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

Todd A Miano, PharmD, MSCE, FCCM, Grigor Abelian, PharmD, Mark J Seamon, MD, FACS, Kristen Chreiman, MSN, RN, CCRN, TCRN, Patrick M Reilly, MD, FACS, Niels D Martin, MD, FACS, FCCM

BACKGROUND: Venous thromboembolism (VTE) events are tracked in trauma registries and by administrative data sets. 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 I trauma center from 2004 to 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, CT, and/or ventilation-perfusion scan. Sensitivity, specificity, and predictive values were calculated and compared between databases.

RESULTS: There were 19,353 trauma patients 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. We confirmed 636 of 656 events in registry (positive predictive value, 97%; 95% CI, 95.6% to 98.3%) vs 815 of 890 events in administrative data (positive predictive value, 91.6%; 95% CI, 89.75% to 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 2 databases were diminished when the analysis excluded untreated events and those present on admission. Twenty-three percent of validated deep vein thrombosis events in the registry were upper extremity events.

CONCLUSIONS: The trauma registry showed higher specificity and lower sensitivity compared with administrative data. The low false-positive rate of the trauma registry supports its validity in VTE outcomes research. Additional investigation is needed to evaluate the relevance of the variable sensitivity, likely due to definitional differences. Supplementation of trauma registry data with administrative data can strengthen its completeness. (J Am Coll Surg 2019;228:752–759. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Disclosure Information: Dr Abelian is employed by Bristol-Myers Squibb. All other authors have nothing to disclose.

Disclosure outside the scope of this work: Dr Seamon received book royalties from Wolters Kluwer Health.

Support: This work was supported by grants from the NIH (grants F32HL124914 and T32GM075766 to Dr Miano).

Disclaimer: The NIH had no role in the design of the study, the collection and analysis of the data, or the preparation of the manuscript.

Portions of the data used in this study were presented at the American College of Surgeons Clinical Congress, Washington DC, October 2016.

Received December 12, 2018; Revised February 5, 2019; Accepted February 5, 2019.

From the Center for Pharmacoepidemiology Research and Training (Miano), Center for Clinical Epidemiology and Biostatistics (Miano), Department of Biostatistics, Epidemiology, and Informatics (Miano), Division of Traumatology, Surgical Critical Care and Emergency Surgery (Seamon, Chreiman, Reilly, Martin), Perelman School of Medicine at the University of Pennsylvania, and Department of Clinical Pharmacology and Pharmacometrics, Bristol-Myers Squibb (Abelian), Philadelphia, PA.

Correspondence address: Todd A Miano, PharmD, MSCE, FCCM, Center for Pharmacoepidemiology Research and Training, Perelman School of Medicine at the University of Pennsylvania, 423 Guardian Dr, 110 Blockley Hall, Philadelphia, PA 19104. email: tmiano81@gmail.com

https://doi.org/10.1016/j.jamcollsurg.2019.02.037
ISSN 1072-7515/19

Databases play a prominent role in modern surgical care. Health systems, payers, and regulators rely on databases for benchmarking and process improvement, and 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, 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 2 sources: registries and administrative data (ICD-9 and 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] can be influenced by economic rather than clinical factors, and, in some databases, can 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] and 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 (eg Trauma Quality Improvement Program) rely on registry data,[5] and payers such as the Centers for Medicare and Medicaid Services 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).

Venous thromboembolism is the third 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 the Centers for Medicare and Medicaid Services uses VTE as a quality indicator that impacts hospital reimbursement.[13,16] Although most trauma centers use registry data to study VTE incidence and risk factors,[17-22] VTE quality measures are defined with administrative data.[13,14] Discordance between the 2 data sources could create scenarios where the results of VTE quality improvement efforts are not reflected in the quality measures that guide reimbursement. No earlier studies have reported the validity of registry-defined VTE outcomes, and it is unknown how registry-defined VTEs compare with 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 I trauma center population. We hypothesized that registry events would show higher validity (in terms of sensitivity, specificity, and predictive value) compared with administratively defined events; and the relative validity of the 2 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 I trauma center in Philadelphia, PA. 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), Trauma Quality Improvement Program, and the National Trauma Data Bank, 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 venous thromboembolism

Potential VTE cases were identified by 2 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 National Trauma Data Bank 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 (eg upper vs lower extremity or 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 2 investigators (GA and TAM) using Research Electronic Data Capture electronic data capture tools.[32] Before data collection began, pilot testing of the Research Electronic Data Capture 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 examination or contrast-enhanced CT. 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 CT angiography of the lungs or ventilation-perfusion scan. The CT angiography confirmation required explicit documentation of a filling defect in 1 or more pulmonary arteries and an explicit mention by the radiologist of PE 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 VTEs 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, and negative predictive value with 95% CIs calculated as exact binomial confidence limits.[33] Sensitivity and specificity were compared between databases using the McNemar test, and 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 (eg PE, upper/lower extremity DVT) was considered individually.

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)
Injury Severity Score, median (IQR)	9 (4–17)
Male sex, n (%)	13,599 (70.1)
Select VTE risk factor, 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)
Operation	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.
DVT, deep vein thrombosis; IQR, interquartile range; VTE, venous thromboembolism.

Secondary analyses

We hypothesized that the relative validity of the 2 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: excluding VTE events that were not treated (because the registry definition required treatment after 2011); excluding VTE events that were present at the time of admission—events diagnosed within the first 24 hours of admission; and excluding both present at the time of admission and untreated cases. To ensure our results were not biased

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.

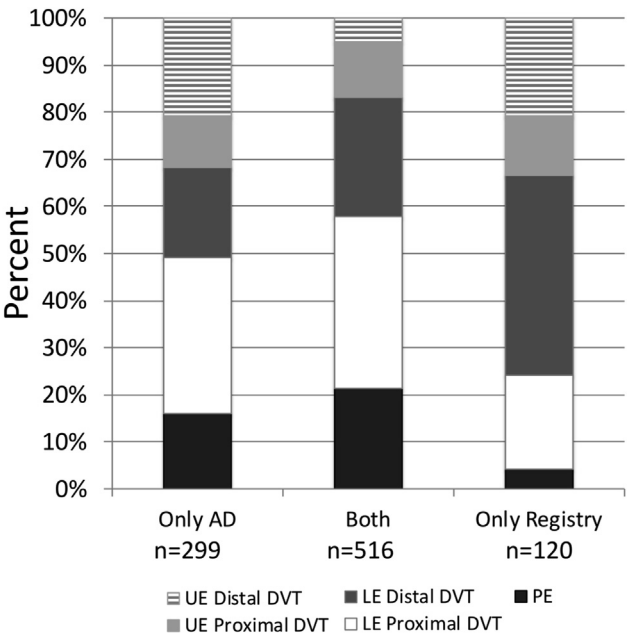

Figure 1. Distribution of thrombosis types identified in only administrative data, only registry data, or both databases. Before chart validation, there were 1,019 patients with potential events identified by the 2 databases (registry n = 656; administrative n = 890). After chart validation, there were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

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. Statistical inference was based on point estimates and corresponding 95% CIs.[37,38] The IRB of University of Pennsylvania approved the study.

RESULTS

We included a total of 19,353 patients (Table 1). Most patients were male and had a blunt traumatic injury. There were 1,019 patients identified as having a potential VTE by the 2 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 (Fig. 1). In particular, 125 of 555 (23%) registry-defined DVT were upper extremity, with 51 of 125 (41%) 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 2 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 (Fig. 1). The results of the primary analysis are shown in Table 3. Administrative data exhibited higher sensitivity (and negative predictive value), and the registry exhibited higher specificity (and positive predictive value). Table 4 shows the validity measures stratified by VTE type. Pulmonary embolism case validity was similar to the overall analysis. However, DVT case validity varied depending on whether the patient had upper vs lower extremity events.

eTable 1 (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 (ie exclusion of untreated and present on admission events). Conversely, the difference in positive predictive value increased as the gold standard definition became more restrictive. Specificity and negative predictive value estimates remained fairly consistent across the various analyses. Sub-group analyses restricted to time periods before (eTable 2 in eDocument 1: 2004

Table 3. Database Validity Measures with 95% Confidence Intervals

Measure	Registry database	Administrative database	Difference, % (95% CI)
Sensitivity			−19.1 (−23.3 to −15.0)
n/N	636/935	815/935	—
Estimate, % (95% CI)	68.0 (65.0 to 71.0)	87.2 (85.0 to 89.3)	—
Specificity			0.3 (0.2 to 0.4)
n/N	18,398/18,418	18,343/18,418	—
Estimate, % (95% CI)	99.9 (99.8 to 99.9)	99.6 (99.5 to 99.7)	—
Positive predictive value			5.4 (3.4 to 7.4)
n/N	636/656	815/890	
Estimate, % (95% CI)	96.9 (95.6 to 98.3)	91.6 (89.7 to 93.4)	
Negative predictive value			−0.9 (−1.2 to −0.7)
n/N	18,398/18,697	18,343/18,463	—
Estimate, % (95% CI)	98.4 (98.2 to 98.5)	99.4 (99.2 to 99.5)	—

to 2010) and after (eTable 3 in eDocument 1: 2011 to 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 with the primary analysis, and the differences were larger in the later time period compared with 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% to 4.8%) (see eTable 4 in eDocument 1 for additional details).

DISCUSSION

Venous thromboembolism is a common complication and leading cause of late mortality after trauma.[15,39] Although evidence suggests that most VTE events can be prevented, many patients might not receive adequate prophylaxis.[40,41] 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 2 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 with our administrative data, with a substantial number of validated events being identified by only one or the other databases (Fig. 1). Although the registry showed superior specificity, the administrative data showed substantially higher sensitivity, particularly for PE events. As expected, components of the VTE definition explained some of the differences in validity between the 2 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 outcomes definitions, and the fact that the 2 databases can 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 with administrative data. The lower capture of these events in the registry might 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 highlight the need for additional 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 comprised proximal and distal locations. In particular, we found that 23% of validated DVT cases in the trauma registry were upper extremity events. Earlier literature suggests that these various thrombosis types might not have the same etiology or risk of subsequent PE.[42-45] As a result, whether upper extremity and/or distal lower extremity events need treatment is controversial.[42-45] 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

Table 4. Validity Stratified by Thrombosis Type

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

DVT, deep venous thrombosis; PE, pulmonary embolism.

fracture) might have varying associations with upper vs lower extremity DVT. In addition, interventions targeted at lowering upper extremity events (minimizing IV catheters) can 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, in addition, should allow data abstractors to differentiate upper vs lower extremity events. Such revisions could enhance the impact of registry-driven quality improvement initiatives.

Outcomes misclassification (eg false negatives and false positives) can introduce substantial bias into research studies.[46] The direction and magnitude of bias are functions of the measure's sensitivity, specificity, and the frequency of the outcomes being studied.[46] When outcomes incidence is low (eg <15%), bias is predominantly a function of specificity. In this scenario, even small deviations from perfect specificity can create strong bias[46] because true positives are quickly overwhelmed by false positives as specificity decreases.[46] 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 with 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 PEs. 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 use 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 might limit generalizability. However, our registry has been in operation for more than 2 decades, is closely monitored through data audits and other quality assurance procedures, and is a contributor to state and national databases. We believe our findings raise important issues that might 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 might 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 might have also limited our ability to determine treatment status, especially if some patients began treatment after discharge. In addition, some VTEs might 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 are 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 use ICD-9-defined events for many years to come.

CONCLUSIONS

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

Author Contributions

Study conception and design: Miano, Abelian, Martin
Acquisition of data: Miano, Abelian, Martin
Analysis and interpretation of data: Miano, Abelian, Seamon, Chreiman, Reilly, Martin
Drafting of manuscript: Miano, Abelian, Martin
Critical revision: Miano, Abelian, Seamon, Chreiman, Reilly, Martin
Final approval: Miano, Abelian, Seamon, Chreiman, Reilly, Martin

REFERENCES

1. Schneeweiss S, Avorn J. A review of uses of health care utilization databases for epidemiologic research on therapeutics. J Clin Epidemiol 2005;58:323–337.
2. Moore L, Clark DE. The value of trauma registries. Injury 2008;39:686–695.
3. Hlaing T, Hollister L, Aaland M. Trauma registry data validation: essential for quality trauma care. J Trauma 2006;61:1400–1407.
4. The National Trauma Data Bank. Available at: www.facs.org/quality-programs/trauma/ntdb. Accessed November 17, 2017.
5. The Trauma Quality Improvement Program. Available at: https://www.facs.org/quality-programs/trauma/tqip. Accessed November 17, 2017.
6. Chee TT, Ryan AM, Wasfy JH, Borden WB. Current state of value-based purchasing programs. Circulation 2016;133:2197–2205.
7. Burns LR, Pauly MV. Transformation of the health care industry: curb your enthusiasm? Milbank Q 2018;96:57–109.
8. Best WR, Khuri SF, Phelan M, et al. Identifying patient preoperative risk factors and postoperative adverse events in administrative databases: results from the Department of Veterans Affairs National Surgical Quality Improvement Program. J Am Coll Surg 2002;194:257–266.
9. Samuel AM, Lukasiewicz AM, Webb ML, et al. ICD-9 diagnosis codes have poor sensitivity for identification of preexisting comorbidities in traumatic fracture patients: a study of the National Trauma Data Bank. J Trauma Acute Care Surg 2015;79:622–630.
10. Wynn A, Wise M, Wright MJ, et al. Accuracy of administrative and trauma registry databases. J Trauma 2001;51:464–468.
11. McCarthy ML, Shore AD, Serpi T, et al. Comparison of Maryland hospital discharge and trauma registry data. J Trauma 2005;58:154–161.
12. Rutledge R, Osler T, Emery S, et al. The end of the Injury Severity Score (ISS) and the Trauma and Injury Severity Score (TRISS): ICISS, an International Classification of Diseases, ninth revision-based prediction tool, outperforms both ISS and TRISS as predictors of trauma patient survival, hospital charges, and hospital length of stay. J Trauma 1998;44:41–49.
13. Centers for Medicare and Medicaid Services. Total Performance Score Information. Available at: https://www.medicare.gov/hospitalcompare/data/total-performance-scores.html. Accessed February 17, 2018.
14. Agency for Healthcare Research and Quality. Patient Safety Indicators. Available at: http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD09_v60.aspx. Accessed October 13, 2017.
15. National Trauma Databank Annual Report. Available at: https://www.facs.org/quality-programs/trauma/ntdb/docpub. Accessed June 12, 2017.
16. Lau BD, Streiff MB, Pronovost PJ, et al. Venous thromboembolism quality measures fail to accurately measure quality. Circulation 2018;137:1278–1284.
17. Knudson M, Ikossi D, Khaw L, et al. Thromboembolism after trauma. An analysis of 1602 episodes from the American College of Surgeons National Trauma Data Bank. Ann Surg 2004;240:490–498.
18. Miano TA, Cuker A, Christie JD, et al. Comparative effectiveness of enoxaparin vs dalteparin for thromboprophylaxis after traumatic injury. Chest 2018;153:133–142.
19. Slavik RS, Chan E, Gorman SK, et al. Dalteparin versus enoxaparin for venous thromboembolism prophylaxis in acute spinal cord injury and major orthopedic trauma patients: 'DETECT' Trial. Trauma 2007;62:1075–1081.
20. Okoye OT, Gelbard R, Inaba K, et al. Dalteparin versus enoxaparin for the prevention of venous thromboembolic events in trauma patients. Eur J Trauma Emerg Surg 2014;40:183–189.
21. Rogers FB, Shackford SR, Horst MA, et al. Determining venous thromboembolic risk assessment for patients with trauma: the Trauma Embolic Scoring System. J Trauma Acute Care Surg 2012;73:511–515.
22. Jacobs BN, Cain-Nielsen AH, Jakubus JL, et al. Unfractionated heparin versus low-molecular-weight heparin for venous thromboembolism prophylaxis in trauma. J Trauma Acute Care Surg 2017;83:151–158.
23. Tamariz L, Harkins T, Nair V. A systematic review of validated methods for identifying venous thromboembolism using administrative and claims data. Pharmacoepidemiol Drug Saf 2012;21:154–162.
24. White RH, Gettner S, Newman JM, et al. Predictors of rehospitalization for symptomatic venous thromboembolism after total hip arthroplasty. N Engl J Med 2000;343:1758–1764.

25. White RH, Romano PS, Zhou H, et al. Incidence and time course of thromboembolic outcomes following total hip or knee arthroplasty. Arch Intern Med 1998;158:1525–1531.
26. Earl-Royal E, Kaufman EJ, Hsu JY, et al. Age and preexisting conditions as risk factors for severe adverse events and failure to rescue after injury. J Surg Res 2016;205:368–377.
27. Mathew S, Smith BP, Cannon JW, et al. Temporary arterial shunts in damage control: experience and outcomes. J Trauma Acute Care Surg 2017;82:512–517.
28. Morris DS, Reilly P, Rohrbach J, et al. The influence of unit-based nurse practitioners on hospital outcomes and readmission rates for patients with trauma. J Trauma Acute Care Surg 2012;73:474–478.
29. Penn Medicine. Data analytics center. Penn Data Store. Available at: http://www.med.upenn.edu/dac/penn-data-store-warehouse.html.
30. American College of Surgeons. The National Trauma Data Standard (NTDS). Available at: http://www.ntdsdictionary.org. Accessed August 21, 2017.
31. Pennsylvania Trauma Systems Foundation data manual. Available at: http://ptsf.org/index.php/resources. Accessed September 9, 2017.
32. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–381.
33. Pepe M. The Statistical Evaluation of Medical Tests for Classification and Prediction. In: Oxford Statistical Science Series. 1st ed. Oxford, UK: Oxford University Press; 2003.
34. Leisenring W, Alonzo T, Pepe MS. Comparisons of predictive values of binary medical diagnostic tests for paired designs. Biometrics 2000;56:345–351.
35. Agresti A, Min Y. Simple improved confidence intervals for comparing matched proportions. Stat Med 2005;24:729–740.
36. Leonard CE, Haynes K, Localio AR, et al. Diagnostic E-codes for commonly used, narrow therapeutic index medications poorly predict adverse drug events. J Clin Epidemiol 2008;61:561–571.
37. Wasserstein RL, Lazar NA. The ASA's Statement on p-values: context, process, and purpose. Am Stat 2016;70:129–133.
38. Greenland S, Senn SJ, Rothman KJ, et al. Statistical tests, P values, confidence intervals, and power: a guide to misinterpretations. Eur J Epidemiol 2016;31:337–350.
39. Acosta JA, Yang JC, Winchell RJ, et al. Lethal injuries and time to death in a level I trauma center. J Am Coll Surg 1998;186:528–533.
40. Goldhaber SZ, Tapson VF, DVT FREE Steering Committee. A prospective registry of 5,451 patients with ultrasound-confirmed deep vein thrombosis. Am J Cardiol 2004;93:259–262.
41. Cohen AT, Tapson VF, Bergmann JF, et al. Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study. Lancet 2008;371:387–394.
42. Palareti G. How I treat isolated distal deep vein thrombosis (IDDVT). Blood 2014;123:1802–1809.
43. Sharpe RP, Gupta R, Gracias VH, et al. Incidence and natural history of below-knee deep venous thrombosis in high-risk trauma patients. J Trauma 2002;53:1048–1052.
44. Malinoski DJ, Ewing T, Patel MS, et al. The natural history of upper extremity deep venous thromboses in critically ill surgical and trauma patients: what is the role of anticoagulation? J Trauma 2011;71:316–321; discussion 321–322.
45. Engelberger RP, Kucher N. Management of deep vein thrombosis of the upper extremity. Circulation 2012;126:768–773.
46. Copeland KT, Checkoway H, McMichael AJ, Holbrook RH. Bias due to misclassification in the estimation of relative risk. Am J Epidemiol 1977;105:488–495.

eDocument 1.
TRAUMA REGISTRY VENOUS THROMBOEMBOLISM DEFINITIONS

Deep vein thrombosis

During the time period from 2004 to 2010, DVT was defined as "an acute occlusive condition documented by one of the following: 1) doppler, 2) duplex ultrasound, 3) venogram, 4) IPG (impedance plysthmography) or 5) autopsy."[1]

During the time period after 2011, DVT was defined as "the formation, development, or existence of a blood clot or thrombus within the vascular system, which may be coupled with inflammation. A venogram, ultrasound, or CT may confirm this diagnosis and the patient must be treated with anticoagulation therapy and/or placement of a vena cava filter or clipping of the vena cava."[1]

Pulmonary embolism

During the time period from 2004 to 2010, PE was defined as an embolus to the lung documented by one of the following: pulmonary arteriography, postmortem examination, initiation of treatment based on radionuclide, or CT with contrast.

During the time period after 2011, PE was defined as a "lodging of a blood clot in a pulmonary artery with subsequent obstruction of blood supply to the lung parenchyma, usually originating from the deep leg veins or the pelvic venous system. Consider the condition present if the patient has a V-Q scan interpreted as high probability of pulmonary embolism or a positive pulmonary arteriogram or positive CT angiogram."[1]

VENOUS THROMBOEMBOLISM PROPHYLAXIS PROTOCOL

All patients were subject to a standard VTE prophylaxis protocol during the study period. On admission, patients were evaluated for VTE risk factors and those with at least 1 risk factor received pharmacologic prophylaxis and mechanical prophylaxis with sequential compression devices. Additionally, at-risk patients received weekly VTE surveillance with lower extremity compression ultrasound for the initial 3 weeks after injury while in the hospital. The protocol recommended the initial compression ultrasound be obtained within 3 days of admission and no later than 5 days after admission. Patients considered to be at very high risk for VTE or with contraindications to anticoagulation were candidates for prophylactic IVC filter placement. All components of the protocol remained constant throughout the study period.

Sensitivity analysis in patients without venous thromboembolism in either database

Because we did not perform chart abstraction on all trauma admissions, we conducted a sensitivity analysis exploring the impact of missed VTE cases among admissions not reviewed. We selected a random sample of 75 patients that did not have VTE diagnosis in either the trauma registry or the administrative data. Using the upper bound of the 95% CIs for these proportions, we recalculated validity measures, assuming that the estimated number of missed VTEs among the databases' negative admissions were false negatives.

Chart abstraction revealed zero extra VTE cases, corresponding to a false-negative rate of 0.0% (95% CI 0.0% to 4.8%). Using the upper bound of the CI around this estimate, we conducted a "worst case scenario" sensitivity analysis by repeating the analysis assuming a 4.8% false-negative rate in the 18,334 patients that were negative by both databases ($n = 880$ potential false negatives). As expected, the estimates of sensitivity and negative predictive value are reduced in this analysis. Notably, however, estimates of specificity and positive predictive value are essentially unchanged. In addition, because the potential false negatives affect both databases, the relative differences between databases are still apparent.

eTable 1. Factors Affecting Database Validity

Measure	Registry database, % (95% CI)	Administrative database, % (95% CI)	Difference, % (95% CI)
Sensitivity			
All patients	68.0 (65.0 to 71.0)	87.2 (85.0 to 89.3)	−19.1 (−23.3 to −15.0)
Exclude untreated	75.9 (72.5 to 79.2)	90.8 (88.5 to 93.1)	−14.9 (−19.3 to −10.6)
Exclude POA	72.4 (69.4 to 75.5)	85.9 (83.6 to 88.3)	−13.5 (−17.8 to −9.3)
Exclude untreated and POA	81.7 (78.4 to 84.9)	89.7 (87.2 to 92.3)	−8.1 (−12.5 to −3.6)
Specificity			
All patients	99.9 (99.8 to 99.9)	99.6 (99.5 to 99.7)	0.3 (0.2 to 0.4)
Exclude untreated	99.0 (98.8 to 99.2)	98.2 (98.0 to 98.5)	0.8 (0.6 to 0.9)
Exclude POA	99.7 (99.6 to 99.8)	99.1 (98.9 to 99.2)	0.7 (0.5 to 0.8)
Exclude untreated and POA	98.9 (98.7 to 99.0)	97.9 (97.7 to 98.1)	1.0 (0.8 to 1.2)
Positive predictive value			
All patients	96.9 (95.6 to 98.3)	91.6 (89.7 to 93.4)	5.4 (3.4 to 7.4)
Exclude untreated	71.9 (68.5 to 75.4)	63.5 (60.3 to 66.6)	8.5 (5.3 to 11.8)
Exclude POA	92.1 (90.0 to 94.1)	80.6 (77.9 to 83.2)	11.5 (8.8 to 14.3)
Exclude untreated and POA	67.8 (64.3 to 71.4)	54.9 (51.7 to 58.2)	12.9 (9.6 to 16.4)
Negative predictive value			
All patients	98.4 (98.2 to 98.5)	99.4 (99.2 to 99.5)	−0.9 (−1.2 to −0.7)
Exclude untreated	99.2 (99.1 to 99.3)	99.7 (99.6 to 99.7)	−0.5 (−0.6 to −0.3)
Exclude POA	98.8 (98.6 to 98.9)	99.4 (99.2 to 99.5)	−0.6 (−0.8 to −0.4)
Exclude untreated and POA	99.5 (99.4 to 99.6)	99.7 (99.6 to 99.8)	−0.2 (−0.4 to −0.1)

POA, present on admission.

eTable 2. Analysis Restricted to Early Time Period (2004–2010)

	Registry database		Administrative database		
Measure	n/N	Estimate (95% CI), %	n/N	Estimate (95% CI), %	Difference, % (95% CI)
Sensitivity	416/577	72.1 (68.4 to 75.7)	478/577	82.8 (79.8 to 85.9)	−10.7 (−16.1 to −5.3)
Specificity	12,379/12,392	99.9 (99.8 to 99.9)	12,346/12,392	99.6 (99.5 to 99.7)	0.3 (0.2 to 0.4)
PPV	416/429	96.9 (95.3 to 98.5)	478/524	91.2 (88.8 to 93.6)	5.7 (3.2 to 8.4)
NPV	12,379/12,540	98.7 (98.5 to 98.9)	12,346/12,445	99.2 (99.0 to 99.4)	−0.5 (−0.7 to −0.2)

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

eTable 3. Analysis Restricted to Later Time Period (2011–2014)

	Registry database		Administrative database		
Measure	**n/N**	**Estimate (95% CI), %**	**n/N**	**Estimate (95% CI), %**	**Difference, % (95%CI)**
Sensitivity	220/358	61.5 (56.4 to 66.5)	337/358	94.1 (91.7 to 96.6)	−32.7 (−38.7 to −26.7)
Specificity	6,019/6,026	99.9 (99.8 to 99.9)	5,997/6,026	99.5 (99.3 to 99.7)	0.4 (0.2 to 0.5)
PPV	220/227	96.9 (94.7 to 99.2)	337/366	92.1 (89.3 to 94.8)	4.8 (1.8 to 8.0)
NPV	6,019/6,157	97.8 (97.4 to 98.1)	5,997/6,018	99.7 (99.5 to 99.8)	−1.9 (−2.3 to −1.5)

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

eTable 4. Sensitivity Analysis Assuming 4.8% False-Negative Rate

	Registry database		Administrative database		
Measure	**n/N**	**Estimate (95% CI), %**	**n/N**	**Estimate (95% CI), %**	**Difference, % (95% CI)**
Sensitivity	636/1,815	35.0 (32.8 to 37.2)	815/1,815	44.9 (42.6 to 47.2)	−9.8 (−12.0 to −7.7)
Specificity	17,518/17,538	99.9 (99.8 to 99.9)	17,463/17,538	99.6 (99.5 to 99.7)	0.3 (0.2 to 0.4)
PPV	636/656	96.9 (95.6 to 98.2)	815/890	91.6 (89.7 to 93.4)	5.4 (3.4 to 7.4)
NPV	17,518/18,697	93.7 (93.3 to 94.0)	17,343/18,463	94.5 (94.3 to 94.9)	−0.9 (−1.1 to −0.7)

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

REFERENCE

1. Pennsylvania Trauma Outcome Study (PTOS) Manual. Available at: http://ptsf.org/registry/resources. Accessed June 12, 2017.