Should We Ablate Atrial Fibrillation During Coronary Artery Bypass Grafting and Aortic Valve Replacement?

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Background. This study evaluates the safety and efficacy of concomitant atrial fibrillation (AF) ablation in patients with AF undergoing coronary artery bypass grafting (CABG) or aortic valve replacement (AVR) or both.

Methods. This is a single-center retrospective study of patients with AF presenting for CABG or AVR or both between 2009 and 2013. They were divided into an ablation group that underwent concomitant AF ablation and a control group that did not. Follow-up data were obtained using telephone interviews. The data were 100% complete with a median follow-up of 30 months.

Results. A total of 375 patients with AF presented for CABG (44%), AVR (27%), or CABG and AVR (29%). The ablation (129 patients) and control (246 patients) groups had similar baseline characteristics. The ablation group had significantly longer cardiopulmonary bypass and cross-clamp times, adding a mean of 31 ± 3 and 22 ± 3 minutes ($p < 0.01$ for both), respectively. There were similar unadjusted rates of hospital mortality (4.7% versus 5.3%, $p = 0.79$), stroke (3.1% versus 3.3%, $p = 0.94$), and reopening (4.7% versus 6.5%, $p = 0.46$) between the groups. The intensive care and hospital length of stays were similar. The ablation group had a lower incidence of postoperative AF (27% versus 78%, $p < 0.01$). Adjusted operative mortality was similar, but the intervention group had significantly lower odds of postoperative AF (odds ratio 0.11, $p < 0.01$). Although there was no difference in mid-term survival, the ablation group had higher mid-term AF-free survival ($p < 0.01$) and a trend toward higher anticoagulation-free ($p = 0.09$) and stroke-free survival ($p = 0.08$).

Conclusions. Concomitant AF ablation in patients with AF undergoing CABG or AVR or both does not increase perioperative rates of mortality or morbidity. Moreover, concomitant AF ablation is effective at reducing postoperative AF burden and increases mid-term AF-free survival.

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Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and frequently presents in association with other cardiovascular problems such as valvular and coronary artery disease [1]. In patients undergoing cardiac operation, preoperative AF is common, with a prevalence of 11% in North America [2]. Preoperative AF portends a poorer outcome after coronary artery bypass grafting (CABG) and aortic valve replacement (AVR). In fact, untreated AF in patients undergoing cardiac operation is associated with increased risk of perioperative stroke and mortality and reduced long-term survival [3–6].

The efficacy and safety of concomitant AF ablation in patients with AF undergoing mitral valve operation has been previously demonstrated [7]. Although mitral valve disease directly contributes to the genesis of AF through left atrial enlargement, patients with aortic valve and coronary artery disease are pathophysiologically distinct from patients with mitral valve disease. Atrial structural abnormalities, including fibrosis, dilatation, ischemia, and hypertrophy, are some of the mechanisms leading to AF. Extracardiac factors such as hypertension or obesity, which are commonly found in these patients, are also known to be involved in AF genesis. Therefore, extrapolation from studies on concomitant ablation in mitral valve operation to patients undergoing aortic valve and coronary operations is inappropriate.

Surgeons in North America remain hesitant to add AF ablation to CABG, AVR, or CABG and AVR with less than 35% of patients receiving concomitant AF ablation, despite a history of AF [2]. The dearth of data on concomitant AF ablation during CABG or AVR combined with the perceived increased operative risk from adding atriotomies necessitates a thorough evaluation of its safety and efficacy during CABG or AVR. The objective of this study is to evaluate the safety and efficacy of concomitant AF ablation during CABG, AVR, or CABG and AVR and its mid-term efficacy in terms of AF recurrence, the need to resume anticoagulation, and stroke-free survival. We hypothesize that adding a

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concomitant AF ablation is safe and does not increase perioperative rate of morbidity and mortality; reduces AF burden postoperatively; and increases AF-free, anticoagulation-free, and stroke-free survival.

Patients and Methods

Study Design

This is a single-center retrospective study of prospectively collected data, which was obtained from the University of Ottawa Heart Institute cardiac surgery and anesthesiology databases. All patients with AF presenting for isolated CABG, isolated AVR, or combined CABG and AVR between 2009 and 2013 were included. These patients were divided into a group that underwent concomitant AF ablation and a control group that did not undergo any ablation procedures. Preoperative, operative, and postoperative data were obtained on all patients, and the two groups of patients were compared. In addition to routine follow-up, all patients or their health care providers were contacted for telephone interviews for vital statistics for a mean follow-up of 32 months, which was complete.

AF during hospitalization was diagnosed using both continuous telemetry and 12-lead electrocardiograms (ECGs). Patients at our center are followed at 30 days, 3 months, 6 months, and 1 year by the surgeon (30 days) and the cardiologist (subsequent follow-ups). Patients who had valve replacement are also followed up yearly thereafter. It is standard that all postoperative patients received a 12-lead ECG, a chest roentgenogram, and routine blood work (complete blood count, electrolytes, blood urea nitrogen, and creatinine) on their first postoperative visit. At subsequent visits it is standard that patients receive a 12-lead ECG, and any further tests were at the discretion of the ordering physician. AF was diagnosed using conventional methods, including both 12-lead ECGs and Holter monitoring. A Holter monitor was ordered at the discretion of the surgeon or cardiologist, which was usually due to patient-reported symptoms of palpitations. However, there was no prespecified protocol for ordering Holter monitoring. The duration of the monitoring was most commonly for 48 hours.

The primary purpose of the study is to compare safety outcomes between patients who had AF ablation and patients who did not. The primary safety end point was the occurrence of death, stroke, or myocardial infarction. Secondary end points included the incidence of postoperative bleeding requiring transfusion of packed red blood cells or reopening, rates of acute renal failure, pneumonia, and prolonged ventilation (>24 hours). Other secondary end points included mid-term survival, stroke-free survival, AF-free survival, and anticoagulation-free survival (freedom from warfarin or novel anticoagulants).

Ethics

The University of Ottawa Heart Institute has approval from its institutional research ethics board to anonymously publish data that are prospectively collected from the perioperative surgery clinic. Data were only used from patients who have provided consent to allow confidential use of their clinical information. Consent was also obtained from patients to collect information from them or their physicians through telephone interviews.

Surgical Technique

The decision to add an AF ablation procedure and the choice of lesion set was at the discretion of the surgeon. For biatrial AF ablation, the Cox-Maze IV lesion set was used as previously described [8]. Left-sided AF ablation used the left atrial lesion set from the Cox-Maze IV. Pulmonary vein isolation (PVI) included lesions encircling both right and left pulmonary veins. These lesions included a cuff of left atrium and at least three different applications of the bipolar clamp were performed on each side. A combination of radiofrequency and cryothermy was used as the energy sources. Cryothermy ablation lines were performed using 2 minutes of adequate contact with the tissue. No classic "cut and sew" procedure was performed in these patients. All patients had a standard median sternotomy, were placed on cardiopulmonary bypass, and underwent diastolic arrest using cold blood cardioplegia. All patients undergoing AF ablation also had a left atrial appendage (LAA) excision, which consisted of amputation and oversewing at the base of the LAA.

Statistical Analysis

Data were imported and analyzed in STATA 14 statistical software (Stata Corporation, College Station, TX). Continuous variables were expressed as a mean $\pm$ standard error or median $\pm$ interquartile range, whereas categorical variables were described as a percentage of the total. Continuous data were compared with an independent Students *t* test when normally distributed and with a Wilcoxon rank sum test when data were skewed. Categorical variables were compared with a χ^2 test or Fisher's exact test when count was less than 5. Multivariable logistic regression was used to adjust for preoperative and operative patient characteristics, including age, sex, type of AF, history of stroke, diabetes mellitus, hypertension, dyslipidemia, chronic obstructive pulmonary disease, left ventricular ejection fraction, redo operation, urgency of procedure, type of operation, and bypass and cross-clamp times. Kaplan-Meier survival curves were used to summarize survival, stroke-free survival, AF-free survival, and anticoagulation-free survival. Log-rank test and Cox regression model were used to compare groups after assessing the feasibility of the proportional hazards assumption. The proportionality assumption of the Cox regression model was tested using plots of log (-log Survival) versus log (time). A p value less than 0.05 was considered statistically significant throughout all analyses.

Results

Between the year 2009 and 2013, 375 patients known to have AF presented for isolated CABG, isolated AVR, or combined CABG and AVR. Those patients were divided

Table 1. Baseline Patient and Echocardiographic Characteristics

Characteristic	No Ablation (n = 246)	Ablation (n = 129)	*p* Value
Age, mean ± SEM, years	74 ± 0.6	72 ± 0.8	0.05
Male sex, %	70	80	0.03
Diabetes, %	37	38	0.91
Hypertension, %	78	74	0.48
Dyslipidemia, %	72	68	0.45
Smoking, %	39	36	0.57
COPD, %	15	17	0.61
Chronic kidney disease, %	16	13	0.56
Stroke/TIA history, %	19	20	0.86
Peripheral vascular disease, %	15	18	0.48
Paroxysmal AF, %	36	46	0.07
Previous AF Ablation, %	1.2	2.3	0.42
LVEF, mean ± SEM, %	48 ± 1.4	49 ± 1.6	0.62
LA diameter, mean ± SEM, cm	4.5 ± 0.1	4.6 ± 0.1	0.44

AF = atrial fibrillation; COPD = chronic obstructive pulmonary disease; LA = left atrium; LVEF = left ventricular ejection fraction; SEM = standard error of the mean; TIA = transient ischemic attack.

into two groups: the control group (246 patients) was comprised of patients who did not undergo any procedure for AF, and the ablation group (129 patients) was comprised of patients who had an AF ablation procedure in addition to CABG or AVR.

The preoperative characteristics of the two groups (Table 1) were quite similar except that the ablation group was slightly younger and more likely to include male patients than the nonablation group. Most patients had nonparoxysmal AF in both groups (no ablation: 64%; ablation: 54%, $p = 0.07$). A considerable proportion of patients had a history of preoperative stroke or transient ischemic attack and peripheral vascular disease, but there were no differences between the groups. The mean LA diameter was also similar between the two groups.

The types of procedures performed and the surgical urgency were balanced between groups, with about half of the patients undergoing CABG and the remaining half divided between AVR and combined CABG and AVR (Fig 1A). Although most operations were performed electively, about one-third had an urgent operation (Fig 1B). The ablation group had significantly longer operative times (Fig 1C). Performing an AF ablation added a mean of 31 ± 3 (range, m8 to 50 minutes) and 22 ± 3 minutes (range, 8 to 34 minutes) (both $p < 0.01$) to the cardiopulmonary and cross-clamp times, respectively. In the ablation group, the majority of patients with paroxysmal AF (69%) underwent PVI, whereas the majority of patients with nonparoxysmal AF (71%) received a full Cox-Maze IV (biatrial) lesion set (Table 2). Of 10 surgeons, 4 performed 95% of the AF ablations, 2 of which performed 72%. For the two most active AF ablation surgeons, one had about equal distribution between the lesion sets (left: 29%, biatrial: 36%, PVI: 35%), and the second performed mostly biatrial (43%) and PVI (57%) lesions. The third surgeon performed mostly biatrial lesions (94%), whereas the fourth surgeon performed mostly PVI and to a lesser extent LA lesions (left: 25%, biatrial: 8%, PVI: 67%). The two most active surgeons had an ablation rate of greater than 75% among patients presenting with AF, whereas the third and fourth surgeons had ablation rates of 25% and 33%, respectively.

The unadjusted perioperative outcomes (Table 3) demonstrate similar rates of death, myocardial infarction, and stroke. Adding an AF ablation procedure to CABG or AVR did not increase bleeding and reopening rates (no ablation: 6.5%, ablation: 4.7%, $p = 0.46$). Softer clinical end points such as acute renal failure, pneumonia, and prolonged ventilation were also similar between the two groups. Performing an AF ablation did not significantly increase postoperative permanent pacemaker insertion rates in this cohort (no ablation: 4.2%, ablation: 5.5%, $p = 0.57$). Both groups had similar intensive care and hospital length of stays. The incidence of postoperative AF was significantly lower in the ablation group (no ablation: 78%, ablation: 27%, $p < 0.01$).

After using multivariable logistic regression analysis to adjust for important clinical characteristics (Table 4), performing an AF ablation remained protective of postoperative AF (odds ratio 0.11, 95% confidence interval: 0.06 to 0.18, $p < 0.01$) but did not influence any of the other end points.

Follow-up data demonstrate no significant difference in mid-term survival (Fig 2). However, there was a trend toward a higher stroke-free survival (Fig 3) in the ablation group ($p = 0.08$), with the curves starting to diverge between the third and fourth years. Similarly, there was a trend toward a higher anticoagulation-free survival (Fig 4) in the ablation group ($p = 0.09$). The ablation group had a significantly higher AF-free survival ($p < 0.01$) (Fig 5). When analyzing whether the AF ablation lesion set influences AF-free survival, there was no significant difference between pulmonary vein isolation, LA, and biatrial lesion sets. However, around the fourth year, the AF-free survival curves begin to diverge (Fig 6).

Comment

We sought to evaluate the safety and efficacy of adding a concomitant AF ablation to patients with AF presenting for CABG, AVR, or CABG and AVR by comparing patients who underwent an ablation with patients who did not. We observed that adding an AF ablation did not increase operative risk in terms of mortality and perioperative complications. However, concomitant AF ablation was associated with significantly reduced postoperative AF burden. Although mid-term survival was similar, there was an increase in AF-free survival and a trend toward an increased stroke-free and anticoagulation-free survival in the ablation group.

Other studies have already shown that patients with AF presenting for cardiac operation have an increased risk of early and late mortality compared with patients without AF [3–6]. The results in this study bolster previous evidence that correction of AF was not associated with

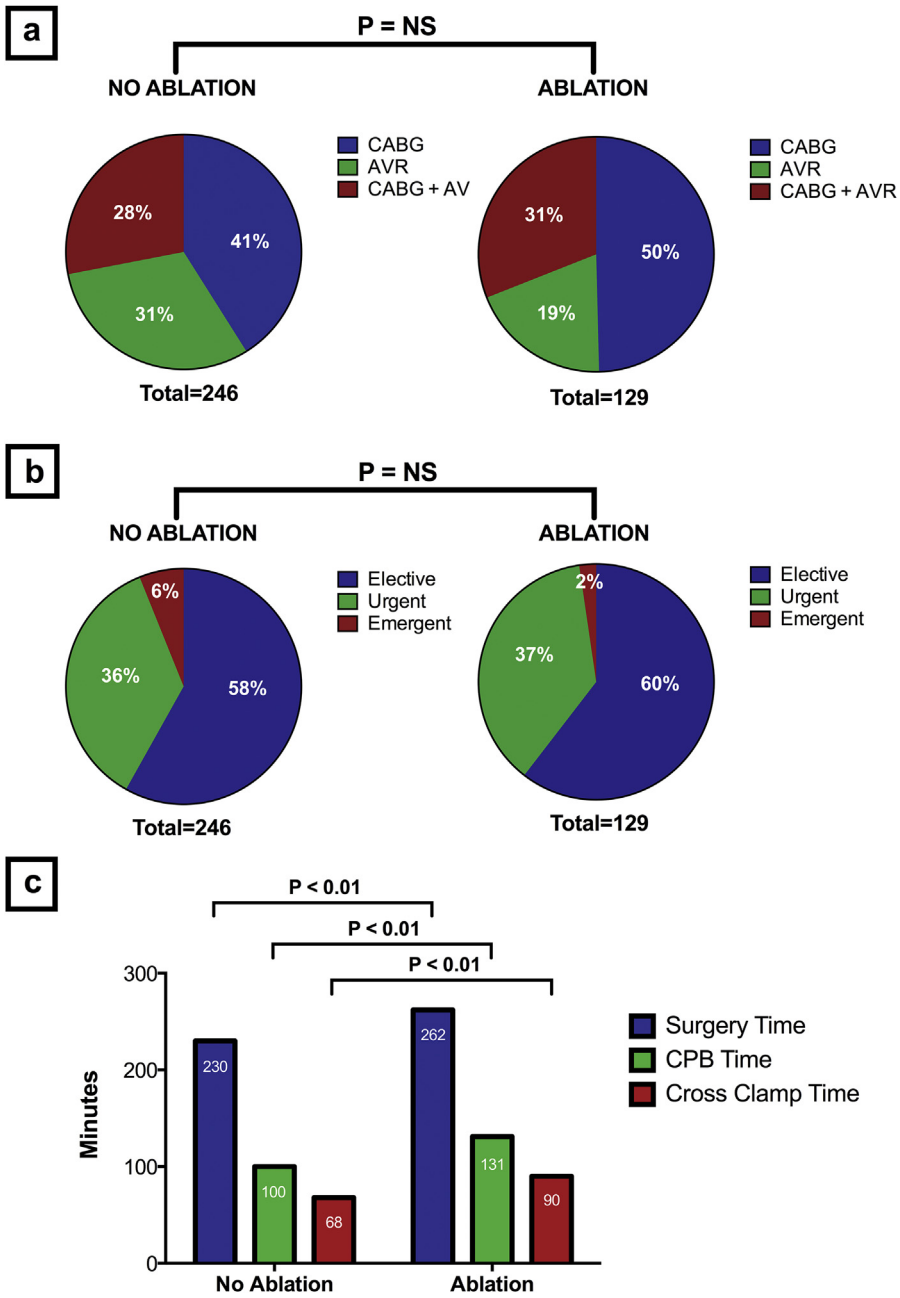

Fig 1. Operative characteristics in ablation and nonablation groups: (A) operation types, (B) surgical urgency, and (C) surgical times. (AV = aortic valve; AVR = aortic valve replacement; CABG = coronary artery bypass grafting; CPB = cardiopulmonary bypass; NS = not significant.)

increased operative rate of mortality or morbidity. However, one of the main strengths of this study is that the ablation group was compared with a control group with AF patients who did not receive an ablation. This is in contrast to some of the previous studies [9, 10] that compared patients with AF receiving an ablation with a control group of patients without AF who did not undergo ablation. Therefore, the increased risk associated with adding a concomitant AF ablation, widely perceived by surgeons, continues to be unfounded. In fact, patients in this study represent a higher-risk population than other studies. The patients had a mean age of 73 years, had significant comorbidities (Table 1), most had nonparoxysmal AF (Table 1), and about a third had urgent operation and combined CABG and AVR (Fig 1). The patients in this study had a similar profile to the patients in a study specifically addressing surgical ablation in high-risk patients [10], both arriving at the same conclusions. Furthermore, adding an AF ablation significantly reduced the postoperative AF burden by a 51% absolute rate reduction. Although other groups found improved long-term survival with concomitant AF ablation [3, 11], this study did not demonstrate a difference in survival. However, there was an observed increase in AF-free

Table 2. Ablation Lesion Sets According to Type of Atrial Fibrillation

AF Type	Lesion Type		
	Left Atrial	Biatrial	PVI
Paroxysmal	21	10	69
Nonparoxysmal	28	51	21
Persistent	24	52	24
Longstanding persistent	30	50	20

Values are %.

AF = atrial fibrillation; PVI = pulmonary vein isolation.

survival and a trend toward an increased stroke-free and anticoagulation-free survival in the ablation group, all of which reflect the efficacy of AF ablation, combined with appropriate LAA management.

From the evidence in the literature, the Heart Rhythm Society guidelines [12] recommend concomitant AF ablation for symptomatic patients with all types of AF and having failed a class I or class III antiarrhythmic drug treatment (IIA indication, level C evidence). For patients with paroxysmal and persistent AF who did not fail antiarrhythmic drugs, a similar recommendation was given (IIA indication, level C evidence). However, patients with long-term persistent AF who did not fail antiarrhythmic drugs, a class IIB recommendation (level C evidence) was given for concomitant ablation. The International Society for Minimally Invasive Cardiothoracic Surgery published a similar set of recommendations [13]. Concomitant AF ablation was given a class I (level A evidence) for its efficacy in restoring sinus rhythm, both in the short and long term. Ablation was also associated with improved exercise tolerance and increased ejection fraction (class IIA, level A evidence), and a reduced risk of stroke and thromboembolic events and increased long-term survival (class IIA, level B evidence). Importantly, adding a concomitant AF ablation is not associated with increased rate of operative mortality or other perioperative complications (class I, level A evidence). Despite the evidence and the recommendations, less than 35% of patients with AF receive concomitant ablation during CABG, AVR, or CABG and AVR [2].

Because all the evidence points to a benefit of ablation without added risk, the reason for the low adoption of concomitant AF ablation is one of three. First, it may be due to lack of awareness of the discussed evidence and guidelines. Second, it may be due to a lack of training or low comfort level in performing a safe and effective AF ablation, especially when a biatrial lesion set is to be added to a complex operation on a high-risk patient [14]. Third, it may be that some surgeons still dismiss observational studies and await a randomized controlled study.

To address these concerns, we need to fill knowledge gaps by disseminating the evidence and recommendations to a wide cardiac surgical audience, not only to those interested in AF operation. Moreover, we need to increase our training opportunities through residencies and fellowships. Third, we may need large prospective trials to fully establish the benefits of concomitant AF ablation and to ensure penetration of this procedure to more surgeons. Once again, AF is prevalent in patients with coronary and aortic valve disease, and it is likely that every cardiac surgeon will encounter such patients. From the data from this study and others, we believe that every

Table 3. Unadjusted Perioperative Outcomes

Outcome	No Ablation (n = 246)	Ablation (n = 129)	*p* Value
Death	5.3	4.7	0.79
Myocardial infarction	6.6	10	0.24
Stroke	3.3	3.1	0.94
Reopening	6.5	4.7	0.46
Acute renal failure	29	33	0.42
Pneumonia	6.9	11	0.19
Prolonged ventilation	22	18	0.35
Pacemaker insertion	4.2	5.5	0.57
LOS in ICU, days	2.5 (4)	3.0 (4)	0.27
LOS in hospital, days	10 (10)	11 (9)	0.60
Postoperative AF	78	27	<0.01

Values are % or median (IQR).

AF = atrial fibrillation; ICU = intensive care unit; IQR = interquartile range; LOS = length of stay.

Table 4. Adjusted Perioperative Outcomes

Outcome	OR with Ablation	95% CI	*p* Value
Death	0.97	0.35–2.70	0.95
Myocardial infarction	1.65	0.75–3.62	0.21
Stroke	0.99	0.29–3.42	0.98
Reopening	0.76	0.28–2.02	0.58
Acute renal failure	1.25	0.78–2.00	0.35
Pneumonia	1.49	0.70–2.17	0.19
Prolonged ventilation	0.76	0.44–1.31	0.32
Pacemaker insertion	1.43	0.52–3.96	0.49
Postoperative AF	0.11	0.06–0.18	<0.01

AF = atrial fibrillation; CI = confidence interval; OR = odds ratio.

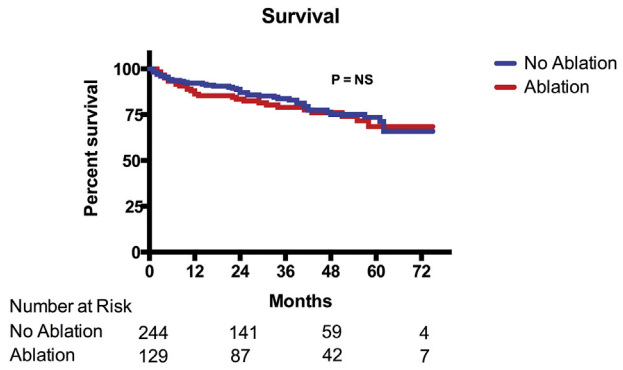

Fig 2. Kaplan-Meier survival curves for the ablation and nonablation groups. (NS = not significant.)

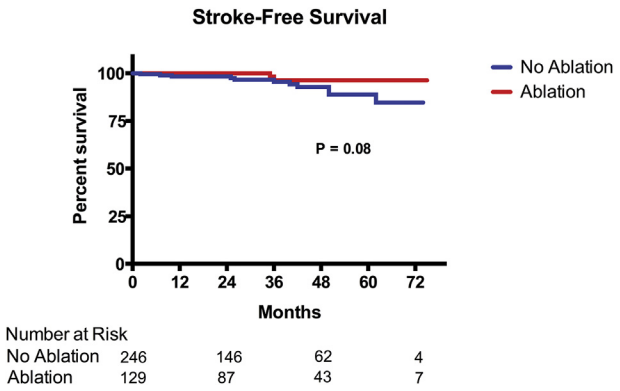

Fig 3. Kaplan-Meier curves of stroke-free survival for the ablation and nonablation groups.

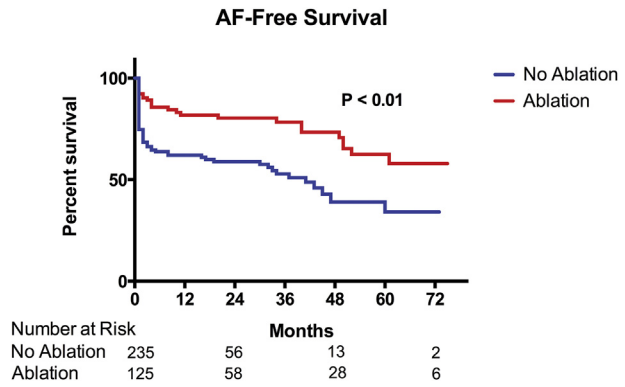

Fig 5. Kaplan-Meier curves of atrial fibrillation-free survival for the ablation and nonablation groups.

patient presenting with AF for a CABG, AVR, or CABG and AVR should be considered for an AF ablation.

A signal that deserves mention and further scrutiny in larger prospective trials is the divergence of stroke-free survival with a trend toward higher survival in the ablation group at around the fourth year. Similarly, a biatrial lesion set seems to begin diverging with a trend toward higher AF-free survival around the fourth year. Although these observations are not statistically significant and will need larger studies to confirm, the corollary is that any major prospective study may need to follow patients up to and beyond 5 years to discern possible differences in hard clinical end points such as stroke-free survival.

The postoperative permanent pacemaker (PPM) insertion rate in this study was lower than that reported [15–19] in the literature (6% to 23%) and not significantly higher in the ablation group compared with the nonablation group (no ablation: 4.2%; ablation: 5.5%, $p = 0.57$). It has been shown that most PPM insertions are due to sinus node dysfunction [19, 20]. However, it remains unclear whether the sinus node dysfunction is a result of the AF ablation procedure or an underlying rhythm disturbance in addition to AF, which only manifests once AF is treated. Without proper atrial ECGs and electrophysiologic studies, this matter remains within the realm of speculation and a subject to be explored in future studies. The only part of the AF ablation that may induce sinus node dysfunction is the right atriotomy (RA)-superior vena cava (SVC) ablation line. The sinus node is a complex structure that is not limited to the RA-SVC junction anteriorly. First, its anatomic distribution and blood supply is variable among different patients [21, 22]. Second, there are tachycardia and bradycardia centers (part of the atrial pacemaker complex) found slightly more lateral and inferior along the right atrium and away from the RA-SVC junction [20–22]. We believe that the RA-SVC ablation line must be quite lateral and slightly posterior for it to avoid potential sinus node dysfunction, which may have contributed to the low PPM rates in this study. Alternatively, our patient population may have a lower prevalence of preoperative sinus node dysfunction. Finally, some patients receive PPM due to atrioventricular node dysfunction, primarily those that had an AVR procedure.

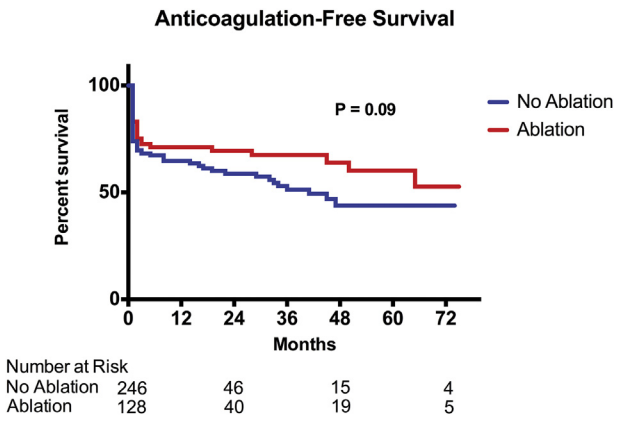

Fig 4. Kaplan-Meier curves of anticoagulation-free survival for the ablation and nonablation groups.

Limitations

This study is a retrospective review with its inherent limitations. Although selection bias may be present due

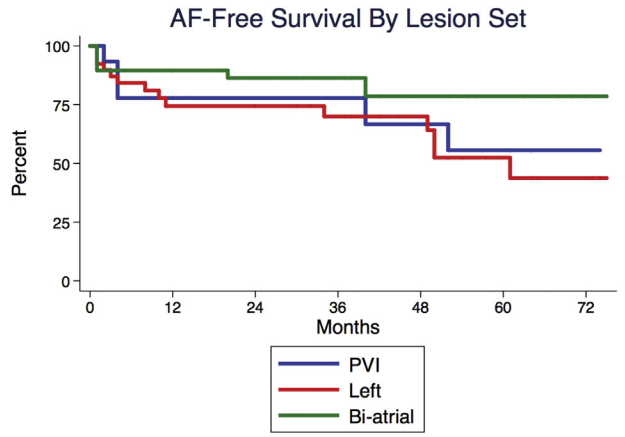

Fig 6. Kaplan-Meier curves of atrial fibrillation (AF)-free survival for pulmonary vein isolation (PVI), left atrial, and biatrial ablation lesion sets.

to differences in unmeasured variables, most of the measured variables in the ablation and control groups were similar at baseline. Furthermore, we adjusted for the few differences in measured variables to limit potential selection bias. Other limitations and sources of bias include the choice of AF ablation lesion set, which was left to the discretion of the surgeon without a prespecified consensus, and some of the analyses included all the AF ablation lesions together to have a large enough number for the analyses. A prospective multicenter study with a larger volume and prespecified AF ablation lesion sets may overcome this limitation and may allow analyses to be performed on each lesion set with sufficient power to derive meaningful conclusions.

During follow-up we diagnosed AF using a combination of 12-lead ECGs and Holter monitoring, which may underestimate the AF incidence in our population. Although continuous monitoring using implantable loop recorders may provide more information, a recent publication reported that the extra information provided by continuous monitoring is riddled with false-positive readings and conventional monitoring (as was done in this study) and is equivalent to continuous monitoring [23]. There remain many barriers to broad implementation of continuous monitoring as was suggested by the investigators.

There was no postoperative or follow-up data pertaining to left ventricular ejection fraction or chamber dimensions. Although these variables were not objectives of the study, it would be interesting to understand how they change in patients who had AF ablation versus patients who did not.

Conclusion

Patients undergoing isolated CABG, AVR, or combined CABG and AVR with a history of AF can undergo concomitant AF ablation without increased surgical risk. Surgical AF ablation in this patient population is effective at reducing postoperative AF burden and may have long-term benefits such as freedom from AF. Concomitant AF ablation should be seriously considered in these patients.

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DISCUSSION

DR VINAY BADHWAR (Pittsburgh, PA): Congratulations on an excellent presentation. Your data mirror that of the national experience, and I congratulate you on publishing your data.

The question I had to you is: Did you examine the reason for not doing a full Cox-maze in terms of the surgeon level and when they defaulted to a PVI? And the second question is: How was the left atrial appendage managed both in the maze patients and in the non-maze AF patients?

DR AL-ATASSI: I did not mention it, similar to the previous presentation, but all the atrial appendages were excised. So we excise and oversewed the left atrial appendage for pretty much anyone coming in with AF for a maze procedure. If someone is coming in with AF and not receiving a maze procedure, I think it depends on the surgeon's patient-by-patient evaluation rather than experience. I do not have a number to quote how many patients in total had the left atrial appendage excised, but all the maze patients had their appendage removed.

In terms of lesion set and surgeon experience, we have not looked at that. We have eight surgeons at our institution, and three or four are more active AF surgeons, whereas the other half are not. So we have not looked at the reasons for PVI, but I suspect it might be due to surgeon experience, coupled with their interpretation of the literature, so it will be interesting to look at.

DR BADHWAR: Those two elements will be important in the study, particularly if they were treated, the AF population that did not have a maze, if they had appendage treated, to document how many of those as you do follow up.

DR AL-ATASSI: That is a great point. Thank you.

DR BOBBY KONG (Ann Arbor, MI): It is great that we look at longer term survival than 30 days. But in this case, you know, as you point out one of the weakness, this is a retrospective study, not a randomized study. But even with that, have you tried to match them, propensity match these patients so that we are comparing apple with apple when we look. I think that is particularly important for long-term survival.

DR AL-ATASSI: After adjusting, we have not seen much differences. And I agree this is always a weakness in retrospective studies. I tried to show that in our baseline characteristics and the types of procedures they had that they are a pretty homogenous group, they are quite similar, so we were lucky in that sense that there were very few differences, only age and male proportion, those were the only things that stood out. Of course, there are other unmeasured variables that may be different that we have not accounted for and which would be resolved with a randomized trial; however, propensity matching would still not adjust for unmeasured variables. After adjusting the message has not changed. We have not done propensity matching, which would be another way to adjust. We should still be retaining a pretty large N because of the homogeneity of the groups if we match, so we can take a look at that. But I suspect the message will not change because we tried a different type of adjusting and it has not, so I suspect it will remain the same message.