Current Trends in Medicine and Clinical Research
ISSN: 3108-1223

Original Article Open Access

Drug Utilization Study of Novel Oral Anticoagulant Drugs in The Treatment and Prevention of Thromboembolic Events in a Tertiary Care Hospital.

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ARTICLE INFO

Article history:
Received 20 December 2025
Revised 10 January 2026
Accepted 01 February 2026
Available online 02 March 2026

Keywords:
Novel oral anticoagulant,
Atrial Fibrillation,
Thromboembolic events,
Bleeding.

ABSTRACT

Background This study aims to assess whether NOACs are used appropriately in the treatment of thromboembolic episodes. Despite the development and usage of various parenteral and oral anticoagulant VKA medications, preventing and treating venous and arterial thrombotic events continues to pose considerable medical challenges. With fewer limitations and less need for monitoring, NOAC provides a more consistent anticoagulation profile.

Materials and methods: A prospective observational study was conducted, involving 50 patients. The demographic details and treatment plan that were used in the study were collected and documented. The HAS-BLED and CHA2DS2-VASc scales were used to assess bleeding and stroke risk. Patients were followed up to identify any adverse events and complications.

Results

The most commonly prescribed therapy was NOAC, which was administered to 72% of the study population. This was followed by rivaroxaban to 24% and dabigatran to 4%. Due to impaired renal function and age, the dose of apixaban was adjusted in 18 patients. The adverse drug reactions were observed in seven patients; most of them were related to apixaban, and DDIs were also due to the same drug. The HAS-BLED score showed bleeding risks ranging from 0 to 4, while the CHA2DS2-VASc score for stroke risk ranged from 0 to 7.

Conclusion

The most commonly used drug was apixaban for stroke prevention in patients with AF, and it also caused the highest number of adverse events. In 18 patients, dose adjustment was required due to factors such as altered renal function and age. DDIs were observed in some patients. Due to bleeding complications, a few patients were switched to other NOACs

INTRODUCTION

Anticoagulants, often known as blood thinners, are prescribed in clinical settings to treat hospitalised patients with acute and deep vein thrombosis (VTE), unstable angina, and atrial fibrillation. These medications help prevent blockages in the coronary arteries and are also used in cardiac invasive procedures. Anticoagulants serve both preventive (prophylaxis) and treatment purposes for venous and arterial thromboembolism.[1]

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Curr. Trends Med. Clin. Res. 2026; Vol.2 Jan-March 2026

Previously, warfarin was the only oral anticoagulant available. Now, non-vitamin K antagonist oral anticoagulants (NOACs) like dabigatran, rivaroxaban, apixaban, and edoxaban are available. These drugs are as effective as warfarin and more convenient since they don't require routine coagulation monitoring. NOACs also have a lower risk of causing intracranial bleeding compared to warfarin.[2]

NOACs (Novel Oral Anticoagulants) are approved for preventing stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) who have risk factors. They are also used to treat venous thromboembolism (VTE) and pulmonary embolism (PE) and to prevent recurrent deep vein thrombosis (DVT) and PE.[3]

The risk of stroke can be assessed using the HAS-BLED or CHA2DS2-VASc scores. The HAS-BLED score evaluates the risk of serious bleeding in patients on anticoagulants or aspirin and applies to both atrial fibrillation and non-atrial fibrillation patients. It is the only score that also predicts the risk of intracranial haemorrhage (ICH).[4]

The HAS-BLED score was introduced in 2010 and is based on a study of 3,450 patients with atrial fibrillation (AF) who were receiving anticoagulant therapy. This scoring tool assesses the likelihood of bleeding in patients according to standard clinical guidelines. Patients with AF are placed into one of three risk levels: a score of 0 indicates a low risk of bleeding, a score from 1 to 2 represents a moderate risk, and a score of 3 or more indicates a high risk.[5]

The CHA2DS2-VASc score is a recognized method for evaluating stroke risk in individuals with atrial fibrillation. It assists healthcare professionals in deciding when anticoagulation therapy for preventing strokes may be necessary. This scoring system has been extensively validated and is incorporated into leading practice guidelines. A significant benefit of the CHA2DS2-VASc score is its user-friendly nature, enabling clinicians to rapidly assess a patient's risk based on a brief list of criteria.[6]

The scoring system uses a range from 0 to 9 points. According to the European Society of Cardiology, patients are classified into three risk categories based on their scores: a score of 0 represents low risk, a score of 1 indicates medium risk, and a score of 2 or above signifies high risk.

Non-vitamin K Antagonist Oral Anticoagulants (NOACs) offer several benefits compared to Vitamin K Antagonists (VKAs). They are highly effective in preventing strokes in individuals with atrial fibrillation (AF) and non-valvular atrial fibrillation (NVAF). Additional advantages include a lower risk of major bleeding, ease of administration, minimal interactions with other medications and food, predictable pharmacokinetic (PK) and pharmacodynamic (PD) profiles, quick onset and offset of action, a short half-life, and the absence of the need for regular laboratory testing.

On the downside, NOACs come with some drawbacks, such as their higher price, the unavailability of specific antidotes, and a relatively limited amount of clinical experience regarding their use.[3]

NOACs (Novel Oral Anticoagulants) are not suitable for use in individuals with severe renal or liver disease because reliable monitoring tests are lacking. They also should not be prescribed to patients with mechanical heart valves, those under 18 years, or elderly individuals. Upcoming research is anticipated to shed light on the effectiveness of NOACs in the prevention and treatment of thromboembolic disorders.[3] All non-vitamin K oral anticoagulants (NOACs) are partially eliminated by the kidneys, with clearance rates of 80% for dabigatran, 50% for edoxaban, 35% for rivaroxaban, and 27% for apixaban. It is essential to adjust dosages for patients with significant kidney impairment to reduce stroke and bleeding risks. Not adjusting the dose may increase bleeding risks, while unnecessary reductions can diminish stroke prevention effectiveness.[7]

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Methods

A prospective observational study was conducted from March to September 2024 across various departments. Patients were enrolled according to the inclusion criteria. Patients demographic details, such as age, gender and treatment details such as drug type, administration route, frequency, dosage, and relevant lab results were collected and documented. All patients were monitored for adverse effects, drug interactions, and any abnormalities during anticoagulant therapy, with bleeding or stroke risks assessed using the HAS-BLED and CHA2DS2-VASc scales, respectively. Follow-up evaluations assessed patient conditions and side effects, while drug efficacy was measured by analysing recurrence data documented at the study's conclusion.

Inclusion and Exclusion Criteria

Individuals, regardless of gender, experiencing thromboembolic events, including both those admitted to the hospital and those receiving outpatient care, and who are being treated with oral anticoagulants as prophylaxis. Pregnant or lactating women, pediatric patients, and those patients receiving palliative care were excluded.

Results

A total of 50 patients were included in the study, of which 36% were female, and 64% were male. The major comorbidities in the study population were AF 64%, HTN 60%, T2DM 54%, IHD/CHF 28%, CVA 20%, CKD 18%, VTE 14%, MI 8%, PVD 4%, CLD 2%. (Table 1)

Apixaban was the medication most frequently prescribed, with 72% patients using it. Rivaroxaban (24%) and Dabigatran (4%) were the next most common. These NOACs were mainly prescribed for the treatment of atrial fibrillation. (Table 2)

The study reported a small number of adverse events, primarily attributed to Apixaban, with Rivaroxaban as a secondary contributor. These events included hematochezia, hematuria, gastrointestinal bleeding, and splenic hemorrhage. (Table 3)

Bleeding risk was assessed using the HAS-BLED score in the study population. Out of 50 patients, 10% patients had a score of 0 indicating low risk, 62% had moderate risk (score 1-2) and 28% had score >3 indiacting high risk of bleeding. (Table 4)

The stroke risk in patients with atrial fibrillation (AF) was evaluated using the CHA2DS2-VASc score. Out of 50 patients studied, 35 were diagnosed with AF. The scores were distributed as follows: 5.71% scored 7, 8.57% scored 6, 31.42% scored 5, 20% scored 4, 17.14% scored 3, 11.42% scored 2, and 2.85% scored 1 or 0. (Table 5)

There were a total of 18 adjustments made to the dosage, primarily due to age-related factors for individuals over 80 and renal-related factors for those with serum creatinine levels exceeding 1.5 mg/dl.(Table 6)

Discussion

The present study aims to evaluate the appropriate use of NOAC in treating and preventing thromboembolic events. It is a prospective observational study that seeks to assess dosing patterns, safety, and associated bleeding risks. The study included a total of 50 patients, with 18 (36%) females and 32 (64%) males, consistent with a study conducted by Chadalavada et al.[1] .Among the 50 subjects, the highest number of patients were found in the age group of 80-89, most patients had comorbidities associated with AF followed by HTN and T2DM and other CV disease, contributing to the development of thromboembolic events.

The most commonly prescribed anticoagulant was apixaban, prescribed to 36 (72%) patients, followed by rivaroxaban for 12 (24%) patients, and dabigatran for 2 (4%) patients. These medications were mainly indicated for AF, PE, DVT, and thrombus prophylaxis. This prescription pattern is similar to a study conducted by Anna Maria Urbaniak et al.[12]

Table 1: Patient demographic details.

Variable	N	%
Gender		
Male	32	64
Female	18	36
Age (years)		
≥65 years	36	72
Comorbidities		
Atrial fibrillation	32	64
Hypertension	30	60
T2DM	27	54
Congestive heart	14	28
Ischemic heart	14	28
CVA	10	20
Chronic kidney	9	18
VTE	7	14
MI	4	8
PVD	2	4
CLD	1	2

Table 2. Prescribing Pattern and Indications of NOACs

NOAC	Patients (n)	%	Indication
Apixaban	36	72	AF, DVT, PE, CVA
Rivaroxaban	12	24	AF, DVT, PE, PVD
Dabigatran	2	4	CVA, Thrombosis

Table 3: ADR occurrence in the study population.

Sl. No.	NOAC	ADR	Causality assessment
1	Rivaroxaban	Hematochezia	Probable
2	Apixaban	Hematochezia	Probable
3	Apixaban	Upper gi bleed	Probable
4	Apixaban	Hematuria	Possible
5	Apixaban	Hematuria	Probable
6	Apixaban	Hematochezia	Probable
7	Rivaroxaban	Spleenic hemorrhage	Probable

Table 4. HAS - BLED SCORE and Observed Bleeding Events

HAS-BLED Category	Patients (n)	%	Bleeding events (n)
0 (Low)	5	10	1
1-2 (Moderate)	31	62	3
>3 (High)	14	28	3

Table 5. CHA2DS2-VASc Score and Stroke Recurrence in AF patients (n=35)

CHA2DS2-VASc	PATIENTS (N)	%	STROKE RECURRENCE
0-1 (Low)	2	5.7	0
2-3 (Moderate)	10	28.5	0
>4 (High)	23	65.7	4

Table 6. Dose Adjustment Pattern of NOACs

NOAC	Dose adjusted (n)	%	Reason for Adjustment
Apixaban	18	36	Age > 80, SCr>1.5 mg/dl
Rivaroxaban	0	0	-
Dabigatran	0	0	-

In the study population, 7 patients experienced ADRs, with apixaban being the main drug associated with ADRs. This finding differed from a study by Anna Maria Urbaniak et al., which indicated that rivaroxaban and dabigatran were associated with more bleeding manifestations. The difference could be due to the lower usage of rivaroxaban in our hospital. [12]

We assessed the risk of bleeding using the HAS-BLED score and the risk of stroke in patients with AF using the CHA2-DS2-VASc score. The HASBLED assessment revealed that 10% of patients were classified as low risk, 62% as moderate risk, and 28% as high risk of bleeding.

Financial support
None

Ethical approval
As this was a prospective observational drug utilization study involving no intervention and using data collected as part of routine clinical practice, formal ethical committee approval was not required. Patient confidentiality was maintained throughout the study, and no identifiable personal information was recorded or disclosed.

Abbreviations
NOAC: Novel oral anticoagulant; TEE: Thromboembolic events; AF: Atrial fibrillation; HTN: Hypertension; T2DM: Type 2 diabetes mellitus; VTE: Venous thromboembolism; ICH: Intracranial hemorrhage; NVAF: Non-valvular atrial fibrillation; DVT: Deep vein thrombosis; PE: Pulmonary embolism; CV: Cardiovascular; ADR: Adverse drug reaction; DDI: Drug–drug interaction; CHF: Congestive heart failure; IHD: Ischemic heart disease; PVD: Peripheral vascular disease; CVA: Cerebrovascular accident; CKD: Chronic kidney disease; MI: Myocardial infarction; CLD: Chronic liver disease; GI: Gastrointestinal; DOAC: Direct oral anticoagulant.

The dose adjustment assessment revealed that dose adjustment was only carried out for apixaban in 18 patients. The reasons for dose adjustment were primarily age>80 and serum creatinine levels exceeding 1.5mg/dl. Additionally, it was noticed that switching between NOACs was primarily due to bleeding manifestations in 5 patients, and the medication was stopped in 12 patients for the same reason. The study found that renal dose adjustment was performed in 12% of the 50 study participants, which is consistent with a study conducted by Xiaoxi Yao et.al.[7]

Conclusion
Based on this study, it can be concluded that the presence of various comorbidities, such as HTN, AF, and T2DM in patients, contributes to the development of thromboembolic events. The most commonly prescribed novel oral anticoagulant (NOAC) was found to be Apixaban, followed by Rivaroxaban and Dabigatran, mainly indicated for AF, deep vein thrombosis DVT, and PE.
The rate of occurrence of ADR and DDIs in the study group was low, indicating a decrease in the ADR and DDI rate associated with the use of NOACs. The ADR and DDI in the study group were seen mostly due to Apixaban and Rivaroxaban.
In this study, we also assessed the risk of bleeding and found that patients who experienced bleeding had a HAS-BLED score ranging from 0 to 4 and were over the age of 50. The patients at higher risk of bleeding were having moderate–to–high HAS-BLED score, and most of them were elderly patients. We also evaluated the risk of stroke in patients with AF using the CHA2DS2-VASc score, which revealed that 83% of them had a high risk of stroke, and among them, 4 patients experienced a stroke while receiving NOAC prophylaxis.
The dose adjustment was also assessed. The dose adjustment was mainly done for apixaban due to the age factor and serum creatinine >1.6mg/dl. Switching between NOACs was also observed, mainly due to bleeding manifestations.

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Conflicts of Interest

The authors declare that there are no conflicts of interest related to this study. The research was conducted independently, and the findings represent the unbiased results and interpretations of the authors.

Financial Support

This study did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. It was conducted as part of academic research under institutional support from RDT Hospital, Andhra Pradesh.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request. The data will be made available to qualified researchers for non-commercial purposes only, subject to ethical and privacy considerations. Due to privacy restrictions, participant data cannot be publicly shared, but can be accessed by contacting the corresponding author.

Protection of humans and animals.

The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval

The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics Committee. The SAGER guidelines were followed according to the nature of the study.

Declaration on the use of artificial intelligence.

The authors declare that no generative artificial intelligence was used in the writing of this manuscript