# Comparison of two modes of long-term ECG monitoring to assess the efficacy of catheter ablation for paroxysmal atrial fibrillation

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**Aims.** Optimal ECG monitoring in detecting recurrences of atrial fibrillation (AF) or atrial tachycardia (AT) after catheter ablation has not been well established. The purpose of this prospective study was to compare the utility of daily ECG monitoring with episodic card recorder (ECR) vs. periodic monitoring with episodic loop recorder (ELR) for the detection of post-blanking AF/AT recurrences during early (Months 4-6) and late (Months 7-12) periods after catheter ablation for paroxysmal AF.

**Methods.** The study included 105 consecutive patients, who received ECR for 12 months and were instructed to send at least 2 random ECG recordings daily with extra-recordings during symptoms. The patients were simultaneously monitored for one week with ELR at the end of each period (Months 6 and 12).

**Results.** Thirty-one and 12 patients with AF/AT recurrence were identified by means of ECR and ELR, respectively. In patients with complete and valid data, ELR technology was inferior to ECR by detecting AF/AT in 5 (31%) of 16 and 5 (26%) of 19 patients with arrhythmia identified by ECR in the early and late period, respectively. Overall, ELR had a sensitivity of 8/23 (35%) for detecting AF/AT recurrence. There was no single patient with AF/AT recurrence on ELR that would not be known from ECR monitoring. Only 2 patients with arrhythmia recurrence were completely asymptomatic throughout the study period.

**Conclusion.** Daily ECG monitoring with ECR was better than periodic monitoring with ELR in detecting AF/AT recurrences during the follow-up periods. Entirely asymptomatic patients with AF/AT recurrences were rare.

Key words: atrial fibrillation, paroxysmal, catheter ablation, ECG monitoring

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### **INTRODUCTION**

Catheter ablation of atrial fibrillation (AF), although more effective in AF abolition and quality of life improvement as compared to antiarrhythmic drugs<sup>1,4</sup>, may have overestimated outcomes due to unrecognized recurrences of AF or atrial tachycardia (AT). Prior studies have shown that longer ECG monitoring can more effectively detect clinically unrecognized recurrent arrhythmias after apparently successful ablation<sup>5-14</sup>. Which mode of long-term ECG monitoring should be preferred in terms of efficacy, comfort, or costs is not clear. Following catheter ablation for paroxysmal AF, even intermittent self-terminating AF/ AT episodes if recurring in clinically significant quantity, should not be missed by continuous ECG monitoring based on principle of endless loop with automatic arrhythmia detection and trans-telephonic ECG transmission limited to a couple of weeks. Likewise, episodic card ECG recorder, if scrupulously applied by instructed patient for longer time, despite some risk of missing shorter-lasting asymptomatic AF/AT episodes, should not fail to detect clinically significant arrhythmia.

The purpose of this prospective study was to compare episodic card recorder (ECR) used for daily ECG monitoring throughout the whole study period with episodic loop recorder (ELR) applied periodically for  $\geq 1$  week at the end of Month 6 and 12 in detecting AF/AT recurrences and ability to evidence post-ablation rhythm status within two successive periods of 12-month follow-up after catheter ablation for paroxysmal AF.

### **METHODS**

### Study hypothesis

We hypothesized that periodical continuous ECG monitoring with ELR applied twice per year for 1 week will identify a comparable number of patients with AF/AT recurrences as discontinuous ECG monitoring with ECR applied daily during the whole 9-month post-blanking follow-up after catheter ablation for paroxysmal AF.

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### **Population**

This prospective study included 105 consecutive patients who underwent their first catheter ablation for paroxysmal AF. Baseline characteristics of the study population are shown in Table 1. Ethical approval was obtained and all patients gave written informed consent. For the purpose of the study, patients were followed for 12 months after the procedure and underwent a repeat ablation when clinically indicated.

#### Catheter ablation

The method of catheter ablation has been described in detail elsewher<sup>15-16</sup>. Briefly, ablation consisted of mandatory pulmonary vein isolation with wide circumferential lesions. It was at the discretion of one of four operators, whether additional lesions to target non-pulmonary vein AF/AT sources, and whether to test noninducibility with atrial pacing up to 300 bpm, and/or with challenge to isoproterenol and adenosine at the end of the procedure. Radiofrequency energy was applied through an irrigated-tip electrode (saline cool flow of 20 mL/min) of the ablation catheter (NaviStar-ThermoCool, Biosense-Webster) limited to temperature and power of 42 °C and 30-35 W, respectively. The maximum power was reduced to 20-25 W during ablation inside coronary sinus.

### **Noninvasive ECG monitoring**

All patients received an ECR (Vitaphone 100 IR, Mannheim, Germany) with imbedded electrodes and buttons for manual activation by the patient upon attaching the recorder against the patient's chest. The duration of a single ECG recording is 30 s, and the recorder memory contains a maximum of 3 ECG recordings. The patients were instructed to send at least two random ECG recordings a day despite the absence of any symptoms, ideally every 12 h. In addition, they were asked to activate the ECG recording whenever they sensed symptoms suggestive of arrhythmia. At Months 6 and 12, the patients simultaneously applied an ELR for ≥7 days. The ELR (Vitaphone Tele-ECG Loop recorder 3100BT) had memory for 15 manually activated or automatically detected ECG recordings of 40-second duration. Despite the limited memory of the recorders, automatic communication between the recorder and dedicated telephone facilitated automatic data transmission onto a central server, thus releasing the memory of ECR and ELR for theoretically infinite ECG recordings.

The data were transmitted by both systems onto the central server of an international company for telemedicine (Medical Data Transfer) whose technicians and physicians manually inspected and analysed each ECG recording, and prepared edited data for final evaluation by the referring and another independent physician.

After exclusion of non-interpretable ECG recordings, the count, occurrence time, and duration of individual AF/AT episodes were registered. The AF/AT episode duration was determined as the time from onset to termination. If they were not clear from discontinuous ECR monitoring, the episode duration was considered as the period between the preceding and subsequent si-

nus rhythm, i.e. rather overestimated. The arrhythmias were correlated with symptoms registered by instructed patients in their symptom diaries.

### Antiarrhythmic drug management after ablation

Class I or III antiarrhythmic drugs were generally discontinued after ablation and might have been restarted in case of early AF/AT recurrence. There was a strategy to adjust antiarrhythmic medication at Month 3 and 6 outpatient visits and maintain the recommended type and dose of antiarrhythmic drug for the whole monitoring period.

### Data processing and statistics

An episode of AF/AT detected after the 3-month blanking period and lasting >30 s was considered a recurrence. AF/AT recurrences were analysed separately within two post-blanking follow-up periods (early: months 4-6; and late: months 7-12) and for the total duration of the study. Correspondence in AF/AT detection between ECR and ELR was assessed within these periods as well as for total follow-up. Similarly, correspondence in AF/AT detection between both follow-up periods was analysed. AF/AT episodes were categorized as symptomatic or asymptomatic according to patients' diaries. Only patients with only asymptomatic AF/AT episodes in a given period were considered "asymptomatic" for that period (or total duration of the study). When a patient underwent early repeat ablation during the study period, corresponding comparative data were excluded from the analysis to avoid inherent bias.

Continuous variables were expressed as means  $\pm$  standard deviation. Categorical variables were expressed as

Table 1. Baseline characteristics.

Females	41 (39%)
Age (years)	58±10
ACEI / ARB	57 (54%)
Betablocker	55 (52%)
Amiodarone	38 (36%)
Propafenone	47 (45%)
Sotalol	14 (13%)
Warfarin	81 (77%)
Antiplatelet therapy	20 (19%)
Heart failure	6 (6%)
Hypertension	72 (69%)
Diabetes mellitus	21 (20%)
Stroke / transient ischemic attack	11 (10%)
Vascular disease	15 (14%)
Hypothyroidism	6 (6%)
Bronchopulmonary disease	8 (8%)
CHA,DS,-VASc score	2.0±1.4
Body mass index (kg/m <sup>2</sup> )	29.4±4.6
LA diameter (mm)	42±6
LV ejection fraction (%)	60±5

Data are shown as mean  $\pm$  standard deviation or counts with percentages. ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin II receptor blocker; LA = left atrium; LV = left ventricle.

percentages. The Kaplan-Meier curve was used to display cumulative arrhythmia-free survival. All analyses were performed using the STATISTICA vers.12 software (Statsoft, Inc.).

### **RESULTS**

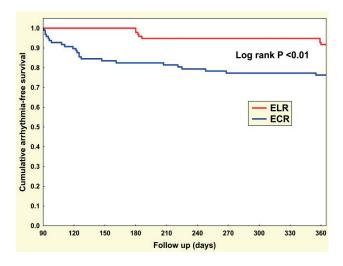
# Ablation procedure characteristics and clinical outcome

During the index ablation, simple pulmonary vein isolation (with possible cavo-tricuspid isthmus ablation) was completed in 80 (76%) patients. Non-pulmonary vein sources were targeted in 25 (24%) patients with AF continuing or induced after PV isolation. Eight patients underwent a repeat ablation procedure during 12-month follow-up period. At the end of follow-up, freedom from post-blanking AF/AT recurrence was achieved in 74 (70%) patients (Fig. 1). There were two complications without permanent sequelae: one tamponade with drainage, and one transient ischemic attack.

### Adherence to monitoring and quality of data

All patients completed monitoring with ECR. Three patients (all free from AF/AT recurrences without antiarrhythmic drugs) terminated monitoring prematurely on days 260, 290, and 302, respectively. Patients who decided to terminate ECR monitoring prematurely were furnished with ELR before the end of their individual monitoring period. The remaining 91 and 11 patients completed ≥350 or 330-349 monitoring days, respectively. Comparison of both ECG recording technologies was not possible in one patient who declined ELR monitoring because of known allergic reaction to adhesive electrodes; ELR at Month 12 was further missing in another 2 patients.

Compliance with ECG monitoring, either ECR or ELR, was rather high and proportion of non-interpretable ECG recordings was low. Minimum monitoring time with ELR was 7 days but it was prolonged in some patients for various clinical reasons. Details are provided in Table 2.



**Fig. 1.** Cumulative arrhythmia-free survival.

Kaplan-Meier curves are displayed for single ablation outcome as assessed by ECG monitoring with episodic "card" recorder (ECR) versus episodic "loop" recorder (ELR). Monitoring with ELR at Months 6 and 12 detected significantly fewer recurrent AF/AT episodes as compared to monitoring with ECR. There were no arrhythmia episodes detected by ELR (and there were generally no AF/AT recurrences) that would not be known from daily ECR monitoring.

# Arrhythmia detection

By ECR, AF/AT was detected in 24 and 23 patients in the periods of Months 4-6 and 7-12, respectively. In 16 of them, arrhythmia was present at both monitoring periods, so that a total of 31 patients with AT/AF recurrence were identified by means of ECR. Eight patients had only a single AF/AT episode lasting between 0.2 - 48 h.

By ELR, AF/AT was detected in 9 and 5 patients at Months 6 and 12, respectively. In 2 of them, arrhythmia was present in both monitoring periods, so that a total of 12 patients with AT/AF recurrence were identified by means of ELR. The arrhythmia was persistent in one patient throughout the whole ELR monitoring at Month 6 (18 days), and in two patients at Month 12 (10 and 12 days).

 Table 2. ECG monitoring.

	ECR	ELR: Month 6	ELR: Month 12
	(n=105)	(n=104)	(n=102)
Days with recorder allocated (n)	363±20	9.3±3.1	9.4±2.6
Days with ECG sent (n)	323±46	9.0±2.9	9.2±2.7
Days with ECG sent (%)	89±12	98±8	98±7
ECG recordings total (n)	721±229	207±300	244±482
ECG recordings / day (n)	2.2±0.6	23.6±36.5	26.1±47.9
ECG recordings interpretable (n)	685±226	205±300	240±481
ECG recordings non-interpretable (n)	37±63	2±4	4±9
ECG recordings non-interpretable (%)	5.0±8.1	2.0±3.7	3.0±5.5
ECG recordings with SR (n)	662±225	195±296	230±480
ECG recordings with AF/AT (n)	23±73	10±65	10±68
ECG recordings with AF/AT (%)	3.1±9.7	2.4±12.4	$2.2 \pm 14.0$
Active monitoring time (hours)	6.0±1.9	216±69	221±64

Data are shown as mean  $\pm$  standard deviation. AF/AT = atrial fibrillation/tachycardia, ECR = episodic card recorder, ELR = episodic loop recorder, SR = sinus rhythm.

**Table 3.** Arrhythmia satus by monitoring period.

		Period: Month 7-12				
		SR asymptomatic	SR symptomatic	AF/AT asymptomatic	AF/AT symptomatic	
Period: Month 4-6	SR asymptomatic	52	4	0	3	
	SR symptomatic	7	11	0	4	
	AF/AT asymptomatic	2	0	1	1	
	AF/AT symptomatic	2	0	4	10	

AF/AT = atrial fibrillation/tachycardia; SR = sinus rhythm. Four patients were excluded because of between-period change of arrhythmia status due to early repeat ablation.

### Arrhythmia recurrence and symptoms

After exclusion of 4 patients with early repeat ablation resulting in elimination of AF/AT, arrhythmia status and symptoms in the remaining patients were compared between periods of Months 4-6 (early) and Months 7-12 (late). The results are summarized in Table 3. Of the 27 eligible patients, arrhythmia recurrence was documented in 20 patients during the early period, while late recurrence was newly detected in 7 patients. Four patients with AF/AT recurrences were completely asymptomatic in the early period; of these 2 patients continued with stable SR, 1 patient continued with asymptomatic arrhythmia, and 1 patient developed AF/AT symptoms. Of note, all new arrhythmia manifestations in the late period were symptomatic.

Importantly, there were 22 of 74 (30%) patients without any AF/AT recurrence who still reported symptoms in the setting of stable sinus rhythm and/or due to atrial premature beats. Such symptoms occurred in 22 and 15 patients within the early and late period, respectively; including 11 patients who were symptomatic within both periods.

### Antiarrhythmic medication during monitoring periods

During Months 4-6, twenty-seven patients were on antiarrhythmic drug: on amiodarone (n=11), propafenone (n=9), or sotalol (n=7). During Months 7-12, twenty patients were taking antiarrhythmic drug: amiodarone (n=11), propafenone (n=4), sotalol (n=4), or dronedarone (n=1). The antiarrhythmic medication was continued throughout the monitoring period to avoid inherent bias in the study outcome.

Of those classified as free from AF/AT recurrences in post-blanking period, propafenone was taken for symptomatic atrial premature beats by 3 patients in both study periods, and by 1 additional patient in the early monitoring period only. Two patients with AF/AT recurrence during the blanking period only remained on amiodarone for both monitoring periods. Finally, 5 patients without any recurrence (n=2) or with recurrence during the blanking period only (n=3) continued to take sotalol (n=3) or propafenone (n=2) during the early monitoring period, which was stopped at Month 6.

# Correspondence between ECR and ELR

After exclusion of 8 patients with early repeat ablation interfering with valid comparison of ECR vs. ELR results,

total 23 patients with post-blanking AF/AT recurrence were available for the analysis. The results are provided in Fig. 1 and Table 4. ELR technology was inferior in detection of arrhythmia recurrence. ELR detected AF/ AT in 5/16 (31%) and 5/19 (26%) patients in whom arrhythmia was found by ECR in early and late periods, respectively. Overall, ELR detected the AF/AT recurrence with sensitivity of 8/23 (35%). There was no single patient with AF/AT recurrence on ELR that would not be known from ECR monitoring. The proportion of asymptomatic recurrences was relatively low (~25%) when assessed separately in the early and late post-ablation period. Only 2 patients with arrhythmia recurrence were completely asymptomatic throughout the duration of the study and their arrhythmias were identified by ECR and not by ELR.

## DISCUSSION

Our study offers two major findings. First, it showed that periodic ≥1-week continuous monitoring with ELR applied at the end of each monitoring period was inferior to 12-month daily monitoring with ECR, and did not detect any AF/AT episode that would not be known from daily discontinuous monitoring with ECR. This occurred despite much shorter duration of active monitoring time with ECR vs ELR (6 vs 216 h), and suggested that the primary benefit of ECR monitoring may result from longterm possibility to record symptom-triggered events. The study further highlighted that asymptomatic patients with arrhythmia recurrences after catheter ablation of AF are extremely rare. Although some arrhythmia recurrences are clearly asymptomatic, others in the same patient are associated with symptoms. Thus, post-ablation ECG monitoring seems to yield the most in patients with unclear intermittent or sporadic symptoms, and is less productive in completely asymptomatic patients.

Asymptomatic AF/AT after catheter ablation for AF appeared to be common in previous studies. In addition, the incidence of asymptomatic arrhythmias may increase after catheter ablation<sup>5,6,10</sup>. Studies employing periodic 7-day ECG Holter reported a rise in the proportion of patients with asymptomatic AF from 5-11% before ablation to 37-53% after the procedure<sup>5,10</sup>. Nevertheless, despite a relatively high 20-50% incidence of asymptomatic recurrences, the proportions of completely asymptomatic

**Table 4.** Arrhythmia recurrences by monitoring technology.

	Period: Months 4-6		Period: Months 7-12		Total study duration	
	ECR	ELR	ECR	ELR	ECR	ELR
AF/AT symptomatic	13	4	15	4	21	8
AF/AT asymptomatic	3	1	4	1	2	0
AF/AT total	16	5	19	5	23	8

AF/AT = atrial fibrillation/tachycardia; ECR = episodic card recorder; ELR = episodic loop recorder. Eight patients were excluded because of early repeat ablation interfering with valid comparison of ECR vs ELR results.

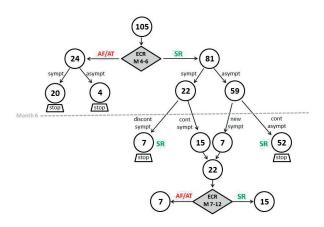
patients was lower and ranged between 9-12% (ref. 6,10-12). In our study with regular daily monitoring for one year, only 2% patients did not recognize any AF/AT recurrence and were exposed to wrong clinical judgement on their ablation outcome. This is less than in the abovementioned studies, however, in accord with other studies (utilizing ECG monitoring including monitoring functions of implanted pacemakers) that have observed only 2-3% of entirely asymptomatic patients with post-ablation AF/AT recurrences<sup>17,18</sup>. Disparities in individual symptom perception may largely depend on how the patients were instructed and able to correctly interpret AF-related symptoms other than palpitations, like dyspnoea, fatigue or incapacity. Importantly, a high proportion (30%) of patients reported symptoms despite the absence of AF/ AT or due to atrial premature beats. This corroborated observations from other studies with 7-day Holter or implantable loop recorders (ILR) that revealed no AF/AT episode in 11-28% of patients with subjective arrhythmia perception<sup>8,19,20</sup>. This finding emphasizes the need for proper instructions given to patients, and reassurance in case of sinus rhythm or minor clinically insignificant recurrent arrhythmias, mainly premature beats.

The detection rate of asymptomatic AF/AT recurrences increases with longer and denser ECG monitoring. Apparently favourable catheter ablation outcomes by mere clinical assessment and 24-hour ECG Holters have been dramatically revised with the use of periodic 7-day ECG Holters<sup>8-10</sup>. According to one study, ECG monitoring lasting less than 4 days missed a great portion of AF/AT recurrences (nearly 60% of episodes were missed with 2-day monitoring), whereas a 4-day recording detected 91% of all recurrences identified with complete 7-day monitoring, and was considered a reasonable compromise<sup>8</sup>.

External discontinuous or continuous ECG monitoring with episodic recorders may further improve the AF/AT detection. Episodic recorder applied every second day for 6 months demonstrated the lowest – 45% – ablation efficacy when compared to 50% efficacy evaluate by 7-day Holter, or 70% efficacy as assessed clinically<sup>5</sup>. Four-month monitoring with episodic recorder versus clinical assessment combined with 24-hour Holter identified post-ablation AF recurrences in 28% versus 14% patients<sup>6</sup>. Periodic loop recorder applied every 3 months for one year detected asymptomatic AF/AT episodes in 21% patients<sup>11</sup>. Trans-telephonic episodic ECG monitoring in 80 patients found 54% of detected AF episodes clinically silent with 9% of entirely asymptomatic patients<sup>12</sup>.

Six-month trans-telephonic ECG monitoring twice a day and upon symptoms showed a significantly lower AF-free survival rate (46%) as compared with monthly 24-hour ECG Holter (79%) (*P*=0.013) or standard ECG (86%, *P*=0.002) (ref.<sup>19</sup>). Finally, monitoring with ILR has an advantage of continuous application for a much longer time<sup>14,20.24</sup>. However; limited memory for real ECG data with storing of overwritten files as frequency histograms has been only partly solved by implementing once-a-day automatic transtelephonic data transmission specifically in asymptomatic patients who may not activate transfer of all necessary ECG recordings. Thus, false AF/AT detection, which was previously shown to exceed 50% (ref.<sup>21,22</sup>), may remain a weak point of ILR monitoring.

The main purpose of the study was to compare the efficacy of two external episodic monitoring systems with trans-telephonic data transmission that differed in (dis) continuity of data acquisition, comfort for patients, and potential costs. Because of specific limits of reliable AF/ AT detection, ideal monitoring devices and duration of application remain challenging, and current guidelines define the ECG monitoring in the assessment of outcome of catheter or surgical ablation rather vaguely<sup>25-27</sup>. Periodic ECG monitoring at 3-month intervals during the first year, and every 6 months during the second post-ablation year was recommended by the 2012 expert consensus statement<sup>26</sup>. Recent expert consensus modified these recommendations to even less extensive clinical follow-up and ECG monitoring<sup>27</sup>. In this study, we were unable to confirm non-inferiority of potentially cheaper continuous automatic patient-independent arrhythmia detection with ELR limited to a time comfortable for patients when compared to daily discontinuous application of ECR for the whole study period. The study confirmed an increased detection rate with longer monitoring duration. In a current pilot project of the Czech Ministry of Health, the minimum 1-month cost of monitoring amounts to 45 for ECR, and 168 for ELR. Considering these prices, the costs of ECR monitoring applied for 273 days post-blanking, and of ELR monitoring applied for 9 days, amounted to 404 and 51, respectively. One can speculate that ELR monitoring prolonged to 4 weeks applied in 3-month intervals could reasonably bring the ELR detection rate closer to that of 9-month post-blanking daily ECR monitoring; however, it would also increase the cost of ELR to 504 as compared to 405 for 9-month ECR. Based on our findings, practical approach to ECG monitoring, pursuing first arrhythmia detection as the primary endpoint, could be, with some degree of uncertainty, rationalized



**Fig. 2.** Detection of first arrhythmia recurrence with episodic card recorder.

The flowchart proposes cost-effective ECG monitoring to detect first arrhythmia recurrence. Episodic card recorder detected arrhythmia recurrence in 24 patients in Months 4-6. Of the remaining 81 patients, 52 patients with sinus rhythm and without symptoms and 7 patients with symptoms that later vanished were event-free up to the end of the study and their ECG monitoring might be dispensable. Further ECG monitoring was desirable in the remaining 22 patients with continuing (n=15) or new (n=7) symptoms. Such rationalized approach would save  $105 \times 3 + 22 \times 6 = 447$  patient-months versus  $105 \times 9 = 945$  patient-months of ECG monitoring. Abbreviations: AF = atrial fibrillation; asympt = asymptomatic; AT = atrial tachycardia; cont = continuing; discont = discontinued; ECR = episodic card ECG recorder; M = month; SR = sinus rhythm; sympt = symptomatic.

as proposed in Figure 2. The flowchart reflects clinical experience that ECG monitoring after paroxysmal AF ablation is yielding mainly in symptomatic patients.

# Limitations

The study was limited by a relatively low number of arrhythmia recurrences after ablation and, therefore, some suggestions mentioned above are not firmly supported. Some patients underwent a repeat ablation during the study follow-up. Their data had to be selectively excluded from several analyses which further reduced the power of the study to detect the difference between the monitoring technologies. Symptoms were not evaluated on an episode-by-episode basis so that the true number of asymptomatic arrhythmia recurrences might be underestimated. The results of the study that investigated a sample of patients with paroxysmal AF may not be valid for patients with different baseline characteristics, e.g. with persistent AF. We also cannot rule out that even daily monitoring with ECR might have missed a clinically significant arrhythmia. This is; however, less likely because the patients' adherence to ECR application was high and ECR provided a high proportion of well-interpretable real ECG recordings stored for visual inspection.

Further, we did not perform a specific analysis of quality of life relative to the use of either episodic ECG recorder. Differences in individual perceptions of ECG monitoring with ECR versus ELR are likely; however, they might be difficult to separate from each other when both recorders were applied simultaneously.

### **CONCLUSION**

This study addressed the clinical utility and costs of different modes of external ECG monitoring to assess the outcome of catheter ablation for paroxysmal AF. Discontinuous daily monitoring with ECR providing short but repetitive ECG recordings for 12 months was better in detecting of recurrent AF/AT episodes. Mandatory 6-month daily monitoring with ECR supplemented with subsequent ECG monitoring only in patients with clinically unclear ablation outcome might be sufficient to facilitate safe anticoagulation management. Periodic monitoring with ELR every three months would need to be prolonged to optimize the detection capacity and offer a reasonable alternative. The proposal of rationalized cost-effective ECG monitoring after catheter ablation will; however, need verification in future studies.

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**Author contribution:** JC, BV, DW, MF: study design, data analysis and interpretation and manuscript preparing; OT, LR, JJ, JS: data collection, some of the sub-analyses and final approval.

**Conflict of interest statement:** None declared.

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