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ANALYZING THE CLINICAL PROFILE AND SHORT- IMMEDIATE-TERM OUTCOMES OF ACUTE AND INTERMEDIATE- RISK PULMONARY THROMBOEMBOLISM IN PATIENTS ADMITTED TO ICU AND EMERGENCY DEPARTMENT- A CLINICAL STUDY

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ABSTRACT

Background: There is a dearth of information in the literature about the short- and immediate-term effects of pulmonary thromboembolism. Nonetheless, the literature has provided a thorough description of the long-term results.

Aim: The goal of the current investigation was to evaluate the clinical profile and short- and immediate-term outcomes of participants suffering from intermediate-risk pulmonary thromboembolism. The benefit of thrombolysis in participants with normotension who had pulmonary thromboembolism was also assessed in this trial.

Methods: Participants in the trial with acute and moderate pulmonary thromboembolism were evaluated. Echocardiography and electrocardiography were performed on all participants upon admission, during their stay, upon discharge, and during follow-up appointments. Anticoagulants or thrombolysis were used to treat the subjects according to their hemodynamic decompensation. The individuals' right ventricular function and pulmonary arterial hypertension were evaluated as echo parameters during the follow-up visits.

Results: Of the 110 individuals evaluated, 52 had intermediate low-risk pulmonary thromboembolism (PTE) and 58 had intermediate high-risk PTE. The study participants were normotensive and had sPESI (simple pulmonary embolism severity index) scores of,2. The ECG pattern in most of the individuals revealed S1Q3T3 with elevated cardiac troponin levels. When followed up after three months, patients treated with thrombolytic drugs showed less hemodynamic decompensation than those treated with anticoagulants, who had clinical signs of right heart failure.

Conclusion: This study contributes to the body of knowledge on the consequences of intermediate-risk pulmonary thromboembolism and the impact of thrombolysis on individuals who exhibit hemodynamic stability. The study found that those with hemodynamic instability had a lower incidence and development of right heart failure. **Keywords**: thrombolysis, pulmonary thromboembolism, hemodynamics, anticoagulants.

INTRODUCTION

A person with pulmonary thromboembolism runs the danger of losing their life. After coronary artery disease and stroke, it ranks as the third most frequent cause of cardiac disease-related death. A significant portion of the world's population is affected, especially those in India, where the incidence is close to 17 cases per 1000 subjects.1

Active malignancy, extended immobilization, acquired trauma following surgery, prothrombin gene mutation, protein C and protein S deficiency, and antithrombin III deficiency, such as hypercoagulable states, are risk factors associated with the etiology of pulmonary thromboembolism. Virchow's triad, which includes the hypercoagulability condition, vascular

endothelial injury, and blood flow restriction that ultimately induce thrombosis, is used to identify the pulmonary thromboembolism prone state.2

As per the guidelines set forth by the European Society of Cardiology (ESC) for acute pulmonary thromboembolism, hemodynamic instability, dysfunction of the right ventricle on computed tomography pulmonary angiography (CTPA), and elevated cardiac troponin levels are indicative of high-risk pulmonary thromboembolism.

Increased cardiac troponin levels and malfunction of the right ventricle's CTPA are indicators of intermediate high-risk pulmonary thromboembolism.3

Any right ventricular dysfunction or high cardiac troponin levels without hemodynamic instability is considered intermediate low-risk pulmonary thromboembolism. Echocardiography records changes in the right heart's hemodynamics and ventricular dysfunction in cases of acute pulmonary thromboembolism. Other diagnostic tools including pulmonary angiography, magnetic resonance imaging (MRI), and computed tomography (CT) can also be used to identify pulmonary thromboembolism. The diagnosis of intermediate risk pulmonary thromboembolism is made in about 60% of cases, which is indicative of the heterogeneous character, normotensive patients, and impaired right ventricular function.4

Anticoagulant therapy is still the gold standard for treating pulmonary thromboembolism; nonetheless, thrombolysis is regarded as the primary treatment option for patients with intermediate- and high-risk pulmonary thromboembolism. Based on the severity of the condition, there is a significant range in the prognosis shown for patients with pulmonary thromboembolism.5.

The mortality rate is less than 1% in low-risk people, while the risk of sudden death increases to 5%–15% in intermediate-risk subjects with elevated RVSP (right ventricular systolic pressure). Right heart failure and chronic thromboembolic pulmonary hypertension are the long-term consequences observed in patients with intermediate-risk pulmonary thromboembolism. However, there is a dearth of information in the literature regarding the immediate and short-term consequences of pulmonary thromboembolism.6

The current investigation set intended to evaluate the clinical profile, as well as the short- and immediate-term results, of patients suffering from intermediate-risk pulmonary thromboembolism. The benefit of thrombolysis in participants with normotension who had pulmonary thromboembolism was also assessed in this trial.

MATERIALS AND METHODS

In order to evaluate the clinical profile and short- and immediate-term results in patients with intermediate-risk pulmonary thromboembolism, a prospective clinical research was conducted. The benefit of thrombolysis in participants with normotension who had pulmonary thromboembolism was also assessed in this trial. The study was conducted at the Rama Medical College, Hapur, Uttar Pradesh, in the department of emergency medicine. The participants that were admitted to the institute were used to recruit the study population.

The study's inclusion criteria included participants who had been clinically diagnosed with acute intermediate-risk pulmonary thromboembolism using computed tomography pulmonary angiography and who had been further classified as either an intermediate low-risk thromboembolism with no hemodynamic instability combined with elevated cardiac troponin levels or right ventricular dysfunction, or as an intermediate high-risk case with no compromise in hemodynamic functions, high cardiac troponin levels, myocardial injury, and acute right ventricular dysfunction. The Geneva scores were used to categorize each subject's risk of pulmonary thromboembolism as low, middle, or high risk. Prior to imaging, the Geneva scores were evaluated, which aids in clinically determining whether pulmonary thromboembolism is present. The likelihood of pulmonary thromboembolism was deemed to be high, intermediate, and low in subjects with scores >10, 4–10, and 0–3.

A total of 18+ participants were evaluated for the study. Subjects with normal T/I or troponin levels, those who had used thrombolytic drugs for 14 days, hemodynamic instability, coagulation problems, and significant bleeding risk were all excluded from the study.

Following final inclusion, each participant had a thorough history taken, and vital indicators such as blood pressure, heart rate, respiration rate, and heart-rate were measured. Additionally, an echocardiogram was used to evaluate arterial hypertension and right ventricular dysfunction. At the time of admission and throughout the course of treatment, which

included the use of vitamin K antagonists, LMWH (low molecular weight heparin), UFH (unfractionated heparin), NOAC (new oral anticoagulants), and other anticoagulant medications or thrombolysis, high levels of cardiac troponin-T were detected. Ventilator support and hemodynamic condition were evaluated as hospital metrics.

Hemodynamic state upon hospital release, as well as any immediate consequences such as improvement or deterioration, were evaluated. At the three-month follow-up appointment, the echo parameters, which included right ventricular functions and pulmonary arterial hypertension, were also evaluated.

With the use of Excel sheets and SPSS software version 21.0, the collected data were statistically examined. The mean and standard deviations of the data were reported. The study compared the parameters using the Chi-square test and the two-sample t-test. At $p<0.05$, statistical significance was determined.

RESULTS

In this study, 110 patients with pulmonary thromboembolism were evaluated. The study sample consisted of 38.1% (n=42) of participants who were 41–60 years old, followed by 27.2% (n=30) of subjects 61–80 years old, 21–40 years old, 10.9% (n=12) of subjects over 80 years old, and 1.8% (n=2) of subjects under 20 years old. In this study, 40% (n = 44) of the participants were female, and 60% (n = 66) were male. Of the study subjects, 30.9% (n = 34) and 69% (n = 76) were smokers and non-smokers, respectively. 52.7% (n=58) and 46.2% (n=52) of the study participants were identified as having intermediate high-risk and intermediate low-risk pulmonary thromboembolism, respectively. Of the study subjects, 12.7% (n = 14), 70.9% (n = 78), and 16.36% (n = 18) had high, middle, and low Geneva scores, respectively.

According to the clinical parameters evaluated at the time of admission, 10.9% (n=12), 20% (n=22), 45.4% (n=50), and 23.6% (n=26) of the study individuals had oxygen saturation of less than 80, 80-89, 90-94, and 95-100, respectively. The research participants with respiratory rates of 16–10, 20–29, and >30 were 5.45% (n = 6), 78.1% (n = 86), and 16.3% (n = 18), respectively. 3.63% (n = 4), 49% (n = 54), and 47.2% (n = 52) of the study participants had a heart rate of <60, 60-100, and >100, respectively. Of the study participants, 16.3% (n=18) had positive troponin-T levels. The study participants with right ventricular systolic pressure values of 0 for mild, moderate, and high, respectively, were 65.4% (n = 72), 3.63% (n = 4), 16.3% (n = 18), and 14.5% (n = 16).

Of the trial participants, 34.5% (n=38) had pulmonary hypertension. An echo showed dilatation of the right ventricle and atrium in 74.5% (n=82) of the research participants. Of the study patients, 41.8% (n = 46) had a change in the ST-T segment, and 18.1% (n = 20) had S1Q3T3. As indicated by Table 1, ECG rhythms in 47.2% (n=52), 47.2% (n=52), 3.63% (n=4), and 1.81% (n=2) of the study individuals revealed sinus tachycardia, sinus rhythm, sinus bradycardia, and junctional rhythm, respectively.

A review of the clinical data throughout the hospital stay revealed that 9.09% (n=10) of the study participants had cancer. The simplified PESI scores for 40% (n=44), 41.8% (n=46), 16.3% (n=18), and 1.81% (n=2) of the study participants were 0, 1, 2, and 3, respectively. The research individuals with respiratory rates of <16, 16–20, 20–29, and >30 were 18.1% (n = 20), 69.09% (n = 76), 10.9% (n = 12), and 1.81% (n = 2), respectively. In the study individuals, the oxygen saturation levels were <60, 60-100, and >100 in 1.81% (n = 2), 72.7% (n = 80), and 25.4% (n = 28), in that order. As seen in Table 2, hemodynamic alterations improved in 89% (n=98) of research participants during a stay.

In 20% of cases (n = 4) when thrombolysis was performed during their hospital stay, NIV (non-invasive breathing) was required; in 30% of cases (n = 27), thrombolysis was not performed. Of the participants who had thrombolysis, 5% (n=1) required intubation, whereas none of the subjects who had no thrombolysis required intubation.

Table 3 summarizes the usage of novel oral anticoagulants, low-molecular-weight heparin, and unfractionated heparin in study subjects where thrombolysis was performed as 40% (n = 8), 95% (n = 19), and 10% (n = 2), respectively. In contrast, these agents were used in 70% (n = 63), 70% (n = 63), and 10% (n = 9) study subjects where thrombolysis was not performed.

When study patients were discharged, respiration rates of less than 16, 16–20, and 20–30 were seen in 20% (n = 4), 60% (n = 12), and 20% (n = 4) of the individuals where thrombolysis was performed, and in 4.4% (n = 4), 73.3% (n = 66), and 22.2% (n = 20) of the subjects where thrombolysis was not performed. In participants undergoing thrombolysis, oxygen saturation values of 80-89, 90-94, and 95-100 were seen in 0, 20% (n = 4), and 80% (n = 16); in subjects not undergoing thrombolysis, the corresponding values were 2.2% (n = 2), 31.1% (n = 28), and 66.6% (n = 60). Heart rates between 60

and 100 and above 100 were observed in 80% (n = 16) and 20% (n = 4) of patients receiving thrombolysis as treatment, and in 95.5% (n = 86) and 4.4% (n = 4) of patients not receiving thrombolysis.

In 20 out of the participants who had thrombolysis, their hemodynamics improved; in the 97.7% of subjects who did not have thrombolysis, their hemodynamics did not improve (Table 4).

There were 96 subjects in all since 14 subjects did not show up at the three-month follow-up. 2.63% (n=2) of the participants died in the absence of thrombolysis, while no subject died after thrombolysis.

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

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)

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

In the study subjects where thrombolysis was performed, the spo2 levels of 80-89, 90-94, and 95-100 were seen in 0, 10% (n = 2), and 90% (n = 18) correspondingly. In the subjects where thrombolysis was not performed, the SPO_2 levels were found in 2.63% (n = 2), 21% (n = 16), and 76.31% (n = 58) patients. In the study participants with thrombolysis, the heart rates were <60, 60-100, and >100 in 0, 70% (n = 14), and 30% (n = 6), respectively. In the study subjects without thrombolysis, the heart rates were 2.63% (n = 2), 78.9% (n = 60), and 18.4% (n = 14), respectively. As indicated by Table 4, clinical right heart failure was observed in 30% (n = 6) of thrombolysis individuals and in 31.57% (n = 24) of study subjects in whom thrombolysis was not performed.

DISCUSSION

According to the study findings, oxygen saturation of less than 80, 80-89, 90-94, and 95-100 was measured at the time of admission and was observed in 10.9% (n = 12), 20% (n = 22), 45.4% (n = 50), and 23.6% (n = 26) of the study participants, respectively. The research participants with respiratory rates of 16–10, 20–29, and >30 were 5.45% (n = 6), 78.1% (n = 86), and 16.3% (n = 18), respectively. 3.63% (n = 4), 49% (n = 54), and 47.2% (n = 52) of the study participants had a heart rate of <60, 60-100, and >100, respectively. Of the study participants, 16.3% (n=18) had positive troponin-T levels. The study participants with right ventricular systolic pressure values of 0 for mild, moderate, and high, respectively, were 65.4% (n = 72), 3.63% (n = 4), 16.3% (n = 18), and 14.5% (n = 16). Of the trial participants, 34.5% (n=38) had pulmonary hypertension.

An echo showed dilatation of the right ventricle and atrium in 74.5% (n=82) of the research participants. Of the study patients, 41.8% (n = 46) had a change in the ST-T segment, and 18.1% (n = 20) had S1Q3T3. According to the ECG rhythm, the study individuals were divided into four groups: 1.81% (n=2), 3.63% (n=4), 47.2% (n=52), and 47.2% (n=52) had sinus bradycardia, sinus tachycardia, and sinus rhythm, respectively. The findings aligned with the earlier research conducted by Chatterjee S et al. (2014) and Paul G et al. (2015), whose baseline characteristics were similar to those of the current study.

It was observed that 9.09% (n=10) of the study individuals had cancer throughout their hospital stay, according to an assessment of the clinical indicators. The simplified PESI scores for 40% (n=44), 41.8% (n=46), 16.3% (n=18), and 1.81% (n=2) of the study participants were 0, 1, 2, and 3, respectively. The research individuals with respiratory rates of <16, 16–20, 20–29, and >30 were 18.1% (n = 20), 69.09% (n = 76), 10.9% (n = 12), and 1.81% (n = 2), respectively. In the study individuals, the oxygen saturation levels were <60, 60-100, and >100 in 1.81% (n = 2), 72.7% (n = 80), and 25.4% (n = 28), in that order. In 89% (n=98) of the study participants, hemodynamic alterations improved during the stay.

These findings were consistent with earlier research by Meyer G. et al. (2014) and Al-Hakim R. et al. (2020), who proposed comparable clinical parameters for hospitalized patients with pulmonary thromboembolism.

NIV (non-invasive ventilation) was required for the need for breathing assistance and the treatment method in 20% (n = 4) of the participants where thrombolysis was performed and in 30% (n = 27) of the subjects where thrombolysis was not performed. Of the participants who had thrombolysis, 5% (n=1) required intubation, whereas none of the subjects who had no thrombolysis required intubation. Novel oral anticoagulants, low-molecular-weight heparin, and unfractionated heparin were used in 40% (n = 8), 95% (n = 19), and 10% (n = 2) of the study subjects when thrombolysis was performed. In contrast, these agents were used in 70% (n = 63), 70% (n = 63), and 10% (n = 9) of the study subjects when thrombolysis was not performed.

These results were in line with earlier research by Xu Q et al. (2011) in 2015 and Piazza G12 (2020), where scientists proposed a similar necessity for mechanical ventilation based on the study's findings. As the study subjects were being discharged, clinical parameters were evaluated. Respiratory rates of <16, 16–20, and 20–30 were observed in 20% (n = 4), 60% (n = 12), and 20% (n = 4) of the subjects where thrombolysis was performed, and in 4.4% (n = 4), 73.3% (n = 66), and 22.2% (n = 20) of the subjects where thrombolysis was not performed. In participants undergoing thrombolysis, oxygen saturation values of 80-89, 90-94, and 95-100 were seen in 0, 20% (n = 4), and 80% (n = 16); in subjects not undergoing thrombolysis, the corresponding values were 2.2% (n = 2), 31.1% (n = 28), and 66.6% (n = 60).

Heart rates between 60 and 100 and above 100 were observed in 80% (n = 16) and 20% (n = 4) of patients receiving thrombolysis as treatment, and in 95.5% (n = 86) and 4.4% (n = 4) of patients not receiving thrombolysis.In 20 out of the participants, thrombolysis resulted in improved hemodynamics; in the other 97.7% of the subjects (n = 88), thrombolysis was not performed.The present study's outcomes were consistent with earlier research conducted by Aujesky D et al. in 2009 and Khemasuwan D et al. in 2015, which also demonstrated a noteworthy enhancement in hemodynamic parameters after thrombolysis.

The ultimate sample size of 96 patients was achieved due to the non-attendance of 14 subjects at the 3-month follow-up, as per the study results. 2.63% (n=2) of the participants died in the absence of thrombolysis, while no subject died after thrombolysis. In the study subjects where thrombolysis was performed, the spo2 levels of 80-89, 90-94, and 95-100 were seen in 0, 10% (n = 2), and 90% (n = 18) correspondingly. In the subjects where thrombolysis was not performed, the spo2 levels were found in 2.63% (n = 2), 21% (n = 16), and 76.31% (n = 58) patients. In the study participants with thrombolysis, the heart rates were <60, 60-100, and >100 in 0, 70% (n = 14), and 30% (n = 6), respectively. In the study subjects without thrombolysis, the heart rates were 2.63% (n = 2), 78.9% (n = 60), and 18.4% (n = 14), respectively. Thirty percent (n=6) of trial participants who received thrombolysis and thirty-five percent (n=24) of those who did not have thrombolysis had clinical right heart failure.

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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