Ablation for atrial fibrillation during mitral valve surgery: 1-year results through continuous subcutaneous monitoring

Alexandr Bogachev-Prokophiev,*, Sergey Zheleznev, Alexander Romanov, Evgeny Pokushalov, Alexey Pivkin, Giorgio Corbucci and Alexander Karaskov

* Department of Heart Valves Surgery, State Research Institute of Circulation Pathology, Novosibirsk, Russian Federation
† Department of Arrhythmia and Electrophysiology Laboratory, State Research Institute of Circulation Pathology, Novosibirsk, Russian Federation
‡ Medtronic BRC, Maastricht, The Netherlands

* Corresponding author: Rechkunovskaya 15, 630055 Novosibirsk 55, Russian Federation. Tel: +7-913-7539546; fax: +7-383-3324550; e-mail: b-pav@rambler.ru (A. Bogachev-Prokophiev).

Received 12 October 2011; received in revised form 2 December 2011; accepted 8 December 2011

Abstract

Continuous monitoring of cardiac rhythm may play an important role in measuring the true symptomatic/asymptomatic atrial fibrillation (AF) burden and improve the management of anti-arrhythmic and anti-thrombotic therapies. Forty-seven patients with mitral valve disease and longstanding persistent AF (LSPAF) underwent a left atrial maze procedure with bipolar radiofrequency and valve surgery. The follow-up data recorded by an implanted loop recorder were analysed after 3, 6 and 12 months. On discharge, 40 (85.1%) patients were in stable sinus rhythm, as documented by in-office electrocardiography (ECG), 4 (8.5%) were in pacemaker rhythm and 3 (6.4%) were in AF. One (2.1%) patient died after 7 months. On 12-month follow-up examination, 30 (65.2%) patients had an AF burden <0.5% and were classified as responders. Three (6.5%) of the 16 non-responders had atrial flutter and 13 (27.7%) had documented AF recurrences with an AF burden >0.5%. Two (4.3%) patients with AF recurrences were completely asymptomatic. Among the symptomatic events stored by the patients, only 27.6% was confirmed as genuine AF recurrences according to the concomitant ECG recorded by the implanted loop recorder. A concomitant bipolar maze procedure during mitral valve surgery is effective in treating AF, as proved by detailed 1-year continuous monitoring.

Keywords: Atrial fibrillation • Mitral valve surgery • Continuous subcutaneous monitoring • Radiofrequency ablation

INTRODUCTION

Surgical ablation of atrial fibrillation (AF) is the standard recommended concomitant procedure during valve surgery [1]. Office electrocardiography (ECG) and 24 h Holter monitoring are commonly used to assess cardiac rhythm after the maze procedure, but any intermittent method of monitoring has limited ability to detect recurrences during the follow-up period [2]. For this reason, the measurement of AF burden by means of continuous monitoring can be clinically relevant and may have a safer and positive impact on the management of medical therapies, such as anticoagulation and anti-arrhythmic therapy. Our group has already developed experience of subcutaneous continuous monitoring in the management of patients with concomitant AF ablation and coronary bypass grafting [3].

The aim of this prospective non-randomized study was to estimate sinus rhythm survival at 12 months in patients who had undergone surgical AF ablation concomitant with mitral valve surgery. AF monitoring was performed by means of an implanted loop recorder.

MATERIALS AND METHODS

Patient population

From February 2009 to April 2010, 47 consecutive patients (mean age 53.5 ± 7.3 years) with mitral valve lesions and AF underwent mitral valve surgery and a concomitant left atrial maze procedure with bipolar radiofrequency. Baseline patient characteristics are listed in Table 1.

Surgical procedure

The scheme of radiofrequency (RF) ablation was a left-side maze procedure. The ligament of Marshall was surgically dissected. The ablations around the right and left pulmonary vein (PV) orifices and left atrial appendage were performed epicardially, usually before aorta cross-clamping. An endo-epicardial connecting line was created between both islands of PVS on the roof and inferior part of the posterior wall (box lesion). The base of the left atrial appendage was connected with the left superior PV endocardially. To prevent any damage to the circumflex coronary artery, we used the technique of complete left atrial

© The Author 2012. Published by Oxford University Press on behalf of the European Association for Cardio-Thoracic Surgery. All rights reserved.
bipolar ablation described by Benussi et al. [4]. The left atrial appendage was excluded in all cases. The ablation procedure was performed by using a dry bipolar radiofrequency ablation clamp (AtriCure Inc., Cincinnati, OH, USA) (Fig. 1).

Intra-operative conduction block was validated in all patients after the aorta had been opened and regular rhythm restored.

The implanted device

Continuous subcutaneous monitoring was performed by means of the REVEAL XT 9529 implantable loop recorder (ILR) (Medtronic Inc., Minneapolis, MN, USA). This device is highly sensitive in detecting AF episodes and highly accurate in measuring the duration of AF in terms of daily burden [5].

Patients were provided with the REVEAL XT Patient Assistant (Medtronic Inc.), a tool that allows each patient to store the ECG through the implanted device during symptoms.

Table 1: Preoperative patient characteristics

<table>
<thead>
<tr>
<th>Preoperative data</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>53.5 ± 7.3</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>18 (38.3%)/29 (61.7%)</td>
</tr>
<tr>
<td>Preoperative NYHA functional class</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>5 (10.6%)</td>
</tr>
<tr>
<td>III</td>
<td>39 (83.0%)</td>
</tr>
<tr>
<td>IV</td>
<td>3 (6.4%)</td>
</tr>
<tr>
<td>AF duration (years)</td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>17 (36.2%)</td>
</tr>
<tr>
<td>3-5</td>
<td>25 (53.2%)</td>
</tr>
<tr>
<td>&gt;5</td>
<td>5 (10.6%)</td>
</tr>
<tr>
<td>History of TIA/stroke</td>
<td>4 (8.5%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>11 (23.4%)</td>
</tr>
<tr>
<td>LVEF, (%)</td>
<td>59.2 ± 8.1</td>
</tr>
<tr>
<td>Mean LA size, (mm)</td>
<td>61.5 ± 9.2</td>
</tr>
<tr>
<td>LA thrombosis</td>
<td>2 (4.3%)</td>
</tr>
</tbody>
</table>

TIA: transient ischemic attack; LVEF: left ventricular ejection fraction; LA: left atrium.

Definition of atrial fibrillation-free patients (responders)

Patients with an AF <0.5% at each follow-up examination were considered AF-free (responders). The same criterion to define responders had been used in previous studies published by our group [3]. Patients with AF% >0.5% were classified as non-responders. AF was visually confirmed by the investigators through the analysis of the stored ECGs.

Postoperative and follow-up care

In cases of stable sinus rhythm, we administered amiodarone at an infusion rate of 900 mg/day for 3 days after surgery. Thereafter, 200 mg/day was administered orally and was maintained for 3 months (blanking period). In the event of sinus bradycardia, amiodarone was not administered and atrial pacing performed. In all cases, all anti-arrhythmics were discontinued after 3 months. Oral anticoagulation was discontinued in patients who had undergone valve repair or valve tissue replacement who were responders, as documented by ILR 3 months post-procedure, and low-dose aspirin (100 mg/day) was started. Patients with mechanical valves were on lifelong anticoagulation.

The data stored by the ILR were collected every 3 months during the 12-month follow-up. In non-responders, the telemetric data and the stored ECGs were used to tailor the antiarrhythmic therapy and/or to guide a percutaneous ablation procedure.

Statistical analysis

Results are expressed as mean values ± SD or as numbers and percentages, as appropriate. Student’s t-test was used for comparison of continuous data, and the Chi-square test was used for comparison of categorical data. The Kaplan–Meier analysis with the log-rank test was performed to determine the probability of success, estimated as the percentage of responders. For the success rate, all patients experiencing a recurrence from 3 to 12 months were considered to have failed. All reported P-values were based on two-sided tests and a P-value of <0.05 was considered significant. All statistical calculations were performed using the SPSS version 13.0 software (SPSS Inc., Chicago, IL, USA). The authors had full access to and take responsibility for

Figure 1: RF bipolar ablation technique. (A) Left atrial ablation line pattern; (B) bipolar ablation of left pulmonary veins.
the integrity of the data. All authors have read and agree to the manuscript as written.

RESULTS

Surgical and early postoperative data

In 2 (4.3%) cases of left atrial thrombosis (transoesophageal echocardiography findings), the entire scheme of the procedure was performed after aorta cross-clamping.

The mean ablation time was 12.6 ± 6.7 min. Absence of atrial capture (conduction block) during pacing from PV was obtained in 44 (93.6%) patients. In the remaining 3 (6.4%) patients without conduction block, additional lesions were created until conduction block was achieved. Finally, complete disconnection of the PVs from the LA was successfully achieved in all patients.

Important intraoperative characteristics are shown in Table 2.

At the end of the surgical procedure, the ILR was implanted in the left parasternal area, which required 6.7 ± 3.1 min on average. As a consequence of bradycardia, atrial temporary pacing was provided in 32 (68.1%) patients. The duration of temporary pacing was 2–8 days post-procedure.

The mean ICU stay was 2.3 ± 1.1 days and the mean hospital stay was 15.2 ± 1.1 days.

No patients died. No procedure-related complications occurred with regard to either ablation or the monitoring device. Re-exploration for bleeding was required in one patient (2.1%). There were two (4.2%) postoperative cerebral ischaemia events (one stroke and one transient ischaemic attack). Superficial sternal wound infection was found in one (2.1%) patient. No perioperative myocardial infarctions were recorded.

Early recurrence of AF was pharmacologically (10 patients) or electrically (5 patients) cardioverted after exclusion of intracardiac thrombosis by transoesophageal echocardiography. Four (8.5%) patients required pacemaker implantation before discharge, owing to sinus node dysfunction. Stable sinus rhythm was documented in 40 (85.1%) patients on discharge. Three (6.4%) patients were discharged in AF (after two unsuccessful attempts at electrical cardioversion).

Follow-up

Patient follow-up examinations were scheduled at 3, 6 and 12 months postoperatively.

At the first follow-up examination (end of the blanking period), 25 (53.2%) patients were AF-free, according to the ILR data (AF < 0.5%). Five (10.6%) patients (three had AF on discharge and two had AF recurrences) underwent successful electrical cardioversion to restore sinus rhythm.

At the 12-month follow-up examination, 30 (65.2%) patients had no documented atrial arrhythmias (AF burden <0.5%) and were deemed responders. Three (6.5%) patients out of 16 non-responders had atrial flutter (1 (2.1%) left atrial flutter and 2 (4.3%) typical flutter) and 13 (27.7%) had AF (AF burden >0.5%). All patients with atrial flutter underwent catheter ablation. Figure 2 shows atrial arrhythmia-free survival from the day of the operation up to the 1-year follow-up examination.

In two (4.3%) patients, AF recorded by the ILR was completely asymptomatic.

One (2.1%) patient underwent pacemaker implantation for sinus node dysfunction.

One (2.1%) patient died after 7 months, the cause of death being mechanical mitral valve thrombosis. This patient was included in Kaplan–Meier estimates of AF-free survival.

One (2.1%) patient suffered two strokes: at 3 and 5 months; drug therapy significantly reduced the neurological deficit.

Analysis of symptoms

Patients were provided with the Patient Assistant tool to collect the ECG during symptoms (e.g. palpitations). During the overall follow-up period, patients stored the ECG concomitant with 279 symptomatic events by activating the Patient Assistant tool. Analysis of the stored ECG traces showed genuine AF in only 27.6% of cases (Fig. 3).

---

Table 2: Intraoperative characteristics

<table>
<thead>
<tr>
<th>Operative data</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic cross-clamping time (min)</td>
<td>65.2 ± 10.8</td>
</tr>
<tr>
<td>Cardiopulmonary bypass time (min)</td>
<td>84.1 ± 15.4</td>
</tr>
<tr>
<td>Mitral valve lesion</td>
<td></td>
</tr>
<tr>
<td>Rheumatic</td>
<td>37 (78.7%)</td>
</tr>
<tr>
<td>Degenerative</td>
<td>10 (21.3%)</td>
</tr>
<tr>
<td>Mitral valve repair</td>
<td>5 (10.6%)</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>42 (89.4%)</td>
</tr>
<tr>
<td>Mechanical valve</td>
<td>38 (80.9%)</td>
</tr>
<tr>
<td>Tissue valve</td>
<td>4 (8.5%)</td>
</tr>
<tr>
<td>Left atrium thrombectomy</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>Tricuspid valve repair</td>
<td>9 (19.1%)</td>
</tr>
</tbody>
</table>

Figure 2: Kaplan–Meier estimates of atrial arrhythmias freedom by implantable loop recorder.

Figure 3: Cardiac rhythm by implantable loop recorder during symptomatic episodes (SR: sinus rhythm; ST: sinus tachycardia; PC: premature contractions; AF: atrial fibrillation).
DISCUSSION

Based on literature, this is the first study to clarify the AF status through detailed continuous monitoring during 12 months of follow-up in patients after bipolar RF ablation of longstanding persistent AF (LSPAF) concomitantly with mitral valve surgery. The percentage of responders at 12 months was 65.2%. Our data show a lower success rate than the results of previously published studies, which report freedom from AF in 80–85% of patients after 1 year [4, 6, 7]. However, previous reports regarding the success of the maze procedure have usually been based on telephone interviews, office ECG and 24 h Holter monitoring. The discrepancy can therefore be simply explained by the more accurate and reliable diagnostic tool used for AF monitoring in the present study. Also, we demonstrated that symptoms are an unreliable means of assessing the success rate of the procedure. Only in 27.6% of the patients, symptoms were truly AF, confirmed by ECG traces, i.e. patient-related symptoms after AF ablation did not correlate with underlying rhythm in more than 70% of the cases. Therefore, continuous monitoring is the only reliable and accurate method of correctly classifying the underlying rhythm based on a patient’s symptoms.

There are currently no clear recommendations for continuous AF monitoring after the maze procedure [8].

Two recently published studies utilized prolonged rhythm monitoring in patients undergoing concomitant maze procedure and valve surgery [9, 10]. The main objective of both studies was to compare short- and long-term monitoring of heart rhythm. Hanke et al. [10] used subcutaneous continuous monitoring, as we did in our study, but their study involved a small heterogeneous group of patients (valve and coronary patients, different ablation devices and lesion sets), which precludes comparison with our data. Both of the above-mentioned studies clearly showed that long-term monitoring yielded significant advantages in evaluating postoperative cardiac rhythm after concomitant maze and mitral valve surgery.

In the present study, we defined responders as those patients with AF <0.5%. The reason for adopting this cut-off has previously been explained by our group [3]. Interestingly, some patients with restored sinus rhythm on hospital discharge were classified as non-responders (AF >0.5%) at the 12-month follow-up examination, as analysis of the stored ECG confirmed paroxysmal AF. Any intermittent monitoring method, such as in-office ECG or 24 h Holter, would probably have failed to identify those patients as patients with AF recurrences, since they were asymptomatic.

Data from the Stroke Prevention in Atrial Fibrillation (SPAF) trial suggest that the risk of ischaemic stroke is similar in patients with paroxysmal AF or LSPAF [11]. According to ACC/AHA guidelines, it is reasonable to discontinue warfarin in patients who undergo concomitant mitral valve repair or valve tissue replacement and maze procedure, if they do not have risk factors for stroke [12]. In 7 (14.9%) of the 9 patients from our study who also underwent mitral valve repair (or valve tissue replacement), anticoagulation therapy was discontinued 3 months after surgery, on the basis of ILR data. There were no thromboembolic events in these patients during the overall observational period. All 37 (78.7%) patients with implanted mechanical valves were on lifelong anticoagulation and would not benefit from stopping anticoagulation in any case. The assessment of AF recurrences in order to make decisions about anticoagulation therapy should not be based on in-office ECG and sporadic Holter monitoring. We believe that patients who undergo mitral valve repair (or valve tissue replacement) and successful concomitant AF ablation can benefit from continuous monitoring, in that it can enable anticoagulation therapy to be safely discontinued, which in turn improves quality of life. However, as this study was not designed to assess the withdrawal of anticoagulation therapy, no clinical conclusion can be expressed on this topic.

Study limitation

The study was prospective. However, as it was non-randomized and conducted in a single centre, we cannot extrapolate our data to general clinical practice. On the other hand, we ensured homogeneous management of each procedure. More large-scale clinical trials are needed on this issue.

CONCLUSIONS

A concomitant bipolar maze procedure during mitral valve surgery is effective in treating LSPAF, as proved by detailed 1-year continuous monitoring. Continuous long-term monitoring after surgical AF ablation in mitral valve patients is a safe method of obtaining accurate information about cardiac rhythm development, as indicated by daily AF burden.

FUNDING

Conflict of interest: Giorgio Corbucci is an employee of Medtronic. Other co-authors have no conflict of interests to disclose.

REFERENCES

APPENDIX. CONFERENCE DISCUSSION

Dr S. Hunter (Middlesbrough, UK): I have two questions. First, what is the cost of one of these devices? It seems logical. As you say, it is a good way to guide removal of anticoagulation and anti-arrhythmic therapy. There are an awful lot of ablations performed around the world and that will be a huge cost. What is the cost of the individual device? Secondly, I know it is a small series and you had a lot of rheumatic patients, but you appear to have a very high incidence of permanent pacemakers; at the end of the follow-up it was 10%. Can you explain that?

Dr Bogachev-Prokophiev: I don’t know about cost of this device, because it is clinical research in our institute. Regarding your second question, when we started to perform atrial fibrillation ablation, our results were the same as reported in other publications, and about 10% for sinus node dysfunction per year after ablation is the same.

Dr Hunter: I would contest that. It is not the same. Ten percent is very high. And going back to the previous point, I think it is important when you are presenting this data that you give those of us that have budgets exactly what the cost will be to use this device.

Dr S. Benussi (Milan, Italy): I think the cost is a little less than the ablation device, at least in Europe. Did you insert the device via a median sternotomy or through a separate incision?

Dr Bogachev-Prokophiev: Yes, we performed a separate incision and also we have a group through a median incision. We compared our results and it was the same; during implantation of the device through a median incision, there were no additional noises from the implantable loop recorder. For cosmetic reasons, the device can be implanted through a median sternotomy.

Dr Benussi: Cosmetic reasons are an issue, but I suspect that the surgeon of the patient who had wound infection would have thought night and day about making a separate incision next time rather than possibly compromising the median sternotomy or the mediastinum if you get infection of the device and vice versa.

Dr Bogachev-Prokophiev: Maybe, but in our study we have only one case of superficial infection.

Dr N. Ad (Falls Church, VA): The cost in the US is $3,800 per device, so it is significant. I agree with that. A word of caution, though. One, about discontinuing anticoagulation. You should never base discontinuance of anticoagulation on rhythm only. You should always have echo and make sure that atrial function is reasonable and at least you don’t see atrial smoke, because you can have perfect sinus rhythm with smoke on the left side and you can have a high rate of stroke and so on and so forth.

But tell me, how did you retrieve the data from the device? Because the perception of most surgeons is the device is recording 24/7, but the memory of the device is only 48 minutes and only 36 minutes for atrial arrhythmia. So all you can have is rate strips on which to base your diagnosis, and not ECG. So how did you retrieve the data and assume that you really have AF burden?

Dr Bogachev-Prokophiev: We observed the data when the patients came to our clinic and also when they saw their local cardiologists who send data from ILR results to our centre. As for criteria, in the previous work the burden of atrial fibrillation was 0.5% per day; it is about 3.6 hours per week. These criteria as described in a previous work are enough to determine the risk of stroke in patients.

Dr Ad: I understand all this, but I believe there is a perception here that is wrong. If you don’t download the data all the time you don’t really have a reliable system. What do you do at every office visit, you download the memory of the device. So you may have 80% AF or you may have less. Do you know what I mean? If you don’t download the data, you don’t actually review the strips, it is worthless.

Dr Bogachev-Prokophiev: If you have data as a responder and the patient is a candidate to discontinue anticoagulation therapy, we discontinued it.