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Effect of Prophylaxis of Amiodarone and Magnesium to Prevent Atrial Fibrillation in Patients with Rheumatic Valve Disease Undergoing Mitral Valve Replacement Surgery

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Abstract

Context:

Maintenance of sinus rhythm is superior to the incidence of atrial fibrillation (AF) in patients with rheumatic valve disease undergoing mitral valve replacement (MVR) surgery.

Aim:

To evaluate the effect of prophylactic combination of intravenous (i.v.) amiodarone and magnesium sulfate (MgSO₄) in patients undergoing MVR surgery.

Materials and Methods:

One hundred and twenty patients with valvular heart disease with or without AF were randomly divided into two groups. Group I ($n = 60$) received amiodarone (3 mg.kg^{-1} in 20 mL saline) + MgSO₄ (30 mg.kg^{-1} in 20 mL saline), and Group II ($n = 60$) received 40 mL of normal saline. The standardized protocol for cardiopulmonary bypass was maintained for all the patients.

Statistical Analysis:

Continuous variables were expressed as mean \pm standard deviation and categorical variables were summarized as frequencies and percentages. Student's independent t -test was employed for comparing continuous variables. Chi-square test was applied for comparing categorical variables.

Results:

Before surgery, AF was observed in 58.3% of patients in Group I and in 53.3% of patients in Group II ($P = 0.581$). Postoperatively, in the intensive care unit, 26.7% of the patients in Group I and 71.7% in Group II had AF ($P < 0.001$). At the time of discharge, 30% of patients in Group I and 73.3% of patients in Group II had AF ($P < 0.001$).

Conclusion:

A single combined prophylactic intraoperative dose of i.v. amiodarone and MgSO_4 decreased postbypass arrhythmia in comparison to the placebo group in patients of MVR surgery.

Keywords: Amiodarone, atrial fibrillation, magnesium sulfate, mitral valve replacement, rheumatic valve disease

INTRODUCTION

Arrhythmia is a common complication after valve surgery and is a major reason for morbidity and mortality.[1] The incidence of atrial arrhythmia after coronary artery bypass grafting (CABG), mitral valve replacement (MVR), aortic valve replacement, and heart transplantation is 31.9%, 63.6%, 48.8%, and 11.1%, respectively.[2] These arrhythmias increase mean hospital stay by 4.9 days.[3] Atrial fibrillation (AF) is also associated with increased thromboembolic complications (17%–18%) and decreased cardiac output.[4] Preoperative risk factors for AF include advanced age, male sex, hypertension, diabetes mellitus, history of AF, postoperative withdrawal of beta-blocker, impaired cardiac function, chronic lung disease, chronic renal failure, use of cardiopulmonary bypass (CPB) and cardioplegia, myocardial ischemia and reperfusion, and electrolyte imbalance.[5]

Amiodarone has shown the most promising results among all antiarrhythmic drugs, with successful conversion and maintenance of normal sinus rhythm (NSR) in 50%–70% of patients with rapid onset of the antiarrhythmic effect of intravenous (i.v.) amiodarone. Prophylactic amiodarone is effective in preventing the genesis of arrhythmias in the presence of a large irritative arrhythmia prone left atrium (LA) as observed in rheumatic heart disease.[6] The use of low-dose i.v. as well as oral amiodarone for 3–5 days before and then after the CABG has significantly reduced the development of AF.[7]

Low magnesium (Mg) concentrations are independent risk factors of AF after cardiovascular surgery.[8] Minimal negative inotropic effect and high therapeutic window of i.v. Mg sulfate (MgSO_4) have proposed it as an efficient and safe agent in the treatment of AF.[9,10] MgSO_4 significantly decreases the incidence of all types of postcardiac surgery arrhythmias and hospital length of stay in patients undergoing cardiac surgery.[11]

A number of prophylactic regimens including amiodarone and MgSO_4 have been proposed for the prevention of AF after cardiac surgery. However, the optimal dose and timing of the prophylactic agents remain unclear. This prospective randomized, double-blind, placebo-controlled study was designed to test whether intraoperative administration of i.v. amiodarone and MgSO_4 combination would reduce the incidence of AF in patients undergoing MVR.

MATERIALS AND METHODS

The study was conducted over a period of 2 years from February 2018 to February 2020. The study was a prospective, randomized, double-blind, placebo-controlled trial, approved by the Ethical Committee of the Institution. Written informed consent was obtained from all the patients 1 day before surgery.

The demographic record of the patients included name, age, sex, occupation, marital status, and number of other issues. A detailed history was taken especially related to history of breathlessness, palpitations, cough, hemoptysis, chest pain, syncope, recurrent chest infections, and fatigue. A special note was made about the history of rheumatic fever, joint pain and swelling, diabetes mellitus, hypertension, and rheumatic prophylaxis. Each patient was classified under the New York Heart Association (NYHA) classification.

The study was conducted on the consecutive adult patients who underwent elective MVR surgery. All adults >18 years of age, with sinus rhythm/AF, with stable hemodynamics were enrolled in this study.

Those excluded from the study included pregnant patients, patients having thyroid disease, heart rate <50/min, NYHA Class IV, sick sinus rhythm, A-V block, elevated liver enzymes, serum creatinine >2 mg.dL⁻¹, those patients receiving cimetidine, phenytoin, cholestyramine, and cyclosporine, and those who were either allergic to amiodarone or had received amiodarone therapy in the past.

Using GPOWER software version 3.0.10 (Heinrich Heine University Dusseldorf, Germany), it was estimated that the least number of patients required in each group with effect size of 0.25, 80% power, and 5% significance level is 60. Since we have to compare two groups in our study, we have included 120 patients in our study.

The patients were randomly divided into two groups using envelope method. Group I patients were given i.v. injection of amiodarone 3 mg.kg⁻¹ in 20 mL saline via burette plus MgSO₄, 30 mg.kg⁻¹ in 20 mL saline via burette, while Group II (control group) patients were given 40 mL saline. The burettes were prepared by an anesthesia assistant who was not involved in the administration of drugs to the patients and data collection. All the burettes were properly covered and no anesthetist as well as perfusionist was aware of these preparation.

All patients received similar premedication in the form of 1 mg oral lorazepam at night before surgery and 0.1 mg.kg⁻¹ of injection morphine sulfate plus 0.5 mg.kg⁻¹ of injection promethazine intramuscular (im) 1 h before surgery. All preoperative drugs except antiplatelet, digoxin, and diuretics were continued till the morning of surgery day.

All baseline monitors were attached preoperatively – electrocardiogram, noninvasive blood pressure (IBP), pulse oximetry (SpO₂), temperature probe, IBP, and central venous monitoring.

Induction of general anesthesia was done with i.v. injection of midazolam 0.05 mg.kg⁻¹, fentanyl 1 µg.kg⁻¹, and etomidate 0.3 mg.kg⁻¹. Injection rocuronium 0.9 mg.kg⁻¹ was used for muscle relaxation, followed by maintenance doses with rocuronium 0.05 mg.kg⁻¹. Anesthesia was maintained with oxygen, air, fentanyl, and isoflurane. Heparin (4 mg.kg⁻¹) was administered i.v. to achieve adequate anticoagulation with target activated clotting time of 480 s. The CPB circuit was primed with phenol, sodium bicarbonate, mannitol, and heparin. Hematocrit was maintained at 21%–28% during CPB.

Myocardial protection was achieved by antegrade cold cardioplegia at 4°C and St. Thomas solution-based crystalloid-blood (1:4) cardioplegic solution into the root of the aorta after aortic cross-clamp. As per the institutional protocol, nitroglycerine infusion (0.5 µg.kg⁻¹.m⁻¹) was started at the onset of CPB to achieve adequate rewarming. All the patients were rewarmed at 36°C; serum potassium was optimized to 4–4.5 mEq.L⁻¹ by adding potassium chloride incremental doses to venous reservoir.

At the start of rewarming, injection amiodarone (20 mL) and injection MgSO₄ (20 mL) in combination was given to Group I patients and normal saline (40 mL) was given to Group II patients. Thereafter, rhythm monitoring was done to note down whether the same was sinus or AF.

The recorded data were compiled and entered in a spreadsheet (Micro Excel) and then exported to the data editor of SPSS Version 20.0 (SPAA Inc., Chicago, Illinois, USA). Continuous variables were expressed as mean \pm standard deviation and categorical variables were summarized as frequencies and percentages. Student's independent *t*-test was employed for comparing continuous variables. Chi-square test was applied for comparing categorical variables. A $P < 0.05$ was considered statistically significant. All P values were two tailed.

RESULTS

One hundred and twenty patients were enrolled and randomized into two groups, Group I ($n = 60$) received amiodarone + MgSO_4 and Group II ($n = 60$) received normal saline. All patients completed the study and underwent intra- and post-operative monitoring and assessment. There was no significant difference in the baseline characteristics of the patients, comorbidities, anesthetic technique, and type of procedure used in the two groups [Table 1].

During the preoperative period, the incidence of NSR and AF in both the groups was comparable ($P = 0.581$) [Table 2]. At the end of surgical procedure and during the time of discharge, there was significantly higher frequency of arrhythmia that was mainly AF in Group II as compared to Group I ($P < 0.001$ and $P < 0.001$, respectively) [Table 2]. CPB time in both the groups was comparable ($P = 0.104$) [Table 3]. Aortic cross-clamp time was also comparable in both the groups ($P = 0.645$) [Table 3].

The relationship of AF with size of LA is shown in Table 1. Twelve patients in Group I have LA size of < 45 mm, 40 patients have LA size between 45 and 52 mm, and eight patients have LA size of > 52 mm. However, 15 patients in Group II have LA size of < 45 mm, 40 have between 45 mm and 52 mm, and 5 have > 52 mm [Table 1]. LA size was comparable in both the groups and was statistically insignificant ($P = 0.589$) [Table 1].

As far as the use of inotropes (adrenaline) is concerned, 58 patients in Group I required adrenaline infusion and all patients in Group II required adrenaline infusion in the operation theater and in the postoperative care ward, which on comparison was found to statistically insignificant ($P = 0.496$) [Table 3].

DISCUSSION

The present study observed that age, gender, comorbidities such as diabetes, hypertension, smoking, anesthesia technique, and type of procedure were not significantly related to the development of postoperative AF ($P > 0.05$). These results are similar to those of Mathew *et al.* [12]

Benefits of restoration of NSR in patients with rheumatic AF are relief of symptoms, prevention of fast ventricular rate-induced dysfunction, improved exercise tolerance, improved quality of life, possible reduction in embolic strokes, and improved survival. [13]

In standalone studies, amiodarone and MgSO_4 , respectively, have been proved to be useful in the prevention of postoperative AF. Mitchel *et al.* reported in their Papabear trial that amiodarone significantly reduced postoperative AF incidence (16.1%) compared to placebo (29.5%) i.e., by 13.4%. [14] Tiryakioglu *et al.* showed that prophylactic use of MgSO_4 was effective at preventing arrhythmia following CABG. [15] Atreya *et al.* in their study noticed a decrease in the incidence of AF by 11% in cardiac surgery patients with the use of perioperative amiodarone. [16] Sasa *et al.* used prophylactic amiodarone in patients of CABG or valve replacement and observed a decrease of 14.6% in the incidence of AF. [17] Alghamdi *et al.* also found a highly significant reduction in relative risk of AF with the addition of MgSO_4 . [18]

These results are similar to our study, where AF in Group I was reduced by 31.6% from pre- to post-operative period and by 28.3% from preoperative to the time of discharge ($P < 0.001$) [Table 2]. However, in Group II, it was increased by 18.4% from pre- to post-operative period and further increased by 20% from preoperative to the time of discharge ($P < 0.001$) [Table 2]. The greater decrease in the incidence of AF in our study was because we used the combination of $MgSO_4$ and amiodarone, whereas in previous studies, they have used either $MgSO_4$ or amiodarone as prophylaxis.

Rajagopalan *et al.* noted that $MgSO_4$ infusion alone did not increase the rate of successful cardioversion of AF.[19] Cook *et al.* also concluded in their study that $MgSO_4$ supplementation alone does not prevent postoperative AF after cardiac surgery.[20] Both these studies used only $MgSO_4$ for prophylaxis of AF.

Our results are similar with the study conducted by Cagli *et al.*, who also used the combination of both drugs and concluded that together these agents are tolerable and work more effectively in high-risk patients than they do on their own.[21]

Dave *et al.* confirmed that the CPB time >100 min showed a significant association with the onset of postoperative AF, but the duration of CPB in our patients was less than that and was comparable in both the groups[22] ($P = 0.104$) [Table 3].

There are a number of studies that have reported reduction in the incidence of AF following open heart surgeries; however, after reviewing the literature, no study could be found that showed the role of combination of single i.v. bolus of amiodarone and $MgSO_4$ in reduction of incidence of postvalvular heart surgery arrhythmias.

In the present study, all patients in both the groups had mitral valve disease and underwent MVR either with mechanical or tissue prosthetic valve, while in previous studies, patients having different valve involvements and valve repairs were also included. Patients were monitored for 48 h in the intensive care unit for any kind of arrhythmias. The study did not witness any significant incidence of hypotension or bradycardia in either of the groups. Before discharge of patients, the incidence of AF was also significantly low in Group I as compared to Group II ($P < 0.001$) [Table 2]. The onset of antiarrhythmic effect of i.v. amiodarone is rapid. Therefore, the use of i.v. amiodarone as a prophylaxis to postvalvular surgery arrhythmia is more logical.

The mechanism underlying the benefit of the combination of amiodarone and $MgSO_4$ could only be speculative. Amiodarone has antiarrhythmic class III effect prolonging the duration of both action potentials and the refractory period as demonstrated by the increase of the QTc interval. This effect is related to its interaction with the potassium current at the cardiac cellular membrane.[23] The known close relation between the homeostasis of potassium and Mg might explain the synergism with amiodarone.

The limitation of our study includes that we do not monitor Mg concentration in the studied group. It is well known that patients presenting for cardiac surgery are frequently Mg deficient. If serum Mg level was assessed during the study, it may conclude that the therapeutic effect of Mg administration has been achieved by the correction of preexisting hypomagnesemia. We only recorded in-hospital episode of AF, without considering AF episodes that might have occurred after discharge.

We recommend further trials to study the correlation between the intracellular and the serum levels of Mg and their relation to AF after MVR surgery.

CONCLUSION

Previous reports have emphasized the requirement of a loading dose regimen of amiodarone before or at the time of surgery with maintenance dose; however, in our study, initiation of amiodarone treatment by combining with MgSO₄ at the time of rewarming without maintenance dose was found to be an effective, simple, well-tolerated, and cost-effective therapy for prevention of AF in patients undergoing MVR.

i.v. prophylactic combination of amiodarone and MgSO₄ bolus is effective in cure and prevention of arrhythmias following MVR surgery in patients with mitral valve disease with or without AF. The dose of amiodarone (3 mg.kg⁻¹) plus MgSO₄ (30 mg.kg⁻¹) is well tolerated and more effective in these patients.

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Conflicts of interest

There are no conflicts of interest.

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Figures and Tables

Table 1

Comparison of baseline characteristic between Group I and Group II

Variable	Group I (n=60), n (%)	Group II (n=60), n (%)	P
Age (years), mean±SD	42.85±10.16	44.06±12.58	0.563
Gender (male:female)	32:28	29:31	0.584
Height (cm), mean±SD	161.72±8.37	159.31±7.62	0.104
Comorbidities			
Diabetic mellitus	23 (38.3)	20 (33.3)	0.567
Hypertension	24 (40)	22 (36.7)	0.707
Smoking	14 (23.3)	17 (28.3)	0.532
Left ventricular function (EF), mean±SD	52.31±5.38	53.60±4.92	0.173
NYHA class			
Class II	28 (46.7)	34 (56.7)	0.273
Class III	32 (53.3)	26 (43.3)	
Type of mitral valve			
Mitral regurgitation	5 (8.3)	5 (8.3)	0.924
Mitral stenosis	34 (56.7)	36 (60)	
Mixed	21 (35)	19 (31.7)	
LA size (mm)			
<45	12	15	0.589
45-52	40	40	
>52	8	5	

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The data is presented as mean±SD and analyzed using unpaired *t*-test or as *n* (%) and analyzed using Chi-square test.
 NYHA=New York Heart Association, EF=Ejection fraction, LA=Left atrium, SD=Standard deviation

Table 2

Comparison of incidence of sinus rhythm and atrial fibrillation in Group I and Group II at preoperative, postoperative, and at the time of discharge

Variables	Group I (n=60), n (%)	Group II (n=60), n (%)	P
Preoperative			
Sinus rhythm	25 (41.7)	28 (46.7)	0.581
Atrial fibrillation	35 (58.3)	32 (53.3)	
Postoperative			
Sinus rhythm	44 (73.3)	17 (28.3)	<0.001*
Atrial fibrillation	16 (26.7)	43 (71.7)	
At discharge			
Sinus rhythm	42 (70.0)	16 (26.7)	<0.001*
Atrial fibrillation	18 (30.0)	44 (73.3)	

The data are presented as n (%) and analyzed using Chi-square test. *Highly statistically significant difference ($P<0.001$)

Table 3

Intraoperative events in Group I and Group II

Intraoperative events	Group I (n=60)	Group II (n=60)	P
CPB time (min), mean±SD	80.19±7.62	77.84±8.09	0.104
ACC time (min), mean±SD	62.91±9.17	62.18±8.14	0.645
Basal HR (beats/min), mean±SD	103.87±13.41	107.05±12.63	0.184
Inotrope used (adrenaline)	58	60	0.496

The data are presented as mean±SD and analyzed using unpaired *t*-test. CPB=Cardio pulmonary bypass, ACC=Aortic cross clamp, SD=Standard deviation

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