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Effect of electrocautery maze procedure and amiodarone in rheumatic valvular heart disease patients with atrial fibrillation undergoing mitral valve replacement surgery

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Abstract

Introduction: Electrocautery maze and amiodarone will ensure a better controlled sinus rhythm throughout the immediate postoperative period and will make it smoother.

Objective: To study the effect of electrocautery maze procedure and amiodarone in RHD patients with AF undergoing mitral valve replacement surgery.

Materials and Methods: This randomized prospective double blind clinical trial was carried out among 40 patients undergoing mitral valve replacement surgery in a tertiary care hospital. Randomization was done by using lottery method. Patients were randomly assigned in one of the following two groups.

Group I: (CM, n = 20) Cautery maze procedure was done and 100ml normal saline infused over 20 min before induction.

Group II: (CM + A, n = 20) Cautery maze procedure was done & Amiodarone 3 mg/kg body weight diluted in 100 ml normal saline infused over 20 minutes before induction.

Results: In present study 75% patients in group I and 85% patients in group II were in sinus rhythm at ACC release. 10% patients in group I while 5% patient had ventricular tachycardia/fibrillation at ACC release. 1 patient in group I and no patient in group II had recurrence of AF within 3 days postoperatively. There was no statistically significant difference in the mean value of extubation time 9.95±1.31 in group I & 10.80±4.61 in group II & even in ICU stay 4.75±1.74 days in group I, 5.15±1.13 days in group II.

Conclusion: The combination of both electrocautery maze procedure and amiodarone may have a better control over atrial fibrillation than only electrocautery maze procedure alone.

Keywords: Atrial fibrillation, Electrocautery, Amiodarone

Introduction

Cardiovascular diseases and their complications are still a global burden. With all the technical advances as an aid to the present day cardiologists and cardiac surgeons and in spite of in depth studies and volumes of research being done, there still are areas in cardiology where people believe that the final word has not been said as yet. Atrial fibrillation (AF), one of the most commonly encountered and sustained cardiac arrhythmia continue to be one of such areas.[(1)]

The prevalence of AF is increasing worldwide.[(2)] In developed countries, a predominant cause of AF is elderly age while in developing countries like India; it is predominantly attributed to valvular heart disease, mitral stenosis (MS) and mitral regurgitation (MR) of rheumatic origin. AF is associated with the risk of thromoembolic complications in 17%-18% of patients.[(3,4)]

Oral amiodarone therapy needs frequent visits to the hospital and intense monitoring for side effects. However, the onset of the anti-arrhythmic effect of intravenous amiodarone is rapid.[(5,6)] NSR is difficult to achieve and maintain in patients with RHD.[(7)] Hence special efforts should be made to correct AF during surgery.[(8)]

Intra-operative radiofrequency ablation is a novel surgical principle for the treatment of atrial fibrillation in combination with a standard open-heart operation.[(9)] It is based on the original concept of the maze procedure developed and introduced by James Cox. Application of radiofrequency current replaces the incisions and sutures of the standard maze technique.[(10)]

In literature combined effect of both pharmacological and surgical treatment of atrial fibrillation has not been studied. We feel that the multimodal attack of AF "electrocautery maze and amiodarone" will ensure a better controlled sinus rhythm throughout the immediate postoperative period and will make it smoother.

The purpose of the study is therefore to study the effect of electrocautery maze procedure and amiodarone in rheumatic valvular heart disease patients with atrial fibrillation undergoing mitral valve replacement surgery.

Materials and Method

Study Setting: The present study was carried out in the department of Anesthesiology (CVTS OT), in a tertiary care hospital run by State Government after approval by the college ethical committee.

Source of study population: Patients with AF undergoing mitral valve replacement surgery were included in present study.

Study design: The study design was randomized prospective double blind clinical trial. Randomization was done by using lottery method.

Study duration: The present study was carried out from January 2010 to November 2011.

Inclusion Criteria: Patients between 16 to 60 years of both sex with NYHA class III or IV and having persistent chronic AF posted for MVR.

Exclusion Criteria:

1. Pregnancy,
2. Resting heart rate of < 50/min,
3. Uncontrolled heart failure,
4. Sick sinus rhythm,
5. Atrioventricular block and serum creatinine > 2 mg/dl
6. Patients receiving cimetidine, phenytoin, cholestyramine, and cyclosporine for therapeutic reasons
7. Known allergic to amiodarone or receiving amiodarone therapy
8. Thyroid disease
9. No consent
10. Acute valve endocarditis
11. Redo surgery.
12. After entering into study if the patients required rescue treatment in a form of amiodarone infusion or temporary pacing
13. Death

Sample size: Sample size calculation was done with the help of statistical software in Master 1.0 based on proportion of AF at aortic clamp release in study Effect of prophylactic amiodarone in patients with rheumatic valve disease undergoing valve replacement surgery [11] & Effect of single intra-operative dose of amiodarone in patients with rheumatic valvular heart disease and atrial fibrillation undergoing valve replacement surgery.[12]

Proportion is the 1st P1 =0.0714

Proportion is the 2nd P2 =0.2875

Population risk difference = 2

With confidence interval as 95% it came out to be 18 patients in each group with the help of following formula.

$$n \frac{Z^2_{1-\frac{\alpha}{2}} \left[P_1(1-P_1) + P_2(1-P_2)\right]}{d^2}$$

Where,

P_1 : Proportion in the first group

P_2 : Proportion in the second group

d_2 : Population risk difference (Absolute precision) hence we have taken 20 patients in each group

Preoperative requirement: A detailed pre anesthetic evaluation including history of present illness, general examination, systemic examination, airway assessment was carried out in each patient. Appropriate laboratory tests were carried out.

Intervention: 40 patients were randomly assigned in one of the following two groups.

Group I: (CM n = 20) Cautery maze procedure was done and 100ml normal saline infused over 20min before induction.

Group II: (CM + A n = 20) Cautery maze procedure was done & Amiodarone 3 mg/kg body weight diluted in 100ml normal saline infused over 20 minutes before induction.

Study drug used throughout study period was made available through hospital supply as Inj. Cardarone 150 mg/ 3 ml and was of the same brand.

After approval by the institutional ethical committee and preoperative valid informed consent, patients were included in study. On night prior to surgery, Tab. Diazepam 5 mg and Tab. Ranitidine 150 mg, were given to all patients. All the patients received the morning dose of beta-blockers, calcium channel blockers, & Digoxin. Patients were taken inside operating room after confirming overnight fasting.

Phillips Multichannel monitor (Philips IntelliVue MP70 multi-para monitor) was used to monitor & record parameters. Sedation with IV Fentanyl 2-4 μg/kg and Midazolam 0.05 mg/kg was administered. The right internal jugular vein was cannulated with triple lumen central venous catheter, left radial arterial, & right femoral arterial line were established under local anesthesia & invasive blood pressure as well CVP was monitored. Inj. cefotaxim 20 mg/kg and tranexamic acid 10 mg/kg were administered intravenously to all the patients as a part of institutional protocol.

Study drug given as above mentioned protocol by anesthesiologist who was blinded for study. Patient was induced with Inj. Thiopental 3-5 mg/kg. Neuromuscular block was achieved with IV Vecuronium 0.15 mg/kg. Intubation was done with the appropriate sized cuffed endotracheal tube. After inflating cuff and securing the tube, controlled mechanical ventilation was started and anesthesia was maintained on O_2 with inhalational anesthetic agent (1%-2% Sevoflurane or 0.6% -1.2% Isoflurane according to vital parameter) on semi closed circle system with CO_2 absorber and flow rate of 4 lit/min. (Datex Ohmeda Excel SE with Ohmeda 7000 Ventilator).

Trans-esophageal probe (iE33 Phillips machine) was inserted to evaluate mitral stenosis/regurgitation, condition of valve, presence of clot, systolic and diastolic function.

Infusion of Fentanyl, Midazolam, Vecuronium were administered as per needs (mixture of Vecuronium 20 mg, Midazolam 10 mg, Fentanyl 500 mcg diluted to 50 cc started as infusion).

Heparin was given at a dose of 300 U/kg before cannulation and supplemented as necessary to maintain ACT > 400 sec while on Cardio Pulmonary Bypass.

Pump prime consisted (of 1200ml balanced electrolyte solution and 500ml of tetra starch containing 25meq of sodium bicarbonate and 5000 units of heparin mannitol 100 ml, lasix 1 mg/kg) CPB was maintained with roller pump utilizing a membrane oxygenator. All patients underwent standard non-pulsatile normothermic or mildly hypothermic (28°C to 32°C) cardiopulmonary bypass. Myocardial protection was induced with 15-20 ml/ kg of cold high potassium cardioplegia (16 mmol potassium in 20 ml plegiocard solution) through the aortic root after aortic occlusion. The valve replacement was carried out under CPB with mild hypothermia.

Cautery maze procedure was done at this time. The maze lines are performed with a surgical electrocautery using ballpoint tip. During procedure the operative field was kept as dry as possible; this can usually be achieved by using two suckers. Also the lungs are freed from blood by forced manual ventilation, and then the endotracheal tube is disconnected from the ventilator. The contact between the electrode and the endocardium was kept good, otherwise the impedance rises and current delivery is shut off. The impedance can also rise if there is blood around the probe. The heat may cause formation of small coagula, and in such cases the probe was cleaned with wet gauze.

As per the institutional protocol, nitroglycerine infusions 0.5 µg/kg/min and dopamine 5 µg/kg/min were started at the onset of re-warming. All the patients were re-warmed to 37°C. Serum potassium levels were optimized to 4 – 4.5 mEq/L throughout surgery to prevent arrhythmia induced by hypo-hyperkalemia.

Initial rhythm after the aortic cross clamp release was noted. If it was AF, cardio version was attempted with internal paddles with stepwise increasing energy (10J, 20J, 30J). If the HR was less than 60/min, pacing (epicardial) was initiated, if the patient had ventricular fibrillation (VF) or ventricular tachycardia (VT), this was also treated with internal defibrillation with stepwise increasing energy. If the patient had atrioventricular block A-V sequential pacing (epicardial) was initiated. Adrenaline 0.05 µg/kg/min was started for ionotropic support if hypotension (systolic blood pressure less than 90 mmHg) was encountered despite 10µg/kg/min of dopamine infusion.

After patient weaned from bypass, Heparin was neutralized with Protamine 1.5 mg/100 U intravenously to achieve ACT 80 to 120 sec.

Blood sample was collected for Hb, ABG & serum electrolytes at the following time points. After induction,

- Before induction, after induction
- During and bypass

ACT was done at following time-

- Baseline
- After Heparin administration
- After Protamine titration
- Post operatively if bleeding is > 200 ml/hour

Patient monitored as per standard hospital protocol for cardiac surgery throughout perioperative course (vitals, urine output, Hb, ABG & Serum. Electrolytes)

Patients were also observed for any complication like stroke, acute myocardial infarction & thromboembolism.

Statistical analysis: Statistical analysis of continuous parameters was presented as mean ± SD. Continuous parameters were compared between group I and group II by performing unpaired t-test. Categorical variables were analyzed by Chi square test. For small numbers Fisher Exact Test was applied whenever required. WILCOXON Rank Sum Test was used to compare change in heart rate, systolic blood pressure, diastolic blood pressure, central venous pressure from baseline in both the groups for non-randomized data. *p* value less than 0.05 was considered as statistically significant. *p* value less than 0.001 was considered highly significant. Data was analyzed by statistical software STATA version 10.0

Results

Table 1: Adverse outcome occurring in both groups

	Group I CM (n=20)	**Group II CM + A (n=20)**
Stroke	Nil	Nil
AMI	Nil	Nil
Thromboembolism	Nil	Nil

None of the patients in both the groups had any of the adverse outcomes.

Table 2: Mean heart rate in both groups

Time interval	**Heart rate (/min)**		**p value**
	Group I CM (n=20) Mean ± SD	**Group II CM + A (n=20) Mean ± SD**	
Baseline	94.52 ± 17.84	102.5 ± 27.74	0.3415
Pre-bypass	86.45 ± 9.07	86.25 ± 21.94	0.1801
Post-bypass	86.65 ± 6.18	83.4 ± 6.90	0.3101

1 hour	82.1 ±7.26	91.75 ± 15.36	0.3862
2 hour	95.1 ± 13.13	90.85 ± 13.21	0.2391
3 hour	93.45 ± 12.54	79.75 ± 11.20	**0.0160**
4 hour	82.2 ± 8.48	83.4 ± 10.01	0.8603
5 hour	86.1 ± 7.90	83.2 ± 9.25	0.2790
6 hour	81.75±7.07	82.15 ± 7.94	0.5789
9 hour	82.95 ± 5.92	80.2 ± 8.84	0.3455
12 hour	84.2 ± 6.64	83.35 ± 6.41	0.6358
18 hour	81.7 ± 4.36	81.5 ± 3.31	0.6651
24 hour	82.4 ± 6.44	76.15 ± 3.18	0.1751

Table 4 shows that both the groups were comparable with respect to mean heart rate in both the groups. In group II during 3rd hour shows significant decrease in mean heart rate as compared to group I.

Table 3: Mean systolic blood pressure in both groups

Time interval	Systolic blood pressure (mm Hg)		p value
	Group I CM (n=20) Mean ± SD	Group II CM + A (n=20) Mean ± SD	
Baseline	120.53±9.20	114.7±12.21	0.0733
Pre-bypass	109.85 ± 6.39	110.6 ± 6.02	0.1191
Post-bypass	105.7 ± 4.69	105.85 ± 8.14	0.1291
1 hour	101.1 ± 6.11	102.2 ± 5.80	0.0545
2 hour	94.5 ± 20.46	113.55 ± 5.82	0.001
3 hour	117.9 ± 6.06	110.6 ± 7.44	0.0758
4 hour	102.6 ± 6.77	111.25 ± 4.66	0.001
5 hour	112.95 ± 4.74	111.1 ± 5.05	0.5155
6 hour	113.35 ± 5.62	110.6 ± 5.73	0.2495
9 hour	111.7 ± 5.41	111.25 ± 5.09	0.0903
12 hour	111.8 ± 4.56	111.1 ± 4.07	0.2072
18 hour	113.0 ± 6.0	110.6 ± 4.45	0.4240
24 hour	111.3 ± 3.62	110.3 ± 4.36	0.1669

The mean systolic blood pressure in both the groups was comparable & was not statistically significant.

Table 4: Mean diastolic blood pressure in both groups

Time interval	Diastolic blood pressure (mm Hg)		p value
	Group I CM (n=20) Mean ± SD	Group II CM + A (n=20) Mean ± SD	
Baseline	72.21±9.56	69.65±9.76	0.4125
Pre-bypass	66.40±3.15	67.7±5.47	0.3569
Post-bypass	59.18±13.91	64.1±2.46	0.1055
1 hour	61.96±14.54	63.63±3.63	0.8814
2 hour	60.94±13.99	66.9±3.97	0.1754
3 hour	61.15±14.19	66.45±3.53	0.2114
4 hour	62.61±14.78	65.1±2.63	0.6833
5 hour	68.36±15.55	75.5±9.51	0.1068
6 hour	62.45±14.62	65.95±2.76	0.3498
9 hour	61.17±14.25	65.8±3.60	0.1427
12 hour	62.96±14.68	66.7±3.62	0.3286
18 hour	64.04±15.06	65.95±2.98	0.5779
24 hour	62.06±14.20	66±4.30	0.4555

The mean diastolic blood pressure in both the groups was comparable & was not statistically significant.

Table 5: Mean central venous pressure in both groups

Time interval	Central venous pressure (mm Hg)		*p* value
	Group I CM (n=20) Mean ± SD	Group II CM + A (n=20) Mean ± SD	
Baseline	6.15±0.68	6.30±0.65	0.4793
Pre-bypass	6.55±0.51	6.15±0.48	0.0276
Post-bypass	6.3±0.57	6.5±0.513	0.7274
1 hour	5.05±1.19	5.5±1.31	0.1599
2 hour	5.20±1.24	4.65±1.42	0.2888
3 hour	5.60±0.89	5.6±0.82	0.2719
4 hour	5.85±0.81	5.45±1.09	0.1505
5 hour	5.70±0.57	6.4±0.50	0.2273
6 hour	6.55±0.51	6.4±0.51	0.6412
9 hour	6.40±0.59	6.65±0.93	0.6754
12 hour	6.30±0.57	6.45±0.60	0.9321
18 hour	6.601±0.59	6.35±0.67	0.2302
24 hour	6.05±1.09	6.05±0.60	0.2671

Table 7 shows that the mean central venous pressure in both the groups were comparable & were not statistically significant.

Discussion

The present study, "Effect of electrocautery maze procedure & amiodarone in rheumatic valvular heart disease patients with atrial fibrillation undergoing mitral valve replacement surgery," was carried out in our institute a tertiary care hospital run by State Government. We included 40 patients of both sex between 16 to 60 years age group undergoing mitral valve replacement surgery. They were randomly divided in one of the following two groups.

Group I: (CM n=20) Cautery maze procedure was done 100ml normal saline infused over 20 minutes before induction.

Group II: (CM + A n=20) Cautery Maze procedure done and amiodarone 3mg/kg body weight bolus diluted in 100ml normal saline infused over 20 minutes before induction.

Vardas et al,[13] Vora et al,[8] Selvaraj et al[12] & Kumar Kar et al[11] compared amiodarone with placebo. Results from these studies depict that amiodarone is always better than placebo in maintaining sinus rhythm. Vardas et al,[13] Vora et al[8] Kumar Kar et al[11] all had more than 80% conversion to sinus rhythm. Galve et al[14] used digoxin in his control group and in present study cautery maze procedure is used as other group. Both digoxin and cautery maze procedure are used for treatment of atrial fibrillation still, in both present study and study done by Galve et al,[14] amiodarone group had more percentage of patients converting to sinus rhythm.

Cochrane et al,[15] Selvaraj et al[12] and present study found decrease in heart rate from (146 to 89), (95.1 ± 26.11) to (85.5 ± 21.49) and (102.5 ± 27.74) to (89.2 ± 25.71) respectively.

Kumar Kar et al[11] found no patient in AF at the end of surgery in amiodarone group and present study also found the same result in electrocautery maze and amiodarone group (group II).

In present study none of the patients in cautery maze group (group I) were in AF at the end of surgery whereas, Kumar Kar et al[11] found 4 patients in AF in placebo group.

Inamdar et al[16] found, 100% freedom from atrial fibrillation intraoperatively.

Galve et al,[14] Selvaraj et al,[12] Kumar Kar et al,[11] found (12%), (12.8%), (14.29%) respectively. In present study no patient in electrocautery maze and amiodarone group (group II) had recurrence of AF in ICU.

Selvaraj et al[12] in his study found that 9 out of 42 (21.4%) patients in amiodarone group and 22 out of 40 (55%) in control group were in AF on the first postoperative day.

In present study, only 1 patient out of 18 in group I (cautery maze group) was in AF to whom amiodarone infusion was started. This patient was not available for further observation in study as per our study criteria.

Conclusion

The combination of both electrocautery maze procedure and amiodarone may have a better control over atrial fibrillation than only electrocautery maze procedure alone.

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