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Impact of Amiodarone on Rate vs Rhythm control in Patients with Atrial Fibrillation

Running Title: Impact of Amiodarone in Rate vs Rhythm control in AF

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Abstract: ***Atrial fibrillation (AF), the most common sustained arrhythmia, poses a significant clinical challenge owing to irregular and rapid heart rhythms, increasing the risk of thromboembolic events, particularly stroke. The choice between heart rate control and rhythm restoration is a critical aspect in managing AF. To study the impact of amiodarone on rate vs rhythm control in patients with atrial fibrillation. A prospective, observational study was conducted over six months at the Aditya Birla Memorial Hospital, Pune. Inclusion criteria were patients aged ≥18 years with acute AF episodes who received intravenous amiodarone. Data, including demographics, comorbidities, cardiac history, amiodarone dosage, and outcomes, were collected. The risk of thromboembolism was assessed using the CHA2DS2VASc score. Descriptive statistics were used for data analysis. Of the 119 enrolled patients, 61% had recent-onset AF. Hypertension (86%) and diabetes (44%) were prevalent comorbidities. Amiodarone, primarily administered as a 150mg bolus, resulted in 78% achieving rhythm control. The thromboembolism risk assessment revealed 88% patients at high risk. Anticoagulant prescriptions varied based on the risk assessment. Amiodarone demonstrated significant efficacy in achieving rhythm control, particularly in recent-onset AF patients with preserved left ventricular function. This study underscores the importance of individualized thromboembolism risk assessment based on CHA2DS2VASc scores to guide appropriate anticoagulant use. This comprehensive approach to AF management emphasizes the significance of addressing both rate and rhythm control along with thromboembolism prevention. These findings provide valuable insights for enhancing the understanding and management of atrial fibrillation.***

Keywords: Amiodarone, Atrial Fibrillation, Rate control, Rhythm control, CHA2DS2VASc score

1. Introduction

Atrial fibrillation (AF) is characterized by disorganized, rapid, and irregular atrial activation with loss of atrial contraction and with an irregular ventricular rate that is determined by AV nodal conduction.[1] It refers to supraventricular tachyarrhythmia that can lead to blood clots, stroke, heart failure and other heart-related complications.[2,3] The most frequent cardiac arrhythmia is Atrial Fibrillation and in United States it affects 2.2 million population.[4] Based on data from the Framingham Heart Study (FHS), the prevalence of AF has increased by 3-fold over the last 50 years. The Global Burden of Disease project estimated the worldwide prevalence of AF at approximately 46.3 million individuals in 2016.[5] In the United States alone, 3-6 million people have AF and It has been estimated that 6-12 million people worldwide will suffer from this condition in the US by 2050 and the figure in Europe is around 9 million people and is expected to be around 17.9 million by 2060.[6]

The three main types of atrial fibrillation based upon the pattern of episodes include:

- **Paroxysmal AF:** self-terminating AF, i.e., spontaneous restoration to normal within 48 hours or less than seven days.
- **Persistent AF:** AF that lasts longer than one week, not self-terminating, needs medical or electrical cardioversion after seven days or more.
- **Permanent AF:** persistent and long-standing AF in which restoration of normal rhythm is no longer possible.[3,7]

The clinical presentation of AF can vary from asymptomatic AF to cardiogenic shock and CVA- Cardiovascular accidents. Although 90% of Atrial Fibrillation episodes may be symptom-free, many individuals have a variety of symptoms, such as – palpitations, dyspnea, fatigue, dizziness, angina, decompensated heart failure, hemodynamic dysfunction, tachycardia-induced cardiomyopathy, and systemic thromboembolism.[8]

There are many causes of atrial fibrillation (AF); however, they are strongly associated with other cardiovascular diseases. Any condition that leads to inflammation, stretching of myocardium, ischemia, increase in sympathetic nervous system (SNS) stimulation of the atria, and electrolyte imbalance affecting the anatomy of the heart may result in the development of atrial fibrillation. In some cases, the cause was iatrogenic.[9]

The primary approach to treat atrial fibrillation typically involves maintaining a normal heart rhythm through cardioversion and the use of antiarrhythmic medications. Currently, amiodarone is the most commonly prescribed antiarrhythmic drug because of its proven effectiveness and safety.[10] The objective of rhythm control is to restore and maintain a normal sinus rhythm, while rate control aims to regulate the heart rate, reduce symptoms, improve blood flow, prevent heart failure, and minimize the risk of adverse cardiovascular outcomes.[11,12] However, the effectiveness of amiodarone in controlling the rate versus rhythm in atrial fibrillation patients is still being evaluated, and more research is needed to establish its efficacy in this context.[13]

Cardioembolic stroke is the most concerning complication of atrial fibrillation (AF). Owing to abnormal blood flow in the left atrium associated with disorganized electrical signals and an absence of coordinated atrial contractions, in addition to endothelial dysfunction and other prothrombotic conditions, thrombi often form in the left atrial appendage (LAA). When that thrombus 'breaks free', it can embolize to the peripheral or (more commonly) the cerebral arterial beds.[14] The risk of stroke in patients with AF has been estimated between 1% and 20% annually. In the United States, this arrhythmia may be responsible for >70,000 ischemic strokes each year representing 10%–12% of all ischemic strokes. Atrial Fibrillation increases the risk of stroke, which is a leading cause of death worldwide.[15]

First developed in 2001, the CHADS2 score method is a risk assessment model that has been broadly used by clinicians to estimate the risk of stroke or thromboembolism. All risk factors were considered equivalent, with the exception of prior stroke or transient ischemia and individuals more than 75 years of age which are marked with a higher score.[14] Oral anticoagulation is the therapy of choice for moderate and high thromboembolism risk patients with atrial fibrillation and any of the known additional risk factors. Asymptomatic patients younger than 65 years with atrial fibrillation and none of the other risk factors are at low risk and should be treated with aspirin or should not be treated at all.[16]

2. Materials And Methods

Study Design and Ethical Approval:
A prospective, observational study was conducted at the Aditya Birla Memorial Hospital, Pune for a duration of six months after permissions and ethical approval was obtained from the Ethics Committee of the hospital.

Inclusion Criteria:
Patients ≥ 18 years of age, those with an acute episode of Atrial Fibrillation who had received IV Amiodarone, with or without comorbidities and those who were willing to participate were included in the study.

Exclusion Criteria:
Pregnant and lactating women, patients aged <18 years and patients undergoing chemotherapy were excluded from the study.
The study was initiated by recruiting eligible patients based on inclusion criteria. Prior to participation in the study, patients were thoroughly informed about the study using the Patient Information Sheet and written informed consent was obtained from patients or their relatives. Data were collected in the self-designed Patient Profile Form, including demographic details of the patient, comorbidities, history of cardiac intervention, type of AF, and hemodynamics. In addition to the above, parameters like doses of amiodarone, pre and post amiodarone heart rate and heart rhythm using ECG reports, pharmacotherapy for management of stroke, discharge medications were also obtained from patient records. Thromboembolism risk assessment was done by using CHA2DS2VASc score where one point is assigned for the presence of each of the following: history of congestive heart failure (CHF), history of hypertension (HTN), diabetes mellitus (DM), vascular disease, age between 65 – 74 years and female sex and two points are assigned for age ≥ 75 years and history of TIA or stroke. A score of 0 indicates low risk of future stroke and TIA, A score of 1 indicates moderate risk and a score of 2 or greater is considered high risk. Prescription pattern of anticoagulants and aspirin for management of thromboembolism was also studied. The collected data was transcribed into Microsoft Excel, and descriptive statistics were employed for the analysis of the results. Subsequently, these results were then compared with those documented in existing literature.

3. Results

A total of 119 patients were recruited during the study period to analyse the impact of amiodarone in rate vs rhythm control patients with atrial fibrillation.

Demographics:
A total of 119 patients participated in the study. Subjects were categorized into four age groups, comprising 6% of patients aged 20-39 years, 17% aged 40-59 years, 65% aged 60-79 years, and 13% aged 80-99 years (Figure 1). Out of the total subjects, 74 (62%) were male, and 45 (38%) were female. Among all patients, 72 (61%) had recent-onset/ paroxysmal AF, and 47 (39%) had persistent/permanent AF (Table 1).

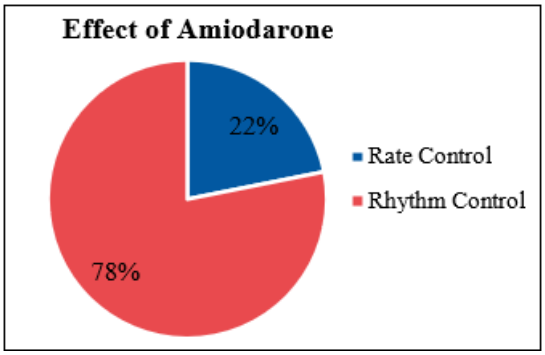

Figure 1: Classification of patients based on age groups

Comorbidities:
The prevalence of comorbidities in AF patients is depicted in (Table 1). Hypertension was the most observed comorbid condition in 86% of patients, followed by Type 2 Diabetes Mellitus in 44% of patients. A history of Cerebrovascular Accident was noted in 34% of patients, and 28% had ischemic heart disease. Patients were also classified based on Left Ventricular Ejection Fraction (LVEF). Out of all patients, 63% had reduced LVEF (≤40%), and 37% had preserved LVEF (>40%) (Table 1).

History of Cardiac Intervention:
Among the 119 patients in the study, 65% had no history of any cardiac intervention. Meanwhile, 24% had a post-PTCA status, 6% had undergone CABG, and 6% had undergone Valve Replacement surgery (Table 1).

Amiodarone Dosage:
Of the total 119 patients, 96% received a 150mg IV bolus dose of Amiodarone, while only 4% received a 300mg IV bolus dose. The majority of patients (39%) received a 600mg infusion of Amiodarone at 2.1 ml/hr. Thirty-three percent received a 900mg infusion at 2.1 ml/hr, 10% received a 1200mg infusion at 2.1 ml/hr, and 18% did not receive any infusion. Among all enrolled patients, 54% were switched to oral Amiodarone therapy, with the most common dosage being 200mg in 45% of patients, while 100mg was prescribed to 9% of patients (Table 2).

Effect of Amiodarone:
Among the total 119 patients, 78% achieved rhythm control, and only 22% achieved rate control after receiving Amiodarone (Figure 2).

Among patients with recent-onset/paroxysmal AF, 74% achieved rhythm control, while 12% achieved rate control. In contrast, among patients with persistent/permanent AF, 26% achieved rhythm control, and 88% achieved rate control (Table 1). Among patients with LVEF ≤40%, 32% achieved rhythm control, while 54% achieved rate control. Conversely, among patients with LVEF >40%, 68% achieved rhythm control, and 46% achieved rate control (Table 1).

Death occurred in 24% of patients out of total enrolled patients.

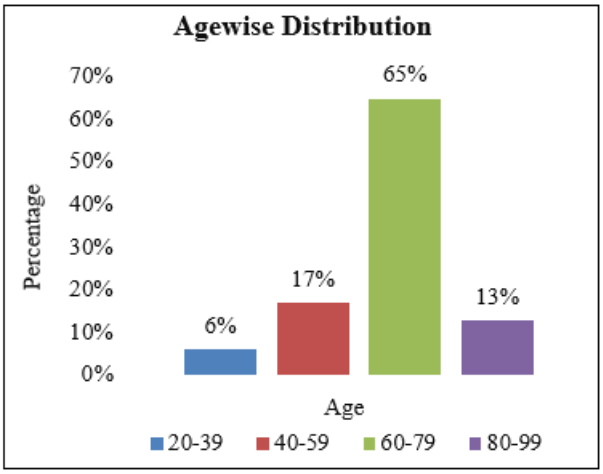

Figure 2: Effect of Amiodarone on Rate Control and Rhythm Control.

Thromboembolism Risk and Its Management:
The mean CHA2DS2VASc score was 3.75 ± 1.84. Out of all enrolled patients, 88% were at high risk, 8% were at moderate risk, and 3% were at low risk of developing thromboembolism (Table 3). Aspirin was administered to 75% of patients in the low-risk group, and one patient did not receive any blood thinner. Among the 10 patients with moderate risk, 60% received Aspirin, and 40% received parenteral anticoagulants, with Enoxaparin being the most common in 30% of patients. Out of the total patients with high thromboembolism risk, 50% received Enoxaparin, 38% received Heparin, 6% received Dalteparin, and 7% did not receive any anticoagulant (Table 3).

4. Discussion

This research involves a comprehensive examination of 119 patients who underwent an episode of atrial fibrillation (AF), with the primary focus on evaluating the effects of amiodarone on rate control versus rhythm control. This study shows that male patients i.e., 62% (74) are more prone to develop AF than female patients i.e., 38%. These observations align with the previous study conducted by **Faniel & Schoenfeld**, including 26 consecutive patients out of which 14 were male and 12 were female.[17] Data from the **Framingham Heart Study** showed that male sex is associated with a 1.5-fold risk of developing AF compared with women.[5]

In this study of total population of 119 patients, 72 patients (61%) belonged to recent onset/ paroxysmal type of AF and 47 patients (39%) belonged to persistent/ permanent type of AF, which shows that the number of patients suffering from recent onset/ paroxysmal type are more than persistent/ permanent type of AF. A study performed by **Horiuchi et al.,** shows eleven patients were considered to have recent-onset, transient, or paroxysmal AF and the remaining 9 to have persistent or long-standing persistent AF based on clinical histories including ECG findings and/or subjective symptoms before and after hospitalization.[18]

Among the total population of 119 patients, four common comorbidities were observed in the patients with AF amongst which 102 patients (45%) had hypertension, 52 patients (23%) had diabetes mellitus, 40 patients (18%) had cerebrovascular accident and 33 patients (15%) had ischemic heart disease. According to a study conducted by **Benjamin**, the most significant risk factors for developing atrial fibrillation were age, hypertension, heart failure, and valvular heart disease. Other significant risk factors included diabetes, left ventricular hypertrophy, and myocardial infarction.[19] A study conducted by **Dzeshka et al.,** suggests that patients with hypertension have a 1.7-fold higher risk of developing AF than those without hypertension. Patients with DM have a 34% greater risk of developing AF and the risk increases by 3% for every additional year of diagnosis.[20] Another study conducted by **Darby & DiMarco**, suggests that Valvular heart disease has been associated with a 1.8- and 3.4-fold increased risk for AF in men and women, respectively.[21]

In total 119 patients were recruited, out of which 77 patients (64%) had no history of cardiac surgery, 24 patients (20%) have undergone PTCA, 10 patients (8%) have undergone

CABG, 6 patients (5%) have undergone valve replacement and 4 patients (3%) have undergone PCI. A study conducted **Burrage et al.,** shows Atrial fibrillation after cardiac surgery (AFACS) is the most common postoperative complication following cardiac surgical procedures and occurs in 25% after isolated coronary artery bypass grafting (CABG), 30% after isolated valvular procedures, and 40–50% following combination CABG/valvular operations.[22] According to the study conducted by **Atreya et al.,** it was concluded that among patients undergoing coronary bypass surgery without previous arrhythmias, perioperative amiodarone is associated with a lower risk of atrial arrhythmias and shorter LOS (Length of stay).[23]

In this study it was found that major population i.e.- 96% (114 patients) received the loading dose of 150mg whereas only 4% (5 patients) received the loading dose of 300mg. A study performed by **Florek & Girzadas**, tells that the loading dose of 150mg for amiodarone is often preferred in certain situations because it allows for a more rapid attainment of therapeutic levels in the body. In this study it was found that 600 mg of infusion dose was most frequently given to 46 patients (39%) followed by 900 mg dose to 39 patients (33%) followed by no requirement of infusion dose in 22 patients (18%) and 1200 mg of dose given to 12 patients (10%).[24] A study conducted by **Chokesuwattanaskul et al.,** tells that the recommended infusion dose of amiodarone is typically administered over a period of 24 hours. In the past, infusion dose of 900 mg was commonly used. However, higher doses of amiodarone have been associated with an increased risk of side effects. Thus, a lower infusion dose of 600 mg is now often preferred to minimize the potential side effects.[25]

Within the total population of 119 patients, 78% achieved rhythm control, and only 22% achieved rate control after receiving Amiodarone. The study performed by **Delle Karth et al.,** concluded that upto 45% of patients achieved sinus rhythm within 4 hrs post amiodarone administration in patients with AF.[26]

Among patients with recent-onset/paroxysmal AF, 74% achieved rhythm control, while 12% achieved rate control. In contrast, among patients with persistent/permanent AF, 26% achieved rhythm control, and 88% achieved rate control. Similar results were observed in previous study conducted by **Roy et al.,** which showed that for recent onset of AF, amiodarone is often used for rate control and conversion of AF to sinus rhythm.[27] This study showed that amiodarone was effective in converting AF to sinus rhythm and maintaining sinus rhythm compared to placebo. Also, a randomized, single-blind, multicentred trial conducted by **Cybulski et al., n.d.** to assess the efficacy of intravenous amiodarone in cardioversion of recent-onset paroxysmal atrial fibrillation concluded that amiodarone is effective in the termination of AF lasting < 24 h.[28]

This study observed that the patients with HFpEF had better rhythm control which aligns with the findings of the study performed by **Kelly et al.,** which showed that the patients aged 65 years and older with HFpEF and AF when treated with Amiodarone had rhythm control and were associated with lower 1-year mortality compared with treatment with rate control, even after risk adjustment.[29]

In this study maximum patients were at high risk of thromboembolism among which 23 patients had CHA_2DS_2VASc score above 5, about 8% (10) were at moderate risk and about 3% (4) were at low risk. Similar results were found in the study conducted by **Gažová et al.,** which suggested that CHA_2DS_2-VASc scores identified 43.8% of the patients as low to intermediate risk (score 0–1) and 56.2% of the patients as high risk (score ≥2). Increasing CHA_2DS_2-VASc scores were not only accompanied by an increase in the incidence of stroke ($P_{trend} < .001$) but also by an increase in the 3 to 5 years mortality. Aspirin was administered to 75% of patients in the low-risk group, and one patient did not receive any blood thinner. Among the 10 patients with moderate risk, 60% received Aspirin, and 40% received parenteral anticoagulants, with Enoxaparin being the most common in 30% of patients. Out of the total patients with high thromboembolism risk, 50% received Enoxaparin, 38% received Heparin, 6% received Dalteparin, and 7% did not receive any anticoagulant.[30] According to **American College of Cardiology, n.d.** CHA2DS2-VASc clinical stroke risk score should be used to identify patients at "low risk" (CHA2DS2-VASc score = 0 in men, or 1 in women), who should not be offered antithrombotic therapy. Antiplatelet therapy alone is not recommended for stroke prevention in AF (Class III). Oral anticoagulation (OAC) is recommended for stroke prevention in AF patients with CHA2DS2-VASc score ≥2 in men or ≥3 in women, and it should be considered in patients with a CHA2DS2-VASc score of 1 in men or 2 in women, with treatment individualized based on net clinical benefit and patient values/preferences.[31]

5. Limitations

1) The study's limited duration impeded the observation of long-term effects associated with amiodarone use.
2) Limited data on the social history of patients, either due to incomplete records or unavailability, hindered the comprehensive study of risk factors associated with the disease.
3) The smaller sample size restricted the variability in the data, potentially limiting the statistical significance of the results.
4) As a single-centre study, the generalizability of the results to other populations is questionable. In order to apply the findings to a different population, a larger population study would be necessary.

6. Conclusion

Amiodarone emerges as a highly effective intervention for achieving rhythm control, particularly in cases of recent onset or paroxysmal atrial fibrillation with preserved left ventricular function. The consistent efficacy of a 150mg bolus dose, supplemented with infusion, showcases its reliability for both rate and rhythm control. However, it becomes evident that treatment outcomes are intricately linked to patient-specific factors, including age, comorbidities, and cardiac intervention history. Significantly, the study underscores the pivotal importance of addressing thromboembolism risk in the studied cohort of atrial fibrillation patients. The individualized assessment based on CHA2DS2VASc scores plays a key role in guiding the appropriate use of anticoagulants, revealing a considerable

portion of patients identified as being at high risk for thromboembolism. This underscores the need for a comprehensive approach to atrial fibrillation management where thromboembolism prevention is deemed as crucial as rate and rhythm control.

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Conflict of Interest
The authors declare no conflicts of interest.

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Table 1: Demographics and Baseline Characteristics

Variable	Rate Control (n = 26)	Rhythm Control (n = 93)
	No. (%)	
Age	64.8 ± 35.5	65.8 ± 34.1
Gender		
Male (n = 74)	16 (62)	58 (62)
Female (n = 45)	10 (38)	35 (38)
Type of AF		
Recent onset/paroxysmal AF (n = 72)	3 (12)	69 (74)
Persistent/permanent AF (n = 47)	23 (88)	24 (26)
Comorbidities		
Valvular Heart Disease (n = 1)	0 (0)	1 (1)
Triple Vessel Disease (n = 3)	0 (0)	3 (3)
Hypothyroidism (n = 5)	2 (8)	3 (3)
Chronic Obstructive Pulmonary Disease (n = 7)	1 (4)	6 (6)
Rheumatoid Heart Disease (n = 9)	4 (15)	5 (5)
No Comorbidity (n = 10)	2 (8)	8 (9)
Acute Coronary Syndrome (n = 12)	1 (4)	11 (12)
Chronic Kidney Disease (n = 15)	3 (12)	12 (13)
Ischemic Heart Disease (n = 33)	6 (23)	27 (29)
Cerebrovascular Accident (n = 40)	9 (35)	31 (33)
Diabetes Mellitus (n = 52)	12 (46)	40 (43)
Hypertension (n = 102)	21 (81)	81 (87)
History of Cardiac Intervention		
Valve replacement (n = 4)	0 (0)	4 (4)
CABG (n = 11)	3 (12)	8 (9)
PTCA (n = 31)	7 (27)	24 (26)
No cardiac intervention (n = 77)	17 (65)	60 (65)
LVEF		
<= 40% (n = 44)	14 (54)	30 (32)
> 40% (n = 75)	12 (46)	63 (68)

Table 2: Classification of patients based on Amiodarone Dosage.

Dosage Form	Rate Control (n = 26)	Rhythm Control (n = 93)
	No. (%)	
Bolus Dose		
150mg (n = 114)	25 (96)	89 (96)
300mg (n = 5)	1 (4)	4 (4)
Infusion @ 2.1ml/hr		
1200mg (n = 12)	3 (12)	9 (10)
900mg (n = 39)	13 (50)	26 (28)
600mg (n = 46)	9 (35)	37 (40)
No Infusion (n = 22)	1 (4)	21 (23)
Oral Dose		
100mg (n = 11)	0 (0)	11 (12)
200mg (n = 42)	11 (42)	42 (45)
No Oral Dose (n = 40)	15 (58)	40 (43)

Table 3: Distribution of patients based on Anticoagulant given

Anticoagulant Given	Low risk (n = 4)	Moderate risk (n = 10)	High Risk (n = 105)
	No. (%)		
Aspirin (n = 9)	3 (75)	6 (60)	0 (0)
Enoxaparin (n = 55)	0 (0)	3 (30)	52 (50)
Heparin (n = 41)	0 (0)	1 (10)	40 (38)
Dalteparin (n = 6)	0 (0)	0 (0)	6 (6)
No Anticoagulant (n = 8)	1 (25)	0 (0)	7 (7)