

**EM ADVANCES**

# Is pretest probability assessment on emergency department patients with suspected venous thromboembolism documented before SimpliRED D-dimer testing?

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**ABSTRACT**

**Background:** The SimpliRED D-dimer assay is commonly ordered by emergency physicians for suspected pulmonary embolus or deep venous thrombosis. A pretest probability (PTP) assessment is required for the results of this diagnostic test to be interpreted correctly and applied appropriately. Without this assessment, the physician may misinterpret the test results and proceed to unnecessary diagnostic imaging (DI) or inappropriate discharge. Our objectives were to measure the documentation rate of PTP for emergency department (ED) patients on whom a SimpliRED D-dimer assay was performed for suspected venous thromboembolism (VTE) and to determine if the clinical management decisions that followed were in keeping with current recommendations.

**Methods:** In this medical record review, we used a random number generator to select 100 charts from all 760 patients who had a SimpliRED D-dimer performed during a 3-month period at an academic tertiary care centre with 3 EDs. Trained data abstractors, blinded to the study hypothesis, abstracted explicitly defined data from each chart. An independent abstractor assessed the reliability of 15 of the charts that were randomly chosen.

**Results:** Suspicion of VTE was documented in 97 of the 100 charts. There was no documentation of PTP assessment for 62 of the 97 cases. Ten had a positive D-dimer but 5 of these had no evidence of subsequent DI. Of the 97 charts reviewed, 24 documented decisions were in discordance with published clinical management recommendations for VTE.

**Conclusion:** In the majority of ED cases of suspected VTE, PTP assessment was not documented and approximately one-quarter of these documented decisions were in discordance with established recommendations for the given test results. This suggests that PTP assessments are not being conducted in a significant proportion of cases and the diagnostic test results are misinterpreted, applied incorrectly or both.

**Keywords:** pretest probability, emergency department, venous thromboembolism, SimpliRED D-dimer, medical record review

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Abstract presented orally at the CAEP Annual Assembly, Victoria, BC, June 2007, by Camala Smith.

Submitted Oct. 31, 2007; Revised July 20, 2008; Accepted July 24, 2008

*This article has been peer reviewed.*

CJEM 2008;10(6):519-23

**RÉSUMÉ**

**Contexte :** Les médecins d'urgence demandent couramment de faire le test de D-dimères SimpliRED en cas de suspicion d'embolie pulmonaire ou de thrombose veineuse profonde. Une évaluation de la probabilité clinique pré-test est nécessaire pour que les résultats de ce test diagnostique puissent être interprétés correctement et appliqués de façon appropriée. Sans cette évaluation, le médecin pourrait mal interpréter les résultats du test et procéder à des examens d'imagerie diagnostique inutiles ou donner au patient son congé alors qu'il ne devrait pas le faire. Nos objectifs étaient, d'une part, de mesurer les taux de consignation en dossier d'évaluation de la probabilité pré-test pour les patients à l'urgence chez qui un test de D-dimères SimpliRED a été réalisé en raison de soupçons de thromboembolie veineuse (TEV) et, d'autre part, de déterminer si les décisions relatives à la prise en charge clinique qui ont suivi étaient conformes aux recommandations actuelles.

**Méthodes :** Pour cette étude de dossiers médicaux, nous avons utilisé un générateur de nombres aléatoires pour choisir 100 dossiers de patients parmi ceux de 760 patients qui ont subi un test de D-dimères SimpliRED au cours d'une période de 3 mois à un centre hospitalier universitaire de soins tertiaires doté de trois médecins d'urgence. Des analystes de données qualifiés, travaillant à l'insu de l'hypothèse de l'étude, ont extrait de chaque dossier médical des données définies explicitement. Un analyste indépendant a évalué la fiabilité de 15 dossiers choisis au hasard.

**Résultats :** La suspicion de TEV a été documentée dans 97 des 100 dossiers examinés. Il n'y avait pas de preuves d'évaluation de la probabilité pré-test dans 62 des 97 cas. Dix ont obtenu un résultat positif au test de D-dimères, mais aucune preuve d'examen d'imagerie diagnostique subséquente n'a été repérée dans cinq cas. Dans 24 des 97 dossiers examinés, la décision relative à la prise en charge était non conforme aux directives cliniques.

**Conclusion :** Dans la majorité des cas de suspicion de TEV se présentant à l'urgence, l'évaluation de la probabilité pré-test n'a pas été consignée en dossier et environ un quart des décisions consignées en dossier relatives à la prise en charge de la TEV n'étaient pas conformes aux recommandations établies à cet égard. Cela donne à penser que dans un pourcentage important de cas, on n'évalue pas la probabilité pré-test et les résultats des tests diagnostiques sont mal interprétés, appliqués incorrectement, ou les deux.

**Introduction**

Deep venous thrombosis (DVT) is a common condition with a lifetime cumulative incidence of 2%–5% and, if untreated, can lead to a potentially fatal pulmonary embolism (PE).<sup>1</sup> Of the normotensive patients diagnosed with PE in the emergency department (ED), 3% die within 48 hours of diagnosis. Forty percent of survivors experience persistent pulmonary hypertension or right ventricular damage.<sup>2</sup>

The SimpliRED D-dimer (BBInternational) is a readily available, autologous red cell agglutination assay that uses a chemical conjugate of a monoclonal antibody specific to D-dimer, which is a fibrin degradation product. This test is a marker for the process of endogenous fibrinolysis, which is detectable in patients with DVT. Kline and colleagues<sup>2</sup> reported that D-dimer testing can result in a significant reduction in the use of ultrasonography for DVT. Moreover, Wells and coworkers<sup>3</sup> demonstrated that the combination of a pretest probability (PTP) score of less than 4 using their clinical prediction rule and a negative SimpliRED D-dimer result decreases risk for PE to an acceptable level, that is, to a level that allows safe discharge.

Our objectives were to measure the documentation rate

of PTP for ED patients on whom a SimpliRED D-dimer was performed for suspected venous thromboembolism (VTE) and to determine if the clinical management decisions by the clinicians were in keeping with current recommendations.

**Methods**

We conducted a medical record review at an academic tertiary care centre in Ontario with 3 EDs and a combined annual ED census of approximately 102 000. A single group of emergency physicians (EPs) provides EP coverage for all 3 EDs. This study was approved by the Research Ethics Board at Hamilton Health Sciences Corporation and McMaster University.

Sample size calculation was based on the desired precision of our primary outcome, which was the proportion of charts with documentation of the PTP. Assuming that the documentation rate was approximately 75% ( $\alpha = 0.05$ ) we determined that we would need to review 63 charts to produce a confidence interval (CI) about our estimate of the primary outcome that was not wider than 5%. The sample was increased to 100 to allow for an unknown proportion

of ineligible charts (i.e., D-dimer tests that were ordered for a reason other than suspected VTE).

We used a random number generator to select 100 charts from a list of all 760 patients who underwent SimpliRED D-dimer testing during a 3-month period. ED records were reviewed by 2 trained data abstractors using explicit criteria. They were blinded to the study's objectives. A priori exclusion criteria were as follows: the D-dimer assay was performed for an indication other than VTE, that is, the presenting complaint, documented history or physical exam were inconsistent with suspected VTE, the ED record was unavailable or both.

The following data were abstracted from the ED records:

- Presenting complaint: patient's initial presentation was recorded to determine suspicion of VTE.
- PTP assessment: the ED record was searched for a score, list of criteria, statement of VTE risk or any other evidence of PTP assessment using the Wells or other criteria for either DVT or PE.
- D-dimer testing: the orders were reviewed to confirm that the EP ordered the D-dimer. We also recorded the results of the test as negative or positive.
- Follow-up: any diagnostic imaging (DI) for VTE.

Data was entered into a study-specific Microsoft Access

form (Microsoft Corp.) with drop-down menus for all data fields to minimize transcription errors in data entry.<sup>4</sup>

The performance of data abstractors was assessed by a third individual who reviewed a random sample of 15 cases that were included in the study. We intended to resolve differences by consensus and then, if necessary, by arbitration. We calculated the inter-rater reliability of the 2 data abstractors and, if there was less than 100% agreement, they were reported as a  $\kappa$  coefficient with 95% CIs. All other measures are reported as frequency counts and percentages with 95% CIs.

## Results

Of the 100 randomly selected ED records of SimpliRED D-dimer tests ordered, 3 charts were excluded because the reason for D-dimer testing was not VTE (Fig. 1). This left a total of 97 cases for inclusion in the final analyses. Inter-rater reliability assessment of 15 of the 97 randomly chosen records revealed 100% agreement between the data abstractors. The results of the review revealed that a total of 35 (36%, 95% CI 26.5%–45.6%) cases had documented evidence of PTP assessment using the Wells or other criteria for either DVT or PE. There was no documented evidence

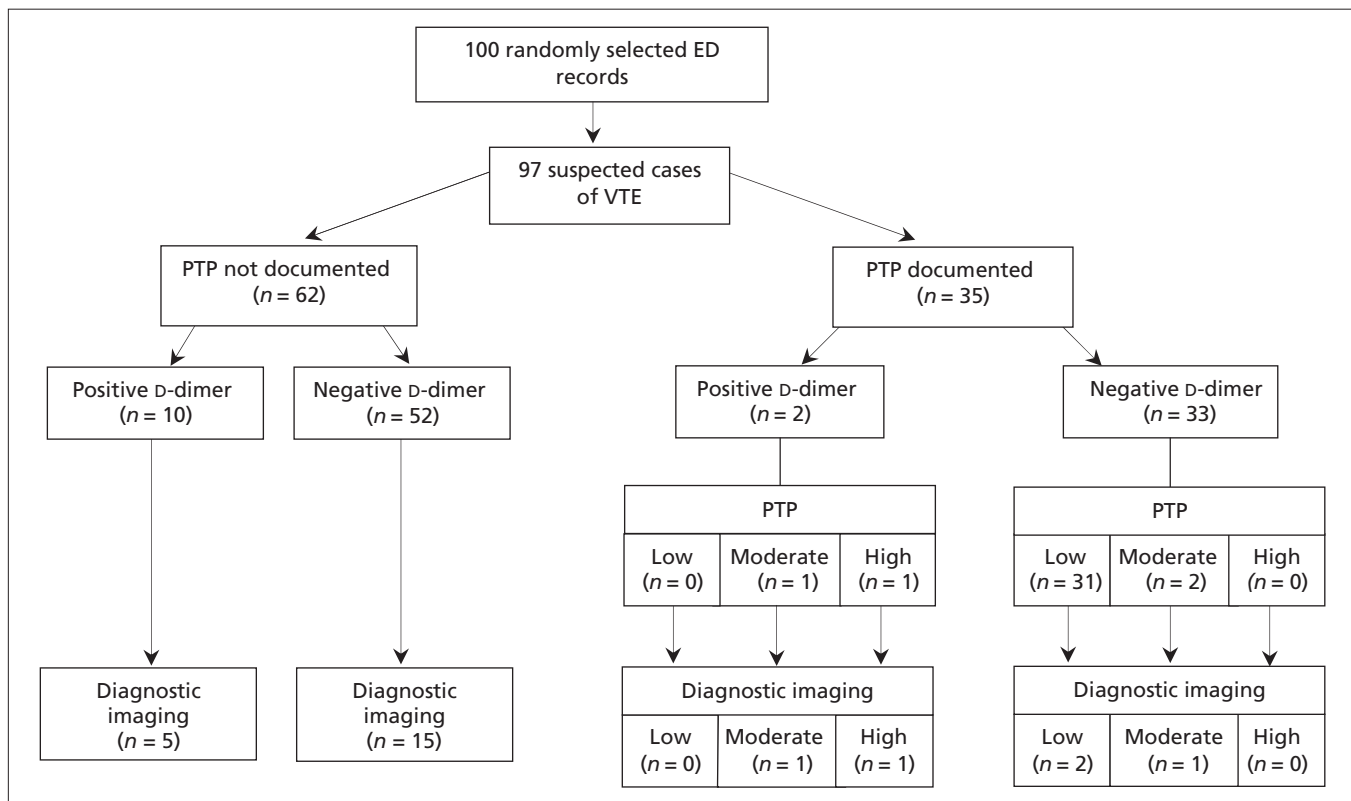


Fig. 1. Recorded pretest probability (PTP) and subsequent diagnostic testing. ED = emergency department; VTE = venous thromboembolism.

of PTP assessment in the charts of the remaining 62 (64%, 95% CI 53.4%–72.6%) cases. The documented management of 24 of the 97 cases (25%, 95% CI 16.2%–33.3%) was in discordance with current recommendations (Table 1).

## Discussion

Our study revealed that PTP was documented in only 35 of 97 charts of ED patients with suspected VTE. This was considerably lower than our estimated 75% rate of documentation. Our finding that 24 of the 97 charts documented care that was in discordance with the clinical decision guidelines suggests that either the assay was not being used as recommended or the results of the assay were being misinterpreted. In 19 of the 24 cases, management in discordance with recommended guidelines resulted in potentially inefficient care. In 15 of those cases, no PTP was calculated. Despite a negative D-dimer, all 15 cases had DI performed. Depending on whether the PTP result would have been high- or low-risk, either the SimpliRED D-dimer or DI, respectively, was overused. In 3 cases, DI was performed despite documentation of a low or moderate PTP and a negative D-dimer. One case with a documented high-risk PTP did not require a D-dimer test and, instead, should have proceeded directly to DI. More worrisome is the fact that in 5 of the 24 cases, the discordant management was potentially harmful to the patients, since positive D-dimer results were not followed with DI.

The failure to comply with clinical management recommendations may be justifiable if alternative diagnoses are identified during the investigation. However, studies of the incidence of PE in patients who are admitted with chronic obstructive pulmonary disease demonstrate that even in the setting of an alternative diagnosis, the prevalence of PE can be as high as 25%.<sup>5</sup>

Several studies have shown the D-dimer assay to have a negative predictive value<sup>6,7</sup> as high as 99.5% in patients with low PTP.<sup>8</sup> This method was used in Wells and colleagues<sup>11</sup> clinical outpatient study and was found to be

effective in ruling out VTE when combined with PTP assessment. Goldstein and colleagues<sup>9</sup> showed that when the D-dimer assay was used as a screening tool without a PTP assessment, it actually increased use of DI. More importantly, it can lead to the premature discharge of patients at high risk for VTE. Wells and coworkers<sup>3</sup> further demonstrated that a PTP score of less than 4 using their clinical prediction rule combined with a negative SimpliRED D-dimer indicated a lower risk for PE to a level that would allow for safe discharge.

In a recent survey, 68% of respondents reported being familiar with at least 1 of 2 clinical prediction rules for PE.<sup>10–12</sup> This same survey also identified reasons why physicians do not apply clinical prediction rules for suspected VTE. The reasons listed were medicolegal concerns, difficulty remembering and applying the rule, a belief that clinical gestalt is better and the respondents' belief that none of the rules have been validated to their satisfaction.<sup>12</sup> Regardless of the reason, 40% of the inappropriate diagnostic strategies are at least partially related to physicians not properly factoring clinical probability into their diagnostic decision.<sup>13</sup>

## Limitations

The greatest limitation of this study is that the absence of a recorded result does not preclude the possibility of PTP being calculated. However, some clinical information relating to the PTP would normally be recorded on the ED chart of a patient with suspected VTE and, as stated in our methods, we accepted a score, list of criteria, statement of VTE risk or any other evidence of PTP assessment using the Wells or other criteria for either DVT or PE. Since this study was completed at a single academic centre, our findings might not be readily generalized to other EDs. Although many of the patients in this study were seen by junior house staff, who were not necessarily familiar with the role of the SimpliRED D-dimer in the investigation of suspected VTE, the ordering of these tests was supervised by staff physicians. A final limitation, common to all retro-

**Table 1. Twenty-four cases managed in discordance with recommendations**

No. of patients	PTP assessment	PTP result	D-dimer result	DI performed	DI recommended	D-dimer recommended
5	No	—	Positive	0/5	Yes	—
1	Yes	High	Positive	1/1	—	No
3	Yes	2 low, 1 moderate	Negative	3/3	No	—
15	No	—	Negative	15/15	No, if low–moderate PTP	No, if high PTP

DI = diagnostic imaging; PTP = pretest probability.

spective studies, is the missing data. This was primarily due to illegible charts and may have led to under-reporting of pretest calculation for a small number of charts.

## Conclusion

PTP was not documented in the majority of ED cases of suspected VTE. Approximately 25% of these charts documented management that was in discordance with established recommendations for the investigation of suspected VTE. This suggests that PTP assessments are not being conducted in a significant proportion of cases and the diagnostic test results are misinterpreted, applied incorrectly or both. Therefore, future studies might best serve ED patients by identifying methods to improve EP compliance with recommended diagnostic strategies.

**Competing interests:** None declared.

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