The Heart Surgery Forum #2007-1060
10 (4), 2007 [Epub May 2007]
doi: 10.1532/HSF98.20071060

Online address: http://cardenjennings.metapress.com

Intravenous and Oral Amiodarone for the Prevention of Postoperative Atrial Fibrillation in Patients Undergoing Off-Pump Coronary Artery Bypass Surgery

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ABSTRACT

Background. Atrial fibrillation is still a frequent complication that increases morbidity after coronary artery bypass grafting. This prospective randomized study is designed to define efficacy of postoperative amiodarone prophylaxis in preventing atrial fibrillation after off-pump coronary artery bypass grafting.

Methods. One hundred forty-four patients who underwent elective off-pump coronary artery bypass grafting were enrolled for the study. Seventy-six patients (amiodarone group) received 5 mg/kg loading amiodarone infusion in the first postoperative hour, followed by 10 mg/kg for the first 24 hours. After 24 hours, patients received 600 mg/day amiodarone orally for 7 days and 200 mg/day until the end of the postoperative first month. Sixty-eight patients received placebo (control group).

Results. Preoperative characteristics and operative variables of the patients were similar in both groups. Incidence of new-onset atrial fibrillation and maximal ventricular rate response were recorded. The incidence of new-onset atrial fibrillation (11.8% versus 26.5%) ($P = .025$) and maximal ventricular rate response (109 ± 13.8 beats/min versus 124.5 ± 13.9 beats/min) ($P = .011$) were significantly lower in the amiodarone group. Duration of atrial fibrillation was 17.5 ± 8.1 hours for the amiodarone group compared with 32.7 ± 12 hours for the control group ($P = .002$).

Conclusion. Postoperative intravenous amiodarone prophylaxis followed by oral amiodarone significantly reduces the incidence of atrial fibrillation after off-pump coronary artery bypass grafting and the ventricular rate during atrial fibrillation.

INTRODUCTION

Atrial fibrillation (AF) is a frequent complication that occurs in 10% to 40% of the patients who undergo coronary artery bypass grafting (CABG) [Leitch 1990; Creswell 1993; Aranki 1996; Mathew 1996]. Although AF is usually benign, it may occasionally result in severe complications [Mathew 1996; Aranki 1996; Taylor 1987]. Because of the loss in contribution of normal atrial contraction on cardiac output, this may result in hemodynamic deterioration during the postoperative period. Management of postoperative AF is focused mainly on antiarrhythmic drugs such as verapamil, propranalol, and digoxin but has not been accepted for routine treatment [Csicsko 1981; Hammon 1984; Davison 1985]. Amiodarone is a class III antiarrhythmic drug with a broad pharmacologic spectrum that includes β-receptor, α-receptor, and sodium, calcium, and potassium channel antagonism and has been reported to be effective in converting AF to sinus rhythm and in the treatment of refractory AF [Gosselink 1992; Zarembski 1995]. Although being a class III antiarrhythmic drug, amiodarone also has class I, II, and IV actions, which provides a unique antiarrhythmic profile, and it can be taken orally after high-dose preloading [Butler 1993; Doggrell 2001].

The present prospective study investigates the efficacy of postoperative short-term intravenous amiodarone prophylaxis followed by oral amiodarone in the prevention of AF after off-pump CABG (OPCAB).

Received February 26, 2007; accepted April 24, 2007.

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MATERIALS AND METHODS

After Institutional Review Board approval and written informed consent was obtained, 144 patients who underwent first-time elective OPCAB were enrolled for the study. Exclusion criteria were concomitant operations such as valve repair or replacement, aneurysmectomy, myocardial infarction less than one month before surgery, 2nd or 3rd degree atrioventricular block, sick sinus syndrome, previous AF history, renal insufficiency, previous stroke or transient ischemic attack, preoperative antiarrhythmic therapy other than β-blockers, Ca^{++} channel blockers and digitalis, thyroid disease, abnormal liver function tests, left ventricular ejection fraction <30%, pre-existing bradycardia heart rate <60 beats/min at rest, preoperative use of amiodarone, and conversion to on-pump CABG.

Protocol

One hundred forty-four patients underwent CABG without cardiopulmonary bypass and cardioplegic arrest. Seventy-six

Table I. Preoperative Demographics and Variables

	Amiodarone Group	Control Group	*P*
Age, y	59.9 ± 6.4	60.7 ± 5.8	.426
Sex, male/female	21/55	21/47	.668
New York Heart Association class	2.2 ± 0.6	2.2 ± 0.6	.963
Diabetes mellitus	17	13	.632
Hypertension	33	29	.925
Prior myocardial infarction	31	25	.621
Chronic obstructive pulmonary disease	11	8	.632
Left ventricular ejection fraction, %	49.6 ± 7.5	48.9 ± 7.3	.632
Left main coronary artery disease	3	2	1.0
No. of diseased vessels	2.4 ± 0.6	2.5 ± 0.6	.365
Preoperative β-blockers	23	15	.265

patients (amiodarone group) received prophylactic amiodarone and 68 patients received placebo (control group).

Postoperatively in the intensive care unit, amiodarone infusion was given 5 mg/kg in the first hour and 10 mg/kg for 24 hours followed by 600 mg/day orally 3 times a day for the next 7 days and 200 mg/day in a single dose until the end of the first month. Patients randomized for the control group received a matching dose of 5% glucose for the first 24 hours and switched to standard postoperative medication. β-blockers were continued in patients who were receiving β-blockers preoperatively if possible; this was chosen to avoid the increased incidence of AF because of β-blocker withdrawal.

Operative Technique

After a median sternotomy and harvesting the bypass grafts, heparin (150 U/kg) was administered. The Octopus Tissue Stabilizer (Octopus-3 28400; Medtronic, Minneapolis, MN, USA) was used for the stabilization of the target coronary artery. First, the proximal anastomosis of the vein grafts was constructed by the help of a partially occluding aortic-side clamp. The left anterior descending artery was the first coronary artery that was revascularized in all of the cases. The target coronary artery was stabilized and occluded proximally by the help of a bulldog clamp and then the distal anastomosis was performed. No coronary shunts were used during the distal anastomosis. Heparin was antagonized with protamin sulphate until the activated clotting time decreased below 200 seconds.

Postoperative Monitoring

After the operation, heart rate and rhythm of the patients were continuously monitored by individual bed-side monitors (Datex-Ohmeda Instrumentarium, Helsinki, Finland) during the first 72 hours. Twelve-lead electrocardiography (ECG) recordings were performed before surgery, 2 hours after surgery, and then daily until hospital discharge. All persistent arrhythmias were confirmed with 12-lead ECG. After 72 hours, trained nurses performed clinical observations every 4 hours. If there was any clinical suspicion of arrhythmia, an ECG was recorded and continuous ECG monitoring was restarted in the case of any documented arrhythmia. In this study, we included episodes of AF lasting longer than 10 minutes.

Potassium deficiency was promptly treated when necessary to maintain electrolyte balance within the normal range.

Statistical Analysis

Statistical analyses were performed with the Statistical Package for Social Sciences (SPSS, Chicago, IL, USA). All continuous variables were expressed as mean ± SD. Comparison of groups' categorical variables were analyzed by the chi-square and the Fisher exact test was used if expected contingency table cell frequency was less than 5. Independent samples *t* test was used to assess differences between the amiodarone group's and control group's noncategorical or continuous variables.

The relationship between the presence of AF and perioperative variables were investigated with univariate analysis in the whole patient group. Independent predictors of AF were then determined by multivariable logistic regression analysis including the variables found to be statistically significant on univariate analysis. A *P* value less than .05 was considered statistically significant.

RESULTS

Preoperative characteristics of amiodarone and the control groups are presented in Table 1. Both amiodarone and control groups were similar with respect to mean age, sex, New York Heart Association functional class, diabetes mellitus, hypertension, prior myocardial infarction, number of diseased vessels, and preoperative use of β-blockers.

Operative variables of the amiodarone and control group are presented in Table 2.

There were no significant differences in the incidence of intraoperative and postoperative adverse events and complications when the amiodarone group was compared with the control group (Table 2).

Table 2. Operative Variables and Postoperative Adverse Events

	Amiodarone Group	Control Group	*P*
Grafts per patient	2.3 ± 0.5	2.4 ± 0.6	.286
Use of left internal thoracic artery	75	67	.937
Perioperative myocardial infarction	2	2	1.0
Use of intra-aortic balloon pump	1	2	.602
Transient neurologic deficit	2	2	1.0
Stroke	1	0	1.0
Re-exploration for bleeding	1	2	.602
Wound Infection	4	2	.684
In-hospital mortality	2	1	1.0

Table 3. Incidence and Duration of Postoperative Atrial Fibrillation

	Amiodarone Group	Control Group	*P*
Postoperative atrial fibrillation	9	18	.025
Maximum ventricular rate, beats/min	109 ± 13.8	124.5 ± 13.9	.011
Duration of atrial fibrillation, h	17.5 ± 8.1	32.7 ± 12	.002

There were a total of 3 in-hospital mortalities: 2 (2.6%) in the amiodarone group due to multiorgan failure and low cardiac output and one (1.5%) in the control group due to sepsis with multiorgan failure. Amiodarone administration was stopped in 4 patients (5.2%) because of sinus bradycardia (44, 42, 41, and 38 beats/min, respectively), bradycardia resolved spontaneously after discontinuation of amiodarone and AF did not occur in any of these patients. No patients in the amiodarone group had other adverse reactions or significant side effects within the first month following CABG.

Postoperative Atrial Fibrillation

Overall incidence of AF in the whole patient group was 18.8%, being 11.8% in the amiodarone group and 26.4% in the control group ($P = .025$).

The maximum ventricular rate during AF in the amiodarone group was 109 ± 13.8 versus 124.5 ± 13.9 in the control group ($P = .011$). There was significant difference between the amiodarone group and control group in the duration of AF (17.5 ± 8.1 versus 32.7 ± 12, $P = .002$; Table 3).

Results of the univariate analysis for the association of each variable with AF are presented in Table 4. Advanced age and no amiodarone usage was found to be associated with AF. Multivariable logistic regression analysis of AF predictors including age and the usage of amiodarone indicated both advanced age and no amiodarone usage were the independent predictors of postoperative new-onset AF ($P = .0177$ with OR = 0.89, CI = 0.82-0.98; and $P = .0356$ with OR = 0.38, CI = 0.16-0.94, respectively; Table 4).

AF converted to sinus rhythm spontaneously or with antiarrhythmic medication other than amiodarone. Electrical cardioversion was not performed on any patient. None of the patients had symptomatic AF within the first month after discharge.

DISCUSSION

AF is the most common rhythm disturbance that occurs after cardiac surgery. Preoperative and operative factors such as increasing age, hypertension, chronic obstructive pulmonary disease, greater number of grafts, poor left ventricular function, preoperative β -blocker withdrawal, myocardial ischemia, cardioplegic arrest, systemic and cardiac hypothermia, mechanical manipulation of the atrium, and atrial ischemia were reported to increase the incidence of postoperative AF [Rousou 1985; Ferguson 1987; Aranki 1996; Mathew 1996; Ducceschi 1999; Dorge 2000]. Although thought to be transient and benign, AF is not always well tolerated; patients with AF may have hemodynamic instability, thromboembolic events, and anxiety and AF has been shown to increase costs and lengthen hospitalization [Aranki 1996]. The strategy for prevention of postoperative AF has been focused mainly on antiarrhythmic medication such as digitalis, β-blockers, and calcium channel blockers [Csicsko 1981; Hammon 1984; Davison 1985]. The principles of treatment for postoperative AF are the control of the ventricular rate, anticoagulation,

Table 4. Univariate and Multivariable Analysis for the Presence of Atrial Fibrillation

	Univariate Analysis			Multivariable Analysis		
	AF (n = 27)	Without AF (n = 117)	*P*	OR	95% CI	*P*
n, amiodarone/control	9/18	67/50	.025	0.38	0.16-0.94	.0356
Age, y	62.9 ± 5.8	59.7 ± 6	.012	0.89	0.82-0.98	.0177
Sex, male/female	9/18	33/84	.597			
Diabetes mellitus	7	23	.470			
Hypertension	9	53	.258			
Prior myocardial infarction	11	45	.827			
Ejection fraction, %	49.2 ± 6.8	49.3 ± 7.5	.930			
Chronic obstructive pulmonary disease	6	13	.124			
Preoperative β-blockers	8	30	.672			
Diseased vessels	2.5 ± 0.5	2.4 ± 0.6	.353			
Grafts per patient	2.4 ± 0.5	2.3 ± 0.5	.373			
Left internal thoracic artery usage	27	115	1.0			
Intra-aortic balloon pump	0	3	1.0			
Deaths	1	2	.466			
Preoperative myocardial infarction	2	2	.160			
Wound infection	1	5	1.0			
Transient stroke	2	2	.160			

and conversion to sinus rhythm. Amiodarone is a class III antiarrhythmic drug with a mild β-blocker and calcium channel blocker activity and increases the refractory period of atrioventricular node as well as the atrial and ventricular muscle. With such properties, oral and intravenous amiodarone was used to prevent postoperative new-onset of AF in several studies [Hohnloser 1991; Gosselink 1992; Butler 1993; Zarembski 1995; Daoud 1997; Redle 1999; Dorge 2000; Lee 2000; Doggrell 2001]. But there is no consensus about the optimal dose of the drug. With our short-term intravenous usage of amiodarone after a loading dose combined with oral administration regimen, we showed that amiodarone reduced the postoperative AF more than 50% and reduced ventricular rate and duration of AF significantly after OPCAB.

Some authors have reported their investigations on the incidence of AF after OPCAB with conflicting results. Cohn and colleagues reported similar AF rates after one-vessel minimally invasive direct CABG with anterior minithoracotomy [Cohn 1999]. Puskas and colleagues reported that after off-pump multivessel CABG with sternotomy, AF incidence was similar to that with on-pump CABG [Puskas 1998]. In conflict to Puskas and Cohn, Ascione and colleagues reported that AF incidence is significantly lower after OPCAB when compared with a similar cohort of patients undergoing CABG with CPB [Ascione 2000]. In their study with 2569 patients, Salomon and colleagues reported that OPCAB did not reduce the incidence of AF, with AF rates between 8.8% and 9.4% in a similar cohort of patients [Salamon 2003]. This lower incidence of AF was attributed to standard usage of β-blocker prophylaxis.

In light of these findings, this prospective study is designed to determine the efficacy of prophylactic intravenous amiodarone after OPCAB. There are controversial reports on the efficacy of amiodarone prophylaxis on the incidence of AF after conventional CABG. Reddle and colleagues in their placebo-controlled study reported that preoperative and early postoperative oral amiodarone prophylaxis did not significantly reduce the incidence of postoperative AF [Redle 1999]. However, Daoud and colleagues reported a double-blind study of oral amiodarone as prophylaxis to prevent AF after cardiac surgery and showed that oral amiodarone significantly reduces the incidence of AF after cardiac surgery, including patients who underwent valvular or CABG surgery [Daoud 1997].

Hohnloser and colleagues performed a placebo-controlled study of intravenous amiodarone for prophylaxis of AF after conventional on-pump CABG in 77 patients; amiodarone infusion was given after surgery in a loading bolus of 300 mg for 2 hours followed by 1200 mg for 24 hours for 2 days and 900 mg every 24 hours for the next 2 days. This significantly reduced the incidence of AF, but in this study amiodarone was discontinued in 18% of the patients because of sinus bradycardia and excessive QT prolongation [Hohnloser 1991]. In our study, we showed that postoperative use of intravenous amiodarone reduced the incidence of AF more than 50% after OPCAB and also reduced the ventricular rate, and there were 4 patients (5.2%) in whom we discontinued amiodarone therapy because of sinus bradycardia; this difference might be because of our use of intravenous amiodarone in a lower dose only for 24 hours and beginning the oral therapy after the first 24 hours. In their study, Lee and colleagues supported this suggestion by including 150 randomized patients in whom 74 patients received intravenous amiodarone in a loading dose of 150 mg and maintenance 0.4 mg/kg per hour for 3 days before and 5 days after the surgery, the control group received a matching dose of glucose infusion [Lee 2000].

Postoperative arrhythmia is a severe complication that increases mortality and morbidity, especially in patients with severe left ventricular dysfunction [Lauer 1995]. Although the negative inotropic effect of amiodarone is minimal and transient, it may be caused by its antisympathetic effect but usually does not lead to a decreased cardiac output [Kowey 1997]. Therefore, amiodarone may be well tolerated in patients with severe left ventricular dysfunction. As it was not our primary aim to investigate the effect of amiodarone in patients with severe left ventricular dysfunction with our exclusion criteria of a left ventricular ejection fraction less than 30%, the first drawback of our study was that our results may not be applicable to the cohort of patients with severe left ventricular dysfunction. Discontinuation of β-blockers postoperatively may lead to a higher incidence of atrial tachyarrhythmias, and there are some clinical trials demonstrating that prophylactic β-blockers have benefits on postoperative AF as well as some other studies with conflicting results [Abel 1983; Hammon 1984; Martinussen 1988; Shafei 1988]. The limited number of patients receiving β-blockers preoperatively because patients' preoperative management was directed by the patients' own cardiologist in different institutes without a standardized protocol might be a drawback of our study. We think that randomization of patients may compensate for the negative effect of nonstandardized preoperative treatment, thus there was no difference between the number of patients receiving β-blockers preoperatively. In the present study, patients receiving β-blockers preoperatively, if possible, continued to receive them postoperatively. On the other hand, because of the limited number of patients receiving β-blockers in the present study, the reduction in the incidence of postoperative AF may thus be attributed to the effect of amiodarone.

As it is mentioned above, there are several reports about amiodarone prophylaxis for prevention of AF after on-pump CABG, but as far as our review in the literature there were very few reports specifically focused on amiodarone prophylaxis to prevent AF after OPCAB. There was only one case study in which Gallagher et al used intravenous amiodarone during OPCAB procedures in the operating room to prevent AF only in 3 patients [Gallagher 2001]. And in another study, although it was not designed for the comparison of the effect of amiodarone for prevention of AF after OPCAB, Kerstein et al compared 51 patients who received 0.73 mg/min intravenous amiodarone undergoing CABG (either off-pump or on-pump) with 92 patients that did not receive amiodarone. In the intravenous amiodarone group, there were 41 patients who were operated on without CPB and there were 25 patients in the control group operated on without CPB. The incidence of AF in the amiodarone off-pump group was 4.9% and 28% in the nonamiodarone control group [Kerstein 2004]. Similar to

Kerstein et al, our study with a limited number of patients showed that postoperative prophylactic usage of intravenous amiodarone followed by oral amiodarone in patients who undergo OPCAB significantly reduces the incidence of AF without important and significant side effects. It also reduces the duration of the AF and ventricular rate after OPCAB.

In conclusion, postoperative short-term intravenous prophylactic amiodarone followed by oral amiodarone for the prevention of AF is safe and efficient after OPCAB.

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