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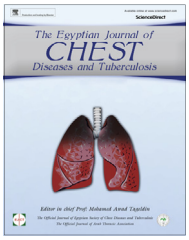

ORIGINAL ARTICLE

Diagnostic accuracy of D-dimer assay in suspected pulmonary embolism patients

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KEYWORDS

Pulmonary embolism;
Pulmonary angiography;
D-dimer

Abstract *Background:* Pulmonary embolism (PE) is a frequent and potentially severe disease. So objective testing is required to establish or exclude the presence of pulmonary embolism.

Aim: This study was carried out to evaluate the diagnostic accuracy of D-dimer test in suspected pulmonary embolism patients.

Patients and Methods: This study was carried out on 30 patients with clinical and radiological signs suspicious of PE. All cases were subjected to the following: evaluation of clinical probability by Revised Geneva Score, plain chest X-ray, CT pulmonary angiography (CTPA), electrocardiographic examination, arterial blood gases analysis, calculated alveolar arterial oxygen (PA-aO_2) gradient, duplex ultrasonographic, D-dimer assay, and measurement of partial end tidal carbon dioxide ($PetCO_2$).

Results: PE confirmed in 22 cases by CTPA, 20 cases of PE (91%) had positive D-dimer and 2 cases (9%) had negative D-dimer test. The sensitivity, specificity and accuracy of D-dimer in diagnosis of PE were (90%, 37.5%, and 26.6%) respectively. The sensitivity of D-dimer in evaluation of PE when clinical probability of PE low or intermediate was (100%), its specificity was (37.5%), its negative predictive value (NPV) was (100%) and its positive predictive value (PPV) was (67.7%), while in high clinical probability its sensitivity was (83.3%), specificity was (100%) and its PPV was (100%). There was statistically significant difference among the negative and positive PE cases as regards the $PetCO_2$ result ($P < 0.05$). The sensitivity of $PetCO_2$ in diagnosis of PE was (68%) its specificity was (87.5%), NPV was (50%) and its PPV was (93.7%).

Conclusion: D-dimer alone cannot exclude or confirm the presence of PE. The combination of D-dimer, $PetCO_2$ $\leqslant$28.5 mmHg and the clinical probability could improve diagnostic accuracy in patients with suspected PE.

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Introduction

Pulmonary embolism (PE) is a frequent and potentially severe disease, an accurate and rapid diagnosis of PE remains difficult in clinical practice because of non-specific clinical presentation also treatment carries significant potential side effects, so objective testing is required to establish or exclude the presence of pulmonary embolism. Although pulmonary angiography is being considered as the definitive diagnostic technique or "gold standard" in the diagnosis of acute pulmonary embolism, it suffers from limitation in its use as a result of being relatively expensive, time-consuming and involves radiation and contrast exposure [1].

In recent years, various combinations of non-invasive aids to diagnose, including the assessment of clinical probability, D-dimer testing, end tidal carbon dioxide ($PetCO_2$), venous compression ultrasonography of the legs (CUS) and ventilation perfusion lung scanning or CT pulmonary angiogram (CTPA), have been developed and validated to reduce the need for pulmonary angiography [2].

Pulmonary computed tomography angiography (CTPA) has become the preferred method to confirm or exclude PE. It has been shown to have high specificity, sensitivity, and negative predictive value for the diagnosis of acute PE [3].

D-dimer is a fibrin degradation product (FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. It is so named because it contains two cross linked D fragments of the fibrinogen protein [4].

D-dimers are not normally present in human blood plasma, except when the coagulation system has been activated, as in the presence of thrombosis or disseminated intravascular coagulation. The D-dimer assay depends on the binding of a monoclonal antibody to a particular epitope on the D-dimer fragment. The binding of the antibody is then measured quantitatively by one of various laboratory methods [4].

D-dimer assays were characterized by having good sensitivity and negative predictive value, but poor specificity because elevated D-dimer may be present due to various causes as liver disease, high rheumatoid factor, inflammation, malignancy, trauma, pregnancy, recent surgery as well as advanced age [5].

The aim of this study is to evaluate the diagnostic accuracy of D-dimer assay in patients with suspected pulmonary embolism.

Patients and methods

Patients

This study was performed on 30 patients with clinical suspicion of pulmonary embolism admitted at the Chest Department and Respiratory Intensive Care Unit, Zagazig University Hospitals during the period from January 2010 to October 2011. There were 18 males and 12 females with mean age 49.1 ± 10.1 years. Patients were classified according to final diagnosis by CTPA into 22 cases positive for PE (73.3%) and 8 cases negative for PE (26.7%).

Inclusion criteria

The included patients were suspected to have pulmonary embolism according to:

1. Clinical history and symptoms suggestive of PE [1,2].
2. Clinical examination and signs that raise the suspicion of PE [1].

Exclusion criteria

Patients were excluded from the study if they: have renal insufficiency, patients refusing to do CTPA and those having hypersensitivity to IV contrast.

Methods

All the studied patients were subjected to the following:

1. Full medical history taking stressing on risk factors and symptoms suggestive for PE.
2. General and local chest examination for signs of PE and leg examination for signs of DVT.
3. **Evaluation of clinical probability by Revised Geneva Score:**
   Consisting of calculation of Revised Geneva Score and categorization of clinical probability of PE as low, intermediate, or high [6].
4. **Plain chest X-ray (postero-anterior and lateral views)** to detect radiological finding suggestive of PE [7].
5. **Arterial blood gases analysis.**
6. **Alveolar–arterial oxygen Gradient:**A-aO_2 gradient $\leqslant$20 mmHg was considered normal. While A-a gradient $>$20 mmHg was considered abnormally wide [8].
7. **Electrocardiography (ECG)** was used to search for changes suggestive of PE [9].
8. **Routine investigation:** Complete blood picture, liver, kidney functions and bleeding profile.
9. D-Dimer assay.
10. Using the ELFA technique (Enzyme Linked Fluorescent Assay).The assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). The D-dimer cut off value $\geqslant$500 ng/ml was considered positive and results $<$500 ng/ml were considered negative [10].
11. **Lower limb duplex:** Done by a Doppler ultrasound device (Toshiba sonolayer) with superficial probe (7.5) MHz, for the diagnosis of DVT according to Pezzullo et al. [11].
12. **End tidal CO_2:** Measurement by quantitative capnometry (patient monitor, medical industry, model M3, Borg Ell-Arab) using a nasal cannula. Cut off point was calculated by the Receiver operating characteristic curve (ROC curve) which equals 28.5 mmHg. $PetCO_2$ was considered positive if $\leqslant$28.5 mmHg.
13. **Pulmonary CT angiography:** Performed for all patients using (Dual slice Hi speed spiral CTPA). It is the gold standard for the final diagnosis of pulmonary embolism.

Statistical analysis

Data were entered and analyzed using the Microsoft Excel software. Data were summarized using the arithmetic mean (X), the standard deviation (SD), chi-square and student t-test.