MEDICAL SCIENCE MONITOR

CLINICAL RESEARCH

e-ISSN 1643-3750
© Med Sci Monit, 2016; 22: 2846-2851
DOI: 10.12659/MSM.897333

Received: 2015.12.29
Accepted: 2016.01.08
Published: 2016.08.12

Value of Implantable Loop Recorders in Monitoring Efficacy of Radiofrequency Catheter Ablation in Atrial Fibrillation

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Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Source of support: Departmental sources

Background: The aim of this study was to evaluate the value of the implantable loop recorder (ILR) in diagnosing atrial fibrillation (AF) and assessing the postoperative efficacy of radiofrequency catheter ablation (RFCA).

Material/Methods: A total of 32 patients who successfully underwent RFCA were selected. These patients discontinued antiarrhythmic medication with no AF recurrence for more than 3 months after RFCA, and underwent ILR placement by a conventional method. The clinical manifestations and information on arrhythmias recorded by the ILR were followed up to assess the efficacy of AF RFCA.

Results: The mean follow-up period was 24.7±12.5 months. Of 32 patients with ILR information, 27 had successful RFCA and 5 had recurrent AF. The follow-up results obtained by traditional methods showed 29 patients with successful RFCA and 3 with recurrent AF ($P<0.05$). Among the 18 patients with clinical symptoms, 13 had recorded cardiac arrhythmic events (72.2%) and 5 showed sinus rhythm (27.8%). The ILRs recorded 18 patients with arrhythmic events (56.3%), including 12 cases of atrial arrhythmias, among whom 5 recurred at 9, 12, 16, 17, and 32 months after AF RFCA; there were also 2 patients with ventricular tachycardia (VT) and 4 with bradycardia.

Conclusions: The value of ILR in assessing the efficacy of AF RFCA was superior to that of traditional methods. ILR can promptly detect asymptomatic AF, and can monitor electrocardiogram features after RFCA, thus providing objective evidence of efficacy.

MeSH Keywords: Atrial Fibrillation • Catheter Ablation • Implantable Neurostimulators • Self Efficacy

Full-text PDF: http://www.medscimonit.com/abstract/index/idArt/897333

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Background

Atrial fibrillation (AF) is a common arrhythmia with a high rate of disability and mortality, and with no curative medication. In recent years, radiofrequency catheter ablation (RFCA) has become the first-line treatment for patients with AF who have poor medication control, intolerance, or unwillingness to take long-term medication, but the success rate has been unsatisfactory. Currently used traditional assessment methods such as the electrocardiogram (ECG) and dynamic ECG have difficulty in capturing and storing information when symptoms occur. However, a considerable proportion of AF cases are asymptomatic [1,2], and the evaluation of RFCA success and recurrence of AF is unsatisfactory, especially with regard to long-term effects. Because the patterns of onset, duration, and symptoms of post-RFCA arrhythmias are variable, defining the criteria for success and failure of AF RFCA is difficult. Therefore, the follow-up efficacy and management after RFCA have become prominent research topics.

The implantable loop recorder (ILR) has filled this gap in knowledge [3–8], and can provide important data, such as the AF load, ventricular rate during AF, average day-night heart rate, and activity trends in patients with AF with or without symptoms after RFCA, thus providing an objective basis for judging the success and recurrence rate, and optimizing postoperative medical decisions [9,10]. This study selected 32 subjects who successfully underwent AF RFCA and were without recurrence for more than 3 months. An ILR was placed in these patients, with the aim of monitoring the efficacy of AF RFCA and the changing pattern of arrhythmias.

Material and Methods

Basic characteristics of the patients

AF RFCA was successfully performed on a total of 32 patients in the Department of Cardiology, the First Affiliated Hospital of Kunming Medical University, from May 2009 to January 2014. The patients had no postoperative clinical symptoms, and antiarrhythmic drugs were withdrawn, with no AF recurrence for over 3 months as assessed by ECG and dynamic ECG. All 32 patients were selected for the study, including 22 men and 10 women aged 23 to 68 (average age: 55.7±12.3). The patients had symptoms such as palpitations and chest tightness preoperatively; 20 had paroxysmal AF, and 12 had persistent AF, among whom 5 had undergone secondary RFCA. Diagnostic evaluation revealed 3 patients with coronary heart disease, 8 with hypertensive heart disease, 1 with hypertensive plus coronary heart disease, 2 with bradycardia-tachycardia sick sinus syndrome plus permanent cardiac pacemaker implantation, and 18 with non-organic heart disease. This study was conducted in accordance with the Declaration of Helsinki and with approval from the Ethics Committee of Kunming Medical University. Written informed consent was obtained from all participants.

Implantation method

The patients and their families received preoperative information and gave signed informed consent. First, a relay wire device was used to select the optimal implantation site; second, the ILR was placed at the left parasternal 2nd–4th intercostal region under sterile conditions using conventional technique; and third, the patients and their families were taught proper use of the trigger and to record the onset time and features when symptoms occurred.

Setting of ILR working parameters

According to the postoperative disease conditions, the criteria for arrhythmia assessment by ILR (Figure 1), as well as the criteria for acuity and stability, were set by the programmer [7].

Follow-up method

First, a file for ILR follow-up on postoperative day 7 and months 1, 3, and 6 was established, after which follow-up was performed once every 6 months or 1 year. A patient with discomfort was followed up immediately. The follow-up recorded post-RFCA clinical symptoms and episodes; according to the arrhythmia types recorded by the ILR, and appropriate drugs were administered or other intervention methods were performed. ILR was used to follow up efficacy after the intervention, and the ILR operating parameters were adjusted if necessary. Battery power was monitored, and the ILR was removed under aseptic conditions when the battery was depleted.

Statistical methods

SPSS 16.0 software was used for statistical analysis. Measurement data are expressed as mean ± standard deviation ($\bar{\chi}\pm s$), and the intergroup comparison used the paired *t* test. The count data are expressed as cases or a percentage, and the intergroup comparison used the χ^2 test, with $P<0.05$ considered as statistically significant.

Results

Follow-up results

All 32 patients had successful placement of an ILR and were followed up, and no postoperative complications such as infection or bleeding occurred; 14 patients received a Reveal RDX9528 ILR, and 18 received a Reveal XTTM9529 ILR. The

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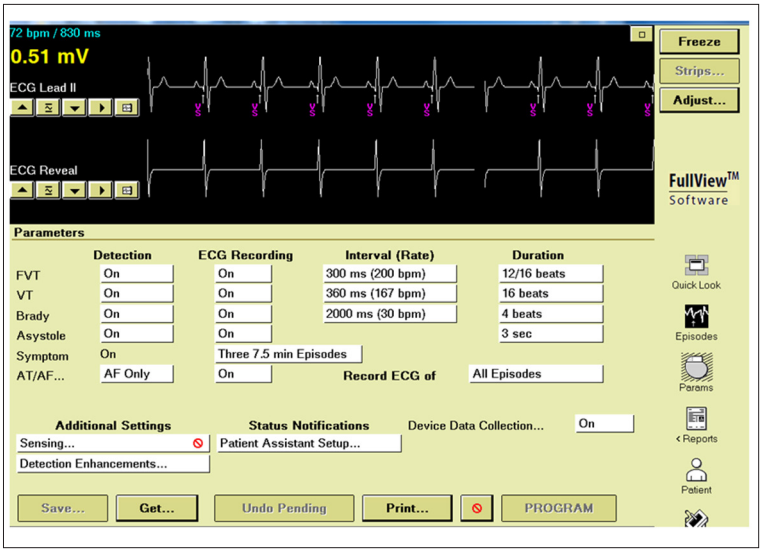

Figure 1. Criteria of arrhythmia assessment by ILR.

follow-up duration was 12 to 47 months (average: 24.7±12.5 months). Follow-up results using traditional methods (clinical symptoms, ECG, and dynamic ECG) showed that 29 cases had successful RFCA (90.6%) and 3 had AF recurrence (9.4%). Information recorded by ILRs showed that 27 cases were successful (84.4%), and 5 had AF recurrence (15.6%) ($P<0.05$). Due to battery depletion, the ILR was removed in 1 patient at postoperative month 42, in 2 patients at month 45, and in 1 patient at month 47.

ILR-stored events

During the follow-up period, the information extracted from ILRs showed that the 32 patients manually and automatically triggered the ILR a total of 782 times: manual triggering occurred 63 times (8.1%), with 45 events stored (71.4%), and 18 non-events (28.6%) recorded; automatic triggering occurred 719 times (91.9%), with 540 events stored (75.1%). Among the 18 patients with clinical symptoms, 13 had cardiac arrhythmic events (72.2%) and 5 had sinus rhythm recorded (27.8%). Among the 14 patients without clinical symptoms, the ILRs recorded 5 patients with arrhythmic ECG events (35.7%). The ILRs recorded 18 patients with arrhythmic events (56.3%), including 12 patients with atrial arrhythmia, among whom 1 each recurred at month 9, 12, 16, 17, and 32 after RFCA; 7 cases were atrial tachycardia (AT) and atrial flutter (AFL), 2 cases were ventricular tachycardia (VT), and 4 cases were bradycardia.

Classification of ILR-stored ECG and difference scatterplots

Among the 585 stored events, there were 45 cases of bradycardia (7.7%), 172 cases of atrial arrhythmia (29.4%), 74 cases of AF (12.6%), 27 cases of VT (4.6%), 210 cases of sinus rhythm (35.9%), and 131 cases of an interference wave (22.4%) (Figure 2).

Follow-up and intervention situations

Among the 18 patients with a recorded arrhythmic ECG event by ILR, 7 patients with atrial arrhythmia (including 1 case of AF) were unwilling to undergo repeat RFCA because the clinical symptoms, event frequency, and duration were significantly reduced compared to before RFCA; thus, they received interventions such as β-blocker therapy and warfarin, and continued ILR monitoring for another 12–19 months, during which only atrial premature beats and short-term paroxysmal AT occurred. The patient with short-term paroxysmal VT showed no recurrence for 10 months after positive psychological intervention and oral administration of β-blockers. One patient with paroxysmal VT had symptoms of syncope and paroxysmal AF before RFCA for AF, but multiple ECGs did not record cardiac electrical activities related to syncope, and he had no symptomatic episodes after RFCA. However, 11 months after the ILR was implanted, this patient fainted again, and the ILR recorded rapid VT at the onset of syncope. Accordingly, this patient received a single-chamber implantable cardioverter-defibrillator (ICD), VT RFCA, and oral β-blocker therapy; the 16-month follow-up revealed sinus rhythm. Among the 4 patients with bradycardia, 3 received a dual-chamber pacemaker and continued ILR monitoring for 20 months with no recurrence of symptoms. Repeat RFCA was performed in 2 patients with AF having clinical symptoms, the 1 AFL case, and the 2 patients with AF having no clinical symptoms, and the postoperative 11- to 39-month ILR follow-ups revealed no recurrence. The 4 patients with AF having recurrence showed monitored AF load by ILR as 25.7±11.4%, 23.9±7.5%, 19.1±5.6%, and 18.7±3.2%.

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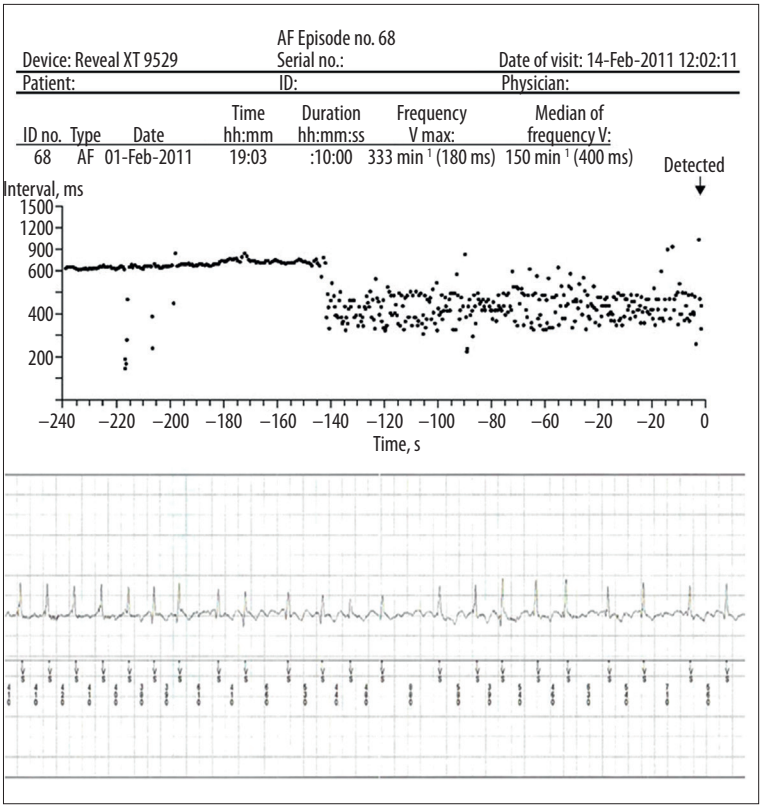

Figure 2. ILR-stored difference scatterplots and ECG of AF.

Discussion

Feasibility of ILR in evaluating the efficacy of AF RFCA

In 1992, the first-generation ILR was invented and used clinically for the diagnosis of unexplained syncope. With the constant upgrading of hardware and software, ILR can diagnose bradycardia and tachycardia, automatically determine VT/ventricular fibrillation (VF) and AT/AF, and calculate heart rate variation and AF load. The traditional determination method of post-AF RFCA efficacy is based on subjective symptoms, ECG, or dynamic ECG, which do not fully reflect the actual heart rate and rhythm changes after RFCA. Lellouche et al. [11] found that the recurrence rate within 1 month after RFCA was 52%. Gersak et al. [12] used ILR to evaluate the results of RFCA, and found that the success rate at the third month was reduced from 86% (routine follow-up measures) to 72%, indicating that the success rate was overestimated by traditional follow-up methods in patients with AF RFCA. In the present study, the 32 patients were all successfully followed up by traditional methods for over 3 months after AF RFCA; thereafter, the conventional methods were continued and ILR was used for monitoring follow-up. When using ILR to evaluate the results of RFCA, the success rate at more than 12 months was found to decrease from 90.6% (traditional follow-up measures) to 87.5%, while the recurrence rate of AF increased from 9.4% (traditional follow-up measures) to 15.6%, indicating that use of ILR to evaluate the efficacy of AF RFCA is feasible, and the results of monitoring efficacy were better than with traditional examination techniques.

The Reveal XTTM9529 ILR has added the function of automatic detection of AF with a difference scatterplot, which is a highly effective and very precise method of diagnosing short-term paroxysmal atrial arrhythmia and asymptomatic AF, which are difficult to identify using traditional follow-up methods after AF RFCA [13]. Whether the AF load after AF RFCA disappears is crucial in assessing the success of surgery, and the AF load should be evaluated whether or not there are clinical symptoms. However, in patients without obvious postoperative symptoms, general dynamic ECG monitoring can affect judgments about the success rate of AF RFCA [14]. The recent XPECT (Reveal® XT Performance Trial) study [15] objectively evaluated ILR functions in detecting and evaluating AF. The study included a total of 206 patients with paroxysmal AF, used conventional Holter monitoring for 2 days, and compared the results with those of ILR. The results showed that AF-detection sensitivity of the latter was 96.1%, with a specificity of 97.4%, a total effective rate of AF load of 98.5%, and a correlation with general Holter examination as high as r=0.976. The newly added AF detection and assessment function of ILR has broadened the clinical application range of this technology; this system helps clinicians to intuitively understand such important information as the patient's daily AF load, ventricular rate at AT/

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AF, average heart rate, daily activities, and heart rate variation. This makes up for the inability of conventional methods to identify the recurrence of AF, thus providing an objective basis for judging the long-term success rate of AF RFCA and optimizing postoperative medical decisions.

Guiding the rational use of anticoagulant drugs

Among post-RFCA patients, asymptomatic AF is very common. Of 5 recurrence cases in this study, 2 were asymptomatic. Asymptomatic AF affects not only the assessment of the RFCA success rate, but also the determination of postoperative anticoagulation measures. Because asymptomatic AF also has a risk of thromboembolism, postoperative termination of anticoagulation might increase the risk in patients with asymptomatic AF. Thus, the timely detection of asymptomatic AF would have important clinical significance in guiding the rational use of anticoagulant drugs. There is no recommendation in the post-RFCA anticoagulation problem-related guidelines for patients with AF. In 2012, the European Society of Cardiology (ESC) published updated AF guidelines [16], and 2 scoring systems were developed for the risks of thromboembolism in patients with nonvalvular AF. High-risk patients (with a score ≥2 points) were still recommended to receive warfarin. An appropriate anticoagulation strategy would have great significance in improving the post-RFCA quality of life and survival rate of patients with AF, as well as for the future development of AF treatment.

Providing a basis for the rational use of antiarrhythmic drugs

In 2010, the AF RFCA experts of the Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhythmia Society (HRS/EHRA/ECAS) pointed out that whether or not patients had recurrences, 1–3 months of postoperative antiarrhythmic drugs was usual [1,17]. Turco et al. [18] conducted a prospective randomized trial to study the effects of antiarrhythmic drugs on post-AF RFCA recurrence. The 107 patients were randomly divided into a pure RFCA group and an RFCA plus amiodarone group. Standard ECG, dynamic ECG, and mobile cardiac outpatient telemetry (MCOT) were used to assess AF recurrence. The 12-month follow-up found no statistically significant difference in the recurrence rate between the 2 groups, but the use of amiodarone increased the incidence of asymptomatic AF. The researchers believed that the continuous administration of antiarrhythmic drug therapy after AF RFCA would not reduce AF recurrence, but would increase the incidence of asymptomatic AF. Therefore, with increased sensitivity of follow-up measures, a more accurate objective basis could be provided to confirm the clinical value of medications after AF RFCA. In the present study, the conditions of the 7 patients with post-RFCA atrial arrhythmia were improved after being given appropriate β-blocker therapy.

Providing a basis for the reimplementation of RFCA

The recurrence rate of atrial arrhythmias after AF RFCA is as high as 20–50%, and the present study had 12 patients with atrial arrhythmias (the recurrence rate was 37.5%). One study [19] showed that early recurrent atrial arrhythmia sometimes disappeared during continuous follow-up, while atrial arrhythmia might persist in some patients. Therefore, repeat RFCA treatment could be one of the treatments for these patients. Observation through use of more intensive monitoring tools could objectively evaluate the characteristics of various atrial arrhythmias after AF RFCA, so that the best strategy and best time of intervention could be established for different types of arrhythmias [20,21]. The 32 patients in this study successfully underwent RFCA, but we still found recurrent AFs, among which 5 cases were successfully treated after repeat RFCA treatment.

ILR value in reducing medical costs and increasing patient compliance

The expected battery life of an ILR could be up to 36 months, but in this study, the battery lives in 4 cases were 42, 45, 45, and 47 months, which is 6–11 months longer than the expected monitoring time. The cardiac arrhythmia events in symptomatic and asymptomatic patients could be continuously recorded, thus reducing the patients' economic burden, and significantly improving compliance and diagnostic efficiency.

Conclusions

The use of ILR in monitoring the efficacy of AF RFCA was better than with traditional examinations. ILR can promptly detect asymptomatic AF and record the onset characteristics of ECG events after AF RFCA, thus providing a basis for objectively determining efficacy and recurrence rates, defining characteristics of other cardiac events, and contributing to development of reasonably effective clinical treatment programs.

Funding

This work was not supported by any funding.

Conflict of interest

All authors have no conflict of interest regarding this paper.

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