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Whose Benchmark Is Right? Validating Venous Thromboembolism Events between Trauma Registries and Hospital Administrative Databases

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Abstract

Background: Venous thromboembolism (VTE) events are tracked in trauma registries and by administrative datasets. Both databases are used to assess outcomes despite having varying processes for data capture.

Study Design: This study was performed at an urban, university-based, level-one trauma center from 2004–2014. Retrospective review of the trauma registry and the hospital's administrative database was performed querying for all VTEs. Each VTE was then validated through manual chart review. Confirmed events were those with radiographic evidence of VTE by ultrasound,

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computed tomography, and/or ventilation/perfusion scan. Sensitivity, specificity and predictive values were calculated and compared between databases.

Results: 19,353 trauma patients were admitted during the study period. 656 VTEs were identified in the registry and 890 were identified via administrative data. 527 potential events were identified by both databases; 129 events were only in registry and 363 were only found in the administrative database. 636/656 events in registry were confirmed: PPV 97% (CI:95.6%-98.3%) vs. 815/890 events in administrative: PPV 91.6% (CI:89.75-93.4%), $p<0.001$. Sensitivity was higher for administrative (87.2 vs. 68.0, $p<0.001$) as 299 confirmed VTE events were not in the registry. Differences between the two databases were diminished when the analysis excluded untreated events and those present on admission. 23% of validated DVT events in the registry were upper extremity events.

Conclusions: The trauma registry showed higher specificity and lower sensitivity compared to administrative data. The low false positive rate of the trauma registry supports its validity in VTE outcomes research. Further investigation is needed to evaluate the relevance of the variable sensitivity, likely due to definitional differences. Supplementation of trauma registry data with administrative data may strengthen its completeness.

Precis

We compared the validity of venous thromboembolism (VTE) diagnoses found in the trauma registry and administrative databases of our institution. There was considerable discordance between databases, with substantial numbers of VTE found in only the administrative or the registry database. These findings have implications for VTE-based quality measures.

Keywords

venous thromboembolism; database validity; benchmarking; quality improvement; trauma

Introduction

Databases play a prominent role in modern surgical care. Health systems, payers, and regulators rely on databases for benchmarking and process improvement, while researchers use them for epidemiologic and comparative effectiveness research (1–3). This is particularly true in the trauma population, where national databases such as the National Trauma Data Bank (NTDB) have enabled large-scale outcomes research and national quality improvement initiatives (4,5). Database-derived measures of quality have a growing economic impact, as hospital reimbursement models increasingly focus on “value” rather than “volume” (6,7). The reliance on databases for these aspects of trauma care makes database validity a key priority.

Trauma databases derive primarily from two sources: registries and administrative data (International Classification of Diseases-9th Revision (ICD-9) and 10th Revision (ICD-10) diagnosis and procedure codes). Trauma registry data are collected specifically for research and quality improvement purposes by trained registrars who follow standardized data definitions (2,3). Administrative data, in contrast, are collected primarily for billing purposes(1). Administrative diagnosis codes lack standard clinical definitions (1), may be

influenced by economic rather than clinical factors, and in some databases, may be affected by limitations on the number of diagnoses that can be entered (1). Some studies have shown poor performance of administrative data in the trauma population (8–10), while others have shown favorable results (11,12). Few studies have systemically compared the validity of registry data vs. administrative data in the same trauma population (9–11). This is an important knowledge gap, as national quality improvement initiatives (e.g. Trauma Quality Improvement Program) rely on registry data (5), while payers such as the Centers for Medicare and Medicaid Services (CMS) rely on administrative data (13,14). The comparative validity of these data sources is particularly relevant for key outcomes that drive quality ratings such as venous thromboembolism (VTE).

VTE is the 3rd most common complication after trauma (15), and represents a major source of preventable morbidity and mortality. The Joint Commission includes VTE in its list of core measures and CMS use VTE as a quality indicator that impacts hospital reimbursement (13,16). Although most trauma centers utilize registry data to study VTE incidence and risk factors (17–22), VTE quality measures are defined with administrative data (13,14). Discordance between the two data sources could create scenarios where the results of VTE quality improvement efforts are not reflected in the quality measures that guide reimbursement. No prior studies have reported the validity of registry defined VTE outcomes, and it is unknown how registry defined VTE compare to those defined with administrative data (23–25). Therefore, our objective was to compare the validity of VTE diagnoses defined using registry data and administrative data in an urban level one trauma center population. We hypothesized that: 1) registry events would show higher validity (in terms of sensitivity, specificity, and predictive value) compared to administratively defined events; and 2) the relative validity of the two databases would vary according to factors related to VTE definition.

Methods

Population and data sources

This was a retrospective cross-sectional study of patients admitted to an urban academic level 1-trauma center in Philadelphia Pennsylvania. Included patients were admitted for at least 24 hours from January 1, 2004 to March 1, 2014. The cohort was created via query of the trauma center registry. Specially trained registrars abstract data both prospectively and retrospectively according to standardized definitions, conforming to state and national reporting guidelines. The registry submits data to the Pennsylvania state trauma systems foundation (Pennsylvania Trauma Outcome Study), TQIP (Trauma Quality Improvement Program), and the NTDB, and is frequently used for research (26–28). We obtained from the registry information on demographics, injury characteristics, and VTE diagnoses. Registry data were linked to administrative data via query of our health-system wide data warehouse (29), from which we obtained data on medications and diagnosis codes (ICD-9-CM).

Database Identification of VTE

Potential VTE cases were identified by two separate queries. We first queried the trauma registry to identify all patients coded as having a VTE event during admission. Trauma

registry definitions for deep vein thrombosis (DVT) and pulmonary embolism (PE) are listed in the eDocument 1. In 2011, the registry definitions were modified to be in accordance with the NTDB criteria (see eDocument 1), which stipulates that recorded DVT events must be treated with anticoagulation or vena cava filter placement to be considered as present (30,31). During the entire study period, the registry DVT definition did not require specification of the thrombosis location (e.g. upper vs. lower extremity; proximal vs. distal).

We then queried the health system data warehouse to identify all patients with a discharge diagnosis code for DVT (451.xx, 453.xx) or PE (415.xx). Patients were considered as positive for VTE in the administrative data if any of the specified codes were present in a secondary position in the list of discharge diagnoses.

Electronic medical record validation procedures

All potential VTE cases from both databases were validated through manual data abstraction from the electronic medical record by two investigators (GA, TAM) using Research Electronic Data Capture (REDCap) electronic data capture tools (32). Before data collection began, pilot testing of the REDCap instrument in 30 patients was conducted (consisting of chart abstraction in duplicate) to ensure clarity of question wording, completeness of the data items, and inter-rater reliability.

Data abstracted included the dates, times and results of all sonographic and/or radiographic examinations relevant to the diagnosis of VTE. These data were used to apply the study defined gold standard definition of VTE. Confirmation of DVT required explicit documentation of thrombosis in a report from a compression ultrasound exam or contrast enhanced computed tomography. Lower extremity DVTs were classified as proximal (thrombosis in the iliac, common femoral, superficial femoral, deep femoral, or popliteal veins) or distal (thrombosis in the peroneal, anterior tibial, posterior tibial, gastrocnemius, or soleal veins). Upper extremity DVTs were classified as proximal (thrombosis in the subclavian, internal jugular, or axillary veins) or distal (thrombosis in the brachial, radial, ulnar, or interosseous veins). Confirmation of PE required a positive computed tomography angiogram (CTA) of the lungs or ventilation-perfusion scan. CTA confirmation required explicit documentation of a filling defect in one or more pulmonary arteries *and* an explicit mention by the radiologist of pulmonary embolism being present. Ventilation-perfusion scan confirmation required explicit documentation of “high probability for pulmonary embolism”. In the absence of radiographic evidence for VTE, autopsy reports were reviewed if available. In the instance of multiple VTE in a single patient, all thrombosis events were recorded. In the primary analysis of all thrombosis types, each patient was only counted once according to the following scheme: classify as PE or proximal lower extremity DVT, whichever occurs first; if neither, then classify as proximal upper extremity DVT or distal lower extremity DVT, whichever occurs first; if neither, then classify as upper extremity distal DVT; if none of the above, classify as none present.

Data Analysis

Primary analysis—Baseline covariates were summarized with descriptive statistics. Using the chart abstracted VTE cases as the gold standard, validity of each database was

evaluated by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% confidence intervals (CIs) calculated as exact binomial confidence limits (33). Sensitivity and specificity were compared between databases using the McNemar test, while predictive values were compared using the generalized score statistic test (34). Confidence intervals for the differences in measures between databases were calculated by the method of Agresti and Min (35). In the primary analysis, all thrombosis types were considered. In secondary analyses, each specific thrombosis type (e.g. PE, upper / lower extremity DVT) was considered individually.

Secondary analyses—We hypothesized that the relative validity of the two databases would vary according to factors related to VTE definition. We explored this hypothesis in a series of analyses in which we modified our “gold standard” VTE definition as follows: 1) excluding VTE events that were not treated (because the registry definition required treatment after 2011); 2) excluding VTE events that were present at the time of admission (POA)—events diagnosed within the first 24 hours of admission; and 3) excluding both POA and untreated cases. To ensure our results were not biased by missed VTE cases among admissions not reviewed, we performed chart review on a random sample of 75 patients that did not have VTE diagnosis in either the trauma registry or the administrative data (36) (see eDocument 1 for detailed methods and results). Lastly, to examine the impact of changes to the trauma registry VTE definitions in 2011, we conducted sub-group analyses in each time period before and after the change of definitions. All primary and secondary analyses were conducted with R version 3.2.2, using the DTComPair package (37). Statistical inference was based on point estimates and corresponding 95% confidence intervals. (38,39). The Institutional Review Board of University of Pennsylvania approved the study.

Results

We included a total of 19353 patients (Table 1). Most patients were male and had suffered a blunt traumatic injury. There were 1019 patients identified as having a potential VTE by the two databases (registry n = 656; administrative n = 890). After chart validation, there were 935 patients with validated VTE events (registry n=636; administrative n=815). The distribution of thrombosis types and treatment rates among the validated patients is shown in Table 2. A considerable proportion of the validated DVTs in both databases were upper extremity events (Figure 1). In particular, 125/555 (23%) of registry defined DVT were upper extremity, with 51/125 (41%) of these being isolated distal upper extremity thrombosis. As expected, treatment rates were highest in patients with either PE or proximal lower extremity DVT, with lower rates observed for upper extremity events.

We observed considerable discordance between the two databases. There were 299 patients with validated cases that were only found in the administrative data and 120 patients with validated cases only found in the registry (Figure 1). The results of the primary analysis are shown in Table 3. Administrative data exhibited higher sensitivity (and NPV), whereas the registry exhibited higher specificity (and PPV). Table 4 shows the validity measures stratified by VTE type. PE case validity was similar to the overall analysis. However, DVT case validity varied depending on whether the patient had upper vs. lower extremity events.

Table S1 (in eDocument 1) shows the results of analyses that explored how measures of validity varied with changes to the definition of the “gold standard” and the source population. Results show that the difference in sensitivity decreased as the gold standard definition became more restrictive (i.e. exclusion of untreated and present on admission events). Conversely, the difference in PPV increased as the gold standard definition became more restrictive. Specificity and NPV estimates remained fairly consistent across the various analyses. Sub-group analyses restricted to time periods before (Table S2 [in eDocument 1]: 2004-2010) and after (Table S3 [in eDocument 1]: 2011-2014) the trauma registry definitional changes showed similar results to the primary analysis, with the exception of results for sensitivity. During the early time period, differences in sensitivity were diminished compared to the primary analysis, whereas the differences were larger in the later time period compared to the primary analysis.

Chart abstraction of 75 patients without either a registry diagnosis of VTE or a discharge diagnosis code for VTE revealed zero extra VTE cases, corresponding to a false negative rate of 0.0 %, (95% CI 0.0, 4.8%) (See in eDocument 1, Table S4 for additional details).

Discussion

VTE is a common complication and leading cause of late mortality after trauma (15,40). Although evidence suggests that most VTE events can be prevented, many patients may not receive adequate prophylaxis (41,42). Consequently, VTE occurrence has been identified as a key quality indicator in recent “pay for performance” reimbursement models (6,7,13). Such reliance on VTE events for quality assessment requires valid VTE measures. Against this backdrop, we conducted the first study that compares the validity of VTE outcomes in the two primary databases used in the trauma population. We observed considerable discordance of VTE events recorded in the trauma registry and administrative database, highlighting potential opportunities for improvement of VTE tracking.

Contrary to our expectation, we did not observe a clearly superior validity of registry defined VTE compared to our administrative data, with a substantial number of validated events being identified by only one or the other databases (Figure 1). Although the registry showed superior specificity, the administrative data showed substantially higher sensitivity, particularly for pulmonary embolism events. As expected, components of the VTE definition explained some of the differences in validity between the two databases. Consistent with these findings, differences in sensitivity increased after the trauma registry definition was changed to require treatment of DVT events. Nevertheless, the pattern of registry data having higher specificity and lower sensitivity remained across all variations of VTE definition. This finding highlights the importance of clear outcome definitions, and the fact that the two databases may identify distinct populations with varying clinical implications. Although registry definitions do not explicitly exclude VTE that were present on admission, these events were less frequently captured in the registry compared to administrative data. The lower capture of these events in the registry may be because such events are not relevant from a performance improvement perspective. However, research that aims to study VTE etiology ideally would identify events present on admission and exclude these patients from

the population to avoid bias. Our data thus highlight the need for further examination of which events should be tracked by trauma registries.

An additional novel finding is that registry defined DVT included a mix of upper and lower extremity thromboses, both of which were comprised of proximal and distal locations. In particular, we found that 23% of validated DVT cases in the trauma registry were upper extremity events. Prior literature suggests that these various thrombosis types may not have the same etiology or risk of subsequent pulmonary embolism (43–46). As a result, whether upper extremity and / or distal lower extremity events need treatment is controversial (43–46). The uncertain clinical significance of upper extremity and distal lower extremity DVT is reflected in the lower treatment rates observed for these event types (Table 2). Differences in the natural history of the various DVT locations might be important from both a quality improvement and research perspective. For example, a given risk factor (lower extremity fracture) might have varying associations with upper vs. lower extremity DVT. In addition, interventions targeted at lowering upper extremity events (minimizing intravenous catheters) may differ from those targeting lower extremity events (increased use of sequential compression devices). These observations suggest that registry VTE definitions should provide explicit guidance on whether upper extremity events should be captured, and further, should allow data abstractors to differentiate upper vs. lower extremity events. Such revisions could enhance the impact of registry driven quality improvement initiatives.

Outcome misclassification (e.g. false negatives and false positives) can introduce substantial bias into research studies (47). The direction and magnitude of bias is a function of the measure's sensitivity, specificity, and the frequency of the outcome under study (47). When outcome incidence is low (e.g. < 15%), bias is predominantly a function of specificity. In this scenario, even small deviations from perfect specificity can create strong bias (47), because true positives are quickly overwhelmed by false positives as specificity decreases (47). The higher specificity of the trauma registry therefore suggests that this data source might be preferred for investigations of VTE etiology and comparisons of prophylaxis strategies. On the other hand, if measurement of overall VTE incidence is of primary interest, the lower sensitivity of the registry compared to the administrative data makes the decision less clear.

Alternatively, our data suggest that researchers might benefit from drawing on both data sources. Query of the administrative data produced an extra 299 validated VTE cases, many of which were pulmonary embolisms. Although reliance solely on the trauma registry might induce minimal bias (given the high specificity), exclusion of the extra cases could reduce study power. Our data suggest that a combined database query, (with chart review of cases found only in the administrative data) might strike an optimal balance between study validity and the expenditure of investigator time and resources. This targeted use of administrative data might also function as a relatively easy and effective quality assurance procedure that registries could employ to ensure complete VTE capture.

Strengths of our study include the large sample size, clear case definitions, rigorous chart abstraction procedures, and careful consideration of VTE definition. Our study also has limitations. First, the single center design may limit generalizability. However, our registry

has been in operation for over two decades, is closely monitored through data audits and other quality assurance procedures, and is a contributor to state and national databases. Thus, we believe our findings raise important issues that may have broad implications for trauma registry validity. Second, the retrospective design is susceptible to bias. For example, our ability to differentiate events that were present on admission may be limited by the inability to interview patients. However, this limitation would not affect our primary findings, which did not consider present on admission status. The retrospective design may have also limited our ability to determine treatment status, especially if some patients began treatment after discharge. In addition, some VTE may have been missed by both databases. However, we conducted a sensitivity analysis of patients not identified by either database that did not reveal any additional VTE events, suggesting bias from missed events is minimal. Lastly, our administrative data is limited to ICD-9 codes and we cannot infer on the relative performance of registry data vs. ICD-10 defined VTE events. However, the conversion to ICD-10 is ongoing, with future studies of VTE needing to utilize ICD-9 defined events for many years to come.

Conclusion

We observed higher specificity and lower sensitivity for registry defined VTE compared to administrative data. The low false positive rate of the registry supports its validity in VTE outcomes research. Further investigation is needed to evaluate the relevance of the variable sensitivity, likely due to definitional differences. Supplementation of registry data with administrative data may strengthen its validity.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

VTE	venous thromboembolism
NTDB	National Trauma Data Bank
ICD-9	International Classification of Diseases-9th Revision
ICD-10	International Classification of Diseases-9th Revision
CMS	Centers for Medicare and Medicaid Services
DVT	deep vein thrombosis
PE	pulmonary embolism
CTA	computed tomography angiogram

VQ	ventilation/perfusion scan
PPV	positive predictive value
NPV	negative predictive value
CI	confidence interval
POA	present at the time of admission
IQR	interquartile range
ISS	injury severity score
AD	administrative database
UE	upper extremity
LE	lower extremity
PTOS	Pennsylvania Trauma Outcome Study

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Figure 1.

Distribution of thrombosis types identified in only administrative data, only registry data, or both databases. Before chart validation, there were 1,019 patients with potential events identified by the 2 databases (registry n = 656; administrative n = 890). After chart validation, there were 935 patients with validated events identified by the 2 databases (registry n=636; administrative n=815), $p<0.0001$. AD, administrative database; UE, upper extremity; LE, lower extremity; PE, pulmonary embolism; DVT, deep vein thrombosis.

Table 1.

Baseline Characteristics

Characteristic	Summary measure, n=19,353
Age, y, median (IQR)	43 (26-59)
Injury mechanism, n (%)	
Blunt	15,578 (80.5)
Penetrating	3768 (19.5)
Unknown	7 (0.0)
ISS, median (IQR)	9 (4-17)
Male sex, n (%)	13,599 (70.1)
Select VTE risk factors, n (%)	
Femur fracture	1,295 (6.7)
Pelvis fracture	1,389 (7.2)
Traumatic brain injury	3,006 (15.5)
Spinal cord injury	505 (2.6)
Malignancy	916 (4.7)
Mechanical ventilation	3,396 (17.6)
Surgery	3,513 (18.2)
Length of stay, d, median (IQR)	4 (2-8)
IVC filter placement, n (%) [*]	
Phase 1 (2004-2010)	779 (6.0)
Phase 2 (2011-2014)	187 (2.9)
VTE incidence, n (%) [†]	
All types	935 (4.8)
Pulmonary embolism	173 (0.9)
Proximal lower extremity DVT	301 (1.6)

^{*} Include both prophylactic placement in those without a thrombosis and placement for treatment in those with thrombosis.

[†] Total number of validated events identified across both databases.

IQR, interquartile range; IVC, inferior vena cava; ISS, injury severity score; VTE, venous thromboembolism; DVT, deep vein thrombosis.

Table 2.

Distribution of Thrombosis Types and Treatment

Thrombosis type*	Treatment rate	
	n/N	%
Pulmonary embolism	168/173	97.1
Lower extremity thrombosis		
Proximal lower extremity DVT	283/301	94.0
Distal lower extremity DVT	106/239	44.4
Upper extremity		
Proximal upper extremity DVT	65/109	59.6
Distal upper extremity DVT	33/113	29.2

* Some patients had multiple events (total 1,341 events in 935 patients). In such instances, each patient was only counted once according to the following scheme: classify as pulmonary embolism or proximal lower extremity DVT, whichever occurs first; if neither, then classify as distal lower extremity DVT or proximal upper extremity DVT, whichever occurs first; if neither, then classify as distal upper extremity DVT; if none of the above, classify as none present.

DVT, deep vein thrombosis.

Table 3.

Database Validity Measures with 95% Confidence Intervals

Measure	Registry database [*]	Administrative database [*]	Difference, % (95%CI)
Sensitivity	636/935 68.0 (65.0, 71.0)	815/935 87.2 (85.0, 89.3)	-19.1 (-23.3, -15.0)
Specificity	18,398/18,418 99.9 (99.8, 99.9)	18,343/18,418 99.6 (99.5, 99.7)	0.3 (0.2, 0.4)
PPV	636/656 96.9 (95.6, 98.3)	815/890 91.6 (89.7, 93.4)	5.4 (3.4, 7.4)
NPV	18,398/18,697 98.4 (98.2, 98.5)	18,343/18,463 99.4 (99.2, 99.5)	-0.9 (-1.2, -0.7)

^{*} The first row of cell denotes the numerator and denominator of each calculation; the second row of cell denotes the estimate with 95% CI.

PPV, positive predictive value; NPV, negative predictive value.

Table 4.

Validity Stratified by Thrombosis Type

Measure	Registry, % (95%CI)	Administrative, % (95%CI)	Difference, % (95%CI)
Sensitivity			
Pulmonary embolism	65.3 (58.2, 72.4)	91.9 (87.8, 95.9)	26.6 (−33.9, −19.3)
Lower extremity DVT	70.6 (66.9, 74.3)	83.4 (80.4, 86.4)	−12.8 (−17.9, −7.6)
Upper extremity DVT	62.3 (56.9, 67.7)	47.5 (42.9, 52.9)	14.9 (6.3, 23.4)
Specificity			
Pulmonary embolism	99.9 (99.9, 99.9)	99.8 (99.7, 99.9)	0.1 (0.08, 0.3)
Lower extremity DVT	99.2 (99.1, 99.3)	99.3 (99.2, 99.4)	−0.1 (−0.3, 0.01)
Upper extremity DVT	98.0 (97.8, 98.2)	99.9 (99.8, 99.9)	−1.8 (−2.0, −1.6)
Positive predictive value			
Pulmonary embolism	90.4 (85.2, 95.6)	79.9 (74.3, 85.5)	10.5 (4.7, 16.7)
Lower extremity DVT	73.9 (70.4, 77.6)	79.9 (76.8, 83.1)	−5.9 (−9.2, −2.4)
Upper extremity DVT	34.6 (30.7, 38.5)	85.7 (80.5, 90.8)	−51.1 (−55.0, −46.7)
Negative predictive value			
Pulmonary embolism	99.7 (99.6, 99.7)	99.9 (99.8, 99.9)	−0.2 (−0.3, −0.2)
Lower extremity DVT	99.1 (98.9, 99.2)	99.5 (99.4, 99.6)	−0.4 (−0.6, −0.2)
Upper extremity DVT	99.4 (99.3, 99.5)	99.1 (99.0, 99.3)	0.2 (0.1, 0.4)