



Original Research Article

CLINICAL PROFILE OF ACUTE PULMONARY THROMBOEMBOLISM AND PROGNOSTIC VALUE OF TROPONIN-T AND sPESI IN ACUTE PULMONARY THROMBOEMBOLISM

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ABSTRACT

Background: Venous thromboembolism (VTE) is common with high recurrence rates. Even though it is lethal, it is overlooked. It is associated with long term complications. For India, large-scale studies are lacking. In view of limited data availability on the clinical prognostication markers of patients with VTE, present study was carried out to study the clinical profile of the patients admitted with pulmonary thromboembolism and also to evaluate certain serum and clinical prognostic indicators.

Materials and Methods: Hospital-based cross-sectional study was carried out among 61 cases with pulmonary thromboembolism. Details were collected in proforma including clinical characteristics, lab parameters, treatment received. Predefined proforma was used for collecting data on patient age, sex, and outpatient or inpatient status at the time of PE diagnosis, clinical presentation, haemodynamic parameters, comorbidities, risk factors for venous thromboembolism (VTE) and bleeding, detailed risk stratification test results based on Simplified Pulmonary Embolism Severity Index score (sPESI), and treatment modalities. In addition, clinical outcomes were captured.

Results: Median age was 48yrs. Male to Female ratio was 1.44:1. Most common presenting complaint was breathlessness (86.9%). Most common sign was tachypnoea (86.8%). Signs of DVT were present in 49.1%. Most common malignancy was Ovarian malignancy (4.9%). Most common ECG feature was sinus tachycardia (80.3%). DVT was seen in 64%. Those with high trop T levels had significantly high chances of RV dysfunction ($p < 0.05$). 14 patients underwent thrombolysis. 52 cases survived and all-cause mortality was 14.76%. Association between trop T and survival was not significant ($p > 0.05$).

Conclusion: Trop T is a reliable marker for RV dysfunction and may reflect the severity of embolism. Patients with low sPESI score have a better outcome.

Keywords: Thromboembolism, prognosis, clinical profile.

INTRODUCTION

Stroke is the most common vascular disease followed by myocardial infarction and venous thromboembolism (VTE). Thus, VTE ranks third in the list. VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE). VTE is very common

with high recurrence rates. Even though it is lethal, it is overlooked. It is associated with long term complications.^[1]

It has been estimated that about 2-3 persons are affected with VTE for every 1000 population every year. As the age increases, the incidence of VTE

increases. Sometimes it is not significant and may not trouble the persons often.^[2]

Any changes that occur in the flow of the blood, vessel wall state, blood composition can lead to the occurrence of VTE. Other factors than can lead to occurrence of VTE are many. To mention a few are low levels of oxygen, blood platelets activation, microparticles concentration etc.^[3]

Out of all the cases of VTE, it has been stated that around 33% of the cases are due to PE and remaining 67% are due to DVT. For India, the large-scale community-based studies are lacking. Even the hospital-based studies on VTE are limited very much. The incidence of VTE is not much different in males and females. As the age increases, the incompetence of the valve of the veins increases, and so the incidence of VTE also increases. Sedentary lifestyle is also one more risk factor for the development of VTE. As the age increase, the vascular resistance also increases and so the incidence of VTE also increases.^[4]

The risk factors are of two types. One that are inherited and the other type is those which are acquired. “V Leiden mutation, Prothrombin gene mutation, Protein C,S deficiency, Antithrombin deficiency” are inherited risk factors for VTE. Cancer, injury, operations, catheter placement, immobilized persons, etc. are acquired risk factors for VTE. Like for coronary artery disease, the risk factors of VTE can be categorized as modifiable and non-modifiable.^[5]

In view of limited data availability on the clinical prognostication markers of patients with VTE, present study was carried out to study the clinical profile of the patients admitted with pulmonary thromboembolism and also to evaluate certain serum and clinical prognostic indicators.

MATERIALS AND METHODS

Hospital based cross sectional study was carried out over a period of one year at Kasturba hospital, Manipal. Approval for the study was taken from the Kasturba Hospital ethics committee before commencement of data collection under IEC 49/2014. Details of all patients had been collected in a prespecified proforma including clinical characteristics, lab parameters, treatment received. Adults of age more than 18 years and those diagnosed with pulmonary thromboembolism were included in the present study. Clinically diagnosed cases without investigative proof, old cases of venous thrombosis on routine follow up with no fresh episode of venous thromboembolism, preexisting cardiac failure and renal failure were excluded.

Patients were selected based on the above-mentioned criteria and were recruited into study after taking consent. A predefined proforma was used for

collecting data on patient age, sex, and outpatient or inpatient status at the time of PE diagnosis, clinical presentation, haemodynamic parameters, comorbidities, risk factors for venous thromboembolism (VTE) and bleeding, detailed risk stratification test results based on Simplified Pulmonary Embolism Severity Index (sPESI) score, and treatment modalities. In addition, clinical outcomes were captured.

Calculation of sample size was based on the estimation of different clinical profile of the study subjects. Based on previous studies minimum prevalence of important clinical features was expected to be within 50%. In order to estimate this proportion with 15% allowable error and 95% confidence level required sample size was estimated to be a minimum of 43. However, data collection was carried out throughout the study duration in spite of meeting the minimum sample size.

Simplified Pulmonary Embolism Severity Index (sPESI) score(1):

A low sPESI was defined as an age ≤ 80 years and absence of systemic hypotension (systolic pressure < 100 mm Hg), tachycardia (heart rate ≥ 110 beats per minute), hypoxia (oxygen saturation $< 90\%$), cancer, heart failure, and chronic lung disease. Presence of any one of these factors was considered to be high sPESI. All 61 patients were categorised into 2 groups based on the sPESI score

1. High risk group: sPESI score of greater than or equal to 1
2. Low risk group: sPESI score of less than 1

High sensitivity Troponin t (Trop t): Venous blood samples were collected within 12hrs of presentation. hsTroponin-T levels were defined by quantitative electrochemiluminescence immunoassays (Eleclys 2010 analyzer, Roche Diagnostics, Mannheim, Germany) with a cut-off value ≥ 0.014 ng/mL). A positive troponin test result was defined as a troponin level above the manufacturers assay threshold for the diagnosis of myocardial injury.

Data analysis was done using Statistical Package for the Social Sciences version 15. Mean \pm SD was used to summarize continuous variables (Normally distributed) and Median (first and third quartile) was used to summarize skewed variables (if mean $> 2SD$). Frequency and percentage were used to summarize categorical variables. The association between two Categorical variables was tested using Pearson's Chi square test. If the expected values in any of the cells of a contingency table were below 5 then Fisher's Exact test was used. A p value of < 0.05 was considered statistically significant.

RESULTS

A total of 61 patients admitted to the hospital who fulfilled the selection criteria were included in the present study.

Table 1: Distribution of study subjects

Characteristics		Frequency	Percentage
Age (years)	< 40	29	47.5
	> 40	32	52.5
Sex	Males	36	59
	Females	25	41
Clinical features	Dyspnoea	53	86.9
	Cough	11	18
	Haemoptysis	4	6.6
	Chest pain	14	23
	Leg swelling	30	49
Clinical signs	Tachypnoea	53	86.9
	Tachycardia	43	70.5
	Raised JVP	33	54.1
	Chest pain	30	49.1
	Hypotension	4	6.5
Risk factors	Present	48	78.7
	Absent	13	21.3

Median age at presentation was 48yrs. The number of patients belonging to the less than 40yrs age group were 29. The remaining 52% were more than 40yrs of age. Out of 61, 36 (59.0%) were males and 25 (41.0%) were females. Male: Female ratio was 1.44:1. 72% belonged to less than 40yrs of age were males. Among the other age groups the number of males was almost similar to the number of females. The most common presenting complaint was breathlessness seen in 86.9% of the patients, followed

by Symptoms of DVT (i.e. swelling, redness and/or tenderness of leg) (49% of patients) and then chest pain, cough and hemoptysis in that order. The most common sign was tachypnoea followed by tachycardia and raised JVP (86.8%, 70.49%, 54.09% respectively). Hypotension was the presenting feature in 4 patients (6.5%). Signs of DVT were present in 49.1% of the patients. Definite risk factors were present in 48 patients constituting to 78.7% of the patients. [Table 1]

Table 2: Distribution as per Prothrombotic states and other features

Characteristics		No of patients
Prothrombotic states	Postpartum / pregnancy	1
	Retroviral illness	1
	Protein C, protein S deficiency	1
	APLA	2
Malignancy	Ovarian Cancer	3
	Breast Cancer	2
	Periampullary carcinoma	2
	Clear cell RCC	1
	GI carcinoid tumor	1
	Endometrial sarcoma	1
	Cholangiocarcinoma	2
	SCC of anterior abdominal wall	1
	NSCC of lung	1

In the present study thrombophilia workup was done in 11 patients of which 2 patients were detected to have APLA followed by one patient with protein S Protein C deficiency. Other prothrombotic states included one HIV infected person, one female in her postpartum period. 14 patients had malignancy out of 61 patients. The most common malignancy

associated was Ovarian malignancy (serous adenocarcinoma) (4.9%) followed by breast cancer, cholangiocarcinoma and periampullary carcinoma seen in 3.27% each. Other malignancies that were seen included endometrial cancer, SCC of the abdominal wall, non-small cell cancer of the Lung, Clear cell variety of RCC and GI carcinoid. [Table 2]

Table 3: Distribution as per ECG and other findings

Findings		Number of patients	%
ECG findings	Sinus tachycardia	49	80.3
	Right axis deviation	36	59.1
	RV strain pattern	33	54.1
	SIQ3T3	16	26.2
	RBBB	11	18.1
X ray findings	Wedge shaped opacity	8	13.1
	Focal oligemia	3	4.9
	Pleural Effusion	3	4.9
	Normal	49	80.3
Echocardiography	Pulmonary Artery Hypertension (PAH)	55	90.1
	RA, RV dilatation	49	80.3

	RV dysfunction	37	60.1
	Normal	6	9.8
CT pulmonary angiography	Main/Lobar artery involvement	41	67.2
	Segmental/sub segmental involvement	20	32.8
	Pulmonary infarction	8	13.1

The most common ECG feature was sinus tachycardia (80.3%) followed by Right axis deviation (59.01%) and RV strain pattern (54.09%). S1Q3T3 was seen in only 26.2% of the patients and RBBB being the least common feature was present in 11 patients (18.03%). In 49 out of 61 patients (80.3%) the X-ray was normal. Wedge shaped opacity was the most common feature which was present in 13% of the patients followed by focal oligemia (4.91%) and pleural effusion. All 61 patients underwent Echocardiography. 55 out of 61 patients (90.1%) had

evidence of PAH which was the most common Echocardiography feature followed by RA, RV dilatation and RV dysfunction (80.3% and 60.65% of patients respectively). 6 patients (9.8%) had a normal echocardiography. All 61 patients underwent CT pulmonary angiography. 41 out of 61 patients (67.22%) had thromboembolism involving the Main/Lobar arteries whereas remaining patients (32.78%) had either segmental/sub segmental artery involvement. Pulmonary infarction was seen in eight patients (13.11%). [Table 3]

Table 4: Distribution as per DVT and other characteristics

Characteristics		Number of patients	%
DVT	Yes	39	64
	No	22	36
Site	Proximal	33	54.1
	Distal	24	39.3
	Both Proximal and Distal	17	27.8
sPESI Risk Category	High Risk	44	70.5
	Low risk	18	29.5
D-Dimer Result	Positive	58	94.5
	Negative	3	4.5
Troponin T Result	High	39	63.3
	Normal	22	36.1

USG venous Doppler of the both lower limbs was done in all the patients included in the study. DVT was seen in 64% of the patients whereas remaining 36% of the patients had no evidence. 33 patients (54.09%) had proximal DVT, 24 patients (39.34%) had distal DVT and 17 patients had proximal as well as distal DVT. 44 out of 61 patients (70.49%) belonged to High-risk category of sPESI and 18

(29.5%) patients belonged to the low-risk category. D-dimer was done in all 61 patients. Any value above the manufacturers was considered to be high. 58 out of 61 patients (95%) of proven PTE cases had D-dimer positive and 3 patients (4.9%) had a negative d dimer. 39 patients out of 61 (63.9%) with PTE had high Trop t whereas 22 patients (36.1%) had normal Trop t. [Table 4]

Table 5: Association between high troponin T and RV dysfunction

Troponin t value	RV dysfunction	No RV dysfunction	Chi square	P value
High	34	5	32.31	< 0.0001
Low	2	20		

34 out of 39 patients with high trop T had RV dysfunction whereas only 2 patients out of 22 patients with no RV dysfunction had High Trop t. this difference was statistically significant. (p <0.001). [Table 5]

Table 6: Treatment and outcome

Characteristics		Number	%
Treatment	LMWH and Oral anticoagulants	60	98.3
	Thrombolysis	14	22.9
	IVC filter placement	8	13.1
	Absolute contraindication for anticoagulation	1	1.6
Outcome	Survived	52	85.2
	Died	9	14.7

14 patients underwent thrombolysis, IVC filter placement was done in 8 patients. LMWH and Oral anticoagulants were used in 60 patients. One patient had an absolute contraindication for anticoagulation (active massive GI bleeding). 52 out of 61 patients with PTE survived and all-cause mortality was seen

in 9 patients (14.76%). Eight patients died due to PTE; one patient died due to thrombolysis related complication. [Table 6]

Table 7: Association between characteristics and outcome

Characteristics		Death	Survived	P value
Troponin t value	High	7	32	0.5903
	Normal	2	20	
sPESI	High risk	9	34	0.1375
	Low risk	0	18	

The association between troponin t value of high range and the death was not found to be statistically significant. ($p>0.05$). Similarly, the association of high sPESI score with death was not statistically significant ($p>0.05$). [Table 7]

DISCUSSION

A number of published studies have shown that incidence of first time VTE increases with age. In the present study, the mean age of presentation was 48 years. A similar study done in India was carried out by S. Calvin Davidsingh et al,^[6] in 35 patients who were newly diagnosed to have pulmonary embolism with a mean age of 52.1 years were included in the study. Present study was comparable to the Indian study. Whereas in another study carried out by Nijkeuter, Mathilde, et al,^[7] in Netherlands had mean age of 58 yrs. In the present study, population above the age of 60 years constituted just 13.1% of the total study. The difference might be because of the younger population of presentation in this hospital and the higher life expectancy in view of better geriatric facilities in the Western Population.

In the present study the male to female ratio of occurrence of PTE is 1.44:1. In the study by M Cushman et al,^[8] rates were higher in men than women, and increased with age in both sexes. S. Calvin Davidsingh et al,^[6] also found that rates were higher in males which was comparable to the present study. However, In the absence of a consistent difference among studies, the incidence of VTE is probably approximately equal in men and women and requires further investigation in this field.

In the present study Immobilization for > 2 days was seen in 14 patients (22.9%). Present study results were comparable to the study carried out by S. Calvin Davidsingh et al 6 where immobility as a risk factor was seen in 22%. According to Cushman et al,^[8] immobilizations as a risk factor was seen in 17%. In the present study, the commonest cause of immobilization being trauma (in 30% of the patients among whom immobilization was a risk factor).

In the present study, antecedent surgery, defined as a major surgery requiring general anesthesia for than >30 min as a risk factor for PTE was seen in 26.2% of patients and malignancy was seen in 22.9%. In the study by Cushman et al 8 25% of their cases had undergone antecedent surgery, and 25% had cancer. In another study carried out by White et al,^[4] in California, 18% had malignancy, 23% had undergone surgery during the last 2 months. The presence of these above risk factors was in comparison with this study.

In this study one patient with PTE was in her postpartum period. According to Heit et al,^[9] among pregnant women, the highest risk for pulmonary embolism is during the postpartum period. Any prophylaxis against these events should be particularly targeted to postpartum women.

In the present study, among the patients with Pulmonary thromboembolism, malignancy was found in 14 patients (out of 61 i.e. 22.9%). Two patients with CA ovary (adenocarcinoma) had undergone an oophorectomy. Two patients of breast carcinoma were on chemotherapy. One patient with GI carcinoid had undergone a hemicolectomy and two patients who had periampullary carcinoma had undergone Whipple's procedure. One patient with lung cancer was on gefitinib. One patient with renal cell carcinoma had infiltration into the veins. The most common malignancy was that of the pelvis and abdomen. Murchison et al,^[10] had conducted a study as per which the cancers with highest risk of association with malignancy were ovarian cancers, lymphomas, kidney and pancreas. Thus, the incidence of abdominal and pelvic malignancies is found to be high the results of which is consistent with the findings in the present study.

In the present study evaluation for various thrombophilia was done in 11 patients out of whom three patients had a positive result for the same. Secondary APLA was seen to be among the major contributors seen in two patients followed by protein C, S deficiency seen in one patient. The assessment of the thrombophilic states in the present study in comparison with other studies is limited by the fact that only 18% of the study population had undergone these tests. However, according to a Spanish multicenter study done by Mateo et al,^[11] which was done in 2132 patients with VTE the overall prevalence of protein deficiencies was 12.85% and antiphospholipid antibodies were found in 4.08% followed by protein C deficiency (3.19%), protein S deficiency (7.27%) and antithrombin deficiency (0.47%).

In the present study, no risk factors were seen in 13 patients (21.3%) (idiopathic PTE). In a similar study conducted by Sompradeekul S et al,^[12] in Thailand on 71 patients, Idiopathic PTE was found in 42.2% of the patients. However, in the study by Cushman et al,^[8] 48% cases had idiopathic VTE, defined as no associated cancer, antecedent trauma, or recent surgery or immobilization. This discrepancy is probably because in the present study presence of other prothrombotic states were considered as a risk factor for PTE.

The mean duration of stay in the hospital was 11.3 days in the present study comparable to the study

conducted by Lee et al,^[13] where the mean duration of stay in the hospital was 11.4 days. In the present study the most common symptom at presentation was dyspnea (in 86.9%) followed by cough, chest pain, hemoptysis with the common sign being tachypnoea (86.9%). 30 patients (i.e. 49%) had symptoms of deep vein thrombosis in the form of swelling and pain of the lower limb. These results are comparable to the study carried out by S. Calvin Davidsingh et al,^[6] who showed that dyspnoea and chest pain were the most common presenting symptoms. In another study conducted in Thailand by Sompradeekul S et al,^[12] on 71 patients the most common presenting symptoms was dyspnea (92%) and most common signs being tachypnoea (63%) followed by tachycardia (54%). 63.9 % of patients with PTE in the present study had proven DVT. 54.09% of the patients and 39.34% of the patients had shown presence of the deep vein thrombosis in the proximal and distal veins alone respectively. The proximal vein involvement was more common in the study by Syed et al,^[14] and by the study by Lee et al,^[13] where 60% of the DVTs were proximal in the later study.

Chest X-ray was normal in most of the patients (80.3%). Similar results were seen in a study conducted in India by S. Calvin Davidsingh et al,^[6] where 85.7% of the patients had normal X-ray and pleural effusion and wedge-shaped opacity were observed in 5.7% of patients. Most common X-ray finding was a wedge-shaped opacity seen in 13.1% of the patients in this study followed by focal oligemia and pleural effusion. In another similar study conducted by Sompradeekul S et al,^[12] the most frequent radiographic abnormalities noted in the present study were pulmonary parenchymal lesions (23.9%).

The most common ECG feature in the current study was sinus tachycardia followed by right axis deviation. RV strain pattern was seen in 33 patients (54.09%). S1Q3T3 was present only in 26.2% of the patients. The presence of RV strain was associated with increased mortality. These findings were comparable to the study conducted by S. Calvin Davidsingh et al,^[6] where sinus tachycardia followed by RV strain pattern were the most common features. Echocardiography helped in the diagnosis and workers have indicated that the severity of pulmonary embolus may be seen from the degree of right ventricular dysfunction and this includes right ventricular distension, tricuspid regurgitation and pulmonary hypertension. In the present study Pulmonary artery hypertension was the most common finding observed in 90% of the patients followed by Right atrial and Right ventricular dilatation (80.3%) and RV dysfunction (60.7%). Features were comparable to the study conducted by S. Calvin Davidsingh et al,^[6] In another study conducted by Sompradeekul S et al,^[12] Echocardiography findings were mostly PAH in the form of elevated right ventricular systolic pressure (RVSP).

D dimer was positive in 95% of the patients which was comparable to a study done by S. Calvin Davidsingh et al⁶ in which D dimer was positive in up to 97.1% of the patients.

In the present study a mortality of 11.4% was noted among the high trop t category and 3.2% mortality among the normal trop t category for which statistical significance could not be proven. However, the percentage of mortality was higher among the High trop t group. According to a meta-analysis done by Becattini et al,^[15] in which 1985 patients were included, high trop t levels had higher risk of short-term death. The difference in the studies may be attributed to the smaller sample size in this study.

In this study that 70.49% of the patients belonged to the high-risk category of sPESI, no deaths were reported in the low-risk group and troponin positivity was seen in 63.9% which were similar to the study conducted by Ozsu et al,^[16] on 213 patients where 72.3% belonged to the high-risk group and no PTE associated mortality rate was detected in sPESI negative patients. In the study conducted by Ozsu et al,^[16] in an outpatient setting, RVD was seen in only 43% and Trop T was high in 68% of the patients with RV dysfunction which was statistically significant. In this study RV dysfunction was present in 59.01% of the patients and 94% patients with RV dysfunction had high Trop t this difference may be attributed to the possible inclusion of relatively stable patients in the study conducted by Ozsu et al,^[16] as it was done in an outpatient setting. However, both these studies show that RV dysfunction was associated with Higher Troponin t levels.

CONCLUSION

The diagnosis of PTE requires high degree of clinical suspicion and may be easily missed. The most common risk factor was presence of recent surgery followed by malignancy and history of immobilization. Chest x ray was normal in most of the patients. Sinus tachycardia and PAH were most common ECG and echocardiography features respectively. Trop T is a reliable marker for RV dysfunction and may reflect the severity of embolism. Patients with low sPESI score have a better outcome.

In this study, higher levels of Troponin T were not significantly associated with mortality ($p > 0.05$). Likewise, classification as high risk according to the simplified Pulmonary Embolism Severity Index (sPESI) score did not show a statistically meaningful relationship with mortality outcomes ($p > 0.05$). However, these results may reflect the limited sample size, highlighting the need for larger, adequately powered studies to more definitively assess these associations.

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