

Vcheck D-dimer test kit performance comparison and clinical efficacy evaluation

Key Words: BIONOTE, Vcheck, D-dimer, DIC, Thromboembolism, Coagulation

Evaluated by 'H' Referral Animal Hospital Small Animal Clinical Research in Korea

Introduction

D-dimers result only from the degradation of cross-linked fibrin, and in contrast to other degradation products, they are specific for active coagulation and fibrinolysis. Several preliminary veterinary studies have shown promise for using D-dimer to screen for DIC and thromboembolic disease prior to overt DIC. Likewise, D-dimer is highly sensitive for the diagnosis of thromboembolic disease. A sensitive D-dimer assay may essentially rule out thromboembolism if negative.

Purpose

The objective of this study was to evaluate the correlation between Vcheck D-dimer and commercially available D-dimer measurement methods (NycoCard™ or Mindray™ (BS390)), and to evaluate the clinical efficacy in patients with heart valve disease, tumor, systemic inflammation, hormonal disease, immune-mediated disease, protein-losing enteropathy and patients with suspected symptoms of thrombosis.

Materials and Methods

Material

- Blood samples were collected from 50 patients with heart valve disease, tumor, systemic inflammation, hormonal disease, immune-mediated disease, and protein-losing enteropathy, and patients with suspected symptoms of thrombosis.
- The vet determined whether the D-dimer test was necessary, considering comprehensive results, such as patient's history, medical examination and blood testing.

Method

- Tests were performed using Vcheck D-dimer and another commercial test kit (NycoCard™) according to the manufacturer's instruction. If there was a difference between the two test results, an additional D-dimer test (Mindray™ (BS390)) was conducted (Table 1).

Table 1. Normal range of the D-dimer tests for different analyzers

Equipment or test reagents	Normal range
Vcheck D-dimer	< 0.3 µg/ml
NycoCard™	< 0.3 µg/ml
Mindray™ (BS390)	< 0.5 µg/ml

Results

- In a total of 49 samples (one sample was excluded due to test error), Vcheck and NycoCard™ showed 93.9% (46 cases) of coincidence, and showed a correlation of $R^2 = 0.854$ (Figure 1).
- There were 12 samples (24.5%) with a difference of 0.2 µg/ml or more, or a difference in interpretation. A total of 3 samples produced inconsistencies in the interpretation of the results, two of which (sample no. 6 and 15) found that normal levels of Vcheck were more helpful for diagnosis, and in the remaining other case (sample no. 33), both results were considered possible (Table 2).

D-dimer results from Mindray™ (BS390) in samples with inconsistent results

- The comparison using Mindray™ was conducted on four samples (No.36, 44, 47, 48), and it was confirmed that all four cases were abnormal and the same analysis was performed on all three analyzers. Mindray™ showed the highest measurements on three samples (No.36, 44, 47), while Vcheck result was the highest on No.48 (The patient died the next day after the last visit).
- Considering the normal range of Mindray™ (< 0.5 µg/ml), the measured value is expected to show the highest tendency, but the highest measured value of Vcheck on No.48 can be interpreted to be the most consistent with the progression of the patient's symptoms.

Conclusion

- There was a high correlation (93.9%, $R^2=0.854$) of D-dimer between Vcheck and NycoCard™.
- In the cases with inconsistent interpretation of results, or with a difference in measurement values of 0.2 $\mu\text{g/ml}$ or more, most measurements from the Vcheck were more useful in the light of the vets' opinion.
- Considering the comprehensive test results and the condition of the patients, Vcheck D-dimer results were considered to be clinically more useful for diagnosing and predicting prognosis.
- Rather than relying on absolute values for measured values above the normal range, it is considered to be a more important criterion for determining the reliability of an analyzer by looking at whether the measured values decrease as the symptoms of patients improve.

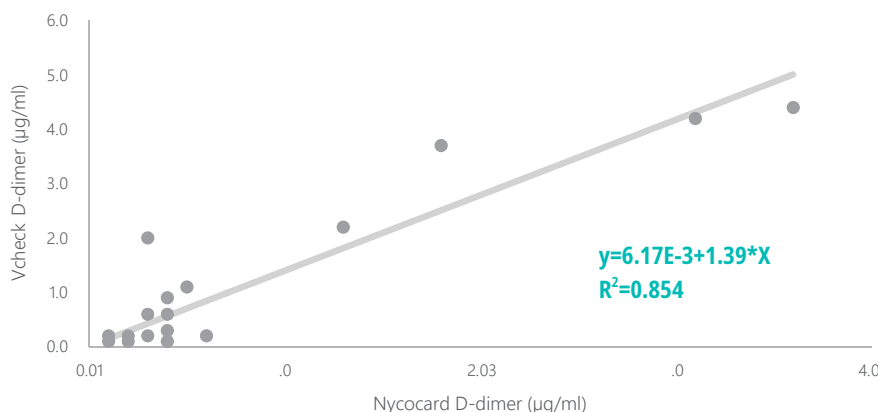


Figure 1. Correlation of Vcheck D-dimer with NycoCard™ in canine plasma samples (N=49)

Table 2. Clinical cases showing a difference of 0.2 $\mu\text{g/ml}$ or more, or a difference in interpretation, which Vcheck D-dimer results are considered to be clinically more useful

Sample No.	Main Symptom	Diagnosis	D-dimer			The reason the Vcheck D-dimer results are considered to be clinically more useful
			Vcheck ($\mu\text{g/ml}$)	NycoCard™ ($\mu\text{g/ml}$)	Mindray™ ($\mu\text{g/ml}$)	
6	cough	normal	< 0.1	0.4	Not tested	Considering the comprehensive test results and the condition of the patients, it is considered that the result within normal range was more helpful for the diagnosis.
12	ascites, dyspnea	cardiac tamponade	0.4	3.2	Not tested	Since the patient is expected to have a rise in D-dimer, both 3.2 and 0.4 are possible, but a value of 3.2 is thought to be an error as the laboratory reported clots were found in the sample.
15	weight loss, lethargy	pancreatitis, renal failure	0.2	0.6	Not tested	Although the patient had gastroenteritis and pancreatitis, the CRP was within the normal range and there were no significant intestinal symptoms. The D-dimer normal result was considered to be more useful for clinical diagnosis.
26	lethargy, anorexia	bacterial endocarditis, non-regenerative anemia	0.6	0.3	Not tested	Considering the stage of SIRS progression in this patient, a high D-dimer level was considered to be helpful in clinical diagnosis and treatment.
48	liver hypertrophy, anemia	gall bladder sludge, hepatitis, renal cyst	2.0	0.3	1.94	In this case, the patient died a day after visiting. Considering this outcome, the higher D-dimer is considered to be helpful for diagnosis and treatment.

Reference

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