

Heather Justice MD
Journal Club Aug. 2006

PICO:

P: In patients with low Pre test probability for PE undergoing D-dimer

I: Does the use of a range of values below negative i.e. 0.5

C: Compared to any value considered negative i.e. 1.2 mcg/ml

O: Significantly change the sensitivity of the test.

In patients with low risk for PE does choosing various cutoffs for d dimer change the sensitivities i.e. cut of 0.5 mcg/ml vs 1.2mcg/ml

Questions to be answered:

What is low risk for PE ?

Wells Criteria

Wicki Criteria (Geneva Rule)

Charlotte Rule

D dimer tests:

Qualitative

Tinaquant *

ELISA

Author, date and country	Patient group	Study type (level of evidence)	Outcomes	Key results	Study weaknesses
Christopher study group 2006 USA	3503 Consecutive patients presenting to the ER with suspected VTE 2206 low PTP	Prospective	VIDAS 428/968 Tinaquant 629/1238 had neg d dimer with low PTP	NPV for Tinaquant 99.2%	No Sen./Spec noted
Diamond S et al 2005 USA	149 patients with suspected DVT	Prospective	129/148 had neg D-dimer Tinaquant 0.5mcg/ml and Neg ultrasound for DVT	Sen. 100% Spec. 48.8% NPV 100%	Evaluating for DVT not PE, no PTP indicated
Curtin N et al 2004 USA	512 with suspected VTE	Retrospective review	483/511 had neg w/u for VTE with level	Tinaquant d-d-dimer 100 % sensitive at level of 0.237	Unable to view entire article. No PTP noted

			of 0.237 mcg/ml having 100 % Sen.	mcg/ml	
Perrier A et al, 1997 Switzerland	671 consecutive ER patients with suspected PE	prospective	197/198 with neg d dimer no PE at 3 month follow up.	D dimer (ELISA) 99.5% sensitive at 0.5 mcg/ml. 93% Spec with cutoff 4000 mcg/L	Not same test as in our population No PTP noted
Le Gal G et al, 2006 France	1721 consecutive ER patients with suspected PE Sub categorized into 308 with history of VTE	Retrospective review of 2 studies	415/1719 pts without history of VTE had neg D dimer and 49/308 with history of VTE had neg D dimer	ELISA 100 % sensitivity with or without history of VTE at 500 mcg/L but less chance of being neg	Small sample No PTP
de Monye W et al, 2002 Netherlands	287 in and outpatients with clinically suspected PE	prospective	For a 95 % Sensitivity Tinaquant 0.18 mcg/ml and ELISA 250 ng/ml	ELISA Sen./Spec 88%/52% and TINAQUANT 82%/61%	No pre test probability
Kruip MJ et al, 2002 Netherlands	234 Consecutive patients with clinically suspected PE	prospective	60/120 patients with low PTP had neg d dimer	ELISA 98 % sensitive in patients with Low PTP	No note of what was used to determine PTP
Righini M et al, 2004 Switzerland	1409 ER patients evaluated for PE with evaluation at different levels of D dimer	Retrospective review of two studies	Sensitivity 100% in all clinical probability# catatogories	ELISA 100 % sensitivity at 500 mcg/L In patients with low clinical probability 93 % Sen. at 700 mcg/L and 77% Sen. at 1000mcg/L	Poor assessment of clinical probabilities

*Lower Limb Venous Compression Ultrasonography

Probability based on History and PE in one study and Geneva score with clinical override in the other.

Conclusion: In evaluating patients suspected of VTE with low probability of VTE based on the clinical decision rule (Wells criteria) the use of D dimer (Tinaquant or VIDAS) at a value of 0.5 mcg/ml essentially rules out VTE with 99-100% NPV.

References:

Christopher study writing group. Effectiveness of managing suspected pulmonary embolism using an algorithm combining clinical probability, d-dimer testing, and computed tomography. *JAMA* 2006;295:172-179.

Diamond S, Goldweber R, Katz S. Use of D-dimer to aid in excluding deep venous thrombosis in ambulatory patients. *Am J Surg* 2005 Jan;189(1):23-26.

Curtin N, Highe G, Harris M, et al Extensive evaluation of the instrumentation laboratory IL test D-Dimer immunoturbidimetric assay on th ACL 9000 determines the D-Dimer cutoff value for reliable exclusion of venous thromboembolism *Lab Hematol* 2004;10(2):88-94.

Perrier A, Desmarais S, Goehring C, et al. D-dimer testing fro suspected pulmonary embolism in outpatients. *Am J Respir Crit Care Med* 1997 Aug;156(2 pt 1) 492-6.

Le Gal G, Righini M, Roy PM, et al. Value of D-dimer testing for the exclusion of pulmonary embolism in patients with previous venous thromboembolism. *Arch Inter Med* 2006 Jan 23;166(2) 176-80

Righini M, Aujesky D, Roy PM, et al. Clinical usefulness of D-dimer depending on the clinical probability and cutoff value in outpatients with suspected pulmonary embolism. *Arch Intern Med* 2004 Dec 13-27;164(22):2483-7

Kruij MJ, Slob MJ, Schijen JH, et al. Use of a clinical decision rule in combination with D-dimer concentration in diagnostic workup of patients with suspected pulmonary embolism: a prospective management study. *Arch Inter Med* 2002 Jul 22;162(14):1631-5

de Monye W, Sanson BJ, Buller HR, et al. The performance of two rapid quantitative D-dimer assays in 287 patients with clinically suspected pulmonary embolism. *Thromb Res* 2002 Sep 15;107(6)283-6.