

Comparison of the diagnostic validity of three POC D-dimer assays

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Background: Patients with chest pain or acute dyspnea suspicious for cardiovascular complications or pulmonary embolism (PE) represent an important group in the daily routine of an emergency department (ED). The early exclusion of PE is a major precondition for goal-oriented diagnostic and therapeutic measures. The fibrin split product D-dimer has shown high negative predictive values for exclusion of PE and venous thromboembolism (VTE). Aim of the study was to evaluate the new point-of-care assay PATHFAST D-Dimer in comparison to VIDAS D-Dimer Exclusion and STRATUS CS D-Dimer.

Methods: 272 patients with symptoms of PE and VTE were included. After admission to the ED blood was drawn and processed to obtain Li-heparin plasma samples which were stored at -70°C until D-dimer measurement. The diagnoses of VTE and PE were established by duplex ultrasound, venography and spiral-CT. The D-dimer values were also determined in plasma samples obtained from 102 healthy individuals in whom DVT or PE was excluded and who served as control group.

Results: Mean D-dimer concentration of the control group and of the patient group with PE was 0.28 (95% CI: $0.25-0.31$) $\mu\text{g/ml}$ and 1.45 (95% CI: $1.23-1.72$) $\mu\text{g/ml}$, respectively. Receiver operator characteristics analysis revealed an optimized cut-off value of 0.466 $\mu\text{g/ml}$ for the PATHFAST D-dimer assay (AUC = 0.975 (95% CI: $0.938-0.993$); Sensitivity: 95% (95% CI: $86-99\%$); Specificity: 89% (95% CI: $82-95\%$)). Therefore we used a rounded up cut-off value of 0.5 $\mu\text{g/ml}$ to examine the diagnostic accuracy of PATHFAST D-dimer to exclude PE. The correlation between PATHFAST and VIDAS results was particularly close for concentrations at or around the critical cut-off value of 0.5 $\mu\text{g/ml}$. The correlation between PATHFAST and STRATUS results was particularly close in the patient group with VTE ($r=0.9694$), whereas slightly lower results were obtained with STRATUS in the control group. With the widely used cut-off value 0.5 $\mu\text{g/ml}$, PATHFAST demonstrated suitable sensitivity but not STRATUS. ROC analysis indicated that optimal cut-off values could be set at either 0.5 or 0.6 $\mu\text{g/ml}$ and at 0.3 or 0.4 $\mu\text{g/ml}$ for PATHFAST and STRATUS, respectively.

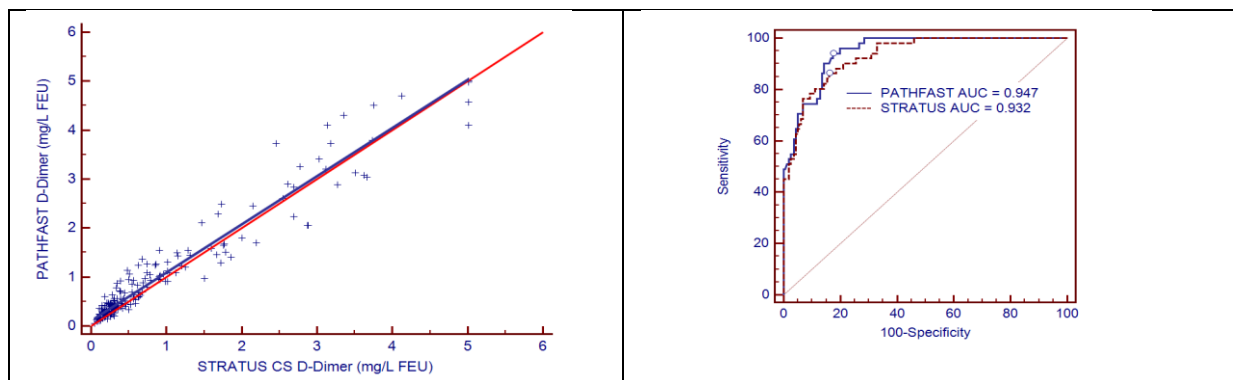


Fig. 1: PATHFAST D-Dimer - STRATUS CS D-Dimer regression line ($r = 0.9840$) and comparison of the ROC curves for discrimination between healthy individuals and patients

Conclusions: By use of the PATHFAST D-Dimer assay only 6 of diagnoses were missed at the time of first presentation compared to 10 diagnoses missed by the VIDAS D-Dimer Exclusion assay yielding higher sensitivity of the PATHFAST D-Dimer assay compared to the VIDAS assay (90% vs. 83%). The STRATUS assays showed comparable performance and appeared to be suitable for the exclusion of VTE in the emergency room setting, whereas PATHFAST demonstrated superior sensitivity. Moreover, the PATHFAST analyzer allows simultaneous determination of D-dimer and cardiac troponin I within 17 min from whole blood samples. Therefore, this method might be useful at the point-of-care for early diagnostic assessment of patients with symptoms of PE or chest pain admitted to the ER or to the chest pain unit.