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CLINICAL PROFILE, IMMEDIATE- AND SHORT-TERM OUTCOMES IN SUBJECTS WITH ACUTE PULMONARY THROMBOEMBOLISM

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ABSTRACT

Background: The literature data is scarce concerning the immediate and short-term outcomes of pulmonary thromboembolism. However, the long-term outcomes have been well described in the literature

Aim: The present study was done to assess the clinical profile and immediate and short-term outcomes in subjects with intermediate-risk pulmonary thromboembolism. The study also evaluated the advantage of thrombolysis in normotensive subjects of pulmonary thromboembolism.

Methods: The study assessed subjects having acute and intermediate pulmonary thromboembolism. For all subjects, echocardiography and electrocardiography were done at the time of admission, during stay, discharge, and at follow-up visits. The subjects were managed with anticoagulants or thrombolysis based the hemodynamic decompensation. At the follow-up visits, subjects were assessed for pulmonary arterial hypertension and right ventricular function as echo parameters.

Results: In 110 assessed subjects, 52 subjects showed intermediate low-risk PTE (pulmonary thromboembolism) and 58 subjects had intermediate high-risk PTE. The study subjects had sPESI (simplified pulmonary embolism severity index) scores of,2 and were normotensive. In the majority of the subjects, the ECG pattern showed S1Q3T3 with raised levels of cardiac troponin. Subjects managed with thrombolytic agents depicted reduced hemodynamic decompensation compared to subjects with anticoagulants where subjects had clinical features of right heart failure on follow-up at 3 months.

Conclusion: The present study adds to the existing literature data concerning the outcomes of intermediate-risk pulmonary thromboembolism and the thrombolysis effects on subjects with hemodynamic stability. The study concluded that the incidence and progression of right heart failure were lesser in subjects with hemodynamic instability.

Keywords: Anticoagulants, Hemodynamics, Pulmonary Thromboembolism, Thrombolysis

INTRODUCTION

Pulmonary thromboembolism is a condition that put the life of the affected person at risk. It contributes as the third most common cause of death caused by cardiac diseases following coronary artery disease and stroke. It affects a large human population globally including India with an incidence of nearly 17 subjects per 1000 subjects.[1] The risk factors correlated to the etiology of the pulmonary thromboembolism include active malignancy, prolonged

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immobilization, acquired trauma secondary to the surgery, antiphospholipid syndrome, prothrombin gene mutation, protein C and protein S deficiency, and antithrombin III deficiency like hypercoagulable states. Pulmonary thromboembolism predisposed state is identified using Virchow's triad including the hypercoagulability state, vascular endothelial damage, and blood flow obstruction which finally cause thrombosis.[2]

Following the guidelines by ESC (European Society of Cardiology) for acute pulmonary thromboembolism, high-risk pulmonary thromboembolism is identified by hemodynamic instability, dysfunction of the right ventricle CTPA (computed tomography pulmonary angiography), and the presence of elevated levels of cardiac troponin. Intermediate high-risk pulmonary thromboembolism is identified as dysfunction of the right ventricle CTPA along with increased levels of cardiac troponin.[3] Intermediate low-risk pulmonary thromboembolism is identified as no hemodynamic instability with either elevated levels of cardiac troponin or right ventricular dysfunction. In acute pulmonary thromboembolism, right heart hemodynamic alterations and ventricular dysfunction is identified on echocardiography. Pulmonary thromboembolism can also be identified using other diagnostic aids such as computed tomography (CT), MRI (magnetic resonance imaging), and pulmonary angiogram. In nearly 60% of the subjects with pulmonary thromboembolism, it is diagnosed as intermediate risk pulmonary thromboembolism depicting the compromised right ventricular function, normotensive subjects, and heterogeneous nature.[4]

The gold-standard modality for managing pulmonary thromboembolism remains the use of anticoagulants, however, in subjects with intermediate-risk and high-risk pulmonary thromboembolism, thrombolysis is considered as the mainstay treatment modality. A high variation is seen in depicting the prognosis of subjects with pulmonary thromboembolism based on the disease severity.[5] In low-risk subjects, the mortality rate is <1% with an increase of 5%-15% sudden death risk in subjects with intermediate risk showing increased RVSP (right ventricular systolic pressure). The long-term outcomes in subjects with intermediate-risk pulmonary thromboembolism are shown to be right heart failure and chronic thromboembolic pulmonary hypertension. However, the literature data is scarce for immediate and short-term outcomes following pulmonary thromboembolism.[6]

The present study aimed to assess the clinical profile, and immediate and short-term outcomes in subjects with intermediate-risk pulmonary thromboembolism. The study also evaluated the advantage of thrombolysis in normotensive subjects of pulmonary thromboembolism.

MATERIALS AND METHODS

The present prospective clinical study was aimed to assess the clinical profile and immediate and short-term outcomes in subjects with intermediate-risk pulmonary thromboembolism. The study also evaluated the advantage of thrombolysis in normotensive subjects of pulmonary thromboembolism. The study was done at Department of General and Respiratory Medicine, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh. The study population was recruited from the subjects admitted to the institute.

The inclusion criteria for the study were subjects with a confirmed clinical diagnosis of acute intermediate-risk pulmonary thromboembolism with computed tomography pulmonary angiography and were further confirmed as the either intermediate high-risk case with no compromise in hemodynamic functions, high cardiac troponin levels, myocardial injury, and acute right ventricular dysfunction or as intermediate low-risk pulmonary thromboembolism with no hemodynamic instability along with raised cardiac troponin levels or right ventricular dysfunction.

For all the subjects, Geneva scores were assessed to calculate the risk as low, intermediate, or high-risk pulmonary thromboembolism. Geneva scores were assessed before imaging which helps in deciding the presence of pulmonary thromboembolism clinically. Subjects with scores >10, 4-10, and 0-3 were considered as having high, intermediate, and low possibility of pulmonary thromboembolism. The study assessed subjects of age >18 years. The exclusion criteria for the study were subjects having normal T/I or troponin levels, using thrombolytic agents for 14 days, hemodynamic instability, coagulation disorders, and high bleeding risk.

After final inclusion, detailed history was recorded for all the subjects followed by assessing the right ventricular dysfunction and arterial hypertension on echo, ECG parameters, blood pressure, respiratory rate, and heart rate as vital parameters. The elevated levels of cardiac troponin-T were recorded at admission and during the treatment that includes using NOAC (novel oral anticoagulants), vitamin K antagonists, LMWH (low molecular weight heparin), and UFH (unfractionated heparin) as anticoagulant agents or thrombolysis. Hospital parameters assessed were

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hemodynamic status and ventilator support. Hemodynamic status while discharged from the hospital along with immediate outcomes as recovery or worsening was also assessed. The echo parameters including pulmonary arterial hypertension and right ventricular functions were also assessed at 3 months follow-up visit.

The data gathered were analyzed statistically using SPSS software version 21.0 and Excel sheets. The data were described as mean and standard deviations. The study utilized the two-sample t-test along with the Chi-square test to compare the parameters. The statistical significance was taken at $p<0.05$.

RESULTS

The present study assessed 110 subjects with pulmonary thromboembolism. The majority of the study subjects were in the age range of 41-60 years with 38.1% (n=42) subjects followed by 61-80 years with 27.2% (n=30) subjects, 21-40 years with 21.8 % (n=24) subjects, >80 years with 10.9% (n=12) subjects, and least in <20 years with 1.8% (n=2) subjects. There were 40% (n=44) females and 60% (n=66) males in the present study. The smokers and non-smokers were 30.9% (n=34) and 69% (n=76) study subjects. In the study, 46.2% (n=52) and 52.7% (n=58) subjects were diagnosed as intermediate low-risk and intermediate high-risk pulmonary thromboembolism. The Geneva scores were high, intermediate, and low in 12.7% (n=14), 70.9% (n=78), and 16.36% (n=18) study subjects respectively.

At the time of admission, the clinical parameters assessed showed that oxygen saturation of <80, 80-89, 90-94, and 95-100 was seen in 10.9% (n=12), 20% (n=22), 45.4% (n=50), and 23.6% (n=26) study subjects respectively. Respiratory rate of 16-10, 20-29, and >30 was seen in 5.45% (n=6), 78.1% (n=86), and 16.3% (n=18) study subjects respectively. Heart rate of <60, 60-100, and >100 was seen in 3.63% (n=4), 49% (n=54), and 47.2% (n=52) study subjects respectively. Troponin-T was positive in 16.3% (n=18) of study subjects. Right ventricular systolic pressure was 0, mild, moderate, and high in 65.4% (n=72), 3.63% (n=4), 16.3% (n=18), and 14.5% (n=16) study subjects respectively. Pulmonary hypertension was seen in 34.5% (n=38) of study subjects. Right atrial, and right ventricular dilation on echo was present in 74.5% (n=82) of study subjects. Change in the ST-T segment was seen in 41.8% (n=46) study subjects and S1Q3T3 was present in 18.1% (n=20) study subjects. ECG rhythm showed sinus tachycardia, sinus rhythm, sinus bradycardia, and junctional rhythm in 47.2% (n=52), 47.2% (n=52), 3.63% (n=4), and 1.81% (n=2) study subjects respectively as shown in Table 1.

During the stay in the hospital, the assessment of the clinical parameters showed that malignancy was present in 9.09% (n=10) of the study subjects. The simplified PESI scores were 0, 1, 2, and 3 in 40% (n=44), 41.8% (n=46), 16.3% (n=18), and 1.81% (n=2) study subjects respectively. Respiratory rate of <16, 16-20, 20-29, and >30 was seen in 18.1% (n=20), 69.09% (n=76), 10.9% (n=12), and 1.81% (n=2) study subjects respectively. Oxygen saturation was <60, 60-100, and >100 in 1.81% (n=2), 72.7% (n=80), and 25.4% (n=28) study subjects respectively. Hemodynamic changes improved during a stay in 89% (n=98) of study subjects as depicted in Table 2.

During their stay in the hospital, NIV (non-invasive ventilation was needed in 20% (n=4) subjects where thrombolysis was done and in 30% (n=27) subjects where thrombolysis was not done. Intubation was needed in 5% (n=1) of subjects with thrombolysis, and in subjects where thrombolysis was not done, intubation was needed in no subject. In subjects where thrombolysis was done, novel oral anticoagulants, low-molecular-weight heparin, and unfractionated heparin were used in 40% (n=8), 95% (n=19), and 10% (n=2) study subjects respectively, whereas, in subjects where thrombolysis was not done, these agents were used in 70% (n=63), 70% (n=63), and 10% (n=9) study subjects respectively as summarized in Table 3.

At the time of discharge in study subjects, respiratory rates of <16, 16-20, and 20-30 were seen in 20% (n=4), 60% (n=12), and 20% (n=4) subjects respectively where thrombolysis was done and in 4.4% (n=4), 73.3% (n=66), and 22.2% (n=20) subjects respectively where thrombolysis was not done. Oxygen saturation of 80-89, 90-94, and 95-100 was noted in 0, 20% (n=4), and 80% (n=16) subjects with thrombolysis and in 2.2% (n=2), 31.1% (n=28), and 66.6% (n=60) subjects respectively where thrombolysis was not done. Heart rate of 60-100 and >100 was seen in 80% (n=16) and 20% (n=4) subjects with thrombolysis as treatment and in 95.5% (n=86) and 4.4% (n=4) subjects where thrombolysis was not done. Hemodynamics improved in 100% (n=20) subjects where thrombolysis was done and in 97.7% (n=88) subjects where thrombolysis was not done (Table 4).

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At the 3 months follow-up, 14 subjects did not turn up making a final sample size of 96 subjects. No subject died following thrombolysis, whereas, 2.63% (n=2) subjects died where thrombolysis was not performed. The spo2 levels of 80-89, 90-94, and 95-100 were seen in 0, 10% (n=2), and 90% (n=18) study subjects respectively where thrombolysis was done and in 2.63% (n=2), 21% (n=16), and 76.31% (n=58) subjects respectively where thrombolysis was not done. Heart rate was <60, 60-100, and >100 in 0, 70% (n=14), and 30% (n=6) study subjects respectively with thrombolysis and in 2.63% (n=2), 78.9% (n=60), 18.4% (n=14) study subjects respectively where thrombolysis was not done. Clinical right heart failure was seen in 30% (n=6) subjects with thrombolysis and in 31.57% (n=24) study subjects where thrombolysis was not done as shown in Table 4.

DISCUSSION

The study results showed that at the time of admission, the clinical parameters assessed showed that oxygen saturation of <80, 80-89, 90-94, and 95-100 and was seen in 10.9% (n=12), 20% (n=22), 45.4% (n=50), and 23.6% (n=26) study subjects respectively. Respiratory rate of 16-10, 20-29, and >30 was seen in 5.45% (n=6), 78.1% (n=86), and 16.3% (n=18) study subjects respectively. Heart rate of <60, 60-100, and >100 was seen in 3.63% (n=4), 49% (n=54), and 47.2% (n=52) study subjects respectively. Troponin-T was positive in 16.3% (n=18) of study subjects. Right ventricular systolic pressure was 0, mild, moderate, and high in 65.4% (n=72), 3.63% (n=4), 16.3% (n=18), and 14.5% (n=16) study subjects respectively. Pulmonary hypertension was seen in 34.5% (n=38) of study subjects. Right atrial, and right ventricular dilation on echo was present in 74.5% (n=82) of study subjects. Change in the ST-T segment was seen in 41.8% (n=46) study subjects and S1Q3T3 was present in 18.1% (n=20) study subjects. ECG rhythm showed sinus tachycardia, sinus rhythm, sinus bradycardia, and junctional rhythm in 47.2% (n=52), 47.2% (n=52), 3.63% (n=4), and 1.81% (n=2) study subjects respectively. These results were consistent with the previous studies of Chatterjee S et al[7] in 2014 and Paul G et al[8] in 2015 where authors reported comparable baseline parameters as in the present study.

It was seen that during the stay in the hospital, the assessment of the clinical parameters showed that malignancy was present in 9.09% (n=10) of study subjects. The simplified PESI scores were 0, 1, 2, and 3 in 40% (n=44), 41.8% (n=46), 16.3% (n=18), and 1.81% (n=2) study subjects respectively. Respiratory rate of <16, 16-20, 20-29, and >30 was seen in 18.1% (n=20), 69.09% (n=76), 10.9% (n=12), and 1.81% (n=2) study subjects respectively. Oxygen saturation was <60, 60-100, and >100 in 1.81% (n=2), 72.7% (n=80), and 25.4% (n=28) study subjects respectively. Hemodynamic changes improved during the stay in 89% (n=98) of study subjects. These results were in agreement with the previous studies of Al-Hakim R et al[9] in 2020 and Meyer G et al[10] in 2014 where authors suggested similar clinical parameters during hospitalization in subjects with pulmonary thromboembolism.

For the need for breathing assistance and treatment modality used, NIV (non-invasive ventilation was needed in 20% (n=4) subjects where thrombolysis was done and in 30% (n=27) subjects where thrombolysis was not done. Intubation was needed in 5% (n=1) of subjects with thrombolysis, and in subjects where thrombolysis was not done, intubation was needed in no subject. In subjects where thrombolysis was done, novel oral anticoagulants, low-molecular-weight heparin, and unfractionated heparin were used in 40% (n=8), 95% (n=19), and 10% (n=2) study subjects respectively, whereas, in subjects where thrombolysis was not done, these agents were used in 70% (n=63), 70% (n=63), and 10% (n=9) study subjects respectively. These findings were comparable to the previous studies of Xu Q et al[11] in 2015 and Piazza G[12] in 2020 where authors suggested the need for mechanical ventilation in a similar proportion as seen in the results of the present study.

On assessing the clinical parameters at the time of discharge in study subjects, respiratory rates of <16, 16-20, and 20-30 were seen in 20% (n=4), 60% (n=12), and 20% (n=4) subjects respectively where thrombolysis was done and in 4.4% (n=4), 73.3% (n=66), and 22.2% (n=20) subjects respectively where thrombolysis was not done. Oxygen saturation of 80-89, 90-94, and 95-100 was noted in 0, 20% (n=4), and 80% (n=16) subjects with thrombolysis and in 2.2% (n=2), 31.1% (n=28), and 66.6% (n=60) subjects respectively where thrombolysis was not done. Heart rate of 60-100 and >100 was seen in 80% (n=16) and 20% (n=4) subjects with thrombolysis as treatment and in 95.5% (n=86) and 4.4% (n=4) subjects where thrombolysis was not done. Hemodynamics improved in 100% (n=20) subjects where thrombolysis was done and in 97.7% (n=88) subjects where thrombolysis was not done. These results were in line with the previous studies of Aujesky D et al[13] in 2009 and Khemasuwan D et al[14] in 2015 where

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authors reported a significant improvement in hemodynamic parameters following thrombolysis as in the present study.

The study results showed that at the 3 months follow-up, 14 subjects did not turn up making a final sample size of 96 subjects. No subject died following thrombolysis, whereas, 2.63% (n=2) subjects died where thrombolysis was not performed. The spo2 levels of 80-89, 90-94, and 95-100 were seen in 0, 10% (n=2), and 90% (n=18) study subjects respectively where thrombolysis was done and in 2.63% (n=2), 21% (n=16), and 76.31% (n=58) subjects respectively where thrombolysis was not done. Heart rate was <60, 60-100, and >100 in 0, 70% (n=14), and 30% (n=6) study subjects respectively with thrombolysis and in 2.63% (n=2), 78.9% (n=60), 18.4% (n=14) study subjects respectively where thrombolysis was not done. Clinical right heart failure was seen in 30% (n=6) subjects with thrombolysis and in 31.57% (n=24) study subjects where thrombolysis was not done. These results were similar to the studies of Falsetti L et al[15] in 2022 and Casazza F et al[16] in 2018 where authors reported a lesser incidence of right heart failure following thrombolysis compared to the use of anticoagulants.

CONCLUSION

Within its limitations, the present study adds to the existing literature data concerning the outcomes of intermediate-risk pulmonary thromboembolism and the thrombolysis effects on subjects with hemodynamic stability. The study concluded that the incidence and progression of right heart failure were lesser in subjects with hemodynamic instability.

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TABLES

Parameter	**Percentage (%)**	**Number (n=110)**
Oxygen saturation		
<80	10.9	12
80-89	20	22
90-94	45.4	50
95-100	23.6	26
Respiratory rate		
16-20	5.45	6
20-29	78.1	86
>30	16.3	18
Heart rate		
<60	3.63	4
60-100	49	54
>100	47.2	52
Troponin-T		
Negative	83.6	92
Positive	16.3	18
Right ventricular systolic pressure		
0	65.4	72
Mild	3.63	4
Moderate	16.3	18
High	14.5	16
Pulmonary hypertension		
Absent	65.4	72
Present	34.5	38
Right atrial, right ventricular dilation on echo		
Absent	25.4	28
Present	74.5	82
ST-T segment change		
Absent	58.18	64
Present	41.8	46
S1Q3T3		
Absent	81.8	90
Present	18.1	20
ECG rhythm		
Sinus tachycardia	47.2	52
Sinus rhythm	47.2	52
Sinus bradycardia	3.63	4
Junctional rhythm	1.81	2

Table 1: Clinical features at the time of admission in study subjects

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Parameter	Percentage (%)	Number (n=110)
Malignancy		
Present	9.09	10
Absent	90.9	100
Simplified PESI scores		
0	40	44
1	41.8	46
2	16.3	18
3	1.81	2
Respiratory rate		
<16	18.1	20
16-20	69.09	76
20-29	10.9	12
>30	1.81	2
Oxygen saturation		
80-89	3.63	4
90-94	65.4	72
95-100	30.9	34
Heart rate		
<60	1.81	2
60-100	72.7	80
>100	25.4	28
Hemodynamic changes		
Improvement	89	98
Worsening	10.9	12

Table 2: Clinical parameters at the time of stay in study subjects

Parameter	Thrombolysis	
	Done % (n=20)	Not done % (n=90)
NIV		
Used	20 (4)	30 (27)
Not	80 (6)	70 (63)
Intubation		
Used	5 (1)	0 (0)
Not	95 (19)	100 (90)
Unfractionated Heparin		
Used	10 (2)	10 (9)
Not	90 (18)	90 (81)
LMWH		
Used	95 (19)	70 (63)
Not	5 (1)	30 (27)
NOAC (novel oral anticoagulants)		
Used	40 (8)	70 (63)
Not	60 (12)	30 (27)

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Table 3: Need for ventilatory support and anticoagulant use in study subjects

Parameter	Thrombolysis		Total n=110 (%)
	Done n=20 (%)	Not done n=90 (%)	
Respiratory rate			
<16	4 (20)	4 (4.4)	8 (7.27)
16-20	12 (60)	66 (73.3)	78 (70.9)
20-30	4 (20)	20 (22.2)	24 (21.81)
Oxygen saturation			
80-89	0	2 (2.2)	2 (1.81)
90-94	4 (20)	28 (31.1)	32 (29)
95-100	16 (80)	60 (66.6)	76 (69)
Heart rate			
60-100	16 (80)	86 (95.5)	102 (92.7)
>100	4 (20)	4 (4.4)	8 (7.27)
Hemodynamics			
Improvement	20 (100)	88 (97.7)	108 (98.1)
Worsening	0	2 (2.2)	2 (1.81)

Table 4: Clinical parameters at the time of discharge in study subjects

Parameter	Thrombolysis		Total n=96 (%)
	Done n=20 (%)	Not done n=76 (%)	
Death			
Alive	20 (100)	74 (97.3)	94 (97.9)
Dead	0	2 (2.63)	2 (2.08)
Spo2			
80-89	0	2 (2.63)	2 (2.08)
90-94	2 (10)	16 (21)	18 (18.75)
95-100	18 (90)	58 (76.31)	76 (79,16)
Heart rate			
<60	0	2 (2.63)	2 (2.08)
60-100	14 (70)	60 (78.9)	74 (77)
>100	6 (30)	14 (18.4)	20 (20.8)
Clinical right heart failure			
Yes	6 (30)	24 (31.57)	30 (31.25)
No	14 (70)	52 (68.4)	66 (68.75)

Table 5: Clinical parameters at 3 months follow-up in study subjects