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ORIGINAL ARTICLE

Implantable loop recorder monitoring after concomitant surgical ablation for atrial fibrillation (AF): insights from more than 200 continuously monitored patients

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Abstract Different follow-up methods have been used to report success rates after AF ablation. Recent studies have shown that intermittent rhythm monitoring underestimates the actual AF recurrence rate. We therefore report our experience with continuous rhythm monitoring by implantable loop recorder (ILR) in a large patient cohort. Between 09/2008 and 12/2012, 343 cardiac surgical patients underwent concomitant surgical AF ablation. ILR implantation was performed in 206 patients. ILR interrogation was accomplished at 3, 6 and 12 months postoperatively. Successful ablation was defined as AF Burden <0.5 %. Primary outcome of the study was freedom from AF at 12-month follow-up. Mean patient's age was 70.5 ± 7.4 years. No major ablation- or ILR-related complications occurred. In 4 patients (1.9 %) ILR had to be explanted due to ILR-related wound infection ($n = 2$) or chronic pain ($n = 2$). Survival rate at 1-year follow-up was 96.6 %. Freedom from AF rate after 1-year follow-up was 68.5 and 63.6 % off antiarrhythmic drugs, respectively. Statistically significant predictors for successful ablation at 1-year follow-up were smaller LA diameter, shorter duration of AF and preoperative paroxysmal AF. Demographic data, indication for surgery, lesion set and used energy source had no impact on freedom from AF after 1 year. Continuous ILR monitoring after concomitant surgical AF ablation was safe and feasible, with registered freedom from AF rate of 68.5 % at 1-year follow-up. Thus continuous rhythm monitoring provides reliable outcome data and helps to guide antiarrhythmic therapy.

Keywords Atrial fibrillation · Surgical ablation of atrial fibrillation · Implantable loop recorder monitoring · Arrhythmia surgery

Introduction

Atrial fibrillation (AF) is associated with an increased number of thromboembolic events, including stroke, and an increased mortality rate [1]. Furthermore, it can lead to heart failure and results in an increased number of hospitalizations [2, 3]. Therefore, concomitant surgical AF ablation is recommended by guidelines for symptomatic patients as well as for asymptomatic patients at low risk for the surgical ablation procedure [3, 4].

Detection of AF recurrence after ablation procedure is often based on intermittent rhythm monitoring strategies, although these methods have limitations due to their limited monitoring period. Recent studies have shown that intermittent rhythm monitoring, based on 12-lead ECG overestimates the success rate after AF ablation procedure. Even repeated 24-h Holter-ECG monitoring has been shown to underestimate actual AF recurrence rate after ablation [5–7].

The XPECT trial has shown high sensitivity (96.1 %) and negative predictive value (97.4 %) for detection of AF

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episodes by subcutaneous implantable loop recorder (ILR) Reveal XT (Medtronic Inc.) [8]. This device is programmed to detect arrhythmia episodes by analysis of irregularity and incoherence of R–R intervals. The Reveal XT is able to detect duration of AF episodes as well as AF burden, defined as percentage of time the patient is in atrial fibrillation during follow-up. Aim of this study was to investigate safety and efficacy of continuous rhythm monitoring using the Reveal XT implantable loop recorder, and to identify outcome predictors after concomitant surgical AF ablation.

Materials and methods

From September 2008 to December 2012, 343 patients underwent concomitant surgical AF ablation in our institution. Of those patients, 206 received intraoperative subcutaneous implantable loop recorder implantation (Reveal XT, Medtronic Inc.) and were included in this retrospective data analysis. The study has been approved by the local ethics committee and is in accordance with the ethical standards laid down in the Declaration of Helsinki 1964. Only 206 of 343 patients received an ILR, as some patients refused ILR implantation and when we first started ILR therapy in 2008 some surgeons were reluctant to implant an ILR. ILR was implanted in a parasternal area of the chest at the end of the surgical procedure. 82 (39.8 %) patients received surgical AF ablation due to paroxysmal AF, while 124 (60.2 %) patients were treated due to persistent- or longstanding-persistent AF.

Ablation technique

The used energy sources included argon-based epimyocardial cryoablation in 63 patients (30.6 %) (CryoICE Cryoablation probe, Atricure Inc., West Chester, Ohio, USA and Cryo Cath Surgical Ablation Probe, Medtronic Inc., Minneapolis, Minnesota, USA), unipolar endomyocardial radiofrequency ablation in 66 (32.0 %) (Cardioblate unipolar RF pen, Medtronic Inc., Minneapolis, Minnesota, USA), and bipolar epi-/endomyocardial radiofrequency ablation in 77 (37.4 %) (Cardioblate BP2 device and Cardioblate Surgical Ablation System Generator, Medtronic Inc., Minneapolis, Minnesota and Atricure Isolater Synergy Ablation Clamp, Atricure Inc., West Chester, Ohio, USA) (Table 1).

Single pulmonary vein isolation was conducted in 42 (15.1 %) patients. Extended left atrial ablation was performed in 88 (70.2 %) patients using the left atrial ablation lesion set of the Cox Maze IV procedure with pulmonary vein ablation, box lesion, left atrial appendage and isthmus isolation. Biatrial ablation was conducted in 76 patients (36.9 %) with persistent- or longstanding-persistent AF in whom right atrial ablation was performed in addition to the above-mentioned lesion set. Right atrial lesions included intercaval lines, isolation of the cavo-tricuspid isthmus, right atrial appendage and terminal crest.

Statistical analysis

A retrospective single-center data analysis was accomplished. Primary endpoint of the study was freedom from AF at 12-month follow-up. All statistical analyses were performed with SPSS statistical software version 21.0 (SPSS Inc., Chicago, Illinois, USA). Continuous values are expressed as mean ± standard deviation and were compared with Student's *t* test. Categorical variables are displayed as frequency and percentages and were compared using the Chi-square test or Fisher's exact test as appropriate. A p value of <0.05 was considered statistically significant. The reported p values are two-sided. Uni- and multivariate logistic regression analyses were used to identify independent predictors for SR after 12 months. The parameters considered for univariate analysis were age, gender, left atrium (LA) diameter, type and duration of AF, left ventricular ejection fraction (LVEF), type of concomitant procedure, lesion set, energy source, and early recurrence of AF. For multivariate analysis, significant covariates and covariates which from our experience had been considered clinically relevant were included. These were age, gender, type and duration of AF, surgical procedure, LVEF, and LA diameter.

Follow-up

Follow-up with ER interrogation was conducted 3, 6 and 12 months postoperatively. AF recurrence was defined as an AF burden >0.5 % or a single stored AF episode with duration >30 s on ER interrogation. All stored episodes were manually validated during follow-up visits. The postoperative and discharge rhythm results were obtained using 12-lead electrocardiography (ECG). The antiarrhythmic drugs and anticoagulation regimens were maintained for 3 months postoperatively in all patients and then adapted according to the ILR rhythm results. In patients without contraindications, amiodarone was used as the first-line antiarrhythmic drug therapy; otherwise, other class III antiarrhythmic drugs were used for at least 3 months postoperatively.

Results

Baseline patient characteristics are shown in Table 2. The mean patient age was 70.5 ± 7.3 years, 71.8 % of patients were male. The mean left ventricular ejection fraction (LVEF) was 52.6 ± 10.0 %. Mean left atrial diameter was 53.4 mm.

Table 1 Surgical procedures and energy sources

	$n = 206$
Isolated CABG *n* (%)	36 (17.5)
Isolated AVR *n* (%)	21 (10.2)
Isolated MVR *n* (%)	45 (21.8)
CABG + valve	76 (36.9)
Other *n* (%)	28 (13.6)
RF bipolar *n* (%)	77 (37.4)
RF unipolar *n* (%)	66 (32.0)
Cryoablation *n* (%)	63 (30.7)

Table 2 Patient demographics

	$n = 206$
Age (years)	70.5 ± 7.3
Gender (male *n*, %)	134 (65.1)
AF duration (years)	3.9 ± 3.2
LA diameter (mm)	53.4 ± 8.3
Paroxysmal AF *n* (%)	82 (39.8)
LVEF (%)	52.6 ± 10.0
Diabetes *n* (%)	47 (22.8)
Renal insufficiency *n* (%)	18 (8.7)
Prior stroke *n* (%)	15 (7.3)
CAD *n* (%)	96 (46.6)

Mean history of AF was 4.3 ± 3.1 Performed surgical procedures were isolated coronary artery bypass grafting (CABG) in 36 patients, aortic valve replacement in 21 patients, and mitral valve repair or replacement in 45 patients. A combined CABG and valve operation was performed in 76 patients; other surgical procedures made up the remaining 28 cases. 5 patients (2.4 %) experienced perioperative stroke. Postoperative new permanent pacemaker implantation rate was 6.7 % (14/206). One-year survival rate was 96.6 %.

No major ablation- or ILR-related complications occurred in any of the patients. Minor ILR-related complications were observed in 4 patients (1.9 %) resulting in device explantation due to ILR-related local wound infection ($n = 2$) or chronic pain ($n = 2$).

Rhythm outcome

Follow-up with ILR interrogation was 100 % complete at 3 and 12 months, at 6 months only 71 % (145 patients). Freedom from AF immediately after the procedure and at the time of discharge, obtained by 12-lead ECG, was 64 and 56 %, respectively (Fig. 1). At 3 and 6 months of follow-up, freedom from AF was 61 and 64 %, respectively.

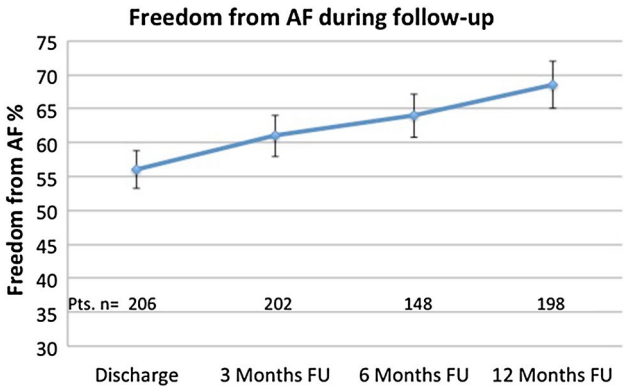

Fig. 1 Rhythm rates during follow-up

One-year follow-up revealed an overall rate of freedom from AF of 68.5 %, freedom from AF off class I or III antiarrhythmic drugs was 64 %. Freedom from oral anticoagulation at 12-month follow-up was, however, only 31.1 %.

Uni- and multivariate logistic regression analysis was used to identify predictors for successful AF ablation. The only statistically significant predictors for freedom from AF at 12-month follow-up were shorter LA duration ($p = 0.032$, OR 1.32, CI 0.87–1.95), smaller LA diameter ($p = 0.01$, OR 1.61, CI 0.64–2.21) and preoperative paroxysmal AF ($p = 0.003$, OR 2.41, CI 1.43–5.21, freedom from AF: 78 % paroxysmal AF vs. 63 % persistent AF).

Further demographic data, surgical procedure, lesion set and used energy source had no statistically significant impact on rate of freedom from AF after 1 year.

AF burden

The mean AF burden of all patients was 26.2 ± 40.1 % at 3 months of follow-up. At 12 months of follow-up, a reduced mean AF burden of 17.3 ± 32.4 was seen in the entire patient cohort irrespective of ablation success. Distribution of AF burden is shown in Fig. 2a, b.

Discussion

Atrial fibrillation is associated with an increased risk for stroke, heart failure and reduced survival and has been reported as an independent risk factor for mortality after cardiac surgery [9–11]. Concomitant AF surgery is an established procedure with low risk- and excellent outcomes reported in literature [12–20].

At 1-year follow-up we observed in our study a rate of freedom from AF of 68.5 and 63.6 % off antiarrhythmic drugs, respectively. In contrast to nearly all other

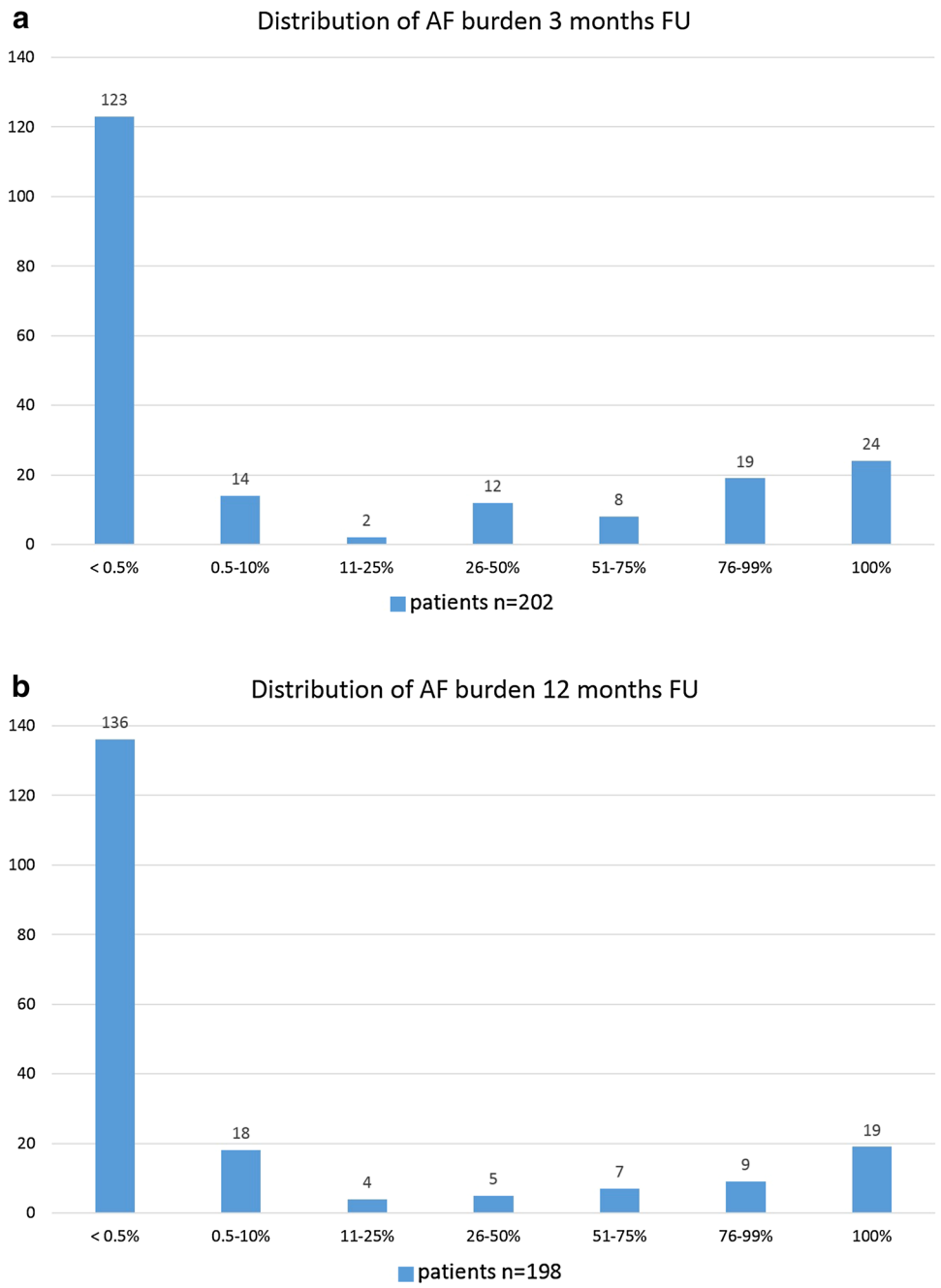

Fig. 2 **a** Distribution of AF burden at 3-month follow-up. **b** Distribution of AF burden at 12-month follow-up

previously published studies, reporting success rates after surgical AF, the results in our study were obtained by continuous ILR rhythm monitoring. It needs to be stressed, that in most of the previous published studies, ablation success was defined by use of 12-lead ECG or 24-h Holter monitoring [12–18].

Recent studies comparing the accuracy of rhythm detection using different follow-up methods after AF ablation have shown that intermittent rhythm monitoring underestimates the actual AF recurrence rate [5, 7]. Furthermore, after AF ablation, even patients with failure of ablation, may have reduced AF burden and less symptoms, which makes the detection of AF recurrence with snapshot follow-up methods more difficult and unreliable [5–7].

Charitos et al. have investigated and analyzed rhythm results in 647 patients with implantable cardiac monitoring devices (such as pacemaker or ILR). With the help of computer simulation, they evaluated the sensitivity of the 4 most commonly used intermittent monitoring strategies (24-h and 7-, 14-, and 30-day Holter-ECG) with various monitoring frequencies. They found out, that in their patient population, monitoring with four-times 24-h

Holter-ECGs had only sensitivity of 52 %, detecting AF recurrence in only half of their patients. The authors conclude that evaluation of interventional therapies using only 24-h ECG as a monitoring strategy, should be interpreted cautiously because a great proportion of patients will be misclassified. AF recurrence will be underestimated and procedural success overestimated [7].

Furthermore, a recent prospective randomized study, the CRYSTAL AF trial, showed that detection of AF in patients with cryptogenic stroke is more effective with ILR monitoring, compared to conventional 24-h Holter-ECG monitoring. They randomized 441 patients with cryptogenic stroke without history of AF to ILR- or 24-h Holter monitoring. Primary endpoint of the study was time to first detection of AF (AF episode >30 s.) within 6 months. Compared to 24-h Holter patients, AF was significantly more often detected in ILR patients during 6- and 12-month follow-up period (6 months: 8.9 vs. 1.4 %; $p < 0.001$, 12 months 12.4 vs. 2.0 %; $p < 0.001$). This was another study to show, that at least in patients with paroxysmal AF, the actual AF rate will be underestimated with discontinuous rhythm monitoring.

The use of continuous rhythm monitoring allows for a more accurate detection of actual AF recurrence rate and helps to evaluate different therapeutical approaches more accurately. However, it has to be admitted that there are some technical limitations of the used ILR including its limited storage capacity of 49.5 min. Therefore, in patients with a high AF burden, not all stored episodes can be validated manually and there is a certain risk to under- or overestimate actual AF burden of the patients. On the other hand, the ER used in this study classifies heart rhythm for each subsequent time interval of 2 min, and only detects AF episodes with a duration of at least 2 min. However, in previous published studies it has been shown that the REVEAL is an excellent tool to predict freedom from AF, due to its high negative predictive values (NPV) [8]. In any case, its ability to detect AF episodes is certainly far better than 24-h Holter recordings, 7- or 30-day monitoring [5, 21, 22].

Additionally, an important observation in our study was the increase of freedom from AF rate between 3- and 12-month follow-up. In this study, we could also show a reduction of AF burden over time, even in patients in whom ablation failed. Measurement of AF burden is a relatively new possibility to get a close idea of the time a patient spent in AF. In our opinion, if a patient has an AF burden of 0 % over a certain period of time, we can consider the ablation as successful, and the patient as AF free. Nevertheless, the impact of reduction in AF burden and the resulting consequences remain to be defined yet. In future, larger prospective studies need to be performed, to determine clinically relevant cut-off values for the AF burden, with regard to anticoagulation and antiarrhythmic drug regimen. Due to the lack of randomized controlled studies regarding impact of AF burden reduction on patients' clinical outcome, many of our patients were still on oral anticoagulation despite very low AF burden at 12-month follow-up. Only 31.1 % of our patients were free from oral anticoagulation although 68.5 % had an AF burden less 0.5 %. However, it has to be admitted that cessation of oral anticoagulation is nowadays mainly guided by CHADS-VASc Score. Future prospective studies need to determine the necessity for oral anticoagulation in patients with different AF burdens.

In a previous published study by our group [23], including only patients with persistent AF, we showed higher rate of freedom from AF in patients receiving biatrial lesion set, compared to those with left atrial lesion set only. We did not find these differences in the present study; however, it has to be admitted that in this study also patients with paroxysmal AF were included. While all patients in the group receiving biatrial ablation had persistent AF, 63 % of patients in the LA group had paroxysmal AF. This might have influenced the results, as patients with preoperative paroxysmal AF had significantly higher rate of freedom from AF during follow-up.

Limitations

The major limitation of this study is that we used a retrospective data analysis. Disadvantages of a retrospective, non-randomized study, including unknown confounders as well as selection and detection bias, cannot be completely avoided. Further limitations are given due to the technical aspects of ILR with its limited storage capacity. Therefore, not all AF episodes detected by the ILR can be manually validated and there is a certain risk to over- or under-estimate the actual AF burden. Furthermore, the 2-min blanking period of the ILR may result in underestimation of some AF episodes.

Conclusion

ILR monitoring after concomitant surgical AF ablation was safe and feasible without major ILR-related complications. Continuous rhythm monitoring detected rate of freedom from AF was 68.5 % at 1-year follow-up. Statistically significant predictors for successful ablation at 1-year follow-up were smaller LA diameter, shorter duration of AF and preoperative paroxysmal AF (compared to patients with preoperative persistent- or longstanding-persistent AF). ILR monitoring provides reliable outcome data and helps to guide antiarrhythmic drugs.

Compliance with ethical standards

Conflict of interest None.

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