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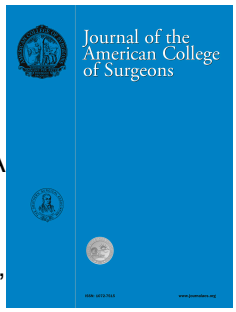

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Venous Thromboembolism after Inpatient Surgery in Administrative Data vs NSQIP: A Multi-Institutional Study

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Brief Title: Determining Postoperative Venous Thromboembolism

Abstract

Background

Previous studies have documented significant differences between administrative data and registry data in the determination of postoperative venous thromboembolism (VTE). The goal of this study is to characterize discordance between administrative and registry data in the determination of postoperative VTE.

Study Design

This study was performed using data from the American College of Surgeons NSQIP merged with administrative data from 8 different hospitals (5 different medical centers) between 2013 and 2015. Occurrence of postoperative vein thrombosis (VT) and pulmonary embolism (PE) as ascertained by administrative data and NSQIP data were compared. In each situation where the two sources disagreed (discordance), a two-clinician chart review was performed to characterize the reasons for discordance.

Results

The cohort used for analysis included 43,336 patients, of which 53.3% were female and with an average age of 59.5 years. Concordance between administrative and NSQIP data was worse for VT (kappa=0.57, 95% CI [0.51-0.62]) than for PE (kappa=0.83, 95% CI [0.78-0.89]). A total of 136 cases of discordance were noted in the assessment of VT; of these, 50 (37%) were explained by differences in the criteria used by administrative vs. NSQIP systems. In the assessment of postoperative PE, administrative data had a higher accuracy than NSQIP data (odds ratio for accuracy=2.86, 95% CI [1.11-7.14]) when compared against the two-clinician chart review.

Conclusions:

This study identifies significant problems in ability of both NSQIP and administrative data in the assessment of postoperative VT/PE. Administrative data functioned more accurately than NSQIP data in the identification of postoperative PE. The mechanisms used to translate VTE measurement into quality improvement should be standardized and improved.

Keywords: Postoperative venous thromboembolism, postoperative pulmonary embolus, postoperative deep venous thrombosis, surgical outcomes, public reporting, quality of care

Introduction

Postoperative venous thromboembolic events (VTE; for the purposes of this paper, the term venous thromboembolism is defined as vein thrombosis and/or pulmonary embolus) are a major source of postoperative morbidity and mortality. Of the estimated 150,000 to 200,000 VTE-associated deaths that occur each year in the US, approximately one-third occur after an operation.[1] Given the rate and severity of VTE-associated morbidity, efforts to monitor and report VTE rates are a focus of multiple stakeholders. The occurrence of VTE is a Patient Safety Indicator (PSI) as monitored through the Agency for Healthcare Research and Quality (AHRQ).[2] Institutional rates of PSI events are the basis for alterations in institutional reimbursement through the Centers for Medicare and Medicaid Service's Value Based Modifier program.

Any data-driven approach to quality of care relies on data integrity. Systems that assess occurrences of venous thrombosis (VT) and pulmonary embolism (PE) in postoperative patients necessarily use one of two mechanisms – administrative data or clinical registry data. Administrative data are generated automatically by the billing functions of each hospital. Clinical registry data are assumed to be collected prospectively by trained staff, generally using detailed criteria to guide data ascertainment.

When directly compared, administrative data and clinical registry data give very different representations as to the occurrence of postoperative VTE. Lawson et al examined the agreement between the National Surgical Quality Improvement Program (NSQIP) and administrative data in the determination of VT/PE within a cohort of 117,752 surgical patients.[3] Their results were surprising, noting that a majority (68-75%) of VTE events identified in administrative data were

not considered to be events within the NSQIP registry. This degree of discordance between these two systems deserves focused investigation.

With this study our goal was to characterize the specific reasons for the lack of agreement between administrative data and registry data in the determination of postoperative VTE. In order to achieve this goal a consortium of 5 academic medical centers (8 hospitals) was assembled. This study is not hypothesis-driven, but rather seeks to apportion discordance among reasonable explanations.

Methods

Cohort

This study includes data from a total of 5 different medical centers, including 8 distinct hospitals. Each of these hospitals has decentralized/separate mechanisms for generating administrative data and NSQIP data. Within each of these hospitals, administrative data and NSQIP data were merged for patients undergoing an operation between January 1st 2013 and September 30th 2015. The end date of this study was chosen because of the transition from International Classification of Disease Coding from the 9th to the 10th Clinical Modification on October 1st 2015. The unit of observation for this study was an inpatient operation and the associated perioperative hospitalization.

Definition of Complications - NSQIP

Within the NSQIP, the occurrence of a PE is established with a new diagnosis of pulmonary embolus (PE) based on an imaging study (e.g. computed tomography, V-Q scan, transesophageal echocardiography). Fat emboli and cement emboli are not considered to be PE.

The criteria guiding the identification of a vein thrombosis (VT) event in the NSQIP are more complicated. The NSQIP defines a VT based on 1) a new definitive diagnosis of VT based on imaging and/or pathology, and 2) treatment for the VT with anticoagulation, placement of an inferior vena cava filter, or clipping of the vena cava. Documentation that a patient either refused therapy or that therapy was warranted but not provided (e.g. patient at high risk for bleeding) satisfies the treatment criterion. Of note, the NSQIP criteria do not discern between deep VT and superficial VT (a thrombosis of either type is considered a VT).

Definition of Complications – Administrative Data

Within administrative data, the occurrence of complications was identified on the basis of International Classification of Disease Coding, 9th Clinical Revision (ICD-9) codes. The specific codes that were included to represent VT/PE were chosen to match the approaches used by the AHRQ PSI program as well as earlier research comparing NSQIP data and administrative data (Table 1).[3, 4] The occurrence of PE in administrative data was identified on the basis of a single family of ICD-9 codes (415.1*x* – Pulmonary embolism and infarction). Several different ICD-9 codes were used to determine the occurrence of VT. These include one code family (451.1*x*) that denotes deep VT, and the remainder that are ambiguous as to whether the VT was deep or superficial.

Complications Present on Admission/Post-Discharge

Both administrative data and the NSQIP have mechanisms to determine whether a VT/PE occurred before or after surgery, and these mechanisms function differently. Within administrative databases, any diagnosis that is attributed to a particular hospitalization is accompanied by a designation as to whether the diagnosis is present on admission (POA) or not. The NSQIP does not include any determination regarding whether a VT/PE was present at the time of surgery, but stipulates that a diagnosis of VT or PE must be made in the intraoperative or postoperative context.

By their nature, administrative data do not report VT/PE events that occur post-discharge. NSQIP, however, identifies these complications up to 30 days after the index operation. In situations where the NSQIP identified a complication after discharge the NSQIP determination was changed to "no", in order to reflect only occurrences during the index hospitalization. These observations were retained in the analysis.

Exclusion Criteria

Several exclusion criteria were applied in order to allow for the most reasonable comparison between the administrative and NSQIP datasets. First, outpatient operations were excluded, as these patients have a minimal period within which to observe the occurrence of VT/PE events. Second, operations for which administrative data noted a VT or PE that was POA were excluded. Third, cases where chart review found a VT or PE more than 30 days after the index operation were excluded as these occurrences fall outside the scope of the NSQIP.

Chart Review

Each situation of discordance between administrative data and NSQIP data was reviewed independently by two clinicians, within the academic campus where the hospitalization occurred. One of the two reviewers had to be an attending surgeon, and NSQIP surgical case reviewers could not function as a reviewer. When any of the elements of these two reviews differed, the two reviewers were asked to reconcile their evaluations and give a consensus resolution. Cases where chart review determined that a VT or PE was present before surgery or where the diagnosis of a postoperative occurrence was unclear were excluded from analysis.

Forearm and arm veins (including hand, antecubital, cephalic) were considered superficial veins with the exception of brachial veins, ulnar veins, and interosseous veins (considered deep veins). All other vein sites were considered deep, including those in the abdomen (hepatic, portomesenteric, vena cava), neck (jugular), and chest (innominate, axillary, subclavian). Vein thromboses associated with pedicled/free flaps were considered superficial VT.

Statistical Analysis

Cohen's Kappa was used to quantitatively analyze the agreement between the two data sources in this study. This test statistic can vary between -1 (poor agreement) and 1 (perfect agreement).

The relative accuracy of administrative and NSQIP data compared to a gold standard was analyzed using a generalized estimating equation (GEE). A GEE approach is an extension of the generalized linear model (GLM) used to analyze correlated outcomes.[5] In this study, each observation was evaluated by administrative and NSQIP data; hence the assumption of

independence for GLM was violated and the standard errors of the model estimates would not be robust. For comparisons of accuracy, therefore, we relied on a GEE approach using logit link function (for binary data) and an exchangeable covariance structure to account for the dependence of the outcomes. The DTComPair package in R 3.3.3 (R Core Team, Vienna, Austria) was used for these analyses.

Institutional Review

This research study was reviewed by the Institutional Review Board (IRB) of each of the participating hospitals.

Results

Cohort

The overall cohort of analysis included 43336 operations (Figure 1). Characteristics of these patients are shown in Table 2. Patients undergoing these operations had an average age of 59.5 years and were predominantly (53.3%) female. The number of cases analyzed among the 8 hospitals varied between 3082 and 8121 per hospital.

Analysis of VT

A total of 43171 operations were analyzed for VT, after exclusion of 165 cases where VT was considered as present on admission within administrative data (Figure 1). The overall rates of VT in administrative and NSQIP data were 0.6% and 0.4%, respectively. Concordance between these two data sources for determining VT was moderate (kappa = 0.57, 95% CI [0.51-0.62]). A total of 298 operations were identified as having an associated postoperative VT event in either

administrative or NSQIP data. Of these 298 cases, a minority (118 = 40%) were identified in both NSQIP and administrative data. The majority of the 298 cases (180 = 60%) were identified by only one of the two data sources, and these cases were considered "discordant" for VT. A two-clinician chart review was performed for each of these, and on the basis of this review 44 cases were excluded because of the presence of preoperative VT (39 cases), the diagnosis of a postoperative VT was unclear (1 case), or because chart review found the postoperative VT to have occurred more than 30 days after the index operation (4 cases).

Within the subgroup of 136 operations with discordant VT assessments, the underlying reasons for discordance were characterized (Table 3). Of these, 51 (38%) were cases where administrative data found a VT and NSQIP data did not; 35 (26%) cases represented situations where NSQIP data showed a VT and administrative data did not. The remainder of discordant cases (50/136 = 37%) were explained by differences in criteria.

There were two situations in which differences in criteria explained discordance. First, in cases where a superficial or deep VT was present and reported accurately in administrative data but no treatment was documented (case does not meet NSQIP criteria); this occurred in 42 cases. Second, in cases were a thrombosis was present in a flap vein and a thrombectomy was performed; this occurred in 8 cases. Thrombectomy was not considered treatment for a vein thrombosis by the NSQIP until 2017, and therefore these cases would not meet NSQIP criteria.

Analysis of PE

A total of 43272 operations were analyzed for PE, after exclusion of 64 cases where PE was considered as present on admission within administrative data (Figure 1). The overall rates of PE in administrative and NSQIP data were both 0.2%. Concordance between these two data sources for determining PE was good (kappa = 0.83, 95% CI [0.78-0.89]). A total of 113 operations were identified as having an associated postoperative PE event in either administrative or NSQIP data. Of these 113 cases, a majority (81 = 72%) were identified in both NSQIP and administrative data. A minority of cases (32 = 28%) was identified by only one of the two data sources, and these cases were considered "discordant" for PE. A two-clinician chart review was performed for each of these, and on the basis of this review 12 cases were excluded because of the presence of preoperative PE (4 cases), the diagnosis of a postoperative PE was unclear (5 cases), or because chart review found the postoperative PE to have occurred more than 30 days after the index operation (3 cases).

Unlike for VT, the criteria for identification of PE is similar in both administrative and NSQIP systems. Therefore, an analysis of the relative accuracy of these two sources in identifying cases with postoperative PE was possible. In order to perform such an analysis, the assumption was made that situations where a PE was identified in both NSQIP and administrative data was a "true positive" and situations where both data sources found no PE were "true negatives". When the two data sources were discordant, the outcome of the chart review was considered to be the actual outcome ("gold standard"). The 9 cases where chart review found a preoperative PE or where the diagnosis of postoperative PE was unclear were excluded. Outcomes of this comparison are shown in Table 4. Accuracy was 99.9% for both systems, but this table reflects the very low PE event rate (0.2%). A system that detected no PE event rates in *any* observations,

therefore, would have a 99.8% accuracy. The kappa value, which is less sensitive to underlying event rates, was higher for administrative data (0.97, 95% CI [0.95-0.99]) than for NSQIP data (0.91, 95% CI [0.86-0.95]).

In order to apply a likelihood estimate to this difference, we considered accuracy (agreement between with the two-clinician chart review) to be a dichotomous outcome. A comparison of accuracy (based on GEE model) found that administrative data had a greater accuracy than NSQIP data for the determination of PE (odds ratio for accuracy = 2.86, 95% CI [1.11-7.14]).

Discussion

VT and PE are clinically important and potentially preventable postoperative complications that pose a significant clinical and economic burden to patients and the overall healthcare delivery system. Mechanisms that measure and report the occurrence of VT and PE are now an important part of pay for performance through the CMS Value-Based Modification program.[6] In the US, the two most important systems that function to monitor and report rates of VTE are administrative data and the NSQIP. This study questions the ability of both of these systems to accurately discern the occurrence of these important complications.

In order to generate an appropriate level of granularity, this considered VT and PE separately and found very different results in terms of the way in which these two types of complications were ascertained. For PE, administrative data and NSQIP data functioned relatively well. Although data from these two sources had high levels of agreement with each other (kappa = 0.83, 95% CI

[0.78-0.89]), administrative data had a greater degree of accuracy than NSQIP data (OR for accuracy = 2.86, 95% CI [1.11-7.14]).

The analysis of VT was more troubling. A majority (60%) of cases that were identified by administrative data or the NSQIP as having a postoperative VT were "discordant". Based on a two-clinician chart review process, we were able to characterize the reasons for this high level of discordance. First, administrative and NSQIP mechanisms differ in the criteria used to define an occurrence. The NSQIP does not actually analyze/report rates of VT, but rather "vein thrombosis requiring therapy". Under the NSQIP definition, a VT is only a VT if therapy (e.g. anticoagulation, caval filter, etc) is applied. While therapy is a reasonable benchmark of severity in many cases, the use of this criterion raises questions about the nature of a complication. If a complication occurs and it is untreated, is it not a complication? Importantly, this criterion is not applied by administrative coding mechanisms. Out of 136 discordant occurrences, 42 differed because of this treatment criterion. Second, both administrative data and NSQIP data demonstrated issues with accuracy. The majority of these problems were false negatives (56/136 = 41%), but false positives also occurred (30/136 = 22%). These errors were distributed approximately evenly within the administrative and NSQIP datasets. Finally, it is worth noting that superficial and deep VTs are not considered distinctly/separately by *either* administrative data *or* the NSQIP. The NSQIP complication "vein thrombosis requiring therapy" can be based on a thrombotic complication in any venous structure. Within administrative data, several ICD-9 codes are commonly lumped together under the term "deep venous thrombosis", but the code descriptions (Table 1) actually include deep and superficial VTs.

Our study has limitations which should be noted. The 8 hospitals from which the patient cohort was obtained may not be representative of the universe of domestic hospitals, and the operational characteristics of the administrative and NSQIP systems that are reported here may not therefore be generalizable. Also, the methods used in this study necessarily considered the two-clinician chart review as a "gold standard", but there is still the possibility that this review yielded errors. This chart review was also restricted to only those cases where discordance was present, rather than all cases (including concordant cases). Finally, our reliance on data that use the ICD-9 coding system (recently replaced by ICD-10) may limit the interpretation of our findings.

Despite these limitations, this study has importance for parties interested in using outcomes reports to monitor and reduce the clinical burden of postoperative VTE. In theory, such reports are an essential part of any data-driven approach to improving quality of care. Our results, however, shed light on how many issues exist in reporting a simple "VTE rate". At least some of these issues are the direct result of the different criteria that are currently used by administrative data vs. NSQIP to define vein thrombosis. These are not the only issues, though. Inaccuracies – primarily false negatives – are present in both of the systems currently used to identify postoperative VT/PE.

The challenges in accurately measuring rates of these complications are large enough to pose a significant barrier to effective quality improvement. What then is the best way to advance the science? There are two main paths that could be taken to overcome the challenges in outcomes measurement that are described in this study. First, the mechanisms of outcomes measurement could be buttressed. A consensus definition as to how each of these data sources should define

vein thrombosis is a straightforward, reasonable step that would improve the usefulness of both administrative and NSQIP data. This will not address problems with incomplete ascertainment/false negatives, however. A second option might be to pivot away from outcomes measurement toward a process-oriented approach. Intuitively, any improvements in VTE outcomes are necessarily the result of improved processes of care. Several studies, however, have failed to show a clear relationship between institutional rates of VTE prophylaxis (process) and VTE rates (outcomes).[7-9] Complicating the picture even further is a 2013 study showing that the relationship between VTE processes and VTE outcomes is confounded by institutional propensity to perform studies to diagnose VTE – "surveillance bias".[10]

Despite these historical difficulties, it may be that process-oriented approaches to quality measurement were abandoned too early. To date, the process measures that have been used to characterize VTE prophylaxis are primitive at best. The Surgical Care Improvement Project (SCIP) VTE-1 measure (initiated 4th quarter 2009) assessed the receipt of prophylaxis ordered anytime from hospital arrival to 48 hours after an operation.[11] SCIP VTE-2 focused more on the perioperative period, and examined only the delivery of prophylaxis within 24 hours before/after an operation.[12] Subsequent measures VTE-3, VTE-4, and VTE-5 dealt with technical measures of anti-coagulation delivery, but VTE-6 introduced a novel concept – an outcomes/process hybrid. This measure rates the occurrence of "potentially preventable" VTE by assessing the receipt of prophylaxis (any) between admission and a VTE event. Each of these measures is critically flawed by a failure to appropriately characterize VTE prophylaxis, as a single dose of prophylaxis is sufficient to meet each of these measures, but may be completely insufficient in the context of best evidence. A powerful solution to this problem would be to use a more

comprehensive approach to monitoring VTE prophylaxis that encompasses a broader set of discrete processes (mechanical prophylaxis, chemoprophylaxis, and ambulation) throughout the hospitalization. This approach has been proposed but has not yet taken root in policy.[13] A renewed focus on improving the measurement of processes related to VTE prophylaxis should be undertaken in order to advance the goal of VTE-related quality improvement.

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Table 1. International Classification of Disease Codes Used to Identify Venous Thrombosis and Pulmonary Embolus

ICD-9 Diagnosis description	ICD-9 Diagnosis code
Pulmonary embolus	
Pulmonary embolism and infarction	415.1x
Vein thrombosis	
Vein thrombosis of deep vessels of lower extremities	451.1x
Vein thrombosis of lower extremities, unspecified	451.2
Vein thrombosis of other sites	451.8
Vein thrombosis of unspecified site	451.9
Other venous embolism and thrombosis of deep vessels of lower extremity	453.4x
Other venous embolism and thrombosis of other specified veins	453.8
Other venous embolism and thrombosis of unspecified site	453.9

ICD-9, International Classification of Disease, 9th Clinical Modification.

Table 2. Characteristics of Patient Population

Characteristic	Data
n	43,336
Age, y, mean ± SD	59.5 ± 15.8
Sex	
Male	19,959 (46.1)
Female	23,087 (53.3)
Missing	290 (0.7)
Surgical subspecialty, n (%)	
Cardiac	81 (0.2)
General surgery	15,611 (36.0)
Gynecology	2,458 (5.7)
Neurosurgery	3,162 (7.3)
Orthopedics	9,467 (21.8)
Otolaryngology	2,271 (5.2)
Plastics	1,888 (4.4)
Thoracic	1,034 (2.4)
Urology	4,223 (9.7)
Vascular	3,141 (7.2)
Length of stay, d	
Mean ± SD	59.5 ± 18.8
Median	3
Interquartile range	4
Year of operation, n (%)	
2013	15,418 (35.6)
2014	15,944 (36.8)
2015	11,974 (27.6)

Data source was multi-institutional NSQIP/administrative data, 2013-2015.

Table 3. Explanations for Discordance Between Administrative and NSQIP Data in Assessment of Venous Thrombosis

Explanation	No. of cases
Administrative data positive for VT, NSQIP data negative for VT	51
Administrative data identified VT when none present (administrative data false positive)	20
Superficial VT* present/treated, not identified in NSQIP data (NSQIP false negative)	3
Deep VT present/treated, not identified in NSQIP data (NSQIP false negative)	28
Administrative data negative for VT, NSQIP data positive for VT	35
Deep VT present, not identified in administrative data (administrative data false negative)	25
NSQIP data identified VT as present/treated when no VT present (NSQIP false positive)	8
NSQIP data identified VT as present/treated when VT present/untreated (NSQIP false positive)	2
Differences in criteria	50
Superficial or deep VT present, not treated *and* administrative+/NSQIP–	42
Thrombosis in flap vein, thrombectomy performed *and* administrative+/NSQIP–	8
Total	136

*Flap veins were *not* included as superficial VT for the purposes of this row.

VT, venous thrombosis.

Table 4. Performance of Administrative and NSQIP Data in Determination of Pulmonary Embolus, Relative to Gold Standard

Database	Chart-review PE (gold standard)*		Sensitivity, %	Accuracy, %	Kappa
	No	Yes			
Admin-determined PE			98	99.9	0.97, 95% CI [0.95-0.99]
No	43,161	4			
Yes	2	96			
NSQIP-determined PE			85	99.9	0.91, 95% CI [0.86-0.95]
No	43,163	2			
Yes	15	83			

*Analyses of accuracy in this table are based on 2 assumptions. First, that the 2-clinician chart review performed in this study represents a "gold standard" determination. Second, that in all situations where the NSQIP and administrative data were concordant, both systems were "right."

Admin, administrative data; PE, pulmonary embolus.

FIGURE LEGENDS

Figure 1. Cohort inclusion flow chart; data source was multi-institutional NSQIP/administrative data, 2013-2015. Admin, administrative data; PE, pulmonary embolus; POA, present on admission; Preop, preoperative; VT, vein thrombosis.

Précis:

This study found significant differences between administrative and NSQIP data in the determination of postoperative vein thrombosis and pulmonary embolus. The mechanisms used to translate venous thromboembolism measurement into quality improvement should be standardized and improved.

Figure 1