SimpliRED D-dimer assay did not rule out venous thromboembolism in the emergency department


**Question**
Can a negative test result using the SimpliRED D-dimer assay rule out venous thromboembolism (VTE) in patients who present to the emergency department with suspected deep venous thrombosis (DVT) or pulmonary embolism (PE)?

**Design**
Blinded comparison of D-dimer assay results with the diagnostic standard of compression ultrasonography for DVT and ventilation perfusion scintigraphy and pulmonary angiography with lower-extremity ultrasonography as needed for PE.

**Setting**
Emergency department of a tertiary care hospital in Portland, Maine, United States.

**Patients**
198 consecutive patients (mean age 55 y, 59% women) were screened, and 173 were included. The inclusion criterion was being considered at high risk for VTE (DVT or PE).

**Description of Test and Diagnostic Standard**
D-dimer assays were done on a citrated blood sample in the laboratory using the SimpliRED assay kits; any agglutination was considered to be a positive test result. Proximal DVT was diagnosed with compression ultrasonography of the common femoral, superficial femoral, or popliteal vein. PE was diagnosed using a high-probability ventilation perfusion scan, positive findings on pulmonary angiography, or positive findings on lower-extremity ultrasonography. VTE was considered to be present if a new diagnosis was made or if an unexplained death occurred within 1 month after initial nondiagnostic test results.

**Main Outcome Measures**
Sensitivity and negative likelihood ratio of D-dimer assay for VTE, DVT, and PE.

**Main Results**
57 patients (33%) had VTE (16 patients had DVT, and 41 had PE). 8 patients (5%) died during follow-up. The sensitivities for VTE, DVT, and PE were not high: The SimpliRED D-dimer assay did not rule out VTE, DVT, or PE. For the 26 patients who had pulmonary angiography, the sensitivity for PE using D-dimer assay results was also low (50%, 95% CI 10% to 90%).

**Conclusion**
In patients at high risk for venous thromboembolism who presented to the emergency department, the SimpliRED D-dimer assay did not rule out deep venous thrombosis or pulmonary embolism.

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<tr>
<th>Disorder</th>
<th>Sensitivity (95% CI)</th>
<th>–LR (95% CI)</th>
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<tbody>
<tr>
<td>Venous thromboembolism</td>
<td>65% (53 to 77)</td>
<td>0.47 (0.32 to 0.68)</td>
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<tr>
<td>Deep venous thrombosis</td>
<td>56% (32 to 81)</td>
<td>0.61 (0.34 to 1.11)</td>
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<tr>
<td>Pulmonary embolism</td>
<td>60% (54 to 83)</td>
<td>0.42 (0.26 to 0.66)</td>
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*Abbreviations defined in Glossary.

We believe that physicians should not use D-dimer testing to exclude VTE unless the following criteria are met. First, extensive evidence must exist to confirm high sensitivity, negative predictive value, and reproducibility for the specific assay under consideration in appropriate patients (outpatients with few or no comorbid conditions). Second, institutions considering adopting a specific assay should carefully standardize their technique and, ideally, evaluate its performance characteristics in their center. Third, the test should be incorporated into a well-validated diagnostic algorithm that is uniformly used by all clinicians who order the test.

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References