Epicardial Ultrasonic Ablation of Atrial Fibrillation During Concomitant Cardiac Surgery Is a Valid Option in Patients With Ischemic Heart Disease

Mark A. Groh, MD; Oliver A. Binns, MD; Harry G. Burton, III, MD; Gerard L. Champsaur, MD; Stephen W. Ely, MD, PhD; Alan M. Johnson, MD

Background—Surgical therapy of atrial fibrillation concomitant to coronary bypass grafting using epicardial Ultrasound technology was assessed after a minimum 6-month follow-up.

Methods and Results—A cohort of 98 consecutive patients with a mean age of 72±7.58 years and a primary diagnosis of ischemic heart disease had surgery for structural disease. Coronary artery bypass grafting was isolated (n=51) or associated (n=47) with various combinations of aortic, mitral, tricuspid, and left ventricular restoration surgery. Atrial fibrillation duration ranged from 6 to 360 months (mean 71 months) and was permanent in 47 patients, paroxysmal in 34, and persistent in 17. Left atrial mean diameter was 48±6.71 mm. A circumferential ablation was performed off-pump, before the concomitant procedure, and was always associated with an epicardial mitral line lesion using the same technology. At 3-, 6-, and 12-month visits, patients were routinely evaluated by physical examination, ECG, chest X-ray, and 24-hour Holter. There were 1 early death (1%) and 4 extracardiac late deaths. A pacemaker was implanted in 4 patients. Mean follow-up time was 325 days, 2 patients being lost to follow-up. Freedom from atrial fibrillation and flutter at the 6-month visit was 84% for the entire population, 76% in patients with permanent, and 91% in patients with paroxysmal atrial fibrillation. At the 1-year visit, 85% were free from atrial fibrillation or flutter.

Conclusion—Epicardial beating heart ablation using therapeutic ultrasound is safe, reliable, and can easily treat atrial fibrillation in a difficult surgical population of patients with primary ischemic heart disease. (Circulation. 2008;118[suppl 1]:S78–S82.)

Key Words: atrial fibrillation ■ ultrasound ■ ischemic heart disease ■ coronary surgery ■ clinical outcomes

Atrial Fibrillation (AF) is the most prevalent cardiac rhythm disorder, affecting 2.2 million patients in the United States and approximately 6 million patients worldwide. The incidence of AF increases with age with a prevalence of 4% in the population over 60 years and of more than 9% after 70 years of age.1–3 As the general U.S. population ages, the cohort of patients undergoing surgical repair of structural heart disease is also advancing and hence the incidence of AF is increasing in this group. Furthermore, AF has been identified as an incremental risk factor for time related mortality and morbidity in the context of surgery for ischemic heart disease.4 Recent publications based on extensive series of patients undergoing coronary artery bypass graft (CABG) procedures5–6 have shown that uncorrected preoperative atrial fibrillation was associated with increased late cardiac morbidity and mortality and poor long-term survival. Their conclusions were that the data supported consideration of atrial fibrillation surgery at the time of coronary artery bypass grafting.

In February of 2005 we launched an active program of surgical AF ablation investigating a novel approach based on an epicardial, beating heart ultrasonic-based technology (Epicor Medical, St. Jude Medical Inc).7 All patients with AF concomitant to ischemic heart disease and subjected to cardiac surgery underwent an AF ablation and were consecutively and prospectively entered in the study. The objective of the study (approved by the local ethics committee with informed consent obtained from the patients) was to retrospectively analyze our experience with this approach and its effect on morbid and mortal outcomes in this population previously recognized to be at high surgical risk.8

Materials and Methods

Patients and Procedures

A cohort of 98 consecutive patients (25% female) with a primary diagnosis of ischemic heart disease associated with various forms of AF were prospectively enrolled in the study after undergoing a CABG at Mission St Joseph Hospital, Asheville, NC, between 2/15/2005 and 10/30/2006. Coronary bypass surgery was isolated in 52% and associated in 48% of the cases to various combinations of concomitant surgery (Table 1). Globally, 44 patients or 45% had 4 or more grafts, for an overall average 3.5 grafts per patient.

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Results

Early intraoperative and postoperative complications (up to 30 days or longer if the patient remained hospitalized) were represented by an isolated transient ischemic accident leaving no neurological deficit by discharge in a 72-year-old patient after isolated CABG and a sternal infection. There were 6 episodes of AF before the patient’s discharge and 4 conduction disturbances requiring the implantation of a pacemaker.

There were also 7 episodes of pneumonia requiring medical therapy and 12 episodes of pleural effusions requiring thoracentesis from 8 to 90 postoperative days. Finally, a patient had to be reoperated on 14 months after the procedure for prosthetic valve dysfunction. There were noticeably no surgical revisions for bleeding. There was one early death, on day 9, in a 69-year-old patient with a history of intestinal ischemia and left main stenosis who had an acute and massive intestinal infarction.

There were 4 extracardiac late deaths, occurring more than 30 days after surgery. The causes were multiorgan failure in a patient on hemodialysis and sepsis associated with a chronic indwelling venous port, 2 cases of Methicillin-resistant Staphylococcus aureus pneumonia with generalized sepsis, and esophageal cancer.

None of the early or late events was deemed related to the device or the procedure.

Efficacy was evaluated in terms of “Freedom from AF” over time. Among the original 98 patients enrolled in the study, 2 patients were lost to follow-up. The mean follow-up time was 325 days, median 282 days with a range of 8 to 665 days. Given early and late mortality, there were 91 patients available for follow-up analysis at 6 months, and 39 patients available at 12 months. All patients with pacemakers underwent pacemaker interrogation in search of a silent arrhythmia.

Freedom from AF was further defined as absence over time of AF or of any form of “left atrial reentry tachycardia” (LART), or any left-sided flutter or focal tachycardia of any duration at the 24-hour Holter monitoring.

Right-sided flutter, as seen in one patient who required a secondary catheter ablation, is commonly unknown or “hidden” behind AF at the time of surgery, and was not considered a failure because neither the device nor the procedure

Table 1. Procedures Associated With CABG in 47 Patients

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No.</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral valve surgery</td>
<td>16</td>
<td>29</td>
</tr>
<tr>
<td>Isolated</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Mitrotricuspid</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Isolated aortic valve surgery</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Dor procedure</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>With mitral repair</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Aortic root surgery</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>ASD closure</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td></td>
</tr>
</tbody>
</table>

Detailed demographics are summarized in Table 2. Patient age (Figure 1) was greater than 70 years in 62% (61 patients). LVEF was less than 40% in almost half (41 patients) and less than 30% in almost one fourth (22 patients). AF was permanent in 47 patients (48%), paroxysmal in 34 (35%), and persistent in 17 (17%).

Comorbidities included hypertension (78%), hypercholesterolemia (69%), history of smoking (68%), diabetes (43%), cerebrovascular disease (25%), peripheral vascular disease (19%), previous stroke (7%), and renal failure (2%). A prior cardiac open-heart procedure had been done in 10 patients, with findings at operation that did not preclude an epicardial ablation using the Epicor technology.

AF ablation was performed after the sternotomy by inserting the Epicor device circumferentially around the pulmonary veins on the beating heart, before the initiation of bypass, during an approximately 10-minute algorithm as described elsewhere. A mitral line lesion was also routinely performed after lifting the apex of the heart and exposing the posterior pulmonary veins. Once exposure was obtained, a specific hand held epicardial “wand,” using the same ultrasonic technology, was activated to connect the previously created circumferential line to the mitral annulus in the line of the left inferior pulmonary vein (Figure 2). This portion of the procedure was also done off pump and generally required an 85-second maximum application.

Postoperative Protocol

Anticoagulant therapy (Coumadin) was started after transitioning from Heparin in the immediate postoperative period and maintained for a minimum of 1 year. Prophylactic antiarrhythmic drug (generally Amiodarone) was started intravenously at the completion of the procedure and maintained orally for at least 3 months after surgery at a dose of 200 mg/d. External cardioversion was not recommended in the early postoperative period to allow full maturation of the ablation line. However, if AF persisted postoperatively beyond 10 weeks, cardioversion was performed. A physical examination, standard 12-lead ECG and 24-hour Holter monitoring were performed systematically at the 3-, 6-, 12-, and 18-month follow-up visits.

Statistical Analysis

Data were entered into a computerized database and analyzed with a statistical package (STATISTICA; StatSoft, Inc). The descriptive summary of data included mean±standard deviation and 95% confidence intervals for continuous variables and proportions for categorical variables. Between-group differences were assessed with t tests and analysis of variance in more than 2 groups for continuous variables and χ2 tests for nominal variables.

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.
were designed to treat atrial rhythms originating on the right side of the heart. Patients with a pacemaker were assigned to recurrent AF if mode switching had occurred or if any supraventricular rhythm other than atrial pacing or normal sinus rhythm was observed.

At 6-month follow-up, freedom from AF and LART was globally 84%, 76% in patients with permanent AF, and 91% in patients with paroxysmal AF. At the 6-month follow-up visit, 6 patients or 6.5%, equally distributed in the 2 Groups (permanent and paroxysmal AF), were still receiving an antiarrhythmic drug.

At 1-year follow-up, when 39 patients could be evaluated (3 of them, or 7.7% still being on some antiarrhythmic drug), freedom from AF and LART was 85% in the whole population. Sample sizes of paroxysmal and persistent AF subsets were inadequate to draw valid conclusions. Beyond 6 months, 4 patients who remained in left-sided flutter were controlled by cardioversion and Amiodarone.

While our population consisted actually of patients in whom ischemic heart disease was the primary diagnosis, we separated them for the purpose of analysis in 2 subgroups, 51 patients in whom CABG was isolated and referred to as “Isolated” and 47 in whom it was associated to a variety of intracardiac surgical procedures and referred to as “Associated” group.

When compared (Table 3), the 2 groups showed no significant differences in age, gender distribution, height, AF duration, left atrial diameter, size of Epicor device used, and number of grafts per patient. They showed significant differ-

<table>
<thead>
<tr>
<th>Variable</th>
<th>Associated</th>
<th>Mean</th>
<th>SD</th>
<th>Isolated</th>
<th>Mean</th>
<th>SD</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>72.52</td>
<td>7.16</td>
<td>71.22</td>
<td>7.97</td>
<td>0.40</td>
<td></td>
</tr>
<tr>
<td>Gender ratio</td>
<td></td>
<td>0.70</td>
<td>...</td>
<td>0.78</td>
<td>...</td>
<td>0.36</td>
<td></td>
</tr>
<tr>
<td>Weight, kg</td>
<td></td>
<td>82.98</td>
<td>13.79</td>
<td>94.61</td>
<td>24.17</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Height, cm</td>
<td></td>
<td>169.88</td>
<td>11.67</td>
<td>171.94</td>
<td>17.23</td>
<td>0.57</td>
<td></td>
</tr>
<tr>
<td>AF duration, months</td>
<td></td>
<td>76.10</td>
<td>88.91</td>
<td>66.58</td>
<td>54.40</td>
<td>0.55</td>
<td></td>
</tr>
<tr>
<td>Proportion permanent AF</td>
<td></td>
<td>0.39</td>
<td>...</td>
<td>0.57</td>
<td>...</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>LVEF, %</td>
<td></td>
<td>36.57</td>
<td>13.01</td>
<td>45.44</td>
<td>13.40</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>LA diameter, mm</td>
<td></td>
<td>49.64</td>
<td>6.29</td>
<td>50.46</td>
<td>16.89</td>
<td>0.80</td>
<td></td>
</tr>
<tr>
<td>Epicor Cinch size</td>
<td></td>
<td>9.89</td>
<td>1.39</td>
<td>9.84</td>
<td>1.25</td>
<td>0.85</td>
<td></td>
</tr>
<tr>
<td>Bypass time, min</td>
<td></td>
<td>144.55</td>
<td>56.40</td>
<td>83.85</td>
<td>29.13</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Cross-clamp time, min</td>
<td></td>
<td>102.61</td>
<td>48.48</td>
<td>57.37</td>
<td>25.26</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Graft No. per patient</td>
<td></td>
<td>3.28</td>
<td>1.39</td>
<td>3.73</td>
<td>1.23</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>6-month freedom from AF</td>
<td></td>
<td>0.90</td>
<td>...</td>
<td>0.77</td>
<td>...</td>
<td>0.08</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations as in Table 2. In italic, statistically significant variables.
ences in weight, LV ejection fraction, bypass, and cross-clamp times, the latter two explained by the necessary longer procedure time when there was an additional surgery and changes in LVEF by the impact on an additional lesion on global LV function. Finally, efficacy was also similar in the 2 groups, which could hence be seen as a single entity for the purpose of discussion.

Discussion
Coronary bypass grafting is the procedure most commonly done in cardiac surgical practice today and given the current demographic trends, it should be offered to a growing number of older patients in whom the incidence of AF will also undoubtedly grow in parallel.7,10 However, AF ablation concomitant to CABG is seldom reported, or the series have been limited in the surgical literature.11–12

A possible interpretation for this apparent paradox might be that surgical AF ablation during concomitant cardiac surgery has not been evaluated with ablation technologies that did not increase the surgical risk of the global procedure. Historically, most ablation techniques were designed to isolate presumed AF triggers originating in the pulmonary vein orifices as described by Haissaguerre.13 Such typical lesions are generally created under cardiopulmonary bypass after opening the left atrium and use energy sources such as radio-frequency, microwave or laser delivering the thermal energy locally through the atrial wall.14–18 The procedures were designed to closely replicate the original lesion set described by J. Cox for a successful treatment of AF, but without the operative time and morbidity cost of the classic “cut and sew Maze.”19 However, an approach requiring a left atriotomy in patients undergoing CABG will inevitably increase cardiopulmonary bypass and cardiac exclusion times, morbidity, and mortality. The technical challenge of the small left atrium adds to this issue and further discourages concurrent CABG and Maze procedures of all types.

In contrast, an ablation technique that can be used on the beating heart before the initiation of bypass during an average 10-minute algorithm and without the necessity to perform a left atriotomy is a valid alternative, particularly because the efficacy of this technique has been proven to be at least equivalent to the current offers.7 The current series has an early mortality rate of 1%, no bleeding complications, and an incidence of postoperative stroke of 1%. Additionally, the population under study with mean age of 71.85 years and a LV ejection fraction below 40% in 42% of the patients is, according to the STS database score, a high-risk population profile whose mortality and morbidity would be expected to be much higher than observed. In these circumstances, a less-invasive AF therapy applied on the beating heart by an epicardial approach is definitely an attractive solution, particularly in patients operated on through a minimally invasive approach.20

An additional benefit of the technology seems to be the observed low incidence of AF episodes (6.12%) before the patient’s discharge from the hospital. There is ample surgical literature on the incidence of AF after CABG surgery, commonly reported to be as high as 30%.21 Although the mechanism of postoperative AF in patients who were previously in sinus rhythm might be different, the observation of a 4-fold drop in AF incidence in the postoperative period after CABG surgery is a matter for reflection. Our patients typically display a slow junctional rhythm requiring isolated atrial stimulation for the first few postoperative days and thus maintain a stable hemodynamic status during the initial recovery period, which is a potential benefit in elderly patients with ischemic heart disease and an impaired LV function.

Our study has a number of limitations, among which are the sample size and the observation time. We plan to continue to follow the original population to confirm an initial positive trend, and to continue enrolling patients to validate our first observations on a larger scale. A larger sample with appropriate control would help determine whether the beneficial trend of AF suppression in CABG patients continues and results in long-term survival advantage as proposed in previous studies.5–6

Disclosures
Mark A. Groh, MD is a consultant for and receives honorarium (moderate) from St Jude’s Medical. Gerard L. Champsaur, MD is a consultant for and receives honorarium (moderate) from St. Jude’s Medical.

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