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Original Article

Amiodarone versus direct current cardioversion in treatment of atrial fibrillation after cardiac surgery

Kalp cerrahisi sonrası gelişen atriyal fibrilasyon tedavisinde amiodarone ve doğru akım kardiyoversiyonun karşılaştırılması

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ABSTRACT

Aim: Postoperative atrial fibrillation is common after cardiac surgery and is associated with higher rates of complications and mortality. Despite the importance of postoperative atrial fibrillation, the most effective management strategy for this common surgical complication remains uncertain. The aim of this study was to evaluate the effectiveness of amiodarone and early direct current cardioversion to restore sinus rhythm in new onset postoperative atrial fibrillation.

Material and Methods: This was a prospective, open-labeled randomized- controlled trial. A total of 50 patients who had new onset postoperative atrial fibrillation longer than 30 minutes were enrolled in the study; 26 patients were randomized to control group and 24 to amiodarone group. Patients in whom sinus rhythm did not return within 24 hours, then external electrical direct current cardioversion was performed for both groups. The primary endpoint of the study was a restoration of sinus rhythm at the 24th hour. Secondary endpoints needed for direct current cardioversion, success rate, sinus rhythm at discharge, sinus rhythm at 30th days and crossover rates.

Results: There was a significantly higher number of patients with sinus rhythm at the 24th hour in the amiodarone group than the control group (79.2% vs. 46.2%, p=0.022). Need for direct current cardioversion (p=0.022) and crossover ratio (p=0.021) were significantly higher in control group than amiodarone group. Direct current cardioversion success rate, normal sinus rhythm at discharge and 1st month did not differ significantly between groups.

Conclusion: Amiodarone therapy seems effective in restoring sinus rhythm within 24 hours and decreases the need for direct current cardioversion.

Keywords: antiarrhythmic agents; atrial fibrillation; cardiovascular surgery; post-CABG atrial fibrillation

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ÖZ

Amaç: Atriyal fibrilasyon kalp cerrahisinden sonra sık görülmektedir. Postoperatif atriyal fibrilasyon komplikasyonların ve mortalitenin artmasına neden olmaktadır. Ancak tedavisi hususunda fikir birliği yoktur. Bu çalışmanın amacı postoperatif dönemde yeni başlayan atriyal fibrilasyonu olan hastalarda amiodaron kullanımı ile erken dönemde doğru akım elektriksel kardiyoversiyonun sinüs ritmininin sağlanması üzerine olan etkilerini karşılaştırmaktır.

Gereç ve Yöntemler: Çalışma prospektif, randomize, açık kontrollü olarak tasarlanmıştır. Çalışmaya kalp cerrahisi sonrası 30 dakikadan uzun yeni başlangıçlı atriyal fibrilasyonu olan toplam 50 hasta alındı; 26 hasta kontrol grubuna; 24 hasta amiodaron grubuna randomize edildi. Her iki grupta da 24 saat içinde sinüs ritminin sağlanamadığı hastalarda doğru akım elektriksel kardiyoversiyon uygulandı. Çalışmanın birincil son noktası 24. saatte sinüs ritminin sağlanmasıydı. Çalışmanın ikincil son noktaları ise doğru akım elektriksel kardiyoversiyon oranı, başarı oranı, taburculukta sinüs ritminin varlığı, 30. günde sinüs ritminin varlığı ve grup değiştirme oranıydı.

Bulgular: Amiodaron grubunda 24. saatte sinüs ritminde olan hasta sayısı kontrol grubuna göre anlamlı olarak daha fazla saptandı (%79,2'ye karşı %46,2, p = 0.022). Doğru akım kardiyoversiyon oranı (p = 0,022) ve grup değiştirme oranı (p = 0,005) kontrol grubunda anlamlı derecede yüksekti. Taburculukta ve birinci ayda sinüs ritmi varlığı ve doğru akım kardiyoversiyon başarı oranları açısından gruplar arasında anlamlı fark saptanmadı.

Sonuç: Amiodaron tedavisi 24 saat içinde sinüs ritmininin sağlanmasında etkin görünmekte ve doğru akım kardiyoversiyon ihtiyacını azaltmaktadır.

Anahtar kelimeler: amiodaron; atriyal fibrilasyon; kalp cerrahisi; doğru akım kardiyoversiyon

Introduction

Postoperative atrial fibrillation (POAF) is the most common complication and rhythm disturbance occurring after cardiac surgery [1]. Its incidence ranges from 28-33% in contemporary series [2]. POAF is associated with an increase in the risk of operative death, renal insufficiency, stroke and prolonged hospitalization [3,4]. It is generally a self-terminating arrhythmia and despite the importance of POAF, the most effective management strategy remains still uncertain. Previously, many strategies, such as beta-blockers, intravenous magnesium, sotalol, amiodarone, and atrial pacing have been used to prevent POAF [5-7]. A medium-sized recent study randomized patients with POAF to either rhythm control with amiodarone or to rate control and the authors did not find a difference in hospital admissions during a 60-day follow-up [8]. Current guidelines recommend direct current cardioversion (DCCV) or antiarrhythmic drugs for the restoration of sinus rhythm (SR) in POAF with hemodynamic instability. Rhythm control therapy is recommended to improve AF-related symptoms in hemodynamically stable patients. Amiodarone or vernakalant are effective antiarrhythmic drugs in converting POAF to sinus rhythm [1]. Amiodarone is the most accessible antiarrhythmic drug but has several side effects limiting its use.

Material and Methods

The aim of our study was to evaluate the effectiveness of amiodarone and early DCCV postoperatively to restore SR in patients with new-onset AF after cardiac surgery. Local ethics committee approved the study and informed consent was obtained from participant(s)

Patient Population and Study Protocol

This study was a prospective, open-labeled randomized controlled trial. Patients with coronary artery disease who had new-onset AF longer than 30 minutes after cardiac surgery were considered for enrollment. Random generated numbers table was used for randomization. Exclusion criteria were: permanent AF, known paroxysmal AF, emergent cardiac surgery, hypotension (blood pressure lower than 90 mm Hg), and use of amiodarone in the prior 2 months. The study was conducted in compliance with the Declaration of Helsinki. The research protocol was approved by the local ethics committee of Baskent University. Informed consent was obtained from all patients.

A total of 822 patients who underwent cardiac surgery were prospectively evaluated and patients with known AF (135 patients) were excluded. Postoperative AF longer than 30 minutes developed in 102 patients: 16 patients were excluded because of treatment with amiodarone in the prior 2 months, 10 were excluded because of contraindications to amiodarone, 18 were excluded because of hemodynamic instability and 8 were excluded because patient or surgeon did not accept to attend to the study. Thus, a total of 50 patients (mean age, 68 ± 8 years; 33 men) fulfilling the inclusion criteria were included to the study; 26 patients were randomized to control group and 24 to the amiodarone group. Rhythm monitoring was done by 24-hour telemetry monitoring and confirmed with 12-lead electrocardiography during hospital follow up. All patients were questioned for AF at the 30th day, 12-lead electrocardiography (ECG) and a 48 hours Holter monitoring were performed.

The amiodarone group received 300 mg of amiodarone bolus intravenously (iv) in 30 minutes and an iv infusion of 50 mg/hours over a 24-hour period afterward. If SR returned within 24 hours, then iv infusion was discontinued (Figure 1). If SR did not return

within 24 hours, then DCCV was performed. After iv amiodarone infusion, oral amiodarone was maintained at 400 mg twice daily for 5 days and 200 mg twice daily for the following 25 days.

The therapy for the control group was determined according to physician preferences and beta-blockers, calcium channel blockers and/or digoxin were used to slow heart rate, with a goal of achieving a resting heart rate of less than 100 beats per minute. (Figure 1). If SR did not return within 24 hours, then DCCV was performed. In the control group, if SR did not return after DCCV patients were switched to the amiodarone group if the surgeon thought that such treatment was necessary to alleviate symptoms or improve hemodynamic status.

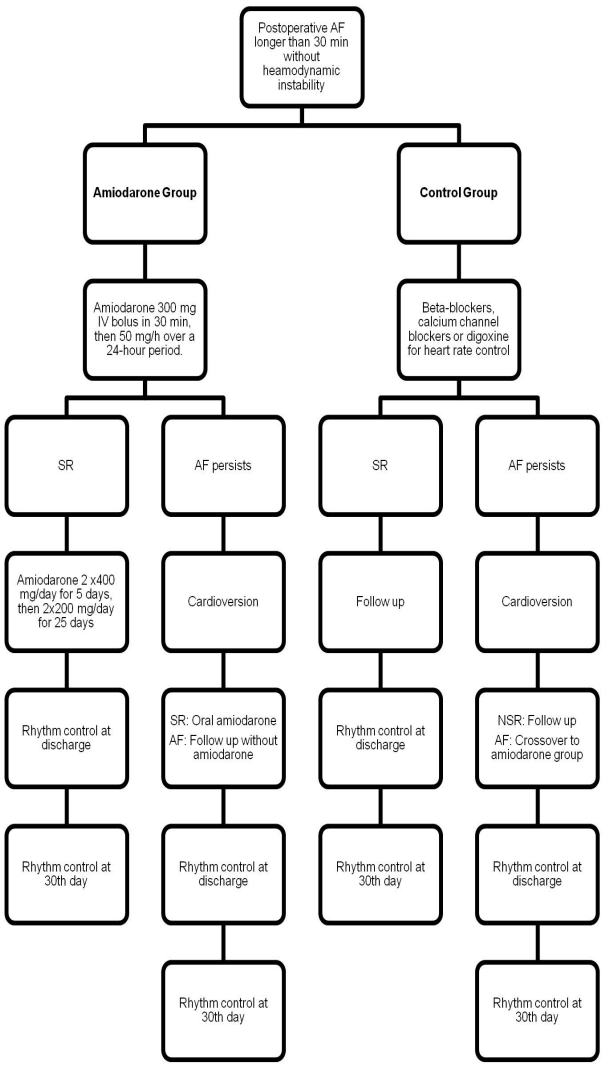

Figure 1: Study protocol

All patients received anticoagulant therapy in the hospital with heparin, but at the time of discharge, anticoagulant therapy was continued according to the surgeon's preferences.

Primary endpoints of the study were a restoration of SR at the 24th hour and needs for DCCV ratio. Secondary endpoints of the study were DCCV success ratio, SR at discharge, SR at 30th days and crossover ratio.

Statistical Analysis

MINITAB 15.0 statistical software was used for the sample size calculations and power analysis. We determined the sample sizes for the statistical tests by power/sample size formulas. The power analyses of the tests were conducted to determine the number of participants needed to detect the critical value with an adequate level of statistical power. Alpha levels for the analyses were set at 0.05. To achieve the power of 0.80 sample size of 25 in per groups were adequate.

The statistical package SPSS (Statistical Package for the Social Sciences, version 17.0, SSPS Inc, Chicago, Ill, USA) was used for statistical analyses. Intention to treat analysis was used to evaluate primary and secondary endpoints. Continuous variables are expressed as means ± standard deviation (median). All continuous variables were checked with Shapiro-Wilks normality test to show their distributions. Continuous variables with normal distributions such as age, left ventricle diameters, duration of intubations, levels of low-density lipoprotein (LDL) cholesterol and potassium were compared using the Student's t-test. Continuous variables with abnormal distributions such as body mass index, mean left ventricular ejection fraction, by-pass pump time, aorta cross-clamp time, length of hospital stay, postoperative AF onset time, number of grafts, left atrial diameter, right atrial diameter, levels of fasting blood glucose, hemoglobin, creatinine and sodium were compared using the Mann-Whitney U test. For categorical variables, the chi-square test was used. Values for p less than 0.05 were considered statistically significant.

Results

Postoperative AF developed in 102 patients (14.8% of patients without known AF); 50 of these patients underwent randomization. The mean age was 67.9±8.1 years, and 66% were male. Baseline clinical, laboratory and echocardiographic characteristics of both groups were similar (Table 1). Cardiac surgery operation properties were similar in the two groups and most of the patients underwent coronary artery bypass graft surgery (Table 2). The average time to onset of POAF was similar between groups (59.1±38.9 to 58.9±31.8 hours). Statistics about the primary and secondary endpoints are demonstrated in Table 3. There was a significantly higher number of patients with SR at the 24th hour in the amiodarone group than the control group (19 patients 79.2% vs. 12 patients 46.2%, p=0.022). Need for DCCV was significantly higher in control group than amiodarone group (53.8% vs. 20.8%, p=0.022). The DCCV success rate was slightly higher in the amiodarone group than the control group but this difference did not reach statistical significance. DCCV was performed to 11 patients in the control group and SR returned in 6 patients. DCCV was performed to 2 patients in the amiodarone group and SR returned in both patients (54.5% vs. 100%, p=0.487). DCCV was not performed in 3 patients in the control group and 3 patients in the amiodarone group because the patients or surgeon refused the therapy.

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Table 1. Demographic and clinical characteristics of patients

	Control group n = 26	Amiodarone group n = 24	p value
Age, year	68.6±8.2 (67)	67.4±8.5 (69)	0.601
Body mass index, kg/m2	27.9±3.6 (27.4)	27.1±4.3 26.0)	0.332
Male, n (%)	16 (61.5)	17 (70.8)	0.559
Clinic presentations of patients previous CABG			
SAP, n (%)	7 (26.9)	10 (41.7)	0.373
USAP/NSTEMI, n (%)	15 (57.7)	10 (41.7)	0.396
Atypical angina, n (%)	1 (3.8)	1 (4.2)	1.000
Others, n (%)	3 (11.5)	3 (12.5)	1.000
Hypertension, n (%)	25 (96.2)	22 (91.7)	0.602
Diabetes mellitus, n (%)	13 (50)	10 (41.7)	0.584
Smoking, n (%)	15 (57.7)	15 (62.5)	0.779
Dyslipidemia, n (%)	19 (73.1)	17 (70.8)	1.000
History of previous MI, n (%)	13 (50)	7 (29.2)	0.159
COPD, n (%)	2 (7.7)	3 (12.5)	0.661
History of PAF, n (%)	0	2 (8.3)	0.225
History of previous PCI, n (%)	4 (15.4)	4 (16.7)	1.000
History of previous CABG, n (%)	2 (7.7)	3 (12.5)	0.661
Left ventricular ejection fraction, %	45.2±10.8 (43.5)	49.8±9.0 (51)	0.139
Left ventricular systolic dysfunction, n (%)	19 (73.1)	13 (54.2)	0.239
Left atrial diameter, cm	4.1±0.7 (3.9)	4.1±0.7 (4.1)	0.724
All mitral regurgitation, n (%)	18 (69.2)	17 (77.3)	0.746
Severe mitral regurgitation, n (%)	1 (3.8)	1 (4.2)	1.000
Right atrial diameter, cm	3.6±0.3 (3.6)	3.7±0.7 (3.6)	0.915
Left ventricular diameter, cm	4.8±0.7 (4.7)	5.0±0.6 (4.9)	0.349
Fasting blood glucose (mg/dL)	119±38 (111)	110±25 (105)	0.433
Creatinine (mg/dL)	1.0±0.4 (0.9)	0.9±0.2 (0.9)	0.203
LDL cholesterol (mg/dL)	117±30 (124)	114±39 (105)	0.777
Haemoglobin (g/dL)	12.3±2.0 (11.9)	12.4±1.8 (11.9)	0.778

CABG: Coronary artery by-pass graft surgery, SAP: Stable angina pectoris, USAP/NSTEMI: Unstable angina pectoris/Non ST elevation myocardial infarction, MI: Myocardial infarction, COPD: Chronic obstructive pulmonary disease, PAF: Paroxysmal atrial fibrillation, PCI: Percutaneous coronary intervention, LDL: Low-Density Lipoprotein.

Table 2. Surgical and postoperative atrial fibrillation data

	Control group n = 26	Amiodarone group n = 24	p value
Perioperative beta-blocker, n (%)	20 (76.9)	18 (75)	1.000
Perioperative ACEI or ARB, n (%)	21 (80.8)	15 (62.5	0.211
Perioperative statin, n (%)	12 (46.2)	13 (54.2)	0.778
Operation type			
Isolated CABG, n (%)	24 (92.3)	19 (79.2)	0.239
CABG plus valve surgery, n (%)	2 (7.7)	5 (20.8)	0.239
Number of grafts/patient	3.2±1.2 (3)	2.9±1.4 (3)	0.477
Bypass pump time, min	89±32 (75)	85±41 (77)	0.621
Aorta cross-clamp time, min	43±26 (39)	56±37 (45)	0.354
Continuous Monitor follow up duration, hour	121±90 (98)	104±37 (96)	0.938
Length of hospital stay, day	10.3±5.4 (7.5)	8.7±2.8 (8.5)	0.739
Intubations length, hour	16.9±8.1 (15)	13.9±6.7 (12.5)	0.167
Onset time of atrial fibrillation, hour	59.1±38.9 (47)	58.9±31.8 (48)	0.983
AF mean ventricular rate, beat/min	121±21 (125)	138±21 (134)	0.004

ACEI: Angiotensin-converting enzyme inhibitors, ARB: Angiotensin receptor blockers, CABG: Coronary artery bypass graft surgery

Table 3. Primary and secondary endpoints of study and complications

	Control group n = 26	Amiodarone group n = 24	p value
Primary endpoints			
Sinus rhythm at 24th hour, n (%)	12 (46.2)	19 (79.2)	0.022
Need for DCCV, n (%)	14 (53.8)	5 (20.8)	0.022
Secondary endpoints			
DCCV performed, n (%)	11 (42.3)	2 (8.3)	0.009
DCCV success rate, n (%)	6/11 (54.5)	2/2 (100)	0.487
DCCV not performed, n (%)	3 (11.5)	3 (12.5)	1.0
Sinus rhythm at discharge, n (%)	23 (88.5)	24 (100)	0.236
Sinus rhythm at 30th day, n (%)	20 (83.3)	21 (95.5)	0.349
Crossover, n (%)	10 (38.5)	5 (20.8)	0.021
Complications			
Patients with any postoperative complications, n (%)	10 (38.5)	6 (26.1)	0.382
Death, n (%)	2 (7.7)	0	0.491
Any infection, n (%)	4 (15.4)	4 (17.4)	1.000
Renal impairment (creatinine > 2.0 mg/dL), n (%)	3 (11.5)	0	0.237
Myocardial infarction, n (%)	1 (3.8)	0	1.000
Stroke, n (%)	2 (7.7)	3 (12.5)	0.655
Respiratory failure, n (%)	3 (11.5)	1 (4.3)	0.612
Atrio-ventricular block, n (%)	1 (3.8)	0	1.000
Hypotension, n (%)	1 (3.8)	3 (12.5)	0.612

DCCV: Direct current cardioversion

Crossover ratio was significantly higher in control group (10 patients 38.5% vs. 5 patients 20.8%, p=0.021). Reasons for the crossover in the control group were unsuccessful DCCV (4 patients), patients or surgeon preference to refuse DCCV at the 24th hour (3 patients) and repetitive AF attacks after the restoration of SR (3 patients). Reasons for the crossover in amiodarone group were symptomatic bradycardia (2 patients) and severe QT prolongation (3 patients). In hospital follow up SR was achieved in all patients in the control group who crossed over to amiodarone group. Sinus rhythm incidences at discharge and 30th days were similar between groups (Table 3).

Complication rates were similar between groups (Table 3). Two patients (7.7%) died during the study period in the control group and no patients died in the amiodarone group. One of these patients died after a severe stroke and the other patient died after respiratory failure and sepsis. There were 2 (7.7%) ischemic strokes in the control group and 3 (12.5%) ischemic strokes in amiodarone group. All patients with stroke were on SR when stroke developed and three of them were on oral anticoagulant therapy. Thyroid function abnormalities were detected in 2 patients and referred to an endocrinologist.

Discussion

In this study, we showed that amiodarone therapy significantly increases SR rate at the 24th hour and decreases the DCCV requirement and crossover ratio.

Postoperative AF developed in 14.8% of our patients. Although POAF incidence changes between series our result confirm that it is still a common complication after cardiac surgery. Gillinov AM et al. showed that average time to the onset of POAF was 2.4 days among their patients [8]. The average time to the onset of POAF in our patients was similar between groups (59.1±38.9 to 58.9±31.8 hours, p=0.91) and consistent with the literature.

Postoperative AF is usually accepted as a transient situation and spontaneous conversion to SR thought to be high [9,10]. The spontaneous conversion rate in our study was lower than previous studies. This may be related to relatively small sample size, but strongly supports that POAF is not always a transient condition in contrast to suppose. Most of our POAF cases (more than 50% percent) did not return to SR without anti-arrhythmic therapy at the 24th hour.

A study comparing rhythm versus rate control in POAF showed that a total of 89.9% of patients in the rate control group and 93.5% of those in rhythm control group had a stable, sustained heart rhythm without AF at discharge (P = 0.14). And from discharge to 60 days, the percentages fell to 84.2% in the rate-control group and 86.9% in the rhythm-control group (P = 0.41) [8]. Similar to

these findings our results showed that SR rates at discharge and 30th day were similar between amiodarone and control groups. This result may be related to high DCCV rate and amiodarone usage after the 24th hour in the control group. A high number of patients had to use amiodarone and needed DCCV therapy after the 24th hour in the control group. At the end of the study, most of the patients (33 of 50 patients, 66%) received amiodarone and amiodarone therapy was effective in restoring SR even started after the 24th hour of AF in the control group.

The risk factors of POAF are advanced age, previous history of AF, male gender, left ventricular systolic dysfunction, left atrial enlargement, valvular heart surgery, chronic obstructive pulmonary disease, chronic renal failure, diabetes mellitus, rheumatic heart disease and obesity [9]. Previously, beta-blockers, amiodarone, bi-atrial pacing, statins, magnesium and steroids were shown to be effective in the prevention of POAF [5-7,9]. And many drugs such as digoxin, propafenone, sotalol, dofetilide, ibutilide, procainamide, flecainide, diltiazem, esmolol and amiodarone were tested to treat POAF [10]. In one study, ibutilide was more effective than placebo for treatment of POAF [11]. But there is very little evidence to support any of these drugs over another. Current guidelines suggest only amiodarone or vernakalant and DCCV restore sinus rhythm in patients with POAF [1]. But the level of evidence is C for these recommendations because of the lack of prospective studies. Stronger recommendations are partly based on prevention trials and extrapolation from Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) trial which evaluated nonsurgical patients. We aimed to clarify the scientific gap in this subject but we could not reach a high number of patients as discussed under study limitations subheading.

Amiodarone, a class III antiarrhythmic drug, has been used extensively in the treatment of AF in the short and long-term. Intravenous high-dose amiodarone safely facilitates the conversion of recent onset paroxysmal AF to NSR [12]. A meta-analysis demonstrated that 18 trials (3295 patients), with a variety of dosing strategies, have evaluated amiodarone for the prevention of postoperative AF and amiodarone reduced AF from an average incidence of 33.2% in the control group to 19.8% (OR 0.48, 95% CI 0.40–0.57) and amiodarone was associated with an increased risk of bradycardia (OR 1.66, 95% CI 1.73–2.47) [7]. Symptomatic bradycardia (2 patients) and severe QT prolongation (3 patients) were the main side effects seen among our patients treated with amiodarone. Previously, some studies evaluated amiodarone for the treatment of new-onset AF after cardiac surgery but none had a placebo group or evaluated amiodarone and DCCV together [13-18]. In these studies amiodarone treatment regimens were generally similar, administering 5 mg/kg intravenously over 5 to 30 min, followed by a maintenance dose of 15-40 mg/h. We used a similar dose compatible with literature. These studies demonstrated that the rate of conversion to SR at the 24th hour was similar with amiodarone, digoxin, propafenone and ibutilide [13-17]. In contrast to these studies, we showed that amiodarone significantly increases the rate of conversion to SR at the 24th hour. One study demonstrated that quinidine might be superior to amiodarone but more complications occurred with quinidine [18].

Conventional treatment strategies are similar to other AF patients in patients with POAF including prevention of thromboembolic events, control of the ventricular rate, and restoring/maintaining sinus rhythm. In a retrospective study, Samuels et al. showed that amiodarone and early DCCV were more effective than non-amiodarone therapies in restoring SR for patients with AF after elective cardiac surgery and complication rates were similar between groups [19]. Similar to Samuel et al.'s findings complication rates were similar between groups in our study. There were 2 (7.7%) ischemic strokes in the control group and 3 (12.5%) ischemic strokes in the amiodarone group. Three patients were on oral anticoagulant therapy when stroke developed. Although this study was not designed to compare anticoagulation strategies, this result may be related to inadequate use (or inadequate doses) of anticoagulants and shows the importance of adequate anticoagulation in POAF. Crossover rates may seem high (38.5% in control group vs. 20.8% in amiodarone group) but crossover rates were 15 to 38% in AFFIRM trial which evaluated stable nonsurgical patients who were not acutely ill as our patients [20].

Study Limitations

This was a single center study. The sample size is relatively small, and the study is openly labeled. But a trial with the power to detect differences in these endpoints has to enroll thousands of patients. During 1 month follow up, stroke was observed in 5 (10%) patients and one of these patients died. A quality-of-life questionnaire would have provided effects of treatment. But not included because of the short duration of the study and the effects of surgery would overshadow the effects of POAF and treatment. All patients were questioned for AF at the 30th day a 12-lead ECG and 48 hours Holter monitoring was performed but a continuous home monitoring system was not used. This might have led to an underestimation of the true incidence of AF. A total of 6 patients (3 patients in the control group, 3

patients in the amiodarone group) did not complete the full course of study because of the patients or surgeons preferences.

Conclusion

Our study is the first randomized, prospective, controlled study conducted to evaluate the effect of amiodarone and early DCCV on POAF. We showed that POAF is not a transient situation and spontaneous conversion to SR is seen less frequently than expected and most of the patients need amiodarone or DCCV. Amiodarone therapy seems effective in restoring SR in the first 24 hours. Amiodarone decreased the DCCV requirement and it was effective in restoration of SR even used after 24 hours.

Declaration of conflict of interest

The authors received no financial support for the research and/or authorship of this article. There is no conflict of interest.

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