Noninvasive long-term ECG monitoring vs. loop recorder implantation for the atrial fibrillation management

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Abstract

Objective: The objective of the study was to estimate the efficacy of a noninvasive ambulatory ECG monitoring (NIAM) in comparison with implantable loop recorder (ILR) in patients with atrial fibrillation (AF).

Methods: Thirty-two patients 58 [47; 73] years of age with AF were included in the study. Patients were randomized into two groups: in group I ($n = 15$), "Reveal XT" ILR was used for invasive ECG monitoring up to 3 months; in group II ($n = 17$), "Spyder" device was used for NIAM up to 14 days.

Results: In both groups, at least one AF episode was detected during 14 days of monitoring. The overall count of AF episodes was 25 in NIAM group and 28 in ILR group. The mean time between AF start and its registration by a physician was 8 hr in NIAM group and 20 hr in ILR group ($p = .005$). The diagnostic value parameters of NIAM were as follows: sensitivity—80.1%, specificity—73.1%; positive predictive value—74.1%; and negative predictive value—79.2%. The same parameters in ILR group were comparable with NIAM: sensitivity—78.6%; specificity—69%; positive predictive value—71%; and negative predictive value—77%. At the same time, continued monitoring with ILR for longer than two weeks did not lead to a significant change in the sensitivity and specificity of the method.

Conclusion: In patients with paroxysmal AF, the diagnostic value of both NIAM and ILR is comparable. An increase in the duration of ECG monitoring for longer than two weeks does not provide additional diagnostic information.

KEYWORDS

atrial fibrillation, ECG monitoring

1 | INTRODUCTION

Atrial fibrillation (AF) is not only the most common arrhythmia, but also having the greatest clinical significance due to its large influence on mortality and disability, mainly due to an increased risk of ischemic stroke (January et al., 2019; Powers et al., 2018; Stroke Risk in Atrial Fibrillation Working Group, 2007).

Treatment of AF regardless of its etiology is a challenge for the health system. The annual cost of treatment for patients with

AF in the EU countries is close to 13.5 billion euros, in the United States—6.65 billion dollars, plus 2.93 billion dollars only for hospitalization. (Coyne et al., 2006) Due to the data of implantable devices, asymptomatic AF episodes are recorded more often than the symptomatic ones (Flaker et al., 2005; Healey et al., 2012). Therefore, outpatient ECG monitoring is an important and integral part of the management of patients with paroxysmal AF. In many cases, the adoption of clinical decisions, such as the administration of antiarrhythmic drugs or correction of their dose, the need

for cardioversion, and the anticoagulation therapy are based on the possibility of recording both the presence of an arrhythmia and its burden (Capucci et al., 2005; Glotzer et al., 2009). In addition, prolonged monitoring of the ECG may reveal other concomitant rhythm and conduction disorders that also require treatment.

Paroxysmal AF can remain undiagnosed when using traditional approaches to ECG monitoring, each of which has its advantages and disadvantages (Table 1).

At first glance, the problem was in many respects solved with the introduction into clinical practice of implantable loop recorders (ILR). They allow monitoring for a long follow-up period which is comparable to the implantable antiarrhythmic devices. However, this method is invasive, that is especially important in children, and ILRs have a limited amount of memory, which allows recording only a few short-term episodes. As a result, their actual diagnostic significance reaches only 43%–50% during 2 years of monitoring (Brignole et al., (2006); Edvardsson et al., 2011; Furukawa, Maggi, Bertolone, Fontana, & Brignole, 2012). Currently developed systems for non-invasive long-term ECG monitoring have the advantages of ILR and lack of the disadvantages of Holter monitors (Burke et al., 2015; Hickey et al., 2010; Tan, Engel, Myers, Sandri, & Froelicher, 2008).

The objective of the study was to estimate the efficacy of a long-term noninvasive ambulatory ECG monitoring (NIAM) in comparison with implantable loop recorder (ILR) in patients with atrial fibrillation (AF).

2 | METHODS

The study design was approved by the Local Ethical Committee. All patients provided written informed consent.

The study included 32 patients 58 [47; 73] years of age with the diagnosis of a paroxysmal AF of different etiologies and the absence of the other types of rhythm or conduction disorders established by a cardiologist. The patients had a high EHRA symptoms rate, and all of them were selected for scheduled catheter ablation due to the

ineffectiveness of antiarrhythmic therapy. Patients' characteristics are presented in Table 2.

All patients were randomized into two groups. In group I ($n = 15$), invasive long-term ECG monitoring using "Reveal XT" (Medtronic) ILR was performed up to three months. In all cases, CareLink remote monitoring system was used. All patients underwent ILR implantation under local infiltration anesthesia with 1% lidocaine solution. The implantation site was selected using measuring instrument in accordance with the manufacturer's recommended parameters: The amplitude of the R wave is not less than 0.2 mV when viewed on the programmer screen or 0.3 mV when viewing the ECG paper record, the amplitude of the R wave at least twice the amplitude of the T and P waves. In thirteen patients, ILR was implanted under the skin of the anterior surface of the left thoracic region, in two female patients—under the mammary gland through the incision along the anterior axillary line. After implantation, the skin was sealed with an intradermal suture; then, the quality of the ECG record was again tested in the vertical and horizontal body position, as well as with the movements of the ipsilateral upper limb. Patients were discharged on the next day after implantation.

Each patient was given a patient module, a portable battery-powered device for telemetric communication with ILR. It allows patients to initiate the recording of an ECG fragment into the ILR memory when symptoms of AF appear.

The AF was detected using an internal ILR algorithm based on the analysis of the dispersion of the R–R intervals and the detection of the P wave. The analysis takes two minutes, after which, if the ECG meets the algorithm criteria, the fragment is recorded in the device memory. The ILR can record up to 14 AF episodes, after which, in the event of a new episode of the AF, it is overwritten starting from the very first of the previously recorded episodes. The longest of the episodes, exceeding 10 min, always remains stored on the device. Every night, the device transmits a fragment from the last 10 s of the longest AF paroxysm through the 3G or LTE network to the cloud server using the CareLink wireless module. In addition, the patient can independently transmit wirelessly to the server full information about all the episodes over the past day.

TABLE 1 Methods of ACG monitoring

Method	Advantages	Disadvantages
Noninvasive		
Office ECG	Comprehensive information due to many leads. The possibility of asymptomatic arrhythmia recording	Short-term monitoring
Holter monitoring	Technically simple procedure. The possibility of asymptomatic arrhythmia recording	Short-term monitoring. Кратковременность мониторинга. More than one day recording requires replacement of electrodes and batteries
Event recorder	Long-term monitoring. Assessment of relation between symptoms and arrhythmia	Not suitable for asymptomatic arrhythmias. Requires starting of the record by the patient himself
Invasive		
Implantable loop recorder	Long-term monitoring. Remote monitoring. The possibility of asymptomatic arrhythmia recording	High costs. False positive and false-negative results. Does not provide therapy for arrhythmias
Implantable antiarrhythmic devices (ICD, CRT, pacemakers)	Long-term monitoring. Remote monitoring in certain types of devices. The possibility of asymptomatic arrhythmia recording. Additional therapeutic options	Only with indications for therapy. High costs. Invasiveness and related complications

TABLE 2 Clinical characteristics of the patients

Parameter	ILR group (n = 15)	NIAM group (n = 17)	p
Clinical data			
Age (years)	57 [47; 70]	59 [49; 73]	.564
Sex (male/female)	9 (60%)/6 (40%)	11 (64.7%) / 6 (35.3%)	.927
Arterial hypertension	10 (66.7%)	12 (70.6%)	.886
Diabetes mellitus	3 (20%)	4 (23.5%)	.851
CHF	13 (86.7%)	15 (88.2%)	.688
CAD	2 (13.3%)	2 (11.8%)	.688
Therapy			
β -blockers	11 (73.3%)	13 (76.5%)	.838
Calcium antagonists	3 (20%)	4 (23.5%)	.851
Digoxin	1 (6.7%)	2 (11.8%)	.909
Amiodarone	8 (53.3%)	9 (52.9%)	.739
Propafenone	5 (33.3%)	5 (29.4%)	.886
Sotalol	2 (13.3%)	3 (17.6%)	.879
Anticoagulants	15 (100%)	17 (100%)	–
Antiplatelet	2 (13.3%)	2 (11.8%)	.688
Statins	2 (13.3%)	2 (11.8%)	.688
Diuretics	13 (86.7%)	15 (88.2%)	.688
ACEI/ARB	15 (100%)	17 (100%)	–
Echocardiographic data			
LV EDD (mm)	58 [53; 61]	57 [51; 61]	.422
LV ESD (mm)	37 [32; 40]	36 [31; 38]	.207
LV EF (%)	47 [42; 51]	49 [44; 53]	.176
LA diameter (mm)	43 [40; 47]	46 [42; 48]	.087
LA volume (ml)	101 [93; 111]	106 [96; 113]	.089
RVSP (mm Hg)	28 [24; 31]	28 [25; 31]	.336
Arrhythmia parameters			
Symptomatic AF	15 (100%)	17 (100%)	–
Paroxysmal AF	15 (100%)	17 (100%)	–
Arrhythmia duration (months)	17 [8; 23]	18 [10; 23]	.451
EHRA symptom score	3.5 [3.2; 3.8]	3.5 [3.2; 3.8]	.867
Sinus rhythm at the moment of monitoring start	12 (80%)	13 (76.5%)	.851

Abbreviations: ACEI, angiotensin-converting enzyme inhibitors; ARB, angiotensin receptor blockers; CAD, coronary artery disease; CHF, chronic heart failure; EDD, end-diastolic diameter; EF, ejection fraction; ESD, end-systolic diameter; LA, left atrium; LV, left ventricle; RVSP, right ventricular systolic pressure.

In addition to detecting AF and calculating the AF burden, all ILRs were programmed for the following parameters:

- bradycardia: heart rate <30 beats/min in more than four consecutive intervals;

- tachycardia: heart rate >160 beats/min in more than 16 consecutive intervals;
- pause: ≥ 3 s;
- fast VT: R-R ≤ 260 ms in more than 30 of 40 consecutive intervals;
- VT: R-R ≤ 340 ms in more than 16 consecutive intervals;
- episodes recorded manually: 3 $\times$ 7.5 min.

Scheduled visits to verify the devices were planned for a period of 14 days and 3 months after implantation, unscheduled visits—after documentation at least two episodes recorded manually, or when indicating the presence of automatic records on the patient's assistant.

In group II (n = 17), water-proof “Spyder” (WEB Biotechnology, Singapore) was used. ECG was noninvasively recorded for up to 14 days or until the patient refused to continue the study. This NIAM device analyzes three leads of the ECG, from which it automatically selects one of the most high-amplitude and the least noisy for recording. In the process of monitoring, it continuously transmits data via Bluetooth protocol to any smartphone running Android OS, which, in turn, through the 3G or LTE network continuously transmits data in encrypted form to a cloud server from which they can be considered and analyzed by a physician in real mode time. The patient can also at any time independently see his ECG on the smartphone screen using a special application and by clicking on a special button, manually transmit to the server information about the presence of symptoms of AF at that time. The detection criterion used for NIAM was the AF episode of any duration in contrast with ILR which can detect AF episodes only longer than 2 min. At the end of the analysis, the patient is given an automated conclusion. Thus, in contrast to ILR, when using NIAM, the physician has the opportunity to analyze the patient's ECG at any time, not only when the patient visits the clinic or after transmitting ILR daily record to the CareLink server.

Statistical analysis was performed using Statistica 6 software (Statsoft). Absolute values, percentage, medians, and interquartile ranges were calculated. The statistical significance was checked using the chi-squared and Mann-Whitney criteria. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the NIAM and ILR were determined using 2 $\times$ 2 tables.

3 | RESULTS

All patients from both groups achieved the target duration of monitoring. In both groups, at least one AF episode was recorded in all patients during 14 days of monitoring. During the first 14 days, 25 episodes were recorded in the NIAM group and 25 episodes in the ILR group. A Kaplan–Meier analysis of time to first AF detection for each device over the first 14 days is presented on Figure 1. Within 3 months, the number of these episodes in the ILR group was 162. The average time between the onset of paroxysm of arrhythmia and its registration by a physician was in the 8 [3; 16] hours in the NIAM group and 20 [17; 22] hours in the ILR group (p = .005).

FIGURE 1 A Kaplan-Meier analysis of time to first AF detection for each device over the first 14 days with log-rank statistics

TABLE 3 Symptomatic AF by NIAM

	AF	No AF	Overall
Symptoms present	20	7	27
No symptoms	5	19	24
Overall	25	26	51

Tables 3 and 4 show data on the relationship between the presence of symptoms and AF episodes confirmed by physician. In Table 5, the relationship between symptoms and different types of rhythm is presented. All types of other detected rhythms, which were subjectively interpreted by patients as AF, are also presented in Table 5.

Thus, the diagnostic values of NIAM in AF paroxysms detection were as follows:

- sensitivity—80.1% (CI—64.5%–100%);
- specificity—73.1% (CI—58.1–83.7%);
- positive predictive value—74.1% (CI—59.7%–84.3%);
- negative predictive value—79.2% (CI—63%–90.6%).
- The same indices of ILR were comparable with NIAM:
- sensitivity—78.6% (CI—63.9%–89.5%);
- specificity—69% (CI—54.8%–79.5%);
- positive predictive value—71% (CI—57.7%–80.9%);
- negative predictive value—77% (CI—61.1%–88.7%).

Moreover, the continuation of monitoring with ILR for longer than two weeks did not lead to a significant change in the sensitivity and specificity of the method (Table 6):

- sensitivity—79.7% (CI—74.3%–84.4%);

TABLE 4 Symptomatic AF by ILR during the first 14 days

	AF	No AF	Overall
Symptoms present	22	9	31
No symptoms	6	20	26
Overall	28	29	57

TABLE 5 All types of detected rhythms, which were subjectively interpreted by patients as AF

Rhythm	ILR group (n = 15)	NIAM group (n = 17)	p
Sinus rhythm	5	5	.883
AF	22	20	.895
Atrial flutter	1	1	.525
Ectopic atrial tachycardia	1	1	.525
Ventricular ectopic beats	2	0	.525

- specificity—65.7% (CI—60.4%–70.4%);
- positive predictive value—69.8% (CI—65.1%–73.9%);
- negative predictive value—76.5% (CI—70.3%–81.9%).

The same can be said about the assessment of the AF burden: In the NIAM group, it was 6.8% [3.9; 12.3%] for 14 days period, in the ILR group—7.1 [4; 13.6%] ($p = .187$).

4 | DISCUSSION

The study compared the diagnostic value of two modern methods of long-term ECG monitoring—ILR and NIAM—in patients with symptomatic paroxysmal AF.

TABLE 6 Symptomatic AF by ILR during 3 months

	AF	No AF	Overall
Symptoms present	129	56	185
No symptoms	33	107	140
Overall	162	163	325

Even though patients had the opportunity to stop monitoring at any time, none of them wished to do so, which indicates that both methods are well tolerated. At the same time, studies on the efficacy of NIAM using other devices have reported that a portion of patients wished to retire early due to discomfort caused to the patients by the device (Rosenberg, Samuel, Thosani, & Zimetbaum, 2013; Sanna et al., 2014). It is possible that such discomfort can be caused not by the type of the device itself but by the adhesive electrodes used together with it.

All patients examined during at least two weeks of monitoring had at least one episode of AF, most of which were symptomatic. Therefore, in general, it was demonstrated that, despite the longer monitoring period and the use of remote monitoring in both groups, the ILR technology in patients with paroxysmal AF has no advantages over the NIAM in assessing the arrhythmia symptom and its burden. Apparently, this is due to an opportunity for the doctor to evaluate the ECG at any time during noninvasive monitoring, as well as a disadvantage of ILR such as the lack of continuous ECG recording during the entire follow-up period. It is possible that with the use of the NIAM technology in patients with rare and/or asymptomatic paroxysms of AF, the advantage of ILR will be revealed.

It has also been established that NIAM allows faster detection of AF episodes, although the clinical significance of early detection of paroxysm in the studied group of patients is apparently low, since all those who were examined previously had a diagnosis of AF, and they all were treated by anticoagulants. However, early detection of paroxysm for the first time in asymptomatic patients could affect the earlier prophylactic use of anticoagulants.

The study confirmed the previously known fact that often episodes interpreted by patients as AF paroxysms are in fact other arrhythmias or, more rarely, sinus rhythm. Despite the diagnosed symptomatic paroxysms, many of patients at the same time had episodes of asymptomatic AF that is also confirmed by the data of other researchers (Disertori et al., 2011; Pontoppidan, Nielsen, Poulsen, & Hansen, 2009). All these facts confirm the necessity of using long-term ECG monitoring for assessing the condition of AF patients, even after ablation.

It turned out that the increase in the duration of ECG monitoring for more than two weeks in the examined patient population does not provide additional diagnostic information. Given this fact, NIAM seems to be more preferable, because this method, unlike ILR, is noninvasive and can be applied on an outpatient basis.

The limitations of this study include the fact that both methods were compared in different patient groups, albeit randomly. Obviously, in the future, the possibility of simultaneous ECG recording of both types of devices in the same patients should be envisaged, as was done by other investigators when Holter monitoring

was compared with ILR or NIAM (Hindricks et al., 2010; Rosenberg et al., 2013).

5 | CONCLUSION

1. In patients with paroxysmal AF according to ILR or NIAM data, symptomatic and asymptomatic AF episodes are recorded, as well as symptomatic and asymptomatic episodes of other arrhythmias mistakenly interpreted by patients as AF paroxysms. 2. In patients with paroxysmal AF, the ILR and NIAM methods are comparable in the accuracy of detection of asymptomatic episodes of both AF and other arrhythmias. 3. In patients with symptomatic AF, an increase in the duration of ECG monitoring for longer than 2 weeks does not provide additional diagnostic information.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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