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Development and Validation of a Risk Stratification System for Pulmonary Embolism After Elective Primary Total Joint Arthroplasty

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ABSTRACT

Introduction: Stratification of patients into different risk categories for pulmonary embolism (PE) after total joint arthroplasty (TJA) may allow clinicians to individualize venous thromboembolism prophylaxis based on an appropriate risk-benefit scale.
Methods: Patients undergoing primary total hip arthroplasty (THA) or total knee arthroplasty (TKA) as part of the American College of Surgeons National Surgical Quality Improvement Program were identified. Independent risk factors for PE within 30 days of surgery were identified and used to develop a point-scoring system to estimate the relative risk for PE. For validation, the system was tested on patients undergoing TJA at a single institution.
Results: A total of 118,473 patients were identified, including 72,673 (61.3%) undergoing TKA and 45,800 (38.7%) undergoing THA. The incidence of PE within 30 days of the index arthroplasty was 0.50%. The risk factors associated with PE were age ≥70, female gender, higher body mass index (25-30 kg/m^2 and ≥30 kg/m^2), and TKA (vs THA); anemia was protective. The point scores derived for each of these factors were as follows: anemia: −2; female: +1; body mass index 25-30 kg/m^2: +2; body mass index ≥30 kg/m^2: +3; age ≥70 years: +3; TKA: +5. The point-scoring system was then applied to 17,384 patients from a single institution. Single-institution patients categorized as low risk using the point-scoring system had a 0.44% 90-day risk for PE (95% CI = 0.29%-0.58%); medium risk, 1.51% (95% CI = 1.18%-1.84%); and high risk, 2.60% (95% CI = 2.09%-3.10%).
Conclusion: This point-scoring system predicts risk for PE after TJA and may help surgeons to optimize selection of chemical prophylaxis.

Pulmonary embolism (PE) is one of the most serious complications that can occur after total joint arthroplasty (TJA) [1-5]. As a result, TJA patients are commonly prescribed postoperative anticoagulation in an attempt to reduce the risk of PE. However, anticoagulation regimens are not benign, as they may increase the risk for bleeding, hematoma formation, wound healing problems, and deep infection [3,6-8]. Surgeons must weigh the benefits of anticoagulation against the risks when determining which type of PE prophylaxis to use for any given patient. To do so, surgeons might benefit from a better understanding of which patients are at greatest risk for PE.

Risk factors for PE after surgery have been characterized in both the general [9-11] and orthopedic [12-17] surgical literature. However, many of these studies have been limited by the use of administrative data, which have known imperfections [18-21], or by small sample size. Moreover, such studies typically present results of regressions identifying statistical associations. However, they do not typically provide clinicians with practical risk stratification systems based on their data and hence cannot be easily applied to practice by clinicians at this time. Finally, although Parvizi et al [12] did develop a practical system for risk stratifying patients, the system was based on administratively coded patient characteristics and the system was not evaluated for validity among a second population. Any sample of patients and set of data

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collection procedures have inherent biases; validation in a second population with differing data collection methods provides reassurance that such biases are not exclusively responsible for observed results.

As a result of the weaknesses in this literature, it is currently difficult for clinicians who would like to provide differential anticoagulation based on individual patient risk profiles to do so. Hence, many clinicians use the same prophylaxis regimen for the vast majority of their patients.

In this context, the purpose of the present study is to develop a risk stratification system for PE after elective primary TJA using a nationwide prospective surgical registry. Both total hip arthroplasty (THA) and total knee arthroplasty (TKA) cases will be included and discriminated between. The system will be based on chart-abstracted clinical data (taken from clinical charts) rather than administratively coded billing data. We posit that in order for a risk stratification system to be widely adopted, it should be validated in a second patient population with differing data collection methods. Hence, the nationwide registry-derived risk stratification system that is developed here will then be evaluated among a population of patients from a single institution for which warfarin was used for VTE prophylaxis.

Methods

Development of a Risk Stratification System for PE Using the ACS-NSQIP

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) is a surgical registry located at several hundred community and academic institutions nationwide [22-25]. As part of the program, sampled patients are prospectively registered before major surgical procedures. Sampled patients are then followed by highly trained data collection nurses during the first 30 postoperative days for the development of adverse events, including PE. PE is captured both before and after discharge, and when PE does occur, the postoperative day of occurrence is recorded. Of note, the program undergoes routine continuous auditing and has consistently demonstrated a high degree of accuracy of its demographic, comorbidity, and adverse event data [24].

For the present study, patients were identified who underwent elective primary THA or elective primary TKA as part of the ACS-NSQIP during 2006-2013. Patients undergoing primary TKA were identified using Current Procedural Terminology (CPT) code 27,130, whereas patients undergoing primary THA were identified using CPT code 27,447. The International Classification of Diseases 9th Revision diagnosis code field and additional associated CPT code fields were then used to exclude patients not clearly undergoing elective primary TJA. Specifically, patients whose cases involved additional unrelated procedures, acute trauma, major ligament reconstruction, preoperative infection, prosthesis revision, or hardware removal were excluded. Patients undergoing surgery nonelectively were excluded. Patients missing data for any demographic, comorbidity, laboratory, or procedural characteristic were excluded.

Patients were stratified by the following demographic characteristics: age (<70 or ≥70 years), sex (male or female), body mass index (<25, 25-30 [overweight], or ≥30 kg/m^2 [obese]), and functional status (independent or dependent). Similarly, patients were stratified by the following comorbidity characteristics: diabetic status (nondiabetic, non–insulin-dependent diabetes mellitus, or insulin-dependent diabetes mellitus) and presence of hypertension (defined by NSQIP as greater than 140/90 "most of the time" or requiring antihypertensive medication), chronic obstructive pulmonary disease, current smoking status, and anemia (defined as preoperative hematocrit <39 in males and <36 in females [26]). Finally, patients were stratified by the following procedural characteristics: procedure type (primary THA or primary TKA), anesthesia type (regional or general), and operative time (<90 minutes or ≥90 minutes).

Bivariate and multivariate Cox proportional hazards models were then used to test for demographic, comorbidity, and procedural associations with PE after TJA in this population. The final multivariate model was selected using a backward stepwise elimination process initially including all demographic, comorbidity, and procedural characteristics and eliminating characteristics with the highest *P*-values one by one until all characteristics had $P < .05$. A nomogram was then applied to the final multivariate model to assign point values for generation of a point-scoring risk stratification system. The maximum number of points per risk factor for the risk stratification system was set to 5. Threshold total point values were selected for low-, medium-, and high-risk total score categories such that the patients were partitioned most closely into 3 equally sized groups. Of note, the size and number of groups was arbitrary; we rationalized that 3 equally sized groups was an easy, potentially effective way for clinicians to mentally partition the population. The average risk for PE and 95% CIs were calculated for each of the 3 risk groups.

Test of Performance of the Risk Stratification System Among a Single-Institution Cohort

A second cohort of patients was then identified for testing of performance of the risk stratification system. Of note, there was partial overlap of this cohort with patients in the aforementioned study by Parvizi et al [12]. The authors maintain a prospective TJA registry at their institution into which patients are registered at the time of surgery. The registry includes demographic, comorbidity, and procedural characteristics. This registry was initially searched for all cases of primary TJA performed during 2000-2011. For the present study, an additional inclusion criterion was receipt of warfarin prophylaxis (determined by chart review of individual patient records). The standard warfarin protocol included administration of warfarin the evening after surgery and subsequent targeting of the international normalized ratio to 1.8-2.0 for 6 postoperative weeks.

The demographic, comorbidity, and procedural characteristics that had been included in the ACS-NSQIP–derived risk stratification system were extracted from the single-institution registry for each of the patients in the single-institution cohort. These included procedure type (primary TKA or primary THA), age (<70 or ≥70 years), sex (male or female), body mass index (<25, 25-30 [overweight], or ≥30 kg/m^2 [obese]), and anemia (defined as preoperative hematocrit <39 in males and <36 in females [26]). Patients missing any of these data points were excluded from the present study.

For included patients, all individual patient charts were reviewed for occurrence of PE or admission to other hospitals within 90 days of surgery. This included a review of telephone records and all follow-up notes with particular attention paid to detecting any mention of admission to hospitals other than the index. As part of routine practice, clinical suspicion for PE led to either chest CT scan or ventilation/perfusion scan. A PE was considered to have occurred if there were (1) symptoms potentially suggestive of a PE and (2) a chest CT scan read as positive for PE or a ventilation/perfusion scan read as high probability for PE.

The ACS-NSQIP-derived point-scoring system was then applied to these single-institution patients. The total points were summed for each patient. Based on the total points and the categories defined previously, patients were stratified into low-, medium-, and

high-risk groups. The average risk for PE and 95% CIs were calculated for each of the 3 groups. Risk stratification category was tested for association with occurrence of PE using Pearson's chi-squared test. The level of significance was set at $P < .05$.

Required ACS-NSQIP Statement

"The ACS-NSQIP and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors."

Results

Development of a Risk Stratification System for PE Using the ACS-NSQIP

A total of 133,796 ACS-NSQIP patients were initially identified as having undergone a procedure with one of the primary TJA CPT codes. Of these, 118,473 (88.5%) met the additional inclusion criteria, of whom 45,800 (38.7%) underwent primary THA and 72,673 (61.3%) underwent primary TKA. The 30-day risk for PE was 0.50% (95% CI = 0.46-0.54).

After stepwise selection of the final multivariate model, the following characteristics were identified as having independent associations with occurrence of PE: age ≥70, female gender, higher body mass index (25-30 and ≥30 kg/m^2), and TKA (vs THA); anemia was protective (Table 1). In post hoc pairwise comparisons between body mass index categories within the multivariate model, all 3 post hoc pairwise comparisons had $P < .05$, suggesting that it was valid to treat the 3 categories as distinct in the final multivariate model and subsequent risk stratification system.

Based on these associations, a nomogram was used to develop a point-scoring system for risk stratification (Table 2). The point-scoring system was applied to the ACS-NSQIP patients such that each patient was assigned a total number of points. Low-, medium-, and high-risk categories were assigned across the spectrum of total points to most closely divide patients into 3 equal groups; hence, the 35,900 patients (30.0%) with approximately the lowest third of total points (≤4 points) were categorized as low risk, the 38,737 (32.7%) patients with approximately the middle third of total points (5-8 points) were categorized as medium risk, and the 43,836 patients (37.0%) with approximately the highest third of total points (9-12 points) were categorized as high risk (Table 3). Patients categorized as low risk had a 0.20% risk for PE (95% CI = 0.15%-0.25%), patients categorized as medium risk had a 0.46% risk for PE (95% CI = 0.39%-0.53%), and patients categorized as high risk had a 0.78% risk for PE (95% CI = 0.69%-0.86%).

Table 1
Final Multivariate Model for Associations With Pulmonary Embolism in the American College of Surgeons National Surgical Quality Improvement Program Population.

Characteristic	HR	95% CI	*P* Value
Anemia[a]			.013
No	Ref.		
Yes	0.7	0.6-0.9	
Sex			.046
Male	Ref.		
Female	1.2	1.0-1.4	
Body mass index (kg/m^2)[b]			<.001
<25	Ref.		
25-30 (overweight)	1.4	1.1-2.0	
≥30 (obese)	1.8	1.3-2.4	
Age (y)			<.001
<70	Ref.		
≥70	1.7	1.4-2.0	
Procedure			<.001
Primary total hip arthroplasty	Ref.		
Primary total knee arthroplasty	2.6	2.1-3.2	

HR, hazard ratio; Ref., reference.
[a] Anemia was defined as hematocrit <36 in females or hematocrit <39 in males.
[b] All 3 possible post hoc pairwise comparisons of the body mass index categories were statistically significant (<25 vs 25-30 kg/m^2 [$P = .023$]; <25 vs ≥30 kg/m^2 [$P < .001$]; 25-30 vs ≥30 kg/m^2 [$P = .035$]).

Table 2
Point System for Risk Stratification for Pulmonary Embolism Derived From Final Multivariate Model in the American College of Surgeons National Surgical Quality Improvement Program Population.

Characteristic	Points
Anemic (HCT <36 for females, <39 for males)	−2
Female	+1
Body mass index 25-30 kg/m^2 (overweight)	+2
Body mass index ≥30 kg/m^2 (obese)	+3
Age ≥70 y	+3
Primary TKA (vs primary THA)	+5

HCT, hematocrit; TKA, total knee arthroplasty; THA, total hip arthroplasty.

Test of Performance of the Risk Stratification System Among a Single-Institution Cohort

A total of 22,878 single-institution patients were initially identified as having undergone a primary TJA procedure. Of these, 17,384 (76.0%) met the additional inclusion criteria, of whom 8731 (50.2%) underwent primary THA and 8653 (49.8%) underwent primary TKA. The 90-day risk for PE was 1.24% (95% CI = 1.07%-1.40%). After assigning points using the risk stratification system, 8247 (47.4%) patients were categorized as low risk, 5362 (30.8%) were categorized as medium risk, and 3775 (21.7%) were categorized as high risk (Table 4). Risk stratification category was associated with the risk for PE ($P < .001$). Specifically, patients categorized as low risk had a 0.44% risk for PE (95% CI = 0.29%-0.58%), patients categorized as medium risk had a 1.51% risk for PE (95% CI = 1.18%-1.84%), and patients categorized as high risk had a 2.60% risk for PE (95% CI = 2.09%-3.10%).

Discussion

PE is one of the most important potential complications of TJA [1-5]. As a result, patients undergoing TJA commonly receive VTE prophylaxis postoperatively in an attempt to decrease the risk of this potentially fatal event. However, chemical prophylaxis is associated with an increased risk for bleeding, with more vigorous anticoagulation such as low-molecular-weight heparin carrying a greater risk and less vigorous modalities such as aspirin carrying a lower risk [3,6,7]. Hence, it would be useful for both clinicians and investigators to have a tool to approximate a patient's relative risk for PE to aid in selecting among the various agents available. The present study provides clinicians with a relatively easy method to perform this type of categorization preoperatively.

Based on review of 118,473 patients who underwent TJA, this study proposes a risk stratification system based on 5 simple patient characteristics that are known before surgery (age, sex, body mass index, preoperative hematocrit, and procedure type). In the proposed system, each of these characteristics has an associated point value, and the points are summed for each patient. Based on each patient's total points, patients are then placed into one of the 3 risk groups. As a hypothetical example, using Table 2, a 60-year-old female patient with normal hematocrit and normal body mass index undergoing THA would be assigned only 1 point and thus be treated as low risk for PE. In contrast, a 60-year-old female patient

Table 3
Designation of Low-, Medium-, and High-Risk Categories and Corresponding Risk for Pulmonary Embolism in the American College of Surgeons National Surgical Quality Improvement Program Population.

Category (Total Points)	Number of Patients	Number of PEs	Risk for PE (%)	
			Risk	95% CI
Low risk (≤4 points)	35,900	72	0.20	0.15-0.25
Medium risk (5-8 points)	38,737	178	0.46	0.39-0.53
High risk (9-12 points)	43,836	340	0.78	0.69-0.86

PE, pulmonary embolism.

with normal hematocrit and a body mass index of 36 kg/m^2 undergoing TKA would be assigned 9 points and thus be treated as high risk for PE.

The risk stratification system was developed using the ACS-NSQIP, which represents a distinct advantage over prior efforts at risk stratification [12-17] in that the present study is based on a larger sample of high-quality nonadministrative data [24]. However, all data sets are prone to potential biases. Hence, it is difficult to change practice or institute clinical recommendations based on a single retrospective review. In the case of the ACS-NSQIP, major limitations include 30-day rather than 90-day follow-up, as well as the lack of information on which form of chemical prophylaxis was used for each patient. For these reasons, the ACS-NSQIP–derived risk stratification system was tested for performance in a distinct cohort derived from a single institution. This single-institution cohort was limited only to patients receiving warfarin prophylaxis, and the analysis included PEs occurring until the 90th postoperative day.

The ACS-NSQIP–derived risk stratification system performed well in the single-institution cohort, validating its use among a typical primary TJA population. Among the single-institution cohort, the risk for PE varied markedly and statistically significantly between risk strata, with patients in the lowest-risk stratum having only a 0.44% 90-day risk, patients in the medium-risk stratum having a 1.51% 90-day risk, and patients in the highest-risk stratum having a 2.60% 90-day risk.

The risk factors identified in the present study have all been previously identified as risk factors for PE and/or VTE [12-17]. Patients with greater age have been identified as at greater risk in several studies [12,13,16]. Similarly, greater body mass index has been identified as a risk factor [12,13,17]. It is interesting that patients undergoing TKA had a greater risk for PE than patients undergoing THA. This has been identified previously [12,14,16] and may be related to differences in intraoperative manipulation or postoperative positioning predisposing to venous status and thrombosis.

The finding that anemia was protective against PE is intuitive and correlates with the fact that hematocrit is associated with viscosity [27], and hyperviscosity contributes to the hypercoagulability component of Virchow's triad. However, the finding is contradictory to the finding by Parvizi et al [12] that anemia is a risk factor for PE. The difference in findings is likely explained by the fact that Parvizi et al used administrative coding to identify anemia in their study, whereas we used preoperative hematocrit (with exclusion from the study of any patients missing this preoperative laboratory value). Administrative coding is subject to an array of potential biases that may have confounded the prior result [18-21]. Prior studies have identified large differences in the rates at which administrative and chart-abstracted data capture various comorbidities [18,19]. Moreover, it is likely that various specific biases are introduced in administratively coded data, wherein particular patients may be more likely to have their comorbidities up-coded because of financial incentives. Finally, it is worth noting that administrative coding for anemia may have particularly low sensitivity [20]. Further work may be needed to explore these differing results.

A limitation of the present study is that there are well-known risk factors for PE that could not be evaluated because such data were not included in the NSQIP. Perhaps most importantly, this includes histories of VTE or thrombophilia [13,28], which have been shown to be associated with substantially elevated risk. The presented risk stratification system is optimal for use in patients without these well-known severe risk factors—it is optimal for discriminating among the "standard-risk" population using readily available demographic and comorbidity information. Patients with histories of VTE or thrombophilia should be excluded from the use of this risk stratification system and treated as is prudent for their specific condition.

There are additional limitations that the reader should consider when interpreting our results. As previously described, the risk stratification system was developed without knowledge of prophylaxis received and with only 30-day follow-up; however, it was validated in a population in which the type of prophylaxis was known (all patients received warfarin) and in which patients were followed for 90 days. Second, the study only evaluated symptomatic PEs, and hence, asymptomatic events were not recorded or screened for. However, symptomatic PE is probably the most clinically relevant event to patients and surgeons performing TJA, and recent guidelines such as the American Academy of Orthopaedic Surgeons clinical practice guideline for the prevention of venous thromboembolic disease use this same end point [1]. Third, both the ACS-NSQIP and single-institution data could potentially fail to capture all patients with symptomatic PE, particularly those presenting to outside institutions. To reduce this risk in the single-institution cohort, all telephone records and postoperative follow-up notes were reviewed for any discussion of VTE or admission to other hospitals. Fourth, the ACS-NSQIP does not provide unique identifiers for institutions and surgeons, so adjustments for hospital and surgeon volume and repeated measures could not be made. Fifth, the NSQIP database does not capture whether PE was central vs subsegmental.

In summary, we identified 5 preoperative variables that were predictive of PE and can be used to stratify patients into low-, medium-, or high-risk categories for PE. Patients with histories of VTE or thrombophilia should be excluded from use of this scoring system and treated as is prudent for their individual condition. Among those eligible for scoring with this system, use of the system may assist the clinician in choosing among the various forms of prophylaxis available. For example, low- and medium-risk patients might receive aspirin, whereas high-risk patients might receive warfarin. Please note that our data do not directly support this lattermost suggestion; however, prospective studies might be conducted to evaluate whether use of this strategy can optimize the balance between occurrence of PE and occurrence of complications related to chemical prophylaxis.

Table 4
Validation of Risk Stratification System in a Single-Center Population.

Category (Total Points)	Number of Patients	Number of PEs	Risk for PE (%)	
			Risk[a]	95% CI
Low risk (≤4 points)	8247	36	0.44	0.29-0.58
Medium risk (5-8 points)	5362	81	1.51	1.18-1.84
High risk (9-12 points)	3775	98	2.60	2.09-3.10

PE, pulmonary embolism.
[a] Risk stratification group was associated with risk for pulmonary embolism (Pearson's chi-squared test; $P < .001$).

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