A negative quantitative latex D-dimer assay helped to rule out venous thromboembolism

Bates SM, Grand'Maison A, Johnston M, et al. **A latex D-dimer reliably excludes venous thromboembolism.** Arch Intern Med. 2001 Feb 12;161:447-53.

QUESTION

In patients with suspected venous thromboembolism (VTE) (i.e., deep venous thrombosis [DVT] or pulmonary embolism [PE]), can a quantitative latex D-dimer assay rule out VTE?

DESIGN

Blinded comparison of the results of the latex D-dimer test (MDA D-Dimer, Organon Teknika Corporation, Durham, NC, USA) with objective testing done at presentation and during follow-up (3 mo).

SETTING

4 tertiary-care university medical centers in Ontario, Canada.

PATIENTS

595 patients (60% women) with suspected VTE (317 with suspected DVT and 278 with suspected PE).

DESCRIPTION OF TESTS AND DIAGNOSTIC STANDARD

All patients had a clinical examination and were classified into low-, intermediate-, or high-probability categories according to a previously validated model. Patients with suspected DVT or PE were tested objectively by using 1 of several validated algorithms. All patients without objective evidence of DVT or PE at presentation were followed for 3 months. Those with symptoms of VTE during follow-up were tested objectively to confirm or exclude the diagnosis.

MAIN OUTCOME MEASURES

Sensitivity and specificity of D-dimer test results for VTE, DVT, and PE.

MAIN RESULTS

The prevalence of VTE was 19%. 21% of patients with suspected DVT were DVT-positive, and 17% of patients with suspected PE were PE-positive. Positive D-dimer test results had poor likelihood ratios (1.3 to 2.2); thus, a positive test result was not helpful for ruling in VTE. Negative test results had low likelihood ratios (0.0 to 0.25), making them useful for ruling out VTE, especially in patients with low or intermediate pretest probabilities (Table).

CONCLUSION

A negative MDA latex agglutination D-dimer test result helped to rule out venous thromboembolism (deep venous thrombosis or pulmonary embolism) in patients with suspected venous thromboembolism.

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Characteristics of D-dimer test for suspected venous thromboembolism (VTE) (deep venous thrombosis [DVT] or pulmonary embolism [PE]) for varying pretest probabilities (PPs)*

Disease	PP	Patients	Sensitivity (95% CI)	Specificity (CI)	+LR	–LR
VTE	All	All	96% (90 to 99)	45% (40 to 49)	1.8	0.09
	Low	All	100% (74 to 100)	54% (47 to 61)	2.2	0.0
	Intermediate	All	96% (86 to 100)	40% (36 to 46)	1.6	0.10
	High	All	93% (82 to 99)	28% (14 to 44)	1.3	0.25
	All	Cancer	97% (82 to 100)	46% (30 to 63)	1.8	0.07
DVT	All	All	97% (89 to 100)	47% (40 to 53)	1.8	0.06
PE	All	All	94% (83 to 99)	42% (36 to 40)	1.6	0.14

*Diagnostic terms defined in Glossary; +LRs calculated from data in article.

COMMENTARY

Diagnosis of VTE is still a challenge in current clinical practice. The hazards of this difficult diagnosis include underdiagnosing VTE with possibly fatal consequences, prescribing anticoagulants to a patient who does not have VTE, and ordering a series of expensive tests that are not useful. The clinical goal is to use a rapid, accessible, and inexpensive test that confidently rules out VTE. The study by Bates and colleagues shows that a negative quantitative D-dimer test alone can rule out VTE in some patients, especially those with a low clinical probability of the disease. Although previously validated (1, 2), one could argue that this method of clinical stratification into low, moderate, and high probability of VTE is still somewhat subjective, and a repeat study could give different results in other clinical practices. Despite this restriction, the value of the test in the mixed group of patients with low or moderate pretest probability of VTE remains clinically useful (sensitivity 97%, specificity 46%, +LR 1.8, and –LR 0.07). Although mentioned, the economic consequences of the D-dimer assay have not been fully assessed. Finally, other D-dimer assays have proved efficient in clinical practice but only in smaller groups of patients (3).

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