Critical Review Form
Diagnostic Test

A Rapid Bedside D-Dimer Assay (Cardiac D-Dimer) for Screening of Clinically Suspected Acute Aortic Dissection, *Circ J* 2005; **69:** 397 –403

Objectives: **"To show the utility of rapid bedside DD (D-dimer) assay in the detection of AAD (acute aortic dissection). The second goal was to clarify whether positive predictive value could be increased if the rapid bedside DD value and blood pressure reading upon admission were used in combination". (p. 397)**

Methods: **Consecutive patients admitted to the Nippon Medical School (Tokyo, Japan) Coronary Care Unit from November 2002 through June 2004 were eligible if AAD was suspected. AAD was suspected in patients with sudden onset of chest and/or back pain and no definitive ECG findings of AMI. AAD was diagnosed by contrast enhanced CT. DD levels were measured by rapid bedside assay (based on antigen-antibody reaction and diode read). In the reference group, the DD was simultaneously measured by means of a second generation latex agglutination assay. Additionally, investigators assessed the diagnostic accuracy of SBP > 150 mmHg or SBP > 180 mmHg in isolation or in combination with bedside DD.**

The reference group was composed of those with thoracic or abdominal aneurysm, as well as those with unstable angina, AMI, gastritis, PE, atrial fibrillation and undifferentiated chest pain syndromes. Abnormal D-dimer was > 0.5 µg/mL. Investigators used a Bonferroni correction for multiple comparisons.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did clinicians face diagnostic uncertainty?**	Yes. "Consecutive patients in whom AAD was suspected or not ruled out, who were admitted to the cardiac care unit". (p. 397)
B.	**Was there a blind comparison with an independent gold standard applied similarly to the treatment group and to the control group?** **(Confirmation Bias)**	Although not clearly stated all patients presumably underwent CT scans but the authors do not state who interpreted the CT or whether that individual was blinded to the D-dimer result.

C.	**Did the results of the test being evaluated influence the decision to perform the gold standard?** **(Ascertainment Bias)**	Uncertain because the authors do not state whether clinicians or investigators were blinded to the D-dimer result.
II.	**What are the results?**	
A.	**What likelihood ratios were associated with the range of possible test results?** **<u>D-dimer alone (see 2x2 table to right)</u>** **Sensitivity = 100% (95% CI 91-100)** **Specificity = 54% (95% CI 48-54)** **LR^+ = 2.2 (95% CI 1.7-2.2)** **LR^- = 0 (95% CI 0-0.2)** **<u>D-dimer & sBP > 180 (see 2x2 table to right)</u>** **Sensitivity = 40% (95% CI 29-45)** **Specificity = 96% (95% CI 89-99)** **LR^+ = 9.6 (95% CI 2.7-37)** **LR^- = 0.6 (95% CI 0.56-0.79)**	• 78 patients (46 male, median age 68) including 30 with acute aortic dissection presenting median 4.5 h after symptom onset. • Results of bedside assay correlated well with the latex agglutination. • Time from onset of symptoms was <1 h in two patients with AAD and both had D-dimer levels > 0.5 µg/mL. • No differences were noted in D-dimer level between Type A or B dissections, thrombosed or patient dissection. • Bedside D-dimer > 0.5 µg/mL had sensitivity 100%, specificity 54% for AAD. When combined with systolic BP > 180 mmHg sensitivity 40% and specificity 96% (2x2 tables below respectively, diagnostic test characteristics to left). CT+ CT- D-dimer >0.5 30 22 D-dimer <0.5 0 26 --- CT+ CT- D-dimer >0.5 and SBP ≥180 12 2 D-dimer <0.5 and/or ≥180 18 46

III.	How can I apply the results to patient care?	
A.	**Will the reproducibility of the test result and its interpretation be satisfactory in my clinical setting?**	Uncertain - need to assess among ED patients with suspected dissection. The current CCU-based population almost certainly is a spectrum bias.
B.	**Are the results applicable to the patients in my practice?**	Uncertain – these are CCU patients. Likely sicker with less signal to move ratio.
C.	**Will the results change my management strategy?**	Not based on this study, but certainly D-dimer for AAD worth further evaluation.
D.	**Will patients be better off as a result of the test?**	Yes, if these findings are validated on EM patients. "In cases that a rapid assay shows no DD level elevation, we can rule out AAD promptly and we can spare the time for unnecessary enhanced CT which (can) impair renal function". (p. 402)

Limitations

1) **Failure to reference or use STARD criteria for reporting diagnostic research findings.**
2) **Uncertain external validity or reproducibility of reference group. CCU patients differ in illness severity and disease spectrum from general ED chest pain patients. Clinical suspicion of AAD may also differ significantly between clinicians.**
3) **Failure to report 95% around sensitivity and specificity or to report LR's at all.**
4) **Failure to blind clinicians or outcome assessors (Radiologists) to D-dimer results.**
5) **Failure to declare that all patients had CT.**
6) **No exclusion criteria stated. What about renal failure, contrast allergy or known aneurysm?**
7) **No assessment of patient important outcomes (survival, QOL).**
8) **No statement of training or inter-rater reliability assessment for bedside test.**

Bottom Line

Small single-center Japanese CCU based study demonstrating excellent sensitivity of bedside D-dimer > 0.5 µg/mL in distinguishing acute aortic dissection from other chest pain syndromes. Future research should assess the reliability of bedside D-dimer among more general ED chest pain patients while also assessing D-dimer diagnostic test performance among patients stratified as low or intermediate risk for AAD.