Evaluation of Surveillance Bias and the Validity of the Venous Thromboembolism Quality Measure

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IMPORTANCE Postoperative venous thromboembolism (VTE) rates are widely reported quality metrics soon to be used in pay-for-performance programs. Surveillance bias occurs when some clinicians use imaging studies to detect VTE more frequently than other clinicians. Because they look more, they find more VTE events, paradoxically worsening their hospital's VTE quality measure performance. A surveillance bias may influence VTE measurement if (1) greater hospital VTE prophylaxis adherence fails to result in lower measured VTE rates, (2) hospitals with characteristics suggestive of higher quality (eg, more accreditations) have greater VTE prophylaxis adherence rates but worse VTE event rates, and (3) higher hospital VTE imaging utilization use rates are associated with higher measured VTE event rates.

OBJECTIVE To examine whether a surveillance bias influences the validity of reported VTE rates.

DESIGN, SETTING, AND PARTICIPANTS 2010 Hospital Compare and American Hospital Association data from 2838 hospitals were merged. Next, 2009-2010 Medicare claims data for 954,926 surgical patient discharges from 2786 hospitals who were undergoing 1 of 11 major operations were used to calculate VTE imaging (duplex ultrasonography, chest computed tomography/magnetic resonance imaging, and ventilation-perfusion scans) and VTE event rates.

MAIN OUTCOMES AND MEASURES The association between hospital VTE prophylaxis adherence and risk-adjusted VTE event rates was examined. The relationship between a summary score of hospital structural characteristics reflecting quality (hospital size, numbers of accreditations/quality initiatives) and performance on VTE prophylaxis and risk-adjusted VTE measures was examined. Hospital-level VTE event rates were compared across VTE diagnostic imaging rate quartiles and with a quantile regression.

RESULTS Greater hospital VTE prophylaxis adherence rates were weakly associated with worse risk-adjusted VTE event rates ($r^2 = 4.2\%$; $P = .03$). Hospitals with increasing structural quality scores had higher VTE prophylaxis adherence rates (93.3\% vs 95.5\% for lowest vs highest quality quartile; $P < .001$) but worse risk-adjusted VTE rates (4.8 vs 6.4 per 1000, lowest vs highest quality quartile; $P < .001$). Mean VTE diagnostic imaging rates ranged from 32 studies per 1000 in the lowest imaging use quartile to 167 per 1000 in the highest quartile ($P < .001$). Risk-adjusted VTE rates increased significantly with VTE imaging use rates in a stepwise fashion, from 5.0 per 1000 in the lowest quartile to 13.5 per 1000 in the highest quartile ($P < .001$).

CONCLUSIONS AND RELEVANCE Hospitals with higher quality scores had higher VTE prophylaxis rates but worse risk-adjusted VTE rates. Increased hospital VTE event rates were associated with increasing hospital VTE imaging use rates. Surveillance bias limits the usefulness of the VTE quality measure for hospitals seeking to identify a high-quality hospital.
enous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is a common postoperative complication that remains a leading potentially preventable cause of postoperative morbidity and mortality.1 The Agency for Healthcare Research and Quality developed a risk-adjusted postoperative VTE rate measure, Patient Safety Indicator 12 (PSI-12).2 Endorsed by the National Quality Forum in 2008, the VTE outcome measure has been incorporated into numerous quality improvement programs and public reporting initiatives, including the Centers for Medicare & Medicaid Services 2015 Value-based Purchasing program.3

However, measuring VTE rates may be flawed because of surveillance bias,4–6 in which variation in outcomes reflects variation in screening and detection, or “the more you look, the more you find” phenomenon. This can occur in a number of ways: hospitals may use screening protocols, in which asymptomatic patients routinely undergo VTE imaging studies on a certain postoperative day,1,7,8 or clinicians have a lower threshold to order a VTE imaging study for patients with minimal or equivocal signs or symptoms (eg, any leg swelling prompts a venous duplex). Hospitals that are more vigilant and perform more imaging studies for VTE may identify more VTE events, thus resulting in paradoxically worse performance on the VTE outcome measure.

If VTE rates are subject to a surveillance bias, then (1) higher VTE prophylaxis adherence should not be associated with lower VTE rates (ie, process-outcome dissociation), (2) hospitals with more characteristics reflecting quality (ie, accreditations and characteristics that generally are thought to be associated with better performance and lower complication rates) should demonstrate better VTE prophylaxis adherence rates but worse VTE rates, and (3) hospital risk-adjusted VTE rates should be related to hospital VTE imaging use rates.

To examine the effect of surveillance bias on the validity of VTE as a quality measure, 3 analyses were performed. First, we used national hospital-level data to examine the relationship between hospital VTE prophylaxis adherence and VTE event rates. Second, these data were also used to examine the associations between hospital characteristics reflecting higher quality and hospital VTE prophylaxis and event rates. Third, the associations between hospital VTE imaging and VTE event rates were examined with patient-level Medicare claims data.

Methods
This study was approved by the Northwestern University Institutional Review Board.

Comparison of VTE Rates With Process and Structural Measures

Data Sources
To evaluate the association between VTE rates (PSI-12), VTE prophylaxis adherence (SCIP-VTE-2 [Surgical Care Improvement Project for VTE]), and structural measures of hospital quality, we used publicly reported hospital-level data on VTE prophylaxis rates and risk-adjusted VTE performance from the 2010 Centers for Medicare & Medicaid Services Hospital Compare program (October 2011 release)9 and data on hospital characteristics from the 2010 American Hospital Association Annual Hospital Survey.

Measures
SCIP-VTE-2 measures the proportion of surgical patients who received appropriate VTE perioperative prophylaxis (mechanical or chemoprophylaxis, depending on the operation group).10 PSI-12 measures the hospital inpatient postoperative VTE rate per 1000 surgical discharges, adjusted for differences in case mix.2,11 Inclusion and exclusion criteria for SCIP-VTE-2 and PSI-12 are similar.2,10

To measure the structural quality of hospitals, we a priori selected 8 hospital characteristics previously used to examine health care quality and which reflect a hospital’s resources and focus on programs intended to provide higher-quality care12–18: (1) bed size (<300 beds, ≥300 beds); (2) accreditation by the Joint Commission, (3) Commission on Cancer, (4) or as a level 1 trauma center; (5) presence of a residency training approved by the Accreditation Council for Graduate Medical Education; (6) provision of burn care services or (7) transplant surgery services; and (8) whether a hospital disseminated reports to its community on quality and costs of health care services. A summary score was created for each hospital’s overall structural quality (0 to 8, with 8 representing the highest quality).

Statistical Analysis
The association between hospital risk-adjusted VTE rates and VTE prophylaxis adherence rates was examined with bivariate Spearman correlations. To evaluate the association between hospitals’ summary score of structural quality and their performance on the VTE process and outcomes measures, we divided hospitals into quartiles according to their structural quality summary scores. Risk-adjusted VTE rates and VTE prophylaxis adherence rates were examined across quartiles of structural quality scores with 1-way analysis of variance, with Bonferroni correction for pairwise differences in means and Cuzick extension of the Wilcoxon signed rank test for trends.19 All tests were 2-sided, with significance set at .05.

Assessment of VTE Imaging Use and Event Rates

Data Source and Patients
To construct hospital-level VTE imaging rates and risk-adjusted VTE rates, patient-level data were obtained from the Medicare Provider and Analysis Review, Carrier, and Outpatient claims files. Fee-for-service Medicare beneficiaries aged 65 years or older who had one of 11 major operations (abdominal aortic aneurysm repair, coronary artery bypass graft, craniotomy, colectomy, cystectomy, esophagectomy, gastric bypass, lung resection, pancreatic resection, proctectomy, or total knee arthroplasty) between January 1, 2009, and December 31, 2010, were identified with International Classification of Diseases, Ninth Revision (ICD-9) codes (eTable 1 in the Supplement). Agency for Healthcare Research and Quality PSI-12 exclusions were applied.2
Trends. All tests were 2-sided, with significance set at .05. As a supplemental approach to characterize surveillance bias that preserves full range of variation in both VTE imaging and complication rates, we used quantile regression to examine whether imaging rates had differential effects across the distribution of risk-adjusted VTE event rates. The association of VTE imaging and VTE event rates was assessed at the 25th, 50th (median), 75th, 85th, 95th, and 99th quantiles of the VTE event rate distribution.

Additional Analyses
Four additional analyses were performed. First, we assessed whether publicly reported hospital VTE performance from Hospital Compare 2010 also demonstrated a surveillance bias.

Second, to better account for differences in patient risk factors across VTE imaging use quartiles, a more comprehensive risk-adjustment approach was performed with additional patient-level covariates (eTable 2 in the Supplement).

Third, analyses were repeated with a hierarchical regression model with hospital random intercepts.

Fourth, a competing hypothesis is that high VTE imaging use hospitals may not provide adequate VTE prophylaxis, thus resulting in higher VTE rates and correspondingly requiring more VTE imaging studies. We tested this alternative explanation by comparing SCIP-VTE-2 adherence across VTE imaging use quartiles.

Results

Comparison of VTE Rates With Process and Structural Measures
In 2010, 2838 hospitals reported VTE process and outcome measures to Hospital Compare (Table 1). The mean hospital VTE prophylaxis (SCIP-VTE-2) adherence rate was 94.51% (95% CI, 94.29% to 94.73%). The mean risk-adjusted PSI-12 VTE rate per 1000 discharges was 5.35 (95% CI, 5.24 to 5.45). SCIP-VTE-2 adherence was weakly correlated with hospital PSI-12 rates (r² = 4.2%; P = .03) (Figure 1) in the opposite direction than expected: hospitals with higher SCIP-VTE-2 adherence also had higher (not lower) PSI-12 rates.

Compared with hospitals with the lowest structural quality scores (lowest quartile; fewest characteristics reflecting quality), those with the highest ones (highest quartile; most characteristics reflecting quality) had significantly better performance on the SCIP-VTE-2 process measure (93.27% for lowest quartile vs 95.47% for highest quartile; P < .001) but paradoxically worse performance on the PSI-12 VTE outcome measure (4.77 per 1000 for lowest quartile vs 6.37 per 1000 for highest quartile; P < .001) (Figure 2; eTable 3 in the Supplement).

Assessment of VTE Imaging Use and Event Rates
Facilities in the Medicare sample were excluded that reported fewer than 10 total cases (n = 73 hospitals) or no VTE imaging studies during the study period (n = 445 hospitals; n = 9442 patients) (eTable 4 in the Supplement). Of the hospitals with no VTE imaging studies reported, 436 (98%) reported no VTE events. Thus, the analytic sample included 954,526 patients from 2786 hospitals (Table 1). Patient-level event rates were 0.99% for VTE, 0.56% for DVT, and 0.50% for PE. Overall, 8.82% of patients received some form of VTE imaging.

The mean VTE imaging rate in the quartile with the highest VTE imaging use was more than 5-fold that in the lowest quartile (167.05 vs 31.55 per 1000 discharges; P < .001) (Table 2). The mean unadjusted VTE rate in the quartile of hospitals with the highest VTE imaging use was 15.07 per 1000 discharges compared with 4.34 in lowest-quartile hospitals (P < .001).

Risk-adjusted VTE rates increased significantly in a stepwise fashion across VTE imaging use quartiles (Table 2). The mean risk-adjusted VTE rate in the lowest VTE imaging use quartile was 4.99 per 1000 discharges compared with 13.46 in the highest quartile (P < .001 trend and pairwise) (Figure 3A). The mean risk-adjusted DVT rate in the lowest DVT imaging use quartile was 1.79 per 1000 discharges compared with 9.14 in the highest quartile (P < .001 trend and pairwise) (Figure 3B). The mean risk-adjusted PE rate in the lowest PE imaging use quartile was 2.81 per 1000 discharges compared with 7.38 in the highest quartile (P < .001 trend and pairwise) (Figure 3C). Similar findings were observed when each of the 11 procedures was examined.
individually, except gastric bypass, which could not be modeled individually because of a very low VTE event rate.

Using quantile regression to characterize the association between VTE imaging rates and risk-adjusted VTE event rates, we found a positive association between imaging and VTE events across the distribution of VTE event rates. However, we found larger effects among hospitals with the highest VTE event rates (eTable 5 in the Supplement). For example, a unit change in VTE imaging rates increased the 25th quantile of risk-adjusted VTE by 0.025 (95% CI, 0.016-0.033) compared with 0.129 (95% CI, 0.102-0.156) for the 95th quantile and 0.457 (95% CI, 0.293-0.620) for the 99th quantile.

Four additional analyses were performed. First, publicly reported overall hospital risk-adjusted VTE rates from Hospital Compare increased across VTE imaging use quartiles (3.94 to 7.32 per 1000 discharges; \( P < .001 \)), and the proportion of hospitals with “worse than national rate” designations also increased across VTE imaging use quartiles (0.15% to 19.03%; \( P < .001 \)) (Table 2).

Second, because the findings could be due to sicker patients being treated at the highest VTE imaging use hospitals, the analysis was performed with additional patient-level covariates for risk adjustment than those specified for Agency for Healthcare Research and Quality PSI-12, but the association between hospital VTE imaging use and VTE rate persisted (eTable 6 in the Supplement).

Third, hierarchical models yielded a similar but slightly blunted relationship between VTE imaging rates and VTE event rates (eTable 6).

Fourth, although the findings could be affected by hospital variation in VTE prophylaxis use practices, mean hospital performance on VTE prophylaxis administration (SCIP-VTE-2) was not significantly worse in the highest VTE imaging use quartile (Table 2).

Discussion

Our results raise concerns about the validity of using VTE rates as a hospital quality metric. Instead of finding the expected relationship between higher VTE prophylaxis adherence rates and lower VTE events rates, we found that VTE prophylaxis rates were positively correlated with VTE event rates (\( I^2 = 4.2\%; P = .03 \)). A paradoxical relationship was also found between a measure of hospital structural characteristics reflecting quality and VTE event rates: hospitals with higher structural quality scores had better VTE prophylaxis adherence rates (93.3% lowest quartile vs 95.5% highest quartile; \( P < .001 \)), but they had unexpectedly higher risk-adjusted VTE rates (4.8 per 1000 lowest quartile vs 6.4 per 1000 highest quartile; \( P < .001 \)). Most important, hospital VTE rates were associated with the intensity of detecting VTE with imaging studies. Hospitals in the lowest quartile for VTE imaging rates obtained a mean of 32 studies per 1000 discharges, whereas those in the highest quartile obtained 167 imaging studies per 1000 discharges. Lowest imaging rate quartile hospitals diagnosed 5.0 VTEs per 1000 discharges, whereas the highest imaging rate quartile hospitals found 13.5 VTEs per 1000 discharges. These findings support the surveillance bias hypothesis, suggesting that VTE rates reflect the hospital staff’s vigilance in looking for postoperative VTE, not true quality of care.

Comparison of VTE Rates With Process and Structural Measures

Our results are consistent with those of 2 previous studies that did not find a relationship between better VTE prophylaxis adherence and lower VTE rates. Moreover, we found that better VTE prophylaxis adherence rates are weakly associated with

<table>
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<th>Data Sets and Characteristics</th>
<th>No. (%)</th>
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<tr>
<td>Hospitals from Hospital Compare and AHA Data Sets</td>
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</tr>
<tr>
<td>Hospital structural quality characteristics</td>
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<tr>
<td>Total bed size ( \geq 300 )</td>
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<td>Joint Commission accreditation</td>
<td>2428 (85.6)</td>
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<td>Commission on Cancer accreditation</td>
<td>1303 (45.9)</td>
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<td>ACGME accreditation</td>
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<tr>
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<tr>
<td>Burn services</td>
<td>130 (4.6)</td>
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<tr>
<td>Transplant services</td>
<td>381 (13.4)</td>
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<tr>
<td>Quality and cost reporting to community</td>
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<td>No. of structural “quality” characteristics, mean (SD) [range]</td>
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<td>Transfer status</td>
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<td>Type of surgery</td>
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<td>Abdominal aortic aneurysm repair</td>
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<tr>
<td>Colectomy</td>
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<td>Coronary artery bypass graft surgery</td>
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<td>Proctectomy</td>
<td>18 871 (2.0)</td>
</tr>
<tr>
<td>Total knee arthroplasty</td>
<td>480 965 (50.4)</td>
</tr>
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</table>

Inpatient events

| VTE | 9423 (0.99) |
| DVT | 5375 (0.56) |
| PE | 4792 (0.50) |

Imaging received

| VTE | 844 155 (8.82) |
| DVT | 58 244 (6.10) |
| PE | 36 065 (3.78) |

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; AHA, American Hospital Association; DVT, deep vein thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism.

* \( N = 2786 \) hospitals.
unexpectedly worse risk-adjusted VTE rates. Although this could be due to problems with the process measure, it suggests an issue with the VTE outcome measure, as would be expected if VTE measurement is subject to a surveillance bias.

We also found that hospitals with increasing numbers of structural quality characteristics (ie, larger hospitals with more accreditations and engagement in quality initiatives that typically suggest high-quality care) had better VTE prophylaxis (SCIP-VTE-2) adherence rates, as one would anticipate, given their increased resources and focus on quality; but they unexpectedly had higher VTE rates (PSI-12). These paradoxical findings suggest that the lack of an association between VTE process and outcome may more likely be due to problems with the VTE outcome measure, consistent with surveillance bias.

Assessment of VTE Imaging Use and Event Rates

The presence of a surveillance bias may explain the lack of expected correlations between VTE rates, VTE prophylaxis rates, and structural quality measures and is consistent with previous observations in trauma patients. A previous study found no differences in DVT rates for the lowest 3 quartiles of venous duplex ultrasonographic use were found, yet higher DVT rates in the highest quartile of venous duplex ultrasonography were observed. This study was limited by the quality of the self-reported data, reflected in that data from only 147 of 700 hospitals could be analyzed. To our knowledge, no previous studies have investigated surveillance bias outside the trauma patient population. Using Medicare claims data offered us more complete information on imaging and VTE event
rates across a broad, nationally representative sample of operations and hospitals.

The trauma patient population is unique because routine screening of asymptomatic patients for DVT is common at many trauma centers, but there is variation in the use and application of screening protocols. Surveillance bias might explain high VTE rates in trauma patients because routine screening in asymptomatic patients results in more screening tests, with correspondingly higher VTE event rates. Similarly, routine screening protocols have been used for orthopedics, neurosurgery, and bariatric patients and may contribute to higher VTE rates at hospitals using such practices. The significant association between surveillance imaging use and higher risk-adjusted VTE rates that we found when examining individual procedures, such as colorectal surgery, suggests that surveillance bias influences VTE rates for patients and procedures where VTE screening protocols are not generally used. Importantly, this indicates that there are differences in hospital practices or culture in regard to thresholds for ordering VTE diagnostic imaging studies in symptomatic patients.
Fifth, chest computed tomography and magnetic resonance imaging are performed for a variety of indications other than to evaluate a patient for PE. We could not ascertain why imaging tests were conducted from the Medicare data, so there is likely some error in assuming all the imaging tests for PE were truly for the evaluation of PE. However, surveillance bias was present in separate analyses of DVT in which indications for the imaging study, venous duplex, are specific.

Implications

Our study calls into question the merit of the PSI-12 VTE outcome measure as a quality measure and its use in public reporting and performance-based payments. Hospitals reported to have the highest risk-adjusted VTE rates may in fact be providing vigilant care by ordering imaging studies to ensure that VTE events are not missed. Patients selecting hospitals according to publicly available metrics may be misled by currently reported VTE performance. The measure could be counterproductive if a hospital performs poorly on the VTE outcome metric, expends efforts to improve VTE prophylaxis resulting in increased awareness and vigilance in looking for VTE, and then finds more VTEs and becomes an even worse performer on the VTE measure.

A quality metric affected by surveillance bias may have unintended consequences. Clinicians may change practice by using VTE surveillance imaging less frequently, ordering chemoprophylaxis in low-VTE-risk populations, and increasing prooperative inferior vena cava filter use. Alternatively, hospitals with higher VTE imaging rates may be overusing VTE imaging and detecting otherwise asymptomatic VTE, which leads to treatment with anticoagulants or IVC filters and could cause harm. Surveillance bias likely influences other quality metrics, and the possibility that it might perversely encourage the wrong practices should be carefully considered when quality metrics are developed.

Conclusion

Although there is considerable attention given to measuring and improving hospital VTE rates, our findings suggest that a surveillance bias influences the validity of VTE measurement. The publicly reported PSI-12 VTE outcome measure reflects the intensity of VTE imaging rather than actual quality of care and should likely not be used for accountability purposes in quality measurement.
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