Monitoring of atrial fibrillation burden after surgical ablation: relevancy of end-point criteria after radiofrequency ablation treatment of patients with lone atrial fibrillation

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Abstract

Studies have shown that continuous rhythm monitoring enables the detection of significantly more atrial fibrillation (AF) episodes than routine follow-up of patients, i.e. based on perception of symptoms or on 24–48 h Holter monitoring. The positive outcome of radiofrequency ablation (RFA) may be easily overestimated, especially in patients with paroxysmal AF. Thirty-three consecutive patients, aged 59.4 ± 8.9 years (range 38–75 years) participated in this study. All patients had documented AF episodes with an AF duration of 9.4 ± 7.1 years (range 1.5–25 years). A new monitoring device, the AF-Alarm was used to more accurately assess the outcome after surgical isolation of pulmonary veins. The AF-Alarm was applied for a duration of 128 ± 42.5 h (range 49–191 h) during a period of 8–15 days. The success rate was 87% based on serial electrocardiograms (ECGs) and 24–48 h Holter monitoring during regular outpatient visits. Combination of ECG, Holter and AF-Alarm data yielded a significantly lower success rate, i.e. at the latest follow-up 69% of the patients were free from AF after surgical ablation (P < 0.05). Furthermore, the AF-Alarm device demonstrated a dissociation between symptoms and atrial arrhythmic events and confirmed the occurrence of asymptomatic AF episodes. The most important limitation of the AF-Alarm device was noise detection with oversensing and inappropriate detection of non-existing AF episodes in 9% of patients. Long-term follow-up of the patients seems to be essential as success rates of the initial ablation procedure might vary over time. External recorders like the AF-Alarm may be used as an additional tool to document symptomatic and asymptomatic episodes of atrial arrhythmias in the outpatient setting.

Keywords: Atrial fibrillation; RF ablation; Monitoring device

1. Introduction

In general, atrial fibrillation (AF) is associated with a doubling of cardiovascular mortality, an increased risk of systemic emboli and stroke (4- to 5-fold increase in non-rheumatic patients and 18-fold increase in patients with rheumatic valve disease), and a deterioration in cardiac function due to a combination of loss of atrial transport, irregular or rapid ventricular rates, and progressive cardiomyopathy. The increased mortality associated with AF is independent to the underlying cardiovascular condition. Martinek et al. [1] demonstrated in a series of 14 patients with a pacemaker device and treated with pulmonary vein radiofrequency ablation (RFA) for their drug-refractory and highly symptomatic AF, that continuous monitoring enables the detection of significantly more AF episodes than routine follow-up of patients, i.e. based on perception of symptoms or on 24–48 h Holter monitoring. The outcome of RFA in patients with AF is likely easily overestimated, especially in patients with paroxysmal AF [1–10]. Recurrences of atrial arrhythmias might increase the risk for stroke, therefore, adjustment of anticoagulant drug regimen should be based on appropriate monitoring. In this respect, the definition of an ‘atrial arrhythmic episode’ can be questioned as some guidelines refer to a minimum time period of 30 s, increasing the likelihood of erroneous diagnosis of sinus rhythm [1–3]. In this study, we evaluated the additional value of a new external cardiac rhythm monitoring device, i.e. the AF-Alarm device in patients with paroxysmal AF who underwent surgical RFA.

2. Methods

From January 2006 to January 2008, 33 patients were included in the minimal invasive surgical pulmonary vein isolation registry. We evaluated the medium-term results of a novel ablation technique to eliminate AF by means of an irrigated bipolar RF ablation device. All patients consented to their data being registered and used for publication as did the Board of Hospital Administrators. All patients underwent a minimal invasive pulmonary vein isolation and left atrial appendage ligation (MIPI) procedure. Patients were followed in the outpatient clinic or follow-up data were obtained from attending or referring physicians.
2.1. Surgical procedure

In a supine position under general anesthesia, a double lumen tube was introduced. Defibrillator pads were placed on the thoracic wall. In the right hemithorax, a 10-cm incision in the fourth intercostal space in the anterior axillary line was placed. The pericardium was opened anterior to the phrenic nerve. Two stay sutures were placed in the pericardium. Blunt dissection of Waterston’s Groove was performed followed by a blunt dissection and opening of the oblique sinus (OS) caudal of the right inferior pulmonary vein (RIPV). Then, blunt dissection and opening of the OS cranial of the right superior pulmonary vein (RSPV) between RSPV and the right pulmonary artery was performed. The Navigator was used to pass a tape around the RSPV and RIPV in one or separately, or the Navigator was used to apply the bipolar ablation device directly.

Introduction and application of the bipolar device around the pulmonary veins after gentle traction of the tape and ablating the left atrial wall adjacent to the junction with the pulmonary veins. RF energy was applied twice per pulmonary vein pair. Isolation was confirmed with pacing maneuvers at the LA-PV junction. The left hemithorax was opened similar to the right hemithorax, except for the incision of the pericardium, that was incised posterior of the phrenic nerve. Additional left atrial appendage ablation or removal or exclusion with stapler or preferably with endoloop was performed.

2.2. Cardiac rhythm monitoring

Early postoperative care, including anticoagulant manage-

ment, was similar as for routine cardiac surgery. Cardiac rhythm was continuously monitored after surgery until stable rhythm returned. Temporary epicardial wires attached to the right ventricle as well as to the right atrium were used to pace the patient, to monitor the rhythm, or to overdrive the atrium. Postoperative atrial arrhythmias were treated with sotalol 80–160 mg or amiodarone 200 mg and combined with direct-current cardioversion if necessary. After discharge, patients were seen in the outpatient clinic within four weeks, at three months, at six months and at 12 months after operation, or earlier when necessary. Antiarrhythmic drugs were tapered gradually after cardiac rhythm was considered stable. The presence of atrial contraction as documented by transthoracic and transesophageal Doppler echocardiography was performed at three and six months after surgery and related to the presence of electrical activity in the surface electrocardio-
gram (ECG). In all patients at variable time points, but minimally three months after the surgical procedure, the external loop recorder was applied for a duration of 128 ± 42.5 h (range 49–191 h) during a period of 8–15 days. The ECG was recorded in this time period by means of the AF-Alarm including a patient cable and using three skin-electrodes. The patient was requested to manually activate the AF-Alarm device in detail.

2.3. AF-Alarm device

The AF-Alarm is a battery powered electronic arrhythmia detection device with ECG recording capabilities. The AF-Alarm provides the patient with an audible and visual signal upon detection of AF and provides storage of ECG strips and RR intervals at AF onset and termination.

The AF-Alarm device (Fig. 1) provides extra buttons that can be used to program the device but also to mark symptomatic episodes. Automatic detection as well as manual triggers result in the storage of the digitized ECG.

For automatically detected episodes, the ECG during the 2-min ‘onset’ time window is stored, as well as the 2-min time window within which ‘sinus rhythm’ is detected; for manually triggered episodes the time window from 2 min before until 2 min after the trigger is stored in the device memory.

2.4. Statistical analysis

Categorical variables are expressed as frequencies and percentages. Continuous data are presented as mean ± S.D. Comparison of continuous variables was performed with the Student t-test. Comparison of proportions was performed with \( \chi^2 \) analysis or Fisher’s exact test. All \( P \)-values are two-sided and \( P < 0.05 \) was considered statistically significant. A two-tailed \( P < 0.05 \) indicated statistical signifi-
cance. Statistical analysis was performed using SPSS (SPSS Inc, Chicago, IL, USA).

3. Results

3.1. Patient characteristics

Thirty-three patients, aged 59.4 ± 8.9 years (range 38–75 years) participated in the RF MIPI registry. All patients had documented AF episodes with an AF duration of 9.4 ± 7.1 years (range 1.5–25 years). Each AF episode lasted 4–24 h. Thirteen patients (39%) had paroxysmal AF and 20 patients (61%) had persistent AF. Clinical characteristics of the patients are summarized in Table 1.

![Fig. 1. AF-Alarm device (a) and an example of ECG signals registered with this device (b).](image-url)
3.2. Cardiac rhythm after surgical PV isolation and LAA ligation

The mean follow-up duration was 15±5.3 months (range 3–30 months). Fig. 2 shows cardiac rhythm at the latest follow-up based on ECG, combination of ECG and Holter and combination of ECG, Holter and AF-Alarm recordings. During follow-up, sustained sinus rhythm, including atrial rhythm (AR) or an atrial-based paced rhythm (ABPR) was present in 87% of patients based on ECG only, 84% based on ECG plus Holter and the success decreased to 69% after combining the ECG, Holter and AF-Alarm data (P<0.05). Antiarrhythmic drugs were used in 64% of survivors who were free of AF. Oral anti-coagulation was taken by 97% of patients. In the postoperative period when the AF-Alarm registrations were made, 19 patients were free from anti-arrhythmic medication and three were not treated with anti-coagulant medication. The AF-Alarm device confirmed successful ablation in 69% of patients as indicted by 0% AF burden (time spent in AF). One patient demonstrated the presence of persistent AF, as revealed by an AF-burden of 99%. In three patients (9%) automatic recordings were documented by the AF-Alarm which appeared inappropriately detected either as a result of noise registration (muscle potentials and/or poor connection/contact of ECG-electrodes with skin, Fig. 3) or to frequent pre-mature atrial contractions jeopardizing and misleading the detection algorithm (Fig. 4).

In five patients, manually triggered ECG registrations during presence of symptoms correlated with sinus rhythm; in a sixth patient the symptoms correlated with the presence of a non-sustained ventricular tachycardia.

4. Discussion

Conversion to and maintenance of sinus rhythm is often chosen as the primary end-point in studies looking at the success rate of AF ablation, however, many controversies exist in the determination of the success rate of the ablation procedure. The success rates also vary with the treatment of persistent or paroxysmal AF, the applied ablation procedures and evidence for potential underlying substrates.

As nicely indicated by previous studies [6–10], the success rate varies if one looks at freedom from AF recurrences with or without associated symptoms. Vasamreddy et al. [6] demonstrated that studies requiring an intensive monitoring of the recurrences of episodes lack from a sufficiently high patient compliance since they lack the consistency to accurately register every occurrence of symptomatic episodes, even when using a special wireless monitoring system that was applied in every patient on several occasions for five consecutive days.

The use of long-term ECG-observational devices to document presence or recurrence of arrhythmic episodes have been frequently proposed but rarely implemented. Several
devices are commercially available to allow out-of-hospital monitoring of the analogue ECG-signal for up to 96 continuous hours. Subsequent analysis to identify arrhythmic episodes as short as 30 s requires adequate attention and resources. Continuous recording might help to better detect asymptomatic episodes as compared to discontinued recordings – e.g. triggered by occurrences of symptoms or at fixed time points during the day – which methodology often suffers from low patient compliance adhering to the protocol. Implantable devices assure 100% patient compliance, yet available devices are rather expensive. External devices, such as the AF-Alarm, allow for easy application and fast diagnosis of relevant ECG information while offering a good cost/effectiveness balance and assuring high patient compliance.

The outcome of this observational study confirms that continuous observations is a good tool to document the absence/presence of asymptomatic episodes which will trigger subsequent medication adjustments. In this particular study, one patient was even diagnosed to have a non-sustained ventricular tachycardia during the extended period of ECG registration.

4.1. Limitations and shortcomings

It has been suggested to take a blanking or stabilization period into account of some three months post-ablation prior to assessing the recurrence of arrhythmias. In this stabilization period, the rate of recurrences might gradually decay and is not representative for the final clinical outcome, yet documentation of recurrences might help to better understand the remodeling process that is ongoing. Unfortunately today, too limited observations allow for such an adequate understanding.

If patients would have been monitored in the current study for longer time periods, there is a likelihood that more patients would have demonstrated recurrences. Longer registration periods merely depend on the tolerance of the patient to wear the sticky electrodes longer. This study was applied in only 33 patients, representing only a small sample of the current population presenting itself in the outpatient clinic. Therefore, observed ablation success rates are only indicative.

5. Conclusion

This study demonstrates that the longer the observational period the lower the success rate post-surgical ablation for AF. Furthermore, the current observed results demonstrate that the use of an external cardiac rhythm monitoring device like AF-Alarm is feasible to support the diagnosis of atrial arrhythmic recurrences in a better way than current standard practice. AF-burden is a continuous measure and a better parameter to assess success of the ablation therapy. Assessment of the AF-burden at regular time intervals allows optimal titration of the anti-arrhythmic and anti-coagulant therapies. In the future, implantable loop recorders may offer an objective mean to document occurrences of atrial episodes while the patient is out of the hospital and no longer under direct control of the treating physician. Thus, demonstration of long-term absence of recurrences seems to be the most solid end-point to determine success of the initial ablation procedure.

References


eComment: Monitoring of atrial fibrillation burden after surgical ablation

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During the last decade, catheter and surgical ablation of atrial fibrillation (AF) has evolved from an experimental method to a procedure that is now commonly performed throughout the world. Recurrent AF after ablation occurs in up to 50% of patients and could be in a form of short periods of AF or persistent AF with less or without symptoms. This is of significant relevance as most of these episodes are not recognized and can lead to thromboembolic events. And evaluation of the long-term efficacy of the ablation is still one of the unresolved questions which investigators are facing.

In this article, Beukema et al. demonstrated the additional value of a new external cardiac rhythm monitoring device (AF-Alarm) in 33 patients with paroxysmal AF who underwent surgical radiofrequency ablation [1]. Studies have shown that the more intensively the patient is monitored and the longer the period of the monitoring, the greater the likelihood of detecting both symptomatic and asymptomatic AF [2]. For this reason, it is very important to find an objective method to determine AF burden. In most cases routine electrocardiogram (ECG) and 24-h Holter monitoring are the standard strategies used by investigators. Implantable loop recorders are also available now to monitor symptomatic and asymptomatic episodes of AF and possess up to three years longevity.
episodes, but also accurate for the measurement of AF burden and highly reliable for the exclusion of the presence of AF. The drawback is that implantable devices are rather expensive and require additional intervention. In this case continuous search of external devices providing long-term monitoring of ECG and offering optimal cost-effectiveness balance is one of the main interests of the clinicians.

References

