

D-Dimers test performed on "Routine" analysers, a useful assay for rapid investigation in Symptomatic Outpatients with Suspected Pulmonary Embolism.

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Accurate detection of pulmonary embolism remains difficult and the differential diagnosis is extensive. In most cases, further testing is required to determine whether anticoagulant therapy is appropriate. Therefore, to reduce testing and improve diagnostic accuracy, laboratory tests have been evaluated for use as adjuncts to non-invasive testing. In this context measurement of plasma D-Dimers, specific degradation products of cross-linked fibrin, has been found to be particularly relevant to the evaluation of pulmonary embolism in patients admitted to an emergency ward with low or moderate pre-test probability. To this end, measurement of D-Dimers seems to be useful in a clinical decision tree designed to minimize the number of patients who require higher cost and invasive exploration methods such as angiography. In fact, it's important to insist on the excellent sensitivity and negative predictive value of the D-Dimer assays - contrasting with their lack of specificity due to increasing levels in other pathologies such as haematoma, liver cirrhosis, intra-vascular disseminated coagulation and neoplasia.

Some studies have attempted to evaluate the diagnostic performances in pulmonary embolism exclusion of the quantitative D-Dimer assay performed on routine analysers to reduce turnaroundtime of analysis. We could take for example the evaluation of the quantitative latex agglutination assay Tina-quant D-Dimers (Roche diagnostic, Mannheim) run on LX 20, a biochemistry analyser (Beckman Coulter) (Cliniques Universitaires St Luc, Bruxelles, Belgium). Results were compared with the conventional VIDAS D-Dimers (Biomérieux, Marcy l'Etoile, France), an ELISA test. The final diagnosis of pulmonary embolism was based on scintigraphy and/or lung scan results.

This study incorporated 268 patients, 148 women and 120 men (mean age = 55 years), admitted with suspected pulmonary embolism at the emergency unit.

The Citrated plasma samples were tested singly with the Tina-quant D-Dimer run on LX-20 (x) and in duplicate with another D-Dimers test, The ELISA VIDAS D-dimer method. Results from Tina-quant D-Dimers performed on the LX-20 analyser and VIDAS were compared and subjected to a retrospective clinical study keeping the pulmonary Embolism cut-off value at 500 ng/ml. In the 268 patients who had been diagnosed by lung CT-scan and/or lung scintigraphy, 26 were PE positive according to our previous hospital prevalence (11%) and 242 were PE negative. Sensitivity and specificity values obtained at the 500ng/ml cut-off value for Tina-quant D-Dimers performed on the LX-20 were about 100% (95%-confidence interval C.I 95-100%) and 61.5 % (C.I 59.4-65.7%) respectively and for the VIDAS about 100% (C.I 95-100%) and 54.5 % (C.I 51.8-57.2%). Negative predictive values were about 100% for both methods.

This study confirm the fair sensitivity and Negative Predictive value of this D-Dimers assay performed on routine analyser in such a pathology. So if the Negative Predictive Value is excellent, the specificity and the Positive Predictive Value are low.

So, the performances of some D-Dimers assays run on routine analysers appeared as a very interesting approach in diagnostic tree for pulmonary embolism exclusion in symptomatic outpatients and those methods are often cheaper, faster and with higher stability of calibration than conventional D-Dimers testing. Finally, the most important benefit goes for patients by reducing turn around time of analysis. To conclude, considering the actual development of laboratory automation, according to quality control process, we could

insist importance of the development of assays that could be integrated and/or loaded on analysers taking part to the laboratory automation system or on consolidated analysers.