Introduction

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Clinical diagnosis remains the prevalent approach to confirm or refute the presence of deep vein thrombosis and pulmonary embolism. Clinical trials performed adopting the proper research methodology have consistently demonstrated that only 20-30% and 30-50% of patients with clinically suspected venous thrombosis and pulmonary embolism, respectively, have the diagnosis confirmed by objective testing. Contrast venography and pulmonary angiography have for many years been the only objective methods for the diagnosis of deep vein thrombosis and pulmonary embolism. More recently, several noninvasive diagnostic methods or strategies have been developed and evaluated.

Evaluation of a new diagnostic technique is performed in three separated but consecutive phases. Incomplete adherence to these principles had led to the introduction of many invalid or inaccurate methods into clinical practice.

First, objective criteria for the presence or absence of venous thromboembolism should be defined and the technical aspects of the test should be standardized. The variation in the interpretation of the objective test result among observers should be determined.

In the second phase, the outcomes of the test are compared blindly to the results of the gold standard (contrast venography or pulmonary angiography), which is performed in all patients in order to generate the indices of accuracy, i.e., sensitivity, specificity and predictive values. Care should be taken that this evaluation is performed in a broad spectrum of consecutive patients. The failure to include a broad spectrum of patients, including patients with disorders frequently confused with venous thrombosis and pulmonary embolism, may result in a falsely high estimate of accuracy. An additional aim of the phase of the evaluation is to determine if the new method is suitable for all categories of patients. If the test has a sufficiently high sensitivity and specificity, the clinical validity and applicability of the technique should be investigated in the third phase.

The objective of the third phase is to document the safety and the effectiveness of the method in a sufficiently large sample of consecutive patients to determine whether management decisions about treatment can be based on the outcome of the test. Patients in whom the diagnosis is rejected on the basis of normal test result(s) should be carefully followed up to ensure that no excess rate of morbidity or mortality from venous thromboembolism occurs. Alternatively, patients with an abnormal test should have the findings confirmed.

When a new diagnostic test has complied with the requirements of each of these three phases, it can be recommended for clinical use. The recommendation should specify the patient category for which the diagnostic test has been shown to be appropriate, since the various objective tests have different diagnostic accuracies depending on the nature of the patient category under investigation.

The present issue of Haemostasis provides the reader with an update on the diagnosis of venous thrombosis and pulmonary embolism. The authors are to be congratulated for the excellent chapters they have prepared and for their efforts to take into account both the up-to-dateness and the assessment of the trial methodology.