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Upper Extremity Deep Vein Thrombosis: A Community-Based Perspective:

The Worcester Venous Thromboembolism Study

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Abstract

Purpose—The purpose of this study was to examine the magnitude, risk factors, management strategies, and outcomes in a population-based investigation of patients with upper, as compared to lower, extremity deep vein thrombosis diagnosed in 1999.

Methods—The medical records of all residents from Worcester, Massachusetts (2000 census=478,000) diagnosed with ICD-9 codes consistent with possible deep vein thrombosis at all Worcester hospitals during 1999 were reviewed and validated.

Results—The age-adjusted attack rate (per 100,000 population) of upper extremity deep vein thrombosis was 16 (95% CI 13, 20) compared to 91 (83,100) for lower extremity deep vein thrombosis. Patients with upper extremity deep vein thrombosis were significantly more likely to have undergone recent central line placement, a cardiac procedure, or an intensive care unit admission than patients with lower extremity deep vein thrombosis. Although short and 1-year recurrence rates of venous thromboembolism and all-cause mortality were not significantly different between patients with upper, versus lower, extremity deep vein thrombosis, patients with upper extremity deep vein thrombosis at presentation or in follow-up.

Conclusions—Patients with upper extremity deep vein thrombosis represent a clinically important patient population in the community setting. Risk factors, occurrence of pulmonary embolism, and timing and location of venous thromboembolism recurrence differ between patients with upper as compared to lower extremity deep vein thrombosis. These data suggest that strategies for prophylaxis and treatment of upper extremity deep vein thrombosis need further study and refinement.

Introduction

It is generally assumed that the occurrence of upper extremity deep vein thrombosis has increased in the last several decades. However, the actual incidence of upper extremity deep vein thrombosis in the community-setting, the profile of patients at increased risk for the development of upper extremity deep vein thrombosis, and the clinical sequelae of this condition, particularly with regards to development of recurrent venous thromboembolic events, remains unclear.

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The objectives of the Worcester Venous Thromboembolism study are to provide more contemporary population-based data about the clinical epidemiology of venous thromboembolism as well as its management and associated outcomes. The purpose of the present investigation was to describe and compare incidence rates, patient profiles, management strategies, and subsequent outcomes in residents of the Worcester, Mass metropolitan area diagnosed with upper versus lower extremity deep vein thrombosis in 1999.

Methods

Computerized printouts of all Worcester residents with healthcare encounters in which any of 34 ICD-9 diagnosis codes possibly consistent with venous thromboembolism (see Appendix A) had been listed in 1999 were obtained from each of the 12 hospitals serving the Worcester area. These data queries were not limited to discharge diagnoses but also encompassed all outpatient activities. In order to identify Worcester residents with potential venous thromboembolism who sought care outside of the Worcester area, we queried the Massachusetts Health Data Consortium which collects information on all Massachusetts residents seeking health care at hospitals throughout Massachusetts, as well in adjacent states.

The medical records of all persons meeting the geographic inclusion criteria were subsequently reviewed and validated by trained abstractors using pre-specified criteria based on a modification of a classification schema proposed by Silverman et al (see Appendix B).1 Patients were considered to have an upper extremity deep vein thrombosis if an internal jugular, innominate, subclavian, or axillary vein thrombosis was confirmed by ultrasonography or venography. Patients were considered to have a lower extremity deep vein thrombosis if thrombosis of the iliac, femoral, popliteal, or calf veins was confirmed by ultrasonography or venography.

Data collection

Information was collected from medical records about patient demographic and clinical characteristics, diagnostic test results, and hospital management practices. Surgery included major operations where general or epidural anesthesia lasted 30 minutes or longer. Medical history variables defined as "recent" were those occurring or active in the 3 months prior to deep vein thrombosis.

Simultaneous conduct of medical record review at all area hospitals and review of state and national mortality records, enabled collection of information about recurrent venous thromboembolism, major bleeding, and/or mortality at the same time as information about the index event. Some form of additional follow-up was obtained in >99% of all patients.

Potential cases of recurrence of venous thromboembolism were classified using criteria similar to that employed for incident cases – however, a definite recurrence of deep vein thrombosis required the new occurrence of thrombosis in a previously uninvolved venous or pulmonary segment. Major bleeding was defined as any episode of bleeding requiring transfusion or resulting in hospitalization (or prolongation of hospitalization), stroke, MI, or death.

Analysis

Rates of initial and total deep vein thrombosis, stratified according to location (upper versus lower), were calculated based on U.S. census estimates of the Worcester population in 2000 (n = 477,800). Differences in the distribution of characteristics between patients with upper

versus lower extremity deep vein thrombosis were examined using chi-square tests of statistical significance for categorical variables and t tests for continuous variables.

Multivariate regression analysis was carried out to identify medical history variables independently associated with upper as compared to lower extremity deep vein thrombosis. Candidate variables for inclusion in the regression model included patient age, sex, race, current hospitalization, and the medical history variables listed in table 1. Candidate variables possibly associated with the outcomes of interest (p<0.25 after univariate analysis) were included in the multivariate models. Variables with p>0.05 were eliminated in a stepwise fashion so that only variables with a statistically significant association with the outcome of interest were included in the final regression models.

Results

The study sample consisted of 483 Worcester men and women with validated acute deep vein thrombosis. Of these, 69 patients were diagnosed with upper extremity deep vein thrombosis (14%), while the majority (86%) was diagnosed with lower extremity deep vein thrombosis. The mean age of the study sample was 65 years, 54% were women, and 91% were Caucasian.

Incidence and Attack Rates of Venous Thromboembolism

The age-adjusted incidence and total rates of upper extremity deep vein thrombosis were 15 (95% CI 12, 19) and 16 (95% CI 13, 20) respectively, compared to 74 (95% CI 67, 82) and 91 (95% CI 83, 100) per 100,000 population for lower extremity deep vein thrombosis. Incidence and total rates of upper extremity deep vein thrombosis did not differ significantly by gender (males: 16 and 17 per 100,000; females 14 and 15 per 100,000).

Characteristics of Patient with Upper Extremity Deep Vein Thrombosis versus Lower Extremity Deep Vein Thrombosis

Patients with upper extremity deep vein thrombosis were younger, more likely to be nonwhite, and had a lower body mass index than patients with lower extremity deep vein thrombosis (Table 1). Patients with upper extremity deep vein thrombosis were more likely to experience deep vein thrombosis during a hospital admission for a non-venous thromboembolism related diagnosis, to have had a recent central venous catheter, infection, active malignancy, or intensive care unit discharge but less likely to have a prior history of venous thromboembolism.

After multivariate analysis, patients with upper extremity deep vein thrombosis were more likely to have had a recent central venous catheter (OR 21.7, 95% CI 9.3-50.0), recent cardiac procedure (OR 4.2, 95% CI 1.2-14.2), or recent intensive care unit discharge (OR 3.8, 95% CI 1.4-10) than patients with a lower extremity deep vein thrombosis.

Characteristics of Patients with Upper Extremity Deep Vein Thrombosis and Recent History of Central Venous Catheter

Of the 69 patients with upper extremity deep vein thrombosis, 43 (62%) had a history of recent central venous catheter placement. In 38 out of these 43 patients, central venous catheter position was in the same upper extremity as the subsequent deep vein thrombosis. Type/location of central line placement in these patients included PICC (peripherally inserted catheters) (29%), internal jugular (29%), subclavian (12%), and other (e.g. Hickman[®], Tessio[®], Groshong[®]) (30%).

Patients with upper extremity deep vein thrombosis and a history of recent central venous catheter placement were more likely to have a history of recent hospitalization, surgery, severe infection, intensive care unit discharge, intubation, or fracture than patients without central venous catheter placement (Table 2).

History of Prophylaxis

We examined the prior utilization of deep vein thrombosis prophylaxis in three subsets of patients who developed deep vein thrombosis during or after hospitalization or surgery: 1) Patients who developed deep vein thrombosis during hospitalization for another illness (n=125); 2) patients who developed deep vein thrombosis as outpatients but had been hospitalized in the preceding 3 months (n=190); and 3) patients who developed deep vein thrombosis within the 3 months following surgery (n=147; 95 of these patients were also included in group 2). Prior utilization of anticoagulation prophylaxis during these high-risk periods in patients with upper extremity deep vein thrombosis was 60%, 49%, and 56%, respectively. Corresponding rates of anticoagulant prophylaxis in patients with lower extremity deep vein thrombosis were 43%, 36%, and 36%, respectively.

Treatment Practices

Patients with upper extremity deep vein thrombosis were less likely to be acutely treated with unfractionated heparin, but equally likely to be treated with low-molecular-weight heparin, as compared to patients with lower extremity deep vein thrombosis (Table 3). Fewer patients with upper extremity deep vein thrombosis were prescribed warfarin at hospital discharge than those with lower extremity deep vein thrombosis.

Outcomes

None of the thirty-day, 6-month, or 1-year outcomes (major bleeding, venous thromboembolism recurrence, mortality) was significantly different in patients with upper versus lower extremity deep vein thrombosis (Table 4). Of the 10 recurrent deep vein thromboses occurring in patients with upper extremity deep vein thromboses, 7 occurred in the ipsilateral upper extremity. Of 40 recurrent deep vein thromboses occurring in patients with lower extremity deep vein thrombosis, 26 were in the ipsilateral leg, 10 were in the contralateral leg, and 4 were in the upper extremity.

None of the patients presenting with upper extremity deep vein thrombosis were also diagnosed with a concomitant pulmonary embolism whereas pulmonary embolism was clinically recognized in 15% of patients presenting with lower extremity deep vein thrombosis. Only 1 patient with upper extremity deep vein thrombosis was diagnosed with pulmonary embolism at 30 days – no other clinically recognized pulmonary embolism occurred in this group over a one-year follow-up period. Five patients with lower extremity deep vein thrombosis suffered a pulmonary embolism within the first month; an additional 7 patients developed clinically recognized pulmonary embolism by 1 year.

All-cause mortality at 1, 6, and 12 months did not differ significantly between patients with upper versus lower extremity deep vein thrombosis.

Discussion

This population-based study provides the only available data on the actual incidence of upper extremity deep vein thrombosis in a well-defined community. Approximately 1 in 7 deep vein thromboses in this community of approximately 500,000 people occurred in the upper extremity. Extrapolated to the U.S. population, our data suggest approximately 50,000 cases of upper extremity deep vein thrombosis occur annually.

Clinical Profile of Patients with Upper Extremity Deep Vein Thrombosis

We were able to identify important differences in the clinical profile of patients experiencing upper versus lower extremity deep vein thrombosis. Patients with upper extremity deep vein thrombosis were twice as likely to suffer their event during hospitalization and were more likely to have additional hospital-related risk factors. Most notably, approximately 60% of all patients with upper extremity deep vein thrombosis had undergone a central line placement in the preceding 3 months compared with 10% of those with lower extremity deep vein thrombosis. After multivariate analysis, recent central line placement was the clinical variable most strongly associated with upper extremity (as opposed to lower) deep vein thrombosis.

Clinical characteristics of patients with upper extremity deep vein thrombosis compared to those with lower extremity deep vein thrombosis were also examined in a U.S. multi-center registry of nearly 5500 patients, 592 of whom had upper extremity deep vein thrombosis.2 Data from this study suggested that upper extremity deep vein thrombosis occurred in approximately 70% of patients during hospitalization. As in our study, a recent central venous catheter was the strongest independent predictor of upper (versus lower) extremity deep vein thrombosis. Similarly, in a nested population-based case-control study of 625 patients with deep vein thrombosis from 1976 to 1990, recent central line or cardiac pacemaker placement was independently associated with an increased risk of deep vein thrombosis – approximately 9% of all deep vein thromboses within this community were attributable to these procedures.3

These findings also have important implications for the utilization of deep vein thrombosis prophylaxis. Since the most important risk factors of upper extremity deep vein thrombosis prophylaxis are identifiable, and are hospital-related, optimal targeting of prophylaxis to patients at risk should be achievable.

Prophylaxis

Anticoagulant prophylaxis use during high-risk periods in patients subsequently developing upper extremity deep vein thrombosis was suboptimal. The DVT-Free Study reported an even lower utilization rate of anticoagulant prophylaxis in the 30 days prior to upper extremity deep vein thrombosis (\sim 33%) (2).

Our data suggests that placement of a central venous catheter, particularly in acutely ill hospitalized patients, represents a readily identifiable risk factor for upper extremity deep vein thrombosis. Unfortunately, there is very limited literature describing the efficacy of prophylaxis in such patients. Studies assessing prophylaxis with mini-dose warfarin or low-molecular weight heparins in patients with in-dwelling central lines have been limited to ambulatory cancer patients and have provided mixed results.4⁻⁷ No clear benefits associated with prophylaxis in these patients have been reproducibly demonstrated, and in one study, patients receiving mini-dose warfarin suffered an increase in bleeding.6 In our study, most of the patients experiencing upper extremity deep vein thrombosis were non-ambulatory or hospitalized with an acute illness, approximately 25% had a recent intensive care unit stay, and most had additional risk factors, suggesting they were at greater risk for both thrombosis and for bleeding than previously studied patients. Further studies are needed to evaluate the efficacy and safety of prophylaxis in non-ambulatory patients at increased risk for upper extremity deep vein thrombosis, particularly those undergoing placement of a central venous catheters and/or requiring an intensive care unit admission.

Treatment and Outcomes

The majority of patients with deep vein thrombosis in our community study were treated acutely with a heparin product. However, prescription of warfarin at the time of hospital encounter was significantly lower in patients with upper extremity than in those with lower extremity deep vein thrombosis. Aspirin therapy was prescribed at discharge in twice as many patients with upper, versus lower, extremity deep vein thrombosis suggesting that some clinicians may still consider aspirin to be an acceptable alternative to warfarin therapy. Although recent guidelines from the American College of Chest Physicians suggest upper extremity deep vein thrombosis should be treated similarly to lower extremity deep vein thrombosis8, our data suggest a lingering perception among clinicians that upper extremity deep vein thrombosis does not necessarily require aggressive treatment.

Our data also provides some insights about outcomes associated with this condition in the community-setting. At 30 days and 6 months, recurrent venous thromboembolism was approximately 1.7 times more frequent in patients with upper extremity deep vein thrombosis than in those with lower extremity deep vein thrombosis. Interestingly, the temporal profile of recurrent events differed according to initial thrombosis location. Patients with upper extremity deep vein thrombosis experienced all of their recurrent events within the first 6 months of diagnosis, whereas approximately one quarter of recurrent events in patients with lower extremity deep vein thrombosis occurred between 6 months and 1 year after diagnosis.

None of the patients with upper extremity deep vein thrombosis were diagnosed with pulmonary embolism at presentation whereas pulmonary embolism was clinically recognized in approximately 15% of patients with lower extremity deep vein thrombosis. During follow-up, one patient with upper extremity deep vein thrombosis (1.5%) suffered a pulmonary embolism by 30 days and there were no pulmonary embolism events noted thereafter. In contrast, the cumulative rate of pulmonary embolism increased from 1.2% at 30 days, to 2.2% at 6 months, and to 2.9% at 1 year in patients with lower extremity deep vein thrombosis.

These observations suggest that the population at risk, the natural history, and associated outcomes of upper extremity deep vein thrombosis differ from that of lower extremity deep vein thrombosis. Further studies are needed if we are to effectively target prophylaxis, improve diagnosis, and optimize our treatment (anticoagulant type, duration, intensity) of this condition.

Study Limitations

It is important to recognize that our study is limited by its retrospective observational design. Information about medical history variables and clinical characteristics is limited to that available from the medical record. In addition, although this is one of the larger studies of patients with upper extremity deep vein thrombosis, its sample size is still relatively small. Inasmuch, these data should not be used to support the contention that upper extremity deep vein thrombosis does not warrant treatment to prevent life-threatening pulmonary embolism. Indeed, in a study of 27 patients with venographically confirmed upper extremity deep vein thrombosis, 8 (36%) had objective evidence for concomitant pulmonary embolism by ventilation-perfusion scan and/or pulmonary angiography.9 Clearly, the incidence of pulmonary embolism associated with catheter and non-catheter related upper extremity deep vein thrombosis requires further study.

Conclusions

In summary, approximately 14% of cases of deep vein thrombosis in this community-based study occurred in the upper extremity. The clinical profile of patients with upper extremity deep vein thrombosis varied considerably from patients with deep vein thrombosis of the lower extremities. These findings have important implications for the targeting of deep vein thrombosis prophylaxis in patients at risk for upper extremity deep vein thrombosis. Patients with upper extremity deep vein thrombosis were unlikely to experience pulmonary embolism (at presentation and/or during follow-up) and recurrent deep vein thrombosis tended to occur early and in the previously affected limb. These findings suggest that further study is warranted to define appropriate treatment (e.g. agent, intensity, duration) in patients with upper extremity deep vein thrombosis.

Acknowledgments

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Appendix A

415.1(1,9)	-pulmonary embolism and infarction
451	- phlebitis and thrombophlebitis
451.11	- femoral vein
451.19	- other deep vein
451.2	- lower extremities, unspecified
451.81	-iliac vein
451.83	-deep veins of upper extremities
451.84	-upper extremity, unspecified
451.89	-other (axillary, jugular, subclavian)
451.9	-unspecified site
453.1	-thrombophlebitis migrans
453.2	-vena cava
453.8	-of other specified veins
453.9	-of unspecified site
671.3 (0,1,3)	-deep phlebothrombosis, antepartum
671.4 (0, 2, 4)	-deep phlebothrombosis, postpartum
671.9 (0-4)	-unspecified venous complication of pueriperium
673.2 (0-4)	-obstetrical blood clot embolism
996.73	-Complication due to renal dialysis device, implant, and graft
996.74	-Complication due to other vascular device, implant, and graft
997.2	-phlebitis or thrombophlebitis during or resulting from a procedure

Venous thrombosis ICD-9 codes

Appendix **B**

Criteria for classification of venous thromboembolism events*

Deep vein thrombosis

Definite—if confirmed by venography, compression/Duplex ultrasound, CT scan, MRI scan, or at autopsy.

Probable—if the above tests were not performed, or were indeterminate, but impedance plethysomography, radionuclide venography, or radiolabeled fibrinogen scan test results were reported as positive.

Possible—if all of these confirmatory tests were not performed, or were indeterminate, and two of the following criteria were satisfied - medical record indicates the physician made a diagnosis of deep vein thrombosis, signs and/or symptoms of deep vein thrombosis were documented, and the patient underwent therapy with anticoagulants or an IVC filter was placed.

Pulmonary embolism

Definite—if confirmed by pulmonary angiography, spiral CT scan, MRI scan, or pathology.

Probable—*if* the above tests were not performed, or were indeterminate, but ventilationperfusion scan findings were of high probability.

Possible—if all of the above confirmatory tests were not performed, or were indeterminate, and two of the following criteria were satisfied - medical record indicates the physician made a diagnosis of pulmonary embolism, signs and/or symptoms of pulmonary embolism were documented, and the patient underwent therapy with anticoagulants or an IVC filter was placed.

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^{*}Modification of criteria previously used by Silverstein et al in the Olmstead County study of venous thromboembolism (4). Given increasing acceptance over the last decade of compression/Duplex ultrasound as a single diagnostic modality for deep vein thrombosis, we have classified patients with deep vein thrombosis confirmed by compression/Duplex ultrasound as *definite* whereas these patients would be classified as *probable* by Silverstein's criteria.

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Demographic and Clinical Characteristics of Patients According to Location of Deep Vein Thrombosis*

Variable	Upper Extremity Deep Vein Thrombosis (n=69)	Lower Extremity Deep Vein Thrombosis (n=414)	P-value
Demographic Factors			
Age (mean, years)	59	66	< 0.001
Age (years, %)			
<55	42.0	25.6	
55-64	8.7	11.1	0.04
65-74	18.8	22	
≥75	30.4	41.3	
Female (%)	47.8	54.6	0.29
Race (%)			
Caucasian	86.7	91.7	
Black	1.5	3.2	0.002
Asian	1.5	0.0	
Hispanic	8.8	2.0	
Unknown	1.4	3.1	
Body Mass Index (%) **			0.02
<25	45	34.7	
25-30	42.5	30.3	
>30	12.5	35.0	
Risk Factors (%)			
>48 hr Bed Rest in last month	39.1	46.9	0.48
Recent Prior Hospitalization ^{\dagger}	56.5	36.5	< 0.001
Recent surgery \dot{t}	48.5	27.9	< 0.001
Recent Malignancy †	43.5	32.8	0.07
Recent Severe Infection $^{\dot{\tau}}$	49.3	32.4	0.01
Admission of non-venous thromboembolism related diagnosis (immediately prior venous thromboembolism)	43.5	23	< 0.001
Recent central venous Catheter ^{\dot{t}}	62.3	11.8	< 0.001
Prior venous thromboembolism	8.7	19.8	0.03
Recent Intensive Care Unit Discharge $^{\dot{\tau}}$	24.6	15.2	0.05
Recent Intubation ^{$\dot{\tau}$}	18.8	15.0	0.41
Recent Hormonal Therapy †	7.3	7.7	0.89
Recent Fracture \dot{f}	15.9	10.1	0.15
Recent Chemotherapy †	20.3	6.3	< 0.001
Recent Heart Failure $^{\dot{\tau}}$	8.7	5.3	0.26

Spencer et al.

Variable	Upper Extremity Deep Vein Thrombosis (n=69)	Lower Extremity Deep Vein Thrombosis (n=414)	P-value
Recent Cardiac Procedures †	11.6	3.3	0.001

* Other risk factors with <5 % prevalence (in descending order of frequency) include: venous stasis/ulcer, family history of venous thromboembolism, varicose veins, superficial thrombophlebitis, prolonged air travel, recent lower extremity paresis, known hypercoagulable state, recent pregnancy or delivery, and recent spinal cord injury

** 146 patients missing data for body mass index

 † Recent = active or occurring within 3 months of diagnosis of VTE

Demographic and Clinical Characteristics of Patients With Upper Extremity Deep Vein Thrombosis According to Recent Central Venous Catheter Status

Variable	Central Venous Catheter	Central Venous Catheter	P-value
	(+) (n=43)	(-) (n =26)	
Demographic Factors			
Age (years, %)			0.41
<55	37.2	50	
55-64	11.6	3.9	
65-74	16.3	23.1	
≥75	34.9	23.1	
Female (%)	46.5	50	0.78
Race (%)			0.17
Caucasian	78.6	100	
Black	2.4	0.0	
Asian	2.4	0.0	
Hispanic	14.3	0.0	
Unknown	2.3	0.0	
Body Mass Index (%)*			0.48
<25	48	40.0	
25-30	36	53.3	
>30	16	6.67	
Risk Factors (%)			
>48 hr Bed Rest in last month	46.5	26.9	0.23
Recent Prior Hospitalization †	67.4	38.5	0.001
Recent Surgery †	60.5	28.0	0.01
Recent Malignancy †	39.5	50	0.72
Recent Severe Infection †	62.8	26.9	0.004
Admission of non-VTE related diagnosis (immediately prior VTE)	53.5	26.9	0.08
Prior VTE	7.0	11.5	0.51
Recent Intensive Care Unit Discharge †	34.9	0.0	0.01
Recent Intubation $\dot{\tau}$	30.2	15.0	0.002
Recent Hormonal Therapy †	7.0	7.7	0.91
Recent Fracture \dot{t}	25.6	0.0	0.005
Recent Chemotherapy †	25.6	11.5	0.16
Recent Heart Failure †	9.3	7.7	0.81
Recent Cardiac Procedures ^{\dagger}	11.6	11.5	0.99

Spencer et al.

*146 patients missing data for BMI

 † Recent = active or occurring within 3 months of diagnosis of VTE

Treatment Strategies in Patients with Venous Thromboembolism According to Location of Deep Vein Thrombosis

Variable Hospital Therapy (%)	Upper Extremity Deep Vein Thrombosis	Lower Extremity Deep Vein Thrombosis	P-value
IV heparin	47.8	61.8	0.03
SQ Enoxaparin	69.6	70.5	0.87
Other parenteral anticoagulant	4.4	0.5	0.03
Warfarin	56.5	73.7	0.004
Aspirin	15.2	7.8	0.07

Outcomes of Patients with Venous Thromboembolism According to Location of Deep Vein Thrombosis

Variable	Upper Extremity Deep Vein Thrombosis	Lower Extremity Deep Vein Thrombosis	P-values
30 day outcomes (%)			
Major Bleeding	11.6	7.5	0.25
Recurrent VTE	8.7	4.6	0.15
Recurrent pulmonary embolism (with or without deep vein thrombosis)	1.5	1.2	0.87
Mortality	4.4	5.8	0.63
6 month outcomes (%)			
Major Bleeding	13.0	9.9	0.43
Recurrent VTE	15.9	9.4	0.10
Recurrent pulmonary embolism (with or without deep vein thrombosis)	1.5	2.2	0.70
Mortality	14.5	12.1	0.57
1 year outcomes (%)			
Major Bleeding	13.3	10.9	0.60
Recurrent VTE	14.5	11.4	0.47
Recurrent pulmonary embolism (with or without deep vein thrombosis)	1.5	2.9	0.46
Mortality	20.3	14.7	0.25