

Diagnostic performance of AQT90 FLEX D-Dimer in patients suspected for deep venous thrombosis - comparison with four well-established D-Dimer tests

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Background

The AQT FLEX platform is an integrated point-of-care test system aimed for acute determination of markers of congestive heart disease, acute myocardial infarction, infection, coagulation and pregnancy using a single whole blood sample. The AQT90 FLEX D-Dimer is a novel time-resolved fluorescence based assay for quantification of D-Dimer in human whole blood or plasma. The present clinical study is the first to establish the diagnostic performance of the AQT90 FLEX D-Dimer test and to compare the performance of the test with four well-established D-Dimer assays.

Patients

We included 170 consecutive patients suspected for DVT in the study. Phlebography was positive in 64 patients (22 distal and 42 proximal) while 106 phlebograms were normal. The area under the ROC curves (AUC), the negative and positive predictive values (NPV, PPV) and the sensitivity and specificity of the five tests were calculated and compared.

Methods

The plasma concentration of D-Dimer was determined with

- AQT90 FLEX D-Dimer (Radiometer Medical, Copenhagen, Denmark)
- Auto-Dimer (Biopool, Umeå, Sweden)
- Liatest D-Di (Diagnostica Stago, Asnières-sur-Seine, France)
- Vidas New (Biomérieux, Marcy-l'Etoile, France)
- AxSYM D-dimer (Axis-Shield, Dundee, UK)

Results

The ROC-curves of the five D-Dimer tests for all patients are shown in Fig. 1. The AUCs according to the location of DVT are presented in Table 1. The NPV, PPV, sensitivity and specificity of the D-Dimer assays are presented in Table 2.

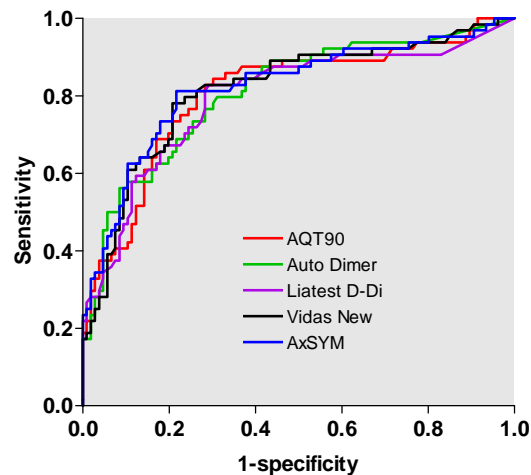


Fig. 1. ROC curves for all patients included

Conclusions

- The AQT90 FLEX D-Dimer test demonstrates excellent performance when used in the diagnosis of DVT.
- The NPV and ROC of AQT90 FLEX D-Dimer demonstrate diagnostic performance comparable to established D-Dimer assays.
- The PPV and specificity of AQT90 FLEX D-Dimer test are superior to the other tests investigated.

Table 1. The area under the ROC-curves (AUC) of the D-Dimer assays according to the location of DVT.

Assay	DVT	AUC (95%CI)*
AQT90	All	0.81 (0.74-0.88)
	Proximal	0.92 (0.87-0.96)
	Distal	0.60 (0.46-0.74)
Auto-Dimer	All	0.81 (0.74-0.88)
	Proximal	0.91 (0.87-0.96)
	Distal	0.62 (0.48-0.75)
Liatest D-Di	All	0.80 (0.72-0.87)
	Proximal	0.91 (0.86-0.95)
	Distal	0.58 (0.44-0.73)
Vidas New	All	0.82 (0.75-0.89)
	Proximal	0.92 (0.87-0.96)
	Distal	0.62 (0.49-0.76)
AxSYM	All	0.82 (0.75-0.89)
	Proximal	0.93 (0.89-0.97)
	Distal	0.63 (0.48-0.77)

*No significant differences were observed between the AUCs of the D-Dimer assays for all DVT, proximal DVT or distal DVT.

Table 2. The NPV, PPV, sensitivity and specificity of the D-dimer assays according to the location of DVT.

Assay (cut-off)	DVT	NPV	PPV	sens	spec
AQT90 (0.50 mg/l)	All	87	63	83	71
	Proximal	99	57	98	71
	Distal	88	28	55	71
Auto-Dimer (0.20 mg/l)	All	88	55	88	58
	Proximal	100	48	100	58
	Distal	88	24	64	58
Liatest D-Di (0.50 mg/l)	All	87	52	88	51
	Proximal	100	45	100	51
	Distal	87	21	54	51
Vidas New (0.50 mg/l)	All	87	46	91	37
	Proximal	100	39	100	37
	Distal	87	19	73	37
AxSYM (0.50 mg/l)	All	87	45	92	32
	Proximal	100	37	100	32
	Distal	87	19	77	32