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Left Atrial Versus Biatrial Maze Procedures in Atrial Fibrillation: Initial Institutional Randomized Trial with Literature Overview

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Abstract

Objectives: The objective of study is to compare in a randomized fashion biatrial and left atrial Maze by continuous event recorder at one year follow-up.

Methods: From January 2011 to December 2012, 19 patients were prospectively enrolled. Patients were allocated in 3 groups regarding their rythm, 7 continuous atrial fibrillation, 8 paroxysmal atrial fibrillation and 4 sinus rhythm with atrial size above 45 mm. Patients were randomized to receive left atrial or biatrial or not receive a Maze. Patients were followed prospectively for 1 year. The interrogation of the recorder was done at 6 and 12 months.

Results: Ten patients showed recurrence of atrial fibrillation at 1 year with a mean atrial fibrillation burden of 30.76%. The recurrence rate was higher in the biatrial lesion group (5 of 6 patients versus 5 of 8 patients; p=0.383) with a mean of atrial fibrillation burden slightly lower than in left lesion group (34.83% versus 38.32%). 50% of patients of biatrial lesion group showed sinus node dysfunction. Only 1 patient of the continuous atrial fibrillation group didn't show a recurrence while 5 patients of the paroxysmal atrial fibrillation group were free of recurrence at 1 year (p=0.049). The mean of atrial fibrillation burden was 68.85% and 3.12% respectively.

Conclusion: Biatrial lesion seems to be not superior to left atrial lesion in term of atrial fibrillation recurrence. Maze ablation is significantly more efficient in patients with paroxysmal atrial fibrillation. Continuous rhythm monitoring is safe, feasible and allows better evaluation of atrial fibrillation recurrence and sinus node dysfunction.

Introduction

Atrial Fibrillation (AF) is often associated with other cardiac diseases, thus compromising the patient's clinical outcome [1,2]. AF is associated with a loss of synchronous atrio-ventricular contraction and a need for anticoagulation resulting in a significant morbidity. Despite anticoagulation, AF has been implicated in up to 15% of all thromboembolic strokes [3]. The maze procedure as an open-heart surgical approach, established by James Cox and coworkers, was found to effectively restore sinus rhythm (SR) and atrial contraction in patients with intermittent and chronic AF [4,5]. During the original procedure, linear lesions in the right and left atria were produced to prevent the occurrence of multiple reentrant wavelets identified during AF. This original Maze operation is extensive, time-consuming and requires great surgical skills. As a consequence, alternative sources of energy, such as radio frequency (RF) have emerged to surgically treat AF [6]. Controversies exist, considering the ideal lesion pattern, regarding the necessity to add right atrial lesions or not to the left atrial lesions. Biatrial lesions have never been compared head to head in a randomized fashion with left atrial maze before the paper of Gilinov for the CTSN investigators [7]. Furthermore, there is a lack of standardization in reporting postoperative results. Most reports indicated the incidence of sinus rhythm on a spot Electrocardiogram (ECG) or 24-hours of continuous cardiac monitoring (CCM) performed at the time a follow-up visit. The use of a reliable technique for continuous monitoring of heart rhythm for over a year postoperatively would allow a more careful evaluation of how prevalent are subclinical forms of atrial fibrillation recurrences [8]. We design this study to evaluate the pattern of recurrence of atrial fibrillation and the AF burden 1 year following mitral surgery comparing the effect of biatrial lesions and left atrial lesions using a continuous monitoring device.

Materials and methods

This study was approved by the local ethics committee/review board. Informed consent was obtained of each patient. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Design of study

From January 2011 to December 2012, we prospectively screened all patients planned for mitral valve surgery from degenerative or rheumatic etiology combined or not to Coronary Artery Bypass Graft (CABG) or tricuspid repair. Patients with severe left ventricular dysfunction, complex congenital anomaly, concomitant aortic valve replacement or planned mitral surgery too complex to attempt a biatrial lesion were excluded from the study. All patients with paroxysmal or continuous atrial fibrillation from chart based on ECG or a sinus rhythm with documented atrial size above 45mm on preoperative echocardiogram were selected and allocated into 3 groups regarding their rhythm. All patients were operated by the same surgeon. Patients of each group were randomized to receive left atrial lesion or biatrial lesion or not receive a concomitant AF ablation at time of mitral surgery.

Radio frequency ablation procedure

AF ablation was achieved through a sternotomy when the mitral

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surgery was associated to a CABG. In all other cases, the procedure was achieved through a minimally invasive approach. The procedure was performed according to protocol described by Sie et al. [6] Radio frequency energy was used to create continuous endocardial lesions mimicking most of the incisions and sutures as described in the Cox maze [9]. For the right side ablation, oblique right atriotomy was made typically under beating heart Cardiopulmonary Bypass (CPB) support. Then, the cavo-tricuspid isthmus isolation was achieved by two or three ablation lines. Another linear lesion from posterior end of atriotomy to superior vena cava was made. A continuous monitoring device «Medtronic Reveal-XT device» was implanted subcutaneously in the pectoral region either in electrophysiology laboratory under local anesthesia one month before surgery when set-up was available or at the end of surgery. The device is removed if indicated 1 year after the time of surgery. The Reveal XT is able to detect the duration of AF episodes and burden, defined as the percentage of time the patient is in AF during follow-up. The Reveal XT Performance Trial (XPECT) trial showed high sensitivity (96.1%) and negative predictive value (97.4%) for the detection of AF episodes by the device [10].

Postoperative management

Postoperative atrial tachyarrhythmia was managed with class I/III anti-arrhythmic medications or electrical cardio version to restore sinus rhythm. If this strategy failed, it was switched to a rate control strategy in combination to anticoagulation. All patients with paroxysmal or continuous atrial fibrillation were routinely anticoagulated with warfarin for 12 months postoperatively with a target International Normalized Ratio (INR) of 1.5 to 2.5. Patients with no preoperative anticoagulation received Warfarin for only 3 months instead. The maintenance of the anticoagulation therapy thereafter was determined according to individual risk factors of thromboembolism. The INR target is 2.5 to 3.5 for patients with prosthetic valve implantation regardless the cardiac rhythm status.

Endpoints and follow-up

Our primary endpoint was to compare biatrial, left atrial maze and mitral surgery alone on atrial fibrillation recurrence by continuous monitoring at 1-year following mitral valve surgery. The secondary endpoints were: 1) Identify subgroups for which maze procedures are efficacious, and permit changes in therapy (anticoagulation, antiarrhythmic drugs). 2) Evaluate the patterns of recurrence of atrial fibrillation with a continuous monitoring device. 3) Evaluate the sensitivity of CCM recordings compared to continuous monitoring as a way to document successful atrial fibrillation treatments at one year. 4) Evaluate the effect of prophylactic maze procedure on mitral valve patients with dilated left atrium presenting for surgery in sinus rhythm. Patients were followed prospectively for 1 year. Outpatient clinics were performed at 3, 6 and 12 months with assessment of functional class, thrombo-embolic events, palpitations and syncopes. The interrogation of the Reveal-XT device was done at 6, 12 months and a CCM was achieved at 12 months for all patients. The AF burden, the freedom of from Atrial Tachyarrhythmias (ATAs) and sinus node dysfunction or block conduction occurrence were extracted from the Reveal data and compared to the CCM data.

Statistical analysis

Recurrence of atrial fibrillations was compared between groups by making use of the log-likelihood ratio statistics. A first comparison was made between biatrial and left atrial lesions groups, and a second comparison was made between continuous atrial and paroxysmal atrial fibrillation groups. The two-sided significance level was set at 0.05.

Results

Demographics

Nineteen patients were enrolled in the study, Computer generated randomization was performed. Seven patients were in the group continuous AF (CAF) randomized in 2 biatrial lesion, 4 left atrial lesion and 1 no AF ablation, 8 patients in the group paroxysmal AF (PAF) randomized in 3 biatrial lesion, 3 left atrial lesion and 2 no AF ablation and 4 patient in the group sinus rhythm with dilated left atrium (SR) randomized in 1 biatrial lesion, 1 left atrial lesion and 2 no AF ablation. The median age was 65 years (range between 42 and 83 years; respectively 72, 62.5 and 63.5 years in CAF, PAF and SR groups). There were 6 men and 13 females. Six patients had previous mitral commissurotomy. Four patients had preoperative stroke, 2 patients had chronic renal failure and 2 patients had chronic lung disease. There were neither previous catheter ablations nor preoperative permanent pacemaker. The Median AF duration in the groups CAF and PAF was 28 months (range between 14 and 39 months). Ten patients had a functional class of 3 or more (all patient of the group CAF and 3 patients in the group PAF). Echocardiogram data show a median left ventricular ejection fraction of 60% (range between 45 and 70%), a median left ventricular end diastolic diameter of 50mm (range between 38 and 65mm) and a median left ventricular end systolic diameter of 33mm (range between 23 and 55mm). The median left atrium diameter was 47mm (range between 35 and 58 mm) and the median peak pulmonary artery pressure was 50mm of Hg (range between 31 and 65mm of Hg). There were 10 patients with more than moderate tricuspid valve regurgitation (6 in the CAF group, 3 in the PAF group and 1 in the SR group).

Early preoperative and postoperative data

We performed 11 mitral valve repairs, 8 mitral valve replacements, 3 concomitant CABG and 4 concomitant tricuspid valve repairs. Sixteen procedures were done through minimally invasive approach. The median CPB time was 104 minutes (range between 59 and 211 minutes) and the median cross clamp time was 75 minutes (range between 45 and 182 minutes). There were no hospital deaths. Two cases of bleeding were reported, 1 intra mediastinal and 1 in the site of Reveal implantation. No major ablation complication occurred. The median hospital length of stay was 9 days (range between 4 and 17 days) and the median intensive care unit length of stay was 3 days (range between 1 and 7 days). Ten patients presented early ATAs, 7 responded favorably to the rhythm control strategy, the 3 others was managed with rate contra strategy. No sinus node dysfunction or blocks were reported necessitating permanent pacemaker. Two patients had transient pacemaker.

Endpoints and follow-up

The follow-up was completed for all patients. No thrombo-embolic events, palpitations and syncopes were reported. All patients had a functional class I except one who was in class II. There were a recurrence of CAF in 5 patients all in the CAF group, and a recurrence of PAF in 4 patients (1 in the CAF group, 3 in the PAF group). New onset of PAF was observed in one patient of the SR group. The median left atrium diameter of these 10 patients was 49mm versus 46 mm for the remaining patients. The mean of AF burden was 30,76% (median 0, range between 0 and 100%). Among the five cases of PAF, only one was detected by CCM. 5 patients presented sinus node dysfunction detected by the interrogation of the Reveal device but not shown on the CCM at 12 months necessitating the implantation of permanent pacemaker. The median age of these patients was 67 years versus 63.5 years for the remaining patients.

To answer to our primary end point, we performed 6 biatrial lesions (2 CAF, 3 PAF and 1 SR) and 8 left lesions (4 CAF, 3PAF and 1 SR). For the biatrial lesion; the AF recurrence ratio was 5 of 6 patients (2 in CAF group, 2 in PAF group and new onset of PAF in SR group). The mean of AF burden for this group was 34.83% (median 22,5%, range between 0 and 100%). 50% of patients presented sinus node dysfunction necessitating permanent pacemaker. While, for left atrial lesion, the recurrence ratio was 5 of 8 patients (4 in CAF group, 1 in PAF group) and the mean of AF burden was 38.32% (median 0, range between 0 and 100%) without statistically significant difference between the two AF ablation strategy (p=0.383). 22% of patients had sinus node dysfunction and received a permanent pacemaker. To respond to our secondary endpoints, only one patient of CAF group didn't show an AF recurrence while 5 patients of the PAF

group were free of AF at 1-year follow-up statistically significant difference between the two groups (p=0.049). The mean of AF burden was 68.85% and 3.12% respectively in the CAF and PAF groups. Recurrence of AF was mostly continuous in CAF group while it was paroxysmal in all cases in the PAF group. Focusing on the SR group, one patient present a new PAF associated to sinus node dysfunction during follow-up, this patient was 74 years old, presented moderate to severe tricuspid valve regurgitation and received a biatrial lesion associated to mitral valve repair without tricuspid valve repair. 2 patients had no AF ablation and were free from AF at 1-year follow-up. The Reveal device, in addition to better evaluate the pattern and the AF burden, bring to light 5 cases of sinus node dysfunction necessitating permanent pacemaker not detected by CCM. This explains the high rate of permanent pacemaker in this study.

Discussion

The surgical treatment of atrial fibrillation concomitant to mitral surgery is gaining important attention. The radio frequency maze procedures are so simple and safe to accomplish that they are currently being done on any patient coming for mitral surgery with atrial fibrillation or flutter. The 1-year efficacy rate has been estimated in multiple publications to be in the 80% range base on CCM or ECG. Various questions remain unanswered: Is there an efficacy gain at using biatrial lesions compare to left sided lesions only? Are there subgroups of patients who despite maze surgery will always have recurrent events? When can we be certain enough that the arrhythmia ablation is successful to stop the anticoagulant treatment? Are there benefits for mitral valve patients with increase left atrial diameter to have prophylactic maze procedures at the time of their mitral surgery?

Biatrial lesions have never been compared head to head in a randomized fashion with left atrial maze before the paper of Gilinov for the CTSN investigators.[7] Some surgeons used the biatrial approach in patients with AF of longer duration or in those requiring concomitant tricuspid valve repair. Other authors used exclusively the biatrial approach to be as close as possible to the original Cox-maze III lesion set [6] while other used exclusively left atrial lesions because they are quicker to make and give sinus conversion rate possibly as effectively [11,12]. In our study, the recurrence rate was higher in the biatrial lesion group with a mean of AF burden slightly lower than in left lesion group. The second finding of the study is the high rate of sinus node dysfunction in the biatrial lesion group. Gillinov et al. [7] reported in a randomized study, no difference in freedom from atrial fibrillation between Left and bi-atrial lesion sets. However, the trial was not planned to have the power to distinguish between these two methods. In the same study, ablation was associated with an increased risk of implantation of a permanent pacemaker, but authors didn't study the difference between the two lesion sets. In the other hand, Pecha et al. [13] in a recent study using the same device employed in our study, a statistically significant higher rate of freedom from atrial fibrillation was observed in patients with a biatrial lesion with lower AF burden. However, they reported a double rate of postoperative pacemaker in patients with biatrial lesion. This study, even if very interesting and based on continuous recorder, has 2 major limitations: a retrospective design and the results of the biatrial ablation may be influenced by a certain learning curve. Two meta-analysis [14,15] including respectively 5885 patients with AF who received cardiac surgery alone or cardiac surgery with concomitant surgical ablation and 4647 patients with persistent or long-standing persistent AF showed statistically higher rates of freedom from AF at all points of follow-up to 3 years in patients with biatrial lesion. Focusing on the higher incidence of pacemaker seen in patients who received biatrial, this has been reported in previous studies [16,17]. This rate is probably related to the right side lines. Furthermore, Robertson et al. [18] support that this risk increases with age. In our study, the median age of patient presenting dysfunction of sinus node was slightly higher (67 versus 63.5 years).

Longstanding atrial fibrillation has a lower probability of cure following maze procedure [19,20] as assessed with spot ECG or symptoms. Similar results were found in our study with significant higher rate of freedom from atrial fibrillation and lower AF burden in the PAF group. Even, the pattern of recurrence of AF was different between the 2 groups mostly continuous in the CAF group.

Thus, it appears mandatory to assess atrial rhythm with continuous monitoring to insure safety of no anticoagulation therapy in these patients. Recent studies [21,22] comparing the accuracy of rhythm detection using different follow-up methods after AF ablation showed that intermittent rhythm monitoring underestimates the actual AF recurrence rate. Charitos et al. [23] reported that AF classification derived from continuous monitoring data reflected the temporal persistence of AF with greater accuracy and with less overlap between the AF classes. There was little agreement between the clinical AF classification and the objective and quantitative measures of AF temporal persistence. Overall, only 46.7% of the clinically classified paroxysmal AF patients were also classified as paroxysmal AF using the more objective device-related criteria. For the persistent AF classification this agreement dropped to 32.7%. And other studies [24] supported that all intermittent and symptom-based monitoring resulted in significantly lower sensitivity (range 31%-71%) and negative predictive value (range 21%-39%) for identification of patients with any ATAs/AF and underestimated ATAs/AF burden compared with continuous monitoring. The Reveal XT Performance Trial (XPECT) trial showed high sensitivity (96.1%) and negative predictive value (97.4%) for the detection of AF episodes by the device [10]. In our study, the Reveal XT allowed a more careful evaluation of how prevalent are subclinical forms of atrial fibrillation recurrences and AF burden. This information would help us not only to better assess the results of surgery but also in the tailoring of anticoagulation management following the maze procedure. In addition, we detected 5 cases of sinus node dysfunction in the recorder interrogation not revealed by CCM.

The fourth unanswered question is whether patients with enlarged left atrium in sinus rhythm preoperatively would benefit from prophylactic concomitant maze. It has been published that 20 to 30% of these patients will develop atrial fibrillation on mid-term follow-up [25]. In this paper from the Mayo clinic looking at 762 patients coming for mitral valve surgery in sinus rhythm, AF occurred in 180 patients (24%). One hundred thirty-six patients (18%) developed early AF (within the first 2 postoperative weeks). Among these patients, AF remained confined to the 2 weeks postoperatively (isolated early AF) in 69 patients (9%), whereas 67 patients (9%) had recurrence of AF (early plus late AF). Another subset of 44 patients (6%) experienced AF only after the 2 postoperative weeks (late AF only). Thus, a total of 111 patients (15%) experienced late AF. The incidence of late AF at 5 and 10 years was 12 ± 1% and 19 ± 2%, respectively. In a more recent paper of the Mayo clinic [26], 573 patients in sinus rhythm undergoing mitral valve repair for severe mitral regurgitation were studied. In a multivariable model, the risk of late AF was independently associated with advanced age (hazard ratio [HR], 1.05), left atrial size greater than 50mm (HR, 1.06), greater than mild preoperative TR (HR, 2.3), and diabetes (HR, 4.8). They conclude that late-onset AF after mitral valve repair for leaflet prolapse is significantly increased in patients with greater degrees of preoperative TR, and late survival is subsequently decreased advocating a concomitant prophylactic AF ablation in these categories of patients. In our study, 2 patients with sinus rhythm and large left atrium had a prophylactic AF ablation, 1 with biatrial lesion set and the other one with left atrial lesion set. The patient who had the biatrial lesion set developed a PAF 5 months after surgery. This patient had also a moderate to severe tricuspid regurgitation preoperatively not addressed. On the other hand, the 2 other patients who didn't receive AF ablation were free from AF at 1-year follow-up. Finally, most of our AF ablation procedures were done through a minimally invasive approach. Recent study [27] supported that AF ablation performed through a right mini-thoracotomy is as effective as sternotomy in the treatment of atrial fibrillation. This approach was associated with fewer complications and decreased mortality.

Limitations of study

The major limitation of this study is the small size of the

population. We planned initially a randomized clinical trial enrolling 135 patients, 45 patients in each group but we stopped the trial mainly because of the apprehension of patients to undergo a second intervention to explant the Reveal. Further limitations are due to technical aspects of the device with its limited storage capacity of 49.5 minutes with risk to over or underestimate AF burden. Furthermore, the recorder only detects AF episodes with a duration of at least 2 minutes. This 2-minute blanking period of the recorder may result in underestimation of AF episodes. Finally, the definition of persistent atrial fibrillation in the guidelines was revised after the trial completed enrollment.

Conclusion

Using a continuous events recorder, biatrial lesion set seems to be not superior to the left lesion set in term of AF recurrence with slightly lower AF burden. Continuous AF seems to be the subgroup of patients who despite maze surgery will always have recurrent events while the AF ablation seems to be efficient in the PAF group. Finally, the cohort of patients with sinus rhythm and large atrium was too small to conclude if the prophylactic AF ablation was benefit to this group of patients. A bigger cohort is mandatory to confirm or infirm these findings.

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