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Original Article

Recurrence of atrial fibrillation within three months after pulmonary vein isolation for patients with paroxysmal atrial fibrillation: Analysis using external loop recorder with auto-trigger function



Shiro Kawasaki, MD, Kaoru Tanno, MD*, Akinori Ochi, MD, Koichiro Inokuchi, MD, Yuta Chiba, MD, Yoshimi Onishi, MD, Yoshimasa Onuma, MD, Yumi Munetsugu, MD, Miwa Kikuchi, MD, Hiroyuki Ito, MD, Tatsuya Onuki, MD, Fumito Miyoshi, MD, Yoshino Minoura, MD, Norikazu Watanabe, MD, Taro Adachi, MD, Taku Asano, MD, Youichi Kobayashi, MD

Division of Cardiology, Department of Medicine, Showa University School of Medicine, 1-5-8 Hatanodai, Shinagawa-ku, Tokyo 142-8555, Japan

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ABSTRACT

Background: Pulmonary vein isolation (PVI) via catheter ablation has been shown to be a highly effective treatment option for patients with symptomatic paroxysmal atrial fibrillation (AF). The recurrence of AF within 3 months after PVI is not considered to be the result of ablation procedure failure, because early recurrence of AF is not always associated with late recurrence. We examined the usefulness of an external loop recorder with an auto-trigger function (ELR-AUTO) for the detection of atrial fibrillation following PVI to characterize early recurrence and to determine the implications of AF occurrence within 3 months after PVI. **Methods:** Fifty-three consecutive symptomatic patients with paroxysmal AF (age 61.6 ± 12.6 years, 77% male) who underwent PVI and were fitted with ELR-AUTO for 7 ± 2.0 days within 3 months after PVI were enrolled in this study.

Results: Of the 33 (62.2%) patients who did not have AF recurrence within 3 months after PVI, only 1 patient experienced AF recurrence at 12 months. Seven (35%) of the 20 patients who experienced AF within 3 months of PVI experienced symptomatic AF recurrence at 12 months. The sensitivity, specificity, positive predictive value, and negative predictive value of early AF recurrence for late recurrence were 87.5%, 71.1%, 35.0%, and 96.9%, respectively.

Conclusions: AF recurrence measured by ELR-AUTO within 3 months after PVI can predict the late recurrence of AF. Freedom from AF in the first 3 months following ablation significantly predicts long-term AF freedom. ELR-AUTO is useful for the detection of symptomatic and asymptomatic AF.

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1. Introduction

Pulmonary vein isolation (PVI) via catheter ablation has been shown to be a highly effective treatment option for patients with symptomatic paroxysmal atrial fibrillation (AF). The recurrence of AF within 3 months after PVI is common and is not considered to be the result of catheter ablation procedure failure, because the early recurrence of AF in this period is not always associated with late recurrence of AF. Therefore, this period is referred to as the “blinking period” [1,2]. However, the clinical significance of early recurrence is controversial because most studies determine AF recurrence on the basis of symptoms [3]. The incidence of

symptomatic and asymptomatic AF recurrence within 3 months after PVI has not been well investigated.

The SpiderFlash-t device (Sorin, France) is an external loop recorder with an auto-trigger function (ELR-AUTO) that detects and records any arrhythmia automatically. We examined the usefulness of ELR-AUTO for the detection of AF within 3 months after PVI to characterize early recurrence and to determine the implications of AF occurrence within 3 months.

2. Material and methods

2.1. Study subjects

Fifty-three consecutive patients who underwent PVI at our hospital between April and December, 2012 and were monitored

* Correspondence to: 5-1-38 Toyosu, Koto-ku, Tokyo 135-8577, Japan.

Tel.: +81 3 6204 6000.

E-mail address: k-tanno@med.showa-u.ac.jp (K. Tanno).

with an ELR-AUTO within 3 months after catheter ablation were enrolled in this study. The patients had highly symptomatic AF that was refractory to drugs. Medical histories were obtained by reviewing the patients' medical records for ECGs and Holter recordings of AF episodes. Written informed consent was obtained from all subjects before catheter ablation was performed.

2.2. Catheter ablation

Warfarin was discontinued 3 days before the procedure. The PVI catheter ablation procedure was performed with electrode catheters placed in the high right atrium, coronary sinus, and His bundle region. The left atrium (LA) was approached via an atrial septal puncture under the guidance of intravascular ultrasound. Heparin was then administered to maintain an activated clotting time of 350 s. Three-dimensional mapping was performed using either a CARTO (Biosense Webster, Diamond Bar, CA) or NavX (St. Jude Medical, St. Paul, MN) system, and then a LASSO (Biosense Webster) catheter was placed in the pulmonary veins (PVs). The ablation applications were delivered with an irrigation catheter at a power setting of 3035 W on the anterior wall and 2025 W on the posterior wall. The endpoint of the ablation was bidirectional block at the PV–LA antrum. The procedure was considered complete when no arrhythmia induction occurred during programmed stimulation (cycle length 200 ms).

2.3. Post-ablation evaluation

For the clinical follow-up, after undergoing ablation, the patients were fitted with an ELR-AUTO for 1–2 weeks within the 3 months following the ablation procedure. Atrial fibrillation burden within 3 months after ablation was defined as an early AF episode lasting for 60 s, with or without symptoms. Symptomatic AF was defined as AF with related symptoms, such as palpitations or chest discomfort.

The patients underwent an electrocardiogram (ECG) recording at the hospital every month during the 3 months after the ablation procedure. Late recurrence, defined as AF detected by any method 12 months after ablation, was evaluated using a 12-lead ECG, Holter ECG, or ELR-AUTO.

2.4. External loop recorder

Regarding the fitting of the ELR-AUTO, the medical technician only installed the device on the first day and instructed the patients on how to attach the device thereafter. From the second day forward, the patients attached the device on their own. The patients placed 1 cathode (white) and 2 anode (red and brown) patches on their body surface. The frequency characteristics of the ECG recordings ranged from 0.05 to 80 Hz. The dynamic range of the input was ± 16 mV to ± 300 mV. The carrier frequency was 200 Hz, and the resolution was 10 μ V.

The automatic detection of arrhythmias allowed the ECG loop recorder to record the 2 min after an event and the 4 min before an event when the patient noticed a symptom and pressed a button on the device. The settings of the automatic detection function of the ELR-AUTO are shown in Table 1. In the case of a supraventricular tachycardia at a rate of 160 beats/min lasting for 10 s or more, the 60 s before and after the event were recorded. When an RR-interval irregularity was maintained for 60 s, the 60 s before and 120 s after the irregularity were recorded. Premature atrial contractions (PAC) occurring within the first 75% of the RR interval were recorded. If a ventricular tachycardia faster than 140 beats/min and lasting more than 8 s occurred, the 60 s before and after it were recorded. Premature ventricular contractions (PVC) were recorded if they occurred within the first 85% of the RR interval.

Table 1
Settings for the ELA-AUTO's automatic detection function.

Disorder	Threshold	Minimum duration (s)	Time before (s)	Time after (s)
SV tachycardia	160	10	60	60
Irregular RR		60	60	120
%SV	75			
Ventricular tachycardia	140	8	60	60
%V	85			
Bradycardia	40	20	60	60
Pause	3000		10	10
Missed beats	1000		10	10

SV tachycardia: supraventricular tachycardia.

Table 2
Patient characteristics.

	Total
Patients (male/female) (n)	53 (41/12)
Age (years)	61.6 \pm 12.6
Disease duration (years)	4.6 \pm 4.4
<i>Echocardiography</i>	
Left atrial diameter (mm)	43.6 \pm 6.1
Left ventricular ejection fraction (%)	61.2 \pm 5.9
DcT (ms)	218.2 \pm 60.4
E/e'	7.2 \pm 6.2
Antiarrhythmic drug (n)	27
<i>Underlying disease</i>	
HT (n)	23
DM (n)	5
Dyslipidemia (n)	16
CHF (n)	9

DcT: deceleration time, E/e': ratio between velocities of the E and A waves on Doppler transmitral flow, HT: hypertension, DM: diabetes mellitus, HL: hyperlipidemia, and CHF: congestive heart failure.

For bradycardia of 40 beats/min or less, lasting for 20 s, the 60 s before and after it were recorded. For any pause longer than 3000 ms, the 10 s before and after it were recorded. In the case of an RR interval of 1000 ms or more during block, the 10 s before and after it were recorded. The device was set to record the 4 min before and 2 min after any symptomatic events.

2.5. Statistical analysis

Continuous variables are expressed as mean \pm standard deviation. A *p*-value < 0.05 was considered to indicate a significant difference. For the statistical analyses, JMP version 10.0 software (SAS Institute, Cary, USA) was used.

3. Results

3.1. Patient characteristics

The patient characteristics are shown in Table 2. There were 53 subjects, including 41 male and 12 female patients, with a mean age of 61.6 \pm 12.6 years and a mean disease duration of 4.6 \pm 4.4 years. Echocardiography findings revealed that the mean left atrial diameter was 43.6 \pm 6.1 mm and the mean ejection fraction was 61.2 \pm 5.9%.

Table 3
Symptomatic and asymptomatic atrial fibrillation.

	ER+symptom+	ER+symptom−	p-Value
Patients (male/female) (n)	10 (9/1)	10 (7/3)	NS
Age (years)	59.4 ± 13.8	63.4 ± 8.0	NS
Disease duration (years)	6.1 ± 3.6	2.2 ± 2.1	0.01
<i>Echocardiography</i>			
Left atrial diameter (mm)	46.2 ± 7.9	42.7 ± 5.0	NS
Left ventricular ejection fraction (%)	61.7 ± 9.3	62.8 ± 4.9	NS
DcT (ms)	197.8 ± 68.4	234.0 ± 71.0	NS
E/e'	7.0 ± 1.1	5.5 ± 1.0	0.01
Antiarrhythmic drug (n)	7	5	NS
<i>Underlying disease</i>			
HT (n)	4	7	NS
DM (n)	1	2	NS
Dyslipidemia (n)	1	5	0.04
CHF (n)	0	2	NS

ER: early recurrence, ER+symptom+: symptomatic and asymptomatic recurrent AF group, ER+symptom−: asymptomatic recurrent AF groups, and NS: non-significant. Other abbreviations are as in Table 2.

3.2. Catheter ablation

Complete isolation was achieved in 51 patients with an incomplete isolation in 2 patients. In 2 patients, we were able to confirm a unidirectional block, but this was left untreated so as not to prolong the procedure time excessively. When AF was induced by programmed atrial stimulation after PVI, linear ablation of the LA roof and mitral isthmus was performed ($n=6$). When common atrial flutter was induced by programmed atrial stimulation, linear ablation of the cavotricuspid isthmus was performed ($n=18$).

3.3. AF within 3 months after ablation

AF episodes were recorded by the ELR-AUTO in 20 (37.7%) of the 53 patients. There was no significant difference in the incidence of AF with regard to gender, age, echocardiographic findings, oral medications, or underlying disease. Ten of the 20 patients (50%) who experienced AF had both symptomatic and asymptomatic AF, whereas 10 (50%) had only asymptomatic AF. Table 3 shows details of the group with both symptomatic and asymptomatic recurrent AF ($n=10$) and the group with only asymptomatic recurrent AF ($n=10$) among the patients in whom AF was detected by ELR-AUTO monitoring. There was no significant difference between the 2 groups with regard to gender, age, echocardiographic findings, oral medications, or underlying disease. However, patients with symptomatic AF had a longer history of atrial arrhythmia than patients with asymptomatic AF (6.1 ± 3.6 vs. 2.1 ± 2.1 years, $p < 0.01$). In addition, the E/e' ratio (between the velocities of the E and A waves on Doppler transmitral flow) was higher in patients with symptomatic AF than in patients with asymptomatic AF (7.0 ± 1.1 vs. 5.5 ± 1.0 , $p < 0.01$).

3.4. Events for which patients activated the ELR-AUTO

The patients activated the ELR-AUTO for a total of 393 events. Fig. 1 shows the ECG classifications of those events. Of the 393 events, 177 (46%) showed normal sinus rhythm (NSR), 88 (22%) were PACs, 47 (12%) were AF, 37 (9%) were PVCs, and 43 events (11%) could not be classified because of excessive noise.

3.5. ECG recordings detected automatically by ELR AUTO

Fig. 2 shows an analysis of a total of 5728 recordings obtained by the ELR-AUTO automatically. Each recording was confirmed and

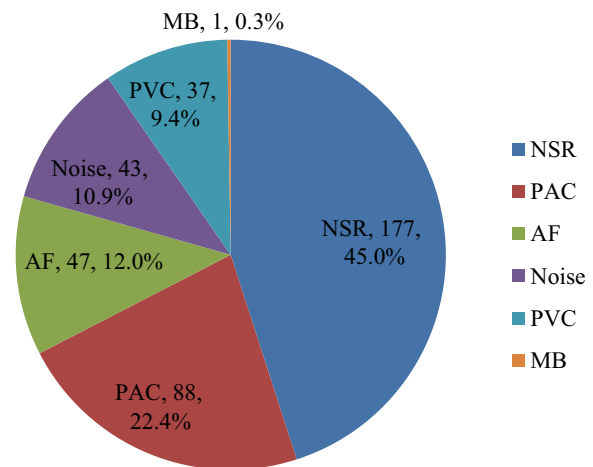


Fig. 1. The events for which patients activated the ELR-AUTO. There were a total of 393 events. This chart shows the ratio of events recorded when the patients felt symptoms. A total of 393 events were detected, and among those associated with subjective symptoms, the patients experienced the following: 177 events (45%) of sinus rhythm, 125 events (31%) of a combination of atrial premature contractions and premature ventricular contractions, 47 events (12%) of atrial fibrillation, and 43 events (11%) of recording failure. AF: atrial fibrillation, MB: missed beats, NSR: normal sinus rhythm, PAC: premature atrial contractions, and PVC: premature ventricular contractions.

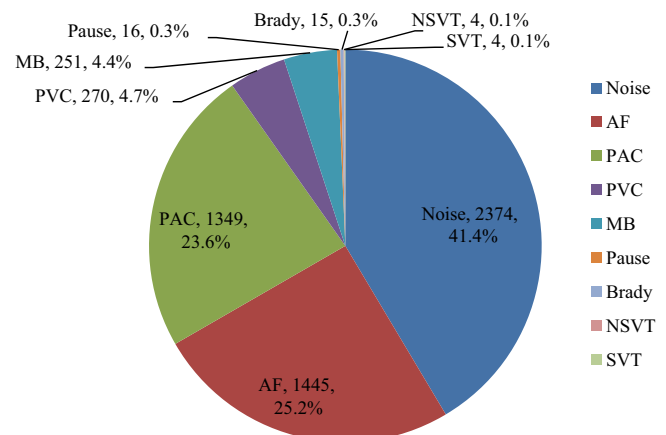


Fig. 2. The ECG recordings that were detected automatically by ELR-AUTO. This graph shows the ratio of asymptomatic events detected automatically. There were a total of 5728 events, of which 1445 (25%) were atrial fibrillation. Additionally, 1349 events (24%) were premature atrial contractions, and 2374 events (42%) were recording failures. NSVT: non-sustained ventricular tachycardia and SVT: sustained ventricular tachycardia. Other abbreviations are as in Fig. 1.

classified by a specialized doctor. Of the 5728 recordings, 2374 (42%) were noise, 1445 (25%) were AF, 1349 (24%) were PACs, 270 (5%) were PVCs, 251 (4%) were missed beats, 16 (0.27%) were pauses, 15 (0.26%) were bradycardias, 4 (0.06%) were supraventricular tachycardias, and 4 (0.06%) were ventricular tachycardias.

3.6. Number of AF episodes per day

A total of 1492 AF episodes were recorded by the ELR-AUTO in 20 patients. Fig. 3 shows the incidence of AF for each day during the ELR-AUTO monitoring period. The blue bar indicates the number of AF episodes recorded by patient activation, while the red bar indicates the number of episodes recorded automatically. Forty-seven of the 1492 episodes (3.2%) recorded were symptomatic AF.

3.7. Early AF and late symptomatic AF

Fig. 4 shows the results of the long-term follow-up of the recurrent (n=20) and non-recurrent (n=33) AF groups. There was no significant difference between the groups with regard to age, disease duration, echocardiographic findings, underlying disease, or late recurrence; however, there was a significantly lower incidence of late recurrence in patients who had no early recurrence.

Table 4 shows the characteristics of the late recurrent and non-late recurrent AF groups. There was no significant difference between the groups with regard to age, disease duration, or underlying disease; however, in patients without any late recurrence, the left atrial diameter was significantly smaller, and the male/female ratio was significantly lower. Late recurrence occurred in a significantly greater number of patients who had experienced AF recurrence within 3 months after PVI (8 patients; 20%) than in those who had not. Seven of the 20 patients (35%) who had experienced AF within 3 months after PVI had symptomatic AF recurrence at 12 months. The sensitivity, specificity, positive predictive value, and negative predictive of early AF recurrence for late recurrence were 87.5%, 71.1%, 35.0%, and 96.9%, respectively.

3.8. The incidence of AF recurrence for each month

The incidence of AF recurrence detected by ELR-AUTO for each month after PVI is shown in Fig. 5. The incidence of patients with

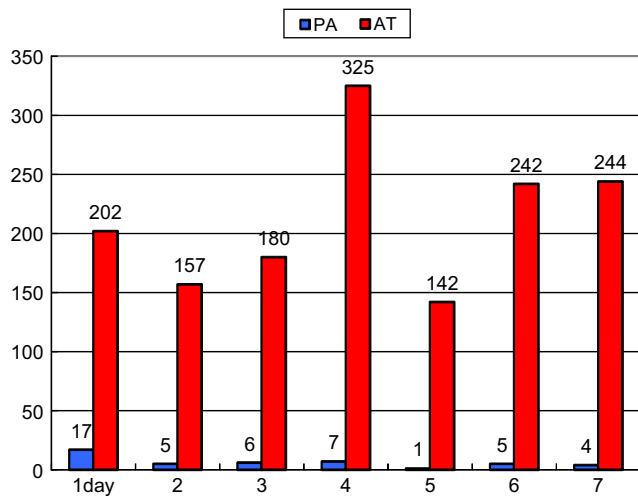


Fig. 3. Number of episodes of atrial fibrillation each day. The total number of events per day in which a recurrence of paroxysmal atrial fibrillation was observed. PA: patient activated and AT: auto-trigger.

early or late recurrence did not differ significantly among the months when ELA-AUTO recording was performed.

4. Discussion

4.1. Main findings

Most of the AF burden was asymptomatic. Freedom from AF in the first 3 months following PVI predicts long-term AF freedom.

4.2. AF recurrence within 3 months after PVI

To our knowledge, there are no previous reports that evaluated the recurrence of AF within 3 months after PVI using ELR-AUTO. Previous trials have reported AF recurrence rates of 35–65% within 3 months after PVI [1,4–7]. Several recording systems, such as the Holter ECG, event recorder, trans-telephonic monitoring, external loop recorder, or implantable loop recorder (ILR), were used to identify AF recurrence in those studies. We could not compare the results of those trials because of differences in the types of patients, ablation strategies, definitions of recurrence, and ECG monitoring. However, with longer monitoring times, the detection rate of AF recurrence increased. In addition, continuous monitoring is necessary to detect AF recurrence, because most AFs after PVI were asymptomatic.

A few studies reported that incomplete PVI was a predictor of recurrence [2,8]. Only 2 patients had incomplete isolation in this study, but they did not have early or late AF recurrence. It is

Table 4 Late recurrence.

	LR+	LR–	p-Value
Patients (male/female) (n)	8 (8/0)	45 (33/12)	0.003
Age (years)	61.6 ± 6.9	61.6 ± 13.5	NS
Disease duration (years)	6.1 ± 4.2	4.7 ± 4.6	NS
<i>Echocardiography</i>			
Left atrial diameter (mm)	47.6 ± 6.3	42.9 ± 5.9	0.04
Left ventricular ejection fraction (%)	59.2 ± 6.8	61.5 ± 5.8	NS
DcT (ms)	204.0 ± 49.6	220.8 ± 62.3	NS
E/e'	5.7 ± 1.2	7.6 ± 6.5	NS
Antiarrhythmic drug (n)	5	22	NS
<i>Underlying disease</i>			
HT (n)	5	18	NS
DM (n)	1	4	NS
Dyslipidemia (n)	2	14	NS
CHF (n)	1	8	NS

LR: late recurrence. Other abbreviations are as in Tables 2 and 3.

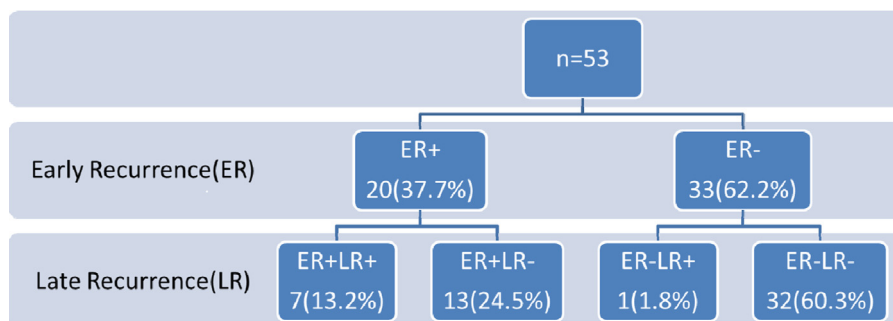


Fig. 4. Results of long-term follow-up. Late recurrence occurred in a significantly higher number of patients who had experienced recurrence of atrial fibrillation (AF) within 3 months after pulmonary vein isolation (8 patients; 20%) than in those who had not. Seven of the 20 patients (35%) who experienced AF within the 3 months had symptomatic AF recurrence at 12 months. ER: early recurrence and LR: late recurrence.

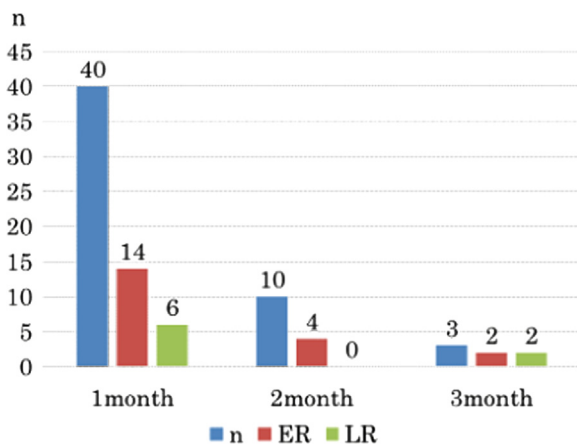


Fig. 5. The incidence of AF recurrence for each month. The incidence of AF recurrence detected by ELR-AUTO for each month after pulmonary vein ablation is shown. The incidence of patients with early or late recurrence did not differ significantly among the months when ELA-AUTO was performed. ER: early recurrence and LR: late recurrence.

probable that a unidirectional block contributes to the suppression of the trigger and perpetuation of AF, and that PVI causes local denervation of the ganglionic plexus around the superior PV left atrial junctions during the ablation procedure [9].

4.3. Symptomatic and asymptomatic AF

In the present study, the presence or absence of symptoms during AF recurrence was examined. The symptomatic recurrence group had a significantly longer disease duration and higher E/e' compared to the asymptomatic AF recurrence group. E/e' reflects diastolic dysfunction. Kosiuk et al. reported that diastolic dysfunction was correlated with symptom severity in AF [10]. A possible explanation for that observation is a strong dependence of the hemodynamic performance of the whole system on intact atrial function, because the functional reserve of the impaired left ventricle is greatly reduced during AF.

Neumann et al. also examined the detection of AF by symptoms using a portable ECG event recorder in patients who underwent PVI; they found that the detection of AF based on symptoms was inaccurate [5]. Using ILR evaluation, Verma et al. found that the incidence of asymptomatic AF before PVI was 52.0%; however, the incidence of asymptomatic AF increased to 79.0% after PVI. After PVI, the number and duration of AF episodes were decreased, as was heart rate variability [11]. In this study, the incidence of asymptomatic AF was 97%; therefore, we concluded that the recurrence of AF after PVI could not be evaluated on the basis of patient-reported symptoms.

4.4. Early recurrence and late recurrence

In the present study, it was hypothesized that patients with early AF recurrences would have a significant trend toward late AF recurrences. Oral et al. and Joshi et al. reported that AF recurrence 2 weeks after ablation was a predictor of late phase recurrences [1,3]. In addition, Joshi et al. reported that AF recurrence from 2 weeks to less than 3 months was not related to late recurrence. On the other hand, Choi et al. reported that early recurrence within 3 months after PVI was associated with late recurrence [12]. In those studies, early recurrence was correlated with late recurrence. In this study, the result was similar; however, the positive predictive value was very low, and the negative predictive value was high. This finding is promising. Freedom from atrial fibrillation in the first 3 months following PVI predicts long-term

AF freedom. Because most AF episodes were asymptomatic, the auto-trigger function of the ELR-AUTO was useful [1,3–7].

4.5. Usefulness of ELR-AUTO for identifying AF recurrence

Currently, Holter and trans-telephonic monitoring are the main modalities for the identification of arrhythmia recurrence. However, Ziegler et al. reported that intermittent and symptom-based monitoring had lower sensitivity and a lower negative predictive value for the identification of patients with AF, and underestimated the AF burden compared with continuous monitoring [13]. Verma et al. used ILRs to evaluate AF recurrence after PV isolation and reported that the proportion of asymptomatic events increased after PV isolation [10]. Kapa et al. used ILRs after catheter ablation to investigate early and late AF recurrence [7]. They reported that the rate of AF recurrence was 47% from 1 to 6 months and 18% from 6 to 12 months [7]. Reiffel et al. investigated the Holter ECG, ELRs, and automatic detection function ELRs, and reported that the auto-detection ELRs were useful for the detection of asymptomatic arrhythmias [14]. Continuous monitoring is necessary to identify AF recurrence. Martinez et al. also reported the usefulness of the ELR for arrhythmia diagnoses [15]. There are also reports that asymptomatic events increase after PVI, and it is thought that an ELR-AUTO with an automatic detection function would be useful for the evaluation of AF events after PVI ablation.

4.6. Incidence of AF recurrence for each of the first 3 months

It would be extremely useful to know the best timing for performing ECG monitoring within the first 3 months (1 month, 2 months, or 3 months after PVI) for predicting long-term AF recurrence. In this study, no optimal timing of ELR-AUTO monitoring could be determined, because no significant relationship was found between the month within which early recurrence was detected after PVI and late recurrence.

4.7. Limitations

This was a retrospective study, and the number of cases was small. Some recordings could not be analyzed because of the level of noise. The physicians and laboratory technicians confirmed all of the waveforms. In addition, the algorithm for the detection of an irregular RR interval with ELR-AUTO has not been published. Therefore, some AF episodes might have been missed. In addition, the recurrence rate of atrial tachyarrhythmias with a regular ventricular response under 160 beats/min would be underestimated, because this ELR-AUTO did not detect them.

5. Conclusion

AF recurrence within 3 months after PVI can predict the response to catheter ablation at 12 months. Freedom from AF in the first 3 months following ablation significantly predicts long-term AF freedom. ELR-AUTO is useful for the detection of symptomatic AF and asymptomatic AF.

Conflict of interest

None of the authors have any conflict of interest regarding this study.

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