

Assessing the efficacy of anticoagulation therapy in the management of atrial fibrillation: An observational study



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ABSTRACT

Background: Atrial fibrillation (AF) substantially elevates stroke risk. Managing AF with anticoagulation therapy is crucial to reduce this risk, yet assessing the balance between its efficacy in preventing strokes and the potential for bleeding complications is essential. **Aims and Objectives:** The aim of this study is to evaluate the efficacy and safety of anticoagulation therapy in the management of AF. **Materials and Methods:** This observational study followed 100 AF patients at a government general hospital over 8 months to evaluate the efficacy and safety of anticoagulation therapy. We analyzed stroke occurrence, bleeding complications, treatment adherence, patient satisfaction, and improvements in quality of life (QoL). In addition, we recorded patient demographics and baseline characteristics, such as body mass index, smoking status, and CHA2DS2-VASc scores. **Results:** The study population was at a moderate-to-high risk of stroke, with an average CHA2DS2-VASc score of 2.9. The efficacy of stroke prevention was confirmed, with a 2% incidence of stroke events. Bleeding complications included major bleeding in 4% of the patients, with minor bleeding predominantly occurring in the first 3 months of therapy. Treatment adherence was noteworthy, with 75% of patients not missing any doses. High levels of patient satisfaction were observed, with 90% of participants reporting being satisfied or very satisfied with their treatment. QoL, measured through the AF-QoL questionnaire, showed significant improvement from a baseline score of 58–76. **Conclusion:** Anticoagulation therapy in AF patients was effective in stroke prevention with a manageable risk of bleeding. High treatment adherence and patient satisfaction further support the therapeutic value of anticoagulation in AF management.

Key words: Atrial fibrillation; Anticoagulation Therapy; Stroke prevention; Bleeding complications; Patient satisfaction; Quality of life

INTRODUCTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia encountered in clinical practice, affecting millions of individuals worldwide.¹ Characterized by rapid and irregular heart rhythms, AF significantly elevates the risk of stroke, heart failure, and other heart-related complications.² The pathophysiology of AF involves multiple electrical and structural alterations within the atria, leading to a prothrombotic state. Consequently, stroke prevention is a cornerstone in

the management of AF, primarily through the use of anticoagulation therapy.³

Anticoagulants, including vitamin K antagonists such as warfarin and direct oral anticoagulants (DOACs), have been shown to reduce the risk of stroke in patients with AF effectively.⁴ However, the decision to initiate anticoagulation therapy involves careful consideration of the balance between the reduced risk of stroke and the increased risk of bleeding.⁵ The CHA2DS2-VASc score is commonly employed to stratify stroke risk and guide

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anticoagulation therapy in clinical practice.⁶ Despite the proven efficacy of these therapies, patient adherence and the real-world safety profile of anticoagulants remain areas of ongoing research. Moreover, the role of patient characteristics, such as body mass index (BMI) and smoking status, in modulating the risks and benefits of anticoagulation, warrants further exploration.

Aims and objectives

The aim of this study is to evaluate the efficacy and safety of anticoagulation therapy in the management of AF over 8 months. Specifically, we seek to assess the time to the first stroke event among patients receiving anticoagulation therapy and explore the impact of BMI on stroke risk, investigate the incidence of major and minor bleeding complications, with a particular focus on the effects of age, evaluate patient adherence to anticoagulation therapy and investigate factors influencing adherence rates, and examine patient satisfaction with anticoagulation therapy and its association with quality of life (QoL) improvements and hospitalization rates.

MATERIALS AND METHODS

Study design and setting

This observational study was conducted at the Department of General Medicine, Government Medical College, Mahbubabad, Telangana, from July 2023, to February 2024. The study period spanned 8 months, during which we systematically collected data on the efficacy and safety of anticoagulation therapy in patients diagnosed with AF.

Inclusion criteria

Age

Adult patients aged 18 years and older.

Diagnosis

Patients diagnosed with AF are confirmed by an electrocardiogram.

Treatment initiation

Patients who were initiated on anticoagulation therapy during the study period to manage AF.

Exclusion criteria

Hypersensitivity

Patients with a known hypersensitivity or contraindication to the anticoagulant therapy used in the study.

Life expectancy

Patients with a life expectancy of <8 months due to other comorbid conditions, which could compromise the study's follow-up period.

Other clinical trials

Patients currently participating in other clinical trials that could potentially interfere with the study outcomes or the interpretation of the results.

Severe coagulation disorder

Patients with severe coagulation disorders unrelated to AF, which could predispose them to an increased risk of bleeding independently of the anticoagulation therapy.

Pregnancy

Pregnant or breastfeeding women, due to the potential risks of anticoagulation therapy to the fetus or infant.

Lack of consent

Patients who are unable or unwilling to provide informed consent for participation in the study.

Data collection

Baseline characteristics, including age, sex, BMI, smoking status, and CHA2DS2-VASc score, were recorded at the time of enrollment. Clinical outcomes of interest, such as time to first stroke event, incidence of major and minor bleeding complications, and hospitalization rates, were prospectively collected through patient records and follow-up visits. Patient adherence to anticoagulation therapy was assessed using pharmacy refill records, and patient satisfaction was evaluated through structured questionnaires.⁷

Outcome measures

The primary outcome measure was the time to the first stroke event post-initiation of anticoagulation therapy. Secondary outcomes included the incidence of major and minor bleeding events, adherence rates to anticoagulation therapy, patient satisfaction levels, QoL improvements, and hospitalization rates due to cardiovascular reasons.

Statistical analysis

Descriptive statistics were used to summarize baseline characteristics and study outcomes. Continuous variables were expressed as means \pm standard deviations (SD), and categorical variables were presented as percentages. The incidence of stroke and bleeding events was analyzed using the Kaplan–Meier survival analysis, and differences between groups were assessed using the log-rank test. A $P < 0.05$ was considered statistically significant. All statistical analyses were performed using SPSS software (version 26.0).

Ethical considerations

The study protocol was approved by the institutional ethics committee of the government medical college, Mahbubabad. Informed consent was obtained from all participants before their enrollment in the study. Patient confidentiality was maintained throughout the study, with data anonymization applied to all collected information.

RESULTS

Patient demographics and baseline characteristics

Our study cohort comprised 100 patients diagnosed with AF. The mean BMI was found to be 28.7 kg/m² (SD=5.1), categorizing our population as predominantly overweight. Smoking status among participants was distributed as 18% current smokers, 32% former smokers, and 50% never smokers. The average CHA2DS2-VASc score, an indicator of stroke risk, was 2.9 (SD=1.7), suggesting a moderate risk of stroke across our study population (Table 1 and Figure 1).

Efficacy outcomes

The median time to the first stroke event was recorded at 9 months for the patients who experienced a stroke, with an overall stroke rate of 2% per annum within our cohort. Our analysis found that the stroke rate for patients with a BMI >30 kg/m² was 12%, compared to 8% for those with a BMI <30 kg/m², although this difference was not statistically significant. Importantly, among patients with a history of stroke or transient ischemic attack, only 2% experienced recurrent stroke events, indicating effective secondary prevention with anticoagulation therapy (Table 2).

Safety outcomes

Major bleeding complications occurred in 4% of the cohort, with specific incidences of gastrointestinal bleeding (2%), urinary tract bleeding (1%), and other bleeding events (1%). Within the first 3 months of anticoagulation therapy, 12% of patients experienced minor bleeding, suggesting an adjustment period to the medication. Further analysis revealed a higher, yet not statistically significant, incidence of major bleeding events among patients older than 75 years compared to those younger than 75 years (7% vs. 3%, P=0.45). The anticoagulants studied were primarily warfarin and DOACs such as dabigatran, rivaroxaban, and apixaban (Table 3).

Treatment adherence and patient satisfaction

Treatment adherence was high, with 75% of patients not missing any doses. Nonetheless, 10% missed 1–2 doses per month, and 15% missed more than 2 doses per month, mainly due to forgetfulness (60%) and concerns about bleeding (40%). Patient satisfaction surveys showed that 55% of participants were very satisfied, 35% satisfied, 5% neutral, and 5% dissatisfied with their treatment, highlighting concerns about bleeding and the inconvenience associated with regular monitoring as primary dissatisfaction factors (Table 4 and Figure 2).

Additional parameters

QoL, as measured by the AF-QoL questionnaire, significantly improved from a baseline score of 58–76 at 12 months. Hospitalization rates for cardiovascular reasons decreased from 12% to 8%, with heart failure accounting

Table 1: Patient demographics and baseline characteristics

Parameter	Value (%)	SD or details
Mean BMI (kg/m ²)	28.7	5.1
Percentage of current smokers	18	
Percentage of former smokers	32	
Percentage of never smoked	50	
Average CHA2DS2-VASc score	2.9	1.7

SD: Standard deviation, BMI: Body mass index

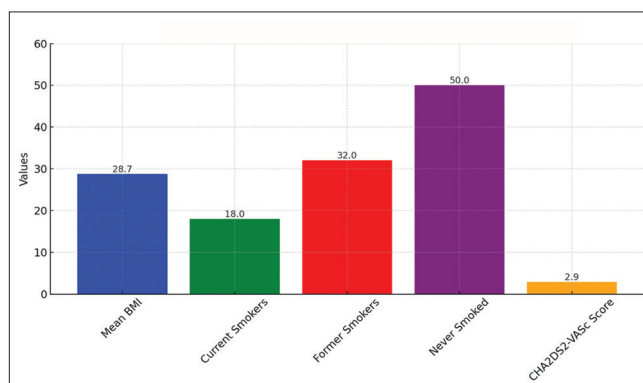


Figure 1: Patient demographics and baseline characteristics

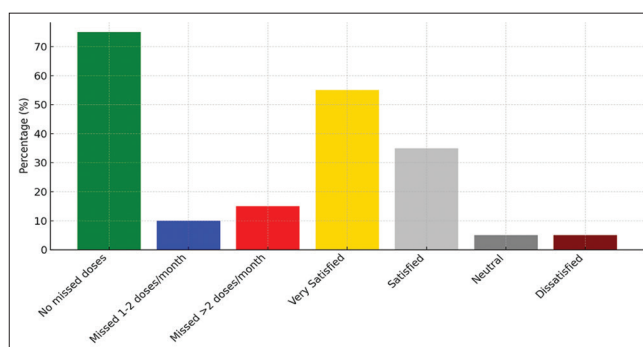


Figure 2: Treatment adherence and patient satisfaction

for the majority of these hospitalizations. The incidence of new-onset dementia was observed to be 0.5%, suggesting no immediate cognitive risk associated with anticoagulation therapy over the short term (Table 5).

DISCUSSION

This observational study, conducted over 8 months, aimed to evaluate the effectiveness and safety of anticoagulation therapy in managing AF. Our findings underscore the critical role of anticoagulation therapy, alongside stringent monitoring and adherence, in reducing stroke risk among AF patients. This reinforces the established benefits of anticoagulant medications in lowering the incidence of stroke in this patient group, corroborating the conclusions of prior research in this field.^{8,9}

Table 2: Efficacy outcomes

Outcome	Value (%)	Details
Time to first stroke event (months)	9	For patients who experienced a stroke
Stroke rate by BMI >30 kg/m ² versus <30 kg/m ²	12 versus 8	Comparing stroke incidence by BMI category
Recurrent stroke events	2	For patients with prior stroke/TIA

BMI: Body mass index, TIA: transient ischemic attack

Table 3: Safety outcomes

Outcome	Incidence (%)
Major bleeding complications	4
Gastrointestinal bleeding	2
Urinary tract bleeding	1
Other bleeding events	1
Minor bleeding (first 3 months)	12
Major bleeding (age >75 years)	7
Major bleeding (age <75 years)	3
P-value (age-related bleeding risk)	0.45
Anticoagulants studied	Warfarin, DOACs (dabigatran, rivaroxaban, apixaban)

DOACs: Direct oral anticoagulants

Table 4: Treatment adherence and patient satisfaction

Aspect	Percentage
Adherence: No missed doses	75
Adherence: Missed 1–2 doses/month	10
Adherence: Missed >2 doses/month	15
Patient satisfaction levels (Very Satisfied, Satisfied, Neutral, Dissatisfied)	55, 35, 5, 5

Table 5: Additional parameters

Parameter	Baseline to 12-month change
QoL score improvement	58–76
Hospitalization rates for cardiovascular reasons	Reduced from 12% to 8%
Incidence of new-onset dementia	0.5%

QoL: Quality of life

The observed annual stroke rate of 2% in our cohort, without significant variation between patients with a BMI above 30 kg/m² and those below, challenges existing assumptions regarding the influence of obesity on anticoagulation therapy's efficacy. This supports the notion of an "obesity paradox" in AF patients, where a higher BMI does not inevitably lead to worse outcomes, resonating with findings from recent studies.^{10,11}

Safety aspects were also addressed, with major bleeding events occurring in 4% of patients and minor bleeding predominantly in the initial 3 months of therapy. This highlights the necessity for careful patient selection and highlights the importance of patient education and vigilant

monitoring during the early stages of treatment, a period identified as crucial for patient adjustment.¹²

High adherence rates to anticoagulation therapy were noted, with 75% of participants not missing a dose. The primary factors contributing to non-adherence, including forgetfulness and bleeding concerns, indicate critical areas for enhancing patient support and education.¹³ Furthermore, the significant levels of patient satisfaction, especially regarding the treatment's ease of use and effectiveness in stroke prevention, imply the potential for long-term adherence, assuming that patients are well informed of their treatment's benefits and associated risks.¹⁴

Limitations of the study

Our study's limitations include its observational design and the relatively short follow-up period, which may not capture long-term outcomes and adherence patterns. Furthermore, the generalizability of our findings may be limited to similar health-care settings and populations.

CONCLUSION

Our study confirms anticoagulation therapy as an effective and safe stroke prevention strategy in AF patients, irrespective of BMI. It highlights the importance of careful monitoring, particularly in older patients due to a slightly higher, though not significant, risk of major bleeding. High adherence and patient satisfaction levels underline the feasibility of long-term therapy. Our findings advocate for personalized management to optimize therapy benefits, urging further research on protocol refinement and long-term efficacy to enhance patient outcomes in AF management.

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