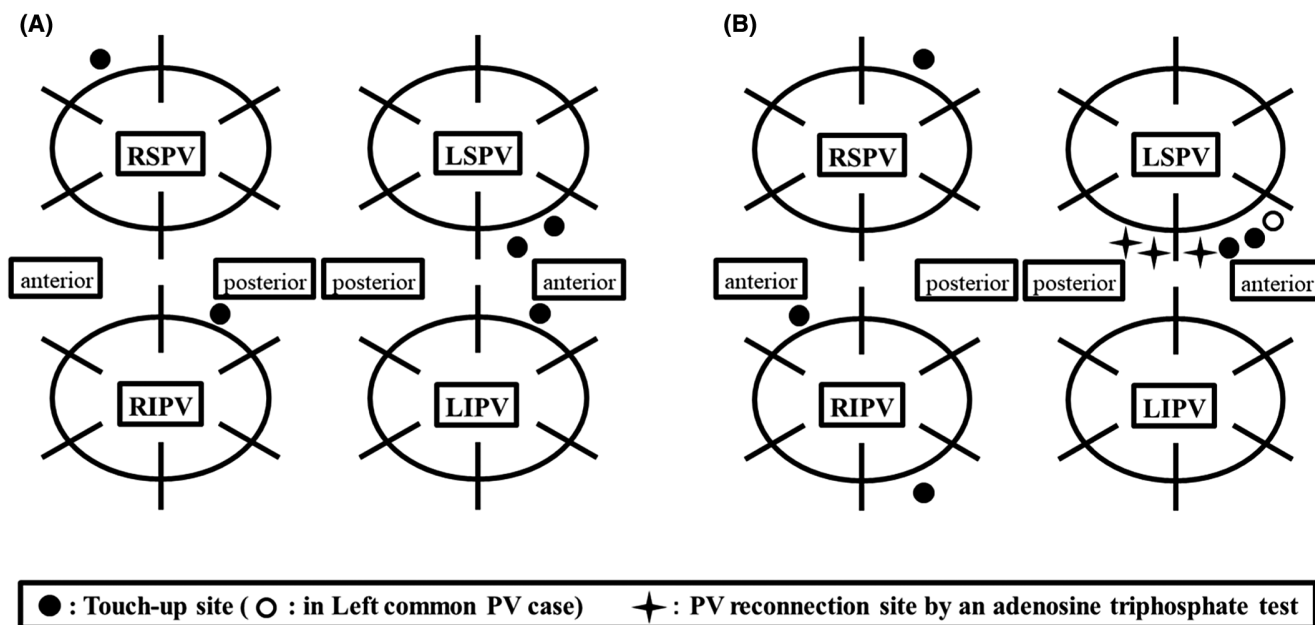


FIGURE 3 Distribution of the touch-up sites by a radiofrequency catheter and PV reconnection sites by an adenosine triphosphate test. The dots indicate the touch-up sites, and stars indicate the PV reconnection sites by an adenosine triphosphate test. The (A) dragging group and (B) point-by-point group

#### 4.4 | Usefulness of the manual dragging method in the automatic driving era

Recently, this device was updated and added the option of a new ablation mode (RAPID), in which the laser arc generator is swept around the PV antrum by an integrated motor drive at a predefined speed for continuous automatic dragging ablation (LB3). LB3 shortened procedural time.<sup>10,11</sup> Our manual dragging maneuver was devised based on LB3 automatically rotating at 2°/s with 13 or 15 W. Hence, the irradiation energy of each site using our manual dragging can be equivalent to LB3. However, Tohoku et al. reported that single-sweep PVI using LB3 was achieved in only 56% of cases.<sup>17</sup> For example, if the field of view cannot be developed in stable concentric circles, the generator position must be manually moved flexibly. Even in the automatic LB era, our manual dragging maneuver could help to keep efficacy and should be a compliment to RAPID mode.

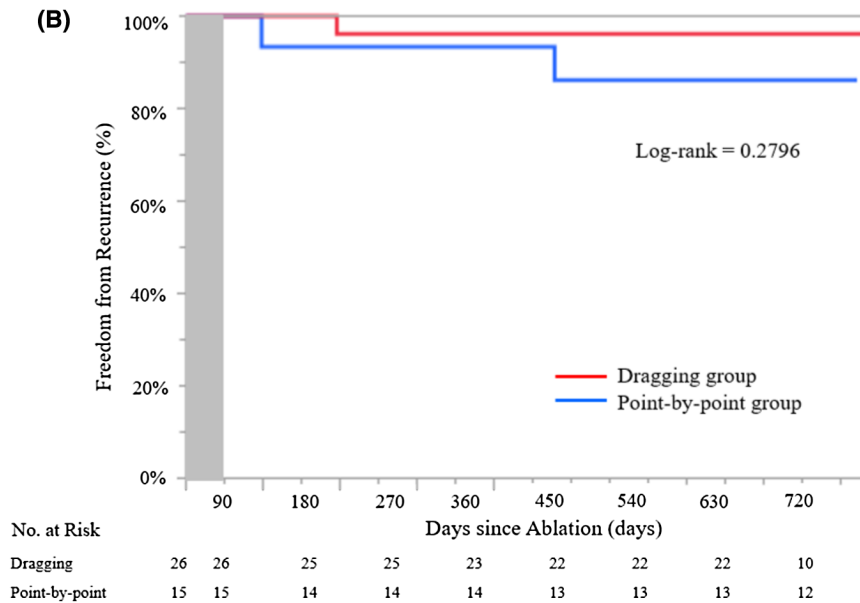
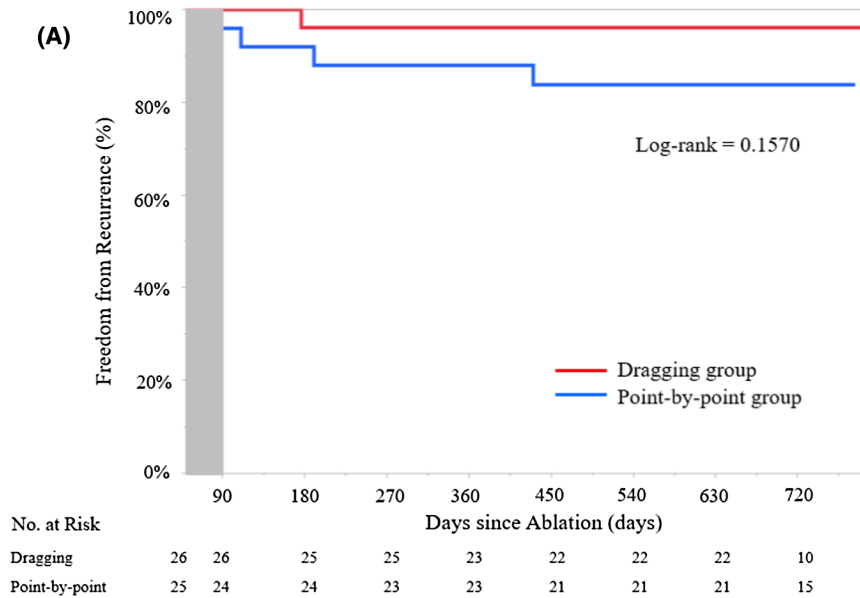
#### 4.5 | Safety outcomes

No serious complications were observed in the dragging group. The laser irradiation method may help avoid overirradiation and complications. One incidence of phrenic nerve injury was observed in the

point-by-point group. It was known that ablation at the distal site of the right PV, especially the RSPV, is at a higher risk of phrenic nerve injury.<sup>18</sup> There is a white line marker on the maximum diameter section of the LB that can be seen with the endoscope. To prevent laser irradiation at the distal site of the PV, it is important to confirm the shape and position of the maximum diameter of the LB. One case of vasospastic angina occurred in the dragging group before the LB ablation procedure, which was unlikely to be related to LB ablation.

## 5 | LIMITATIONS

This was a single-center, retrospective, observational study. The learning curve bias of the operators could not be excluded because of the nonrandomized continuous case-series study. Since the dragging method is manual, there may have been heterogeneous deliveries of the laser irradiation energy to the tissue. In sites where the endoscopic view is poor and the esophageal temperature rises, the dragging speed may become faster, and the delivered laser energy may become lower. Therefore, further multicenter, randomized, comparative studies with more cases are necessary to fully delineate the true efficacy of the dragging technique.



**FIGURE 4** (A) Kaplan–Meier plot of the time to the recurrence event. (B) Kaplan–Meier curve comparing the dragging group with the after learning point-by-point group. The events were the first atrial arrhythmia recurrence after a 3-month blanking period (gray field). The freedom rate from the recurrence events was similar between the dragging (red line) and point-by-point (blue dashed line) groups

	Dragging	Point-by-point	<i>p</i> value
Phrenic nerve palsy, <i>n</i> (%)	0 (0)	1 (4)	0.4902
Coronary vasospastic angina, <i>n</i> (%)	1 (3.85)	0 (0)	1.0000
Cardiac tamponade, <i>n</i> (%)	0 (0)	(0)	–
Symptomatic stroke/TIA, <i>n</i> (%)	0 (0)	(0)	–
Left atrial esophageal fistula, <i>n</i> (%)	0 (0)	(0)	–
Pulmonary vein stenosis(>75%), <i>n</i> (%)	0 (0)	(0)	–
Gastrointestinal disorder, <i>n</i> (%)	0 (0)	(0)	–

**TABLE 3** Complications



## 6 | CONCLUSIONS

In conclusion, we compared the manual dragging method using the LB1 catheter with the conventional point-by-point method in patients with paroxysmal AF. The manual dragging laser irradiation technique using LB1 shortened the procedure time of PVI while preserving the acute and chronic clinical effectiveness and safety.

### ACKNOWLEDGMENTS

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### CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

### DECLARATIONS

The study was approved by the Institutional Review Board of Kobe City Medical Center General Hospital. An opt-out system was used to obtain the patients' consent for the use of their clinical data for research purposes. Registry and the Registration No. zn211212.

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