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Research Article

Evaluation of Direct Oral Anticoagulant Utilization and Safety in Patients with Venous Thromboembolism at an Academic Medical Center

Nhi Nguyen, Helen Calmes*, Genet Aramde, Hareanna Campbell, Ethan Austin

University Medical Center New Orleans Department of Pharmacy, New Orleans, Louisiana, United States

***Corresponding author:** Helen Calmes, University Medical Center New Orleans 2000 Canal Street, New Orleans. Louisiana 70112, United States

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Abstract

Venous thromboembolism (VTE) is a complex condition that requires appropriate anticoagulation to optimize outcomes. This study evaluated adherence to guideline-recommended direct oral anticoagulant (DOAC) therapy at a tertiary referral hospital in the Southern United States. A retrospective, single-center chart review was conducted from January 1 through December 31, 2023, including adults aged 18 years or older who received a DOAC or another anticoagulant for acute VTE. The primary outcome was the appropriateness of DOAC therapy, defined as correct dose, frequency, and duration per current guidelines. Secondary assessments included VTE risk factors, bleeding events, and mortality. A total of 140 patients were included (mean age 55.9 ± 18 years); 64% were female, 73% were Black, 40% had a history of VTE, and 71% initiated DOAC therapy during hospitalization. The most common indications were deep vein thrombosis (44%), pulmonary embolism (30%), and concurrent DVT/PE (19%). Apixaban was the predominant DOAC prescribed (97%). Overall, 70% of patients received a guideline-recommended loading dose, while 30% did not; among those without a loading dose, 64% had received parenteral anticoagulation before transitioning to a DOAC. An indication mismatch occurred in 16% of cases. Immobility was the most common VTE risk factor (59%). Major bleeding occurred in 6% of patients, and clinically relevant non-major bleeding occurred in 1%. These findings demonstrate variability in DOAC dosing and duration practices at this institution. Standardized treatment protocols may improve adherence to evidence-based recommendations and optimize outcomes for patients with acute VTE.

Keywords: Direct Oral Anticoagulant (DOAC); Venous Thromboembolism (VTE); Safety; Dosing

Introduction

Venous thromboembolism (VTE) is a complex condition that affects many patients in both inpatient and outpatient settings. Multiple risk factors compound the risk of disease. Correct treatment dosing must be used to lower the risk of recurrent VTEs (rVTEs) and complications that could arise from inadequate dosing and duration.

Recommendations for Antithrombotic Therapy in VTE Disease are described in the American College of Chest Physicians (CHEST) [2,3], the American Society of Hematology (ASH) Guidelines on VTE [6], and the European Society of Cardiology (ESC) Guidelines on the Diagnosis and Treatment of an Acute Pulmonary Embolism (PE) [5], which were used as primary references in the study.

VTEs can be divided into pulmonary embolism (PE) and deep vein thrombosis (DVT). DVT occurs when a blood clot forms in a deep vein, most often in the lower leg, thigh, or pelvis. DVTs can also form in the arms, particularly when an intravenous line is in place. A PE occurs when a clot breaks free and travels through the bloodstream to the lungs [1]. While many cases are associated with hospitalization, approximately two-thirds occur in the outpatient setting. Direct oral anticoagulants (DOACs), such as dabigatran (a direct thrombin inhibitor) and the factor Xa inhibitors rivaroxaban, apixaban, and edoxaban, have demonstrated efficacy comparable to that of vitamin K antagonists (warfarin) and improved safety for long-term treatment and prevention of arterial and venous thromboembolic events [2,17].

Based on current literature and prior clinical trials of various DOACs, multiple international guidelines exist for the treatment of VTE.

According to the 2016 CHEST guidelines, anticoagulation therapy should be discontinued after three months in patients with an acute proximal DVT of the leg or PE provoked by surgery. Shorter treatment durations are not recommended. Extended anticoagulation may be warranted in patients with persistent provoking factors or ongoing prothrombotic conditions, such as active malignancy [2,3]. Patients with a proximal DVT or PE provoked by a nonsurgical transient risk factor should discontinue anticoagulant therapy after 3 months. A minimum of 3 months of DOAC treatment is usually recommended for patients with a first unprovoked VTE, and the patient is at an elevated risk of bleeding [3]. Extended therapy (6,9, or 12 months) should be considered in those with a low or moderate risk of bleeding. Patients with rVTEs who are on an oral anticoagulant should be changed to Low Molecular Weight Heparin (LMWH) therapy [3].

Recurrent venous thromboembolism, encompassing both DVT and PE, is a chronic, high-risk condition with an approximately 30% recurrence rate over 10 years, with risk highest in the first 6-12 months. Risk is highest for unprovoked events, cancer, or active, untreated clotting disorders. Extended, individualized anticoagulant therapy is often required to prevent fatal pulmonary embolism [7].

The 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism, developed in collaboration with the ERS (European Respiratory Society), recommend a DOAC for acute-phase treatment of intermediate- or low-risk pulmonary embolism [5]. The most recent guidelines for pulmonary embolism recommend that, for patients with acute PE requiring oral anticoagulation, DOACs are recommended as first-line therapy over vitamin K anticoagulants (VKAs) or warfarin, provided no contraindications exist, due to their favourable efficacy in preventing recurrent VTE and their lower risk of major bleeding [8,17].

In patients with a high or intermediate probability of PE, anticoagulation should be started usually with parenteral, weight-adjusted subcutaneous LMWH and fondaparinux, or intravenous unfractionated heparin (UFH) [4]. Phase III clinical trials have demonstrated the non-inferior efficacy of a single oral drug anticoagulation strategy using higher lead-in or loading doses of apixaban (at a dose of 10 mg twice daily) for 7 days or rivaroxaban (at a dose of 15 mg twice daily) for 3 weeks [4,5].

The 2020 ASH guidelines define the treatment period for acute DVT/PE as “initial management” (first 5-21 days), “primary treatment” (first 3-6 months), and “secondary prevention” (beyond the first 3-6 months) 6 Shorter courses of anticoagulation (3-6 months) are preferred for acute DVT/PE associated with a transient risk factor. For most patients with unprovoked DVT/PE or DVT/PE associated with a chronic risk factor, the guidelines recommend indefinite anticoagulation.

The study hospital has developed institutional guidelines for ordering based on the existing literature including dosing and treatment duration with DOACs (apixaban, rivaroxaban, dabigatran, and edoxaban). However, DOAC regimens vary in practice, as prescribers often consider patient characteristics and comorbidities. Current anticoagulation dosing for VTE for patients with normal renal function, normal weight, and no concomitant interacting medications is outlined below (Table 1):

DRUG	Lead in Treatment for VTE Treatment	Treatment Phase Dosing for VTE Treatment
Apixaban	10 mg twice daily for 7 days	5 mg twice daily
Rivaroxaban	15 mg twice daily for 21 days	20 mg once daily
Dabigatran	Parenteral Anticoagulation for 5 to 10 days	150 mg twice daily
Note: Edoxaban is not available at the study institution; therefore, dosing is not included.		

Table 1: Dose Recommendations for VTE Treatment.

This study aimed to evaluate the proper prescribing of VTE treatment by analyzing dosing, frequency, and duration. In addition, the use of loading-dose strategies was reviewed. The ultimate goal is to improve the quality of care by reviewing dosing strategies and the clinical characteristics of patients prescribed DOACs for VTE treatment at a tertiary referral academic medical center located in the Southern United States.

Materials/Methods

The study was conducted at a tertiary referral teaching hospital in an urban area in the Southern United States. The study consists of a retrospective evaluation of prescribing trends at the hospital and adherence to CHEST, ASH, ESC, and institutional guidelines for VTE treatment [2-5]. This research examined the clinical characteristics of treated patients and the dosing of anticoagulants in those who received formulary DOACs. The premise is that improper dosing and duration of anticoagulation therapy can increase the risk of rVTEs and adverse effects. Earlier studies indicate that accurate dosing leads to improved patient outcomes, shorter hospital stays, and a reduced risk of recurrent venous thromboembolism [9,10].

A list of eligible patients was generated for those on DOAC therapy with an order for deep vein thrombosis or pulmonary embolism (All patients included in the study were identified from the electronic medical record (EPIC™). They were included if they were admitted to the hospital between January 1, 2023, and December 31, 2023, and met the inclusion criteria.

The inclusion criteria were all adult patients who received DOAC as primary treatment for acute VTE. In accordance with institutional policy, the prescriber must specify the indication for use for all anticoagulation orders. This allows appropriate screening, monitoring, and interventions by pharmacists. The patients were selected based on the indication coded DVT or PE. Exclusion criteria included any patient under 18 years of age, incarcerated patients, pregnant or lactating patients, or anticoagulation ordered for a diagnosis other than VTE.

Demographic data on qualifying patients, clinical indicators (e.g., renal function, weight), documentation of VTE, length of stay, and other anticoagulants ordered during their stay were collected.

The primary outcome was the assessment of the appropriateness of DOAC dosing (dose, frequency, and duration of treatment) in patients with VTE.

Safety endpoints were major bleeding or clinically relevant non-major bleeding (CRNMB) while on DOAC treatment. These are defined as [14-16]:

1. Fatal bleeding: Bleeding that directly results in death.

2. Bleeding in a critical area/organ:

a) Intracranial (brain)

b) Intraspinal (spine)Intraocular (eye)

c) Retroperitoneal (abdominal cavity behind the peritoneum)

d) Pericardial (sac around the heart) Intra-articular (joint)

e) Intramuscular bleeding leading to compartment syndrome.

3. Severe blood loss:

a) Bleeding, causing a fall in haemoglobin of >2 g/dL (>20 g/L) or more, or

b) Bleeding requiring transfusion of two or more units of whole blood or red cells.

Other incidents of minor bleeding were reported if included in the electronic medical record.

Results

A total of 1216 potential patients were identified. A sample size of 164 patients was calculated to achieve an 80% confidence level with a 5% margin of error (Calculator.net). Patients were selected using simple random sampling, with a randomized list generated for chart review.

Two hundred and nine (209) patients were reviewed (all with a diagnosis of PE or DVT), and 140 met the inclusion criteria for the period from January 1, 2023, to December 31, 2023.

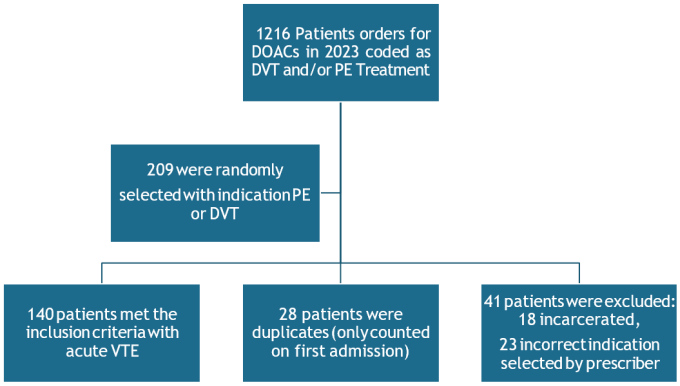

Figure 1: Patient Selection.

The majority were excluded because the prescriber's indication selection was incorrect (23) or because they were incarcerated (18) at some point during their hospitalization. Twenty-eight (28) patients were duplicates (readmitted during the study period for the same indication). These patients were only included once during their first admission with an active DVT or PE. Baseline characteristics of the patient population are described in Table 2 below:

Baseline Demographics	n=140
Age (years), mean + SD	55.9 + 18.0
Female, n (%)	89 (64)
African American, n (%)	102 (73)
BMI (kg/m2); mean + SD	28.8 + 11.4
Creatinine Clearance (ml/min) (median, Q2, IOR)	83.4 (52.3-116.0)
History of venous thromboembolism, n (%)	56 (40)
BMI: Body Mass Index, SD: standard deviation	

Table 2: Baseline Characteristics.

The mean age was 55.9 ± 18.0 years, 63.6% were female, and 72.9% identified as African American. The mean BMI was 28.8 ± 11.4 kg/m², and the median creatinine clearance was 83.4 mL/min (IQR 52.3–116.0). A history of venous thromboembolism was present in 40.0% of patients.

The prescriber must select an indication before ordering anticoagulation at the study hospital. Approximately 11% of the patients studied had a primary indication other than current VTE, yet VTE treatment was selected (Figure 2).

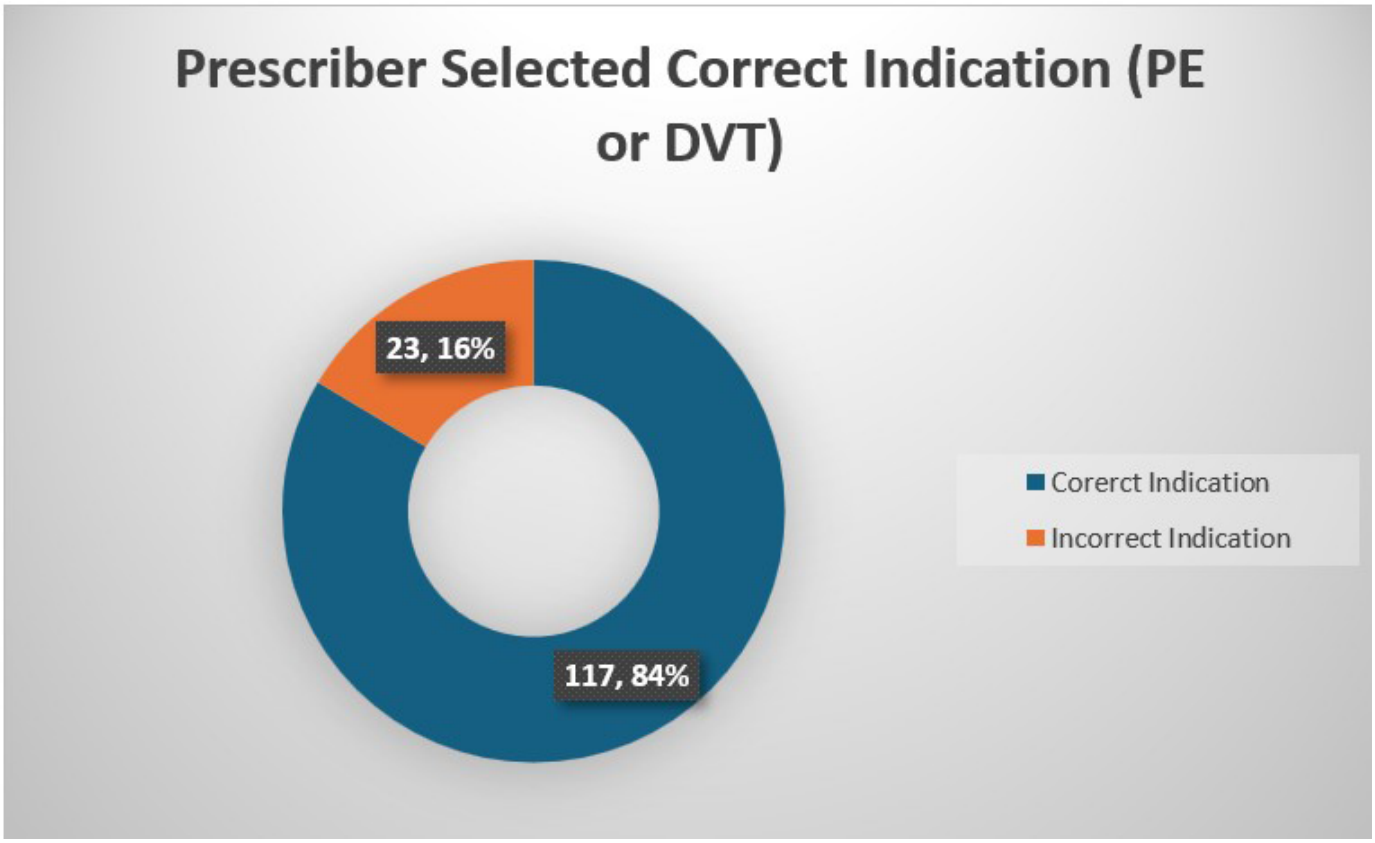

Figure 2: Order Indication Mismatched.

- Of those with the appropriate indication selected, a loading dose is needed in 110 of the patients.
- Sixty-four percent (64%) of patients received a loading dose (LD) in accordance with the guideline recommendations.

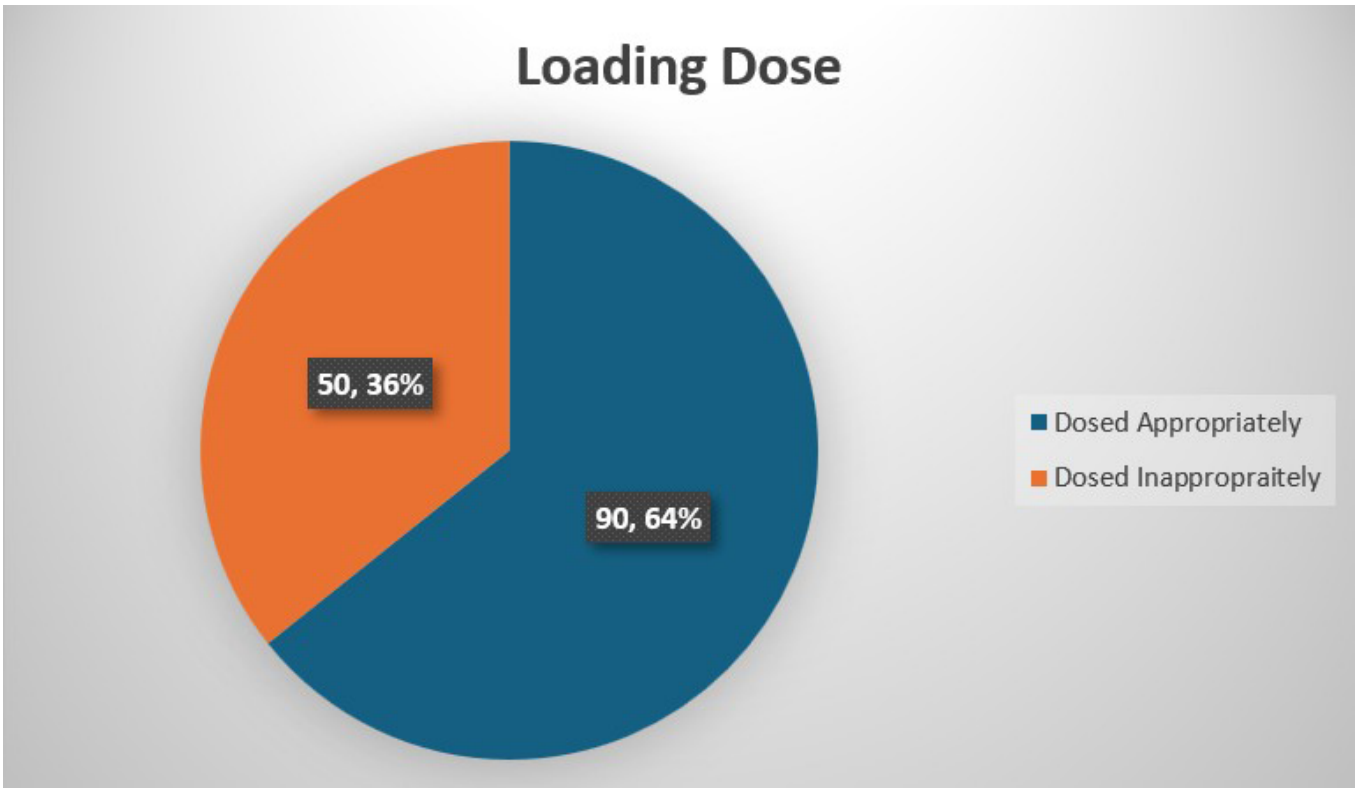

Figure 3: Loading dose.

A total of fifty (50) patients did not receive a loading dose.

- Twenty-seven (27) patients received LMWH or UFH before starting DOAC; 76% of these patients received fewer than the recommended 7 days.
- Twenty-three (23) patients did not receive an oral loading dose and had no injectable anticoagulant before starting DOAC.
- Nineteen (19) patients had recurrent VTE and continued their home dose (no loading dose was given for the new VTE).
- Four (4) patients had a history of malignancy (no note in the chart explaining the decision not to administer a loading dose).

Of the DOACs on formulary, apixaban was the most often prescribed (97%). Secondary endpoints are summarized.

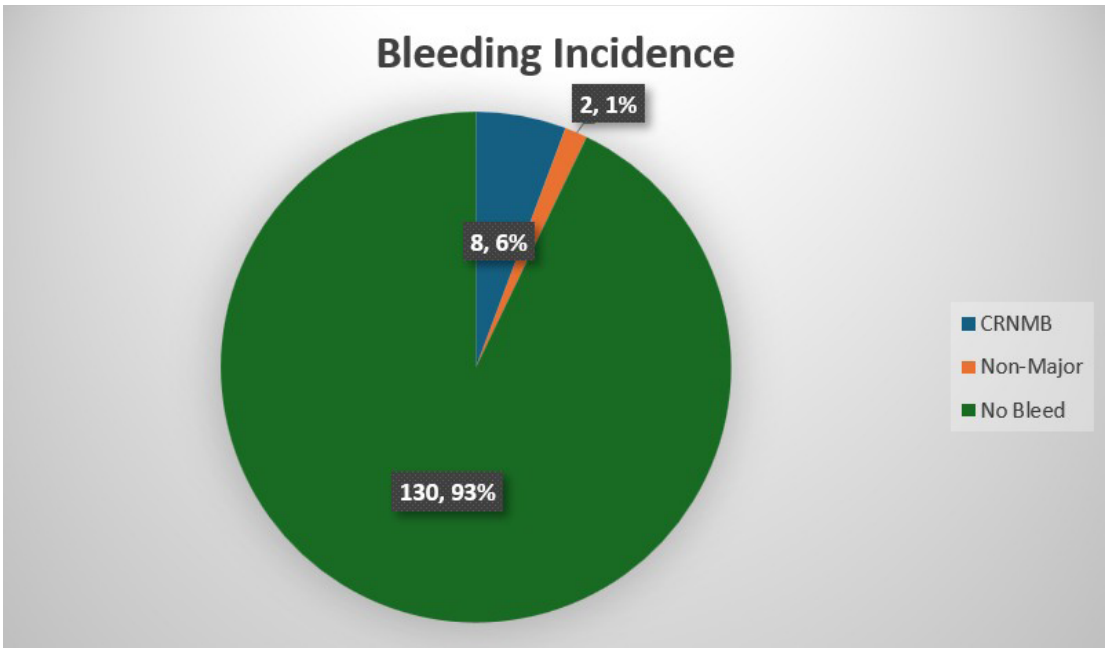

Figure 4: Incidence of Bleeding.

- Bleeding events occurred in 6% of patients, with 1% experiencing CRNMB.
- Major bleeding was recorded in eight (8) patients (~5.7%).
- Non-clinically relevant bleeding occurred in two (2) patients (~1.4%).

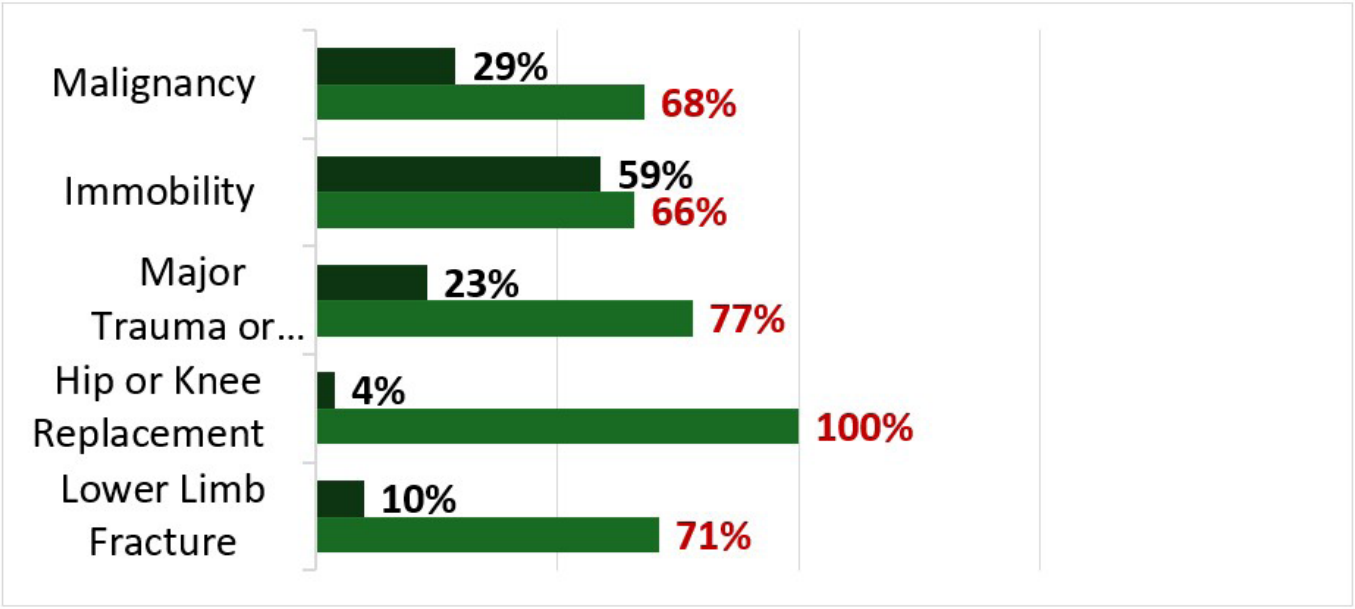

Figure 5: Concomitant Risk Factors.

Patients were also evaluated for underlying risk factors or disease states that may predispose to VTE.

- The most common patient risk factor was immobility (59%), with 10% having non-modifiable factors such as paraplegia, being bedridden, and being wheelchair-bound. Of those with mobility issues, 66% received a DOAC loading dose.
- Malignancy accounted for 29% of the identified risk factors. Of these patients, 68% received the loading dose.
- Among the remaining patients with risk factors, i.e., major surgery or trauma (23%), joint replacement surgery (4%), and lower-limb fractures (10%), more than 70% received the oral loading doses.
- The all-cause mortality incidence was 8.5% (12 patients).

Discussion

In this retrospective evaluation of patients with venous thromboembolism, 209 records were reviewed from a random sample of 1,216 potential cases, exceeding the prespecified sample size to achieve an 80% confidence interval with a 5% margin of error. Of these, 140 patients met the inclusion criteria for acute deep vein thrombosis or pulmonary embolism between January 1, 2023, and December 31, 2023, after exclusion of miscoded diagnoses, incarcerated individuals, and duplicate admissions.

Adherence to guideline-recommended direct oral anticoagulant loading-dose regimens was achieved in 64% of eligible patients, reflecting moderate alignment with evidence-based practice standards. Apixaban was the most frequently prescribed DOAC, accounting for 97% of cases, consistent with established formulary utilization patterns and prescriber preferences. No patients were newly initiated on dabigatran for the treatment of venous thromboembolism, as all individuals receiving dabigatran were continued on pre-admission therapy.

Immobility was the most commonly identified risk factor, present in 59% of patients, while a smaller proportion (10%) had non-modifiable risk factors, including paraplegia or chronic bedridden status. Based on the data reviewed, 66-100% of the highest-risk patients, as defined by underlying risk factors, received the proper loading dose for the prescribed DOAC. This demonstrates the need for improved hospital prescribing to ensure adequate anticoagulation.

Bleeding occurred in 6% of patients, with clinically relevant non-major bleeding reported in 1%, suggesting an overall acceptable safety profile within this cohort.

Collectively, these findings indicate moderate yet incomplete adherence to guideline-directed anticoagulation strategies for the management of venous thromboembolism. Implementation of targeted interventions to improve compliance with recommended loading-dose regimens may optimize therapeutic outcomes while preserving an acceptable bleeding risk profile. Further investigation into barriers to guideline adherence is warranted to inform the development of effective quality improvement initiatives.

The indications selected in the computerized order entry system contribute to the misclassification of our patients, resulting in many not meeting the inclusion criteria. The most common misclassification was patients with previous VTE and atrial fibrillation (the atrial fibrillation is the primary indication) and those with recurrent VTE (not a current VTE). In addition, the latest information has emerged on extended VTE treatment with DOACs. This was not accounted for by the selections available for prescribers.

Therefore, changes to existing ordering indications or diagnoses were proposed. The anticoagulation indication options within the computerized provider order entry system were revised to improve accuracy, standardization, and alignment with current guideline-directed therapy. Previous indication selections within the electronic medical record (EMR) included broad or inconsistently worded categories such as deep vein thrombosis, pulmonary embolism, chronic atrial fibrillation, and thrombosis associated with heparin-induced thrombocytopenia. These were updated to more clinically specific and contemporary indications, including stroke prevention in non-valvular atrial fibrillation (NVAF), treatment of active DVT or PE with correct dosing guidance, prevention of recurrent VTE, extended VTE treatment, prevention of serious cardiovascular events in coronary artery disease (CAD) or peripheral artery disease (PAD), thromboprophylaxis in hospitalized acutely ill medical patients, prevention of thromboembolism following total hip or knee replacement, and treatment of heparin-induced thrombocytopenia (HIT). These updates were intended to reduce misclassification of indications, improve prescribing accuracy, and enhance anticoagulation stewardship within the electronic medical record system.

To account for patients not receiving appropriate lead-in therapy, the second portion of the changes was to link treatment for acute PE or DVT to the correct ordering of apixaban and rivaroxaban.

In this retrospective evaluation of 209 reviewed records (140 meeting the inclusion criteria for acute DVT or PE), adherence to guideline-recommended DOAC loading doses was observed in 64% of eligible patients, with apixaban accounting for 97% of prescriptions and an overall low bleeding rate of 6% (1% CRNMB). Misclassification of VTE cases was frequently driven by electronic ordering indications, particularly overlapping atrial fibrillation or prior VTE diagnoses, highlighting the need to refine computerized order entry to improve patient identification and data accuracy.

Several limitations should be considered when interpreting the findings of this retrospective evaluation. First, the study was conducted at a single center and utilized a retrospective chart review design, which may limit the generalizability of the results to other institutions and patient populations. Retrospective analyses are also dependent on the accuracy and completeness of documentation in the electronic medical record, which can introduce information and documentation bias. Additionally, although 209 records were

reviewed, only 140 patients met the inclusion criteria, resulting in a relatively modest sample size that may limit the ability to detect less common outcomes such as major bleeding events.

Another important limitation was the high degree of patient misclassification within the computerized provider order entry system. Many patients were incorrectly categorized as having acute VTE when the primary indication for anticoagulation was another condition, most commonly atrial fibrillation with a prior history of VTE or recurrent/chronic VTE, rather than a new acute event. This contributed to a substantial number of exclusions and may reflect limitations in the selection of electronic order-entry indications and coding accuracy. Furthermore, because apixaban accounted for 97% of prescribed direct oral anticoagulants (DOACs), the findings may not generalize to other DOACs, such as rivaroxaban, edoxaban, or dabigatran. No assessment was performed to evaluate the provider's rationale for deviating from guideline-recommended loading-dose regimens; therefore, the clinical justification for nonadherence could not be determined. Lastly, the study did not evaluate long-term clinical outcomes, including recurrent thrombosis, hospital readmissions, or mortality, thereby limiting the assessment of the overall clinical impact of loading-dose adherence practices.

Despite the limitations, this study provides several clinically meaningful and practice-relevant findings that strengthen its significance. First, the evaluation addresses an important gap in real-world anticoagulation management by assessing adherence to guideline-recommended direct oral anticoagulant loading-dose strategies for acute venous thromboembolism, an area with limited published institutional data. Because inappropriate loading-dose utilization may increase the risk of recurrent thrombosis or bleeding complications, identifying adherence patterns has direct implications for patient safety and quality of care.

Additionally, the study highlights important operational and systems-based issues within computerized provider order entry and diagnostic coding processes. The identification of substantial patient misclassification demonstrates how electronic health record documentation and indication selection can significantly affect both clinical workflow and research accuracy. These findings may help inform targeted quality improvement initiatives to optimize indication documentation, improve anticoagulation prescribing practices, and enhance clinical decision support tools.

The study is also notable for evaluating anticoagulation practices in a real-world patient population rather than within the controlled environment of a clinical trial. This provides insight into actual prescribing behaviors, formulary utilization patterns, and adherence challenges encountered in routine clinical practice. The predominance of apixaban use reflects contemporary prescribing trends and provides practical guidance on institutional management strategies for VTE treatment.

Finally, the observed low incidence of CRNMB suggests that, despite incomplete adherence to guideline-directed loading-dose regimens, overall safety outcomes remained acceptable within this cohort.

These findings generate hypotheses for future prospective studies and support the need for further investigation into provider-level and system-level barriers to guideline adherence. Collectively, the study provides valuable quality assurance and practice-optimization data that may be used to improve anticoagulation stewardship and patient outcomes.

Conclusion

In summary, while the majority of patients received guideline-concordant DOAC therapy, adherence to loading doses remains suboptimal and represents a key opportunity for improvement. The low incidence of bleeding supports the overall safety of current prescribing practices; however, system-level factors—particularly misclassification within the computerized order entry system—contribute to inappropriate patient categorization and may affect treatment optimization. Implementation of revised ordering indications and linkage to correct dosing pathways for acute PE and DVT is expected to enhance guideline adherence, improve therapeutic accuracy, and support ongoing quality improvement efforts.

Conflict of Interest Statement

None of the authors have conflicts of interest to disclose.

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Total Sample Size	n=140
Age, Years (average + SD)	55.9 + 18
Gender, n (%)	
Male	51 (36%)
Female	89 (64%)
Race/Ethnicity	
White	34 (24%)
Black	102 (73%)
Hispanic	2 (1.4%)
Asian	1 (0.9%)
Other	1 (0.7%)

Table 3: Demographic Information.

BMI (Kg/m2) (average + SD)	28.8 + 11.4
Creatinine Clearance (ml/min) (median, Q2, IOR)	83.4 (52.3,116.0)
Duration of Hospital Stay, days. (median, Q1, Q2)	7 (3,13)
Previous History of VTE, n (%)	56 (40%)

Table 4: Baseline Characteristics.

Setting of DOAC Treatment Initiation, n (%)	
Inpatient	100 (71.4%)
Outpatient	37 (26.4%)
Not Initiated	3 (2.2%)
VTE Treatment Indication, n (%)	
PE	42 (30%)
DVT	62 (44%)
PE and DVT	27 (19%)
Afib and VTE	6 (4%)
Other	3 (2%)
Order Indication Mismatch, n (%)	36 (26%)
DOAC, n (%)	
Apixaban	136 (97%)
Rivaroxaban	3 (2%)
Other	1 (1%)
Use of Loading Dose, n (%)	98 (70%)
Use of Parenteral Anticoagulation, n (%)	84 (60%)
Type of Parenteral Anticoagulation, n(%)	n=98
LMWH	39 (40%)
UFH	44 (45%)
LMWH and UFH	15 (15%)
Secondary Outcomes	
Patient Risk Factors, n (%)	
Lower Limb Fracture	14 (10%)
Hip or Knee Replacement	6 (4%)
Major Trauma or Surgery	32 (23%)
Existing Heart Conditions	74 (53%)
Immobility	83 (59%)
Malignancy	40 (29%)
Hormone Therapy	2 (1%)
Autoimmune Disease	13 (9%)
Active Infection	57 (41%)
Smoking	56 (40%)
Safety Outcomes	
Bleeding While on DOAC, n (%)	
Major Bleeding	8 (6%)
Clinically relevant non-major bleeding	2 (1%)
AFib: Atrial Fibrillation	

Table 5: Setting of DOAC Treatment Initiation.

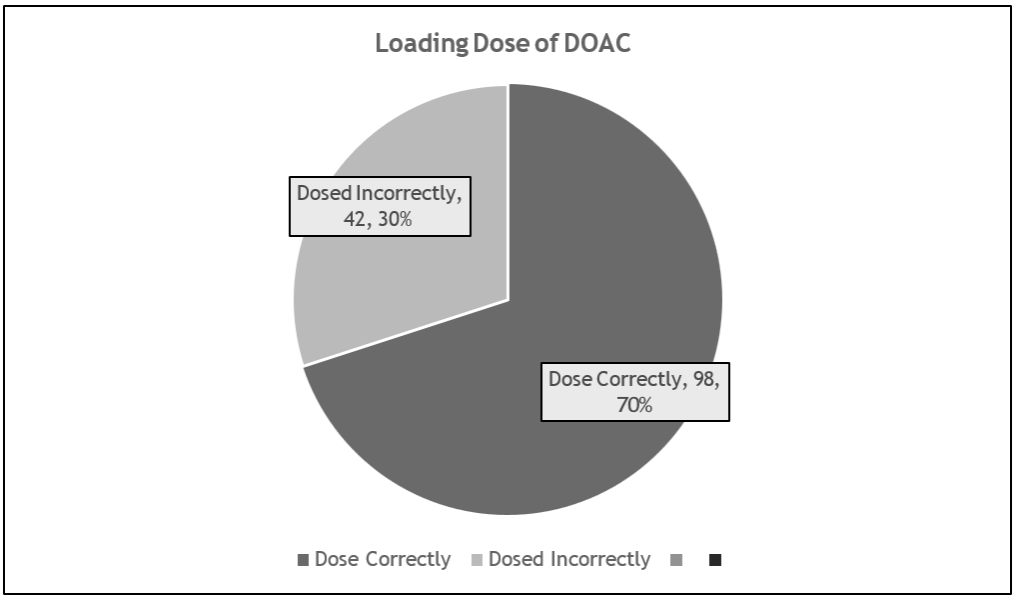

Figure 6: Loading Dose of DOAC.

Proposed Computerized changes to EMR selection:

FROM:

- Deep vein thrombosis
- Hip surgery deep vein thrombosis prevention.
- Knee replacement deep vein thrombosis
- Prevent thromboembolism in chronic atrial fibrillation.
- Prevention of venous thromboembolism recurrence
- Pulmonary embolism, thrombosis in heparin-induced thrombocytopenia
- Thrombosis with thrombocytopenia syndrome

TO:

- Stroke prevention in non-valvular atrial fibrillation (NVAF)
- Prevention of recurrent deep vein thrombosis and pulmonary embolism
- Treatment of active pulmonary embolism or deep vein thrombosis->correct dosing
- Prevention of serious cardiovascular events in CAD/PAD patients (coronary artery disease/peripheral artery disease)
- Prevention of thromboembolism in hospitalized acutely ill medical patients.
- Prevention of Thromboembolism after Total Hip or Total Knee Replacement
- Extended treatment for VTE
- Treatment of heparin-induced thrombocytopenia.