

Original Research Article

Efficacy of prophylactic use of sotalol versus amiodarone in the prevention of new onset post operative atrial fibrillation post off pump coronary artery bypass surgery

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ABSTRACT

Background: Atrial fibrillation (AF) is one of the most common arrhythmias following cardiac surgery, occurring in 20-40% of cases, and contributes significantly to increased ICU and hospital stay. While studies exist on sotalol and amiodarone individually for preventing new-onset AF post off-pump CABG, no study has directly compared their effectiveness.

Methods: Seventy-two patients undergoing off-pump CABG were randomised equally into two groups of 36. Group A received IV Amiodarone 6 mg/kg 30 minutes pre-incision, continued as oral Amiodarone 200 mg BD for 3 days then 100 mg BD for 2 days postoperatively. Group S received oral Sotalol 80 mg on the morning of surgery, continued at 80 mg BD postoperatively. Included patients had diabetes mellitus, hypertension, and preserved LV systolic function. Exclusion criteria comprised of COPD, CKD, PVD, moderate-to-severe LV dysfunction, emergency surgery, and pre-existing AF.

Results: Post-operative AF (POAF) occurred in 25% of Group A and 27.77% of Group S, with all cases presenting on post-operative day 2. No statistically significant differences were found between groups across heart rate, blood pressure, graft count, inotropic score, ICU stay, hospital stay, or ventilation duration. The only notable difference was cost Rs.170 for amiodarone versus Rs.10 for sotalol favouring sotalol.

Conclusions: Amiodarone and sotalol demonstrated comparable efficacy in preventing POAF following off-pump CABG. A larger study with broader inclusion criteria is recommended to better define the relative effectiveness of both agents.

Keywords: Sotalol, Amiodarone, Post operative atrial fibrillation, Off pump coronary artery bypass surgery

INTRODUCTION

Atrial fibrillation, though doesn't pose a major risk to life most of the times, is the commonest arrhythmia noted post cardiac surgery. It is noted in about 20 to 40% of the individual's undergoing surgery on the heart.¹ The reasons include older age and it usually lasts for a short duration. Other risk factors include male gender, prior history of atrial fibrillation, discontinuation of medications like beta blocker in the pre operative period, congestive heart failure

and imbalance in electrolytes. Atrial fibrillation might require additional medical treatment and extended hospital and ICU stay at times.² Many antiarrhythmic agents have known to be used in the treatment and prevention of atrial fibrillation resulting in different responses to different medications.^{3,4}

Studies have shown that beta blockers decline the onset of atrial fibrillation in coronary artery bypass grafting individuals and also in patients who undergo valve

surgeries. It has shown to be of benefit when administered just before or immediately after surgery.⁵ Studies comparing beta blockers have been done and studies involving sotalol have been found to have a good safety margin and is a major drug in preventing atrial fibrillation.^{6,7} Some studies were done with amiodarone as a drug in the management of atrial fibrillation. Amiodarone which is a class 3 antiarrhythmic drug widens the refractory duration of ventricular and atrial muscle and AV nodes.⁸ Additionally, it has minimal activity in beta blocking and calcium channel blocking.⁹ The frequent side effects of this drug include bradycardia and atrioventricular block because of the calcium channel blocking property.¹⁰ Some studies have proven the role of low dose amiodarone in preventing post operative atrial fibrillation after CABG.

Atrial fibrillation occurring post operatively after coronary artery bypass grafting occurring as a new onset is known to be a transient, limited condition. It is seen to be associated with increased stroke rates. Studies reporting the incidence of POAF after CABG and the most effective medications in the prevention of the same are limited.¹¹⁻¹⁴

As per a study published in 2024, It is believed that about 30% of patients who underwent CABG develop new onset AF after the procedure. Incidence was found to be around 20 to 40% in previously published big scale studies. Most studies involved intermittent monitoring. The maximum level of monitoring performed in these researches was the telemetric monitoring until discharge from the hospital. Other methods included 12 channel electrocardiograms, holter investigations for 72 hours and multi day telemetric monitoring. The drawbacks with these were when there is a stop of the monitoring, the potential to detect arrhythmias also end. The next is the ability to detect AF with monitoring done intermittently is much lower than that with monitoring done continuously.^{15,16} The benefits of OPCAB over on pump coronary artery bypass surgery include a decline in the occurrence of atrial fibrillation, reduction in transfusions of blood and products and drop in the incidence of acute renal failure.^{17,18}

The aim is to assess the efficacy of prophylactic use of sotalol versus amiodarone in preventing POAF in patients planned to undergo off pump coronary artery bypass grafting (OPCAB).

The objectives of the study are to assess the efficacy of prophylactic use of sotalol versus amiodarone in preventing POAF in patients undergoing OPCAB, assess the duration of ICU stay and entire hospital stay and assess the cost effectiveness of both drugs.

METHODS

This randomized controlled study included a sample size of 72 participants and was conducted at Chettinad Super Speciality Hospital over a period of 18 months, from October 2024 to February 2026.

After obtaining approval for the study from the institutional human ethics committee for the study, with reference number IHEC-I/3149/24, on 17/10/2024, the study was conducted.

Patients who present with CAD-TVD, across age groups, planned for CABG were randomized into two groups. A total of 72 patients were taken up for the study and randomized into 2 groups with 36 in each group with sotalol and amiodarone as the drug administered. The patients included were diabetics, hypertensives and those with adequate LV systolic function. Patients with COPD, CKD, PVD, moderate to severe LV dysfunction, emergency surgery and pre-existing atrial fibrillation were excluded from the study. Group A received Inj. Amiodarone 6 mg/kg about 30 minutes prior to skin incision and Group S received T. Sotalol 80 mg on the morning of the surgery at 5:30 am and these medications were continued in the post-operative period from POD#0 as T. Amiodarone 200 mg BD for 3 days followed by 100 mg BD for 2 days and T. Sotalol 80 mg BD. If the patient developed bradycardia (HR <40bpm), Atropine (0.01 mg/kg every 3-5 minutes; maximum dose 0.04 mg/kg) would be administered until desired heart rate (>40bpm) is achieved. If the patient developed bradycardia with hypotension, IV Ephedrine (bolus dose 5-10 mg) would be administered until MAP>60 is achieved. If no bradycardia is noted, the same drug was continued until POD#5 or discharge, whichever came first. Patients were monitored closely to note the incidence of atrial fibrillation in the post-operative period with a continuous display of ECG and NIBP. If the patient was found to have atrial fibrillation, ECG strip was taken and the conventional institutional protocol for treating atrial fibrillation was followed. If electrolyte derangements were noted, corrections were done accordingly. (K deficit (mmol) = (desired potassium level current potassium level) x weight (in kg) x 0.4). The rhythm was monitored and once normal sinus rhythm was recorded, the dosage of the drugs was tapered. This was followed up till the first review which was a week from the date of discharge.

For non-inferiority design, the formula is:

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta}}{\delta_0} \right)^2 \times p \times (1 - p)$$

Sample size: 72; Group A=36; Group S=36

Where, Significance level $\alpha=0.05$; Power $(1-\beta) =0.20$; Ratio of sample size, treatment group1/group2=1

Expected proportion in the treatment group=0.22; Expected proportion in the control group=0.10(preoperative use of sotalol versus atenolol for atrial fibrillation after cardiac surgery. Rafael Sanjuan et al); Margin=0.2; Drop rate (%)=20.

RESULTS

No mortality in both groups.

Results of the study is discussed under the following headings; Baseline Parameters; Intra-operative Haemodynamic Parameters - Heart Rate, SBP & DBP; VIS score; Post-operative Haemodynamic Parameters - Heart Rate, SBP & DBP; Post-op Atrial Fibrillation.

Baseline parameters

The mean heart rate, SpO₂, systolic blood pressure (SBP), and diastolic blood pressure (DBP) were compared between the two study groups. No difference which was statistically significant was observed in any of the baseline parameters ($p>0.05$), indicating that both groups were similar at baseline.

Table 1: Baseline parameters.

Baseline parameters	Group	N	Mean	Std. dev.	Mean diff.	P value by 't' test
Heart rate	Group A	36	85.44	8.52	1.389	0.450
	Group S	36	86.83	6.92		
SpO ₂	Group A	36	98.75	0.94	0.361	0.125
	Group S	36	99.11	1.04		
SBP	Group A	36	117.22	11.37	3.056	0.218
	Group S	36	120.28	9.41		
DBP	Group A	36	73.89	9.34	2.500	0.235
	Group S	36	76.39	8.33		

Table 2: Intra-operative haemodynamic parameters - heart rate, SBP and DBP.

Time point	Metric	Group	N	Mean	Std. Dev.	Mean diff.	P value (t-test)
30 min	Heart Rate	Group A	36	93.44	5.21	2.722	0.022*
	Heart Rate	Group S	36	90.72	4.61		
	SBP	Group A	36	133.50	7.99	2.500	0.197
	SBP	Group S	36	131.00	8.30		
	DBP	Group A	36	86.39	6.14	0.944	0.486
	DBP	Group S	36	85.44	5.27		
1 hour	Heart Rate	Group A	36	91.56	8.80	2.167	0.271
	Heart Rate	Group S	36	89.39	7.74		
	SBP	Group A	36	129.06	7.37	2.333	0.201
	SBP	Group S	36	126.72	7.94		
	DBP	Group A	36	83.39	5.32	2.444	0.052
	DBP	Group S	36	80.94	5.18		
2 hours	Heart Rate	Group A	36	94.11	5.43	1.889	0.127
	Heart Rate	Group S	36	92.22	4.94		
	SBP	Group A	36	127.00	6.58	1.667	0.289
	SBP	Group S	36	125.33	6.64		
	DBP	Group A	36	82.83	4.44	2.278	0.043*
	DBP	Group S	36	80.56	4.94		

* $p<0.05$ indicates statistical significance.

Table 3: VIS score.

Group	VIS score				P value by 't' test
	N	Mean	SD	Mean diff.	
Group A	36	9.44	3.33	0.361	0.610
Group S	36	9.08	2.60		

Intra-operative haemodynamic parameters

Heart rate

A statistically significant difference was observed at 30 minutes, with a higher mean heart rate in Group A (93.44 ± 5.21) compared to Group S (90.72 ± 4.61)

($p=0.022$). No significant differences were noted at 1 hour and 2 hours ($p>0.05$).

SBP

Mean systolic blood pressure values at 30 minutes, 1 hour, and 2 hours were comparable between both groups. No,

statistically significant difference was observed at any intraoperative time point ($p>0.05$).

DBP

A statistically significant difference was observed at 2 hours, with a higher DBP in Group A (82.83 ± 4.44) compared to Group S (80.56 ± 4.94) ($p=0.043$). No significant differences were noted at 30 minutes and 1 hour ($p>0.05$).

VIS score

The mean VIS score was 9.44 ± 3.33 in Group A and 9.08 ± 2.60 in Group S. There was no difference noted to be statistically significant in VIS score between the two study groups ($p=0.61$).

Post-operative haemodynamic parameters

Heart rate

The mean heart rate values were comparable between the two groups at all postoperative time points. A statistically

significant difference was observed at POD 2, where the mean HR in Group S was 118.00 compared to 112.56 in Group A ($p=0.001$). No significant differences were noted at all other time points ($p>0.05$).

SBP

The mean systolic blood pressure values were similar between both groups at all postoperative time points. No, statistically significant differences were observed in SBP during the postoperative period ($p>0.05$).

DBP

The mean diastolic blood pressure values were comparable between both groups at all postoperative time points. No, statistically significant differences were observed in DBP during the postoperative period ($p>0.05$).

Post-op atrial fibrillation

25% of the Group A had POAF which is lower than 27.77% in Group S but the POAF difference between the groups was not significant statistically ($p>0.05$).

Table 4: Post-operative haemodynamic parameters - Heart rate, SBP & DBP.

Time point	Metric	Group	N	Mean	Std. Dev.	Mean diff.	p value (t-test)
POD 1	Heart Rate	Group A	36	90.44	4.69	1.333	0.208
	Heart Rate	Group S	36	89.11	4.21		
	SBP	Group A	36	123.11	6.80	0.333	0.826
	SBP	Group S	36	122.78	5.96		
	DBP	Group A	36	79.61	4.66	0.833	0.526
	DBP	Group S	36	78.78	6.31		
POD 2	Heart Rate	Group A	36	112.56	4.44	5.444	0.001*
	Heart Rate	Group S	36	118.00	3.85		
	SBP	Group A	36	119.50	7.63	0.722	0.662
	SBP	Group S	36	120.22	6.25		
	DBP	Group A	36	75.67	6.60	0.389	0.798
	DBP	Group S	36	76.06	6.24		
POD 3	Heart Rate	Group A	36	85.11	4.52	0.389	0.714
	Heart Rate	Group S	36	85.50	4.44		
	SBP	Group A	36	118.94	7.40	0.278	0.875
	SBP	Group S	36	119.22	7.47		
	DBP	Group A	36	74.61	6.03	1.222	0.405
	DBP	Group S	36	75.83	6.35		
POD 4	Heart Rate	Group A	36	84.50	3.43	0.389	0.677
	Heart Rate	Group S	36	84.89	4.39		
	SBP	Group A	36	116.11	7.66	2.167	0.258
	SBP	Group S	36	118.28	8.45		
	DBP	Group A	36	75.28	6.54	0.556	0.757
	DBP	Group S	36	74.72	8.51		
POD 5	Heart Rate	Group A	36	84.50	3.78	0.833	0.339
	Heart Rate	Group S	36	83.67	3.56		
	SBP	Group A	36	113.89	8.03	1.389	0.486
	SBP	Group S	36	115.28	8.78		
	DBP	Group A	36	73.06	8.22	0.667	0.702
	DBP	Group S	36	72.39	6.39		

* $p<0.05$ indicates statistical significance.

Table 5: Post-op atrial fibrillation.

Post-op Atrial Fibrillation	Group		Total	Chi sq. p value
	Group A	Group S		
Yes	9 (25%)	10 (27.77%)	19 (26.38%)	0.79
No	27 (75%)	26 (72.22%)	53 (73.61%)	
Total	36 (100%)	36 (100%)	72 (100%)	

Atrial fibrillation was noted in 25% of Group A and 27.77% of Group S individuals. All the patients were noted to have atrial fibrillation on post operative day 2. There was no difference made out to be significant statistically between the groups and also no significant difference was observed in terms of age, with history of diabetes, hypertension, intra operative heart rate, systolic and diastolic blood pressures monitored intra operatively, number of grafts done for the patient, vasoactive inotropic score, heart rate checked post operatively, post operative systolic and diastolic blood pressures, duration of stay in the ICU, total length of stay in hospital and ventilation hours duration. The only significant difference was the cost which was Rs.170 for Group A and Rs.10 for Group S, which proved beneficial for the patients (clinical significance)

DISCUSSION

According to our study, the prevention of new onset atrial fibrillation is not statistically significant in either of the groups. Twenty five percent of patients in amiodarone group and nearly twenty eight percent of the patients in the sotalol group were found to have post operative atrial fibrillation particularly on the post-operative day 2 but the POAF difference between both the groups was not statistically variable.

The mean age was not statistically significant and while looking at the gender, majority was found to be males accounting to 80.55% and females accounting to 19.44%. No, statistically significant difference was seen in patients with diabetes and hypertension in the occurrence of atrial fibrillation as a new onset. The mean EF was 56.7%±3% in the amiodarone group and 55.8%±3.5% in the sotalol group; which is not statistically significant.

There was no difference identified significantly observed in terms of age, heart rate intra operatively, systolic blood pressure intra operatively monitored, intra operatively monitored diastolic blood pressure, no of grafts done for the patient, vasoactive inotropic score, heart rate post operatively monitored, post operative systolic and diastolic blood pressure, duration of stay in ICU, total length of stay in the hospital and time of ventilation hours.

Cost effectiveness was found to be better with Tab. Sotalol since it costed the patient only about Rs.10/ tablet while Inj.Amiodarone costed about Rs.170/ 2 vials.

In a study which involved sotalol for prophylaxis of AF published by Patel et al, it was shown that patients treated with prophylactic sotalol had a dip in the occurrence of atrial fibrillation post operatively compared to those individuals managed with conventional beta blockers.¹⁹

Auer et al studied 253 patients which again showed a significant drop statistically in the count of atrial fibrillation in individuals who took Sotalol compared to those who treated with beta blockers.²⁰

Janssen et al conducted his study on 130 patients and proved that 2.4% of population he studied, treated with sotalol was noted to have AF post operatively compared to 15.3% that was treated with metoprolol.²¹

Parika et al in his study had a count of about 191 patients which again revealed a lesser incidence of AF in the bunch which had sotalol as the study drug which was about 16% versus 32% of patients who had AF with metoprolol as the study drug.

It was concluded in this metanalysis that prophylactic administration of sotalol may be quite a bit extra effective than other beta blockers to prevent the atrial fibrillation post operatively.²²

Aerra et al from Liverpool, UK, did a retrospective study on 103 patients who underwent coronary surgery. The study was done based on the administration of T.Sotalol 40 mg two times in a day from post operative day one to 42 days from the start of the medication along with Inj.Magnesium 2 g immediately after procedure and on the very primary post-operative day. The other group did not receive either magnesium or sotalol and the two groups had identical variables-based patients. It was concluded in this study that the combined use of sotalol and magnesium significantly reduced the onset of the arrhythmia atrial fibrillation in the post-operative period after coronary surgery.²³

Ghurram et al about incidence of post-operative atrial fibrillation. The study was conducted with 748 patients being taken into account. Out of that, 16.7% (127 patients) developed POAF. It also showed that 99.2% of post-operative atrial fibrillation developed in the patients above the age of 50. The risk variables mentioned for the initiation of POAF were increasing age, emergency surgery, renal dysfunction pre operatively, myocardial infarction, severe systolic dysfunction of the left ventricle, intra-aortic balloon pump usage, sepsis in the post-operative period, and EUROSCORE II more than 3. It also

stated that the ventilation hours and duration of inotropes usage were higher in this subset. It was stated that the post-operative atrial fibrillation increases morbidity of the patient, the duration of total hospital stays and the decreased survival of these patients after off pump coronary bypass surgeries.²⁴

Sanjuan et al studied the pre surgical administration of sotalol comparing with atenolol for atrial fibrillation post cardiac surgery. This study was done on about 253 patients that were randomized and one group received T.Atenolol 50 mg/day while the other group received T.Sotalol 80 mg BD. It was noted that 17.45% of patients (44/253) had atrial fibrillation after surgery.

It was proven that oral sotalol was noted to have lesser count of atrial fibrillation after bypass surgery. A difference which was significant statistically was noted among the two groups with the atrial fibrillation incidence seen in 34 patients accounting to 22% and it was 10% in the patients who received sotalol (10 patients) which again proved that sotalol was effective in the avoidance of atrial fibrillation post cardiac procedures.²⁵

Gomes et al studied administration of Sotalol in the dose, ranging from 80 mg to 120 mg which showed a significant decline in the post-operative atrial fibrillation in individuals posted for CABG without major side effects. It was suggested that sotalol would prove a better option in individuals undergoing CABG for the prevention of atrial fibrillation post operatively without heart failure and significant left ventricular dysfunction.²⁶

Wurdeman, in his meta-analysis of ten researches, compared the efficacy of amiodarone and sotalol after CABG. His results showed that both sotalol and amiodarone were effective in declining the onset of atrial fibrillation post operatively and flutter. But there was no significant difference between sotalol and amiodarone for the efficacy. It was concluded that either sotalol or amiodarone could be used prophylactically in seeing a drop in the occurrence of atrial fibrillation event and flutter post coronary artery bypass grafting surgery.

Johnson et al studied the relation between exposure of sotalol and amiodarone and total mortality in individuals with post operative new onset atrial fibrillation after CABG. 930 patients were taken up for the study. At the baseline, it was noted that the subjects who were treated with sotalol had fewer comorbidities. The conclusion was sotalol was associated with a lesser risk of mortality with amiodarone showing increased risk of mortality but it was not common across all subgroups. This further suggested that more detailed research would be required to study the safety of amiodarone and sotalol in individuals with post operative atrial fibrillation.²⁷

Mooss et al published the article on amiodarone or sotalol for the management of atrial fibrillation post cardiac procedures, to assess the decrease of post-operative cardiac surgery arrhythmia events. About 160 patients

were involved in the study with 134 patients undergoing isolated CABG, 17 patients planned for CABG and aortic valve replacement, 9 patients planned for isolated aortic valve replacement and 1 patient's procedure was deferred. They were randomized to receive sotalol 80 mg BD or amiodarone 15 mg/kg administered intravenously over 24 hours followed by amiodarone oral dose of 200 mg TDS. These medications were initiated during the time of surgery and continued till discharge or for one week, whichever was earlier. It was noted that atrial fibrillation was seen in 17% of the individuals in the group who received amiodarone and also 25% of the subjects who received sotalol. The time duration of atrial fibrillation was also monitored which showed a significantly shorter duration of the atrial fibrillation in group that received amiodarone compared to group that received sotalol. It was also noted that patients undergoing replacement of aortic valve or CABG with aortic valve replacement had a lesser incidence of atrial fibrillation with amiodarone (7%) compared to sotalol (82%). It was concluded that amiodarone and sotalol shared a similar safety profile and efficacy in reduction of atrial fibrillation post operatively. It was also noted that the haemodynamic effects were found to be similar between sotalol and amiodarone except that the stroke volume was lower in the sotalol group. It was found that in complex procedures, atrial fibrillation occurred more commonly with sotalol than with amiodarone.²⁸

Amr et al in anaesthesia researches, studied the trial of amiodarone as a loading dose intraoperatively for prevention of atrial fibrillation post cardiac surgery. The sole idea of this study was to evaluate the use of single parenteral loading dose of amiodarone intraoperatively as a prophylactic medication to prevent atrial fibrillation. The IV amiodarone was administered over a period of half an hour just prior to skin incision. The control group was the group which was given normal saline at the same time. It was noted that the patients who had amiodarone showed normal sinus rhythm and the incidence of AF was negligible. It was concluded that a single intraoperative shot of amiodarone was effective significantly in preventing the of new event of atrial fibrillation post operatively after cardiac procedures.²⁹

Limitations

The occurrence of post-operative atrial fibrillation as a new onset post-surgery was not statistically significant since the sample size is small and also only patients with diabetes mellitus and systemic hypertension were considered for the study while patients with COPD, CKD, PVD were excluded from the study. Patients with adequate LV systolic function were only considered for the study.

CONCLUSION

In this study, there is no difference between Group A and Group S (amiodarone and sotalol) in preventing post operative atrial fibrillation post off pump coronary artery bypass grafting surgery. It is concluded from this study

that a larger study population is needed to assess the effectiveness of sotalol versus amiodarone in preventing new onset atrial fibrillation post off pump coronary artery bypass grafting (OPCAB) and also with multiple variables included. This could aid us in assessing the difference in the response between the two drugs.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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