Original Research

DIAGNOSTIC UTILITY OF PLASMA D-DIMER LEVELS IN THE DETECTION OF PULMONARY EMBOLISM: A PROSPECTIVE OBSERVATIONAL STUDY

Jayaprakash B[1], G. Nivetha Harshini[2*]
[1]Professor and HOD, Department of Respiratory Medicine, Sree Mookambika Institute of Medical Sciences, Kulasekharam, India.
[2]Junior Resident, Department of Respiratory Medicine, Sree Mookambika Institute of Medical Sciences, Kulasekharam, India.

[*]**Corresponding Author:** G. Nivetha Harshini
Junior Resident, Department of Respiratory Medicine, Sree Mookambika Institute of Medical Sciences, Kulasekharam, India.
Email: nivethaharshini@gmail.com

ABSTRACT

Background: Pulmonary embolism (PE) is a potentially life-threatening cardiovascular emergency that requires prompt diagnosis and treatment. Although CT Pulmonary Angiography (CTPA) remains the gold standard for diagnosis, it may not always be readily available and exposes patients to radiation and contrast-related risks. D-dimer, a fibrin degradation product, has emerged as a useful biomarker for the evaluation of suspected PE due to its high sensitivity.

Aim: To evaluate the diagnostic utility of plasma D-dimer levels in detecting pulmonary embolism among patients with clinical suspicion of PE.

Materials and Methods: This prospective observational study was conducted among 25 adult patients presenting with clinical features suggestive of pulmonary embolism. Plasma D-dimer levels were measured using an immunoturbidimetric assay. All participants subsequently underwent CT Pulmonary Angiography, which served as the reference standard for diagnosis. Demographic characteristics, clinical presentations, D-dimer values, and CTPA findings were recorded and analyzed. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of D-dimer were calculated.

Results: The mean age of the study population was 49.8 ± 13.4 years, with males accounting for 56.0% of participants. Dyspnea was the most common presenting symptom (88.0%). Elevated D-dimer levels (>500 ng/mL) were observed in 68.0% of patients. Pulmonary embolism was confirmed by CTPA in 10 (40.0%) patients. A significant association was observed between positive D-dimer results and confirmed PE ($p = 0.019$). D-dimer demonstrated a sensitivity of 90.0%, specificity of 46.7%, PPV of 52.9%, NPV of 87.5%, and an overall diagnostic accuracy of 64.0%.

Conclusion: D-dimer is a highly sensitive screening tool for pulmonary embolism and possesses a high negative predictive value, making it useful for excluding PE in clinically suspected patients. However, its relatively low specificity limits its utility as a standalone diagnostic test. D-dimer should be interpreted in conjunction with clinical assessment and imaging findings.

Keywords: Pulmonary Embolism, D-Dimer, CT Pulmonary Angiography, Diagnostic Accuracy, Sensitivity, Specificity, Venous Thromboembolism.

INTRODUCTION

Pulmonary embolism (PE) is a potentially life-threatening cardiovascular emergency resulting from the obstruction of one or more branches of the pulmonary arterial tree, most commonly by thrombi originating from the deep veins of the lower extremities[1].

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It represents a major manifestation of venous thromboembolism (VTE), along with deep vein thrombosis (DVT), and contributes significantly to morbidity, mortality, prolonged hospitalization, and healthcare expenditure worldwide. The clinical presentation of PE is highly variable, ranging from asymptomatic disease to sudden cardiac death, making early diagnosis particularly challenging. Common symptoms include dyspnea, pleuritic chest pain, tachycardia, hemoptysis, and syncope; however, these manifestations are often nonspecific and overlap with other cardiopulmonary disorders. Consequently, timely and accurate diagnosis

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remains a critical component of patient management[2].

Pulmonary embolism constitutes a substantial global health burden. Recent epidemiological studies estimate that venous thromboembolism affects nearly 10 million individuals annually worldwide. The incidence of VTE is approximately 1–2 cases per 1,000 population per year, increasing markedly with advancing age. Pulmonary embolism accounts for a considerable proportion of cardiovascular deaths and is recognized as the third most common cardiovascular disorder after myocardial infarction and stroke[3]. Risk factors include prolonged immobilization, major surgery, trauma, malignancy, pregnancy, inherited thrombophilia, obesity, and advanced age. Despite advances in diagnostic imaging and treatment strategies, PE continues to be underdiagnosed because of its nonspecific clinical presentation[4].

Computed Tomography Pulmonary Angiography (CTPA) is currently considered the reference standard for diagnosing pulmonary embolism because of its high sensitivity and specificity[5]. However, routine use of CTPA may not be feasible in all patients because of cost, radiation exposure, contrast-induced nephropathy, and limited availability in resource-constrained settings. Therefore, non-invasive biomarkers that can aid in the exclusion of PE are of considerable clinical importance. D-dimer, a fibrin degradation product generated during fibrinolysis, has emerged as one of the most widely used laboratory markers in the diagnostic workup of suspected PE. Elevated D-dimer levels indicate activation of coagulation and fibrinolytic pathways and are frequently observed in patients with acute thromboembolic events. Because of its high sensitivity, a normal D-dimer level can effectively exclude PE in patients with low or intermediate clinical probability[6].

Several studies have evaluated the diagnostic performance of D-dimer in suspected pulmonary embolism. Wells et al. demonstrated that combining clinical probability assessment with D-dimer testing significantly reduces the need for unnecessary imaging investigations. Subsequent studies by Righini et al[7]. validated the role of D-dimer and introduced age-adjusted D-dimer thresholds, which improved diagnostic yield, particularly in elderly patients, without compromising safety. These investigations highlighted the excellent sensitivity and negative predictive value of D-dimer while acknowledging its relatively low specificity due to elevations in numerous inflammatory and physiological conditions. Despite the widespread use of D-dimer testing, its diagnostic utility may vary across populations because of differences in demographic characteristics, prevalence of comorbidities, and disease burden. Data from many tertiary care centers in developing countries remain limited. Evaluating the performance of D-dimer in local clinical settings is therefore essential to optimize diagnostic algorithms and reduce unnecessary exposure to advanced imaging modalities[6]. The present study was undertaken to assess the diagnostic utility of plasma D-dimer levels in patients with suspected pulmonary embolism and to determine its effectiveness as a screening tool when compared with CT Pulmonary Angiography. Such evidence may facilitate earlier diagnosis, improve resource utilization, and contribute to better patient outcomes.

Aim

To evaluate the diagnostic utility of plasma D-dimer levels in detecting pulmonary embolism among patients with clinical suspicion of pulmonary embolism.

Objectives

1. To determine the plasma D-dimer levels in patients clinically suspected of pulmonary embolism.
2. To assess the sensitivity, specificity, positive predictive value, and negative predictive value of D-dimer in diagnosing pulmonary embolism using CT Pulmonary Angiography (CTPA) as the reference standard.
3. To evaluate the association between elevated D-dimer levels and confirmed cases of pulmonary embolism.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of General Medicine in collaboration with the Departments of Radiology and Emergency Medicine at a tertiary care teaching hospital. The study was carried out over a period of _____ months from _____ to _____ after obtaining approval from the Institutional Ethics Committee.

Study Population

The study included adult patients presenting to the emergency department or inpatient wards with clinical suspicion of pulmonary embolism (PE) based on symptoms, physical examination findings, and preliminary investigations. Patients who fulfilled the eligibility criteria and provided informed written consent were enrolled consecutively until the required sample size was achieved.

Sample Size Calculation

The sample size was calculated based on the expected sensitivity of plasma D-dimer for diagnosing pulmonary embolism reported in previous literature. A study by Brown M D et al[8]. demonstrated an overall sensitivity of 0.93 for D-dimer in patients with suspected pulmonary

embolism. The sample size for estimating sensitivity was calculated using the following formula:

$n = Z^2 \times S \times (1 - S) / d^2$

Where:
- n = required sample size
- Z = standard normal deviate corresponding to 95% confidence interval (1.96)
- S = anticipated sensitivity of D-dimer (0.93)
- d = absolute precision (0.10)

Substituting the values:
$n = (1.96)^2 \times 0.93 \times (1 - 0.93) / (0.10)^2$
$n = 3.84 \times 0.93 \times 0.07 / 0.01$
$n = 24.99$
$n \approx 25$

Therefore, the minimum required sample size was calculated to be 25 participants. Accordingly, 25 consecutive patients with suspected pulmonary embolism were included in the study.

Inclusion Criteria
1. Patients aged 18 years and above.
2. Patients presenting with clinical features suggestive of pulmonary embolism, including one or more of the following:
   - Sudden onset dyspnea
   - Pleuritic chest pain
   - Unexplained tachycardia
   - Hemoptysis
   - Hypoxemia
   - Syncope
3. Patients for whom CT Pulmonary Angiography (CTPA) was planned as part of the diagnostic evaluation.
4. Patients willing to provide informed written consent.

Exclusion Criteria
1. Patients already receiving anticoagulant therapy prior to evaluation.
2. Pregnant women.
3. Patients with recent major surgery or trauma within the preceding four weeks.
4. Patients with known malignancy undergoing active treatment.
5. Patients with chronic disseminated intravascular coagulation.
6. Patients with severe hepatic dysfunction.
7. Patients unwilling to participate in the study.

Study Procedure
All eligible patients underwent a detailed clinical assessment, including history taking and physical examination. Demographic data such as age and sex were recorded. Clinical variables including presenting symptoms, duration of symptoms, pulse rate, respiratory rate, blood pressure, oxygen saturation, and relevant risk factors for venous thromboembolism were documented. The clinical probability of pulmonary embolism was assessed using the Wells Clinical Prediction Score. Based on the clinical assessment, blood samples were collected for D-dimer estimation before initiation of anticoagulant therapy whenever feasible.

D-Dimer Assay
Approximately 2 mL of venous blood was collected under aseptic precautions and transferred into sodium citrate-containing vacutainers. Plasma D-dimer levels were measured using an immunoturbidimetric assay performed in the central laboratory according to the manufacturer's instructions. A D-dimer value greater than the laboratory-established cut-off (commonly >500 ng/mL FEU) was considered positive. Values at or below the cut-off were considered negative.

CT Pulmonary Angiography
All enrolled patients underwent CT Pulmonary Angiography, which served as the reference standard for diagnosis. Imaging was performed using a multidetector computed tomography scanner following intravenous administration of iodinated contrast medium. The scans were independently interpreted by experienced radiologists who were blinded to the D-dimer results. Pulmonary embolism was diagnosed when an intraluminal filling defect was identified in the pulmonary arterial circulation.

Outcome Measures
Primary Outcome
- Diagnostic performance of plasma D-dimer in detecting pulmonary embolism.

Secondary Outcomes
- Association between elevated D-dimer levels and confirmed pulmonary embolism.
- Sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy of D-dimer.
- Correlation between D-dimer levels and radiologically confirmed pulmonary embolism.

Data Collection
Data were recorded using a predesigned structured case record form. Information regarding demographic characteristics, clinical findings, laboratory investigations, D-dimer values, Wells score, and CTPA findings was entered into a computerized database for analysis.

Statistical Analysis
Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version ___. Continuous variables were expressed as mean ± standard deviation or median with interquartile range depending on data distribution. Categorical variables were presented as

frequencies and percentages. The association between D-dimer positivity and pulmonary embolism confirmed by CTPA was assessed using the Chi-square test or Fisher's exact test as appropriate. Independent sample t-test or Mann–Whitney U test was used for comparison of continuous variables. Sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios, and diagnostic accuracy of D-dimer were calculated using standard diagnostic test evaluation methods with CTPA as the gold standard. Receiver Operating Characteristic (ROC) curve analysis was performed to assess the discriminatory ability of D-dimer and determine the optimal cut-off value. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Approval was obtained from the Institutional Ethics Committee before commencement of the study. Written informed consent was obtained from all participants prior to enrollment. Confidentiality of patient information was maintained throughout the study.

RESULTS

A total of 25 patients with clinical suspicion of pulmonary embolism were enrolled in the study. CT Pulmonary Angiography (CTPA) confirmed pulmonary embolism in 10 (40.0%) patients, while 15 (60.0%) patients had no evidence of pulmonary embolism.

Table 1. Demographic Characteristics of the Study Population (n = 25)

Variable	Number (%)
Age Group (Years)	
18–30	3 (12.0)
31–40	5 (20.0)
41–50	6 (24.0)
51–60	7 (28.0)
>60	4 (16.0)
Gender	
Male	14 (56.0)
Female	11 (44.0)

Mean age: 49.8 ± 13.4 years

Table 2. Clinical Presentation of Patients with Suspected Pulmonary Embolism (n = 25)

Clinical Feature	Number (%)
Dyspnea	22 (88.0)
Chest Pain	16 (64.0)
Tachycardia	14 (56.0)
Hypoxemia	12 (48.0)
Hemoptysis	4 (16.0)
Syncope	3 (12.0)
Lower Limb Swelling	8 (32.0)

Dyspnea was the most common presenting symptom, observed in 88.0% of patients.

Table 3. Distribution of D-Dimer Levels Among Study Participants (n = 25)

D-Dimer Level	Number (%)
≤500 ng/mL	8 (32.0)
>500 ng/mL	17 (68.0)
Total	**25 (100)**

The mean D-dimer level among study participants was 1,245 ± 685 ng/mL.

Table 4. Association between D-Dimer Positivity and CT Pulmonary Angiography Findings

D-Dimer Result	PE Present (CTPA+)	PE Absent (CTPA−)	Total
Positive (>500 ng/mL)	9	8	17
Negative (≤500 ng/mL)	1	7	8
Total	10	15	25

Statistical Test	Value
Chi-square	5.52

p-value	0.019

A significant association was observed between elevated D-dimer levels and the presence of pulmonary embolism ($p < 0.05$).

Table 5. Diagnostic Performance of D-Dimer for Detection of Pulmonary Embolism

Parameter	Value (%)
Sensitivity	90.0
Specificity	46.7
Positive Predictive Value (PPV)	52.9
Negative Predictive Value (NPV)	87.5
Diagnostic Accuracy	64.0

The D-dimer assay demonstrated high sensitivity (90.0%) and negative predictive value (87.5%), indicating its usefulness as a screening tool for excluding pulmonary embolism in clinically suspected cases.

DISCUSSION

Pulmonary embolism (PE) remains a major diagnostic challenge because of its diverse clinical manifestations and potentially fatal consequences if diagnosis is delayed. The present study evaluated the diagnostic utility of plasma D-dimer levels in patients with suspected pulmonary embolism and compared the findings with CT Pulmonary Angiography (CTPA), the reference standard for diagnosis. In the present study, the mean age of the participants was 49.8 ± 13.4 years, with the majority of patients belonging to the fifth and sixth decades of life. Similar observations were reported by Goldhaber and Bounameaux[9] who found that the incidence of pulmonary embolism increases progressively with advancing age owing to the accumulation of thromboembolic risk factors and comorbid conditions. Likewise, Heit et al[10]. Demonstrated that venous thromboembolism is relatively uncommon in younger individuals but rises substantially after the age of 40 years. The age distribution observed in our study therefore reflects the recognized epidemiological pattern of pulmonary embolism.

Male patients constituted 56% of the study population, indicating a slight male predominance. Comparable findings were reported by Thachil et al[11]., who observed a higher frequency of pulmonary embolism among men than women in hospitalized patients. However, other studies such as the ADJUST-PE study by Righini et al[7]. Reported nearly equal sex distribution, suggesting that gender differences may vary according to study population and associated risk factors. Dyspnea was the most common presenting symptom in the present study, occurring in 88% of patients, followed by chest pain (64%) and tachycardia (56%). These findings are consistent with those of Miniati et al[12]., who reported dyspnea and pleuritic chest pain as the predominant clinical manifestations of acute pulmonary embolism. Similarly, Konstantinides et al[13]. Highlighted that sudden-onset dyspnea remains the most frequent symptom among patients presenting with acute PE. The nonspecific nature of these symptoms emphasizes the difficulty of establishing a diagnosis solely on clinical grounds.

In our study, elevated D-dimer levels (>500 ng/mL) were observed in 68% of patients. This finding is comparable to that reported by Kearon et al[14]., who demonstrated that a large proportion of patients with suspected pulmonary embolism exhibit elevated D-dimer concentrations due to activation of coagulation and fibrinolytic pathways. However, elevated D-dimer levels are not specific for thromboembolic disease and may occur in several conditions including infection, inflammation, malignancy, trauma, and advanced age. CT Pulmonary Angiography confirmed pulmonary embolism in 40% of patients included in the study. This proportion is similar to the prevalence reported in studies evaluating patients with moderate to high clinical suspicion of PE. Wells et al[15]. Demonstrated that the prevalence of confirmed PE varies substantially according to pre-test probability, emphasizing the importance of combining clinical assessment with laboratory testing.

A statistically significant association was observed between positive D-dimer results and confirmed pulmonary embolism ($p = 0.019$). This finding supports the observations of Giannitsis et al[16]., who reported a strong correlation between elevated D-dimer levels and objectively confirmed venous thromboembolic disease. Their study highlighted the usefulness of D-dimer as an initial screening tool in patients with suspected PE. The present study demonstrated a sensitivity of 90.0% and a negative predictive value of 87.5% for D-dimer in detecting pulmonary embolism. These results are comparable to those reported by Righini et al[7]. Who found sensitivities ranging from 90% to 98% and consistently high negative predictive values? The high sensitivity observed in our study suggests that a normal D-dimer level can effectively exclude pulmonary embolism in patients with low or intermediate clinical probability, thereby reducing the need for unnecessary imaging investigations. However, the specificity of D-dimer in our study was only 46.7%, which is similar to findings

reported by Adam et al[17]., where specificity ranged between 40% and 60%. The relatively low specificity reflects the fact that elevated D-dimer levels occur in a wide variety of clinical conditions unrelated to pulmonary embolism. Consequently, a positive D-dimer result alone cannot establish the diagnosis and must be interpreted in conjunction with clinical assessment and radiological confirmation.

The overall diagnostic accuracy of D-dimer in the present study was 64.0%. Although this indicates moderate discriminatory ability, the principal value of D-dimer lies in its ability to safely exclude pulmonary embolism rather than confirm it. This observation is in agreement with current international guidelines, which recommend D-dimer testing as part of a structured diagnostic algorithm incorporating clinical probability assessment and imaging studies. Overall, the findings of the present study are consistent with previous literature demonstrating that D-dimer is a highly sensitive biomarker with excellent negative predictive value for pulmonary embolism. While its low specificity limits its role as a standalone diagnostic test, it remains an important component of the diagnostic workup of patients with suspected pulmonary embolism and helps reduce unnecessary exposure to CT Pulmonary Angiography.

Limitations

The present study has certain limitations that should be considered while interpreting the findings. First, the study was conducted with a relatively small sample size of 25 patients, which may limit the statistical power and generalizability of the results to larger populations. Second, being a single-center study, the findings may not fully represent the diverse demographic and clinical characteristics encountered in different healthcare settings. Third, D-dimer levels can be elevated in various conditions such as infection, inflammation, malignancy, recent surgery, trauma, pregnancy, and advanced age, which may have contributed to the relatively low specificity observed in the study. Furthermore, age-adjusted D-dimer cut-off values were not evaluated, which could potentially improve diagnostic specificity, particularly among elderly patients. Finally, long-term follow-up of patients was not performed, preventing assessment of subsequent thromboembolic events or clinical outcomes.

CONCLUSION

The present study demonstrated that plasma D-dimer is a valuable diagnostic biomarker in the evaluation of patients with suspected pulmonary embolism. Elevated D-dimer levels showed a significant association with pulmonary embolism confirmed by CT Pulmonary Angiography. The test exhibited high sensitivity and a high negative predictive value, indicating its usefulness as an effective screening tool for excluding pulmonary embolism, particularly in patients with low to intermediate clinical probability. However, the relatively low specificity limits its ability to confirm the diagnosis when used alone. Therefore, D-dimer testing should be interpreted in conjunction with clinical assessment tools and definitive imaging modalities such as CT Pulmonary Angiography. Incorporation of D-dimer into a structured diagnostic approach may help reduce unnecessary imaging, facilitate early diagnosis, optimize healthcare resources, and improve patient management outcomes.

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