HPR89

Payer Rejections and Prescription Abandonment Among Patients Newly Prescribed Oral Anticoagulants for Venous Thromboembolism

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Introduction

- According to the Centers for Disease Control and Prevention, venous thromboembolism (VTE), including deep vein thrombosis, pulmonary embolism, or both affects approximately 900,000 individuals in the United States (US).[1]
- VTE presents a serious risk of mortality; 30% of all patients with VTE die within 30 days of diagnosis.[2] Recent treatment guidelines recommend direct oral anticoagulants (DOAC) for treatment of VTE.[3,4]
- Formulary restrictions along with prior authorization (PA) requirements, step therapy (ST) requirements, and cost sharing (copayments, coinsurance, and deductibles) results in payer rejections and prescription abandonment.[5-8]
- Real-world evidence regarding the impact of formulary restrictions for oral anti-coagulants (OAC) on patients with VTE is limited.

Objective

- This study described the magnitude of payer rejections and prescription abandonment, subsequent approved OAC claims, and factors associated with rejections among patients with VTE newly prescribed OAC.

Methods

Study design

- This retrospective cohort study used linked data from IQVIA's Longitudinal Access and Adjudication Data (LAAD) Formulary Impact Analyzer (FIA), Professional Fee Claims (Dx) and Hospital Charge Data Master (CDM) databases to identify adult patients with VTE newly prescribed an OAC between 01 October 2016 and 31 October 2021 in the US.
  - The date of the first prescription for an OAC was termed as index date and the first OAC prescribed was termed as the index OAC.

Selection criteria

- Patients were required to have linkage to Dx during the study period (1 October 2015 to 30 April 2022) and medical claim activity and pharmacy activity (defined as ≥1 claim in Dx and FIA) in the first six months of the 12-month baseline period and the last 3 months of the 6-month follow-up period. Pharmacy stability criterion was applied to ensure patient healthcare activity in the database.
- Patients with OAC use during baseline or multiple OAC prescription on index date, with a diagnosis of AF/flutter or procedure code for a mechanical heart valve during baseline, with procedure code for inferior vena cava filter and/or diagnosis or procedure code for pregnancy during the study period were excluded. Additionally, patients with evidence of diagnosis or treatment for cancer during the study period were excluded. Finally, patients with index claims for edoxaban were excluded due to small sample (N=79).

Data sources

- FIA is sourced from retail and mail order pharmacies, representing approximately 63% of the US retail market, with available data dating back to 2013. Dx contains one billion pre-adjudicated claims and three billion records obtained annually from approximately 800,000 office-based physicians and specialists in the US. CDM contains records from over 450 US hospitals, covering 7 million annual inpatient stays and 60 million annual outpatient visits, dating back to 2001.

Measures and outcomes

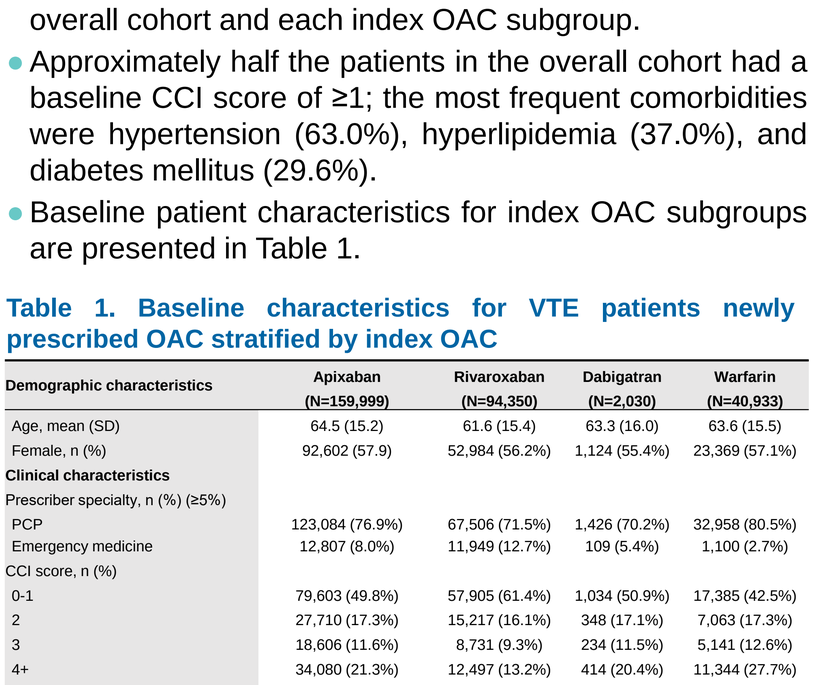
- Baseline demographic characteristics were assessed on the patient's index date; clinical characteristics were evaluated during the baseline period.
- The status of the index OAC claim (i.e., rejected or abandoned) was reported descriptively for the overall cohort, as well as by subgroups identified by index OAC (apixaban, rivaroxaban, dabigatran, warfarin).
- Among patients with rejected index OAC claims, subsequent patient journey including number of additional rejections, reasons for the last rejections, proportion with an eventual filled OAC prescription and time to filled prescription for the index and any non-index OAC were assessed.
- Among patients with abandoned index prescriptions, the proportion with an eventual filled OAC claim and time to paid claim for both the index and any non-index OAC were reported.

Results

Study cohort

- Overall, 297,312 patients were included in the analysis after applying all the selection criteria (Figure 1). Among the overall cohort. 53.8% had an index OAC prescription for apixaban, 31.7% had rivaroxaban, 13.8% had warfarin and 0.7% had dabigatran.

Figure 1: Patient selection flowchart



*Patients with atrial flutter/fibrillation or mechanical heart valve during pre-index period as well as those with any claim for pregnancy, inferior vena cava filter, or cancer diagnosis/treatment during study period were excluded.
** Final sample excluded patients with index claim for edoxaban due to small sample size in that subgroup.
Abbreviations: FIA=Formulary Impact Analyzer; N=Number; OAC=oral anticoagulant

Patient characteristics (Table 1)

- The mean (SD) age for the overall cohort was 63.4 (15.4) years.
- Women accounted for more than half of the patients in the overall cohort and each index OAC subgroup.
- Approximately half the patients in the overall cohort had a baseline CCI score of ≥1; the most frequent comorbidities were hypertension (63.0%), hyperlipidemia (37.0%), and diabetes mellitus (29.6%).
- Baseline patient characteristics for index OAC subgroups are presented in Table 1.

Table 1. Baseline characteristics for VTE patients newly prescribed OAC stratified by index OAC

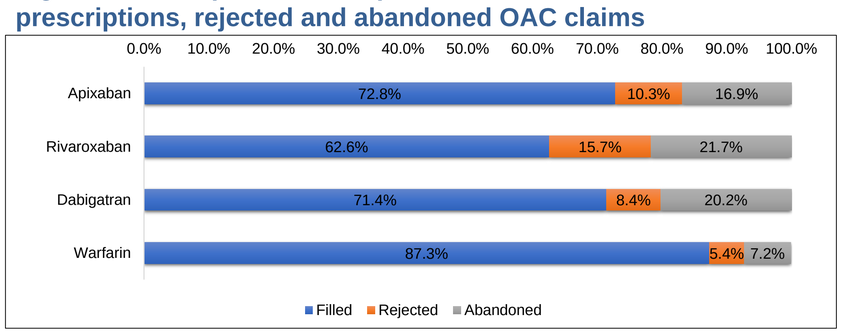
Demographic characteristics	Apixaban (N=159,999)	Rivaroxaban (N=94,350)	Dabigatran (N=2,030)	Warfarin (N=40,933)
Age, mean (SD)	64.5 (15.2)	61.6 (15.4)	63.3 (16.0)	63.6 (15.5)
Female, n (%)	92,602 (57.9)	52,984 (56.2%)	1,124 (55.4%)	23,369 (57.1%)
Clinical characteristics				
Prescriber specialty, n (%) (≥5%)				
PCP	123,084 (76.9%)	67,506 (71.5%)	1,426 (70.2%)	32,958 (80.5%)
Emergency medicine	12,807 (8.0%)	11,949 (12.7%)	109 (5.4%)	1,100 (2.7%)
CCI score, n (%)				
0-1	79,603 (49.8%)	57,905 (61.4%)	1,034 (50.9%)	17,385 (42.5%)
2	27,710 (17.3%)	15,217 (16.1%)	348 (17.1%)	7,063 (17.3%)
3	18,606 (11.6%)	8,731 (9.3%)	234 (11.5%)	5,141 (12.6%)
4+	34,080 (21.3%)	12,497 (13.2%)	414 (20.4%)	11,344 (27.7%)
Comorbidities, n (%) (≥20%)				
Anemia	36,136 (22.6%)	15,656 (16.6%)	457 (22.5%)	12,087 (29.5%)
CHD/IHD	44,676 (27.9%)	19,750 (20.9%)	559 (27.5%)	12,766 (31.2%)
Dyspepsia/stomach discomfort	39,578 (24.7%)	21,939 (23.3%)	538 (26.5%)	10,755 (26.3%)
Diabetes mellitus	49,497 (30.9%)	23,925 (25.4%)	577 (28.4%)	14,147 (34.6%)
Hyperlipidemia	61,474 (38.4%)	32,756 (34.7%)	740 (36.5%)	15,144 (37.0%)
Hypertension	104,362 (65.2%)	53,999 (57.2%)	1,243 (61.2%)	27,721 (67.7%)
Obesity	41,893 (26.2%)	24,068 (25.5%)	486 (23.9%)	11,600 (28.3%)
Procedures, n (%)				
Orthopedic surgery	6,106 (3.8%)	3,181 (3.4%)	69 (3.4%)	1,670 (4.1%)
Central venous catheter	8,520 (5.3%)	3,040 (3.2%)	103 (5.1%)	3,796 (9.3%)
Medications of interest, n (%) (≥20%)				
ACE inhibitors/ARBs	69,473 (43.4%)	37,320 (39.6%)	791 (39.0%)	17,004 (41.5%)
Beta blockers	51,618 (32.3%)	25,243 (26.8%)	587 (28.9%)	14,030 (34.3%)
Gastroprotective agents	59,217 (37.0%)	31,815 (33.7%)	751 (37.0%)	14,682 (35.9%)
Statins	64,253 (40.2%)	33,043 (35.0%)	742 (36.6%)	15,430 (37.7%)

Abbreviations: ACE=angiotensin converting enzyme, ARB=angiotensin receptor blockers, CCI= Charlson comorbidity index, CHD/IHD=Congestive heart disease/ischemic heart disease, OAC=oral anticoagulant, PCP=primary care provider, SD=standard deviation, VTE= venous thromboembolism.

Outcomes for index OAC claims

- Among the overall cohort, 9.1% had payer rejected and 16.7% had abandoned index OAC claims.
- Figure 2 provides the distribution of patients with filled, rejected and abandoned OAC claims within each OAC subgroup.

Figure 2. Proportion of patients with filled index OAC prescriptions, rejected and abandoned OAC claims



Rejected index OAC claims

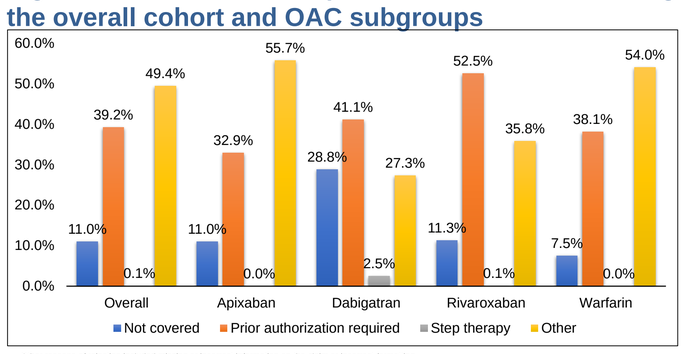
- The majority of patients with rejected index OAC claims in the overall cohort (82.1%) subsequently received an OAC, on average 18.3 days following rejection.
- Prior authorization (PA) requirement was the most common reason for rejections for dabigatran and rivaroxaban while 'missing/incorrect information' on the claim was most common for apixaban and warfarin (Figure 3).

Results (continued)

Factors associated with index rejection of OAC claims

- The index OAC type, insurance type, prescriber specialty, and diagnosis setting were significantly associated with index rejections.
- More specifically, in the overall cohort, patients with index OAC claims for rivaroxaban (odds ratio [OR]: 0.74; 95% confidence interval [CI]: 0.72-0.77) and warfarin (OR: 0.41; 95% CI: 0.39-0.43) had significantly lower odds, while those with dabigatran had significantly higher odds of payer rejection (OR: 1.36; 95% CI: 1.20-1.53) compared to apixaban patients.
- Patients with their index VTE diagnosis in an inpatient setting had lower odds of rejection than those diagnosed in the outpatient setting (OR: 0.86; 95% CI: 0.84-0.89).
- Compared to primary care providers, patients whose index OAC was prescribed by an emergency medicine physician had lower odds of rejection (OR: 0.75; 95% CI: 0.72-0.79) while those with OAC prescribed by cardiologists (OR: 1.45; 95% CI: 1.35-1.55), hematologists/oncologists (OR: 1.24; 95% CI: 1.16-1.33), and pulmonary medicine physicians (OR: 1.15; 95% CI: 1.05-1.26) had significantly higher odds of rejection.

Figure 3. Reasons for rejected index claims among the overall cohort and OAC subgroups



*Other reasons of rejection included missing or incorrect information on the claim or incorrect formatting.
Abbreviations: OAC=oral anticoagulant

Abandoned index OAC prescriptions

- The majority of the patients (90.4%) with abandoned index OAC prescriptions in the overall cohort had subsequent filled prescriptions. Among OAC subgroups, there was a similar pattern with >89% in apixaban, rivaroxaban and warfarin cohorts and 77.1% in the dabigatran with subsequent filled prescriptions.
- The mean time from date of abandoned index prescription to subsequent fill was 15.6 days among those whose fill was for the index OAC and 22.6 days among those with a fill for a non-index OAC. A similar pattern was observed among each OAC subgroup.

Conclusions

- In this real-world study of VTE patients newly prescribed OAC in the US, many patients had their index claim rejected or abandoned their OAC prescription.
- While most eventually received a filled prescription, a considerable proportion of patients in the overall cohort and each OAC subgroup did not receive an OAC after their rejected or abandoned index OAC claim, and those who did receive an OAC experienced a delay in receiving this critical therapy.
- One of the common reasons for payer rejections was prior authorization requirement, potentially imposing administrative burden for physicians as they navigate such access challenges.

Limitations

- Results from retrospective studies must be interpreted with caution and can only establish associations and not cause-and-effect relationships.
- Claims data do not provide as much clinical details as medical records as they are primarily collected for the purposes of payment. Therefore, there was a potential for miscoding or misclassification (e.g., identification of newly treated VTE patients). There was also the potential for under-coding if they were not captured for billing purposes.
- Since this study used open-source databases, there was a loss of visibility to healthcare activity outside of the database contributors. Pharmacy stability requirements were applied to the index prescription pharmacy at the patient level. Nevertheless, FIA has high prescription coverage (e.g., 63% of retail pharmacies in the US). Over-the-counter products were not captured.
- Unlike administrative health plan claims data, it was not possible to define periods of continuous enrollment (CE). Proxies were implemented based on patient activity and pharmacy stability to provide greater assurance that patient healthcare activity within these databases was captured during the study period. The data also lacked information on mortality.

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Disclosures

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