Adherence to Guidelines for Oral Anticoagulation after Venous Thrombosis and Pulmonary Embolism

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OBJECTIVE: Guidelines for oral anticoagulation after deep venous thrombosis (DVT) or pulmonary embolism (PE) have recommended that patients be anticoagulated for at least 3 months after hospital discharge. We sought to determine whether this recommendation was being followed and what patient characteristics predict a shorter than recommended duration of therapy.

DESIGN: Retrospective cohort study using linked health care claims data.

SETTING: Routine clinical practice.

PATIENTS: Five hundred seventy-three members of New Jersey's Medicaid or Pharmacy Assistance for the Aged and Disabled programs aged 65 years and older who were hospitalized for DVT or PE between January 1, 1991 and June 30, 1994.

RESULTS: Of the 573 patients, 129 (23%) filled prescriptions covering less than 90 days of oral anticoagulant therapy. In multivariate models, African-American race was associated with an increased risk of a shorter than recommended duration of therapy (odds ratio [OR], 1.87; 95% confidence interval [CI], 1.14 to 3.08), but age and gender were not. Patients who used anticoagulants in the year prior to admission were less likely to have a short duration of therapy (OR, 0.30; 95% CI, 0.12 to 0.78), than were patients with PE (OR, 0.58; 95% CI, 0.38 to 0.88).

CONCLUSIONS: Nearly a quarter of those anticoagulated following DVT or PE received therapy for less than the recommended length of time after hospital discharge, with African Americans more likely to have a shorter than recommended course of treatment. Further research is needed to evaluate the causes of shorter than recommended duration of therapy and racial disparities in anticoagulant use.

KEY WORDS: oral anticoagulants; deep venous thrombosis; pulmonary embolism; practice guidelines.

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Deep venous thrombosis (DVT) and pulmonary embolism (PE) represent a common source of morbidity and mortality, with an estimated 200,000 to 260,000 hospitalizations annually.^{1,2} Older patients are especially susceptible to DVT and PE, because the incidence of venous thromboembolic events greatly increases with age.²⁻⁴ One study found annual incidence rates of 1.3 and 1.8 per 1,000 for PE and DVT, respectively, among those aged 65 to 69 years; these rates increased steadily to reach 2.8 per 1,000 for PE and 3.1 per 1,000 for DVT among those aged 85 to 89.⁵ Oral anticoagulant therapy has been a mainstay of treatment for such patients to prevent recurrent events.^{6,7} However, the optimal duration of therapy is uncertain. The most recent evidence-based recommendations of the American College of Chest Physicians (ACCP) call for at least 3 months of oral anticoagulant therapy after PE or DVT unless therapy is contraindicated.⁸ The guidelines note that patients with isolated calf vein thrombosis can be followed with serial noninvasive testing if anticoagulation is not used. Earlier recommendations from the ACCP published in 1989 and 1992 also called for at least 3 months of oral anticoagulant therapy for most patients, although a shorter duration of therapy in patients with reversible risk factors, such as estrogen use or transient immobilization, was considered acceptable.^{9,10}

Thus, over the past decade, the general recommendation has been to treat patients with at least 3 months of oral anticoagulant therapy after PE or DVT. The objectives of this study were to assess how frequently such patients in a large population actually filled prescriptions for 3 months of oral anticoagulant therapy, and what demographic and clinical factors predicted a less adequate duration of care.

METHODS

Data Sources

The study sample was selected from data describing all health care encounters for New Jersey residents enrolled in Medicare (Parts A and B), Medicaid, and New Jersey's Pharmacy Assistance for the Aged and Disabled (PAAD) program. All subject identifiers were transformed to anonymous coded subject numbers to protect the privacy of program participants. Eligibility for Medicaid requires an income below the poverty level, whereas the PAAD program provides drug coverage to patients with modest incomes who are not eligible for Medicaid. Data on all hospitalizations, diagnoses, nursing home stays, and filled prescriptions are recorded for all patients dually

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eligible for both Medicare and Medicaid, or Medicare and PAAD. Previous studies have shown a high degree of reliability and validity of Medicaid prescription data.^{11,12}

During the study period, New Jersey's Medicaid program had no deductible or maximum benefit for drugs and charged no copayment for prescribed medications. The PAAD program had no deductible and no maximum benefit but had a \$ copayment for each prescription filled. Neither program had formulary restrictions during the study period. Given the economic incentives to fill prescriptions through these channels, essentially all prescriptions filled by Medicaid and PAAD participants can be determined.

Inclusion and Exclusion Criteria

We extracted information on all patients hospitalized for either DVT (diagnosis-related group [DRG] 128) or PE (DRG 78) who were aged 65 years or older, were discharged from this index hospitalization between January 1, 1991 and June 30, 1994, and were active users of the Medicaid or PAAD pharmacy benefit (Table 1). If patients had multiple events meeting inclusion criteria, the first event was considered the index event. Diagnosis-related group codes were used rather than *International Classification of Diseases* (ICD) diagnosis codes in order to limit the sample to patients whose principal reason for hospitalization was DVT or PE, instead of those with a history of these diseases or who "ruled out" for these disorders during their hospital stay.

We then excluded patients with ICD-9 diagnoses suggesting a nonthrombotic source of emboli (air or fat embolism) during their index hospitalization, those who died or were hospitalized for bleeding, coagulation disorder, or abnormal coagulation profile within 90 days, and those with atrial fibrillation (AF) in the 365 days prior to the in-

dex hospitalization. In addition, we excluded patients who did not fill any prescription for anticoagulants within 14 days of discharge, because it was more likely that such patients had a diagnosis of isolated calf vein thrombosis or an absolute contraindication to oral anticoagulation.

Outcome

The outcome studied was the proportion of patients who had a duration of anticoagulant therapy less than 90 days. We henceforth refer to this duration of therapy as "inadequate therapy," based on previously cited guidelines. Anticoagulant therapy included prescriptions for either warfarin (the vast majority of prescriptions) or dicumarol. We examined prescriptions filled within the first 90 days after discharge, and assigned each a duration based on information contained in each filled prescription on the number of days supplied and the quantity of tablets dispensed. We defined the total duration of therapy as the time between the day of discharge and the final day covered by the last filled prescription. Because gaps in therapy could exist within the measured duration, we also calculated the percentage of days covered by drug therapy within the measured duration. To determine whether a patient was covered by anticoagulant therapy on the day of a recurrent DVT or PE, we added 3 days to the final day of the most recent prescription, because anticoagulation does not stop immediately after cessation of therapy.

Exposures

To assess patient characteristics that could potentially predict a duration of therapy under 90 days, we examined demographic characteristics including age, gender, race, socioeconomic status (reflected in enrollment in Medicaid vs PAAD), or admission to the hospital from a nursing home. We also considered clinical characteristics such as whether the index event was DVT or PE, and whether the patient had transient risk factors for venous thrombosis (hip fracture or surgery in the 90 days before admission) or nontransient risk factors (e.g., malignancy in the year prior to admission). Other predictors examined included whether the patient had used anticoagulants previously, as well as potential contraindications to anticoagulant therapy, such as a history of bleeding, prior use of nonsteroidal anti-inflammatory agents, or a history of falls. Placement of an inferior vena cava filter was also noted.

Another potential predictor of duration of anticoagulation included levels of comorbidity as assessed by the Charlson index,^{13,14} a measure of comorbid disease which has been well studied as a predictor of mortality. It assigns points for specific comorbidities, such as congestive heart failure, diabetes, or renal disease, based on observed outcomes in large cohorts of patients. The present study utilizes the index as adapted for administrative databases, using ICD-9 codes instead of chart review.¹⁴

Table 1. Cohort Inclusion/Exclusion Criteria

Inclusion criteria

- Hospitalizations for PE (DRG 78) or DVT (DRG 128)
- Discharged between January 1, 1991 and June 30, 1994
- Age $\geq$ 65 years on day of admission
- Filled a prescription for any drug
 - within 6 months prior to admission, and
 - more than 6 months prior to admission, and
 - within a year after discharge

Exclusion criteria

- ICD-9 codes for air or fat embolism as cause of index hospitalization
- Did not fill a prescription for oral anticoagulant within 14 days of discharge
- Died within 90 days
- Hospitalized for bleeding, coagulation disorder, or abnormal coagulation profile within 90 days of discharge
- AF noted in 365 days prior to admission

PE indicates pulmonary embolism; DRG, diagnosis-related group; DVT, deep vein thrombophlebitis; ICD-9, International Classification of Diseases, Ninth Revision; AF, atrial fibrillation.

A year of historical data was available for all characteristics studied. To test the robustness of these predictors, we conducted a sensitivity analysis using 2 additional definitions of short duration: less than 75 days and less than 60 days.

Statistical Analysis

We used Pearson χ^2 tests to calculate 2-tailed *P* values for univariate associations between potential determinants and the outcome of <90 days of anticoagulant therapy. Multivariate analyses were carried out using backward selection logistic regression models to calculate adjusted odds ratios for inadequate duration of therapy. Age, gender, and race were included in all models. Other variables with *P* < .2 in univariate analysis were selected for inclusion in the multivariate model, and those with the highest *P* values were removed from the model one at a time until the model consisted of age, gender, race, and all other variables with *P* < .2. We considered associations statistically significant at *P* < .05. The fit of the model to the data was assessed using the Hosmer-Lemeshow goodness-of-fit test, and the overall predictive power of the model was assessed with the *c*-statistic. All results were analyzed using SAS software, version 6.12 (SAS Institute, Cary, NC).

RESULTS

We identified 974 patients hospitalized for DVT or PE during the study period. Of these 974 patients, 573 (59%) were included in the analysis, after excluding 270 patients who did not fill any prescription for an oral anticoagulant within 14 days of discharge, 46 patients who died within 90 days, 10 patients who were rehospitalized for bleeding, coagulation disorder, or abnormal coagulation profile, 73 patients with AF, and 2 patients with diagnoses of air or fat embolism. Of the 573 remaining patients, 183 (32%) were aged 65 to 74 years, 278 (49%) were aged 75 to 84 years, and 112 (20%) were age 85 years or older (Table 2). Women constituted 79% of the study sample, 24% of patients were nonwhite, and 12% were admitted from a nursing home. Most patients had significant comorbidity, as indicated by the 88% of patients who had Charlson scores of 3 or higher. Patients with a history of prior PE or DVT represented 17% of the sample.

Of the 573 patients, 129 (23%) had a duration of oral anticoagulant therapy of less than 90 days (Table 3). Of these 129 patients, 13 (10%) had a duration of less than 30 days, 60 (47%) had a duration of 30 to 59 days, and 56 (43%) had a duration of 60 to 89 days. More than 91% of the 573 patients had prescriptions covering at least 80% of their calculated duration of therapy.

In univariate analyses, we found race, prior oral anticoagulant use, and PE at the time of the index hospital-

Table 2. Demographic and Clinical Characteristics of the Study Sample (N = 573)

Characteristic	n	Duration <90 days, %	P Value*
Age, y			
65–74	183	24	
75–84	278	22	
85+	112	23	.87
Gender			
Female	450	21	
Male	123	27	.20
Race			
White	437	20	
African American	105	30	
Other/missing	31	32	.05
Payer†			
Medicaid	186	22	
PAAD	387	23	.85
Admitted from			
Community	506	18	
Nursing home	67	23	.34
DRG code			
PE	254	18	
DVT	319	26	.02
Charlson Score			
0–2	70	29	
3–5	240	21	
6–8	195	24	
9+	68	19	.49
Prior oral anticoagulant use			
Yes	54	9	
No	519	24	.01
Prior PE or DVT			
Yes	97	22	
No	476	23	.82
History of malignancy			
Yes	33	24	
No	540	22	.85
Prior placement of IVC filter			
Yes	6	17	
No	567	23	.73
History of bleeding‡			
Yes	28	18	
No	545	23	.55
History of falls recorded			
Yes	15	20	
No	558	23	.81
History of NSAID use			
Yes	213	21	
No	360	24	.41
Hip Fracture in past 90 days			
Yes	34	21	
No	539	23	.78
Surgery in past 90 days			
Yes	83	22	
No	490	23	.93

**P* values are from χ^2 tests of association. PAAD indicates Pharmacy Assistance for the Aged and Disabled; DRG, diagnosis-related group; PE, pulmonary embolism; DVT, deep vein thrombophlebitis; IVC, inferior vena cava; NSAID, nonsteroidal anti-inflammatory drug.

†Patients with both Medicaid and PAAD as payers were classified as Medicaid patients.

‡History of bleeding includes prior gastrointestinal hemorrhage, intracranial hemorrhage, or hematuria.

Table 3. Duration of therapy (N = 573)

Duration of Therapy	n (%)
<30 days	13 (2.3)
30–59 days	60 (10.5)
60–89 days	56 (9.8)
Total less than 90 days	129 (22.5)
Total 90 days or more	444 (77.5)

ization to be significantly associated with duration of therapy (Table 2). Compared with white patients, in whom the rate of inadequate duration of therapy was 20%, African-American patients had a 30% rate of inadequate duration; patients whose race was "other" or undefined had a 32% rate of inadequate duration of therapy (for the overall association, $P = .05$). Of patients who had used oral anticoagulants in the past year, 9% had an inadequate duration of therapy as compared with 24% of those who had no prior anticoagulant use in the past year ($P = .01$). Only 18% of patients with PE had an inadequate duration of therapy, compared with 26% of patients with DVT ($P = .02$). No association was demonstrated between duration of therapy and presence of transient risk factors for DVT, specifically pelvic fracture or surgery in the 90 days prior to hospitalization.

In multivariate analyses, we found that African-American race, prior use of anticoagulants, and PE continued to be statistically significant predictors of inadequate duration of therapy (Table 4), with African Americans more likely to have inadequate duration of therapy (odds ratio [OR], 1.87; 95% confidence interval [CI], 1.14 to 3.08). Prior oral anticoagulant users were less likely to have inadequate duration of therapy (OR, 0.30; 95% CI, 0.12 to 0.78), and patients with PE were less likely to have inadequate duration of therapy in comparison with those with DVT (OR, 0.58; 95% CI, 0.38 to 0.88). These characteristics remained significant predictors when short duration of therapy was defined as less than 75 days or less than 60 days of therapy after discharge. The model was found to be a good fit for the data ($P = .34$ by Hosmer-Lemeshow goodness-of-fit test) with moderate predictive power (c -statistic, 0.617).

Of the 573 patients in the sample, 8 (1.4%) had a recurrent event within 90 days (6 DVT, 2 PE). All 8 patients were covered by a filled prescription for an anticoagulant at the time of the event.

DISCUSSION

About a quarter of this population of older patients with DVT or PE did not fill anticoagulant prescriptions during the study period for the minimum 90 days of therapy recommended. This is a conservative estimate, as it includes only those who actually began oral anticoagulants following hospital discharge. Some of the 270 patients who did not initiate therapy (and were thus excluded from the main analysis) may also have required 3 months of therapy, although exactly how many cannot be determined. African-American patients and patients with DVT rather than PE were significantly less likely to complete the recommended minimum course of therapy. The presence of reversible risk factors did not explain shorter duration of therapy in this cohort.

A population-based study from Sweden has examined duration of oral anticoagulant therapy after discharge.¹⁵ In this study, 8% of patients received 1 month or less of anticoagulant therapy, 37% were treated for 2 to 3 months, 32% for 4 to 6 months, and 20% for 7 months or more. Another study examined adherence to recommendations for anticoagulation during the hospitalization period itself, but did not cover the period after hospitalization.¹⁶ Observational studies such as these can complement randomized controlled trials and evidence-based guidelines by measuring how well recommendations are being followed in practice.

Our finding of an association between race and inadequate duration of therapy is consistent with prior studies showing undertreatment of African Americans for ischemic heart disease,^{17,18} glaucoma,^{19,20} and other conditions. This association is unlikely to be confounded by income, because enrollment in Medicaid did not emerge as an important determinant of short duration of therapy in either univariate or multivariate analyses. A recent study using data on Medicare beneficiaries has shown that race remains a persistent determinant of disparities in the use of

Table 4. Crude and Adjusted Odds Ratios for Risk of Short Duration of Therapy*

Odds Ratio	Crude OR (95% Confidence Interval)	Adjusted OR (95% Confidence Interval)
Age, by decade	0.98 (0.74 to 1.29)	1.10 (0.82 to 1.47)
Female	0.74 (0.47 to 1.17)	0.75 (0.47 to 1.20)
African-American race ^{†,‡}	1.66 (1.03 to 2.69)	1.87 (1.14 to 3.08)
Other/undefined race [‡]	1.89 (0.86 to 4.16)	1.96 (0.87 to 4.42)
Prior oral anticoagulant use [†]	0.33 (0.13 to 0.83)	0.30 (0.12 to 0.78)
Pulmonary embolism (vs deep vein thrombosis) [†]	0.63 (0.42 to 0.94)	0.58 (0.38 to 0.88)

*Results from a backward selection multiple logistic regression model, retaining age, gender, race, and all variables with $P < .2$.

[†] $P < .05$.

[‡]The referent for both of these categories is white race.

a variety of health services, even after adjusting for income.²¹ Nonwhite race has also been found to be a marginally significant predictor of noncompliance with anticoagulant therapy in an anticoagulation clinic,²² but the generalizability of this finding to other settings is unclear. Because African Americans may be at an elevated risk of DVT as compared with whites,²³ the consequences of undertreatment may be even more important.

We found that 1.4% of patients went on to have recurrent events within the first 90 days of therapy, a figure consistent with other studies, which have shown recurrence rates ranging from 0.6% to 5% at 90 days.²⁴ Interestingly, all patients in the study sample with recurrent events in the first 90 days were covered by a prescription for anticoagulant therapy; this suggests that failure to follow recommendations for duration of therapy may not be the source of recurrent events in this population. Rather, patients may have been anticoagulated at a subtherapeutic international normalized ratio or may have been noncompliant with therapy. Randomized clinical trials^{25,26} and a population-based study¹⁵ have demonstrated that shorter duration of anticoagulant therapy is a risk factor for recurrent events.

The problem of diagnostic validity is a necessary concern in any study based on health care claims data. We addressed this concern in two ways. First, we included only hospitalized patients for whom DVT or PE was the principal or admission diagnosis by using DRG codes, instead of ICD-9 codes, for DVT or PE. Second, we required that patients fill at least one prescription for oral anticoagulants within 14 days of discharge, thus eliminating patients in whom oral anticoagulants would not be the preferred therapy (e.g., patients with isolated calf vein thrombosis). The study sample is therefore likely to be specific for patients with DVT or PE, enhancing the validity of our conclusions.

The duration of therapy for each patient is likely to be a function of both patient and physician characteristics. Inadequate duration of therapy may result from the patient not refilling a prescription or the physician not prescribing 90 days of therapy, decisions which may have many determinants. We cannot discern the relative contributions of the physician and the patient to the outcome observed; future research is needed to examine physician characteristics (e.g., generalist vs specialist) as potential predictors of duration of therapy as well as health care system issues (such as the presence of managed care or the availability of an anticoagulation clinic).

One limitation affecting this study's generalizability is that the patient sample was drawn from a lower income population. However, we found no difference in anticoagulant utilization between patients of modest income (PAAD) and those who were poor (Medicaid), suggesting that income is probably not a major determinant. Further, it is unlikely that physicians would prescribe different durations of therapy to poor versus modest income patients, especially if the poor had comprehensive drug benefits, as was the case here. In fact, the broad coverage of drug expenses in both the Medicaid and PAAD programs effec-

tively removes cost as a barrier for such patients; utilization rates in patients with less generous medication insurance could be considerably worse.

Another limitation of this study concerns the frequent dosage adjustments often required of patients on oral anticoagulant therapy. If dosage is adjusted downward without a new prescription being written, a duration of therapy calculated based on filled prescriptions will underestimate the true duration of therapy. If dosage is adjusted upward without a new prescription being written, duration of therapy will be overestimated. Thus, patients with durations of therapy close to 90 days might be misclassified, although the direction this bias would take is not clear. However, when we examined factors associated with inadequate duration of therapy in sensitivity analyses using stricter definitions of inadequate duration (less than 75 days and less than 60 days), the findings were virtually identical.

Given that about one quarter of patients studied did not receive 90 days of oral anticoagulant therapy after DVT and PE and that African-American race was associated with an increase in the risk of inadequate duration of therapy, further studies are needed to evaluate the reasons for inadequate duration of therapy after DVT and PE as well as the causes of racial disparities in anticoagulant use.

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