Persistent Challenges in Direct Oral Anticoagulant Prescriptions: Time to Optimize Medication Safety in Hospital and Community Settings

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ABSTRACT **Background:** Direct oral anticoagulants (DOACs) have significantly transformed anticoagulant therapy, improving effectiveness, safety, and convenience in managing thromboembolic conditions. However, concerns persist regarding drug-related problems (DRPs) associated with DOACs, necessitating the establishment of multidisciplinary antithrombotic stewardship programs to optimize the selection, dosing, and monitoring of DOACs.

Objectives: To evaluate the incidence and types of DRPs associated with DOACs, the frequency of clinical pharmacist consultations, the acceptance rates of the clinical pharmacist recommendations, and physicians' adherence to appropriate DOACs prescribing practices.

Methods: A retrospective cohort study was conducted over 4 months in the internal medicine departments at Shamir Medical Center (Assaf Harofeh), Israel. The study included patients aged 18 years and older who were prescribed DOACs (apixaban, rivaroxaban, and dabigatran). Data on patient characteristics and clinical outcomes were collected from electronic medical records. A clinical pharmacist reviewed and reassessed the appropriateness of DOAC prescribing.

Results: During the study period, 415 patients receiving DOACs were identified. Among them, 28.4% had inappropriate DOAC prescriptions leading to 128 recommended interventions. The most common DRP was underdosing (29.7%) followed by unjustified antiplatelet use (26.6%). Clinical pharmacists performed 85.9% of the interventions, with a physician acceptance rate of 72.7%. Patients with inappropriate DOAC prescriptions exhibited increased trends in thromboembolic events and in-hospital mortality.

Conclusions: Despite over a decade of clinical experience with DOACs, DRPs remain a significant challenge. Implementing antithrombotic stewardship programs is critical for optimizing DOACs use, reducing DRPs, and enhancing patient safety.

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Thromboembolic events associated with atrial fibrillation (AF) and venous thromboembolism (VTE) significantly contribute to global morbidity and mortality and healthcare resource utilization [1]. Oral anticoagulants have long been the cornerstone of thromboembolism prevention and management [1]. The emergence of direct oral anticoagulants (DOACs), including factor Xa inhibitors (apixaban, rivaroxaban, edoxaban) and the direct thrombin inhibitor dabigatran, has revolutionized anticoagulant therapy. Compared to warfarin, DOACs offer comparable effectiveness while significantly reducing the risk of major bleeding, particularly intracranial hemorrhage [2].

DOACs advantages, such as fixed dosing, rapid onset, broader therapeutic windows, fewer drug and food interactions, and minimal monitoring requirements, have established them as the preferred first-line therapy for VTE and stroke prevention in nonvalvular AF (NVAF) [3]. Over the past decade, DOAC use has significantly increased while the use of vitamin K antagonists (VKAs) has decreased [4].

Despite their benefits, DOACs are associated with a substantial risk of medication errors, accounting for 8–10% of drug-related errors in hospitals [5,6]. Inappropriate prescribing of DOACs occurs in 8–30% of hospitalized cases, leading to life-threatening complications, including bleeding from overdosing or thrombotic events from underdosing [5,7,8]. These risks highlight the need for initiatives to ensure their safe and effective use.

Multidisciplinary stewardship programs, originally developed for optimizing antibiotics [9], have proven effective in improving adherence to anticoagulant guidelines, reducing inappropriate prescriptions, and minimizing adverse drug events (ADEs) [10]. Given the growing use of DOACs and their associated risks, implementing antithrombotic stewardship programs has become essential. These programs, involving coagulation specialists and clinical pharmacists, aim to optimize the selection,

dosing, and monitoring of DOACs [11]; ensure adherence to guidelines; and educate healthcare teams [12].

In this study, we identified the incidence and types of drug-related problems (DRPs) linked to DOACs in hospitalized patients, evaluate the frequency of DOAC-related consultations by clinical pharmacists, and assess physician adherence to DOACs guidelines.

PATIENTS AND METHODS

This retrospective cohort study was conducted from March to June 2023 in the internal medicine departments at Shamir Medical Center (Assaf Harofeh), in Israel. The study was approved by the ethics committee at the medical center (approval number ASF-0214-23).

Patients aged 18 years and older admitted to our internal medicine departments and prescribed a DOAC (apixaban, rivaroxaban, or dabigatran) for any indication, including those initiated DOACs during hospitalization, were included. The study included patients at all stages of chronic kidney disease (CKD), including patients on hemodialysis. Exclusion criteria included patients under 18, pregnant women, those admitted to non-internal medicine departments, and individuals using anticoagulants other than DOACs.

Eligible patients were identified by a clinical pharmacist through a server-generated SQL report extracted from the hospital's electronic medical records (EMR) system three times per week. Data collected included patient demographics: age, sex, weight, and body mass index (BMI). Clinical details included co-morbidities, serum creatinine, creatinine clearance (CrCl, using Cockcroft-Gault equation), complete blood count (CBC), DOAC indication and dosage, timing of DOAC initiation (pre or during hospitalization), concurrent antiplatelet therapy and its indication, and use of P-glycoprotein (P-gp) or cytochrome P450 3A4 (CYP3A4) inhibitors or inducers. Details also included anti-Xa levels when available. Hospitalization details included admission and discharge dates as well as reason for hospitalization.

For patients with multiple hospitalizations during the study period, only data from their first admission were included.

A clinical pharmacist evaluated the appropriateness of DOAC prescription based on the Israeli drug registry and international guidelines [13,14]. Key factors included patient age, weight, renal function, platelet count, DOAC indication, dosing regimen, additional antithrombotic therapy, and potential drug-drug interactions (DDIs). A prescription was considered inappropriate if it involved overdosing, underdosing, contraindications, lack of therapy despite an indication, unapproved indications, unnecessary additional antithrombotic therapy, or significant DDIs. A specialist in thrombosis and hemostasis was consulted for further evaluation.

DOACs-associated DRPs were categorized into the following groups: adjusting dosage (increase or decrease), altering frequency, measuring anti-Xa level, discontinuing antiplatelet therapy, stopping therapeutic duplication, switching anticoagulants, initiating anticoagulants for untreated indications, assessing the need for anticoagulation, and evaluating the duration of VTE treatment.

We distinguished between DRPs identified and corrected by physicians during hospitalization and those requiring intervention by a clinical pharmacist. The pharmacist communicated with physicians via EMR documentation or phone calls. The number of interventions and the physicians' acceptance rate were recorded.

The primary outcome was the prevalence of DOAC related DRPs and the proportion of pharmacist-led interventions. Secondary outcomes included the overall acceptance rate of the pharmacist's recommendations, acceptance rates by intervention type, and clinical outcomes. Clinical outcomes compared between patients with appropriate and inappropriate DOAC prescription included major bleeding, clinically relevant non-major (CRNM) bleeding (as defined by the International Society on Thrombosis and Haemostasis [ISTH]) [15,16], and thromboembolic events, such as deep vein thrombosis (DVT), pulmonary embolism (PE), and cerebrovascular accident (CVA). These outcomes were documented solely at admission and during the patient's initial hospital stay. Additional outcomes assessed were in-hospital and 30-day post-discharge all-cause mortality rates, as well as 30-day hospital readmission rates.

STATISTICAL ANALYSIS

Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 29.0.1.0 (SPSS, IBM Corp, Armonk, NY, USA). Descriptive analyses summarized patient characteristics and DOAC-related medication errors. The normality of continuous variables was evaluated using the Shapiro-Wilk test and visual inspection of histograms and Q-Q plots.

Categorical variables were presented as frequencies, while continuous variables were reported as mean ± standard deviation for normally distributed data or median

with interquartile range (IQR) for non-normal data. We calculated unadjusted relative risks (RR) with 95% confidence intervals (95%CIs) for thromboembolic events, bleeding events, mortality, and hospital readmissions in patients with appropriate versus inappropriate DOAC prescriptions. Given the sparsity of outcomes, no multivariable adjustment was performed. Because of the limited sample size and low event rates, these analyses were treated as exploratory.

RESULTS

A total of 415 patients on DOACs were identified across seven internal medicine departments. Table 1 summarizes patient characteristics.

Apixaban was the most commonly prescribed medication (79.8%), followed by rivaroxaban (17.3%) and dabigatran (2.9%). The average patient age was 79.6 years, and 49.2% were male. Renal function was normal to mildly impaired in 56.4% of patients, while 17.6% had severe renal impairment (CrCl < 30 ml/min), and 4.1% were on dialysis. The primary indication for DOAC use was AF (89.2%), with VTE treatment and prevention accounting for 6% and 2.2% of cases, respectively. In 0.96% of patients, no clear indication for DOAC use was identified. DOACs were initiated during hospitalization in 15.7% of cases, while 84.3% were prescribed prior to admission. Concomitant antiplatelet therapy was used in 17.3% of patients, while 1.2% received strong CYP3A4 inducers, and none were on DOACs with strong CYP3A4 or P-gp inhibitors.

INAPPROPRIATE PRESCRIPTION AND INTERVENTION

Inappropriate DOAC prescriptions were identified in 118 patients (28.4%), including 93 with apixaban, 23 with rivaroxaban, and 2 with dabigatran. A total of 128 interventions were made to address DOAC-related DRPs: 14.1% by physicians and 85.9% by clinical pharmacists. Table 2 details intervention categories and physician acceptance rates. Key interventions included: increasing DOAC dose (29.7%), stopping unnecessary antiplatelet therapy (26.6%), reducing DOAC dose (18.0%), measuring anti-Xa levels (10.2%), and re-evaluating anticoagulation need (6.3%). Other interventions (each ≤ 2.3%) involved adjusting dose frequency, switching anticoagulants, initiating DOACs for an untreated indication, stopping therapeutic duplication, and evaluating initial VTE treatment duration. Among patients starting DOAC during hospitalization, 29.2% had inappropriate prescriptions, compared to 28.3% of patients already taking DOACs at admission. In a subgroup analysis of DOAC prescription appropriateness by indication and age [Table 3], the proportion of inappropriate prescriptions rose with advancing age among patients with AF. Clinical pharmacists made 110 recommendations, with 72.7% accepted by physicians.

CLINICAL OUTCOMES

Thromboembolic events

Sixteen thromboembolic events occurred (11 with apixaban, 3 with rivaroxaban, and 2 with dabigatran). Among these, 14 were CVA cases and 2 were DVT cases. Two CVA cases were classified as treatment failures with thera-

Table 1. Characteristics of the patie8nts included in the study

Characteristic	Apixaban (n=331)	Rivaroxaban (n=72)	Dabigatran (n=12)	All (N=415)
Age, mean ± SD (years)	80.1 ± 10.0	76.9 ± 9.7	83.6 ± 7.5	79.6 ± 9.9
Male sex, n (%)	161 (48.6%)	37 (51.4%)	6 (50.0%)	204 (49.2%)
Weight, mean ± SD (kg)	76.1 ± 16.3	77.4 ± 15.8	71.6 ± 15.2	76.2 ± 16.2
Hospital stay, median (IQR), days	8.0 (4.0–14.0)	6.0 (3.25–10.75)	7.5 (4.5–12.25)	7.0 (4.0–13.0)
Heart failure, n (%)	162 (48.9%)	20 (27.8%)	7 (58.3%)	189 (45.5%)
Diabetes mellitus, n (%)	158 (47.7%)	33 (45.8%)	7 (58.3%)	198 (47.7%)
Ischemic heart disease, n (%)	146 (44.1%)	28 (39%)	6 (50.0%)	180 (43.4%)
Hypertension, n (%)	271 (81.9%)	57 (79.2%)	11 (91.7%)	339 (81.7%)
CrCl 50 > mL/min, n (%)	180 (54.4%)	49 (68.1%)	5 (41.7%)	234 (56.4%)
Atrial fibrillation, n (%)	301 (90.9%)	57 (79.2%)	12 (100%)	370 (89.2%)
Inappropriate DOAC prescription, n (%)	93 (28.1%)	23 (31.9%)	2 (16.7%)	118 (28.4%)

CrCl = creatinine clearance, DOAC = direct oral anticoagulant, IQR = interquartile range, SD = standard deviation

Table 2. DOAC-associated drug interventions

Intervention	Number of interventions, n (%)	Physician interventions, n (%)	Pharmacist interventions, n (%)	Interventions accepted, n (%)
Increase dose	38 (29.7%)	9 (23.7%)	29 (76.3%)	21 (72.4%)
Stop concomitant antiplatelet	34 (26.6%)	4 (11.8%)	30 (88.2%)	24 (80.0%)
Decrease dose	23 (18.0%)	4 (17.4%)	19 (82.6%)	15 (78.9%)
Measure of anti-Xa levels	13 (10.2%)	0 (0%)	13 (100%)	6 (46.2%)
Evaluate the need for anticoagulation	8 (6.3%)	1 (12.5%)	7 (87.5%)	2 (28.6%)
Other*	12 (9.4%)	0 (0%)	12 (100%)	12 (100%)
Total	128 (100%)	18 (14.1%)	110 (85.9%)	80 (72.7%)

DOAC = direct oral anticoagulant

*Other includes increasing dose frequency (3), switching to another anticoagulant (3), adding a DOAC for an untreated indication (2), stopping therapeutic duplication (2), and evaluating initial venous thromboembolism management duration (2)

Table 3. Appropriateness of DOAC prescription by indication and age group

Indication	Age group (years)	Appropriate DOAC prescription, n/N (%)	Inappropriate DOAC prescription, n/N (%)
Atrial fibrillation	< 65	12/270 (4.4%)	5/100 (5%)
	65–79	112/270 (41.5%)	31/100 (31%)
	≥ 80	146/270 (54.1%)	64/100 (64%)
Venous thromboembolism	< 65	7/23 (30.4%)	2/10 (20%)
	65–79	10/23 (43.5%)	4/10 (40%)
	≥ 80	6/23 (26.1%)	4/10 (40%)

DOAC = direct oral anticoagulant, n = individual group sample size; N = total sample size across groups

peutic anti-Xa levels, while two additional CVA cases were attributed to patient non-compliance. Seven events were linked to DOAC-related DRPs. Among patients with appropriate DOAC use, five thromboembolic events were of unclear cause as no anti-Xa measurement was performed. In our exploratory analysis, unadjusted RR (1.96, 95%CI 0.74–5.13) suggested higher thromboembolic events among patients with inappropriate DOAC prescriptions.

Bleeding events

Major bleeding occurred in 12 patients, 10 on apixaban and 2 on rivaroxaban. Four events were linked to inappropriate DOAC use (3 with overdosing, 1 with unnecessary antiplatelet therapy), while eight were appropriately prescribed. CRNM bleeding was observed in 10 patients (8 on apixaban, 1 on rivaroxaban, and 1 on dabigatran), with 3 linked to inappropriate use (2 with excessive dosing, 1 with unnecessary antiplatelet therapy). Seven were appropriately prescribed DOACs, three recently had percutaneous coronary intervention (PCI) with concomitant antiplatelet therapy. The unadjusted RR for major, CRNM, and total bleeding events in inappropriate versus appropriate DOAC use was 1.26 (95%CI 0.39–4.10), 1.07 (95%CI 0.28–4.10), and 1.17 (95%CI 0.49–2.80), respectively.

During hospitalization, 9.3% patients with inappropriate DOAC use died, compared to 5.4% with appropriate DOAC use (unadjusted RR 1.73, 95%CI 0.83–3.62). At 30-day post-discharge, all-cause mortality was 5.1% for inappropriate and 6.7% for appropriate use (unadjusted RR 0.76, 95%CI 0.31–1.83). The 30-day re-admission rates were 17.8% for inappropriate and 19.8% for appropriate DOAC use (unadjusted RR 0.89, 95%CI 0.57–1.40).

DISCUSSION

The results of this study show that even after a decade of clinical use, DOACs remain a source of frequent medication errors and adverse outcomes. These findings emphasize the importance of pharmacist-led stewardship programs to enhance appropriate anticoagulant therapy in hospitalized patients. Approximately 28% of patients required adjustments due to DOAC-related DRPs, with clinical pharmacists re-

Table 4. Clinical outcomes by appropriateness of DOAC prescription

Outcome	Appropriate (n=297)	Inappropriate (n=118)	Unadjusted RR (95%CI)
Thromboembolic events, n (%)	9 (3.0%)	7 (5.9%)	1.96 (0.74–5.13)
Total bleeding events, n (%)	15 (5.0%)	7 (5.9%)	1.17 (0.49–2.80)
In hospital all-cause mortality, **n (%)**	16 (5.4%)	11 (9.3%)	1.73 (0.83–3.62)
30-day all-cause mortality (post-discharge), **n (%)**	20 (6.7%)	6 (5.1%)	0.76 (0.31–1.83)
Hospital 30-day re-admission, **n (%)**	59 (19.8%)	21 (17.8%)	0.89 (0.57–1.40)

DOAC = direct oral anticoagulant, 95%CI = 95% confidence interval, RR = relative risk

solving 86% of these issues. Physicians implemented over 70% of the pharmacists' recommendations.

Physicians independently corrected only 14% of DOACs-related DRPs, consistent with prior studies reporting that healthcare providers address less than 10% of such cases [17]. This gap may stem from heavy workloads, time constraints, and limited awareness of the complexities of DOAC therapy [18]. Inappropriate DOAC prescriptions often persist because pre-hospitalized prescriptions are continued without consideration of changes in renal function, concurrent medications, or co-morbidities.

The most common intervention involved increasing DOAC doses addressed underdosing, accounting for 30% of all adjustments. This finding aligns with previous studies where underdosing was identified in 12–56% of patients [17] while overdosing was less common (2–37%) [17].

Concerns about bleeding often lead to unjustified underdosing, reducing anticoagulant efficacy and increasing thromboembolic risk by 22%, without significantly lowering the bleeding rate [19]. In our cohort, 25% of thromboembolic events occurred in patients receiving an inappropriately low DOAC dose.

Dual antiplatelet therapy was another concern, with 47% of patients on antiplatelet therapy without a clear indication. This practice significantly increases bleeding risk. Current guidelines recommend limiting dual therapy for 12 months for patients with AF undergoing PCI followed by anticoagulant monotherapy [13]. However, many patients in our study continued antiplatelet therapy beyond the recommended period without justification. Our interventions effectively reduced the inappropriate prescribing of combined antithrombotic therapies, achieving an 80% acceptance rate among physicians, the highest among all recommendations.

In contrast, recommendations regarding the need for anticoagulation had the lowest acceptance rate (29%), particularly in patients without a clear indication for anticoagulation or those requiring dose adjustment after long-term VTE. This finding may reflect gaps in physician familiarity with VTE management guidelines, emphasizing reassessment after 3–9 months of therapeutic anticoagulation based on recurrence and bleeding risks [14].

The recommendation to measure anti-Xa levels had a 46% acceptance rate. While routine monitoring is not required for DOACs, it is critical in emergencies, such as bleeding, thrombosis, emergency invasive procedures, thrombolysis approval, or overdose. Physicians may lack awareness of anti-Xa measurement utility in specific populations, such as those with significant drug interactions, extreme body weights, or severe renal dysfunction. Challenges in interpreting results and linking drug levels to clinical outcomes further contribute to the limited adoption of these recommendations.

Physicians accepted 72% of pharmacist recommendations, consistent with prior studies reporting acceptance rates of 73–84% [10,20]. This high acceptance rate highlights strong support for collaboration efforts to optimize anticoagulant therapy. Non-acceptance may be due to factors like knowledge gaps, confidence in personal judgment, communication barriers, or time constraints. Enhancing education, improving communication, and implementing supportive policies could address these challenges.

Although patients with inappropriate DOAC prescriptions had higher observed rates of thromboembolic events and in-hospital mortality, these differences were not statistically significant [Table 4], likely due to the small sample size and low event rates. Our primary goal in presenting these results is to illustrate potential trends. Consequently, these findings should be regarded as exploratory and underscore the need for larger, well-designed randomized controlled studies to better understand these possible associations. Nonetheless, the findings emphasize the importance of accurate prescribing and the role of pharmacist-led stewardship in minimizing errors and improving patient safety. Antithrombotic stewardship programs have been shown to reduce bleeding, prevent thrombotic events,

shorten hospital stays, and lower mortality and readmission rates, while also cutting healthcare costs [10,12].

STRENGTH AND LIMITATIONS

Key strengths of our study include the ability to promptly identify patients with DOACs-related DRPs and strong collaboration between pharmacists and coagulation specialists. However, limitations of our study include its retrospective design, short duration, single-center focus, and exclusion of non-internal medicine departments. The limited use of edoxaban since its introduction in 2020 restricted our ability to evaluate related DRPs. Furthermore, we did not assess the impact of prescriber education on the long-term effects of interventions on adverse events.

FURTHER DIRECTIONS

Future studies should expand antithrombotic stewardship programs to outpatient populations to address inappropriate anticoagulant prescriptions comprehensively. In addition, long-term studies are needed to evaluate the sustained impacts of these programs on bleeding and thromboembolic events and to refine their effectiveness further.

CONCLUSIONS

Despite the ease of use and years of clinical practice, inappropriate prescribing and DOAC-related DRPs remain common. Our findings suggest that involving clinical pharmacists in anticoagulation stewardship improves prescription practice and supports physicians in optimizing anticoagulant therapy. Larger prospective studies are needed to evaluate the overall benefits of anticoagulation stewardship programs in different settings and their effects on safety and efficacy outcomes.

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