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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

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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.

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 "blanking 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

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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 μV.

The automatic detection of arrhythmias allowed the ECG loop reorder 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 ± 12.6
Disease duration (years)	4.6 ± 4.4
Echocardiography	
Left atrial diameter (mm)	43.6 ± 6.1
Left ventricular ejection fraction (%)	61.2 ± 5.9
DcT (ms)	218.2 ± 60.4
E/*e*′	7.2 ± 6.2
Antiarrhythmic drug (*n*)	27
Underlying disease	
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 ± 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 ± 12.6 years and a mean disease duration of 4.6 ± 4.4 years. Echocardiography findings revealed that the mean left atrial diameter was 43.6 ± 6.1 mm and the mean ejection fraction was 61.2 ± 5.9%.